



GlaxoSmithKline

Do more, feel better, live longer

August 2009 Interim Update

Updates to information in our 2008 Corporate Responsibility report published in March 2009 have been inserted into the relevant sections of the report and are highlighted in blue boxes in a similar style to this text.

Our responsibility

Corporate Responsibility Report 2008

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Corporate Responsibility Report 2008

Corporate responsibility at GSK

Corporate responsibility (CR) is central to our business.

We aim to operate in a way that reflects our values, to understand and respond to stakeholder views and to connect business decisions to ethical, social and environmental concerns. We seek to minimise the negative impacts and maximise the benefits of our business.

Read [a message from our CEO](#) on the importance of CR at GSK.

Every GSK employee is responsible for upholding our values and maintaining high ethical standards. Our [Corporate Responsibility Principles](#) define our approach to our key responsibility issues and provide guidance for employees on the standards to which the company is committed. We communicate with our people to underline our commitment to corporate responsibility and to update them on our progress.

We also engage with our external stakeholders – including healthcare professionals, investors, patients, non-governmental organisations, local communities and suppliers – to identify key issues and to gain feedback on our approach to corporate responsibility.

Our business makes a valuable contribution to society through the medicines and vaccines we produce which improve people's lives. However, we know that the [research and development](#), [manufacture](#) and [sale of medicines and vaccines](#) raise ethical issues. Consequently, the pharmaceutical industry is subject to a high level of public scrutiny and sometimes critical media coverage.

We aim for the highest ethical standards and we regularly report on our progress. This is essential for maintaining good relationships with our stakeholders, achieving the [goals of our strategic priorities](#) and ensuring the future sustainability of our business. It also supports our inclusion in key sustainability indices such as the FTSE4Good index and Dow Jones Sustainability Index. See how we scored in [industry and investor benchmarks](#).

Our [Corporate Responsibility Principles](#) define our approach to our key responsibility issues and provide guidance for employees on the standards to which the company is committed.

Read about our [management structures and processes](#) for advancing progress on our CR Principles.

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Corporate Responsibility Report 2008

Message from the CEO

A new mindset

Welcome to GSK's Corporate Responsibility report which provides information on our activity and performance during 2008.

We want to be a company that is forward looking, innovative and willing to try new approaches and partnerships; a company that is constantly looking for new and sustainable ways to increase access to our medicines and vaccines, especially for those least able to pay.

We have made significant progress in helping to address global healthcare challenges. For example, over the past ten years we have donated over one billion tablets to the programme to eliminate lymphatic filariasis, a debilitating tropical disease and we are doubling manufacturing capacity to 600 million tablets a year. Our commitment to preferential pricing means we offer our AIDS and malaria medicines at not-for-profit prices in the world's poorest countries. We also supply our vaccines to organisations such as GAVI and UNICEF at preferential prices, typically 10-20 per cent of the prices in developed countries.

But for every success story, there are examples of where we could do more. As I review our performance, I believe it is time for a new mindset in our industry and a new contract with society. In these difficult economic times it is a challenge to think beyond short-term performance. But we must look to the long-term and not be distracted by our own economic problems when the needs of the developing world remain just as pressing.

To begin with, there are four areas where we can show we are going to do things differently.

First, we are exploring a more flexible approach to intellectual property rights to incentivise much needed research into medicines for 16 neglected tropical diseases where there is a severe lack of research. One option is a Least Developed Country (LDC) 'patent pool' in to which we would put our relevant small molecule compounds, process patents or other knowledge, and which would allow others access to develop and produce new products.

Secondly, on 1 April 2009 we will reduce our prices for patented medicines in the 50 poorest countries in the world, the LDCs, so they are no higher than 25 per cent of the developed world price. Where possible we will reduce our prices further while ensuring we cover our manufacturing costs so this offer is sustainable. We also recognise the challenge in middle-income countries where there is a wide disparity in incomes and ability to pay. Here our intention is to work on a case-by-case basis recognising that there is no 'one size fits all' solution to improving access to medicines in these countries.

Thirdly, we will seek out partnerships and open the doors of our developing world research centre in Spain. We already know what partnership can achieve – for example, we successfully trialled a malaria vaccine candidate in partnership with the PATH's Malaria Vaccine Initiative and the Bill and Melinda Gates Foundation. If we extend this approach the benefits will be huge.

Fourthly, working with partners such as NGOs, we will reinvest 20 per cent of the profit we make from selling medicines in LDCs to support the strengthening of healthcare infrastructure in these countries. Our sales in LDCs are relatively low so this profit is limited; initially this funding will amount to £1 to £2 million annually. But by our action we hope to send a signal to all multi-national companies operating in LDCs to join us and make a meaningful change in these countries. In all developing countries we must transform GSK into a local company addressing local healthcare needs. Our Brazilian business is leading the way – supplying vaccines and sharing technical expertise to help build local capacity.

We will not forget that significant healthcare challenges exist in developed countries too. We must work in partnership to create a virtuous circle, where industry gets rewarded for demonstrating genuine innovation,

healthcare payers get value-for-money because our medicines save them from high-cost healthcare interventions, and more patients get the medicines they need.

Of course, access to medicines is not the only issue that counts. We want GSK to be recognised around the world - by all stakeholders - as a company with the highest ethical standards.

We made good progress in 2008. We committed to stopping all corporate political contributions from 2009. Our decision to report more fully on our funding for medical education, patient groups and payments to physicians, will increase transparency and provide reassurance to stakeholders. Reflecting our commitment to animal welfare, we took a voluntary decision to end research in great apes, the highest-order of animals next to humans.

It is time for a new mindset in our industry and a new contract with society. With the support of other pharmaceutical companies and partners outside the industry, I believe significant improvements in human health can really be achieved.

Andrew Witty, CEO

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Corporate Responsibility Report 2008

Our Corporate Responsibility Principles

Our Corporate Responsibility Principles identify our key responsibility issues and provide guidance for employees on the standards to which GSK is committed:

Employment practices We will treat our employees with respect and dignity, encourage diversity and ensure fair treatment through all phases of employment. We will provide a safe and healthy working environment, support employees to perform to their full potential and take responsibility for the performance and reputation of the business. Read more about our [employment practices](#).

Human rights We are committed to upholding the UN Universal Declaration of Human Rights, the OECD guidelines for Multi-National Enterprises and the core labour standards set out by the International Labour Organization. We expect the same standards of our suppliers, contractors and business partners working on GSK's behalf. Read more about our approach to [human rights](#).

Access to medicines We will continue to research and develop medicines to treat diseases of the developing world. We will find sustainable ways to improve access to medicines for disadvantaged people, and will seek partnerships to support this activity. Read about our approach in [Access to medicines](#).

Leadership and advocacy We will establish our own challenging standards in corporate responsibility, appropriate to the complexities and specific needs of our business, building on external guidelines and experience. We will share best practice and seek to influence others, while remaining competitive in order to sustain our business.

Community investment We will make a positive contribution to the communities in which we operate, and will invest in health and education programmes and partnerships that aim to bring sustainable improvements to under-served people in the developed and developing world. Read about [our work with communities](#).

Engagement with stakeholders We want to understand the concerns of those with an interest in corporate responsibility issues. We will engage with a range of stakeholders and will communicate openly about how we are addressing CR issues, in ways that aim to meet the needs of different groups while allowing us to pursue legitimate business goals. Read about our [stakeholder engagement](#).

Standards of ethical conduct We expect employees to meet high ethical standards in all aspects of our business, by conducting our activities with honesty and integrity, adhering to our CR principles, and complying with applicable laws and regulations. Read about [ethical conduct](#).

Research and innovation In undertaking our research and in innovating:

- We may explore and apply new technologies and will constructively engage stakeholders on any concerns that may arise.
- We will ensure that our products are subject to rigorous scientific evaluation and testing for safety, effectiveness and quality
- We will comply with or exceed all regulations and legal standards applicable to the research and development of our products

Read more about our [research practices](#).

Products and customers We will promote our products in line with high ethical, medical and scientific standards and will comply with all applicable laws and regulations. Read more about our [marketing ethics](#).

Caring for the environment We will operate in an environmentally responsible manner through systematic management of our environmental impacts, measurement of our performance and setting challenging performance targets. We will improve the efficiency of all our activities to minimise material and energy use and waste generated. We aim to find opportunities to use renewable materials and to recycle our waste. Read more about [environmental sustainability](#).

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Corporate Responsibility Report 2008

Business case for corporate responsibility

Demonstrating that our practices are responsible and ethical benefits the business in the following ways:

- An improved reputation and greater trust in GSK products
- The ability to attract, retain and motivate talented people. This is becoming increasingly important as fewer young people in our major markets choose science-based careers
- Constructive engagement with stakeholders. This helps us to prevent avoidable conflict and identify innovative approaches that benefit GSK and wider society
- Greater access to markets and the ability to influence healthcare policy through improved relationships with regulators and healthcare payers. Helping governments to increase access to medicines and resolve healthcare challenges is particularly important
- Greater ability to anticipate and prepare for legislative changes and maintain a competitive advantage
- Helping to maintain support for the intellectual property system by finding innovative ways to increase access to medicines
- Reduced costs and more efficient use of resources through increased environmental efficiency

Our business strategy

Our business performance and development are driven by three strategic priorities which are supported by our corporate responsibility activities.

We believe that corporate responsibility should be managed as part of our overall business strategy and through our day-to-day business operations. For this reason we do not have a separate corporate responsibility strategy at GSK.

Corporate responsibility and our strategic priorities

We have established strategic priorities which we believe will increase growth, reduce risk and improve our long-term financial performance:

- Grow a diversified global business
- Deliver more products of value
- Simplify the operating model

We believe these priorities will enable us to navigate the coming years more successfully and retain our leading-edge position as a company able to meet patients' and healthcare providers' needs into the future.

Running our business in a responsible way is fundamental to our success and inseparable from our strategic priorities.

We want to work in way that reflects our values, seeks to understand and respond to stakeholder views and connects our business decisions to ethical, social and environmental concerns. In this way we aim to minimise the negative impacts and maximise the positive benefits of our business.

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Our key issues

Our CR reporting is focused on the most material (significant and relevant) issues for our business.

The following factors influence our materiality assessment:

- [Our business strategy](#)
- Our risk management processes.
- [Stakeholder interest, including investor feedback](#)
- Changes in our business and operations, for example the types of product we produce or the locations in which we operate.
- Existing and proposed legislation
- Public opinion and press coverage

We have identified the following responsibility issues as most material to GSK:

- The [contribution our core business makes to health](#) through research, development, manufacture and the sale of medicines and vaccines
- Increasing [access to medicines in under-served communities](#)
- Ethical standards in [research and development](#), and [sales and marketing](#)
- [Our environmental impact, particularly climate change](#)

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Corporate responsibility governance

Our Corporate Responsibility Committee (CRC) of Non-Executive Directors provides high-level guidance on our approach to CR.

The CEO and members of the Corporate Executive Team (CET) are accountable for responsible management of the business and participate in CRC meetings.

During 2008 the Committee members were Sir Christopher Gent (Chair), Dr Stephanie Burns, Dr Daniel Podolsky, Sir Ian Prosser and Tom de Swaan.

The Committee meets three times a year to review our policies and progress on our CR Principles. The Committee reviews our performance against five of our CR Principles annually. These are access to medicines, standards of ethical conduct, research and innovation, employment practices and community investment. Other Principles are discussed at least once every two years. The Committee reports its findings to the Board.

Management of corporate responsibility



During 2008 the CRC reviewed GSK's activity in a number of areas, including access to medicines, community partnerships, humanitarian donations, employee volunteering, sales and marketing practices, disclosure of funding of medical education and patient advocacy groups, product safety and communication of clinical trial results, R&D on diseases of the developing world, use of animals in research, outsourcing of research, research in emerging markets, reduction of employee numbers through restructuring, employee consultation requirements and employment litigation in the US.

The Committee also reviews and signs off the annual performance information published on this website and [our annual CR highlights document](#).

To augment GSK's engagement with stakeholder opinion, in March 2009 Sophia Tickell was appointed as an external advisor to the Corporate Responsibility Committee. Sophia is an Executive Director and member of the Leadership team at SustainAbility, a think tank and consultancy that seeks to enhance business engagement with social and environmental concerns. Sophia has extensive experience of constructively challenging companies to increase their understanding of societal expectations and to develop strategies to meet them. She has gained this experience in her work as a journalist in Latin America, through her work in

international development and her advocacy work at Oxfam and, most recently, through her direction of the investor-led Pharma Futures dialogues which aim to better align societal and shareholder value. Sophia will attend the meetings of the Corporate Responsibility Committee and advise the company in this capacity.

[Read more about the Corporate Responsibility Committee.](#)

Corporate responsibility risks

Our Risk Oversight and Compliance Council (ROCC) coordinates the management of significant business risks. The ROCC also considers reputational and corporate responsibility risks. Read more about [risk management and compliance at GSK](#).

Management structure

CR covers a very diverse range of issues at GSK so we believe it should be managed within our business functions, where the relevant subject experts work. We have a cross-functional team made up of representatives from key business areas which oversees development, implementation and communication of policies, including any responsibility elements, across GSK. The members are senior managers with direct access to our Corporate Executive Team.

We have a small central CR team to coordinate policy development and reporting specifically with respect to CR, and to communicate with socially responsible investors and other stakeholders.

Measuring performance

We have established [metrics and key performance indicators](#) to track our performance on responsibility issues.

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Stakeholder engagement

Stakeholder engagement and dialogue enables us to connect with the views and opinions of the societies in which we operate.

It helps us identify important issues and shape our responses in the interest of our shareholders and wider society.

Regular engagement means we are better informed of emerging and current issues and changing societal expectations. It provides an opportunity for us to voice our approach to responsibility issues, obtain important feedback and build trust.

Most of this discussion takes place in the normal course of business. For example, our scientists regularly meet academics, researchers and other pharmaceutical companies through advisory boards and medical conferences.

Here we describe how we engage with our stakeholders, give examples of our engagement in 2008 by stakeholder group and provide information on how we are responding to the feedback we receive. You will find further examples of our engagement with stakeholders throughout this website.

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How we engage

Healthcare professionals

We engage with healthcare professionals in many ways, including through our sales representatives and when running clinical trials. Read about our [research](#) and [ethics](#) policies governing relationships with healthcare professionals.

Patients

GSK researchers and scientists meet patients as part of our 'Focus on the Patient' initiative. This engagement influences our understanding of diseases and our research priorities, read more in our [case study](#). We also support the work of [patient advocacy](#) groups and we conduct market research via third parties to understand patient needs.

Governments and regulators

We engage in debate on legislation and seek to influence policy decisions that affect GSK. We also [engage with governments](#) on responsibility-related issues.

Healthcare providers

We engage with healthcare providers through our [government affairs](#), marketing and access to medicines activities.

Investors

We meet regularly with investors and socially responsible investors. Read more about our [investor engagement](#) activities.

Employees

We seek feedback from our employees through [regular surveys](#). We also [consult employees](#) on changes that affect them and discuss business developments through regional and national consultation forums.

Local communities

Our interactions with local communities are managed by individual GSK sites. Read more about our [financial and practical support for communities](#) .

Multilateral agencies

We engage with multilateral agencies through our [access](#) and [public health](#) initiatives.

Non-governmental organisations (NGOs)

We engage with international and local NGOs through our [access](#) , [education and public health programmes](#) and as part of our [public policy](#) work.

We also engage regularly with animal welfare organisations. Read more about [animal research at GSK](#) .

Scientific community and academic partnerships

It is important for GSK to be part of scientific debates and we are involved in a number of [academic collaborations](#).

Suppliers

We hold global and regional supplier review meetings where senior GSK managers address and interact with suppliers on key issues. Read more about our [engagement with suppliers](#).

Peer companies

We engage with peer companies through membership of pharmaceutical industry organisations, for example

EFPIA, PhRMA, and IFPMA, and through collaboration on specific projects.

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Engagement with employees

It is important that our employees know about our commitment to corporate responsibility, understand their responsibilities and keep up-to-date with our progress.

Read about our approach to [embedding an ethical culture](#) at GSK.

We keep employees informed about corporate responsibility through our myGSK intranet site and Spirit, our internal quarterly magazine, which feature articles on responsibility issues. Read about how we engage with employees on [environment, health and safety issues](#).

In 2008 at least nine articles on responsibility issues were published in Spirit. These included articles on environmental sustainability, community investments and our efforts to combat diseases of the developing world such as lymphatic filariasis. This year we published four editions of Spirit, distributing 33,500 copies of each edition internally. Additionally, during the year, an online version of the magazine was introduced on the intranet, offering access to more employees.

We distributed our 2007 Corporate Responsibility Review with Spirit magazine and directly to the Corporate Executive Team and GSK Board, senior managers, site directors and all communications staff. News articles and icons on our intranet site were used to guide users directly to the Review. This year we have published a shorter [CR Highlights document](#) to direct people to this website. We are raising awareness of this online CR Report by publicising it on our website and the company intranet.

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Engagement with investors

We held 20 meetings with investors in 2008 to discuss responsibility issues. These comprised one-to-one meetings and teleconferences, and a socially responsible investment (SRI) roadshow.

Investor questions

Some of the questions raised by investors about responsibility issues in 2008 concerned:

- [Access to medicines](#)
- [Clinical trial results disclosure](#)
- [Clinical trials in the developing world](#)
- [Patient safety](#)
- [Our operations in sensitive countries. Read more about GSK's position on human rights](#)
- [Sales and marketing practices. Read more about marketing ethics at GSK](#)
- [Stem cell research](#)
- [Animal research including genetic engineering of animals](#)
- [Environmental issues including climate change and water pollution](#)
- [Political contributions](#)

We also disclose information on our greenhouse gas emissions through the Carbon Disclosure Project (CDP), an investor collaboration.

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Engagement with opinion leaders

Ipsos MORI survey

GSK participated in the Ipsos MORI survey which rates companies according to CR experts' and NGOs' perception of their CR performance. In 2008 nearly three-quarters of the 41 people surveyed thought that GSK took its responsibilities seriously, maintaining the significant improvement made in 2007 compared with 2006. GSK was the seventh-highest rated company on this question (out of 26 companies). Three of 41 respondents spontaneously mentioned GSK as a leader in corporate responsibility; there were no spontaneous mentions of GSK last year.

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Engagement on access to medicines

Engagement on issues relating to access to medicines during 2008 is described in the [Access to medicines section](#).

As well as the engagement during 2008, GSK conducted three formal stakeholder discussions during 2007 to get feedback on our approach to different issues relating to [access to medicines](#). We engaged with influential individuals and organisations with expertise in this area, including NGOs, government representatives, journalists, academics, investors and industry organisations.

The topics covered were:

- Increasing access to HIV/AIDS medicines in developing countries
- Expanding R&D into diseases of the developing world
- Increasing access to medicines in middle-income countries

While we do not necessarily agree with all the comments made by participants, these sessions provided valuable feedback on our approach.

Feedback on GSK's approach in developing countries

Participants felt that GSK has a moral responsibility to make its products accessible to poor people and that access to medicines is also important to GSK's long-term business sustainability.

It was felt that GSK's approach to increasing access in developing countries (R&D, preferential pricing and voluntary licensing) is appropriate, although participants would like GSK to invest more in R&D into diseases of the developing world and do more to remove obstacles to the supply of generic medicines in these countries.

Participants urged GSK to collaborate more with other pharmaceutical companies to address access issues in developing countries. It was felt that an industry-wide approach could help to address issues more quickly and effectively.

Feedback on GSK's approach in middle-income countries,

Participants emphasised the importance of increasing access to medicines in middle-income countries (MICs) where there are still large numbers of very poor people. They encouraged GSK not to treat MICs as we would high-income countries.

Participants felt that GSK does not have a clear strategy on access in MICs. They would like GSK to be clearer on its approach and objectives; in particular they would like to know if we regard MICs as significant commercial markets.

It was pointed out that chronic diseases are a growing problem in MICs. It was suggested that GSK take a broad approach to access that encompasses all its medicines, not just those for high-profile diseases such as HIV/AIDS, malaria and TB.

[Read about the findings from these session in more detail.](#)

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Engagement on EHSS

We have an Environment, Health and Safety and Sustainability Stakeholder Panel in the UK which has provided independent feedback on our performance since 2005.

The panel of 13 members represents customers, suppliers, regulators, public interest groups and investors. Two senior EHSS representatives from GSK regularly participate and other GSK managers attend discussions on specific topics. The panel is facilitated by The Environment Council, an independent charity.

The panel met in April and October 2008 to debate a range of issues including:

- The broad issue of sustainability
- GSK's position on nanotechnology
- Progress with climate change, process safety and green chemistry programmes
- GSK's plans for complying with the EU's Registration, Evaluation and Authorisation of Chemicals (REACH) legislation, mass efficiency improvement and pharmaceuticals in the environment

We have been using the feedback from the stakeholder panel to inform our Environment, Health and Safety and Sustainability programme. The panel is also providing input to the new GSK Sustainability Council composed of senior managers from across GSK.

Panel members provided feedback about the direction the panel should take and the effectiveness of the dialogue. They proposed that the panel should have a broader geographic reach. We have therefore added three new European panel members and are recruiting two more.

The panel finds GSK honest and open in the discussions so they consider their participation to be valuable. However they commented that it takes GSK a long time to demonstrate changes that occur as a result of their suggestions and feedback. We value the feedback we receive from the panel and we will look for ways to speed up our response to their recommendations.

Many of our sites also engage with stakeholders locally on EHSS issues, through activities such as open days, newsletters and community projects.

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Corporate Responsibility Report 2008

About our reporting

Welcome to our 2008 Corporate Responsibility Report.

This year we have reported on our activities and performance online, providing easy access to information on key issues plus the ability to build a [custom version of our 2008 Report](#).

How we report

We report our corporate responsibility activities and performance annually. This website contains a detailed account of our CR policies and performance in 2008. Selected performance information can also be downloaded, [read more about how to use this website](#).

We also publish [Corporate Responsibility Highlights](#) which provides an overview of our approach to CR. It is available in print.

Data relate to worldwide operations for the calendar year 2008, except where stated.

Environmental data are collected from all 79 of our Pharmaceutical, Consumer Healthcare and Nutritionals manufacturing sites, 14 of the 15 vaccines sites (one is not yet in operation), 22 of 31 Pharmaceutical and Consumer Healthcare R&D sites including five whose environmental data are included with their host sites (nine are too small or too new to warrant collection of environmental data in 2008), the US and UK headquarters buildings and 15 smaller offices and distribution centres.

Injury and illness data are collected from all 79 of our Pharmaceutical, Consumer Healthcare and Nutritionals manufacturing sites, 14 of the 15 vaccines sites (one is not yet in operation), 29 of 31 Pharmaceutical and Consumer Healthcare R&D sites (two are considered too new to start reporting), the US and UK headquarters sites, 18 offices and sales groups with more than one million hours worked, and 46 of the smaller offices and distribution centres.

[Data in the environment](#) and [health and safety](#) sections are [independently assured by SGS](#).

We use external guidelines to inform our reporting where relevant. We do not base our report on the Global Reporting Initiative (GRI) guidelines but we have produced a [GRI index](#) to show which elements of the guidelines are covered in the report and to aid comparison with other company reports. We have also joined the UN Global Compact and have provided an [index](#) to show how we are reporting in line with Global Compact expectations.

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Contact

We welcome your feedback on any of the information contained in this report. Please contact us at:

Corporate Responsibility
GlaxoSmithKline plc
980 Great West Road
Brentford
Middlesex
TW8 9GS
United Kingdom

csr.contact@gsk.com

Corporate Responsibility Report 2008

Benchmarking

GSK received the following ratings from benchmarking organisations:

Indexes

Organisation: Access to medicines index - Access to Medicines Foundation and Innovest Strategic Value Advisers

Rating: GSK was ranked highest in the index which assessed companies' contribution to improving access to medicines. GSK was the clear overall leader and was top in five of the eight categories assessed.

Organisation: Dow Jones Sustainability Index

Rating: GSK continued as a member of the Dow Jones Sustainability Index, which covers the top ten per cent of sustainable companies in each sector. GSK was awarded Silver Class and Sector Mover distinctions, improving from Bronze Class awarded in 2007. Classes are awarded to companies relative to the sector leader.



Organisation: FTSE4Good

Rating: GSK was included in the FTSE4Good Index.



Organisation: Global 100 Most Sustainable Corporations - Innovest Strategic Value Advisors

Rating: GSK was included in the 2009 list of the 'Global 100 Most Sustainable Corporations'. Companies are selected because they demonstrate capacity to address sector-specific environmental, social and governance risks and opportunities.

Organisation: Business in the Community - CommunityMark

Rating: GSK was one of 21 companies and the only manufacturing company to be awarded the new CommunityMark, following independent assessment, for outstanding community investment. The Mark is endorsed by the UK government and voluntary sector leaders and was given for our work at local and national level in the UK as well as for our larger international programmes.



Organisation: Business in the Community - Environment Index

Rating: GSK maintained its position in the Platinum League of the 2007 index which assessed 155 companies.

Other investor ratings

Organisation: Ceres

Rating: GSK was ranked 13th overall and 2nd in the pharmaceutical sector in Ceres's climate change governance ranking of 63 of the world's largest companies.

Organisation: Storebrand

Rating: GSK achieved Best in Class status for its leading environmental and social performance. Storebrand assesses indicators including corporate governance, marketing ethics, standards for business partners, occupational health and safety, environmental risk management and labour relations.



Reporting

Organisation: Association of Chartered Certified Accountants (ACCA)

Rating: GSK Corporate Responsibility Report 2007 was shortlisted for an ACCA award, which recognises transparency and credibility in reporting.

Organisation: PwC Building Public Trust Award

Rating: GSK was one of three companies short-listed for the 'People Reporting' award, which assesses the extent to which publicly available information enables stakeholders.

Organisation: SustainAbility Global Reporters benchmark

Rating: GSK's 2007 report scored 66 per cent versus 54 per cent for the 2006 report, with improvements in every category and particularly accessibility and assurance.

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Corporate Responsibility Report 2008

Assurance and internal audit

External assurance of EHS activities

The information we provide about [environment](#), [health and safety](#) activities at GSK has been externally assured by independent, third-party assurers.

Our reporting on environment, health and safety performance is assured by SGS, an external assurer. The assurance process includes verification of key environment, health and safety data through site visits and telephone calls to EHS professionals and review of systems and processes for collecting, collating, analysing and interpreting the data. Read the [EHS assurance statement](#) by SGS.

External assurance of access to medicines activities

In our 2007 CR Report, information on access to medicines was externally assured. Read how we are responding to the [recommendations made by the assurers](#) on our access to medicines activity and reporting.

This year we did not conduct assurance on the CR report other than that described above for the EHS section. We plan to conduct assurance of one new section of the report every other year, so a section of the 2009 report will be subject to external assurance.

Internal audit and assurance

GSK has developed an assurance programme that provides a holistic assessment of internal control processes, risk management and audit within the company. A key part of this programme is an extensive and independent internal audit schedule, delivered by four specialist audit groups. These audits assess compliance with laws, regulations and company standards, and evaluate the effectiveness of the risk management process in identifying, managing and mitigating the more significant risks facing GSK.

- **Global Internal Audit** (GIA) is responsible for evaluating the financial and operational controls that ensure financial reporting integrity and safeguard assets from losses, including fraud
- **Corporate Environment, Health, Safety and Sustainability** (CEHSS) is responsible for assessing the management of health and safety risks and environmental impacts
- **Global Manufacturing Supply Audit and Risk Management** (ARM) assesses the quality and supply risks relating to manufacturing and supply chain processes for GSK commercial products
- **Global Quality and Compliance** (GQC) is responsible for assessing risks relating to medicines, vaccines and medical devices throughout the product development process, including the manufacture of clinical trial material

The central assurance function is responsible for developing the assurance programme, and for ensuring that the GSK audit groups work together in the most efficient and effective way to deliver the audit schedule.

Global Internal Audit audits the other three audit groups for alignment with the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

The CEHSS, ARM and GQC audit groups have additional responsibilities for the auditing of contract manufacturers and key suppliers to GSK.

GSK employs approximately 150 full-time internal auditors across the four audit groups. Audits range in duration from two man-weeks for simple activities where the scope is limited, to several months for an audit involving complex or highly technical processes. The audit teams may also be supplemented by external

experts with specific technical skills, or by the use of guest auditors from within the business.

Audits are conducted based on the level of risk. They regularly assess the level of internal control for a number of responsibility areas, including:

- Animal research
- Business continuity planning
- Community investment
- Conduct of clinical trials
- Employment practices
- Environmental factors
- Ethical conduct
- Financial processes
- Health and safety
- Information technology
- Intellectual property
- Interactions with patient groups
- Manufacturing and supply chain standards
- Patient safety
- Sales and marketing practices

When issues or control deficiencies are identified, the audit groups recommend processes for improvement. GSK managers develop corrective action plans to eliminate the causes of non-compliance and gaps in internal controls. The audit groups track these plans to completion and report results to senior management and the Audit Committee.

Each audit group reports to the Audit Committee as part of the assurance programme, and provides an assessment of whether adequate controls are in place to manage significant risks. Any significant audit results are also reported to the Audit Committee at the earliest opportunity.

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Corporate Responsibility Report 2008

Corporate responsibility data summary

Metric	2004	2005	2006	2007	2008
Access to medicines					
Number of countries supplied with GSK preferentially priced ARVs ¹	57	56	51	31	37
Number of <i>Combivir</i> and <i>Epivir</i> tablets shipped (millions)	66.4	126.3	86.3	85.0	70.0
Number of generic ARVs supplied under licence from GSK (millions)	-	-	120	183	279
GSK <i>Combivir</i> not-for-profit price (\$ per day) ²	0.65	0.65	0.65	0.54	0.54
Voluntary licences granted to generic manufacturers for GSK ARVs (cumulative total) ³	6	7	9	9	9
Value of products donated through GSK Patient Assistance Program in the US (£ millions, 2008-2007 at cost, 2006-2004 at wholesale price (WAC)) ⁴	203	255	200	45	56
Research and Development					
Expenditure on R&D (£ billions)	2.9	3.1	3.5	3.3	3.7
GSK animal research facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (cumulative total) ⁵	10	10	10	10	10
Number of trials published on the GSK Clinical Study Register (cumulative total)	143	2,125	2,760	3,089	3,273
Ethical conduct					
Number of employees completing certification to the GSK Code of Conduct	9600	>12,000	>12,000	>14,000	>14,000
Number of contacts through our ethics compliance channels ⁶	2580	3644	5363	5265	3812
Employment					
Women in management grades (%)	35	35	36	37	38
Ethnic diversity - people of colour (US, %)	19.5	19.6	19.8	20.1	20.5

Ethnic diversity - ethnic minorities (UK, %)	14.8	14.9	18.3	19.1	19.2
Lost time injury and illness rate (cases per 100,000 hours worked)	0.32	0.32	0.34	0.35	0.33

Environment

Number of contract manufacturers audited	35	41	36	55	53
Energy consumption (million gigajoules)	19	19	19	19	19
Water consumption (million cubic metres)	21	22	22	21	20
Ozone depletion potential from metered dose inhalers (tonnes CFC-11 equivalent) ⁷	464	273	182	136	88
Ozone depletion potential from production (tonnes CFC-11 equivalent)	59	51	33	15	5
Ozone depletion potential from refrigeration and other ancillary uses (tonnes CFC-11 equivalent)	3	3	1	1	<1
Volatile organic compound emissions (thousand tonnes)	5	5	4	4	4
Global warming potential from energy sources (thousand tonnes CO ₂ equivalent) ⁸	1,667	1,717	1,704	1,702	1,722
Hazardous waste disposed (thousand tonnes)	71	67	70	72	54

Community investment

Total community investment expenditure (£ millions, 2008-2007 at cost, 2006-2004 at wholesale price (WAC)) ⁴	328	380	302	109	124
Value of humanitarian product donations, including albendazole (£ millions, 2008-2007 at cost, 2006-2004 at wholesale price (WAC)) ⁴	57	41	38	7	12
Number of albendazole tablets donated for prevention of lymphatic filariasis (millions)	67	136	155	150	266

1. Includes ARVs sold at not-for-profit and discounted prices. We are unable to collect data for the number of patients treated.

2. Includes freight and delivery costs. The Médecins Sans Frontières pricing report lists the average cost of generic equivalents.

3. Only eight are currently in force.

4. 2008 and restated 2007 figures reflect value at cost (average cost of goods) rather than wholesale acquisition price (WAC). This is the first year we have valued our donations this way and believe it is a more accurate reflection of the true cost to GSK and is therefore more transparent. 2004 to 2006 figures remain at WAC.

5. This covers over 90 per cent of the animals housed in GSK-owned laboratories.

6. Includes contacts with line managers, compliance officers, our confidential Integrity Helplines or offsite

post office box (in the US).

7. 2004 data do not include inhalers made in Asia.

8. Climate change impact is calculated as CO₂ equivalent using the Greenhouse Gas Protocol developed by the World Resources Institute and the World Business Council for Sustainable Development. Each year we review the CO₂ factors and update the data for all years as appropriate. The greatest changes are generally in the updated factors for electricity.

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Corporate Responsibility Report 2008

Resources and downloads

Reporting

- › [2008 Corporate Responsibility Report](#)
- › [Commitment to transparency and access](#)
- › [Corporate Responsibility Highlights 2008 \(PDF 325Kb\)](#)
- › [GRI Index \(PDF 103Kb\)](#)
- › [Global compact index \(PDF 24Kb\)](#)
- › [Corporate responsibility data summary](#)
- › [Environmental metrics](#)
- › [Archive reports](#)

Additional resources

Access to medicines

- › [Briefing paper: Access to medicines \(PDF 46Kb\)](#)

Findings from stakeholder engagement sessions:

- › [GSK access to HIV medicines workshop \(PDF 63Kb\)](#)
- › [GSK DDW workshop findings \(PDF 68Kb\)](#)
- › [GSK MIC workshop findings \(PDF 87Kb\)](#)

Ethical conduct

- › [GSK Code of Conduct \(PDF 89Kb\)](#)
- › [Employee Guide to Business Conduct \(PDF 4.3Mb\)](#)
- › [GSK European Promotion of Medicines Code of Practice \(PDF 450Kb\)](#)

Human rights

- › [Human rights statement \(PDF 30Kb\)](#)

Public policy and patient advocacy

- › [Our Public policy position statements](#)
- › [Details of relationships with patient groups](#)

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Corporate Responsibility Report 2008

Contribution to global health

How we respond to society's healthcare needs is the most important responsibility issue for GSK. It is also central to our commercial success.

Ill health and disease continue to place a huge burden on society: from the AIDS epidemic in Africa and Asia to the health needs of an ageing population in the developed world and the huge global growth in chronic diseases such as diabetes. Emerging diseases such as pandemic flu pose potentially serious threats. Ill health is also expensive: it can increase healthcare costs and reduce economic productivity.

Our business makes a significant contribution to society by bringing products to market that address the medical needs of patients around the world. We make a contribution in four key areas:

- Preventing disease: we are one of the world's largest producers of vaccines for diseases prevalent in developed and developing countries. We also prevent disease through our community investment, disease awareness work and our over-the counter products
- Treating ill health: many of our products treat diseases that place a high burden on society
- Investing in R&D: our pipeline includes new medicines and vaccines that are needed in developing and developed countries
- Contributing to scientific understanding: we participate in partnerships that advance scientific knowledge and lay the ground for future medical advances

We believe that while our business makes a significant contribution to society, there is more we can do. We are looking at ways to accelerate research into neglected diseases by sharing research resources and findings with other organisations and expanding our partnerships with governments, NGOs and other pharmaceutical companies. We also want to partner with others to support delivery of healthcare services as well as medicines.

Our products are only beneficial if they are accessible and affordable to healthcare payers and patients. Read about our efforts to increase [access](#) to our key products in developing and developed countries and how we support healthcare programmes through [community investment](#).

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Corporate Responsibility Report 2008

The cost of disease

Ill health is expensive for the individual and for society. It is often a result of poverty but it is also an important cause of poverty.

For patients it can mean loss of quality of life, loss of earnings and shortened life expectancy. It can place a great burden on families – for instance the need to care for sick relatives can reduce attendance at school or work. For governments, employers and taxpayers it can mean increased healthcare costs and loss of workforce productivity.

In Africa and parts of Asia, AIDS has had a serious effect on social and economic development, undermining progress towards the Millennium Development Goals and poverty reduction efforts. The World Bank estimates that the deaths of working age adults from HIV/AIDS may subtract one per cent a year from GDP economic growth in some sub-Saharan African countries. In South Africa HIV/AIDS may depress GDP by as much as 17 per cent over the next decade¹. Malaria is estimated to cost African nations at least \$12 billion a year in lost economic output². The economic cost of TB-related deaths, including HIV co-infection, in sub-Saharan Africa is estimated at \$519 billion between 2006 and 2015³.

Read about our [research into diseases of the developing world](#) and our efforts to help people in these countries [access essential medicines and vaccines](#) .

According to the US government's Centers for Disease Control and Prevention (CDC), the costs of chronic disease in the US alone include⁴:

- \$174 billion a year in direct and indirect costs due to diabetes
- \$81 billion in annual medical care costs for arthritis, and total costs including medical care and lost productivity of almost \$128 billion
- \$448 billion projected cost for 2008 for heart disease and stroke

Read about how we are [working in partnership in the US to combat chronic disease](#) and the role of our [vaccines](#) in preventing disease.

1. www.who.int/trade/glossary/story051/en/index.html
2. [Rollback Malaria http://rbm.who.int/globaladvocacy/pr2007-11-29.html](http://rbm.who.int/globaladvocacy/pr2007-11-29.html)
3. <http://www.who.int/mediacentre/news/releases/2007/pr64/en/index.html>
4. www.cdc.gov/nccdphp/overview.htm

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Corporate Responsibility Report 2008

The role of vaccines

Vaccines play a major role in preventing and eliminating disease.

Immunisation is acknowledged by the World Health Organization (WHO) as being ‘among the most cost-effective of health investments’. Immunisation programmes make a substantial contribution to the aims of the United Nation’s Millennium Development Goals for economic growth.

It is estimated that at least three million deaths are prevented and 750,000 children are saved from disability due to vaccines every year¹. The number of deaths in Africa from measles fell 91 per cent between 2000 and 2006 due to better coverage of routine immunisation programmes and targeted campaigns to ensure that children had a second chance to be vaccinated².

Despite this progress vaccines are under-used. It is estimated that the lives of over two million children could be saved each year if existing vaccines were made accessible to all who need them. This will require sustained financing and the development of innovative vaccination programmes.

GSK is among the world’s top vaccine providers. We have over 30 vaccines approved for marketing and over 20 in our R&D pipeline, one-third of which target diseases particularly prevalent in the developing world. GSK vaccines are included in immunisation campaigns in 169 countries worldwide. Over 1,600 scientists work in vaccine research at GSK and we believe our vaccine pipeline is the largest in the industry. We remain committed to researching and developing vaccines for all three WHO infectious disease priorities, tuberculosis, HIV and malaria. Together with the PATH Malaria Vaccine Initiative, in 2008 we demonstrated in phase II trials significant protection against malaria for infants and young children with GSK’s RTS,S candidate vaccine. [Read more about the malaria vaccine.](#)

In 2008 we supplied 1.1 billion vaccine doses. Of these, nearly 80 per cent were shipped for use in developing countries. [Read about our tiered pricing system for vaccines.](#)

Our vaccine portfolio addresses the medical needs of developing and developed countries. Our portfolio covers most of the leading causes of childhood mortality, as defined by the World Health Organization.

Our vaccine range includes products that protect against the following diseases:

Cervical cancer	Pneumococcal disease
Chickenpox	Polio
Diphtheria	Rotavirus
Hepatitis A and B	Rubella
Measles	Seasonal influenza
Meningitis	Tetanus
Mumps	Typhoid
Pandemic influenza	Whooping cough (Pertussis)

1. Ehreth J. The Global Value of Vaccination. Vaccine (2003); 21 (7-8):596-600

2. Progress in Global Measles Control and Mortality Reduction, 2000-2006

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Corporate Responsibility Report 2008

Treating ill health

We help to treat ill health by developing medicines and consumer healthcare products.

We are also [working with governments and employers in the US](#) to find innovative ways to reduce the impact of chronic diseases.

Our pharmaceutical products target diseases in the following areas:

- Anti-bacterials (antibiotics) and anti-malarials: infections, malaria
- Anti-virals: HIV/AIDS, herpes, hepatitis B, influenza
- Cardiovascular: heart failure, hypertension, deep vein thrombosis
- Central nervous system: migraine, epilepsy, anxiety, depression, Parkinson's disease, smoking cessation, anaesthesia, analgesia, anti-emetics
- Dermatology: eczema, dermatitis, psoriasis
- Metabolic: diabetes, osteoporosis, obesity
- Oncology: breast, cervical, lung and ovarian cancer, non-Hodgkins lymphoma, leukaemia, idiopathic thrombocytopenic purpura
- Respiratory and immuno-inflammation: asthma and chronic obstructive pulmonary disease, rhinitis, post-operative ileus
- Urogenital: prostatic hypertrophy, over-active bladder

We also make [vaccines which prevent serious diseases](#).

Our products help to improve health in a number of ways:

- Prolonging life – our anti-retrovirals (ARVs) such as *Combivir* help patients to control the effects of HIV infection for many years. We sell our ARVs to the Least Developed Countries and to countries in sub-Saharan Africa at not-for-profit prices. Read more about our efforts to increase [access to medicines](#)
- Preventing complications – many diseases such as diabetes are progressive if patients do not receive the right treatment they can suffer severe complications. For example, every day in the US diabetes is the cause of an estimated 225 lower limb amputations, up to 66 cases of blindness, and 117 people experiencing kidney failure. *Avandia*, our diabetes treatment, helps patients to control their symptoms, delays the progression of the disease and prevents complications. *Avandia* has now been used by more than seven million people worldwide.
- Improving quality of life – many of our medicines such as those for asthma and diabetes help patients with chronic diseases live full and productive lives. GSK preventative treatments for asthma such as *Seretide/Advair* control the symptoms of asthma and prevent asthma attacks
- Curing infection – we produce antibiotics that treat respiratory tract and other infections. We donate antibiotics to help relief efforts in disaster areas

Paracetamol

Paracetamol is widely used as a low-cost medicine for treating adult and child pain and fever, and is listed as one of the World Health Organization's essential medicines.

GSK produces ten billion tablets each year of our over-the-counter paracetamol product, *Panadol*, which

is available in more than 85 countries. This includes low- and middle-income countries, where we provide more affordable low-cost single-dose packs.

Medical guidelines across the globe recommend paracetamol, the medicine in *Panadol*, as the first-line oral painkiller for chronic diseases such as osteoarthritis due to its efficacy, safety profile and cost-effectiveness. It is also a first-choice treatment for other conditions such as headache, backache and children's fever.

Paracetamol is the recommended treatment for the symptoms of dengue fever, a debilitating and life-threatening disease that is transmitted by mosquitoes in tropical and sub-tropical regions. More than 2.5 billion people are at risk for infection – two-fifths of the world's population – in over 100 countries.

Read about our [efforts to increase awareness of dengue fever and correct treatment](#)

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› **Partnering to combat chronic disease**

Corporate Responsibility Report 2008

Partnering to combat chronic diseases

Healthcare costs in many countries are a concern for patients, healthcare payers and the pharmaceutical industry alike. The increase in prevalence of many chronic diseases such as asthma, diabetes and heart disease is a major contributing factor.

We are working with governments and employers to find new ways to address the problem of chronic diseases while reducing healthcare costs. Our approach, known as the 'triple solution', has three focus areas:

- Prevention – addressing the causes of chronic diseases, such as obesity and smoking, poor diet and lack of exercise
- Intervention – properly managing chronic diseases to prevent complications, avoid hospitalisation costs and reduce time away from work
- Innovation – developing new treatments for costly unmet medical needs such as Alzheimer's disease and stroke

Working with employers and communities

In the US, healthcare is a major source of expenditure for the government, employers and consumers. In 2006, expenditures in the US on healthcare exceeded \$2 trillion.

Additionally, absence from work due to ill health can be a significant cost that often goes unrecognised. We work closely with state and local public health agencies and a large number of employers across the US to help them create health management programmes that remove barriers to healthcare access, reduce healthcare costs and improve health.

Our organisation has worked with more than ten states, five municipalities and 200 employers to:

- Help address some of the diseases that put a great burden on healthcare budgets
- Encourage employers to provide preventative services to workers, for example, regular health screening to detect early signs of disease, awareness campaigns and initiatives to help employees adopt a healthy lifestyle.
- Develop disease management programmes which help employees control their symptoms and stick to their treatment regimens
- Initiate comprehensive wellness initiatives for obesity and smoking, for which we have leading products. Smoking is the leading cause of death and disease in the United States. The direct and indirect costs associated with being overweight and obese are estimated to exceed \$100 billion per year in the US, approximately nine per cent of annual medical expenditures.

We may advise employers to create new incentives for better health management, for example by reducing the co-pay element of prescription medicine charges. This can increase the total amount employers pay for pharmaceuticals in the short term. However, by improving patient medication adherence rates, it can prevent costly complications and time away from work in the longer term, and so help to lower overall healthcare costs.

The Diabetes Ten City Challenge

Each day in the US, diabetes causes an estimated 225 lower limb amputations and up to 66 people to lose their sight. However, with the right treatment many of these complications can be prevented.

The Diabetes Ten City Challenge, supported by GSK, is a partnership of city governments and private employers in ten cities, the American Pharmacist Association (APhA) Foundation and pharmacists. It helps employees with diabetes manage their condition through nutrition and medication and by adopting a healthy lifestyle. It aims to prevent serious side-effects and reduce associated healthcare costs.

Key features include:

- Lower co-pays (the portion of prescription costs paid for by the patient), making medicines more affordable and making it more likely that patients will adhere to their prescribed treatment regimen
- Regular meetings between patients and pharmacists to discuss symptoms and identify any potential complications as early as possible
- Help for participants to set and achieve nutrition, exercise and weight loss goals, including printed materials and meetings with pharmacist coaches

We share the Challenge's findings and resources with other employers outside the ten cities through a dedicated website.

The programme is based on the APhA Foundation's Asheville Project, which helped reduce healthcare costs for participating employees by over 34 per cent and cut absenteeism by 50 per cent on average. A pilot project based on the Asheville Project has now been launched in Japan. Run by a team from Showa University, the pilot will involve 100 diabetes and asthma patients over a two-year period.

Community health centres

In 2008 we donated over \$130,000 to the St Cecilia's health centre in New Orleans' Ninth Ward, a part of the city which saw great devastation during Hurricane Katrina. The money has been used to fund the clinic's Community Diabetes Outreach Program, which has helped it to exceed the US national average for the percentage of diabetics receiving regular tests and controlling their symptoms.

Read more about our efforts to [raise awareness and prevent disease](#).

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Corporate Responsibility Report 2008

Disease awareness and prevention

We are one of the world's largest producers of vaccines which play a vital role in preventing disease.

We also develop over-the-counter products which help people to stop smoking, lose weight and maintain good oral health.

We help to raise awareness among healthcare professionals and the public through our work with patient groups and our own disease awareness campaigns. These can take place to coincide with the launch of a new product or after it is on the market. This can have a positive impact on public health and create commercial benefits for GSK.

Read more about our efforts to [raise awareness](#) and [prevent disease](#).

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› [Raising awareness about disease](#)

Corporate Responsibility Report 2008

Raising awareness about disease

In 2008, we ran a range of disease awareness campaigns including:

Pandemic flu

The World Health Organization considers that the world is now closer to another flu pandemic than at any time since the last outbreak in 1968. In 2008, we held a workshop for journalists at the European Influenza Congress in Portugal to highlight the threat of pandemic flu. Journalists play an important role in raising government awareness of health issues and influencing health policy.

During the workshop, participants spent two hours talking to independent experts, discussing key subjects such as what we can learn from past pandemics, the personal and economic impacts of an outbreak, the role of vaccines and what governments should do to prepare.

Read about [GSK's flu products and our efforts to help prepare for pandemic flu](#).

Cervical cancer

Our vaccine *Cervarix* helps to prevent infection from the cancer-causing types of the Human Papillomavirus (HPV) which most commonly lead to cervical cancer. A year before we launched *Cervarix* in Europe, research in this region showed that as few as two per cent of women knew of the link between HPV and cervical cancer. Since then, we have run disease awareness campaigns across many countries to highlight this link and educate people on the importance of screening to help prevent cervical cancer. The campaigns target healthcare professionals, media, policy makers and women through press articles, educational events for healthcare professionals and support for cervical cancer patient groups and their activities, such as the European Cervical Cancer Prevention Week.

Rotavirus

Rotarix is our vaccine against rotavirus, a leading cause of gastroenteritis infection. Rotavirus is associated with 25 million clinic visits, two million hospitalisations and more than 600,000 deaths worldwide among children under five every year¹. The launch of *Rotarix* in Mexico in 2004 and other Latin American countries was preceded by a widespread disease awareness campaign. To achieve this, GSK educated journalists about gastroenteritis infection caused by rotavirus, its causes, how to prevent it and how to detect its symptoms early. Rotavirus can quickly become fatal if a child becomes dehydrated and does not receive treatment.

Our educational materials discuss vaccination and give guidance on prompt detection and treatment methods.

Chronic diseases in the US

Our US [Healthy Communities](#) programme, which has offered free health screenings in communities across the country, aims to educate people about chronic diseases and encourage them to take better control of their health. People who do not manage their chronic diseases may develop further complications, leading to greater health problems.

In 2008 we announced the findings of nationwide health screenings of 65,000 people conducted as part of the programme. Although approximately 70 per cent of participants reported their health to be excellent, tests indicated that many were not in good health. For example, nearly half of the participants with type 2 diabetes showed poor glucose control. Nearly a third of the asthmatics we screened had poor control of their

condition. Of the individuals with poorly controlled diabetes or asthma, over two-thirds had not visited a primary care physician in the past year².

GSK partnered with the National Association of Chronic Disease Directors (NACDD) and WebMD, the health information site, to help people become more engaged in managing their health. As part of our 'triple solution' approach we encourage people to assess their risk of chronic diseases using a health check tool that provides advice about the five biggest health risks.

Dengue fever

Paracetamol is the recommended effective symptomatic treatment for dengue fever, a debilitating disease that is transmitted by mosquitoes in tropical and sub-tropical regions. Few people know the correct treatment for dengue fever, especially for children. People often use other fever-reducers such as aspirin which can exacerbate bleeding, a symptom of dengue fever. They also seek medical treatment late, which increases the risk of serious complications and death.

Panadol, GSK's over-the-counter paracetamol brand, has a strong presence in regions where dengue fever is prevalent, notably Asia, Africa, the Middle East and Central and South America. GSK is in a position to take the lead in driving global awareness among healthcare professionals and the public against the dengue fever threat. We initiated and sponsored a dengue fever public awareness campaign in high-risk areas including the Caribbean and South-East Asia. We have worked in collaboration with organisations such as UNICEF and the Pan America Health Organization. We also engage with locally respected campaign ambassadors.

The campaigns increase awareness through television, radio and PR activities as well as roadside banners and posters in hospitals, public health centres, pharmacies and drugstores. Local media have picked up on these activities, helping to raise awareness further. Health professionals are targeted to raise awareness and provide information that can help in diagnosis and treatment. Free *Panadol* samples are distributed in hospitals.

A campaign run in Costa Rica during 2006 contributed to a 68 per cent reduction in dengue fever cases as reported by the Board of Health. In 2007, when the campaign did not run, the number of cases increased by 110 per cent. In 2008, GSK activated the campaign again in collaboration with The Board of Health. By the end of 2008, the 'I save lives' campaign contributed to a 72 per cent reduction in dengue cases. Similarly the *Panadol* campaign contributed to decreases in South-East Asian dengue cases especially in Indonesia where the dengue fever fatality rate dropped by 40 per cent in 2008 over the previous year. GSK is planning to continue this campaign in 2009 and beyond.

1. Parashar UD, et al Global illness and deaths caused by rotavirus disease in children. *Emerg Infect Dis* 2003; 9:565-72
2. Data on file

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Corporate Responsibility Report 2008

Preventing disease

Vaccines

Vaccines make a significant contribution to health and are recognised as one of the most successful ways of preventing disease. Vaccines are second only to clean drinking water in reducing the impact of infectious diseases.

GSK is one of the largest suppliers of vaccines and is the leading supplier of childhood vaccines to UNICEF.

Vaccines are designed to eradicate or control disease and on an individual level to prevent disease or limit its severity. They can be highly cost effective and benefit both society and individuals.

Vaccines have widespread endorsement from supranational organisations, including the WHO and the United Nations. The World Bank proposes that governments should make immunisation a priority for their healthcare investment.

Immunisation programmes successfully eradicated smallpox worldwide and have made significant progress towards the elimination of polio. Even when global eradication is not possible, diseases can be reduced to very low levels if vaccination is maintained at high levels. For example, where *Haemophilus influenzae* type b vaccines are used, bacterial meningitis caused by this virus has been dramatically reduced.

The majority of cervical cancers are now preventable with vaccination against the Human Papillomavirus (HPV) combined with cervical screening. GSK's vaccine against HPV, *Cervarix*, is now available in more than 90 high-, middle- and low-income countries around the world and we are committed to working to accelerate global access to the vaccine. *Cervarix* was chosen as the vaccine for the National Immunisation Programme (NIP) in the UK, the largest Human Papillomavirus immunisation programme in the world to date. Since the NIP launch in September 2008, over 70 per cent of girls aged 12 to 13 have been vaccinated.

Consumer healthcare products

Smoking cessation

Smoking is a major public health problem, contributing to around five million premature deaths worldwide every year. Nicotine replacement therapies (NRT) can significantly increase a smoker's chance of stopping. GSK created the first over-the-counter NRT and we now market a range of nicotine replacement brands, including *NiQuitin CQ/NicoDerm*, *Commit lozenge* and *Nicorette*. They have helped more than 6.5 million people stop smoking since 1996.

We estimate that around 20 per cent of smokers currently have access to NRT. We aim to increase this figure to more than 80 per cent by 2013 by launching our nicotine replacement brands in new markets.

Poverty can be a major barrier to NRT purchase, especially in emerging markets. We provide smoking cessation education and counselling support to the Brazilian government as part of its efforts to help low-income smokers who are trying to stop smoking. In 2008, we supported a petition submitted by the New York Commissioner of Health, asking the US Food and Drug Administration (FDA) to allow over-the-counter NRT products to be sold wherever cigarettes are sold and permit the sale of smaller packs with fewer doses that would have much lower prices. The FDA does not currently allow the sale of smaller, or one-day, affordable pack sizes.

In the UK, we support the National Health Service's Stop Smoking Clinics. We provide the clinics with educational materials and run online and telephone support for smokers. We also help train NHS nurses and pharmacists as 'stop smoking' advisers.

Preventing obesity

Obesity is a major cause of ill health and disease such as diabetes. *alli*, our over-the-counter weight-loss treatment, helps people lose weight when combined with a low-fat, reduced calorie diet.

alli has been marketed in the US since 2007. In 2008 it received a positive opinion as a non-prescription product from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use. In January 2009, the European Commission granted a non-prescription licence for the product. Since its launch in the US, six million starter packs of *alli* have been sold, helping millions of people to lose weight.

Read a [case study on how we ensure that *alli* is marketed responsibly](#).

Oral healthcare

It is important that people maintain good oral health, to prevent gum disease and tooth decay. Our oral healthcare products include toothpastes, mouth washes and denture cleaners.

Our facility in Weybridge, UK, which makes global brands *Aquafresh* and *Sensodyne*, is the largest oral healthcare research centre in Europe. Employees from the facility regularly visit oral healthcare conferences and publish articles in journals, to promote the importance of using oral healthcare products such as ours.

We co-sponsor the Innovation in Oral Care Awards with the International Association for Dental Research and we run an award scheme that recognises innovative research into preventing mouth infections and improving oral healthcare diagnostics.

Community investment

We also [invest in community activities](#) that focus on disease prevention. For example, we participate in the Global Alliance to Eliminate Lymphatic Filariasis, a leading cause of disability in tropical countries. [Our PHASE hand-washing programme](#) helps to prevent the spread of diarrhoea-related disease in children in developing countries.

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Investing in R&D

Despite advances in healthcare there are still many diseases for which there is no cure or for which treatments could be improved.

Continued research and innovation is essential. Our investment in R&D into new medicines and vaccines is at the core of our business.

In 2008, we spent £3.7 billion on R&D. Over 80 per cent of this expenditure was in pharmaceutical R&D with the remainder in vaccine and consumer healthcare R&D.

We have nearly 150 prescription medicines and vaccines in clinical development, detailed in R&D of our [Annual report](#). Our current late-stage [pipeline](#) includes products targeting diseases including many forms of cancer, infections, respiratory diseases, autoimmune disorders, metabolic and cardiovascular disease, psychiatric disorders and neurological diseases.

In 2008, nine new products were approved for the first time. We made six first submissions for new products and product line extensions. For example, reflecting our strong focus on oncology, in December 2008 we filed in the US for a licence for pazopanib for the treatment of advanced renal cell carcinoma.

Read about how we ensure [high ethical standards in our R&D activity](#).

Expanding research capabilities and improving productivity

One of our strategic priorities is to improve R&D productivity. During 2008 the R&D organisation was restructured to support this. The changes are described in the R&D section of our [Annual report](#).

In early 2008 we conducted a review, involving external experts, to identify the therapy areas where recent advances in science mean that there is more probability of finding new treatments. Based on the outcomes of the review, we refocused our early-stage research activities on the following areas:

- Biopharmaceuticals
- Immuno-inflammatory diseases
- Infectious diseases
- Metabolic pathways
- Neurosciences
- Oncology
- Ophthalmology
- Respiratory diseases

R&D in China

Our Chinese R&D centre, opened in 2007, now has over 200 employees and in 2008 moved to state-of-the-art facilities in Shanghai. The centre is investigating neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease and multiple sclerosis.

The centre is already progressing an early pipeline from target validation to candidate selection. We intend to develop the centre into our lead facility for global discovery and development activities in neurodegenerative disorders.

The costs of conducting research in China can be lower than in other markets. However, lower costs are

not the primary reason for opening the facility. China offers a huge pool of scientific talent – our 2008 recruitment roadshow reached over 1,200 PhD graduates at ten top universities.

Our R&D in China is conducted to GSK's global quality and ethical standards. All our R&D policies and monitoring procedures are global and apply to our operations in China.

Investing in new areas of science

We are investing in technologies which are providing new opportunities for medical intervention, including:

Stem cell technology

We believe that stem cell science has great potential to aid the discovery of new medicines by improving screening, identification and development of new compounds. Using stem cells could also help us to develop medicines that are safer and more effective.

[Read about our collaboration with the Harvard Stem Cell Institute and our participation in the Stem Cells for Safer Medicines, a public-private partnership.](#)

External collaborations

GSK does not have a monopoly on the best science and we are expanding our collaborations with external partners and business development activities to access innovations from outside our own organisation. We now have 35 external collaborations underway to complement our 35 internal Discovery Performance Units.

Our immuno-inflammation Centre of Excellence for Drug Discovery announced a five-year research partnership with the Immune Disease Institute (IDI) in Boston, US. The partnership will combine IDI's world-class immunological expertise with GSK's pharmaceutical capabilities.

In 2008 we also signed our first agreement with the University of Cambridge to develop a compound with the potential for treating obesity and addictive disorders. The University will contribute know-how and expertise and will bear some of the financial risk for which they will be compensated if the programme is successful. GSK will provide operational support, access to our in-house clinical research and imaging facilities, and background preclinical data on the drug.

Cambridge University will dedicate a team of academic experts in both neuroscience and metabolic disorders. Importantly, the agreement allows the academic scientists the freedom to publish the results from their work on 'incubator' projects.

In 2008 we acquired the pharmaceutical company Sirtris, which is the leader in research into sirtuins, a recently discovered class of enzymes believed to be involved in the ageing process. The combination of the specialist knowledge within Sirtris and GSK's development capabilities will provide the best possible chance of validating this new approach to diseases of metabolism and ageing.

Read more about our investment in new technology in our [Annual report](#).

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Contributing to scientific understanding

We fund basic medical research conducted outside GSK to increase understanding of the human body and the impact of disease.

This is often the foundation for future advances in the diagnosis, treatment and prevention of disease. Often this research is conducted in partnership with others, using very new technologies.

Examples from 2008 include:

Open innovation

In December 2008, we announced a joint £4.1 million investment with the Wellcome Trust to generate 'chemical probes' for 25 proteins involved in epigenetic signalling and to make them available to other researchers, without restriction. The partnership is part of our new commitment to promote openness in research collaborations. GSK and other pharmaceutical companies have traditionally kept research data confidential.

This public-private partnership will be led by the Structural Genomics Consortium, and involve the National Institutes of Health's Chemical Genomics Centre in Washington, US, and the University of Oxford. The initiative could offer a new model for future interactions between academia and industry.

Collaborating to accelerate drug development

In 2008 we renewed our support for the University of Dundee's Division of Signal Transduction Therapy (DSTT), in collaboration with the Medical Research Council and a consortium of other pharmaceutical companies.

The aim of the DSTT is to accelerate the development of drugs that treat diseases such as cancer, diabetes and rheumatoid arthritis by targeting kinase and phosphatase enzymes. The collaboration will provide £10.8 million to the DSTT between 2008 and 2012.

GSK has been working with the PATH Malaria Vaccine Initiative (MVI) since 2001 to develop the paediatric vaccine against malaria, RTS,S/AS. In December 2008 the partnership announced study results which showed that RTS,S/AS provides both infants and young children with significant protection against malaria. Pending national regulatory approvals, phase III studies will start in seven countries across Africa in early 2009.

Patient safety

A GSK team won a 2008 Wall Street Journal 'Technology Innovation Award' for Healthcare IT. The team developed a new software system that helps to screen novel drug candidates for potential safety issues.

The system, known as Molecular Clinical Safety Intelligence (MCSI), helps GSK researchers to screen and prioritise novel drug candidates for potential adverse medical reactions at a much earlier stage, prior to clinical trials. The software enables direct translation of safety knowledge from human clinical experience to early-stage drug discovery for the first time.

Read more about [patient safety](#) at GSK.

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Academic collaborations

We invest in research capabilities at universities, fund leading-edge academic research projects and support science students. We have more academic collaborations than any other UK-based company, providing support of more than £24 million in 2008.

Our support benefits academic institutions through increased funding, technology transfer and access to our research facilities and expertise. It contributes to better scientific understanding and capability in the countries where we operate. It benefits GSK by enabling us to tap into R&D expertise and activity outside the company and expands our potential recruitment pool of better trained scientists.

Our support in 2008 included:

- The Academic Discovery Performance Unit, a new initiative to combine the best academic thinking with GSK's industry expertise
- A new agreement with the University of Cambridge to develop a novel agent with therapeutic potential for treating obesity and addictive disorders
- Alliances with leading universities to help accelerate drug discovery. For example, we have established research agreements with Trinity College Dublin and the University of Manchester
- A collaboration with agencies including the UK Engineering and Physical Sciences Research Council (EPSRC) and the Wellcome Trust to fund projects of mutual interest
- Training in GSK laboratories for undergraduates

The intellectual property rights relating to academic collaborations are typically held by GSK but our partner institutions are free to use the outcome of the collaboration for their own future research. The university also receives a percentage of any financial returns derived from the new intellectual property.

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Corporate Responsibility Report 2008

Pandemic flu: responding to the H1N1 outbreak

Updated 24 August 2009.

We have been preparing for an influenza pandemic flu for many years, researching and developing pre-pandemic and pandemic vaccines, antivirals and face masks, as well as our existing antibiotics portfolio. Our preparations meant we were able to respond rapidly when a new influenza A (H1N1) strain emerged in Mexico in late April 2009.

The World Health Organization's (WHO) decision on 11 June 2009 to move to Pandemic Alert Level 6 sent a particularly strong message to governments and other stakeholders involved in pandemic preparedness to ensure that adequate and robust plans are in place to respond to the new strain of H1N1 (known as 'swine flu').

A collaborative global response involving governments, international organisations and businesses is needed to reduce the impact of H1N1. GSK is committed to supporting governments and health authorities around the world to respond to this challenge.

GSK's contribution

We offer [three key products to combat pandemic flu](#): an H1N1 pandemic vaccine, *Actiprotect* a face mask and *Relenza*, an antiviral. We have invested over US\$2 billion to expand our capacity to manufacture these products.

We believe that the global community should take steps to protect all populations, including those without resources to protect themselves. Read about our efforts to help facilitate [access to Relenza and our pandemic flu vaccine in developing countries](#).

Prevention and treatment – our products

Prevention

Vaccines

Immediately after we received the H1N1 'swine flu' virus strain in late May 2009 we began production of a vaccine that will help protect people against H1N1. We were unable to begin production before this because a vaccine needs to be based on the strain that it is acting against.

We are now in full scale production at our manufacturing facilities in Canada and Germany and are working to make the vaccine available as quickly as possible. We expect to produce several hundred million doses of the H1N1 vaccine, to be delivered from September 2009 onwards. To date, GSK has received orders for 326 million doses. The vaccine is made up of an antigen (which stimulates an immune response to the virus) and an adjuvant (which helps to boost the immune response). The use of an adjuvant should help to increase the effectiveness of the vaccine and it should also mean that less antigen will be needed to produce the same amount of vaccine¹. In addition, in clinical studies with the H5N1 (avian) influenza strain, the adjuvanted vaccine demonstrated the potential to provide protection even if the influenza strain drifts (changes slightly).^{2,3}

Delivery of the vaccine depends on gaining approval from the regulator. We are in discussion with authorities around the world to ensure the regulatory process proceeds as quickly as possible. In 2008, GSK received a European licence for a pandemic vaccine, based on a 'mock-up' dossier containing data on H5N1 avian flu. We anticipate that this provisional licence will speed up registration of the H1N1 vaccine, because we can quickly supplement the data in the dossier with data on the actual H1N1 pandemic strain.

We are currently in discussions with regulatory authorities to develop appropriate clinical development plans for the vaccine. The number of people studied in initial trials will be limited, because we need to provide governments with the vaccine as quickly as possible. Additional studies and ongoing monitoring will therefore be conducted once the vaccine is launched. GSK will rapidly share results of immunogenicity and post-marketing safety and effectiveness studies with the international community.

Face masks

GSK has developed *Actiprotect*, a face mask coated with an antiviral agent that provides a physical barrier that prevents the wearer from inhaling virus particles and kills the flu virus within one minute of contact. *Actiprotect* has not been tested against the pandemic (H1N1) 2009 strain. However, the mask has been shown to inactivate all influenza virus strains that it was tested against including previous strains of H1N1, H5N1, H5N9, H2N2, H3N2, and an influenza B strain.

We currently have limited manufacturing capacity for *Actiprotect*. We have therefore invested in increasing existing manufacturing capacity and are also seeking additional manufacturing capability through discussion with other companies.

Treatment

Relenza (zanamivir) is an antiviral that shortens the duration of flu, helping sufferers to feel better sooner. GSK has been working with governments to supply *Relenza* for use in a pandemic since 2003, when the global spread of avian flu (H5N1) began. Clinical tests show that H1N1 is also sensitive to *Relenza*.

Following the outbreak of the H1N1 strain, we contacted governments around the world to establish demand for *Relenza*, to ensure equitable distribution of existing supplies and to put in place a series of measures to raise production levels. As a result, we now expect to increase our annual production capacity of *Relenza* to 190 million treatment courses by the end of 2009. This is a more than threefold increase on our previous maximum annual capacity of 60 million treatment courses.

Relenza is registered in over 100 countries and we currently have contracts in place to supply it to more than 60 governments.

Supporting access to our pandemic flu products

Many developing country governments lack the resources to protect their populations against H1N1, and they are concerned about their ability to mount an effective, rapid response. GSK is committed to facilitating access to *Relenza* and our pandemic flu vaccine in all countries.

We strongly endorse the principles set out by the Gates Foundation to help guide global allocation of pandemic vaccines, and we support its message that the global community should take all steps necessary to protect all populations, including those without resources to protect themselves.

We have committed to donate 50 million doses of our H1N1 vaccine and 2 million treatment courses of *Relenza* to the WHO for use in developing countries.

To further ensure the vaccine is available to developing countries, and subject to the yield and existing contractual commitments, we have also allocated 20 per cent of H1N1 vaccine production capacity at our Canadian manufacturing site to developing countries. Ten per cent of our new, increased *Relenza* production capacity has also been allocated for developing countries. These commitments include the two donations to the WHO.

We operate a tiered-pricing policy for both our pandemic vaccine and *Relenza*, based on World Bank classification of countries and GAVI eligibility for the vaccine. In line with our [commitments](#) set out in March to make our branded medicines more affordable to the world's poorest people *Relenza* will continue to be available at not-for-profit prices to Least Developed Countries.

We remain committed to engaging in voluntary licence discussions with any companies willing to manufacture and supply zanamivir-containing products, the active ingredient in *Relenza*, for use in developing countries. For example, in 2006 we granted a voluntary licence to the Chinese manufacturer, Simcere, to manufacture and sell products containing zanamivir in China and a number of other countries, including all 50 of the world's Least Developed Countries.

Ensuring business continuity

We have taken steps to ensure that during a flu pandemic we can continue to supply essential pharmaceuticals and vaccines (against influenza and other serious diseases) to patients that need them. Read more about our [business continuity plans](#).

1. Leroux-Roels et al. Antigen sparing and cross-reactive immunity with an adjuvanted rH5N1 prototype pandemic influenza vaccine: a randomised controlled trial. *Lancet* 2007; 370 (9587): 580–89.
2. Leroux-Roels I et al, Broad Clade 2 Cross-Reactive Immunity Induced by an Adjuvant systemed Clade 1 rH5N1 Pandemic Influenza Vaccine *PLoS ONE* 3(2): e 1665. doi:10.1371/journal.pone.0001665
3. Baras et al. Cross-protection against lethal H5N1 challenge in ferrets with an adjuvanted pandemic influenza vaccine. *PLoS ONE* 2008; 3 (1): e1401.

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Q&As

Here we respond to questions raised by our stakeholders

Is your goal to cure disease or to find treatments for ongoing, chronic use?

Ideally we want to cure disease. Our antibiotics help to treat diseases caused by bacterial infection and our anti-parasitic medicines help prevent and treat prevalent diseases such as lymphatic filariasis and malaria.

Unfortunately, there is no known cure for most diseases. Our medicines help reduce symptoms and may need to be taken for long periods. These medicines are still valuable because they may enable the patient to have a more normal lifestyle, for example remaining in work or looking after their family. In many cases we are continuing research to find a cure.

Ideally we want to prevent a disease from occurring in the first place, which is where vaccines have an important role.

What factors do you consider when prioritising your R&D efforts?

There are three main interrelated factors – science, patient need and commercial potential.

We assess scientific opportunities to determine how advances in scientific and disease understanding may lead to innovative new ways to treat or prevent disease. In 2008, we used the outcome of a systematic Therapy Area Review looking at the scientific understanding in 17 therapy areas to refocus our research effort. We continually evaluate the scientific information we obtain on our compounds to help us predict whether they can be developed into effective and well-tolerated medicines.

Assessing patient need is fundamental to R&D at GSK. This ranges from looking for medicines that will treat diseases for which there are no current effective treatments, to the development of medicines that improve on existing treatments in terms of safety, efficacy or ease of use.

Our assessment of the commercial potential of possible new treatments includes: how our product would be differentiated from those of our competitors; the size of the potential market for any new treatment; and the range of conditions it may be suitable for treating.

The better able we are to meet patient needs, the more likely it is that a product will be commercially successful. However, it is not always possible to achieve a return on investment, for example when developing treatments for diseases that are prevalent in the developing world. In some cases, where commercial potential is limited but patient need is high, we may seek ways to [share the costs and risks associated with drug development](#).

Are you researching drugs to treat serious diseases?

Our pipeline and product range includes products against most of the major causes of mortality and morbidity (disease).

Our product launches in 2008 included *Promacta* for treatment of idiopathic thrombocytopenic purpura and *Volibris* for pulmonary arterial hypertension. Our top-selling products in 2008 treat asthma and chronic obstructive pulmonary disease, epilepsy and bipolar disorder, diabetes, herpes and migraine.

Our vaccines portfolio includes vaccines to prevent influenza, hepatitis, rotavirus and Human Papillomavirus infection which can cause cervical cancer. We also make vaccines to prevent many childhood illnesses such as measles and rubella.

How do you measure R&D productivity?

The ultimate measure of our productivity is the delivery of new medicines to meet patients' needs. In 2008,

GSK launched three products based on new chemical or biological entities, six new vaccines and a number of product line extensions that benefit patients. Our target is to sustain a late-stage pipeline of around 30 key assets. However, given that research and development can take longer than ten years, we measure productivity in a number of ways during the R&D process, including:

- The number of compounds in our pipeline, and the emerging risks and benefits of these compounds
- Our success at progressing compounds in our pipeline through clinical trial phases I, II and III and to market registration
- The speed of progress through our pipeline, which is an indication of the efficiency of our R&D processes

Is it true that research productivity is falling in large pharmaceutical companies? How is GSK managing this?

Investment in pharmaceutical R&D has risen while the number of new medicines gaining regulatory approval has remained relatively constant or decreased. We believe there are many reasons for this, including:

- An increasing focus on R&D into chronic degenerative diseases such as Alzheimer's which are scientifically challenging, require longer clinical trials and have increased failure rates
- Significant investment by industry in new technologies which will help deliver innovative medicines in the longer term, for example systems biology tools, genome-wide association scans, new *in vitro* and *in vivo* models and sophisticated imaging equipment
- More extensive requirements from regulators and healthcare payers, including the need to conduct larger clinical studies to evaluate the long-term outcome of treatment with a medicine, as well as higher hurdles for approval
- The effectiveness of existing treatments for some conditions, so that demonstrating improved safety or efficacy of a new treatment is increasingly difficult

Our approach is to focus on meeting patients' needs and increasing the effectiveness and efficiency of R&D. For example, in 2008 we established 35 Discovery Performance Units (DPU) within our established Centres of Excellence for Drug Discovery. DPUs are small groups of scientists focused on a specific disease or molecular pathway, and structured to be as efficient as possible. These organisations combine the entrepreneurial approach of a small company with the resources and reach of a larger organisation.

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Corporate Responsibility Report 2008

Access to medicines

Access to healthcare is one of the world's most pressing social challenges.

Every year millions of people in developing countries die from curable infectious diseases because they do not have access to basic healthcare services, including essential medicines. Millions more are unnecessarily exposed to the threat of ill health through inadequate or ineffective disease prevention strategies.

There are a number of complex factors that prevent access to medicines. There is often a limited prospect of a commercial return on R&D for neglected diseases; there is no unified registration system for medicines which makes the registration process costly, complex and time consuming; in many developing countries there is no distribution network for medicines and no healthcare infrastructure to treat patients and prescribe medicines. However, these problems must not be an excuse for inaction; rather they should indicate where action is most needed.

Over the last decade, the pharmaceutical industry has helped to address healthcare challenges in the developing world by researching new medicines and making them more available and affordable. Despite this progress, the scale of the healthcare crisis means that the industry must now take a more proactive approach. We have identified four key areas through which we will strengthen our approach:

1. Being more flexible on intellectual property
2. Being more flexible on pricing
3. Recognising that we achieve more in partnerships than we do alone
4. Looking at how we can move from being a supplier of medicines to being a partner in delivering solutions

[Read more about our plans in these areas.](#)

Abbas Hussain, President of Emerging Markets at GSK, leads our access efforts. These are also reviewed by the Corporate Executive Team, GSK's most senior team, and by the Corporate Responsibility Committee of the Board.

Increasing access to medicines is important to our business for ethical, reputational and commercial reasons because:

- It is morally the right thing to do and is valued by our shareholders, employees and other stakeholders. It is aligned to our corporate mission and contributes to GSK's reputation and ability to attract and retain talented employees
- Our business objective is to increase the proportion of the world's population that has access to our medicines – currently around 20 per cent. The successful pharmaceutical companies of the future will serve a bigger proportion of the world's population
- Our business relies on the intellectual property (IP) rights system which encourages medical innovation and progress. By taking measures to counter claims that IP is a major barrier to access, and by looking for ways to improve availability and affordability, we can help to increase access while maintaining support for intellectual property rights in our key business areas

The access problem is not confined to the developing world. For example, in the US many people suffer unnecessary ill health because they do not have healthcare insurance.

Our [community investment programmes](#) provide an additional resource for addressing healthcare challenges around the world. They support under-served communities through funding, education, practical support and donations.

We are always looking to refine and improve our contribution to improving access to medicines and in 2009 our CEO Andrew Witty announced a [number of new approaches](#) that we will be pursuing.

“I believe the pharmaceutical industry has a huge role to play. But we need to take much more of a leadership role. Historically we have always reacted to problems. In the future I want us to be proactive, genuinely finding new ways to increase research, increase access and eradicate disease.”

Andrew Witty, CEO (Speech at Carter Center, Atlanta, 4 December 2008)

Highlights

- Announced new approaches to increase flexibility in pricing in Least Developed Countries and intellectual property relating to neglected diseases
- Identified as the industry leader in the first Access to Medicines Index
- Successful results reported from phase II clinical trials of RTS,S, our malaria vaccine candidate for African children
- Entered into new R&D partnership with the Drugs for Neglected Diseases initiative
- Not-for-profit prices for anti-retrovirals reduced
- Positive opinion received from the European Medicines Agency for our pneumococcal vaccine
- 349 million anti-retroviral tablets supplied to developing countries including 279 million tablets supplied by generic manufacturers licensed by GSK
- 1.1 billion vaccines shipped, of which almost 80 per cent went to the developing world.
- Restructured our commercial operations to reflect the needs of patients and business opportunities in emerging markets
- Entered into new partnerships and acquisitions to develop a more relevant product portfolio

Corporate Responsibility Report 2008

Our approach and contribution

GSK is committed to playing our full part in addressing healthcare challenges around the world. Our core business activity, developing and launching new medicines and vaccines, makes a significant contribution.

We recognise that the scale of these challenges requires a coordinated approach and we are looking to expand research partnerships with governments, NGOs and other companies. While support for intellectual property rights is essential to encourage innovation, we want to find ways that we can use our intellectual property flexibly to speed up the development of medicines for neglected diseases, without compromising the sustainability of our business.

There is only so much difference that our activities on R&D, pricing and working in partnerships can make while significant barriers to access remain in developing countries. Key among these barriers is the lack of healthcare infrastructure - both physical and human. Although we are not a health service provider, we want to work with others to deliver healthcare, which can include investing in infrastructure. We will seek new opportunities in this area and are already making a contribution in strengthening infrastructure.

For example in 2008 we donated equipment for a state-of-the-art laboratory at the Lagos State University College of Medicine. Professor Clement Adebamowo, Chairman of the National Health Research Ethics Committee of Nigeria, said that the new laboratory would help Nigeria regain lost ground on health research and reclaim its position as a reputable partner in education and health research.

Playing our part to address global healthcare challenges, both individually and through partnership, is not only the right thing to do, it also makes good business sense.

We work to address global healthcare challenges through action in four areas:

- Improving affordability by preferential pricing of our medicines and tiered pricing of our vaccines in the world's poorest countries, exploring new business models in middle-income countries, and providing discount cards in developed countries
- Investing in research and development that targets diseases affecting the developing world
- Working in partnerships to research new medicines and to help deliver healthcare services
- Undertaking community investment activities and partnerships that foster effective healthcare

We recognise that the developing world in particular poses many healthcare challenges. This requires a long-term commitment. Fundamental to our approach is the need to ensure that our contribution is sustainable and is built into the way we do business.

We have a duty to try to ensure our products are used in a clinically appropriate way in all countries where they are available. This is particularly important in the case of communicable diseases, where inappropriate use of products can speed the development of resistance to treatment.

Our activities are undertaken in partnership with organisations that have relevant specialist knowledge, such as governments, international agencies, charities, other private sector organisations and academic institutions.

GSK was ranked top in the first Access to Medicines Index, published in June 2008. The Index rates companies on their performance according to eight criteria: management, influence, research and development, patenting, capacity, pricing, drug donations and philanthropy. While we retain some concerns with the methodology used in this report, we are pleased that our multi-faceted efforts to make our medicines

more available have been recognised by the Index. This is testament to our innovative and sustainable approach, and the many GSK employees who contribute to our efforts to help address healthcare challenges in the developing world.

Corporate Responsibility Report 2008

The role of others

Improving access to healthcare in developing countries is a complex challenge.

We believe that only a holistic approach embracing prevention and treatment as well as fundamentally strengthening health systems will work. This will require all stakeholders, including the pharmaceutical industry, to work together to increase the resources dedicated to improving healthcare systems.

Pharmaceutical companies, including GSK, must make their medicines [as affordable as possible](#) to people in the world's poorest countries, in a sustainable manner. We must invest in [research into diseases of the developing world](#) because new prevention tools and treatments are urgently needed. Companies must look for ways to use intellectual property rights flexibly to maximise R&D resources for neglected diseases. Rather than just being suppliers of medicines, we must also support governments in their efforts to strengthen health systems, developing innovative ways to deliver our medicines to the people who need them most.

Wealthy nations must give more. New funding is coming from the Global Fund to Fight AIDS, TB and Malaria, the Bill & Melinda Gates Foundation, PEPFAR (The US President's Emergency Plan for Aids Relief), UNITAID and others, but funds are still inadequate and need to be more predictable and sustainable.

Resources are needed to fund research, strengthen health systems, purchase medicines, support disease prevention and discourage the migration of trained healthcare workers from developing countries. The current global financial crisis must not divert resources away from assisting developing countries.

Developing countries themselves must show genuine political commitment to prioritising healthcare in national budgets, addressing stigma and improving affordability by removing import tariffs on medicines.

As part of this approach, middle-income countries must accept their responsibilities and not seek the lowest prices that are offered to the world's poorest countries.

All countries should provide an environment that encourages innovation through support for [intellectual property \(IP\) rights](#), and should avoid measures such as widespread compulsory licensing which may negatively impact on investment in R&D and innovation. A more supportive environment for IP generally will encourage companies to be more flexible with their IP and less defensive. Countries should also address the risk of [product diversion](#) from patients in poor countries to those in wealthier ones.

We lobby governments and policy makers to [advocate a sustainable approach to improving healthcare in the developing world](#). Such an approach must support innovation, which is critical to improving access in the longer term. In 2008 our work in this area included:

- Urging the G8 to continue making healthcare in the developing world a major agenda item
- Supporting the development of a pilot Advance Market Commitment for a pneumococcal vaccine
- Engaging in the work of the WHO's Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property
- Working with the UK government on global health issues and in the development of the Department for International Development's (DFID's) Medicines Transparency Alliance (MeTA) and the review of its Good Practice Framework for pharmaceutical companies
- Playing a leading role in Pharma Futures 3, an industry dialogue exploring the links between sustainable pharmaceutical business models and improved health outcomes in middle-income markets, including

China, India and Brazil

- Discussing IP, innovation and funding with NGOs, foundations and other stakeholders
- Attending WHO Executive Board Meetings and the World Health Assembly
- Meeting with the UN Secretary General, Ban Ki Moon, to discuss priorities in addressing HIV/AIDS
- Contributing to the design of an Affordable Medicines Facility for Malaria
- Playing a leading role in major global health initiatives. For example GSK sits on the Boards of the GAVI Alliance and Roll Back Malaria
- Participating in Board meetings of the Global Fund to Fight AIDS, TB and Malaria and supporting the development of its Quality Assurance standards
- Contributing to development of UN Human Rights Guidelines for Pharmaceutical Companies in relation to access to medicines
- Engaging in the negotiations on the WTO Doha Round to seek sustainable pro-innovation outcomes
- Addressing HIV/AIDS in the EU and neighbouring countries through the European Commission's Bremen Process
- Engaging with the Intergovernmental Meeting on Pandemic Influenza Preparedness
- Contributed to a report being prepared by Paul Hunt, the UN Special Rapporteur on the Right to Health. The report is on GSK's approach to access to medicines. A number of senior executives, including our former CEO, Dr JP Garnier, and our Chairman Sir Christopher Gent, were interviewed. We expect the report to be published in the first half of 2009.

Read more about [our malaria advocacy](#).

Corporate Responsibility Report 2008

Developing countries

Poverty is the underlying cause of the healthcare crisis in many parts of the developing world. In the world's poorest countries, millions of people do not have reliable access to food and clean water, never mind adequate healthcare services.

The healthcare crisis in the developing world is complex, and only a holistic approach will work to improve the situation. This must involve a comprehensive programme of prevention, health education, screening diagnosis and treatment, community care and support. Increasing access to medicines also plays a vital part. In all of these areas, GSK seeks opportunities to make a contribution.

Significant additional funding from national and international sources must be mobilised to really make a difference. The WHO recommends a minimum spend on health of £17 per person per year to provide the most basic health services. Yet the average spend in sub-Saharan Africa is just £5, according to the UK's Department for International Development. The African Region of the WHO suffers more than 24 per cent of the global burden of disease, but has only three per cent of the world's health workers.

The pharmaceutical industry must look to form partnerships to help deliver healthcare services. Political will is needed to aid development and build healthcare infrastructure.

GSK can make an important contribution by:

- **Researching** new treatments and vaccines for diseases affecting developing countries
- **Registering** our products in the countries where they are needed most
- Offering **preferential pricing arrangements** for medicines and tiered pricing for vaccines that are needed most
- Seeking innovative **partnerships** to help improve healthcare in the developing world
- Granting **voluntary licences** to allow companies to manufacture our medicines
- Investing in **projects to support healthcare delivery in under-served communities**

Diseases disproportionately affecting developing countries

- Malaria kills over a million people a year, mostly children under five years old
- Around two billion people worldwide are infected with TB and over 1.5 million people die from the disease each year. No new treatments for TB have been developed in the last 40 years
- UNAIDS estimates that HIV/AIDS-related illnesses killed two million people in 2007 and that over 33 million people worldwide are living with HIV
- Worldwide a woman dies of cervical cancer every two minutes; 85 per cent of these are in the developing world
- Rotavirus infection causes 600,000 deaths each year, mostly in children under two years of age. Up to 85 per cent of these deaths occur in low-income countries

Corporate Responsibility Report 2008

Research and development

For some diseases affecting developing countries there are no effective treatments. In other cases, treatments exist but have become less effective due to drug resistance.

Sometimes treatments are not suitable, for example, because they are difficult to administer in areas with poor healthcare infrastructure or they are too expensive. As a research-based company, we aim to make a major contribution to health in developing countries by researching and developing affordable new vaccines and treatments for infectious diseases. We are currently conducting R&D into 12 diseases of particular relevance to the developing world: bacterial meningitis, chlamydia, dengue fever, hepatitis E, HIV/AIDS, leishmaniasis, malaria, pandemic flu, pneumococcal disease, Chagas disease, human African trypanosomiasis and TB. For more information on our R&D pipeline see our [Annual Report](#).

Biomedical R&D is a costly, risky and time consuming activity. To develop one successful medicine or vaccine it can typically take 10 to 12 years and, on average, including the costs of failures, costs around \$1.2 billion¹. For every 5,000 to 10,000 compounds tested, an estimated five reach clinical trials and only one reaches the market².

What's different about R&D for medicines for the developing world?

GSK scientists working on treatment projects for diseases of the developing world (DDW) make access to medicines a priority right from the start of the R&D process.

When researching a new DDW treatment we emphasise factors such as:

- Heat and humidity resistance – the product must be able to survive in a hot climate where there may not be refrigeration facilities
- Ease of use – it must be easy to use in settings where there are limited healthcare facilities. For example, once-a-day tablets that can be taken at home are preferable to an injectable medicine that must be administered in a hospital or clinic
- Affordability – price is one of the most important factors. We look for molecules and formulations that are straightforward to manufacture and therefore inexpensive to produce

For diseases which disproportionately affect the developing world, but where a market exists in developed countries such as HIV/AIDS, we can still pursue this business model. We will accept all the R&D costs and risks involved on the expectation that there will be a market in wealthy countries that can subsidise poorer ones.

For other diseases of the developing world where no such market exists we have to pursue new ways of working. One solution is the [public-private partnership \(PPP\) model](#), in which businesses and the public sector work together. The model enables collaborators to achieve more together than they would do alone. We are also exploring ways to share knowledge with other organisations to help facilitate and speed up the discovery and development of new medicines. By being more flexible with our intellectual property, we aim to encourage other pharmaceutical companies to follow suit.

We believe GSK is currently the only company researching new vaccines and treatments for all three of the WHO's priority infectious diseases, malaria, TB and HIV/AIDS. We also have an extensive portfolio of R&D projects for diseases of the developing world. We are an industry leader in research into HIV/AIDS treatment, and are currently evaluating multiple second-generation integrase inhibitors in clinical development.

We also look for new treatments for other neglected diseases, typically in collaboration with external partners. For example, we engage in ongoing R&D programmes in leishmaniasis, Chagas disease and human African trypanosomiasis (African sleeping sickness).

We have created a dedicated group to focus on diseases of the developing world which is fully integrated into our pharmaceutical R&D organisation. This group prioritises projects based on their socio-economic and public health benefit rather than on commercial returns. In addition to scientists based in the UK and US, this includes a drug discovery centre at our Tres Cantos R&D site in Spain where over 100 scientists focus primarily on malaria and TB. Half of these scientists are funded by PPPs, the Medicines for Malaria Venture and TB Alliance. A group focused on developing world diseases is also active in our vaccines organisation in Belgium.

We are looking at ways to expand the Tres Cantos site into a global centre of excellence by encouraging investment and collaboration from governments, NGOs and other companies. Our overriding objective is to ensure that GSK makes the best possible contribution to improving the health of those affected by neglected diseases of the developing world. This will be achieved by pursuing an approach that will lead to the most extensive, effective and sustainable pipeline for diseases of the developing world (DDW) by:

- Increasing partnerships with external DDW communities to cover more neglected diseases, more diverse expertise, research tools, novel targets, developable drug candidates and worldwide talent pool including strong links with the best academic groups
- Spreading the DDW remit and learning in developing countries and emerging markets by sharing training activities and science forums for researchers or upcoming scientists from these countries, while avoiding any brain drain downsides
- Strengthening current R&D partnerships with organisations such as with Medicines for Malaria Venture (MMV), TB Alliance, Drugs for Neglected Diseases Initiative (DNDi), International AIDS Vaccine Initiative (IAVI), PATH, Malaria Vaccine Initiative (MVI) and the Aeras Global TB Vaccine Foundation, as well as seeking new partnerships

Read our positions statements on:

- [Clinical trials in the developing world](#)
- [Paediatric medicines](#)
- [Briefing: The treatment of children living with HIV in developing countries](#)

1. Tufts Center for the Study of Drug Development

2. Pharmaceutical Industry Profile 2008, Washington DC, PhRMA March 2008

Corporate Responsibility Report 2008

Malaria

We have been working on a malaria vaccine for over 20 years and have invested more than \$300 million of our own resources to date. We are currently developing a candidate malaria vaccine, RTS,S, in partnership with the PATH Malaria Vaccine Initiative (MVI), which has contributed more than \$100 million.

In 2008, results of two separate phase II trials confirmed the findings of earlier studies that the candidate vaccine provides infants and young children, the most vulnerable groups, with significant protection against malaria. In children aged five to 17 months, the RTS,S/AS01 vaccine reduced the risk of clinical episodes of malaria by 53 per cent over an eight-month period¹. In the other trial, among infants under 12 months who received three doses of a modified RTS,S/AS02 vaccine, the risk of first infection from malaria was reduced by 65 per cent over a six-month period².

Trials also showed that the RTS,S/AS02 vaccine does not interfere with the efficacy of other vaccines administered through existing African national immunisation programmes. This means that in countries where malaria is most prevalent, the vaccine could be delivered through the current immunisation schedule for infants, called the WHO Expanded Program on Immunization (EPI).

Christian Loucq, MVI Director, commented on the significance of the trial results by saying, “we are closer than ever before to developing a malaria vaccine for children in Africa”.

In 2009 we will commence large-scale phase III vaccine efficacy trials in seven African countries across 11 sites. If these trials confirm the safety and efficacy of the candidate vaccine, it could be filed for registration in 2011 and introduced as early as 2012 for children five to 17 months of age. It will take longer to establish efficacy in infants of EPI age (six weeks old) due to the complexity of enrolment for trials, so the earliest the vaccine could be fully available following approval for use in infants is 2014.

[Read more in the malaria vaccine case study.](#)

Update August 2009

The Phase III trial of the RTS,S malaria vaccine candidate started in Bagamoyo, Tanzania, in May 2009.

Our work on malaria treatments includes:

- Tafenoquine, a potential new treatment for the radical cure of *P. vivax* malaria being developed in partnership with the Medicines for Malaria Venture (MMV). As well as causing an acute infection of red blood cells, *P. vivax* causes a dormant infection of liver cells from which the parasites can reactivate, resulting in a reappearance of parasites in the blood and a recurrence of malaria. A radical cure implies the complete elimination of malaria parasites from the body, including the dormant liver stages.
- Tafenoquine offers the potential for a one to two day treatment course and could replace primaquine as the standard of care for a *P. vivax* radical cure. An initial study, commencing in 2009, will focus on further understanding the safety of tafenoquine in subjects with inherited glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- “Tafenoquine is a novel inclusion for MMV’s portfolio. Given its activity against the liver stages of malaria, or hypnozoites, it is an essential part of the fight against *P. vivax* infections. As the malaria elimination agenda moves forwards we need an increasing array of tools against the parasite,” said Dr Timothy Wells, Chief

Scientific Officer at the Medicines for Malaria Venture. "MMV and GSK have worked successfully on a number of malaria projects in the past. Together, we hope to develop a radical cure for *P. vivax* malaria".

- Pyridones, a new class of compounds with the potential to be highly effective against drug-sensitive and drug-resistant strains of both *P. falciparum* and *P. vivax* malaria. Pyridone GSK932121 is being developed in partnership with MMV. We entered 'first time in human' clinical trials early in 2009. A back-up programme included in the GSK/MMV agreement is now well advanced and a candidate for development is expected by mid-2009
- Isoquine, a new 4-aminoquinoline compound. The 'first time in human' clinical trial was completed in 2008. Based on advice from the MMV Expert Scientific Advisory Committee and following discussions with all three partners (GSK, University of Liverpool and MMV), the isoquine project has been terminated until such time as evidence can be provided to demonstrate that adequate therapeutic blood exposures can be achieved after an acceptable oral dosage

1. Bejon P, Lusingu J, Olotu A, et al. Efficacy of RTS,S/AS01E : clinical malaria in 5 to 17 month old children. *N Engl J Med* 2008;359:

2. Abdulla S, Oberholzer R, Juma O, et al. Safety and immunogenicity of RTS,S/AS02D malaria vaccine in infants. *N Engl J Med* 2008;359:2533-44.

3. GSK press release issued 29 February 2008

Dacart and Lapdap

As reported in the 2007 corporate responsibility report, early in 2008 GSK and Medicines for Malaria Venture (MMV) received data from two phase III clinical trials assessing use of the artemisinin-based combination therapy *Dacart* we were developing together.

One trial was primarily designed to establish the efficacy of *Dacart* versus Coartem™, currently the first-line anti-malarial therapy in many endemic countries. The second trial was designed to establish the efficacy of *Dacart* versus *Lapdap* (chlorproguanil and dapsone), another anti-malarial product GSK had developed in a partnership including the World Health Organization and the UK's Department for International Development³.

A key safety finding from these trials was that patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency were found to be more at risk of anaemia after taking either *Dacart* or *Lapdap*. Consequently, given the haematological profile of *Dacart*, and the fact that 10-25 per cent of the population in sub-Saharan Africa is G6PD deficient, GSK and MMV decided to terminate the further development of *Dacart*. For the same reasons, GSK also decided to withdraw *Lapdap* from the market.

This disappointment highlights the highly risky and complex nature of pharmaceutical research and development. However, GSK remains committed to working with partners such as MMV to seek solutions for patients suffering from this devastating disease.



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› **Tuberculosis**

Corporate Responsibility Report 2008

Tuberculosis

Our tuberculosis medicines research is conducted in partnership with the Global Alliance for TB Drug Development (TB Alliance). In January 2008 we announced a renewal, for a further three years, of our joint research programme with the TB Alliance.

Speaking at the time of the announcement, Dr Mel Spigelman, TB Alliance Director of Research and Development, said: "We are encouraged by the success of our pioneering work with GSK, which has nearly doubled the number of TB drug discovery projects in our pipeline. This collaboration is advancing the TB Alliance's mission to develop revolutionary, faster and better TB treatment regimens by exploring new ways to attack the disease".

Our lead TB project on mycobacterium gyrase inhibitors expects to select a candidate for development by mid 2009. Other TB partnership projects under way include:

- Research into biomarkers. Currently, the effectiveness of a new TB drug cannot be determined until 18-24 months after completion of treatment. Biomarkers that enable us to predict at an early stage how patients are responding could significantly speed up TB research
- Mtb72f is our TB candidate vaccine being developed with the Aeras Global TB Vaccine Foundation. Early results are positive, suggesting that the vaccine is safe and produces a strong immune reaction in adults in TB endemic regions. Trials are now planned for infants in TB endemic regions.

Corporate Responsibility Report 2008

HIV/AIDS

We have been involved in AIDS vaccine research for over two decades. GSK is also committed to the development of new molecules that target unmet medical needs in HIV, and there is a pressing need for a variety of new anti-HIV drugs with novel mechanisms of action.

Vaccines

We are now pursuing three separate vaccine strategies. A successful AIDS vaccine might combine several of these approaches:

- Recombinant measles vector – the measles vaccine is one of the most powerful, providing life-long protection against the disease. We are working with the Pasteur Institute in Paris to develop an AIDS vaccine by fusing genes from the HIV virus onto a measles vaccine
- F4co, our own candidate vaccine, will advance into phase I/II trials in HIV-infected subjects in 2009
- An extramural collaborative discovery R&D programme that aims to identify an HIV envelope-based protein vaccine capable of producing broadly neutralising antibodies against HIV infection

In addition, we continue to collaborate with the International AIDS Vaccine Initiative (IAVI) and during 2009 we will be evaluating modifications to our joint programme.

Treatments

GSK is committed to the development of new molecules that target unmet medical needs in HIV, and there is a pressing need for a variety of new anti-HIV drugs with novel mechanisms of action. Integrase inhibitors represent an important new class of compounds for the treatment of HIV, and it is increasingly clear that second-generation integrase inhibitors will be needed to address issues such as drug resistance and dosing complexity. We currently have a number of second-generation integrase inhibitors in the early stages of clinical development.

In February 2009 we announced a licence agreement with Idenix Pharmaceuticals Inc. granting GSK exclusive worldwide rights to IDX899. This is a novel non-nucleoside reverse transcriptase inhibitor (NNRTI) in phase II clinical development being developed by Idenix for the treatment of HIV/AIDS. New NNRTIs are needed to address the increasing prevalence of viral resistance and side effects associated with this drug class. To date, IDX899 has demonstrated high potency with low milligram doses, a high barrier to drug resistance, favourable risk/benefit profile and the convenience of once-a-day administration.

In 2007, there were 2.5 million children living with HIV worldwide – nearly 90 per cent of them in sub-Saharan Africa. We are committed to improving the treatment for children living with HIV/AIDS by developing products designed for use in children and developing scored tablets that simplify treatment.

Scored tablets enable our anti-retrovirals (ARVs) to be broken into two smaller doses which simplifies treatment for children. WHO and UNICEF have stated that access to a tablet form of ARVs could improve treatment options for children able to swallow tablets. Tablets are often easier to store and distribute, and also less complicated to administer than the liquid formulations currently available – particularly when two or three medicines are combined in one pill.

In 2007 we gained approval from the European Commission for new scored tablets for *Epivir*, *Combivir* and *Ziagen*. This will enable children above 14 kilograms weight to benefit from a solid dosage form. In 2008 we received approvals for *Epivir* and *Ziagen* scored tablets from the US Food and Drug Administration and in

February 2009 the FDA approved the scored version of *Combivir*.

The new tablets can make treatment easier for children. For example, a child weighing 20 kilograms can now take half a tablet of *Combivir* in the morning and the second half in the evening in combination with another ARV, instead of requiring 8 ml of *Epivir* solution twice a day plus 12 ml of *Retrovir* solution three times daily.

We have also committed to support four paediatric clinical studies in resource-poor countries to determine the best ways to expand access to HIV/AIDS treatment.

Through our International HIV Collaborative Research Trials (CRT) Programme for resource-poor settings, we are supporting clinical trials that are sponsored by external organisations such as the WHO, the UK's Medical Research Council and the US National Institutes of Health (NIH).

At the end of 2008, 20 trials were under way and a further three planned involving approximately 32,500 patients. Nineteen of the trials are conducted at sites in Africa. These CRTs focus predominantly on public health-related issues in the developing world, such as prevention of mother-to-child HIV transmission, paediatric treatments strategies and HIV-TB co-infection. GSK donates study anti-retrovirals and/or financial support, and also provides scientific input.

Countries in which HIV CRT studies are being conducted include:

African countries	Asia and Latin America countries
South Africa	India
Uganda	Thailand
Zimbabwe	Cambodia
Kenya	Vietnam
Botswana	Brazil
Zambia	Haiti
Tanzania	Peru
Malawi	Argentina
Ethiopia	
Mali	
Nigeria	

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› **Visceral leishmaniasis**

Corporate Responsibility Report 2008

Visceral leishmaniasis (VL)

Sitamaquine is our oral, once-a-day candidate treatment for visceral leishmaniasis (VL), a potentially fatal disease spread by parasites. Data from two phase II proof-of-concept studies in Kenya and India are encouraging overall. After a 28-day course, 85 per cent of patients remained cured at six months^{1 2}.

Sitamaquine was generally well tolerated by patients in these studies. However, there were some concerns regarding renal adverse events seen in a few subjects, some of which appear to be treatment related.

Interpretation of these data is complicated, in particular because VL itself is associated with renal impairment. Before proceeding to phase III trials, we set up a phase IIb study³ to compare the safety and tolerability of a 21-day course of sitamaquine with that of intravenous amphotericin B.

Early results showed comparable efficacy to previous studies, despite the shorter course, and sitamaquine was very much better tolerated than amphotericin. A small number of patients had mild, reversible renal side effects.

We are currently reviewing the utility of sitamaquine as a potential treatment for VL with regulatory authorities and external stakeholders.

1. Wasunna M, Rashid JR, Mbui J et al. A Phase II dose-increasing study of sitamaquine for the treatment of visceral leishmaniasis in Kenya. *Am J. Trop. Med. Hyg.* 73(5):2005:871-876
2. Jha TK, Sundar S, Thakur CP et al. A Phase II dose-ranging study of sitamaquine for the treatment of visceral leishmaniasis in India. *Am J. Trop. Med. Hyg.* 73(6):2005:1005-1011
3. Prasad LS, Sen S, Ganguly. Renal involvement in kala-azar. *Indian J. Med Res* 1992 Jan;95;43-46 - Dutra M, Martinelli R, de Carvalho EM et al. Renal involvement in visceral leishmaniasis. *Am. J. Kidney Dis.* 1985: (6); 22-27

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› **Pneumococcal disease**

Corporate Responsibility Report 2008

Pneumococcal disease

Pneumococcal disease is a global health issue. Each year, *Streptococcus pneumoniae* infections are estimated to kill one million children under five years of age worldwide. There are more than 90 distinct strains (serotypes) of pneumococcus but only 10-15 cause the vast majority of invasive disease in young children.

In January 2009, the European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive opinion and recommended approval of GSK's paediatric pneumococcal candidate vaccine *Synflorix*. The paediatric vaccine is proposed to be indicated for active immunisation against invasive pneumococcal disease and middle ear infections (acute otitis media) caused by *S.pneumoniae* in infants and children from six weeks up to two years. The European Marketing Authorisation for the vaccine is expected to be granted in the first half of 2009.

We submitted a file for this potentially life-saving candidate vaccine to the World Health Organization for prequalification in early 2008. Prequalification is a service provided by the WHO to facilitate access to medicines in less affluent countries.

We have also been in discussions with the Global Alliance for Vaccines and Immunization to accelerate the availability of funding for pneumococcal vaccination through the pilot Advance Market Commitment (AMC) mechanism. AMCs are a new approach to public health funding designed to stimulate the development and manufacture of vaccines for developing countries. Donors commit money to guarantee the price of vaccines once they have been developed, thus creating the potential for a viable future market.

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Corporate Responsibility Report 2008

Neglected diseases

In March 2008, we announced a collaborative research effort with the not-for-profit organisation, Drugs for Neglected Diseases initiative (DNDi), targeting neglected tropical diseases which disproportionately affect the developing world. Research will focus on compounds that may have activity against the most neglected diseases, including visceral leishmaniasis (kala azar), human African trypanosomiasis (sleeping sickness) and Chagas disease.

The collaboration, which has been established for an initial period of two years and may be extended, will focus on identifying and developing compounds from existing GSK programmes and will leverage the expertise of researchers from GSK at our Tres Cantos facility along with leading academic centres like the London School of Hygiene & Tropical Medicine.

The collaboration has been formed to specifically address unmet patient needs as current treatments for these diseases have significant drawbacks, such as difficulty of administration, severe side effects, length of treatment, cost, and emerging parasitic resistance.

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Our plans

In 2009 we plan to:

- conduct a large-scale phase III malaria vaccine efficacy trial in seven African countries
- commence a study focusing on further understanding the safety of tafenoquine in subjects with inherited glucose-6-phosphate dehydrogenase (G6PD) deficiency
- select a candidate for our lead TB project on mycobacterium gyrase inhibitors development by mid-2009
- initiate trials of our candidate TB vaccines in infants
- continue clinical development of multiple second-generation integrase inhibitors for HIV/AIDS
- enter 'first time in human' clinical trials on pyridone932121, an anti-malarial being developed in partnership with MMV (this was achieved in January 2009), and select a back up candidate for development by mid-2009
- review the utility of sitamaquine as a potential treatment for VL with regulatory authorities and external stakeholders.

Pandemic flu

If it happens, an influenza pandemic could have a devastating effect, particularly on the poorest countries that have the least resources and capacity to prepare. GSK is very active in global preparations related to pandemic flu.

Read more about how we are helping countries prepare for [pandemic flu](#).

Corporate Responsibility Report 2008

Public-private partnerships

GSK must remain profitable to sustain our business and to provide funds to enable us to continue to develop new medicines and vaccines. There is often limited prospect of a commercial return on R&D into diseases of the developing world. Public-private partnership (PPPs) enable R&D into these diseases by making this work commercially viable by sharing the risks and costs involved. PPPs speed up the R&D process and enable all partners to do more than they could do on their own.

In a PPP companies such as GSK provide the R&D, technology, manufacturing and distribution expertise. Academic institutions may also provide research and disease area knowledge. Public sector partners, governments and organisations such as the Bill & Melinda Gates Foundation help fund the development and delivery costs and ensure that medicines and vaccines get to the people who need them. Funds are usually channelled through organisations such as the Medicines for Malaria Venture (MMV) which also help to coordinate global R&D activity.

PPPs can work in many different ways. For example, some of our partnerships are centred around our dedicated 'diseases of the developing world' discovery centre at Tres Cantos and our global vaccines business headquartered in Belgium. GSK provides the facilities for medicinal drug discovery and meets all the running costs. Of the 100 scientists at Tres Cantos, half are subsidised by our partner organisations, MMV and the Global Alliance for TB Drug Development.

As compounds move into clinical development, GSK provides the clinical, regulatory and manufacturing expertise and resources through our global R&D and supply network. Partners help fund the cost of running clinical trials and address issues of access and distribution.

This reduces the costs of development and gets new products to patients faster. Research programmes are overseen by joint steering committees with representatives from GSK and our partners.

Under the terms of our agreements, all new treatments resulting from PPPs are made available to disease-endemic countries at affordable prices.

Accelerating Access Initiative

The Accelerating Access Initiative (AAI) is a public-private partnership to accelerate access to care and treatment for HIV/AIDS.

GSK is a founder member of the AAI, formed in May 2000. The AAI is a partnership between UNAIDS, the WHO, the World Bank, UNICEF and UNFPA, and nine research-based pharmaceutical companies - Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Johnson & Johnson, Merck and Co, Inc, Pfizer and Roche.

The objectives of the AAI are to:

- accelerate sustained access and increase use of appropriate, good quality interventions for the prevention/treatment of HIV/AIDS
- ensure that care and treatment reach significantly greater numbers of people in need, through new alliances involving committed governments, private industry, the UN, development assistance agencies, non-governmental organisations and people living with HIV/AIDS

A report from the Accelerating Access Initiative suggests that by December 2007, around 875,000 patients in developing countries were receiving at least one ARV treatment supplied by the nine R&D-based pharmaceutical companies in the AAI. In the two years since December 2005, the total number of

patients in developing countries receiving treatment from the AAI companies had increased by 22 per cent. In Africa alone, over 665,600 patients are being treated with at least one ARV supplied by the AAI companies, an increase of 49 per cent over two years. This has resulted in an over 70-fold increase in the number of people being treated with medicines supplied by the AAI companies in Africa since the establishment of the AAI in May 2000.

Corporate Responsibility Report 2008

Product registrations

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Rapid product registration is important to ensure new medicines reach patients as quickly as possible. But the regulatory process is complex, costly and time consuming. There is little regulatory harmonisation around the world and a distinct submission is required for virtually every country. Companies have to prioritise their regulatory resources. This has led to concerns that pharmaceutical companies are not doing enough to register essential medicines in developing countries, which prevents these countries from taking advantage of preferential pricing offers.

We prioritise registration of our medicines based on commercial considerations, as well as prevalence of disease. We use mechanisms such as the European Medicines Agency (EMA), Article 58, to help facilitate product registration in developing countries. Article 58 allows the Agency's Committee for Medicinal Products for Human Use (CHMP) to give opinions, in cooperation with the World Health Organization, on medicinal products for human use that are intended exclusively for markets outside the EU, such as medicines to treat malaria or leishmaniasis. The positive opinion obtained via Article 58 can then be used to support the registration process in developing countries when conducting their own regulatory reviews.

We regularly review the registration status of our key anti-retrovirals (ARVs) to prioritise registration based on the needs for ARVs. This helps to make *Epivir*, *Retrovir*, *Combivir* and *Ziagen* available as widely as necessary and possible.

Screening and vaccination could prevent many thousands of women from getting cervical cancer. We are working to register our vaccine against Human Papillomavirus (HPV), *Cervarix*, as widely as possible so that women can be better protected from the disease. It is now available in more than 90 high-, middle- and low-income countries around the world, and GSK is committed to doing what it can to accelerate global access to the vaccine. Read more about our position on [cervical cancer prevention](#).

Corporate Responsibility Report 2008

Product registrations

Approach

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Cervical cancer and rotavirus

In October 2007 we submitted *Cervarix*, our vaccine which helps to prevent infection with HPV, to the World Health Organization (WHO) for pre-qualification. Products with pre-qualification status may be used by UN agencies and the GAVI Alliance, as well as in mass vaccination programmes across the developing world. By submitting *Cervarix* for prequalification as early as possible, we are working to eliminate the historical 15-20 year delay for new vaccines to become available in developing countries. We anticipate pre-qualification in the first half of 2009.

Early in 2007, we received pre-qualification status for our rotavirus vaccine, *Rotarix*, from the WHO. We concluded a deal with Brazilian government institute Fiocruz to supply enough *Rotarix* to protect every baby in Brazil against rotavirus for the next five years. This includes a technology transfer agreement under which Fiocruz will produce *Rotarix* for the domestic market and manufacture *Rotarix* for GSK under contract for export to other developing countries. This is similar to existing arrangements in Brazil for our oral polio vaccine, *Haemophilus influenzae* type b (Hib) vaccine and measles, mumps and rubella vaccine. The results of this approach with [Rotarix in Brazil](#) have been impressive.

HIV/AIDS

GSK produces packs of ARVs specifically designed for and distributed in developing countries. These 'access' packs of *Combivir*, *Epivir* tablets, *Epivir* solution and *Trizivir* are now registered in at least 33 countries. This means that these products are available for sale in over 50 of our target 64 countries, including those countries which do not have formal regulatory approval processes. Our second-line ARV, *Ziagen*, is formally registered in tablet form in 28 countries and as oral solution in 23 of our target 64 countries. *Ziagen* access packs are registered in some of these countries and we are in the process of seeking registration in the others.

Flu

To support government preparations for a global flu pandemic, we have registered [Relenza](#) in more than 100 countries. *Relenza* is our anti-viral medicine which can help treat influenza.

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Preferential pricing

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Pricing is one factor that impacts on access to medicines and vaccines in developing countries. We price our medicines preferentially for developing countries and use a tiered pricing system in wealthier middle-income markets where people's ability to pay for medicines varies significantly.

However, price is only one aspect of affordability. The other is ability to pay, which is down to provision and allocation of resources, primarily from governments, and poverty reduction. For the billion people who live on \$1 a day, virtually nothing is affordable.

Early in 2009 we announced a new strategic approach to pricing in the Least Developed Countries (LDCs)¹. From April 2009 we will reduce our prices for patented medicines in the LDCs so that they are no higher than 25 per cent of the price in the developed world. This will be the maximum price – where possible we will go further and reduce our prices more aggressively, while ensuring we cover our manufacturing costs so this offer is sustainable. Price reductions in April 2009 will be for 110 products and formulations across Least Developed Countries, with an average price reduction of 45 per cent.

We will also reinvest 20 per cent of our profits from LDCs back into projects partnering with organisations such as NGOs to widen access and strengthen the healthcare infrastructure of LDCs. Our sales in LDCs are relatively low so this 20 per cent of profit will be limited – initially around £1 to £2 million a year. However, by our action we hope to send a signal to all multi-national companies operating in LDCs to join us and contribute to making a difference.

In many developing countries the healthcare crisis is dominated by the social and economic impacts of HIV/AIDS, TB and malaria. GSK has both anti-retrovirals (ARVs) to treat HIV/AIDS and anti-malarial treatments in our portfolio. We are committed to increasing access by providing these medicines to the Least Developed Countries and sub-Saharan Africa at not-for-profit prices (see key facts box). We negotiate preferential prices for our HIV/AIDS medicines with [middle-income countries](#) on a case-by-case basis.

Read more about [extending our product portfolio in the developing world](#).

Vaccines – our tiered pricing model

Vaccines can make a significant [contribution to public health](#), helping to prevent many potentially fatal infectious diseases. Immunisation is acknowledged by the World Health Organization (WHO) as being 'among the most cost-effective of health investments'.

We make our vaccine portfolio available at preferential prices to developing countries, using a tiered pricing system. Prices are linked to gross national incomes as defined by the World Bank as well as the size of an order and length of a particular supply contract. For the developing world, prices can be as little as a tenth of those for developed countries.

We work with multinational organisations such as GAVI, UNICEF, the WHO and the Pan American Health Organization, governments and non-governmental organisations to provide appropriate and affordable vaccines for developing countries. We typically supply vaccines to GAVI and UNICEF at 10-20 per cent of developed world prices to these organisations.

By selling our vaccines in large volumes through longer-term contracts we are able to significantly reduce the price of each individual dose. This includes basic polio vaccines as well as specially developed combination vaccines that target several diseases. In 2008, of the 1.1 billion vaccine doses we shipped, 78 per cent went

to the developing world.

Many of our vaccines are included in government vaccination programmes in middle-income countries. For example, Rotarix, our rotavirus vaccine, is now included in government vaccination programmes for newborn babies in Brazil, El Salvador, Mexico, Panama and Venezuela. In 2008 we supplied 20 million doses of this vaccine; the vast majority went to developing or middle-income countries.

In addition to tiered pricing, we are looking for innovative ways to increase access to vaccines in poorer countries. One option being explored for Cervarix, our vaccine against Human Papillomavirus, is to partner with a major international non-governmental organisation. Through this partnership we will be able to use this organisation's distribution networks to increase the supply of our vaccine in developing countries, where most deaths from cervical cancer occur.

Preventing product diversion

Product diversion, where not-for-profit medicines are illegally shipped back for sale in wealthier countries, denies treatment to patients in poorer countries. Our anti-diversion measures include specially designed access packs for most of our ARVs, and red rather than white tablets for Epivir and Combivir.

We only enter into [voluntary licences](#) when we know the manufacturer can ensure product diversion will not occur.

1 As defined by the UN: <http://www.un.org/special-rep/ohrlls/ldc/list.htm>

Not-for-profit (nfp) prices for medicines – key facts

- GSK has offered preferential pricing for our anti-retrovirals since 1997 and formal not-for-profit (nfp) pricing since 2001.
- Our nfp prices are sustainable – we do not make a profit on them, but we do cover our costs. This means that we can sustain supply of these high-quality products for as long as they are needed
- Not-for-profit prices apply to GSK's anti-retrovirals and malaria treatments
- Nfp prices are available to all the Least Developed Countries and sub-Saharan Africa – a total of 64 countries
- In addition, PEPFAR projects and eligible Global Fund projects bring this number up to over 80 countries
- Eligible customers include public sector customers and nfp organisations as well as private employers in sub-Saharan Africa providing treatment to uninsured staff
- *Combivir*, our leading combination ARV, is available at \$0.54 a day
- Our nfp prices include insurance and freight costs, unlike the prices quoted by most generic companies. They are applicable to orders of any size and are not dependent on large order quantities

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Preferential pricing

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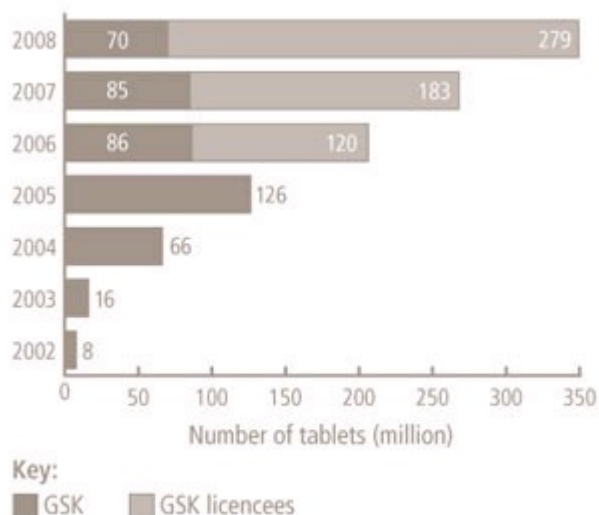
We offer our anti-retrovirals (ARVs) and anti-malarials at not-for-profit (nfp) prices to public sector customers and not-for-profit organisations in 64 countries - all the Least Developed Countries and all of sub-Saharan Africa. In February 2008 we announced significant new price reductions for our ARVs offered on a nfp basis to these countries. This reduction was the fifth time we have reduced prices as part of our pioneering preferential pricing policy originally introduced in 1997. *Combivir*, our leading ARV, now sells at \$197 per patient per year in the least developed countries compared to \$730 in 2001.

The most significant reduction, of almost 40 per cent, was on *Ziagen* oral solution (abacavir). This is recommended by the World Health Organization (WHO) for use in first-line and second-line regimens within resource-limited settings, particularly for children. A number of factors enabled us to implement these price changes, including improvements and efficiencies in manufacturing and supply, and reductions in the costs of active ingredients.

Number of tablets shipped

In 2008, we shipped 11.4 million tablets of nfp *Combivir* and 58.6 million tablets of nfp *Epivir* to the developing world, compared with 13 million and 72 million respectively in 2007. The decline in supply of our own ARVs is more than outweighed by a growth in volumes from our licensees. In 2008 our licensees supplied over 279 million tablets of their versions of *Epivir* and *Combivir* to African countries.

Supply of Combivir and Epivir tablets by GSK*



*This includes preferentially priced tablets supplied by GSK and tablets supplied by our licensees.

During 2008 GSK supplied ARVs at nfp prices to 37 countries, compared with 31 in 2007. We will continue to look for new customers for our nfp ARVs in these countries and regularly review our nfp prices. However, it may well be that our licensees are able to produce first-line ARVs at lower costs and will continue to increase their share of the business.

Patients receiving treatment

It is difficult to estimate the number of patients treated as a result of our preferential pricing agreements, since we do not control healthcare provision. However, the WHO estimates that three million people in the developing world were treated with ARVs by the end of 2007, an increase of one million in a year.

A report from the [Accelerating Access Initiative](#) (AAI) suggests that by December 2007, around 875,000 patients in developing countries were receiving at least one ARV treatment supplied by the nine R&D-based pharmaceutical companies in the AAI. In the two years since December 2005, the total number of patients in developing countries receiving treatment from the AAI companies had increased by 22 per cent. In Africa alone, over 665,600 patients are being treated with at least one ARV supplied by the AAI companies, an increase of 49 per cent over two years. This has resulted in an over 70-fold increase in the number of people being treated with medicines supplied by the AAI companies in Africa since the establishment of the AAI in May 2000.

Read more about how a GSK vaccine has contributed to the elimination of [Hib meningitis](#).

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Pricing in middle-income countries

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Middle-income countries (MICs), such as Brazil, China, Thailand and Indonesia, and some low-income countries such as India are more economically developed than the world's poorest countries, and often have a large and affluent middle class.

They therefore provide greater commercial opportunities than the world's poorest countries. According to a report by accounting firm, PricewaterhouseCoopers, the growing wealth of Brazil, China, India, Indonesia, Mexico, Russia and Turkey means they could account for 20 per cent of the global pharmaceutical market by 2020.

However, many middle income countries also have large numbers of people living in extreme poverty and healthcare demands often outstrip available resources. These challenges are made worse by an increasing incidence of chronic diseases such as asthma and diabetes.

To reflect this situation, in 2008 we restructured our commercial organisation. We split our old International division and created two new regions – Emerging Markets and Asia Pacific. This will enable us to respond to commercial opportunities while reflecting the healthcare environment and individual needs.

Increasing access to medicines in middle-income countries within a responsible commercial framework is complex. It is clear that there is no one universal 'one size fits all' solution. This complexity was a key aspect in the Pharma Futures 3 dialogue, which explored the links between sustainable pharmaceutical business models and improved health outcomes in middle-income markets, including China, India and Brazil. It is vital that we identify the best approaches for GSK to address these complex challenges.

The challenges include:

- Low government healthcare spend relative to gross domestic product (GDP). This can be as low as one per cent of GDP compared with an average of nine per cent in the EU
- Poor healthcare infrastructure, including hospitals, clinics, doctors and nurses
- A high level of income inequality within countries, which can complicate pricing considerations
- The affordability of medicines and vaccines
- Taxes and mark-ups on medicines and vaccines
- Stigma and discrimination associated with certain diseases
- Use of traditional medicines
- Remote rural populations

We recognise that many middle-income countries need assistance. However, we believe a different approach is needed from the one we take in the world's poorest countries.

Our offer to supply medicines at not-for-profit prices and vaccines at highly preferential prices in the world's poorest countries is only sustainable if we can continue to make an adequate return on them in wealthier markets. Many middle-income countries are also growing commercial markets for GSK and represent an

important source of future business for our industry.

Our response in these markets must therefore balance our commercial objectives with our global commitment: to work with governments and other stakeholders to support efforts to deliver our medicines and vaccines to as many needy people as possible. Our approach combines long-established practices such as voluntary licences, tiered pricing for vaccines and preferential pricing for HIV/AIDS and malaria medicines with more innovative strategies that focus on the different socio-economic groups within individual MICs.

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Pricing in middle-income countries

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Our approach to pricing in middle-income markets is constantly evolving and ongoing pricing pilot programmes are informing this evolution. These comprise a mixture of long-established practices and new approaches. We intend to formalise and communicate on our pricing policies in middle-income countries during 2009.

Long-established practices

Tiered pricing for vaccines

Our vaccines are available to 18 GAVI-eligible middle-income countries (MICs), including Indonesia, Sri Lanka and Cuba, at highly discounted prices. Many of our vaccines are also included in government vaccination programmes in middle-income countries.

Preferential pricing for HIV/AIDS and malaria medicines

We negotiate preferential pricing arrangements for HIV/AIDS medicines and anti-malarials with middle-income countries on a case-by-case basis. This is done bilaterally through dialogue with governments. We believe this approach is appropriate because the burden of disease and the resources available to address that burden vary significantly from country to country, and within countries. These arrangements combine a viable and sustainable commercial return for GSK with improved affordability for the healthcare systems concerned.

Novel approaches

We are developing a more flexible, responsive approach to accessing private and public sector markets in MICs. Our strategy focuses on the different socio-economic groups within individual MICs.

It uses the standard classifications for socio-economic groups, the A group being the wealthiest section of society and E being the poorest. Typically, a company such as GSK makes a disproportionate share of its sales to people in the A/B group with sales tailing off quite sharply in the C/D group. Usually we will be unable to compete with low-cost generic medicines for sales to the E group.

We believe the most productive way for us to align our commercial and accessibility goals is to make our products more readily available to the C/D segment of the market. This will free up more government funding for the poorest segment of the population.

We are exploring options through projects including:

- Tiered pricing models within as well as between countries, including those which enable products to be priced differently for the private and public health sectors
- Gauging the relationship between price and volume for selected products in targeted MICs. For example, we may be able to reduce the price of products where we have orders for a sufficiently high volume of products
- Local sourcing and manufacturing arrangements designed to address cost issues

It is too early to draw definitive conclusions from these pilot projects and some results from the pilots are commercially sensitive. In the pilots investigating the relationship between price and volume, the volume

targets were not achieved and the analysis was confounded by unexpected factors such as reduced demand for our diabetes medicine *Avandia*. However, it is clear that there are no simple or universal solutions. We have learned from the projects and will continue to investigate these approaches and establish further pilots where initial pilots have proved inconclusive. For example, we are exploring options such as within-country tiered pricing for vaccines.

It is clear that pricing decisions cannot be assessed in a vacuum and other factors, such as market dynamics including new product introductions and how competitors react to our price changes, have to be taken in to account. It is also evident that not every programme will be suitable for every middle-income country. These pilots are therefore helping to inform our approach in middle-income countries. We are confident that the more successful elements will be incorporated into our long-term commercial strategy and we plan to report more on this during 2009.

Cervarix price reduction – Philippines, Vietnam, Indonesia and South Africa

GSK works in partnership with stakeholders to optimise the availability of its vaccine against human papillomavirus. Improving access to treatment requires many stakeholders working together to develop better infrastructure, distribution channels, adequate funding, better disease awareness and education and the appropriate market dynamics.

GSK is committed to ensuring pricing is not a barrier to access in the developing world and has reduced prices in the Philippines, Vietnam, Indonesia and South Africa. For example, in the Philippines we have reduced the price of *Cervarix* by 60 per cent. In South Africa, the price reduction is of the order of 40 per cent.

GSK has a long track record of tiered pricing for vaccines available in government-led programmes, where we charge reduced prices in countries with lower levels of income. The reduction of the price for *Cervarix* in a number of countries is a further demonstration of our commitment to increasing access to our vaccines.

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Voluntary licensing

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Voluntary licences are granted by patent holders to allow a generics company to manufacture and sell their products. Some people assume that generics are always cheaper than branded products and are seen by many as a key solution to the access crisis in the developing world. Pharmaceutical companies are under increasing pressure to grant licences.

However, generics are not always cheaper and the success of a voluntary licence will depend on the right licensees being chosen. This is particularly true for the treatment of a chronic disease like HIV/AIDS, where the sustainable supply of good-quality anti-retrovirals (ARVs) is key.

We do not believe that voluntary licences are a universal solution to tackling HIV/AIDS or disease in general. In most cases local manufacture of ARVs will make little difference to their affordability and access to patients. This is a point endorsed by the WHO. This is because the real barriers to access are the lack of healthcare infrastructure and resources to pay for medicines regardless of where they come from.

However, funding from the World Bank and other international donors has meant that voluntary licences can have a role to play in efforts to tackle the HIV/AIDS epidemic in sub-Saharan Africa by helping to increase the availability of medicines and contribute to better security of supply.

A decision to grant a voluntary licence depends on a number of factors including, in the case of HIV/AIDS, the severity of the epidemic in that country, local healthcare provision and the economic and manufacturing environment.

We discuss voluntary licences with potential partners on a case-by-case basis. We need to be sure that the manufacturer can provide a long-term supply of good-quality medicines and will implement safeguards to prevent the diversion of medicines to wealthier markets.

We continue to consider the role of voluntary licensing in helping to increase access to medicines in middle-income countries without undermining our commercial business.

Compulsory licences

Compulsory licences are issued by governments and involve intellectual property rights being taken away from the rights holder. Compulsory licences are one of the flexibilities in the World Trade Organization's TRIPS agreement on intellectual property which can be used for humanitarian purposes. However, widespread use of compulsory licences will undermine the [intellectual property framework](#) and be counter-productive in the long term. R&D into new treatments, especially where commercial markets exist such as for HIV/AIDS, depends on protection of intellectual property.

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We granted our first voluntary licence (VL) in 2001 and have now negotiated eight licensing agreements for our ARVs in Africa. Some of our VLs cover individual countries or trade blocs while others cover all of sub-Saharan Africa.

Update August 2009

In July 2009 we agreed a royalty free voluntary licence to enable Aspen to produce our ARV abacavir. This takes the total number of licensing agreements for ARVs in Africa to nine. The offer to grant licences for abacavir is open to all our licensees.

In August 2007 we gave consent to enable a Canadian company, Apotex, to manufacture a generic fixed-dose combination ARV, containing two molecules over which GSK has patent rights, for the treatment of HIV/AIDS in Rwanda.

This consent was granted under Canada's Access to Medicines Regime which reflects the WTO '31f' agreement. This enables governments to authorise the production of certain patented medicines for export. GSK agreed to waive royalties on the basis that Apotex's triple combination generic ARV will be supplied on a not-for-profit basis.

Our licensees supplied 279 million tablets of their versions of *Epivir* and *Combivir* to Africa in 2007. This represents more than 50 per cent growth over 2007, and 130 per cent more than in 2006. We welcome this trend as it gives customers in sub-Saharan Africa greater choice and contributes to better security of supply.

We have granted a VL to Simcere, a Chinese manufacturer, granting them the right to manufacture and sell zanamivir (*Relenza*) containing products in China, and to sell in a number of other countries including all 50 of the least developed countries. Zanamivir is an anti-viral which can help treat influenza and the VL was driven by a specific concern to help ensure sufficient supplies in the event of a global flu pandemic.

Collaboration with local manufacture significantly reduces disease burden of rotavirus – Brazil

We pursue initiatives that have both high public health impact and are commercially viable. An example of this can be seen in the implementation of universal mass vaccination (UMV) programmes in Brazil against rotavirus.

GSK and the Brazilian vaccine manufacturer Fiocruz have had a long-standing partnership for the production of vaccines for diseases causing high mortality and morbidity such as polio, *Haemophilus influenzae* type b (Hib), measles, mumps, rubella and most recently rotavirus. The partnership between GSK and Fiocruz supports all of Brazil's requirements for universal mass vaccination against rotavirus with the *Rotarix* vaccine.

Despite incomplete coverage, the vaccination programme has significantly improved public health:

- A 29 per cent reduction of all hospitalisation due to acute diarrhoea of any aetiology in 2007
- An 85 per cent reduction of rotavirus-related hospitalisations¹
- A reduction in diarrhoea outbreaks due to rotavirus in São Paulo from 36 per cent in 2004 to 8 per cent

in 2008

- A reduction in the proportion of cases of gastroenteritis caused by the rotavirus from 88 per cent in 2004 to 1 per cent in 2008

The rotavirus vaccine is expected to lead to 703 avoided deaths (75 per cent reduction) and 1.7 million avoided cases (54 per cent reduction).

1. Brazilian Ministry of Health statistics

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Access to medicines is not only an issue for the developing world. Even in developed countries some patients cannot afford the medicines they need.

This is a particular problem in the US where many people do not have health insurance and there is limited public health provision.

We have developed Patient Assistance Programs (PAPs) and discount savings cards in the US and we have introduced discount cards in some middle-income countries.

Programmes in the US

Our Patient Assistance Programs (PAPs) and discount savings cards provide prescription medicines to uninsured patients in the US free or at minimal cost. GSK operates several programmes, including [Commitment to Access](#), which covers cancer treatments, and [Bridges to Access](#), which covers other medicines for outpatients. Patients are registered through one phone call from a patient advocate and receive medicine at their local pharmacy or by mail order.

[GSK Access](#) provides extra help for low-income senior and disabled patients enrolled in Medicare Part D. This programme provides free medicines for eligible patients who have spent \$600 or more on prescription medicines during the current year, and whose income is between 135 per cent and 250 per cent of the Federal Poverty Level. The Federal Poverty level is about \$11,000 for a single person, \$14,500 for a couple and \$22,000 for a family of four.

We are a member of [Together Rx Access](#), an industry programme which gives uninsured US citizens 25 to 40 per cent discounts on medicines from GSK and seven other pharmaceutical companies. The programme is open to people who earn up to four times the federal poverty level. Nearly two million Americans are enrolled in [Together Rx Access](#).

We are also working with governments and employers in the US to find new ways to address the problem of [chronic diseases while reducing healthcare costs](#)

Discount cards in other countries

GSK has introduced discount cards in Lithuania and Ukraine to enable low-income patients with chronic diseases such as asthma to obtain prescription medicines at a discount price.

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Programmes in the US

In 2008, more than 415,000 patients received GSK medicines worth over £56 million through our US programmes.

The value of our medicines is calculated using an average cost of goods rather than the wholesale acquisition cost (WAC) that we have used in previous years. This new approach to valuing medicines more accurately reflects the true cost to GSK and is therefore more transparent. We believe we are the first pharmaceutical company to adopt this practice.

The number of patients using our largest patient assistance programmes declined by eight per cent compared with 2007. This is due to a decline in sales for *Avandia* and generic substitution for *Coreg* and *Paxil*. There may also have been an increase in the number of people without insurance delaying visits to the doctor.

This year more than 8,000 patients received over 21,000 30-day prescriptions of GSK medicines through the *Together Rx Access* programme, giving patients discounts of more than \$1.2 million. Since its inception in 2002, *Together Rx Access* has given nearly two million patients savings totalling \$80 million across a wide range of products.

Discount cards in other countries

In Lithuania, our *Orange Card* gives senior citizens and the disabled a discount of up to 60 per cent on the patient co-payment on all GSK prescription medicines. So far more than 60,000 patients have applied for an *Orange Card* and over 450 pharmacies (30 per cent of the pharmacies in Lithuania) are registered to participate. In 2008 the total discount given was £450,000.

Our *Orange Card* in Ukraine gives significant discounts to all asthma and chronic obstructive pulmonary disease patients who need financial support for purchasing *Seretide*, our inhaled treatment for asthma and chronic obstructive pulmonary disease. In 2008 more than 19,000 patients received e-*Orange Cards* and 326 pharmacies were registered to participate in the programme. In 2008 the total discount given on GSK products was £658,000.

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Pricing our medicines

Prices for newly approved medicines are determined on a country-by-country basis.

In some countries, prices are negotiated directly with governments or other payers, for example sickness funds and private health insurers. In others, manufacturers are free to set their own prices subject to other kinds of government controls.

Pharmaceutical R&D is a lengthy and expensive process. To develop one successful medicine or vaccine it can take, on average, ten to twelve years and typically costs around \$1.2 billion¹. For every product that reaches the market, thousands do not make it through the research process.

We seek to ensure that the price of our new products reflects:

- Their clinical value to patients in terms of improved therapy, better safety and fewer side effects
- The high risks associated with R&D
- The need for a fair return on investment
- Affordability for our customers

Ultimately, national price regulation will often amount to a balancing act between managing public healthcare budgets, enabling patient access and rewarding innovation and R&D investment.

We sell our medicines to wholesalers and pharmacies, not directly to patients. These intermediaries often add their own price mark-ups to pharmaceutical products, and in addition duties and tariffs may be imposed on imported products. This affects the price paid by the end customer, for example national health services, hospitals and patients.

1. Tufts Center for the Study of Drug Development

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Intellectual property

Intellectual property (IP) refers to creations of the human mind. There are laws in most countries to stop those creations being used by others. These include patents, copyrights and trademarks.

At an international level, IP is protected through the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Rights Agreement, commonly known as TRIPS.

Patents and other IP rights play a vital role in encouraging the innovation needed to develop new treatments for many of the most serious and life-threatening diseases. We invest considerable time and money to develop each new pharmaceutical product - an average of \$1.2 billion¹ and 10-12 years per product. For every 5,000 to 10,000 compounds tested, an estimated five reach clinical trials and only one reaches the market².

If a new product could immediately be copied and sold by others, we would not be able to continue to fund new research. This would discourage innovation and limit research into newer and better medicines and vaccines.

In relation to the healthcare crisis in the developing world, intellectual property, specifically patents, has been criticised for two broad reasons. Opponents claim that:

- The market-driven IP-based R&D system has led to a mis-prioritisation of R&D resources. This means that R&D prioritisation is based on developed world market opportunities rather than on unmet medical need. This has led to an R&D deficit into diseases of the developing world
- IP has acted as a barrier to access. This has two facets: firstly patents have led to monopoly pricing and have prevented generic competition being able to drive prices down. Secondly, patents have acted as a barrier to follow-on innovation such as the development of fixed-dose combinations

We believe that these concerns have been overstated, but we recognise that we need to seek new approaches to IP to help tackle the healthcare crisis. We believe that the IP system is compatible with R&D into diseases of the developing world. GSK and others in the industry have expanded research into [neglected diseases](#) in recent years. In November 2008 the international trade association, the IFPMA, published data that showed that the number of medicine and vaccine projects undertaken by companies with product development partnerships or on their own had increased to 67, up from 58 in November 2007³.

We believe that patents are a minor issue in preventing people in the developing world from getting access to medicines. There is little or no patent protection for many vital medicines such as treatments for malaria, tuberculosis and diarrhoeal diseases, which kill millions of people a year. Over 95 per cent of the medicines on the World Health Organization's (WHO) Essential Medicines List are not patent protected anywhere in the world, yet the WHO says that one-third of the world's population does not have regular access to these drugs. In Africa and parts of Asia this figure rises to two-thirds of the population.

Poverty is the biggest barrier to effective healthcare in the developing world because it is usually associated with a poorly developed healthcare infrastructure with little or no access to doctors and hospitals. The significant barriers that stand in the way of access to medicines in the developing world must be tackled as a shared responsibility by all sectors of global society.

However, traditionally we have only allowed access to our intellectual property in very controlled situations. We are now exploring ways to be more flexible with our intellectual property that relates to neglected diseases.

IP's primary objective is to incentivise and reward research. However, there are a number of neglected tropical diseases, such as leprose and cholera, where there is a serious lack of research, for a variety of complex reasons. We need to explore how to address this gap, including the use of IP.

One approach might be for a [patent pool](#) to encourage more research into neglected tropical diseases. GSK is placing over 500 granted patents and over 300 pending applications, relating to approximately 80 patent families, in a pool to help others to develop potential medicines for neglected diseases. In addition to providing access to these patent filings, GSK will set out a mechanism to enable third parties to request access to other intellectual property and know-how about its medicines which may help researchers to develop new medicines for neglected tropical diseases.

The aim of any such pool must be to encourage research that would otherwise not happen. If, as we hope, something new comes out of such research, then the full benefits must go directly to the LDCs. Such a pool has to be voluntary, so as to foster an atmosphere of cooperation and to encourage others to join.

A pool is one mechanism we are exploring to achieve these aims. We will also consider new ways of stimulating research.

We will continue to defend our IP robustly outside the pool. Our business is sustained through being rewarded for the discovery and development of innovative medicines. However, in the poorest countries we plan to be much more flexible and will develop our work in this area throughout 2009.

Intellectual property laws can help prevent the distribution of [counterfeit products](#), which present a serious health risk for patients.

1. Tufts Center for the Study of Drug Development
2. Pharmaceutical Industry Profile 2008, Washington DC, PhRMA March 2008
3. www.ifpma.org/News/NewsReleaseDetail.aspx?nID=10975

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WTO and the TRIPS Agreement

Intellectual property (IP) rights are protected globally by the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).

The TRIPS Agreement was signed by all WTO member countries in 1994 and covers all types of IP including patents, copyright and trademarks. It sets minimum standards for IP rights in all WTO member countries.

The Agreement covers all areas of business and society including software, music and the arts, and is designed to encourage innovation in all business sectors.

Developing countries have been given extra time to comply with TRIPS. Some countries, for example India, had until 2005 to introduce patents for pharmaceuticals. The 50 least developed countries of the world, for example Rwanda and Gambia, have until 2016 to comply with the Agreement for pharmaceuticals, and until 2013 for all other sectors.

Patents, TRIPS and access to medicines

There have been concerns that patents and the TRIPS Agreement restrict access to medicines for people in developing countries, by making it difficult for them to obtain cheap generic versions of important drugs such as those used to treat HIV/AIDS. However, the TRIPS Agreement contains a number of public health safeguards that have been clarified by the WTO.

Concerns over TRIPS and access to medicines were addressed in 2001, at the WTO ministerial conference in Doha, when WTO ministers confirmed that IP protection is important for the development of new medicines and that it does not and should not restrict members' rights to protect public health. They also agreed that the TRIPS Agreement could and should be implemented and interpreted in a way that supports public health and promotes access to medicines.

This understanding was captured in the Doha Declaration on TRIPS and Public Health (the Doha Declaration), which confirmed the rights of member countries to use the flexibilities in TRIPS such as compulsory licences to protect public health priorities. Compulsory licensing allows governments to issue a licence so a patented product can be manufactured without the consent of the patent owner.

The WTO members further agreed to modify the TRIPS provisions relating to compulsory licensing in August 2003 so that countries unable to produce pharmaceuticals domestically can import patented products made under compulsory licences abroad. This provision was confirmed as an amendment to the TRIPS agreement by the WTO in December 2005.

GSK supports the Doha Declaration and the agreement on compulsory licensing. We are committed to playing a key role in the access crisis.

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Corporate Responsibility Report 2008

Intellectual property rights in brief

Patents

A patent gives the inventor of a new product the exclusive rights to manufacture, use, sell or import that product or the process used to make it. These rights are granted for a set period, generally 20 years. The term of the patent runs during the lengthy research and development (R&D) period, and often only five to eight years of the patent remains once a product is marketed. Some countries have extended the patent term to compensate for the long R&D process.

Patents are granted on the condition that the inventor publishes a full description of the invention, which would allow someone else to manufacture the product. This helps to build scientific understanding and encourage further research and innovation.

Trademarks

A trademark is a brand name, word, phrase, symbol or design, or a combination of these, that identifies and distinguishes a product or company. The owner of a trademark can prevent its use by a third party.

Trademarks enable our customers to tell our products from those of our competitors and provide reassurance of quality and the origin of the product. They are therefore a vital part of our marketing.

Data exclusivity

Before we can sell a new product we must prove that it is effective and safe to use. All our products are rigorously tested through clinical trials and other medical research. The results of this research are submitted to governments on a confidential basis.

Data exclusivity means that governments cannot use or disclose these data for a fixed period. This ensures that other companies cannot benefit from our research for free - for example to demonstrate the safety and efficacy of generic copies of our products.

In the interest of facilitating timely market access and the need to avoid repetitive animal testing and human clinical trials, competitors may refer to our data after expiration of the period of exclusivity.

Corporate Responsibility Report 2008

The future

Increasing access to medicines is a global challenge.

While encouraging progress has been made in some areas, significant problems remain and new issues are likely to emerge. For example:

- The continued need for a significant scale-up of treatment for HIV/AIDS in sub-Saharan Africa, in resource-poor settings
- A potential global flu pandemic
- The healthcare needs of poor people in middle-income countries
- The growing impact of non-communicable diseases such as diabetes in poor and rich countries
- The death of 2.5 million children each year from vaccine-preventable diseases

In 2009 we will implement programmes in a number of areas to help address these challenges:

- Intellectual property – we will explore ways to be more flexible with our intellectual property rights as they relate to neglected diseases, including exploring the idea of patent pools. We believe that this could speed up the development of new medicines and will encourage other pharmaceutical companies to adopt a similar approach.

Update August 2009

On 24 March 2009 we launched an LDC Neglected Tropical Disease [Patent Pool](#) website which enables interested stakeholders to:

- Access a list of GSK's patent filings on small molecule pharmaceuticals for the treatment of neglected tropical diseases (NTDs). Organisations can apply for licences in areas where we are not developing treatments;
- Request licences to research and develop a treatment for an NTD using a GSK patented technology for small molecules that we are not currently developing;
- Get our help with problems arising in their research and development into small molecule therapeutics to treat NTDs in Least Developed Countries.

In July 2009, the US biotechnology group Alnylam became the first company to follow GSK and contribute some of its patents to the pool.

- Pricing – we will improve transparency in our pricing policies and implement our new pricing policies in least developed countries and continue to evolve new approaches to increase affordability in middle-income countries

Update August 2009

On 1 April 2009 we implemented price reductions on our patented products in the Least Developed Countries (LDCs). Our commitment is that all GSK patented products in these countries will now cost less than 25 per cent of their price in the referenced developed countries.

We reduced prices for seven patented brands (110 individual product lines and formulations) by an average of 45 per cent. In some countries prices were not reduced immediately due to regulatory processes such as needing to obtain government authorisation, however the price reduction process was initiated. We also cut prices in some non-LDC markets in East Africa and Francophone West Africa to reduce the risk that products would be diverted from the LDCs and sold in these wealthier countries, thereby reducing their availability in the LDCs.

- Research – we will evaluate opportunities to expand our Tres Cantos ‘diseases of the developing world’ research centre into a world-class, global centre of excellence. We will do this by encouraging partnerships with governments, NGOs and other pharmaceutical companies.

Update August 2009

We have appointed a leadership team and are working with partners to extend the capacity and scope of the Tres Cantos facility. We are creating a more open and collaborative way of working and providing the facilities and support network needed for visiting scientists to form drug discovery project teams with GSK scientists.

- Healthcare services – we will seek to partner with governments and other stakeholders to help to strengthen healthcare infrastructure and services

Update August 2009

Through our reinvestment initiative GSK will support the governments of five LDCs in addressing priority healthcare challenges, to remove some of the barriers to quality healthcare and to strengthen health infrastructure. This will be achieved through targeted partnerships that will increase access to essential medicines and basic healthcare services. The work will begin before the end of 2009.

In four of the LDCs - one each from the GSK regions of East Africa, Southern Africa, Anglophone West Africa and Francophone West and Central Africa - we will be expanding our maternal and child health activities, with specific focus on children under five through the Integrated Management of Childhood Illness programme.

In one additional LDC we will be piloting a new Child Family Wellness (CFW) model. The CFW micro-franchising model involves building a network of micro pharmacies and clinics to improve access to essential medicines, basic healthcare and prevention services for children and families. The work will use business models that maintain standards, are readily scalable, and achieve economies of scale. GSK is currently working with an NGO, the HealthStore Foundation, which has implemented the model in Kenya, to run viability studies in at least two LDCs in East Africa. We will then select one country in which to implement the initiative.

In July 2009 we announced new commitments to fight HIV/AIDS in Sub-Saharan **Africa**, with a special focus on the care and treatment of children. They include £10 million seed funding to support a public private partnership for research and development of new HIV/AIDS medicines for children, a commitment to seek collaborations with other companies to develop fixed-dosed anti-retroviral combinations, and the creations of a £50m [Positive Action for Children Fund](#).

We are working with the main industry associations on new initiatives to increase R&D and improve access. The first outcome of this activity was the announcement in January 2008 of a grant of \$1 million by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) to the Special Programme for Research & Training in Tropical Diseases (TDR), co-sponsored by UNICEF, UNDP, the World Bank and the WHO. The grant will support TDR’s development of new medicines to combat diseases that disproportionately affect poor people living in developing countries.

Other activities include plans to establish a pilot industry consortium to focus on developing new targets (molecules that can prevent or interrupt disease progression) against diseases of the developing world.

Update August 2009

In April 2009 we announced our intention to combine the GSK and Pfizer HIV businesses to create a [new](#)

company dedicated to the discovery and delivery of HIV treatments. By combining the businesses we will create a specialist unit that is more sustainable and broader in scope than either company's individual business. The new company will particularly look to improve treatments and formulations for children living with HIV. We will continue to offer HIV medicines at not-for-profit prices in the world's poorest countries, and to issue new voluntary licences to diversify production and expand capacity in these markets.

The new company will be responsible for delivering on the commitments announced by GSK in July 2009.

Corporate Responsibility Report 2008

Response to assurance recommendations

Bureau Veritas assured the Access to medicines section of our [CR Report 2007](#) (see details on pages 49-50) and made recommendations for how we could improve our reporting on access to medicines in four key areas.

Below we report these challenges and how we have responded:

1. **Vision** – GSK could further enhance and communicate its overall vision and strategy on access to medicines. This should demonstrate a holistic, long-term approach; articulate the business case; provide context and explain how it is integrated into its overall business strategy.

GSK response: In June 2001, GSK published 'Facing the Challenge' which summarised our approach and contribution to improving access to medicines, and the principles underlying our approach. In 2008 Andrew Witty assumed the position of CEO of GSK and instigated a review of our approach to access to medicines. In a major speech at Harvard University in February 2009, Andrew Witty set out our approach to improving access to medicines in the developing world and the initiatives we will implement in 2009.

2. **Governance** – GSK should provide greater detail on the governance, accountability and management structures for access to medicines and the relationship with external stakeholders.

GSK response: Abbas Hussain, President of Emerging Markets at GSK, leads our access efforts which are also reviewed by the Corporate Executive Team, GSK's most senior management team, and by the Corporate Responsibility Committee of the Board. In 2008, we have continued to engage with stakeholders on access issues including the ATM Index and participating in the development of a report on GSK's approach by Paul Hunt, the UN Special Rapporteur on the Right to Health.

3. **Transparency** – GSK provides significant information and case studies but should also consider how to provide greater transparency on the impacts of its access to medicines initiatives and how to put these into context in relation to its overall operating model.

GSK response: Assessing the impacts of our access to medicines programme is a challenge. We report data on the number of tablets shipped through our preferential pricing programmes and voluntary licence agreements, but it is difficult to translate these figures into numbers of patients receiving treatment as we are not involved in healthcare delivery. Our medicines are also used in combination with medicines supplied by other pharmaceutical companies, so simply converting our shipments into patient numbers would be misleading.

The Accelerating Access Initiative (AAI), a public-private partnership working to combat HIV/AIDS, calculates treatment rates using medicines supplied by the nine R&D-based pharmaceutical companies involved in the partnership. It estimated that by December 2007, around 875,000 patients in developing countries were receiving at least one ARV treatment supplied by the companies.

Where we are able to generate robust data on the impact of our programmes we will seek to do so. For example in October 2008 significant data on the lymphatic filariasis (LF) elimination programme was published in the Public Library of Science (PLoS) Journal of Neglected Tropical Diseases¹. The study found that, in the ten years since GSK's commitment, the LF elimination programme has prevented 6.6 million children from acquiring LF and stopped a further 9.5 million infected people from progressing to more debilitating stages. All of this is the result of the fastest-growing drug administration programme in public health history, delivering what the study calls the 'best buy in public health'.

4. **Measuring performance** – linked to transparency, GSK should consider how to provide relevant indicators that demonstrate the implementation of a long-term strategy and promote comparisons across the industry.

GSK response: We welcome comparisons across the industry on performance on access to medicines; however, since approaches differ significantly between companies, making meaningful comparisons is a challenge. What is right for one company may not be right for another.

A method of ranking companies on their approach to access to medicines was developed during 2008, the Access to Medicines Index. GSK was ranked top in the first Access to Medicines Index, published in 2008. The Index rates companies according to their performance on eight criteria: management, influence, research and development, patenting, capacity, pricing, drug donations and philanthropy. We are pleased that our efforts to make our medicines more available have been recognised by the Index.

Additionally, during 2008 we were asked by Paul Hunt, the UN Special Rapporteur on the Right to Health, to contribute to a report he was preparing on GSK's approach to access to medicines. We cooperated fully and a number of senior executives, including our former CEO, Dr JP Garnier, and our Chairman Sir Christopher Gent, were interviewed. We expect the report to be published in the first half of 2009.

1 www.plosntds.org/article/info:doi/10.1371/journal.pntd.0000317

Corporate Responsibility Report 2008

Case studies

Potential malaria vaccine

Malaria kills more than one million people a year worldwide and makes millions more sick, most of them children living in sub-Saharan Africa. The international community urgently needs a safe and effective vaccine to control the disease. A vaccine, even with a partially effective profile, is a necessary component of a comprehensive malaria control programme and could potentially save hundreds of thousands of lives a year.

Our malaria vaccine candidate RTS,S is the most clinically advanced malaria vaccine candidate in the world. Since its discovery by GSK scientists in 1981, GSK has invested over \$300 million of its own resources in progressing RTS,S to phase III trials. A full set of clinical trials for a successful vaccine candidate can take 10 to 12 years, involve 50,000 to 100,000 volunteers, and cost \$500 million or more. Few vaccine candidates survive this rigorous process, which is one reason why pharmaceutical research and development is so expensive. Creating a malaria vaccine for young children and pregnant women - one of the most important vaccine-development challenges today - is no exception.

In January 2001, GSK and MVI (PATH Malaria Vaccine Initiative), with support from the Bill & Melinda Gates Foundation, entered into a public-private partnership to develop an RTS,S-based vaccine for infants and children living in malaria endemic regions in sub-Saharan Africa. The clinical development of RTS,S is conducted by the Clinical Trial Partnership Committee, a collaboration of leading African research institutes, Northern academic partners, MVI and GSK with support from the Malaria Clinical Trial Alliance. To date, GSK has invested over \$300 million of its own resources to develop the vaccine.

In December 2008, the New England Journal of Medicine published results of two separate studies demonstrating that the malaria vaccine candidate provides both infants and children with significant protection against malaria. In infants, data showed for the first time that the vaccine candidate can be administered as part of existing African immunisation programmes¹. In children aged five to seventeen months, the candidate RTS,S/AS01 reduced the risk of clinical episodes by 53 per cent over an eight-month follow-up period².

RTS,S is now entering pivotal phase III studies, which will be the world's largest malaria vaccine trial to date, involving 16,000 participants in 11 centres in Africa. Most of the places we are doing our trials have limited healthcare infrastructure. With partners we have therefore helped to set up these 11 clinics in seven African countries, with each training doctors, nurses and laboratory staff. We hope this infrastructure will remain long after the trials are completed.

Update August 2009

The Phase III trial of the RTS,S malaria vaccine candidate started in Bagamoyo, Tanzania, in May 2009.

The children who need this vaccine are among the poorest in the world. Price cannot be a barrier to access and we will work with supply organisations such as GAVI and UNICEF to ensure the price is set at the right level. We are also committed to working with the international community to mobilise the resources to fund the vaccine and the infrastructure needed to deliver it.

1. Abdulla S, Oberholzer R, Juma O, et al. Safety and immunogenicity of RTS,S/AS02D malaria vaccine in infants. N Engl J Med 2008;359:2533-44.

2. Bejon P, Lusingu J, Olotu A, et al. Efficacy of RTS,S/AS01E : clinical malaria in 5 to 17 month old children. N Engl J

Extending our product portfolio in the developing world – low- and middle-income countries

In July 2008 GSK entered a partnership with the South African pharmaceuticals company Aspen. This is in line with our aim to grow a diversified business and operate in a way that is adapted to patient needs in low- and middle-income markets.

Aspen's product portfolio covers a broad range of therapy areas relevant to the disease profile in developing countries, including: analgesics (for pain relief), anti-hypertensives (for high blood pressure), bronchodilators (for the treatment of asthma), anti-bacterials, anti-gout agents, anti-inflammatory agents, anti-depressants, anti-fungal agents, anti-histamines (for the treatment of allergies) decongestants, gastro-intestinal agents and dermatologicals (to treat skin conditions).

Through gaining access to Aspen's current portfolio and future pipeline, GSK will be distributing more products and medicines needed by those in low- and middle-income countries. The long-term nature of this collaboration – initially beyond a 10 ten-year period – also underlines GSK's philosophy of investing in a meaningful and sustainable manner in the developing world.

In January 2009 we announced an agreement with UCB S.A. to acquire its current marketed product portfolio across certain territories in Africa, the Middle East, Asia Pacific and Latin America. As a result of the agreement, GSK will acquire several leading pharmaceutical brands in a number of disease areas. These include *Keppra* for the treatment of epilepsy and *Xyzal* and *Zyrtec* for the treatment of allergic rhinitis.

The Aspen partnership and the UCB deal sit alongside the recent acquisition of Bristol Myers Squibb's mature pharmaceuticals businesses in Egypt and Pakistan and the two associated manufacturing facilities. Together, these deals will provide GSK with access to a renewable, high-quality and competitively priced pipeline of branded pharmaceuticals products that complements its existing portfolio of products, and will help drive patient access in low- and middle-income markets.

GSK vaccine eliminates Hib meningitis as a public concern in Uganda

A national, four-year immunisation programme using GSK's *TritanrixHB* Hib vaccine has eliminated Hib meningitis as a public health concern in Uganda, according to the Global Alliance for Vaccines and Immunisations (GAVI)¹. Hib meningitis is a dangerous inflammation of the lining of the brain and spinal cord. GAVI, a public-private partnership that includes the World Health Organization and the World Bank and is supported by the Bill & Melinda Gates Foundation and others, says that the use of *TritanrixHB* Hib between 2002 and 2006 has reduced the number of incidences of the disease in Ugandan children to zero.

The news follows similar results in Bangladesh, Kenya, Chile and the Gambia, as well as Britain and the US, where the vaccine was shown to cut the number of cases of Hib meningitis by at least 88 per cent in a three-to-five year period.

Julian Lob-Levyt, Executive Director of GAVI, says the results are extremely positive. "We can applaud a true success in controlling this deadly disease, which has too often claimed so many lives," he says.

Though developed countries have largely eliminated the disease, Hib vaccine distribution has been slow in poorer parts of the world due to financial and logistical problems, as well as limited awareness of the disease. In Uganda, the government obtained GAVI support to use 16.5 million doses of 5-in-1 vaccines, giving protection against Hib, diphtheria, pertussis, tetanus and hepatitis B. According to a study published in *The Bulletin of the World Health Organization*, the vaccination programme in Uganda is now preventing almost 30,000 cases of severe Hib disease and 5,000 child deaths every year. "The introduction of Hib vaccine has completely changed the epidemiology of bacterial meningitis in Uganda," says Adeodata Kekitiinwa, a paediatrician at Kampala's Mulago Hospital, who co-authored the study.

Hib kills about 400,000 children under the age of five every year, and is linked to around three million cases of illnesses that can result in long-term effects such as deafness, paralysis, mental retardation and learning disabilities. GAVI says that for every child with Hib meningitis in a developing country, there are thought to be five to ten others with Hib-related pneumonia, which is also preventable by vaccination.

1. GSK press release, March 2008

Corporate Responsibility Report 2008

Q&As

Here we respond to questions raised by our stakeholders

Aren't your access programmes just a drop in the ocean, given the scale of the healthcare crisis in the developing world?

The global healthcare crisis is extensive and complex, and the programmes of any single organisation are insufficient on their own. Political will and the effective investment of extra resources are required to support healthcare development and build infrastructure. GSK and the wider pharmaceutical industry do not have the mandate, expertise or resources to address the problem alone. Without a global partnership to address the issues, the efforts of any individual stakeholder will be inadequate. Primary responsibility for dealing with the crisis lies with governments, which can call on international agencies and NGOs for support. GSK is committed to playing a full part in partnerships with these organisations and is seeking new ways to make a contribution.

We focus our access programmes on specific areas where we think we can make a real difference. For example, we research and develop medicines and vaccines that are particularly needed in developing countries, and make them available at lower prices through preferential pricing arrangements and voluntary licences. We are also working to identify other ways that we can support the strengthening of healthcare systems through expanding our pricing policies, by being more flexible with our intellectual property and by investing in healthcare infrastructure.

Why are your medicines so expensive? Wouldn't the most responsible thing you could do be to cut the price of your medicines?

Improving affordability of our medicines is important and we are taking steps to do more in this area. However, as Kevin de Cock, the Head of HIV/AIDS at the WHO, has said "If you work in these countries it is very obvious, very quickly, that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems, particularly in Africa." Therefore, unless action is taken to address the underlying problems of poverty and healthcare infrastructure, reducing prices alone will not solve the problem.

We have to price our products at a level that enables us to continue to fund R&D and discover the medicines and vaccines of the future. We also need to make enough profit so that GSK remains an attractive prospect for investors. While we want to make a difference, cutting prices too far would mean we undermine the long-term profitability and therefore sustainability of our business. Getting this balance right isn't easy. The pricing pilots we have been conducting in recent years have taught us that there are no easy solutions. We believe that the new pricing policies we announced in 2009 will help to improve affordability for the world's poorest and we will continue to learn and refine our approach as we roll out these [policies](#).

Why are so few people with HIV/AIDS receiving treatment in the developing world?

There has been important progress in this area and now over three million people in the developing world are receiving treatment with life-saving anti-retrovirals. This has led to a decline in deaths caused by AIDS despite an increase in the number of people living with HIV. However, there is much more to do. The core issue is that many people in developing countries do not have access to effective healthcare services and are therefore unable to access medicines. Due to poverty, many clinics and patients are unable to pay for even the cheapest basic generic medicines.

The access issue is complex and multifaceted. Pricing of medicines is important, but we believe there are many other more significant barriers. Other factors that play a part are inadequate healthcare resources, lack

of clinics and hospitals, poor distribution networks, low numbers of trained healthcare providers, high levels of patient illiteracy, significant stigma and discrimination, and a lack of political will and inadequate prioritisation of health in government budgets. This is why in 2009 we announced that 20 per cent of the profits we make from selling medicines in least developed countries will be reinvested into projects that strengthen infrastructure and widen access.

Why don't you just donate your AIDS products to the world's poorest?

In common with many other stakeholders, including Oxfam and the WHO, we do not believe that donations of ARVs offer a solution to the AIDS pandemic or for healthcare problems in the developing world more generally. This is a widespread crisis and one which requires a long-term commitment to treatment. This commitment cannot be assured through donations. As WHO Director General Margaret Chan has said "Health systems are the tap root for better health. All the donated drugs in the world won't do any good without an infrastructure for their delivery."

In some limited circumstances donations may be appropriate, for example, in disease elimination efforts such as the Global Alliance to Eliminate LF. We have in the past donated ARVs to support UNICEF Prevention of Mother-to-Child Transmission programmes, and we continue to support collaborative clinical trials to assess the appropriate use of ARVs in resource poor settings.

Why doesn't GSK extend its not-for-profit prices to middle-income countries?

Middle-income countries are not automatically eligible for the not-for-profit prices offered to Least Developed Countries (LDCs) and sub-Saharan Africa. However, they can access medicines at reduced prices. Middle-income countries can secure preferential prices through bilateral discussions with GSK and we are looking at ways to make this process easier.

We are focusing our preferential prices on the countries where the need is greatest and resources are most limited. It is widely accepted that in terms of support for improving healthcare services, these are the LDCs (as defined by the UN) and sub-Saharan Africa. We have been conducting pricing pilots in middle-income countries in recent years which have taught us that there are no easy solutions. However, we will continue to develop policies in middle-income countries that are more flexible on price and therefore more closely reflect a country's ability to pay.

Why don't you allow middle-income countries to buy your ARVs from generic manufacturers?

We have granted eight voluntary licences for our ARVs to African generic companies. Under these arrangements they can supply a number of middle-income countries in Africa. Middle-income countries are generally more economically developed than the least developed countries and often have a large and affluent middle-class. These countries also have large numbers of people living in extreme poverty and healthcare demands often outstrip available resources. We recognise that many middle-income countries need assistance. However, we believe a different approach is needed from the one we take in the world's poorest countries and we will continue to refine our approach during 2009.

Our offer to supply products at not-for-profit prices in the world's poorest countries is only sustainable if we can continue to make an adequate return on them in wealthier markets. Many middle-income countries are also growing commercial markets for GSK and represent an important source of future business for our industry. Our response in these markets must therefore be one that balances our commercial objectives with our global commitment to work with governments and other stakeholders to ensure that our medicines and vaccines reach as many as possible of those who need them.

We believe governments in middle-income countries can improve access by increasing investment in disease prevention and healthcare; eliminating taxation and tariffs on medicines; and creating an environment which allows a strong private healthcare sector to co-exist with public healthcare provision. We are working with governments to find creative ways to meet these goals.

Why don't pharmaceutical companies work together to increase access to medicines?

We are working with the main industry associations on new initiatives to increase R&D and improve access, and we will continue to seek new opportunities to work in [collaboration with all stakeholders](#), including other companies.

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Corporate Responsibility Report 2008

Research practices

We are committed to focusing on the patient in everything that we do. Our R&D pipeline is central to our ability to meet patients' needs.

High ethical standards in R&D are key to protecting participants in our clinical research, ensuring the quality of our research, and maximising the benefits and minimising the risks of our products. High ethical standards are also essential for us to obtain regulatory approval for new medicines, and for patients and doctors to put their trust in our research programmes and products.

We aim to make our medicines as safe as possible by evaluating the risks and benefits at every stage from initial research, through to clinical trials and then after a new product is approved for sale.

We are committed to high levels of transparency about the results of our clinical research and use a number of reporting channels so that those who evaluate the efficacy and safety of our medicines or use our medicines can make informed decisions on their use.

We also recognise that biomedical research can raise ethical concerns including:

- The use of emerging technologies, such as cloning and the use of stem cells
- Animal research
- The storage and use of human tissue
- The protection of personal information about research participants

We participate in discussions on research practices and we regularly [engage with academic scientists, regulators, policy makers and other stakeholders](#) on related issues.

Corporate Responsibility Report 2008

Emerging technologies

Research capabilities are expanding through the development of technologies related to areas of research such as stem cell and genetic research.

These advances are helping to expand the boundaries of scientific understanding. These technologies hold out hope for new ways to treat serious diseases as well as better ways to evaluate the risks and benefits of the medicines we develop. For example, advances in genetic research are beginning to enable identification of patients who are more likely to experience a side effect from a medicine. We use emerging technologies in our research and we are involved in [collaborative research on these technologies](#).

We recognise that research using these emerging technologies can give rise to ethical concerns.

Here we outline our involvement and approach to:

- The use of [cloning technologies](#)
- The use of [stem cells](#)
- [Genetic research](#)
- [Collaborative research on emerging technologies](#)
- Use of [transgenic animals](#)

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› [Cloning technology and stem cell research](#)

Corporate Responsibility Report 2008

Cloning technologies and stem cell research

Cloning technologies

GSK uses cloning technologies to replicate molecules and cells for research. These technologies have provided better ways to evaluate compounds, enabling greater insight into the risks and benefits of potential medicines and helping to create better medicines for patients. This technology is a fundamental component of medicine discovery and development.

GSK does not clone animals. We do not use cloning technologies with the intention of reproducing entire human beings and we do not see a medical or research case for doing so.

Read our [position statement on cloning technologies and stem cell research](#).

Stem cell research

We recognise the importance of being clear about our [approach to stem cell research](#) and the standards we apply in this area of research.

We updated and published our approach to stem cell research in 2008. It sets out the standards we apply when using stem cells, including when using embryonic and foetal stem cells.

In 2008, we began a five-year collaboration with the Harvard Stem Cell Institute (HSCI). This includes a \$25 million investment to support research at Harvard University and a number of affiliated hospitals in the areas of neuroscience, heart disease, cancer, diabetes, musculoskeletal diseases and obesity. The collaboration is overseen by a joint steering committee made up of HSCI and GSK scientists and managers.

We are also a founding member of the Stem Cells for Safer Medicine (SCSM) initiative in the UK. SCSM aims to develop a bank of human cell lines to be used in early medicine discovery. This will provide early identification and elimination of potential toxicity issues before clinical testing. A number of public sector organisations are contributing to the initiative including the Department of Health, the Department for Innovation, Universities and Skills, the Scottish Government, the Medical Research Council and the Biotechnology and Biological Sciences Research Council. An independent ethics review board is being established to review the SCSM ethics policy.

Read more about how we are [collaborating in research on emerging technologies](#).

Corporate Responsibility Report 2008

Genetic research

Genetic variation underpins many aspects of human health, such as why some people get certain diseases while others do not, at what age diseases manifest themselves and how fast they progress. In the last year, more genes have been identified for common human diseases than in the cumulative history of genetics research. Diseases for which genetic risk factors have been identified include diabetes, heart disease, obesity, several cancers, asthma and a number of autoimmune disorders. GSK researchers have led or contributed substantially to several of these findings. These discoveries, and others to come, offer promise for the development of innovative new medicines.

Individual differences in genes also affect how people respond to medicines. Differences in genes can explain why some patients experience adverse responses to certain medicines while others enjoy benefits without such effects; why some individuals require greater doses of medicines than others to achieve the same level of efficacy; and why some groups of individuals respond well to treatment while others do not. GSK scientists are using emerging genetic information to study how medicines can be differentiated to suit groups of patients with different genetic characteristics.

Successful genetics research requires close collaboration between organisations with different areas of expertise. We are engaged in a number of research projects involving academic partners, regulatory agencies and other pharmaceutical companies. Read about our involvement with the [Serious Adverse Events Consortium \(SAEC\)](#) collaboration.

We recognise that people have concerns about some of the applications and standards of genetic research. We aim to address these concerns by being transparent about how and why we conduct genetic research. Any genetic analysis during GSK clinical trials is only undertaken after seeking and obtaining informed consent from the patient. This procedure includes providing information on the purpose and scope of the research and who has access to the genetic research data.

We believe that the pharmaceutical industry shares responsibility with governments for helping to identify and develop policy on genetic research. We refer to guidance from national and international groups to inform our genetic research activities such as the European Medicines Evaluation Agency, the US Food and Drug Administration and the Council for International Organisations of Medical Sciences.

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› [Collaborative research on emerging technologies](#)

Corporate Responsibility Report 2008

Collaborative research on emerging technologies

New scientific knowledge and technologies can be developed for application to medicine discovery and development through collaborative research that combines resources, expertise and know-how from several partners. The benefit of this research is often realised by making the results widely available to the research community.

For example, we are an active participant in the Innovative Medicines Initiative (IMI) a public-private partnership set up by the European Commission and the pharmaceutical industry through the European Federation of Pharmaceutical Industries and Associations (EFPIA). The IMI will support and stimulate collaborative research in Europe involving pharmaceutical companies, smaller bioscience companies, academia, regulators and patient groups with the aim of removing barriers to the discovery and development of new medicines.

Read more about our [investment in R&D and new technologies](#).

More on our [partnerships and academic collaborations](#).

Corporate Responsibility Report 2008

Animal research

Approach

Performance & plans

Animal studies remain a small but vital part of our research. They are the only method that can demonstrate the effects of a potential new medicine in a living body before it is used in humans. In addition, research in animals can provide vital information about the causes of diseases and how diseases may develop.

Safety regulations require us to test all new medicines on animals before they are tested in clinical trials using humans. Most vaccines have to be tested on animals each time a new batch is produced.

Our non-medicinal Consumer Health products or ingredients, for example dietary supplements, are not tested on animals unless there is a specific demand from a regulatory authority or if we determine that a study is needed to support safe use. GSK does not conduct animal testing on our Nutritional Healthcare products or products classified as cosmetics, for example toothpastes marketed in the European Union.

When animals are necessary for our research, we are committed to acting ethically, providing for the animals' health and wellbeing and practising good animal welfare.

Our approach

GSK has animal research laboratories in Europe, Asia and the US. Some animal research is conducted by external contractors on our behalf, representing around six per cent of our total animal use. We estimate that animal research accounts for around five per cent of all GSK research expenditure.

Almost all the animals used by GSK are rodents, mainly rats and mice. We also use rabbits, dogs, non-human primates, fish, ferrets, chickens, pigs, cats, sheep and goats. Together these account for just over one per cent and are listed in order of magnitude of use.

Ultimately GSK would like to see the important benefits of research being achieved and applied to humans without the need for animals in research. We do not believe this can be achieved in the foreseeable future. Our goal is to use animals only when scientifically necessary, use as few as scientifically feasible and to minimise pain and distress. Therefore GSK remains committed to the 3Rs.

The 3Rs

A key aspect of animal welfare is covered by what the biomedical community refers to as the three Rs (3Rs). These Rs are:

- Replacing research using animals with non-animal alternatives or species of the lowest possible order (phylogenetically)
- Reducing the number of animals used in experiments and still obtaining the same information as in a larger study
- Refining techniques to minimise pain and distress and maximise the welfare of animals

Our scientists always try to devise experiments that do not require any animals. When that is not possible, the researchers will work with others to design an experiment so that we obtain the necessary information from the smallest number of animals possible, with the least effect on individual animals.

We implement the 3Rs by using advanced scientific methods, training, raising awareness, and sharing and encouraging best practice. For example, we use ultrasound for imaging heart disease in rats and we have a forum for discussion on global principles for animal housing. [Read more](#) on recent GSK advances in replacing, reducing and refining animal use

In addition we encourage a 3Rs culture at GSK through:

- Regular training for staff involved in the care and use of animals
- Review of study designs by an ethical panel which considers the 3Rs and whether alternatives to animal studies are possible prior to the approval of studies
- Refining techniques to minimise pain and distress and maximise the welfare of animals
- Our internal 3Rs website which champions advances in refinement, reduction and replacement of animal use in medicine discovery and development, and promotes their application across R&D
- A news bulletin on advances in the 3Rs which is updated on a rolling basis and is easily accessible from the 3Rs website
- Our internal Animal Welfare Awards for employees who have made outstanding advances in implementing the 3Rs

Non-human primates

Our policy requires that studies involving animals must use the lowest possible order (phylogenetically) of animal appropriate for the research study. Occasionally, non-human primates may be the only animals where the anatomy and/or physiology of a disease is similar to that in humans. Sometimes only human and non-human primates will be affected by or respond to a potential medicine or vaccine; for instance, a new medicine may be based on a molecule produced by primates, including humans, and would be destroyed by the immune systems of other species. We therefore use non-human primates, only if no species of lower neurophysiological sensitivity is appropriate. The two most common non-human primates species used in research are macaques and marmosets. Of the animal research that we carry out, less than 0.5 per cent involves non-human primates.

Transgenic (genetically modified) animals

Genetically modified animals, also known as transgenic animals, have been genetically adapted by scientists to create new characteristics. Most transgenic animals (over 95 per cent) used in biomedical research are mice. Transgenic strains of animals are developed to answer specific compound or disease-related questions as part of the medicine discovery process. For example, transgenic mice that model Alzheimer's disease have been fundamental in biological research, new compound development and target validation. The use of such transgenic models in mice can sometimes replace the need for studies in higher order animals.

GSK worldwide standards

While recognising differences in country-specific regulations, GSK achieves worldwide standards by using [core principles](#) for the care of laboratory animals. These principles establish our basis for animal work conducted by or on-behalf of GSK. In addition, all GSK facilities and external laboratories conducting research on our behalf must follow all legal and regulatory requirements. In the UK these regulations are the responsibility of the Home Office. In Europe animal research comes under Directive 86/609/EEC and in the US is covered by the Animal Welfare Act 2006.

We also continue to seek voluntary accreditation from recognised agencies such as the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALACi).

Communicating our approach

Some people hold strong views on animal research and testing. We believe it is important to explain the need for animal research and testing and to be transparent about what we do.

Many of our laboratories host visits from schools, colleges, animal welfare organisations and others. We engage regularly with animal welfare organisations and our investors, as well as contributing to the debate in the media.

Protest

We accept the right of lawful protest against animal research as a part of a free society, but condemn the use of violence and intimidation by some who are opposed to animal use. We welcome the shift away from extremism to informed debate.

Corporate Responsibility Report 2008

Animal research

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The great apes family comprises gorillas, chimpanzees, orangutans and bonobos. One species of ape, Pan troglodytes, also known as the ‘common chimpanzee’, has been used in biomedical research for over three decades. The other great apes are not used in biomedical research. In 2008 we took a voluntary decision to no longer carry out research in great apes. Read more in our position statements on the use of [non-human primates](#) and [great apes](#) in research.

As well as the ban on the use of great apes, recent GSK advances in replacing, reducing and refining animal use include:

- Implementing a polio vaccine test at the bulk manufacturing stage that uses transgenic mice instead of non-human primates. These are mice that have been genetically altered to make them susceptible to the polio virus
- Decreasing the number of animals needed for vaccine testing. For example, we included an *in vitro* (non-animal) test in the regulatory submission for our new vaccine against the Human Papillomavirus, *Cervarix*. This means that for many markets new batches of *Cervarix* will not need to be tested in animals
- Developing a transgenic mouse model that mimics an accelerated form of Alzheimer’s disease to replace primates as a primary model for this disorder. Fundamental biological research, compound development and target validation have been carried out using this mouse model, facilitating greater understanding of this disorder and the potential for future therapies
- Implementing new technology to collect blood samples in animal studies. This approach enables analysis to be carried out on much smaller blood samples than traditional techniques. This enables quality data to be obtained using fewer animals
- Working with governments to change regulatory requirements so fewer animals are required for routine testing. A proposal to reduce animal testing originating from GSK’s vaccines business was submitted to the European Vaccine Manufacturers Association and later presented to the European Directorate for the Quality of Medicines in 2007
- Developing *in vitro* alternatives to safety tests which check the potential impact of pharmaceutical process materials on workers’ skin and eyes. No animals have been used in the evaluation of dermal or eye irritation for worker safety purposes since 2006
- Donating our collection of information on commonly used blood collection methods to the UK National Centre for the 3Rs (NC3Rs). Our donation was the founding part of the NC3R’s blood sampling website. This UK site is used by many laboratory staff to choose the most appropriate technique for the humane and efficient sampling of blood

Our internal Animal Welfare Award recognises work that is demonstrably above and beyond the very high standards of care, experimental design and implementation expected in GSK from all employees involved in animal experimentation. To receive the Award, the contribution should have tangible benefits in terms of one or more of the 3Rs and should make a difference to how animal experimentation is conducted at GSK or how animals are routinely cared for.

Recent recipients of our internal Animal Welfare Award have been:

- A team in UK for implementing blood-spot technology in preclinical toxicokinetic (TK) studies. Using this technology meant researchers needed significantly smaller volumes of blood, which therefore meant fewer animals were needed for TK studies
- A member of the Neuroscience department for developing and assessing an alternative method of administering medicines to rats. This replaces the previous method that required restraint during dosing and allows us to train rats to drink the test substance directly from a syringe.
- A team in Italy who developed an innovative nicotine self-administration animal model for pharmacological treatments aimed at smoking cessation. It resulted in a 40-50 per cent reduction in the number of animals needed per study

Number of animals

In 2008 the absolute number of animals used in our laboratories was nine per cent lower than in 1994 while R&D activity has tripled in the same period.

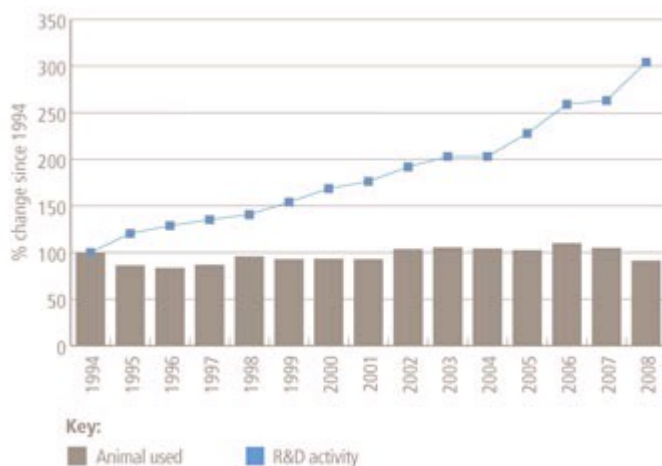
We estimate that the proportion of total GSK animal research conducted by external contractors was lower in 2008 at 6.2 per cent, compared to 7.9 per cent in 2007.

Animals used by GSK in 2008 (per cent)*

Mice	71.1
Rats	20.5
Guinea pigs	7.1
Other rodents	0.2
Rabbits	0.4
Others	0.7

*This does not include animals used by external contractors on our behalf. Of the animals used by external contractors on our behalf in 2008, 88.7% were rodents and rabbits.

Change in R&D activity compared to change in number of animals used by GSK*



* These data do not include animal research conducted by external contractors on our behalf. R&D activity combines our R&D budget and our vaccine sales, the two main drivers of animal use.

We started separately estimating our external animal use in 2002 and to 2008 have recorded external animal use as representing 3.2%, 4.3%, 6.7%, 6.3%, 8.2%, 7.9% and 6.2% of total animal use. The range of external interactions that may involve GSK, directly or indirectly, in animal use is so diverse, and is reported to the regulators by third parties, that we refer to these data as an estimate.

AAALACi accreditation

Our animal laboratories in Belgium, Italy, Spain, the UK and the vast majority of those in the US are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACi), a private, non-profit organisation that promotes the humane treatment of animals in science through voluntary accreditation and assessment programmes. To achieve AAALACi accreditation, an organisation must go through a rigorous assessment by the association which reviews facilities, workers and animal care. To maintain accreditation annual updates and on-site reviews on a tri-annual basis are required. These site visits are conducted by members of the AAALAC Council and other trained professional staff.

This accreditation covers over 90 per cent of the animals housed in GSK-owned laboratories and we are working to extend this accreditation to our other animal facilities.

Our plans

GSK is committed to the 3Rs; a current initiative includes a review of animal models across the business. This will look at the types of studies being performed to ensure the most suitable model is being used and that the appropriate numbers of animals are involved. Our R&D leadership team will review outcomes of this analysis and make recommendations for further initiatives in 2009 and beyond.

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Corporate Responsibility Report 2008

Human tissue research

Research using human tissue or human biological samples is fundamental to the discovery, development and safety monitoring of GSK medicines.

It is vital that this research is conducted in a manner that respects the rights of research participants and meets legal and ethical obligations.

The UK Human Tissue Act 2004 makes consent the fundamental legal requirement for the collection, use and storage of human tissue in the UK. This was introduced in 2004 following events at Alder Hey Hospital and Bristol Royal Infirmary where human tissue was taken, used and stored without consent.

In 2008, we introduced a policy which applies the principles of the UK Human Tissue Act on a global basis for research conducted, sponsored, supported or funded by GSK. This will ensure that the stringent ethical requirements of the UK law are applied wherever research is conducted using human biological samples.

Corporate Responsibility Report 2008

Medical governance

GSK is committed to the highest standards of ethical medical practice. This supports our mission to improve the quality of human life by enabling people to do more, feel better and live longer.

Medical governance at GSK is the system of principles, policies and accountabilities that ensures we apply generally recognised principles of good medical science, medical integrity, ethics and standards. It provides a framework to embed the following principles:

- Patient safety is the fundamental operating principle for GSK ahead of commercial or other interests
- Our clinical research is conducted in an objective, scientific and ethical manner which protects and informs patients
- Promotional practices and the information we provide on our products is ethical, accurate and balanced so that our medicines are used appropriately to benefit and minimise the risks for patients

Medical governance across GSK encompasses the principles, policies and accountabilities of three areas:



We have a framework for medical governance across all our businesses and our Chief Medical Officer (the most senior physician at GSK) has responsibility and authority for establishing an effective medical governance system. Our Corporate Executive Team members are responsible for the performance of, and compliance with this system within their areas of responsibility.

Our Medical Governance Executive Committee establishes policy for medical governance, subject to approval from the Corporate Executive Team. It also ensures that our medical governance systems are operating effectively. Regional medical directors together with their regional presidents and the country/territory medical directors, ensure our policies and systems for medical governance are understood and complied with in the countries for which they have responsibility.

Read about our [patient safety governance framework](#).

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Corporate Responsibility Report 2008

Clinical research

We carry out a series of clinical trials to evaluate investigational medicines for their potential to become new medicines. The effect of the potential medicine will often be compared against marketed medicines or in some cases an inactive substance (a placebo). Successful clinical trial programmes usually have three or four phases, and safety is evaluated throughout the [clinical trials process](#).

We have rigorous procedures and assurance processes to ensure our clinical trials of our medicines are conducted according to the Good Clinical Practice (GCP) guidelines developed by the International Conference on Harmonisation (ICH) and the principles contained in the World Medical Association Declaration of Helsinki on the 'Ethical Principles for Medical Research Involving Human Subjects (2008)'. GSK-sponsored clinical trials are conducted to the same ethical standards irrespective of whether they take place in developed or developing countries.

The safety of those who participate in our clinical trials is of paramount importance. Our [informed consent](#) procedure ensures that all volunteers are informed of aspects of the trial that are relevant to their decision to participate.

All GSK employees involved in conducting trials receive [training](#) on regulatory requirements and GSK policies and trials are subject to audit by our internal audit department and regulators.

Corporate Responsibility Report 2008

Planning and approval

A protocol is developed for each clinical trial. Protocols set out the purpose of the research and explain how the trial will be conducted and the results analysed – including details of the dosage and duration of treatment and the number of participants required. The protocol also defines the measurements that will be used to evaluate the safety and efficacy of the medicine, and appropriate procedures should participants wish to withdraw from the study.

Trial protocols are reviewed by government regulatory agencies in relevant countries when required. Protocols are reviewed by an independent ethical review committee of lay people, medical professionals and scientists. This committee also reviews and approves the information to be provided in the process of seeking informed consent. Ethics committees have the power to reject or stop a clinical trial.

Corporate Responsibility Report 2008

Informed consent

Informed consent means that a potential clinical trial participant voluntarily confirms their willingness to participate after being informed of aspects of the trial that are relevant to their decision to participate. It is documented by means of a written, signed and dated informed consent form.

Informed consent for a clinical trial involves more than just reading and signing a consent form. There are two essential elements; a process to communicate the information and answer any questions, and signed documentation.

The informed consent information is written and communicated in a non-technical style so that a lay person can understand it. It includes a summary of the clinical trial (including its purpose, the treatment procedures and schedule, potential risks and benefits, alternatives to participation and provisions for data protection) and explains participants' rights (including voluntary participation and the right to end participation).

Researchers and health professionals know that a written document alone may not ensure that someone understands what participation means. Therefore, the research team discusses with the person the trial's purpose, procedures, risks and potential benefits, and the participants' rights. If the person decides to participate, the team will continue to update them on any new information that may affect their willingness to continue in the trial. Before, during and even after the trial, the person is given opportunities to ask questions and raise concerns. Thus, informed consent is an ongoing and interactive process.

There may be special cases where obtaining someone's informed consent is not possible such as emergency research scenarios, or when children are below the age of legal consent. In these circumstances consent is sought from someone who is allowed to provide it under local laws and regulations. In situations when someone cannot read but is able to speak and understand the local language, an impartial witness is present during the informed consent process to confirm in writing that the information in the informed consent form was accurately explained and that the potential participant was able to ask questions and gave consent voluntarily.

Corporate Responsibility Report 2008

Post-trial treatment

In general, we are not responsible for the funding of nationally licensed medicines after a trial, because this is the responsibility of governments and other providers as part of national healthcare systems.

However, before beginning trials in diseases or conditions that will continue after the completion of the trial we must be assured that the healthcare system is able to provide, and will take responsibility for, the continued care of patients. In exceptional circumstances nationally licensed medicines may be funded by GSK after the trial so that they can be made available to trial participants who derived a measurable medical benefit. We will continue to fund the medicine until it is funded through the normal healthcare infrastructure or the patient no longer derives a medical benefit.

There may be circumstances when there is a compelling medical rationale for patients to continue to receive an investigational medicine after the clinical trial. In this case, post-trial treatment may be provided in a clinical trial or through expanded access programmes which enable appropriate oversight and reporting of adverse events. In these circumstances, GSK will fund the investigational medicine for as long as the patient benefits from it or until the compound is approved and licensed in that country.

Read more in our public policy on [Clinical trials in the developing world](#)

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› [Clinical trials in the developing world](#)

Corporate Responsibility Report 2008

Clinical trials in the developing world

All GSK clinical trials, wherever they are carried out, are conducted to the same high standard.

GSK does not conduct clinical trials in countries when we know at the outset that there is no intent to pursue registration and make the product available for use in that country.

Additional steps may be needed to ensure that trials in some of the least developed countries are conducted according to the Good Clinical Practice (GCP) guidelines. For example, matching the objectives of informed consent to local culture may be necessary, for instance by involving local leaders and/or family members.

In some circumstances capacity may be provided to help develop a certain skill or competence, or for general upgrading of performance ability, which will facilitate the prospective conduct of clinical research activity not only for GSK but also the broader community.

Read more about [post-trial treatment](#).

Read our position statement on [clinical trials in the developing world](#).

Corporate Responsibility Report 2008

Public disclosure of clinical research

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Pharmaceutical companies are legally required to disclose all relevant data from clinical trials to the appropriate regulatory authorities when seeking approval for a new medicine.

After approval, sponsors have a continuing obligation to provide regulatory authorities with updated safety information from clinical trials. Read more about [patient safety](#)

Safety and efficacy information is provided to doctors through prescribing information which is approved by regulators.

Public disclosure of our research is fundamental to advancing medical science and informing prescribers and patients about scientific findings relating to our medicines. Our Clinical Trial Register was launched in 2004 and is designed to supplement prescribing information and publications in the scientific literature. It contains data relating to marketed medicines and serves as a resource for researchers, medical professionals and the public to use alongside locally approved prescribing information. An improved [Clinical Study Register](#), launched in 2008, has replaced the previous Register and now also includes protocol summaries and enhanced searching capabilities. Read a case study on how the new register is helping to improve access to [clinical trials information](#).

Read our [position statement on disclosure of clinical trial information](#)

Corporate Responsibility Report 2008

Public disclosure of clinical research

Approach

Performance and plans

At the end of 2008 there were protocol summaries of all GSK actively recruiting clinical trials on ClinicalTrials.gov, 180 in total. This is a registry of clinical trials conducted around the world and provides information about a trial's purpose, who may participate, locations and contact details for more information.

At the end of 2008 there were 3,273 clinical trial summaries on our [Clinical Study Register](#). This includes clinical trials of our major marketed products which have been completed since the formation of GSK in 2000, or that were completed before this and are likely to inform medical judgement.

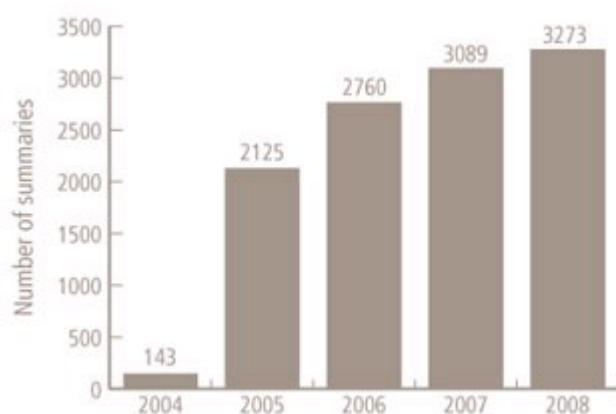
Our objective is to disclose the trial results summaries for all new products on our Register within 12 months of the product reaching the market. We aim to disclose the results of trials completed after a product is approved for marketing within one year of trial completion. We met this objective in 2008.

Update August 2009

An internal audit has subsequently shown that during 2008 the results of a small number of trials were not posted to the Register within 12 months of the product reaching the market. Following the audit the results of these studies were posted to the Register in July 2009. We are improving our procedures for collecting and posting of trial results and expect to meet the objective for 2009

In 2008, a new Clinical Study Register replaced the previous Register and now also provides protocol summaries and enhanced search capabilities to users.

Number of summaries of GSK clinical trials on the GSK Clinical Study Register (cumulative total)



Important steps to build on GSK's commitment to the transparency of our clinical research were taken in 2008. We have committed from January 2009 to:

- Posting information about other types of GSK's clinical research that evaluates our medicines on the GSK Clinical Study Register. We are adding GSK's observational research, meta-analyses and studies of terminated compounds to our current commitment of posting information related to all our clinical trials (phase I-IV) of marketed medicines. In addition we are adding the names of investigators who participate in

our clinical research

- Ensuring that all our clinical research is either published as manuscripts in peer reviewed journals or, when studies are not published, providing context and interpretation via the GSK Clinical Study Register to supplement the result summary which is posted

This will ensure our studies are made publicly available irrespective of whether the results are perceived to be positive or negative for our medicines. Our progress in meeting this commitment can be monitored by external audiences, as the GSK Clinical Study Register will include protocols or plans for our research as studies are initiated, and summaries of the results and references to publications following completion.

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Corporate Responsibility Report 2008

Patient safety

Ensuring the safety of our medicines and medical devices is critically important for the health and wellbeing of patients and the success of our business.

All medicines have potential risks as well as benefits, although not everyone who takes a medicine will experience side effects. It is important that we identify, evaluate and minimise safety concerns to ensure that the overall benefits of a medicine outweigh any risks.

We strive to serve patient interest by promptly detecting potential safety issues with our products and communicating with regulators so that appropriate decisions can be made and actions taken.

Product safety is assessed in clinical trials before a product can be approved for marketing. Sometimes adverse events (potential safety issues) occur after approval when a product is being used by large numbers of patients. We have policies and a governance framework in place to help us detect and act on any adverse events. We have a dedicated team of scientists and healthcare professionals across the world which monitors and communicates safety issues to regulatory authorities.

We are also investing in genetic research to help predict how individual patients respond to a medicine. In the future this will help healthcare providers prescribe safer and more effective medicines.

Read about our [patient safety governance framework](#) and how we [collect and report safety data](#).

Corporate Responsibility Report 2008

Patient safety governance framework

We have a Global Safety Board (GSB) which makes decisions on product safety issues. The Board is led by the Chief Medical Officer and composed of senior physicians and scientists. Its role is to:

- Oversee the safety of all investigational and marketed medicines
- Approve the first administration of investigational medicines to humans
- Define the doses and duration of treatments that are considered safe
- Approve the progression of investigational medicines into pivotal trials (these are trials which provide the primary data on which regulatory approval is based)
- Assess any issues related to patient safety that arise during product development or marketing

Three of our central departments are responsible for recording, investigating and evaluating adverse events and reporting them to the relevant regulatory authorities, for example the US Food and Drug Administration (FDA) or the European Medicines Evaluation Agency (EMA):

- Global Clinical Safety and Pharmacovigilance team (GCSP), part of GSK Research & Development, responsible for the safety evaluation of all our pharmaceuticals and devices
- GSK Biologicals Clinical Safety and Pharmacovigilance department, part of our vaccines business, responsible for the safety evaluation of GSK vaccines
- Consumer Healthcare Product Safety group, part of our consumer healthcare business, responsible for the safety evaluation of consumer healthcare products
- We require that all GSK staff immediately report any issues relating to the safety or quality of our medicines. Read more about our expectations in our [Employee Guide for Business Conduct](#).

Read about our [medical governance](#).

Benefit-risk management

We assess the balance between the benefits and risks of a particular medicine throughout its lifecycle – from early development, during clinical trials, and once the product is on the market.

We evaluate and document all available safety information to build a detailed benefit-risk profile of each product. We use this information to develop a benefit-risk management plan, which identifies ways to improve a product's benefits and minimise any risks. We review and update plans regularly during clinical development and for a period after a product is approved for marketing.

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Collecting and reporting safety data

We receive information on adverse events from several sources, including:

- Unsolicited reports from health professionals and patients
- Post-marketing trials or observational studies
- Investigators who submit clinical study reports
- Regulatory authorities
- Medical and scientific literature
- Newspapers and other media

Each GSK employee is responsible for reporting any adverse event they become aware of. Any adverse events that occur are recorded on our global safety database and clinical trial database and are investigated by our clinical and pharmacovigilance teams. We report potential safety issues to regulatory authorities on a regular basis.

Each country manager is responsible for ensuring the collection of safety information and reporting this to the relevant central safety department and to the local regulatory authority. During 2008, as part of our [2008 Management Certification process](#), over 14,000 managers acknowledged their compliance with our policy on Adverse Event Reporting which specifies that each GSK employee is responsible for reporting any adverse event they become aware of during the conduct of their work. We have added an Adverse Event Reporting button to the front page of myGSK, our intranet site, to make it easier for employees to report any adverse event they may learn about.

Regulators in some countries are also publishing information on adverse events on the internet. For example, data for products marketed in the UK are available via the Medicines and Healthcare products Regulatory Agency. Some safety data are also available in Canada, while in the US the Food and Drug Administration has made the information in its database more accessible to the public by publishing a quarterly report of potential safety issues that it is investigating further.

In 2008, research on our diabetes product *Avandia* continued and a new, FDA required, cardiovascular outcome study was designed and will be initiated in 2009. There was also a combined FDA Advisory Committee review of respiratory products containing long-acting beta2 agonists.

[Read more on the questions raised about *Avandia*.](#)

[Read more on questions about the safety of our products containing long-acting beta2 agonists.](#)

[Read about our medical governance.](#)

Read our position statement on [Pharmacovigilance](#)

Responding to adverse events

Adverse events affect the benefit-risk profile of a product and corrective actions may be needed to minimise the risk. This can include carrying out further clinical trials, modifying the prescribing information, communications to physicians and other healthcare providers or establishing specific methods to minimise risk. Some products are subject to limited distribution programmes, for prescription

by specialist doctors only. In certain cases it may be appropriate to stop a clinical trial or withdraw a product from the market. Our global labelling committees review and approve the prescribing information for all our products and ensure this is updated when appropriate.

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› **Responding to questions about Avandia**

Corporate Responsibility Report 2008

Responding to questions about *Avandia*

Avandia is our leading treatment for type 2 diabetes. In 2007, a meta-analysis published in the New England Journal of Medicine¹ and GSK's own meta-analysis² (submitted to the FDA and other regulators in 2006) were at the centre of a debate on whether *Avandia* may be associated with an increased risk of myocardial infarction and death from cardiovascular causes.

Following an FDA Advisory Committee meeting, the FDA approved updated prescribing information for *Avandia*, including new text in the existing boxed warning, in November 2007. This updated prescribing information summarised data from an FDA meta-analysis of myocardial ischemic events that suggested a risk associated with *Avandia*, and from three long-term clinical trials³ comparing *Avandia* against both placebo and other oral anti-diabetes medicines that did not confirm or exclude the risk. This revised prescribing information included that 'in their entirety, the available data on the risk of myocardial ischemia are inconclusive'.

In 2008, research involving *Avandia* continued, including the cardiovascular outcome study called RECORD, for which results will be available in 2009. In addition, GSK worked to design an FDA-required cardiovascular outcome study of *Avandia*, to be called the TIDE study, to begin in 2009.

Update August 2009

Results of the cardiovascular outcome study RECORD were published in June 2009. RECORD was a large, prospective, randomized, controlled study that was initiated in 2001, and designed to compare cardiovascular outcomes of patients on *Avandia* added to metformin or sulfonylurea to those on metformin and sulfonylurea. The study showed that the combined endpoint of cardiovascular hospitalization or cardiovascular death (which includes heart attack, congestive heart failure and stroke) was not statistically different between the two groups after an average of 5.5 years of therapy.⁴

The TIDE study has started in 2009 as planned.

All medicines, *Avandia* included, carry risks as well as benefits. Because type 2 diabetes is chronic, relentlessly progressive and a life-threatening disease, and because physicians often need to prescribe two or three medicines to help their patients maintain their blood sugar levels, having an array of treatment options is important. GSK believes it is important that *Avandia* is available to support effective treatment of type 2 diabetes.

1. S. Nissen & K. Wolski, Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes, N. Engl. J. Med. 2007; 356: 2457-71
2. A. Cobitz, et al, A retrospective evaluation of congestive heart failure and myocardial ischemia events in 14237 patients with type 2 diabetes mellitus enrolled in 42 short-term, double-blind, randomized clinical studies with rosiglitazone, Pharmacoeconomics and Drug Safety, 2008; 17: 769-781
3. i) P. Home, et al, Rosiglitazone Evaluated for Cardiovascular Outcomes - An Interim Analysis, N. Engl. J. Med. 2007; 357: 28-38; ii) S. Kahn, et al, Glycemic Durability of Rosiglitazone, Metformin, or Glyburide Monotherapy, N. Engl. J. Med. 2006; 355: 2427-43; iii) The DREAM (Diabetes REDuction Assessment with ramipril and rosiglitazone Medication) Trial Investigators, Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomised controlled trial, Lancet, 2006; 368: 1096-105.]

4. P. Home, et al, Rosiglitazone Evaluated for Cardiovascular Outcomes in oral agent combination therapy for type 2 diabetes (RECORD): a multicentre, randomised, open-label trial, *Lancet*, 2009, 373: 2125-2135.

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Corporate Responsibility Report 2008

Questions about the safety of our products containing long-acting beta2 agonists

Long-acting beta2 agonists, known as LABAs, are daily controller medicines that relieve and help prevent airway constriction. Airway constriction is one of the two main components of asthma. LABAs do not treat the other main component of asthma – inflammation. This can be treated by another type of daily controller medicine called an inhaled corticosteroid (ICS). LABAs, including GSK's product *Serevent*, should not be used alone in the treatment of persistent asthma. Leading treatment guidelines recommend that LABAs be used for appropriate patients with asthma only in combination with an ICS.

GSK makes two products containing the LABA salmeterol. *Seretide/Advair* is a combination of salmeterol and the ICS fluticasone, while *Serevent* contains salmeterol alone.

In December 2008 a combined Advisory Committee to the US Food and Drug Administration reviewed the benefit-risk profile of medicines containing LABAs in children and adults with asthma. This review included all LABA-containing products indicated for use in treating asthma, not just GSK's products, and addressed lingering concerns that LABAs may increase the risk of asthma-related death, as current product labels prominently warn. The Advisory Committee makes recommendations to the FDA, which then makes the final decision on any actions required.

For *Seretide/Advair*, the Committee unanimously voted that the benefits of *Seretide/Advair* outweigh the risks for patients 18 years and older. The Committee also voted in favour of a positive benefit-risk profile in younger patients, although the individual votes were mixed. For *Serevent*, the Committee found that the benefits do not outweigh the risks for the treatment of asthma. Concerns were expressed about the potential for *Serevent* to be used alone in the treatment of asthma, contrary to the current prescribing information, in a way that would make the benefit-risk profile unfavourable. In contrast, *Seretide/Advair* is a combination therapy of a LABA and an ICS, so combination use is assured.

Although GSK acknowledges concerns that use of *Serevent* without an ICS is not in the best interests of asthma patients, we favour the option of allowing dual therapy using separate inhalers. Use of separate inhalers is an important treatment option for asthma patients who need an alternative ICS to fluticasone (the ICS contained in *Seretide/Advair*), or the flexibility of ICS doses beyond those available in a combination product. It is also important for asthma patients who receive more favourable reimbursement for separate inhalers.

GSK believes that with appropriate labelling and proactive communication of the risks of using a LABA alone, the potential for misuse of *Serevent* as monotherapy can be acceptably reduced so that dual therapy using separate inhalers remains available for asthma patients who need it.

In September 2008, before the Advisory Committee meeting, GSK submitted a proposed label change to the FDA for *Serevent* to clarify that use in asthma patients must be in combination with ICS, in line with prescribing information in all countries in which *Serevent* is marketed.

We are awaiting the outcome of the FDA's consideration of GSK's proposed label change, and of the Advisory Committee's review. We will actively cooperate with the agency in reaching an appropriate resolution in the best interests of asthma patients.

Corporate Responsibility Report 2008

Performance

We have continued to improve our patient safety systems, safety databases and monitoring processes. Examples from 2008 include:

- Established two more Clinical Toxicities Strategy Panels (comprising internal and external experts) to provide expert safety input throughout the medicine development process. We now have expert panels in four areas: cardiovascular, hepatic, renal and haematological
- Implemented a clinical trials signal detection (CTSD) tool for review of completed study data, in partnership with Lincoln Technologies. This has enhanced our ability to identify and explore safety signals in our clinical trials. The system won a BIO IT award
- Launched a prototype for our Molecular Clinical Safety Programme (MCSP). MCSP is a tool that seeks to better inform decision-making in medicine development by integrating chemistry, pre-clinical and human safety data and enabling us to look for patterns across the different types of safety information. In October 2008 the GSK team won the Wall Street Journal Technology Innovation Award for Healthcare IT for developing this system. The entry was selected by an independent panel of judges, who reviewed more than 700 applications for the awards

Working with others

We work with government officials, industry partners and policy makers in efforts to build an enhanced safety system. For example GSK is the industry lead in the benefit-risk project consortium of the European Commission's public-private partnership, the Innovative Medicines Initiative, which aims to develop methodologies to enhance the assessment of the benefit-risk profile of new medicines.

GSK is a key partner among the US Food and Drug Administration, other pharmaceutical companies and academia in the US to explore the development of a new system for the detection of adverse events and benefits of medicines using large healthcare system databases.

Read about our [collaborative research on emerging technologies](#).

Serious Adverse Events Consortium

In 2007, we co-founded the Serious Adverse Events Consortium (SAEC), a collaboration involving more than 20 partners. The SAEC is working to improve patient safety by identifying genetic variants that predict adverse events such as drug-induced liver injury and a rare but serious severe skin rash called Stevens Johnson Syndrome. GSK scientists co-chair the SAEC scientific management committee and have a seat on the board of directors.

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- › **Maintaining the confidentiality of research participants**

Corporate Responsibility Report 2008

Maintaining the confidentiality of research participants

It is vital that medical information collected during research is protected to maintain the confidentiality of participants. We have rigorous procedures to control the use of research data.

Our research activities are conducted according to fundamental ethical and legal principles, including consent and ethics committee approval. We use a variety of procedures to protect the confidentiality of research participants' data, including data coding, data encryption and restricted access to research databases.

Third parties handling research data on our behalf are required to comply with relevant data protection legislation and standards.

We only collect information about individuals that is relevant to the research study. This includes medical information such as health status, medical conditions (including, on occasions, genetic data), treatment of conditions and ethnic origin. This means that, in the vast majority of instances, we do not collect or store information that can directly identify individuals such as initials, names, addresses or personal ID numbers. Information that can identify individuals is only used in very specific instances required by law and regulations such as safety monitoring and pharmacovigilance.

We retain medical research data using the minimum amount of identifying information and only for the duration reasonably necessary to meet regulatory, legal or research needs.

Corporate Responsibility Report 2008

Working with healthcare professionals

Our policies governing interactions between GSK R&D staff and healthcare practitioners require that:

- All clinical trial investigators must be selected solely on their qualifications to conduct good quality clinical research. Their history of using or not using GSK products must not be taken into account when deciding whether to include or exclude them in a particular trial
- Payments to practitioners are governed by contracts and any compensation reflects fair market value for the work performed
- No payments are offered or made to influence their judgement on whether to enrol or maintain a participant in a clinical study
- Gifts to healthcare professionals involved in research projects for GSK are not permitted.

From 2009, the PhRMA Code on Interactions with Healthcare Professionals also prohibits non-educational gifts to healthcare professionals involved in research. GSK policies have prohibited these gifts to healthcare professionals involved in research since 2006.

We are also committing to disclose research payments made to healthcare professionals and institutions. This will start with payments to US healthcare professionals and institutions for conduct of clinical trials starting in 2010. Thereafter it will be extended to payments for other types of research and to healthcare professionals and institutions outside the US.

Read more about our policies and monitoring systems that govern our [relationships with healthcare professionals](#).

Corporate Responsibility Report 2008

Training and auditing

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Training for clinical trials

All employees involved in designing, conducting, recording and reporting GSK-sponsored clinical research studies are trained in the Good Clinical Practice (GCP) guidelines developed by the International Conference on Harmonisation (ICH). Employees must have completed the required training before undertaking these roles.

We keep detailed training records which are routinely requested by regulatory authorities when undertaking an inspection of GSK clinical research trials.

Auditing for clinical trials

GSK's internal audit department audits the conduct of clinical trials. Audits cover GSK systems and processes, as well as external clinical research organisations and investigators performing clinical research on our behalf.

Trials are selected for audit based on risk. Risk factors include the complexity of the study, the patient population, the location of the study, previous audit history and any unusual findings during the conduct of the study.

Results are reported quarterly to the R&D Compliance Board, and annually to the Risk Oversight and Compliance Council and the Audit Committee of GSK's Board of Directors. Read more about these in the corporate governance section of our [Annual Report](#). Members of our Global Safety Board (GSB) receive individual audit reports on any safety-related findings.

Any concerns or issues identified are fully investigated and appropriate corrective action taken. For GSK staff corrective actions may include development of new training programmes or retraining for the individuals concerned. In more severe cases appropriate disciplinary action will be taken, up to and including dismissal.

For external investigators, GSK may retrain the investigator, or stop working with the investigator. Trial data from noncompliant investigative sites is excluded from the analysis.

Regulatory authorities also carry out inspections of GSK and the investigators we use to conduct clinical trials.

Corporate Responsibility Report 2008

Training and auditing

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Training for clinical trials

In 2008 there were 66,579 training activities related to Good Clinical Practice (GCP). Each 'training activity' represents a successful completion of an e-learning module or instructor-led course related to GCP by one of our employees or contractors.

Auditing for clinical trials

In 2008 we conducted 208 audits. These included:

- 150 audits of investigator sites conducting GSK-sponsored trials. This represents approximately five per cent of investigator sites participating in pivotal clinical trials
- 16 audits of internal GSK systems and processes used in managing clinical trials and data
- 30 audits of clinical research organisations carrying out clinical trials on GSK's behalf
- 12 audits of GSK local operating companies involved in clinical research activities.

WIn addition, 24 investigations were conducted in response to suspected irregularities at investigator sites.

Issues identified at investigator sites included insufficient oversight of clinical trial activities by investigators. Oversight covers all areas of investigator responsibility including: knowledge of the protocol design; appropriate and documented delegation of tasks to skilled personnel; and availability to meet sponsor representatives at regular intervals during the study. Additional training for investigators and implementation of further internal controls are helping to reduce the frequency and significance of this issue.

Inspections of investigators, clinical research organisations, independent ethics committees/Institutional Review Boards and sponsors of clinical trials are also carried out by regulatory authorities to ensure the safety of trial participants, the quality of data and that trials are conducted according to Good Clinical Practice. During 2008 there were more than 40 such inspections of GSK and investigators used by GSK to conduct clinical trials.

The Food and Drug Administration (FDA) conducted a routine Post Marketing Adverse Drug Experience Inspection in 2007. The inspection involved a review of GSK's processes for receiving, capturing and tracking adverse drug experience information for GSK products, as well as reporting these data to the FDA. In the course of the inspection, the inspector focused on GSK's compliance with regulatory requirements for New Drug Application (NDA) Annual Reports and periodic adverse drug experience reports. As a result of the inspection GSK received a warning letter from the agency in March 2008. The FDA determined that for some products, certain required reports submitted by GSK had not included all required information about clinical studies on a timely basis. The FDA letter acknowledges that information not captured in the periodic reports was, in many cases, submitted to the Agency in other reports and communications. In addition, information about the start of clinical trials that was omitted from some reports was available at www.clinicaltrials.gov. Clinical trial results also are posted publicly to GSK's [Clinical Study Register](#).

We acknowledge the seriousness of the issues raised in the warning letter, and corrective steps have been taken or are underway to make sure periodic reports are filed completely and promptly. After the inspection, GSK initiated a review of all applicable processes and reporting systems. We have made and will continue progress in updating procedures and improving compliance in the area of reporting, including additional

training to ensure that all procedures are followed across all product lines. GSK works continuously to monitor and, as necessary, enhance its compliance systems and procedures.

Corporate Responsibility Report 2008

Case studies

Focus on the Patient programme

Our Focus on the Patient programme helps our R&D employees understand patient needs and inspires them to do more to help improve the lives of patients.

In 2008 we held 12 seminars where patients visited GSK sites to help our R&D employees understand the realities of living with their illness. The seminars included discussions on breast cancer, cystic fibrosis, HIV/AIDS, inflammatory bowel disease, schizophrenia, epilepsy, meningitis, hepatitis C, pulmonary hypertension, idiopathic pulmonary fibrosis and migraine headaches. There were over 4,640 attendees at these seminars.

We have also held lunchtime sessions to develop ideas and actions. One session prompted the organisation of a seminar at our site in Verona, Italy, providing insight for local scientists developing medicines for sleep disorders and depression. Another idea led to 'Patient Empowered', a project to improve patients' experience in GSK clinical trials, through patient-focused study design and simplified patient-directed communications.

To inform our employees about the patients they are helping through their work in R&D, regular monthly bulletins highlight key medicines in our pipeline and how they will meet the needs of patients. This helps to motivate employees by reminding them about the importance of their work.

A survey of R&D employees showed over 50% of respondents felt that there was an increase in patient focus across the businesses through greater application of patient focus in work processes and the development of medicines.

Clinical Study Register

It is important that the results of all studies that evaluate medicines are in the public domain. This enables the information to be used to help inform medical judgement and advance medical science.

Traditionally, publication in scientific and medical journals has been sought but there are well recognised limitations:

- Have all studies been published by researchers?
- What if it is not possible to publish a study in a peer reviewed journal?

Posting a summary of each study on the internet when it is initiated enables all studies to be tracked to publication. Studies that are not publicly disclosed can be identified and researchers called to account.

Posting the results after the study is completed means that results are in the public domain, whether or not the study is accepted for publication. GSK provides an online Clinical Study Register, which now contains the results of over 3,000 trials, covering over 100 GSK products dating back to 2000 when the company was formed. Launched in 2004, we are pleased that the site has been a success and our latest figures show that the site is receiving over 25,000 visitors a month.

In 2008 we took further steps to build on our commitment to the transparency of clinical research:

- To help people quickly find the information they need, we launched a revised version of the [Clinical Study Register](#), which includes an improved user interface making it easier for users to find information by disease area or medicine
- We are adding observational research and meta-analyses that evaluate our medicines and studies of

terminated compounds to the Register. This adds to our current commitment to post-protocol summaries and summary results of all GSK's clinical trials (phases I-IV) for our marketed medicines

However, the disclosure of research protocols and results online should be seen as a supplement and not a replacement for the need to publish studies in peer reviewed journals. We believe that the level of public disclosure achieved through posting results on our Register alone is below that achieved through papers published in peer reviewed journals which more fully explain a study and places the results in context.

GSK aims to publish our clinical research of our medicines as more comprehensive papers in peer reviewed journals. When studies are not published we will provide context and interpretation via our register.

Corporate Responsibility Report 2008

Q&As

Here we respond to questions raised by our stakeholders.

How are you assured that the risks for healthy volunteers who take experimental medicines for the first time are minimised?

Before a clinical trial can take place, a new compound must undergo a series of stringent laboratory tests. These tests involve the use of animals and human tissue to predict the effects of an investigational medicine in the human body, including any potential side effects. On the basis of the predictions we establish dosing levels with a sufficient margin of safety and/or appropriate monitoring procedures.

The 'pre-clinical' data from laboratory tests, and our proposal for the design of each 'first time in human' clinical trial, are reviewed by a GSK committee, known as the Global Safety Board, of experienced senior physicians and other experts who are independent of the project team. Regulatory authorities and independent ethics committees must approve the trial before it can go ahead.

Clinical trials are designed to minimise risk. For example, we initially give volunteers a very low dose of the investigational medicine and increase dosing gradually, carefully sequenced among subgroups, to be cautious in our approach. Trials of an investigational medicine being tested in humans for the first time are conducted in clinical units with rapid access to hospital emergency care.

All clinical trial volunteers are provided with information about the study, including potential risks, and have the opportunity to discuss these risks with researchers before deciding whether or not to participate. This is known as informed consent.

You plan to enter in to more research collaborations. How will you ensure that the organisations you partner with meet your research and animal welfare standards?

We recognise that working in collaboration with other organisations brings certain risks. We are developing routine safeguards to ensure our partners work according to the same core principles as GSK, including those that govern our use of animals in research. These checks will be applied when we are evaluating whether to enter into collaboration, and subsequently on an ongoing basis within the framework established to govern a collaboration, typically a Joint Steering Committee. GSK's willingness to enter or continue a collaboration depends on having adequate assurance of a shared commitment to core principles.

GSK is opening an R&D facility in China. Will this affect your research standards? Is it a cost reduction exercise?

We have opened a new R&D facility in China which is focusing on R&D into neurodegenerative disorders, for which better therapies are desperately needed: Alzheimer's disease, Parkinson's disease and multiple sclerosis.

The costs of conducting research in China are currently relatively lower than those in other markets. However, lower costs are not the reason behind the decision to set up this new facility. The new centre enables us to benefit from accessing the vast talent pool and knowledge in life sciences in China, and to increase focus and depth in important disease areas.

Our R&D in China is conducted in accordance with GSK's global quality and ethical standards. All R&D policies and monitoring procedures apply to our operations in China. We have committed significant regional and local resource to ensuring our operations in China comply with both Chinese government requirements and GSK's global standards.

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Corporate Responsibility Report 2008

Ethical conduct

We are committed to creating a strong ethical culture at GSK.

We do this by putting the appropriate policies in place, recruiting the right people and equipping them with tools to make ethical decisions. Putting patients first is the core principle of being an ethical pharmaceutical company. Profit without principle is short lived.

Failure to uphold high standards of ethical conduct carries significant business risk:

- Erosion of trust in GSK and our products including among regulators, doctors and patients
- Fines and litigation resulting in serious financial or legal consequences
- Damage to GSK's reputation

Our [Code of Conduct](#) sets out fundamental standards for all employees. The [Employee Guide to Business Conduct](#) builds on the Code and explains what employees must do to meet its requirements. It provides guidance, including specific examples, on what constitutes unethical behaviour. Strong policies, codes of practice and good training are essential elements of our approach. However, on their own they cannot guarantee that our employees will meet our standards. Our internal compliance systems are designed to identify and address breaches of our codes. We fully investigate suspected breaches and take appropriate disciplinary action, including dismissal where appropriate.

We have clear policies and procedures to [prevent corrupt and anti-competitive behaviour](#). Maintaining high ethical standards in our marketing is also vital and is relevant to patient safety. It is essential that our marketing practices help doctors to prescribe medicines that are in the patient's best interests. Our policies prohibit kickbacks, bribery or other inducements to doctors, and any promotion for unapproved uses of our medicines. Maintaining [high ethical standards during all stages of R&D](#) and once a product is approved for marketing is a key part of our commitment to put the patient first.

Your ethical compass

Our Employee Guide to Business Conduct includes an 'ethical compass' that helps employees deal with ethical issues that are difficult to resolve. When faced with such a situation, we encourage our people to ask themselves these questions:

- Is it legal and ethical?
- Is it consistent with GSK policy and the Code of Conduct?
- Is it consistent with GSK's Mission and Spirit?
- Can I explain it to my family and friends?
- Would I be comfortable if it appeared in a newspaper?

We encourage employees to seek additional guidance and to keep asking questions until they are certain that they are making the right choice.

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Corporate Responsibility Report 2008

Code of Conduct and business ethics

Code of Conduct

The GSK Code of Conduct sets out the standards we expect from our employees and contractors. It contains the following key requirements:

- Conduct business with honesty and integrity and in a professional manner that protects GSK's good public image and reputation
- Build relationships with customers, vendors, suppliers and fellow employees based on trust and treat each of these individuals with respect and dignity when conducting business
- Become familiar with and comply with legal requirements and GSK policy and procedures
- Avoid any activities that could involve or lead to involvement in any unlawful practice or harm to GSK's reputation or image
- Avoid actual or potential conflicts of interest with GSK, or the appearance thereof, in all transactions

[Read the full Code of Conduct.](#)

Our [Employee Guide to Business Conduct](#) builds on the Code and explains what employees must do to meet its requirements.

Business ethics

Corrupt and anti-competitive behaviour undermines fair competition, inhibits economic development and is bad for economies, business and people.

Our [Employee Guide to Business Conduct](#) contains the policies and guidance to ensure that we operate within the letter and spirit of the law and maintain high standards of ethical business behaviour.

Anti-competitive behaviour

We are committed to free and open competition. We succeed as a company because of the high quality and competitiveness of our products and the talent and commitment of our employees.

Our policy on anti-competitive behaviour covers issues such as mergers, abuse of monopoly powers, resale price maintenance, predatory pricing and other restrictive agreements and practices. It sets out the standards of behaviour we expect from our employees and agents.

Preventing corruption

Our policy on anti-corruption forbids payments or inducements to political candidates, legislators, political parties and party officials, or government officials or employees, whether local or national, including officials and employees of government-owned enterprises and of public international organisations. We also have separate policies on political contributions or donations and on acceptance of gifts or entertainment by our employees.

Sample questions from our Employee Guide to Business Conduct

Question: We have received an order for an unusual volume and combination of pharmaceuticals from a new customer in a location noted for political instability. The shipment location is in another country, and the customer has said we should not bother including the usual consumer use information. Is this a problem?

Answer: There are enough red flags here that you need to get advice from the GSK Legal Department. The information you have indicates that this material might be shipped to a prohibited country or used for improper or even terrorist activity. You need to know your customer and get advice on what to do.

Question: A vendor offers to sell a GSK product manager a mailing list of 10,000 names of individuals who are being treated for depression. Are there any concerns with the purchase of such a list?

Answer: Yes. Many countries, including the US and those in the EU, have established strict laws protecting healthcare information that identifies an individual. Written authorisation by each individual is usually required for GSK to receive this information.

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Corporate Responsibility Report 2008

Marketing ethics

We market our prescription medicines and vaccines to doctors, hospitals and governments.

In some countries, such as the US, we also advertise medicines directly to consumers. Our specialist sales representatives meet regularly with doctors and pharmacists to inform them about our medicines and their approved uses.

We believe that sales representatives play an important role in providing up-to-date information to doctors on our products and their benefits and risks to patients. However, we recognise that the marketing of pharmaceutical products raises some challenging issues.

In particular, some people are concerned that marketing by pharmaceutical companies exerts undue influence on doctors, that sales representatives do not always give doctors full information about potential side-effects, or that promotion of unapproved uses of medicines may be occurring. Our regional marketing codes forbid these practices and other unethical conduct. We provide regular training so that our sales teams understand these codes and we conduct monitoring to assess compliance.

Marketing Codes of Practice

The sale and promotion of pharmaceutical products is highly regulated by governments and medical agencies. We have developed marketing codes and policies and provide training for sales representatives to ensure that they understand how to behave ethically and comply with the law. In many countries our codes and policies go beyond legal requirements.

Our products are sold in more than 150 countries around the world. The first priority with any product in any country is [patient safety](#). We have systems and processes to collect, analyse and report safety concerns about our products.

Our marketing codes of practice apply to all employees and agents. They commit us to promotional practices that are ethical, responsible, principled and patient-centred. They prohibit kickbacks, bribery or other inducements to doctors, and any promotion for unapproved uses of our medicines.

These company policies are supported by regional marketing practices codes which apply the same standards but reflect differences in market structures, national healthcare systems and regulations.

A new US PhRMA Code on interactions with healthcare professionals (HCPs) came into effect in January 2009 and we have fully aligned our sales and marketing practices to the requirements of the Code. In some cases, GSK has gone beyond the requirements of the Code, including phasing in a prohibition on giving non-educational items in the US, and reinforcing a \$150,000 cap on payments made to an individual US-based HCP working as a consultant to the company, for example by participating in an advisory board or speaking at GSK-sponsored meetings. Our updated Commercial Practice Policies (CPPs) will be available in the first quarter of 2009.

GSK is initiating a review of all internal, regional codes relating to the sales and promotion of our pharmaceutical products. Through this review, we intend to align, where legally and culturally appropriate, GSK's regional codes. This alignment will lead GSK to develop more detailed global principles guiding the sales and marketing of GSK pharmaceutical products all over the world.

Helping to strengthen industry codes

GSK supports efforts to strengthen marketing standards across the pharmaceutical industry.

This benefits us by creating a 'level playing field' in the countries in which we operate and helps to improve

the reputation of the pharmaceutical industry as a whole.

In 2008, we took an active role in working with the US pharmaceutical industry association, PhRMA, to develop the changes to its Code on Interactions with Healthcare Professionals. GSK will certify compliance to the Code during the first quarter of 2009. The Code will guide the sale and marketing of GSK pharmaceutical products in the US.

Our Marketing Codes of Practice in summary

- Full and accurate information – information can only be provided on approved uses for a medicine. It must be based on valid scientific evidence and must be accurate, balanced, fair, objective, unambiguous and up to date
- Promotional items to healthcare professionals – branded promotional items must be given only occasionally and must be relevant to the practice of medicine. Their nominal value was no more than \$10 or less than £6 in the UK in 2008. From 2009, we will no longer distribute non-educational items in the US, in line with the US PhRMA code.
- Items cannot be given as an inducement to prescribe any of our medicines or to medical professionals retained as consultants to GSK
- Appropriate hospitality for meetings – no entertainment is permitted. Hospitality, such as travel costs or food, may only be provided for meetings with an educational or professional purpose. The level of hospitality must be appropriate to the occasion and must only be provided for relevant healthcare professionals, not spouses, children, office personnel or any other guests
- Decisions about grants for medical education are reviewed by qualified medical or scientific personnel

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Relationships with healthcare professionals

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As well as our marketing codes we have detailed policies and monitoring systems governing our relationship with healthcare professionals in the following areas:

- Medical education programmes – we provide funding to enable physicians, pharmacists, nurses and other healthcare professionals to attend education courses and conferences in therapeutic areas relevant to GSK. We do not consider this to be part of our marketing and our policies state that the content of the education programme or the choice of faculty should be independently approved
- Sponsoring speakers – we provide sponsorship for healthcare professionals to attend conferences to present their research results or to speak on healthcare issues. Speakers must declare during their speech that they are funded by GSK
- Advisory services – we engage with healthcare professionals to understand unmet medical needs and developments in science and treatments. This helps us to understand current and future markets for our products. This engagement may take the form of convening advisory panels or conducting broader market research

Read how we engage with [healthcare professionals who conduct medical research](#) on our behalf.

Our policies and processes vary by region to comply with local laws and industry practices. They meet or exceed the codes on relationships with healthcare professionals from the following industry organisations:

- The Pharmaceutical Research and Manufacturers of America (PhRMA)
- The European Federation of Pharmaceutical Industries and Associations (EFPIA)
- The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- The Japan Pharmaceuticals Manufacturers Association (JPMA)

Our policies and processes are further restricted in the US where they include:

- A limit on payments to healthcare professionals through speaker and advisory fees of \$150,000 a year for an individual physician. The majority of our US healthcare professional consultants receive fees that total less than \$10,000 per year
- A state reporting system for expenditure with healthcare professionals, in line with legislation in several US states. This system can help us to investigate situations where excessive meals and gifts may have been provided by GSK
- A requirement that GSK funding of grants to any healthcare-related group, including [patient advocacy groups](#) and physician associations, cannot exceed 25 per cent of the group's annual income
- A speaker evaluation process covering healthcare professionals sponsored by GSK. This requires our regional medical scientists to evaluate high-frequency speakers, and to provide feedback to the healthcare professionals on their effectiveness and compliance with the GSK Speaker Programmes policy
- A process to monitor questions posed by doctors to our medical information department about off-label uses of our products, and the number and type of referrals made by individual representatives. This helps to ensure that representatives are not promoting off-label uses. All questions from doctors on off-label uses

for our products must now be referred to our medical information department.

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Corporate Responsibility Report 2008

Relationships with healthcare professionals

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United States

We make payments to healthcare professionals for consultancy work such as participating on an advisory board or speaking at GSK-sponsored meetings. The majority of our US HCP consultants receive fees that total less than \$10,000 per year. However, in 2009 we reinforced a cap on payments to HCPs in the US of \$150,000 a year for an individual physician.

It is in our interest that the physicians we work with do not receive excessive funding from GSK. This ensures that their work for GSK does not detract from the time they spend with patients or conducting research, which could reduce their professional credibility and their value to GSK as sources of current medical expertise.

Europe

In 2008, we changed our European code of practice on interactions with healthcare professionals in response to a new Code of Promotion published by the European Federation of Pharmaceutical Industries and Associations. We made the following changes and refinements to our code:

- **Use of consultants** – GSK employees responsible for selecting consultants must have the expertise to evaluate whether the consultant is suitable to meet the identified business need and is of real value to GSK. The consultant is required to declare the consultancy arrangements when speaking publicly on a related issue.
- **Samples** – Product samples are now to be given only in limited numbers and for a limited time, by reference to local standards, for the purposes of familiarisation. This replaces previous limits that were less restrictive and did not specify a quantity or timeframe.
- **Grants and donations** – We introduced a new policy on grants and financial donations to health organisations. We are not involved in how the grant or donation is used and receive no service in return. The new policy states that grants and donations:
 - May only be given to a health organisation in response to an unsolicited request and only for the purposes of healthcare or research
 - Must not be offered or given on the understanding that the recipient will prescribe or recommend our products
 - Must be documented and published externally. To meet this requirement the amount of the grant and the recipient will be published on GSK's website from 2010
 - Are only permitted to health organisations rather than individuals
- **Phase IV clinical studies** – These are studies conducted after a medicine has been approved for marketing. We clarified the principles behind these studies, clearly setting out the terms for GSK and collaborative studies:
 - Studies must not be commissioned as an inducement to prescribe, supply or recommend medicines. They must have a clear scientific and/or educational purpose
 - There must be a contract with the institution undertaking the research

- The trial protocol must be reviewed and approved by an ethical committee, where available
- GSK R&D or medical personnel must approve and supervise studies
- Results will be distributed to investigators

Asia Pacific, Japan and Emerging Markets

GSK continues to be very active in the IFPMA Code Compliance Network and many of our senior country managers have been very supportive of leading industry change as part of strengthening local codes

Nigeria

GSK has received the 'Best Compliant Company' award issued by NAFDAC (the regulatory authority). This award is the first of its kind and aims to encourage compliance among companies in Nigeria and to encourage Nigerians to buy from companies deemed to be compliant by NAFDAC.

Australia

From January 2009, GSK Australia has stopped distributing brand reminders to healthcare professionals, including pens and notepads, with the exception of new brand launches. This aligns our behaviour with community expectations of how we interact with customers.

Our plans

- We will publish grants and donations made in the US during 2009, and in Europe by 2010.
- In Australia, an initiative to move all States to the Victoria operating model will take effect from 1 August 2009, delivering improved control around samples accountability and security, and supporting our aim to achieve the highest levels of professional standards. The field sales force will no longer distribute samples directly to healthcare professionals. Instead, orders will be taken by our medical representatives and samples delivered direct to surgeries from our central warehouse.
- GSK's International Promotion and Marketing Code, applicable to Emerging Markets and Asia Pacific regions, will be subject to its regular two-year review. The last revision incorporated major structural change to align with the structure and content of the IFPMA code and indeed goes further in many cases.

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Corporate Responsibility Report 2008

Direct-to-consumer advertising

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In the US it is legal to advertise prescription medicines to consumers through TV and print advertisements. This is known as direct-to-consumer (DTC) advertising.

New Zealand, Bangladesh and Korea also allow limited DTC advertising. DTC advertising of prescription medicines is not permitted in other markets.

Promoting the use of prescription medicines directly to consumers can raise concerns. Critics believe that it encourages people to request unnecessary treatment, adding to the burden on healthcare systems.

We believe that responsible pharmaceutical advertising is a useful source of health information for patients. It helps to increase knowledge of conditions and educates patients about treatment options. In countries such as the US where DTC advertising is common industry practice, we would be at a competitive disadvantage if we did not promote our products in this way.

Patients must still consult with their physicians about their condition, the appropriateness of a prescription medicine and obtain his or her consent before receiving such medicines.

Prescription medicines in the US

Our DTC Communications policy is based on the PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines.

We have a detailed approval process for DTC advertising, which includes review by legal, regulatory and medical specialists as appropriate. All US marketing employees have received training on our DTC policy.

All DTC television advertisements, including audio and visual components, are submitted to the US Food and Drug Administration (FDA) for review at least 30 days in advance of broadcast.

Members of the public and healthcare professionals can send comments or complaints on DTC advertising to PhRMA's Office of Accountability, which reports the comments and the responses of the companies to the FDA.

The FDA Amendments Act 2007 imposes restrictions on DTC advertising. It gives the FDA the ability to require submission of DTC television advertisements 45 days prior to dissemination and imposes a new standard on presentation of safety information in broadcast advertisements. Companies responsible for false or misleading DTC advertisements can now be fined up to \$500,000. We have implemented these provisions in our DTC advertising in line with the Act's requirements.

We fund disease-awareness campaigns which are designed to increase understanding of a specific disease but are not linked to the promotion of GSK products. These are also governed by our DTC policy. Our disease awareness campaigns include television and print advertisements, and direct mail. They do not mention specific GSK products but make people aware that treatments are available for their condition and encourage them to see their doctor. Campaign materials are branded to indicate that they have been produced by GSK.

Over-the-counter medicines and consumer healthcare products

Our advertising for over-the-counter medicines, oral healthcare and nutritional products is governed by national regulations or codes of practice for advertising. Our over-the-counter medicines are also promoted

to pharmacists, doctors and dentists by our sales teams.

We belong to the Consumer Healthcare Products Association in the US and comply with its Code of Advertising Practices for Non-prescription Medicines.

GSK Consumer Healthcare advertising is reviewed by Copy Review Committees in our larger markets, or by medical and legal personnel in our smaller markets, before publication to ensure it meets our standards.

Advertising to children

Our guidelines for advertising to children prohibit advertising designed to appeal to, or targeted at, children below the legally mandated minimum age. For example, to comply with our guidelines in the UK we do not buy advertising space in children's media and we do not supply vending machines to primary schools.

Sports star sponsorship is important to brands such as *Lucozade Sport*. Our guidelines state that only people who set an appropriate example should be used for sponsorship, and they should have an appeal that is not solely to children below the age of 13.

Our principles for DTC advertising in the US

Our policy requires that DTC advertising should:

- Dedicate an appropriate amount of time to educating healthcare professionals prior to initiating DTC promotion for a new medicine or new therapeutic indication for an approved medicine
- Be designed to educate consumers about the medicine and the condition for which it is prescribed
- Be accurate and supported by evidence
- Include information on the risks and benefits of treatments
- Provide information on other treatment options such as diet and lifestyle changes, where these are referenced in the prescribing information for a product
- Only be targeted at an audience at least 80 per cent of whom are adults

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Direct-to-consumer advertising

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In 2008 no problems with GSK US DTC advertising were identified by the FDA nor did we receive any comments from the PhRMA Office of Accountability relating to GSK DTC print advertisements.

In February 2009 GSK received a letter from the US Food and Drug Administration Division of Drug Marketing, Advertising, and Communications saying that a television advertisement presented a misleading suggestion of superiority to other drug therapies and overstated the efficacy of GSK's product *Avodart*. The advertisement aired from March to September 2008 and was no longer in use at the time the letter was received. We are continuing to make every effort to ensure that future advertisements incorporate the directions provided to us by the FDA.

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Training and awareness

Training and awareness programmes help employees understand the importance of ethical conduct and to apply our policies in practice.

New employees in the UK and the US complete induction training on our [Code of Conduct](#), which is available on our intranet site. Our annual [management certification programme](#) requires managers to confirm that they comply with our ethics policies. The programme covers over 14,000 managers worldwide.

Managers can access three e-Learning modules on ethical leadership. Specialised training is provided for employees working in R&D, manufacturing and sales and marketing, where there are additional regulatory requirements.

Our corporate ethics and compliance intranet contains links to all company policies, ethics and compliance training for new recruits, an ethical decision-making model, an ethics quiz, contact details for compliance officers and the free phone numbers for our Global Confidential Reporting line. As well as this phone line which is available in over 25 languages and can be used for reporting any concerns employees may have relating to compliance with our policies and the Code of Conduct, we also have an Integrity Helpline based in the US. This provides advice to callers, from both within and outside the company, on Code of Conduct issues, as well as being a reporting channel.

Training for employees working in sales and marketing includes:

- Induction training and testing on our marketing code of practice
- Detailed training for sales representatives on the medicines they promote and the diseases they are designed to treat
- Regular refresher courses held at least once a year
- Regular management updates in Europe, Emerging Markets and Asia Pacific and the US on the types of unethical conduct detected and disciplinary actions taken

Ethics training in practice

Ethics training helps employees make the right decisions and apply our policies in practice. For example, new employees are encouraged to ask themselves the following questions before making a decision:

- Is it legal and ethical?
- Is it consistent with GSK policy and the Code of Conduct?
- Is it consistent with GSK's Mission and Spirit?
- Can I explain it to my family and friends?
- Would I be comfortable if it appeared in a newspaper?

We also run ethical decision-making training for established employees and leaders. During training employees explore ethical dilemmas they may face in their work and receive guidance to help them understand the appropriate response. This is one example of an ethical dilemma:

When you arrive at the office, there is a large gift basket filled with very expensive chocolates and other gourmet treats on your desk. You estimate its value at \$250. Enclosed is a note from a consultant: "Thanks for choosing us as your consulting partner. We look forward to working with you."

You should:

- a. Keep the gift for yourself. Since you already chose the consultant, the gift can't be considered as having influenced your decision
- b. Call the owner and explain that while the gift was certainly thoughtful, you cannot accept it because it is against GSK policies to accept such an item. Tell her that you will be returning the gift basket and that you look forward to working with her firm
- c. Put the goodies by the office coffee station for everyone to enjoy

The best solution is to return the gift, answer (b).

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Leading by example

Our senior managers are expected to lead by example by complying with company policies and by supporting their staff to do the same.

This is reinforced annually by a formal 'Management certification on business ethics' in which over 14,000 managers confirm their understanding and compliance with the company policies contained in the [Employee Guide to Business Conduct](#).

Management certification promotes awareness of GSK's ethical standards and company policies. It emphasises the importance of the company policies to thousands of other GSK employees who, in the course of their daily activities, must comply with the law and company policies in the conduct of company transactions.

This is the full certification statement:

- I understand that GSK is committed to the principle of performance with integrity, and in particular, to ensuring that its activities comply with all applicable laws.
- I have received a copy of or have access to the GSK Code of Conduct (POL-GSK_001) and other GSK corporate policies through the Corporate Policy Index page accessible on the Corporate Ethics & Compliance Community.
- I have read and understand The Employee Guide to Business Conduct, accessible on the Corporate Ethics & Compliance Community.
- I have complied with applicable laws, regulations, and GSK corporate and local policies and procedures.
- I understand my responsibility to promptly report any actual or suspected violations of the law, regulations, or GSK corporate and local policies and procedures.
- I have reported all actual or potential compliance issues of which I am aware concerning legal requirements or company policies.

The following statements are also applicable to supervisors with personnel management responsibility:

- All people under my supervision have received copies of or have access to the GSK Code of Conduct and other applicable GSK policies and have been informed of their responsibilities.
- I have put in place appropriate measures to ensure that the people under my supervision comply with applicable laws, regulations, and GSK corporate and local policies and procedures while working on behalf of GSK.
- All new hire employees under my supervision have completed or are scheduled to complete the GSK Corporate Ethics & Compliance new hire training program at GSK Induction or through the Corporate Ethics & Compliance Community.

I have read, understood and shall comply fully with the policies and procedures specified in the learning activity.

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Global

GSK intends that ethics and integrity are a part of all that we do; therefore, the following key ethics and integrity principles and messages are provided to our business training groups across the company for integration into regular training courses:

- GSK has an unwavering commitment to conducting business with integrity and in full compliance with the law
- Every GSK employee is personally and professionally responsible for helping GSK maintain its organisational integrity and good reputation.
- Profits without principles are short lived
- When faced with difficult ethical situations, reference the ethical decision-making model.
 - Is it legal?
 - Is it consistent with company policy?
 - Is it consistent with GSK values and Code of Conduct?
 - Can I explain it to my family and friends?
 - Would I be comfortable if it were printed in the newspaper?
 - Will it benefit all or most of the people involved?
- Our training describes where GSK employees can obtain assistance:
 - Manager
 - Corporate Ethics & Compliance web community
 - Human Resources
 - Legal
 - Compliance officers and champions
 - Integrity Helpline based in the US

Other training and awareness activity in 2008 included:

- Over 14,000 managers completed our self-certification process in 2008
- We launched training for new general managers and site directors on their compliance responsibilities, as well as wider monitoring and compliance arrangements at GSK
- We added 'Performing and Leading with Integrity' training to our induction programme. This focuses on ethical decision making and our code of conduct
- We raised awareness of our Global Confidential Reporting Line through an extensive poster campaign and awareness programmes on our intranet. Our Confidential Reporting phone line is now available in 70 countries and more than 25 languages

Our target to set ethical leadership objectives for all of our top managers was put on hold during the transition to the new CEO. We are planning to implement, track and assess ethical measures at the executive level of the company in 2009.

United States

- Over 9,900 employees and contractors completed compliance refresher training. New hire training was completed by 728 people

- We launched a redesigned training curriculum for new US Pharmaceuticals field sales employees. The curriculum integrates training on ethical commercial practices with sales training, rather than providing it as stand-alone modules. We will integrate compliance training with a range of other sales training programmes in 2009
- We added an ethics section to our employee manual of commercial policies. This expands on the policies to provide information that helps people make the right decisions during commercial interactions

Japan

Our promotion compliance team trained 2,846 employees on the GSK Promotional Code, including the entire sales force, marketing employees, clinical trial monitors and other employees who interact with healthcare professionals. All employees who took this course submitted a letter which pledged compliance with our standards and the law.

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All our managers are accountable for managing risks of non-compliance with our policies in their areas of responsibility. They are overseen by and can seek advice from our corporate ethics and compliance department that promotes effective compliance programmes, addresses compliance issues, and reports problems and progress to senior management and the Board.

We have a dedicated compliance officer for each of our business units: R&D, Manufacturing, Vaccines, Pharma Europe, Pharmaceuticals Emerging Markets, Pharmaceuticals Asia Pacific and Japan, Consumer Healthcare, Corporate, US Pharmaceuticals, and additional compliance representatives in some markets.

Compliance officers are senior managers with direct access to the leadership teams of GSK functions. They are a source of expertise for anyone with a question on ethics or GSK policies. Our corporate compliance officer reports directly to the CEO.

To further develop GSK's internal infrastructure, new full-time compliance director positions were also established during 2008 in Latin America, Middle East-North Africa, Asia Pacific and China. This further demonstrates our ongoing commitment to provide dedicated and focused support to our senior management teams globally. Previously such support was via 'champion' roles which were fulfilled by individuals who had additional functional responsibilities beyond ethics and compliance.

Risk management

Our [Risk Oversight and Compliance Council](#) (ROCC), which includes several Corporate Executive Team (CET) members, oversees risk management and internal control activities. The ROCC is supported by GSK's corporate assurance department and corporate ethics and compliance department. GSK's corporate compliance officer, who chairs the ROCC, regularly reports on significant risks to the CET and the Audit Committee of the Board.

For more information on risk management see the corporate governance section of our [Annual Report](#).

Monitoring for sales and marketing

Sales representatives are supervised by their managers who regularly monitor educational events, visits to doctors and expenses. We use a risk-based approach to determine the frequency of our checks on different districts and individual sales representatives.

In the US, sales representatives that receive inquiries from physicians about off-label uses of GSK products must notify our medical information department, which responds to the inquiry via a medical information letter. Sales representatives must not solicit off-label questions from physicians. Frequent medical information letter requests by a sales representative can indicate that the employee is prompting questions and promoting off-label uses of GSK products. We monitor requests for medical information letters. Our internal audit department regularly audits our sales and marketing practices globally.

Monitoring for payments to healthcare professionals and organisations

Payments are recorded and monitored in different ways in different countries. For example, in the US we have introduced a state reporting system for expenditure with healthcare professionals, in line with legislation in several US states. In Japan, payments to individual healthcare professionals and medical institutions are monitored on a quarterly basis and the results are reported to promotion compliance officers and our internal audit department

These systems help us to identify situations where excessive meals and gifts may have been provided by

GSK.

Reporting channels

Employees are encouraged to seek help on ethical issues and to report any concerns or suspected cases of misconduct. They can do this through their line manager, the Corporate Ethics & Compliance department, a compliance officer or compliance champion, GSK's Human Resources and Legal departments, or through our Global Confidential Reporting Line or the Integrity Helpline in the US. In the US, employees can also report concerns through an offsite post office box or via email.

Reporting channels are promoted through the [Employee Guide to Business Conduct](#), on the GSK intranet and during training.

Addressing misconduct

Our Corporate Ethics & Compliance department monitors and tracks allegations and suspected legal, ethical or policy infractions. It ensures that all such allegations are appropriately investigated. Disciplinary action, up to and including dismissal, is taken where necessary. Serious violations of our policies are reported to the Audit Committee of the Board.

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Corporate Responsibility Report 2008

Monitoring and compliance

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Reviewing our compliance and risk management strategy

In 2007 we conducted a review of our corporate ethics strategy. Based on the results of the review, we took steps during 2008 in the following areas to further embed an ethical culture at GSK:

- Recruitment – we included questions on ethics and integrity in our recruitment process and our GSK Managers Interview Guide. We carried out more extensive pre-employment checks to ensure we recruit people who share GSK's values
- Training – we extended ethics and compliance induction [training](#) to new employees worldwide. We provided extra training and guidance for employees committing minor breaches to prevent them committing serious breaches in future
- Global Confidential Reporting line – we extended our independently managed reporting line to all countries where we operate. For many countries, employees can call in their native language. We undertook an extensive intranet and poster campaign to raise awareness of this service
- Senior management – we developed new training and awareness programmes for site directors and general managers who are key representatives of GSK in the countries and locations where they work. This included individual briefings by the executive team for new appointees on their compliance responsibilities
- Policies – we streamlined the administration of our corporate policies and procedures. This involved reducing the number of policies and procedures by half, and requiring that employees need only have detailed awareness of the policies and procedures specific to their role
- Financial fraud - we established a new fraud risk assessment tool to help us prevent financial fraud. Our finance leadership team will regularly review all financial fraud cases

Progress on meeting our strategy review objectives is reviewed twice a year by the GSK Audit Committee of the Board.

In 2009 we plan to further enhance our Global Confidential Reporting phone line facility. Internet reporting will be introduced in selected countries and languages as our supplier evolves this technology and the number of languages available.

Addressing misconduct

In 2008

- 1,113 employees were disciplined for policy violations
- Of these, 266 were dismissed or agreed to leave the company voluntarily (known as separations)
- Other disciplinary actions included documented warnings (847 instances) and financial penalties
- The 1,113 disciplinary actions included 240 cases of employees breaching sales and marketing codes
- These 240 cases resulted in 30 dismissals or separations from the company. All the other 210 cases resulted in documented warnings

In addition to appropriate discipline, employees staying with the company received retraining and increased monitoring. In some cases retraining is also extended to an employee's colleagues to prevent them making

similar mistakes.

The main types of violations this year included:

- Marketing and promotional activities
- Good manufacturing/good distribution practices
- Falsification of documents
- Travel and expenses claims
- Code of Conduct issues

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Case studies

Suitability for GSK's approved speaker list

As well as ensuring that our employees comply with our policies, it is vital that people working on our behalf meet the highest ethical standards.

In 2008, the US Pharmaceuticals Compliance Department received information through the GSK Integrity Helpline that a healthcare professional (HCP), who was engaged to speak on GSK's behalf, had allegedly failed to comply with company policies during promotional programmes on two consecutive days. GSK reviewed materials from one of the programmes in question and identified a number of issues and policy violations. The person was suspended as a GSK speaker pending the completion of a follow-up investigation. After further investigation, we removed the HCP from our approved speaker list.

Responsible marketing for our weight loss treatment

Nearly two-thirds of US adults are either clinically obese or seriously overweight. This is causing a dramatic increase in life-threatening medical conditions such as heart disease and diabetes, and adding strain to the healthcare system. But even a small amount of weight loss can greatly reduce the risk of developing associated medical problems.

GSK's over-the-counter weight loss product, *alli* (orlistat 60 mg), helps overweight adults lose weight by preventing about 25 per cent of dietary fat from being absorbed in the gut.¹ It helps people lose 50 per cent more weight than diet and exercise alone.² *alli* was launched in the US in June 2007 and since then we have sold over six million starter packs. In 2008, *alli* received a positive opinion from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use and in January 2009, the European Commission granted a non-prescription licence for the product.

It is vital that *alli* is marketed responsibly so that it is used in the right way and only by those who need it. We educate physicians, dieticians and pharmacists to ensure *alli* is sold appropriately and patients receive the right information about the treatment. Our marketing emphasises that using *alli* requires lifestyle changes, including exercise and a low-fat diet, to produce the right results without unwanted side effects. The safety and efficacy profile of orlistat is well documented and has been established through data from more than 100 clinical studies.³

We set up the website www.myalli.com to provide further support for *alli* users. It enables people to set targets, track their weight loss and post success stories. It includes an 'am I ready for *alli*?' quiz, which asks potential users to confirm their commitment to moderating their diet, taking exercise and reading the label carefully. The site also includes '*alli* circles', an online moderated forum where users can share experiences and help each other stay focused on their weight loss targets. The forum gives us valuable feedback from patients on the effectiveness of the product, and we monitor the site for reports of adverse effects which are then reported to the FDA, and for inappropriate content.

In 2008, we donated \$75,000 to Dress for Success (DFS) to mark the one-year anniversary of the US launch of *alli*. DFS is an international non-profit organisation that provides business clothing and career support for disadvantaged women. We encourage *alli* users to volunteer for DFS and to donate clothing that becomes too big for them as they lose weight. DFS has so far received over 38,000 pieces of clothing from *alli* users.

1. Anderson J. Orlistat for the management of overweight individuals and obesity: a review of potential for the 60-mg, over-the-counter dosage. *Expert Opin Pharmacother.* 2007;8 (11):1733-1742.

2. *alli* Summary of Product Characteristics (SPC)

3. Jacob S, Togerson J. Orlistat treatment beneficial in both primary care and tertiary settings. *obesity*

reviews. 2005;6(s1):166.

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Corporate Responsibility Report 2008

Q&As

Here we respond to questions raised by our stakeholders.

Can one company on its own establish high standards of ethical conduct, or is an industry approach required?

We set our own high standards of ethical conduct which we hope will establish a benchmark by which all companies are judged. We also work with other companies through trade associations to develop high ethical standards. We believe that it is in the best interest of patients if the pharmaceutical industry adopts common high standards of ethical conduct. This will also help to improve trust in the industry among all our stakeholders.

A lot of GSK employees were dismissed for unethical conduct. Are your policies working?

In 2008, 266 employees were dismissed or agreed to leave the company voluntarily as a result of policy violations. Unethical conduct occurs in all companies. We believe these figures demonstrate the effectiveness of our monitoring and compliance programmes.

Furthering our ethical culture, recruiting the right people, providing the right training and tools, improving our checks and encouraging people to speak up enable us to identify and address unethical conduct in a consistent and responsive manner.

Is GSK unduly influencing doctors?

We take several approaches to protect against inappropriate influence of doctors, including regional marketing codes of practice, regular training and monitoring. Our policies apply to all employees and agents and commit us to promotional practices that are ethical, responsible, principled and patient centred. They prohibit kickbacks, bribery or other inducements to doctors and any promotion for unapproved uses of our medicines. Our sales force is regularly trained and supervised by managers who monitor educational events, visits to doctors and expenses.

How do you prevent off-label promotion?

All GSK employees dealing with healthcare professionals undergo extensive training and monitoring. They are instructed that only full and accurate information may be provided on approved uses for a medicine. It must be based on valid scientific evidence, and must be accurate, balanced, fair, objective, unambiguous and up to date.

Questions from doctors on off-label uses for our products must be referred to our medical information department. In the US, additional processes are in place for monitoring these referrals to help us ensure that representatives are not promoting off-label uses. We now monitor both the volume of letters responding to questions and the types of referrals made by our individual representatives, for example the number of referrals relating to a particular product or a particular off-label use.

Additionally, our internal audit department regularly audits our sales and marketing practices globally.

The Advertising Standards Authority ruled that health claims in a Horlicks advert shown in the UK were unsubstantiated. Is GSK involved in false advertising?

No, GSK was not involved in false advertising. In 2008, Nepali TV, a Bengali-language satellite channel aimed at viewers on the Indian sub-continent, briefly aired an advert into homes in the UK. However, the advert is intended and approved for use only in India. This was done without our knowledge. The health claims in the advert are not appropriate for the UK as the claims in the advert relate specifically to the Indian market and the Indian diet.

The Advertising Standards Authority in the UK upheld the complaint against Nepali TV for broadcasting the

advert in the UK and did not reprimand GSK.

The UK Office of Fair Trading (OFT) is investigating whether supermarkets and suppliers have been wrongly sharing information on prices. Are GSK consumer products involved?

In 2008 the UK Office of Fair Trading (OFT) began an investigation into potential breaches of competition law by more than 20 companies, including GSK. The OFT is looking into claims that data on pricing was passed to rival companies through suppliers. It has asked GSK for our cooperation, but we have not been accused of breaking the law.

We do not tolerate unethical behaviour. Corrupt and anti-competitive behaviour undermines fair competition, inhibits economic development and is bad for economies, business and people. Our code of conduct sets out our expectations for employees and we conduct training to ensure that we operate within the letter and spirit of the law and maintain high standards of ethical business behaviour.

We are cooperating fully with the OFT and we will take disciplinary action, up to dismissal, if a GSK employee is found to have breached our policies or the law.

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Supply chain

We want to source from companies that maintain high labour and environmental standards.

Inadequate environment, health and safety (EHS) and human rights standards are an indicator of poor management.

This can impact on quality, compromise patient safety and impede continuity of supply of essential medicines. Association with poorly performing suppliers could also damage our reputation.

We conduct detailed assessments of new and existing suppliers to monitor their performance on EHS and human rights issues. We work closely with our suppliers to prevent disruptions to the supply of our key medicines.

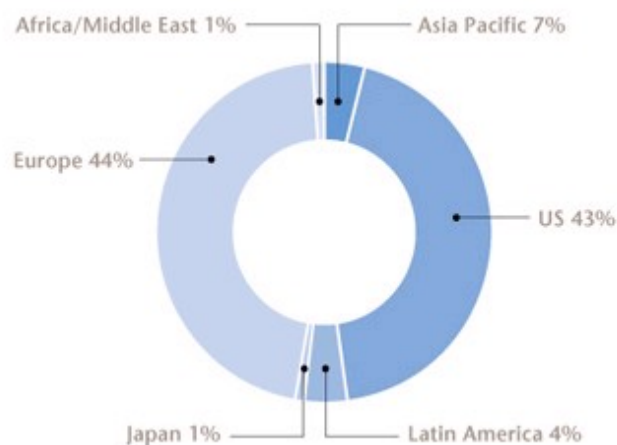
Counterfeit drugs can pose a serious threat to patients. We build anti-counterfeiting features into our products and packaging and we take steps to prevent criminals from making and distributing fake GSK products

We are also working to assess the [environment, health and safety impacts of our manufacturing suppliers](#).

Our Supply Chain

Number of suppliers: 90,000

Spend: £ 8.4 bn



We buy goods and services from around 90,000 suppliers. Our supply chain is complex: it ranges from strategic relationships with suppliers that manufacture active pharmaceutical ingredients, intermediates, raw materials and packaging for GSK medicines to contracts for goods and services such as office equipment, cleaning and security.

Corporate Responsibility Report 2008

Responsibility and our supply chain

Our approach to ensuring high standards for our global suppliers includes:

- Pre-assessments of potential suppliers to gather information and to help evaluation
- Inclusion of human rights clauses in all supplier contracts and full environment, health and safety (EHS) requirements in contracts for critical suppliers
- Review of EHS and human rights in routine supplier engagements (for example business performance meetings)
- EHS audits of potential and existing suppliers
- Regular progress monitoring and additional advice and technical support

Supplier contracts

Our supplier contracts contain EHS requirements based on our [global EHS standards](#) and [human rights clauses](#) based on the International Labour Organization conventions and the UN's Universal Declaration of Human Rights. Companies must agree to our EHS and human rights requirements before they can be included in the selection.

Risk-based approach

Our supply chain is large and complex so we use a risk-based approach to target our efforts. We focus on 'critical suppliers' which are mostly based in Europe, North America and Asia and account for approximately 30 per cent of our supplier spend.

Critical suppliers include contract manufacturers and suppliers that present the greatest risk to GSK on one or more of the following issues:

- Relevance to the supply of essential medicines
- Threats to continuity of supply
- The value of affected products to GSK
- Regulatory requirements
- Hazards associated with manufacturing processes and materials
- Environmental impacts

We develop long-term relationships with critical suppliers and conduct regular monitoring to support the uninterrupted supply of high quality materials and services to GSK.

Training for GSK procurement teams

We train all new procurement employees in our standards and requirements for [EHS](#) and [human rights](#). This emphasises their role in promoting compliance with the standards. Key procurement employees, including procurement managers, receive ongoing training on these topics.

In 2009, we will develop new sustainable procurement guidelines, with supporting training plans, which will focus on sourcing:

- Materials from sustainable sources
- Products with recycled content
- Energy-efficient equipment

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Human rights clause

Our supplier contracts contain a human rights clause (below) which is based on the International Labour Organizations conventions and the UN's Universal Declaration of Human Rights.

We may amend the exact wording of the clause during negotiations with suppliers or during translation to suit local law. These changes will not reduce the contractual impact or intent of the clause.

The GSK standard contract clause for Ethical Standards and Human Rights

Unless otherwise required or prohibited by law, the Supplier warrants, to the best of its knowledge, that in relation to the supply of goods or services under the terms of this Agreement:

1. it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;
2. it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;
3. it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by the Supplier to its employees is safe for habitation. The Supplier provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the Supplier's workplace;
4. it does not discriminate against any employees on any ground (including race, religion, disability or gender);
5. it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;
6. it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;
7. it complies with the laws on working hours and employment rights in the countries in which it operates;
8. it is respectful of its employees' right to join and form independent trade unions and freedom of association;
9. The Supplier agrees that it is responsible for controlling its own supply chain and that it shall encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by Supplier when performing its obligations under this Agreement.

The Supplier shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies.

GSK reserves the right upon reasonable notice (unless inspection is for cause, in which case no notice shall be necessary) to enter upon the Supplier's premises to monitor compliance by the Supplier of the warranties set out in the clause above and the Supplier shall, subject to compliance with law, furnish GSK with any relevant documents requested by GSK in relation thereto. {This sub-section will only be required where there is no general right of audit elsewhere within the Agreement}

Corporate Responsibility Report 2008

Choosing suppliers

We conduct a detailed assessment of critical suppliers before they are selected.

Critical suppliers include contract manufacturers and suppliers that present the greatest risk to GSK on one or more key risk areas. We use questionnaires, on-site reviews and EHS audits to assess their performance on health and safety, environmental and human rights issues.

We assess potential new critical suppliers against [our EHS standards](#). They must achieve a minimum audit score of 50 per cent against the standards if they are to join our supply chain. Following an audit, many suppliers who have not met our requirements implement plans to improve their EHS performance. We monitor their progress and in some cases provide opportunities for training and technical support to enable the supplier to achieve the required standards. We also expect suppliers who have established supply arrangements with us to make improvements and we monitor their progress through reviews and follow-up visits.

The audits also include questions which help us identify potential breaches of the human rights clauses included in supplier contracts. Suppliers are asked for information on policies and practices relating to:

- Age limits for employees
- Discrimination against employees and the local population
- Prevention of abuse of individuals
- Wages, benefits and working hours (whether they meet the legal minimum)
- Rights for workers to organise and recognition of worker organisations

These questions do not contribute to the EHS audit score, but may be a reason not to progress business with a supplier.

Read about our [audit programme which ensures compliance with quality standards](#)

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Monitoring and engagement

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In order to maintain GSK standards in our supply chain, we routinely interact with our suppliers through reviews and follow-up visits by procurement, quality and EHS staff. We consider EHS and human rights issues in all these interactions.

We hold global and regional supplier review meetings where senior GSK managers interact with suppliers on key issues. We provide contract manufacturers with information on the EHS risks associated with the GSK materials they are producing or handling. Our supplier booklet *Working with GSK* includes our ethics policies and requirements.

We conduct regular EHS audits of critical suppliers of pharmaceutical and consumer healthcare products. We focus on the 150 higher-risk suppliers. Supplier facilities are evaluated against our [EHS standards](#) and must achieve a score of at least 50 per cent against these standards to demonstrate acceptable performance and to support continuing supply arrangements. Suppliers develop improvement plans based on the audit findings and we follow up to monitor progress against these plans.

Read a [case study](#) on how we helped a supplier to improve its EHS performance in 2008.

We will provide feedback to suppliers if we identify any issues through the [questions relating to human rights](#). We will require corrective action if the issues present a potential breach of the [human rights clause](#) included in supplier contracts.

Suppliers of promotional items

Many of the gift items for our Indian business are sourced from within India in an industry with a higher risk of the use of child labour.

We conduct unannounced spot checks for these suppliers, often during the night. These focus on maintaining quality standards but are also used to check that suppliers are not using child labour. The spot checks are conducted by GSK procurement and regional sales staff.

We have used the findings from the programme in India to inform our promotional supplier qualification process in other regions. We have begun to conduct more detailed inspection of assembly sites where possible and have added extra checks in regions where child labour is more common.

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Corporate Responsibility Report 2008

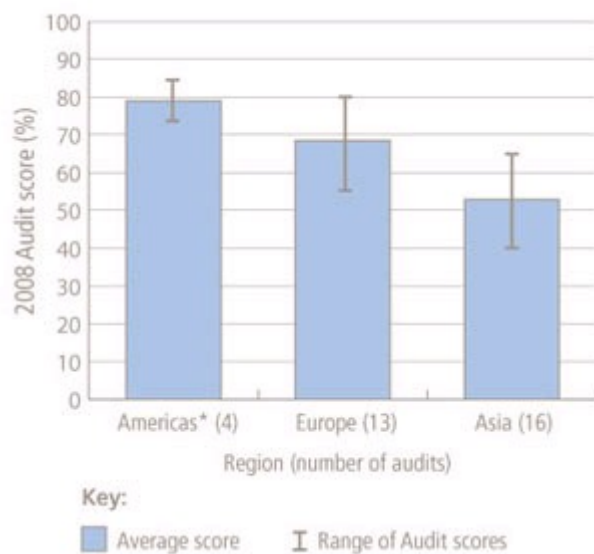
Monitoring and engagement

Approach

Performance

In 2008, we conducted 30 supplier audits and 20 reviews. The average audit score against GSK EHS standards was 62 per cent; the highest score achieved was 84 percent and lowest was 40 percent.

2008 EHS audit scores of key suppliers



* Americas = Canada, North America and South America regions

The higher average scores in North America and Europe, in contrast to the lower average scores in Asia, are largely related to the maturity of EHS management and the supporting legislative framework and its enforcement in these regions. The broad range of scores in the Asia region reflects the higher performing suppliers where there has been long term intervention from GSK. The lower scores relate to suppliers where we have undertaken initial audits and found significant deficiencies in EHS management and risk control.

Five suppliers failed to meet our minimum requirement of 50 percent against GSK EHS standards. Potential new suppliers that scored below the minimum level were either not progressed or work is underway to improve performance to acceptable levels. We work with existing suppliers to ensure necessary improvements are made within an agreed timeframe and that GSK standards are applied in our supply chain.

The most significant audit findings in 2008 occurred mainly in emerging economies. These included:

- No infrastructure for fire protection and poor emergency response capabilities
- Absence of fundamental risk controls for process safety
- Poor control of exposure to hazardous substances
- Poor waste management and environmental controls
- Frequent regulatory findings

No significant issues were identified relating to the human rights questions we ask during audits.

In 2008 we continued to work with a number of key suppliers to help improve their EHS performance. This included:

- Developing closer relationships - We have two full-time positions, in China and India, to support our work with audited suppliers and improve their EHS performance. Their work includes helping the suppliers to develop improvement plans and providing them with coaching opportunities. Read more in our [case study](#) on how we helped a supplier to improve its EHS performance in 2008.
- Attending supplier forums through the R&D-based Pharmaceutical Association Committee (RDPAC), an industry consortium in China. The forums provide the opportunity for GSK to engage with suppliers, and for supplier companies to take advantage of training and networking.
- Making progress in a pilot project for a strategic supplier to achieve 'Highly Protected Risk' (HPR) status. To achieve HPR status, a 'best in class' insurance industry designation, companies must adopt an engineering approach to minimising property and supply chain risks. Our plan is to extend this to other strategic suppliers

Number and type of audits in 2008

	Americas*	Europe	Asia	Africa	Total
Type of supplier					
Primary (raw materials, intermediates and active pharmaceutical ingredients)	3	12	17	0	32
Pharmaceutical (formulations)	3	5	0	1	9
Consumer Healthcare (excipients, actives, raw materials)	0	1	11	0	12
Type of engagement					
Audit	4	13	16	0	33
Review	2	5	12	1	20
Average audit score (per cent)	79	68	53	-	62

Number of suppliers audited between 2002 and 2008

	Total number visits	Americas*	Europe	Asia	Africa	Cumulative Total number visits
2002	9	0	8	1	0	9
2003	18	0	12	6	0	27
2004	29	3	9	17	0	56
2005	40	7	8	23	2	96
2006	32	0	13	18	1	128
2007	55	10	8	37	0	183
2008	53	6	18	28	1	236

* Americas = Canada, North America and South America regions

Suppliers of promotional items

In 2008 we conducted five unannounced spot checks of promotional goods suppliers in India (at least one visit for each company supplying promotional goods to our Indian business in 2008). These uncovered no

evidence of child labour.

Corporate Responsibility Report 2008

Supplier diversity

Small and minority-owned companies are often under-represented in the supply chains of large companies.

In response, the US government and many large companies require their suppliers to source from diverse companies. The Broad-Based Black Economic Empowerment Bill 2003 in South Africa includes similar requirements.

We are working to increase the diversity of our supply chain by providing opportunities for small, diverse businesses to provide us with goods and services. This helps diverse suppliers to sustain their businesses, create jobs and boost their local economies. Our business also benefits. Beyond complying with regulations, supplier diversity encourages innovation and exposes us to new perspectives and fresh ideas.

US programme

In the US, we have a dedicated team working to create opportunities for diverse suppliers to work with GSK and to channel our procurement spend to women and minority-owned companies. Its activities include:

- Participating in national and local diversity councils
- Mentoring high-potential diverse suppliers and providing improvement grants to help them expand their business with GSK and other corporations. Read more in our [case study](#)
- Sponsoring diverse business leaders to attend executive programmes at the Tuck School of Business and Kellogg School of Management
- Sponsoring and attending outreach and networking conferences

We co-sponsor the Congressional Black Caucus Foundation (CBCF), a non-profit organisation that supports African Americans and under-served communities in the US. We are donating \$500,000 between 2005 and 2009 to the Foundation to provide training to help make diverse businesses more competitive. We also support an initiative, run by the CBCF, to help change federal policy that can restrict long-term relationships between minority- and women-owned businesses and major corporations.

We sponsor Roanoke Online, a technology company that hosts an online database and electronic sourcing system for diverse suppliers. This gives large companies, including GSK, better access to diverse suppliers. Corporations gain access to a large, diverse pool of contractors, which ultimately helps them lower their costs, while the small diverse suppliers get the chance to grow their businesses through increased opportunities to supply companies traditionally beyond their reach.

As part of the Adopt a Neighbourhood for Development initiative, our procurement and community relations teams work with local communities in Durham, North Carolina, and Philadelphia, Pennsylvania. These areas are historically deprived and are often overlooked by companies when choosing where to locate their businesses. GSK provides an annual grant to support self-development within the communities to make these areas more attractive as business locations.

Outside the US

GSK's dedicated supplier diversity team is based in the US, but all procurement employees worldwide are responsible for supporting diverse suppliers where possible.

We are a sponsor of the Global Link Programme as part of our role on the International Advisory Board of the US National Minority Supplier Development Council. The Programme helps diverse suppliers develop partnerships with local businesses around the world. In collaboration with two other pharmaceutical

companies, we paid for ten US-based minority-owned companies to visit South Africa in late 2007. The companies met diverse South African businesses and got the chance to form partnerships to help them compete globally. We have also participated in similar trips to Australia, Brazil and China. The initiative has enabled GSK to invest in the local economies of communities we serve and helps ensure our supplier base reflects the diversity of those communities.

GSK is a member of the new UK Minority Supplier Development Council. The Council forms a link between corporations and certified minority business enterprises, with the aim of increasing procurement and business development opportunities.

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› [Fair treatment of suppliers](#)

Corporate Responsibility Report 2008

Fair treatment of suppliers

It is important that we foster relationships with our suppliers which are characterised by mutual trust and respect.

GSK has established procurement policies which require high standards of ethical conduct and integrity. Our [general terms and conditions](#) are on our website.

As part of our supplier review process, we have a two way dialogue to identify areas for mutual improvement and to provide an environment where suppliers can discuss issues and present new ideas.

We support impartiality in all phases of the procurement cycle. Our global electronic bid system ensures all suppliers are treated fairly and equally. The vast majority of suppliers that provide goods and services to GSK are registered on the system. Companies that are invited to bid to supply GSK all receive the same information at the same time, for example invitations to compete and specifications of the supplies required. In 2008, the system managed over 8,000 bidding and negotiation-related events in over 50 countries. For highly competitive goods and services we allow suppliers full transparency of seeing where their bids rank against their competition.

Payment of suppliers

From September 2008 GSK changed its standard payment terms for uncontracted suppliers in the UK and US from 30 days from the receipt of the invoice to 60 days. We will review our terms and conditions with contracted suppliers on contract renewal or earlier.

This step has been taken as part of a project to reduce working capital. We recognise that this may impact the cash flow of our suppliers. However, the new 60-day term brings us more in line with the practice in other industries and is faster than the terms set by some other companies.

We realise this may cause genuine financial difficulty for some organisations and we evaluate the implications of this on a case-by-case basis.

Corporate Responsibility Report 2008

Maintaining quality

Maintaining the quality of the products we make and the materials we buy is essential to the safety of patients and the success of our business.

We conduct quality assessments for all suppliers of ingredients and packaging materials used in all of our products. We agree specifications for our ingredients and packaging materials with our suppliers and apply a set of global auditing standards for each type of ingredient and packaging material that we buy.

We use a risk-based approach to determine the frequency of audits. In 2008 we conducted 558 audits of our ingredient and packaging material suppliers, compared to 776 in 2007 and 740 in 2006.

On receipt at GSK sites, samples are taken and testing is performed according to a testing protocol. All samples are tested for identity. Every batch is also tested against our quality specification.

Examples of additional measures in place to maintain quality in our supply chain and prevent contamination include the use of dedicated transport, use of tamper evident seals and the use of sophisticated analytical tools to check the authenticity of the materials we receive.

Helping suppliers to meet our quality standards

We conduct quality assessments of all potential suppliers. This enables us to identify companies that meet our required standards as well as those we can work with to make the necessary improvements.

For example, we identified one of our existing chemical suppliers in Asia that had the expertise to supply the final active ingredient for a GSK product. We worked closely with the supplier to help them develop the technical processes and quality standards to begin trial manufacturing in 2001. This included site visits to advise on configuration of plant and building modifications and assistance in preparing documentation required by regulators. In 2006, the US Food and Drug Administration conducted a four day quality and compliance inspection of the site, which resulted in no adverse findings and approved the site for supply to the US market.

Raising employee awareness of our commitment to quality

In 2008, Andrew Witty, GSK's CEO, endorsed a new, internal quality statement which stresses the importance of quality across all of our business activities, including the critical aspect of product quality. We raised awareness of this statement through discussion at internal Quality Councils throughout our business units, through new articles on our global intranet site, myGSK, and through posters for display at all facilities.

Quality statement



Quality is at the heart of all activities that support the discovery, supply and marketing of products to our patients and customers. Quality is critical to building trust with society and, therefore, to our future business success.

Andrew Witty, Chief Executive Officer

› Home › Responsibility › Supply chain › **Security of supply**

Corporate Responsibility Report 2008

Security of supply

Ensuring a continuous supply of high quality medicines is essential to the patients who depend on our products, as well as to the success of our business.

It is vital that security of supply is not compromised at any stage of the distribution chain. We prepare for major incidents that may disrupt supply, ranging from large-scale theft of products to natural and man-made disasters near a facility.

Strategy directors from each therapy area have overall responsibility for security of supply. Divisional heads meet our procurement teams every month to discuss any potential issues.

GMS (our manufacturing business) implements contingency plans for 'medically critical' products. We define products as 'medically critical' if life-saving or those where if they were not available to patients, there is likelihood of serious detriment to health and there is no known alternative. These plans are defined on a product-by-product basis and may include holding sufficient stocks of products or active pharmaceutical ingredients.

We work with all critical suppliers to encourage them to implement their own contingency plans. In high-risk countries we will set up joint ventures to ensure that we maintain control over the distribution chain. We have three global contracts for suppliers that deliver goods between GSK facilities and distribute products to market. We conduct regular high-level operational reviews of these suppliers, which include security elements.

Read about the measures we are taking to [protect our employees in the event of a pandemic flu outbreak](#) to ensure the supply of critical medicines is not disrupted.

Corporate Responsibility Report 2008

Counterfeiting

Approach

Performance

According to the World Health Organization (WHO), less than one per cent of pharmaceutical products sold in developed countries are counterfeit, but in the developing world this figure may be higher than 10 per cent, and up to 30 per cent in some countries.

Counterfeit drugs come in many variations, and may contain:

- None of the legitimate active ingredient
- The active ingredient in reduced or sub-therapeutic amounts
- A completely different and/or inappropriate active ingredient
- Impurities such as unapproved colourants or microorganisms
- Packaging that falsifies the product description or expiry date

Most counterfeit drugs are not subject to quality control, hygiene standards, testing of ingredients and monitoring of product specifications or equipment. Counterfeiting is a threat to public health, potentially causing harm to patients and even death.

We add anti-counterfeiting features to our product packaging. These include holograms, security seals, complicated background patterns that are difficult to photocopy or scan, as well as a wide variety of covert identifiers which are added using print technologies and sophisticated markers. These help us to identify counterfeits and gather evidence against offenders. Our Packing Design Technology and Security team in the UK carries out forensic examinations of all suspected counterfeit GSK products.

Our sales representatives worldwide also play an important role in helping to discover counterfeit products through continual observation of the local market. Our Corporate Security department investigates every potential case of counterfeiting. It uses internal and external investigators to collect information, which we then assess and report to the relevant government authorities to set in motion official law enforcement action.

As well as removing fake products from the market, one of our primary aims is to trace the products back to source, to shut down the manufacturers and their partners (for example the packaging printers and distributors). We provide training for regulatory authorities, such as the State Food and Drug Administration (sFDA) in China, law enforcement agencies and customs officers in many parts of the world.

GSK works very closely with the wider pharmaceutical industry to investigate cases of counterfeiting and we also raise awareness with governments internationally, pressing for stricter laws and more severe penalties. GSK is a founding member of the Pharmaceutical Security Institute (PSI), which coordinates information collection and investigations within the industry internationally. The PSI is influential in helping to shape anti-counterfeiting policy among national governments and international organisations. Together with the PSI, GSK is a major contributor to the WHO's internationally represented anti-counterfeiting working groups.

Internet pharmacies

There is evidence that a large number of internet pharmacies are involved in the sale of counterfeit or diverted medicines or illegal generic substitutions (switched at the time of delivery for the requested

brand name product).

Some internet pharmacies provide sub-standard product, engage in a fraud against the customer (using their credit card information for other fraudulent activity) and ignore local laws and regulations relating to licences, prescriptions and patient information, seemingly operating with immunity from prosecution.

Internet pharmacies have flourished over the past few years and it is likely that this rise will continue as it provides a lucrative, low-risk opportunity for direct selling to patients in a global and largely unrestricted market.

The UK Medicines and Healthcare products Regulatory Agency estimated in 2004 that 600,000 British patients purchased prescription only medicines on the internet and the US FDA reported that 100,000 pills are purchased through internet pharmacies each month in the state of Kentucky alone.

Corporate Responsibility Report 2008

Counterfeiting

Approach

Performance

In 2008 there were 289 reported cases of counterfeiting of GSK products.

These resulted in 94 raids, during which 84 suspected counterfeiters were arrested and £7 million worth of counterfeit products were found.

Of the 94 raids, 22 took place at criminal manufacturing facilities and 54 at wholesale/distribution outlets. The 22 factories represent criminal operations that were capable of mass production of counterfeit medicines and other healthcare products. The raids on these facilities undoubtedly prevented huge amounts of counterfeit product from entering legitimate markets around the world, much more than the £7 million worth of product found at the time of the raids.

In 2008 there was a reduction in the number of reported cases of counterfeiting. We see this as a positive sign that anti-counterfeiting measures are working.

The number of raids by GSK has risen by 30 per cent as a result of our own proactive security and investigations activity. The number of raids is not directly related to the number of reported cases of counterfeits, these are based on intelligence from our security and investigations activity.

GSK is recognised as a leader by the industry in combating counterfeit medicines, and currently chairs the Pharmaceutical Security Institute.

Anti-counterfeiting

	Number of reported cases of counterfeit	Number of raids	Number of arrests	Value of counterfeit products found during raids
2008	289	94	84	£7 million
2007	429	71	127	£15 million
2006	248	57	94	£10 million
2005	334	47	31	£13 million

Corporate Responsibility Report 2008

Case studies

Mentoring diverse suppliers in the US

Callis Construction Services (CCS) is a minority-owned contracting company in Durham, North Carolina. The company's President, Jesse Callis, took part in our diverse supplier mentoring programme, beginning in 2004, which helps suppliers form partnerships with GSK and other large corporations.

As part of the programme, we assessed CCS's business processes and identified issues preventing the company becoming a GSK preferred supplier. Concerns ranged from management accessibility to the ability to scale up their supply to the needs of GSK. The company implemented improvements based on our recommendations which enabled it to become a preferred supplier and win business worth around \$2.8 million.

The success of this partnership enabled CCS to contribute to its local community. It paid for two employees to attend a local university and Mr Callis developed a training programme with Durham Technical College which prepares minority construction workers for management positions on major projects in the area.

When asked about his relationship with GSK, Mr Callis said, "GSK has been a wonderful mentor. They are a real leader in their commitment and actions to help diverse minority suppliers. In my case, they provided assistance that has led to a very significant growth of my business. This in turn has provided jobs for others in the Durham and surrounding area ensuring that monies paid by GSK stay in the local communities. This is a win for everyone involved."

Helping to improve supplier performance

In some cases we provide assistance to suppliers that fail to meet our minimum EHS and quality standards to improve their performance. This enables companies to improve their work practices and win more business. It helps us to develop the supply chain we need to provide a secure supply of high quality medicines.

For example, in 2008 we provided support to a potential supplier of active pharmaceutical ingredients in India. The supplier received an audit score of 41 per cent, below our 50 per cent minimum standard. Following the audit we made recommendations for improvement, provided coaching and facilitated meetings between the supplier and expert consultants.

In 2008 the supplier achieved an audit score of 55 per cent and was accepted as a GSK supplier. The audit found that the company is managing key risks effectively and has established a detailed improvement programme. We will continue to monitor progress against this improvement plan.

The success of this collaboration relied on the efforts of GSK staff as well as the willingness of the supplier to recognise that improvements were needed. It has resulted in a more secure supply chain for GSK and a safer working environment for workers at the facility.

› Home › Responsibility › Supply chain › **Q&As**

Corporate Responsibility Report 2008

Q&As

Here we respond to questions raised by our stakeholders.

What are you doing to raise standards in your supply chain?

We have long-term relationships with our critical suppliers and we offer them training and support to help them raise standards. Our monitoring process is a key part of raising awareness of our expectations and identifying areas where suppliers need to improve. We work with our suppliers to help them make the necessary changes identified.

Are there human rights risks in your supply chain?

GSK's supply chain is large and complex, and like all similar supply chains, contains a risk of human rights violations. These risks vary considerably based on the type of supplier and the goods or service we are sourcing. Our manufacturing and R&D suppliers employ skilled workers so there is a lower risk of human rights violations. Our EHS audits aim to ensure good working conditions at these supplier facilities. There are considerably higher human rights risks in suppliers that employ low-skilled workers, for example promotional goods suppliers. We conduct spot checks of these suppliers in India.

Our supplier selection process aims to ensure we only enter relationships with suppliers that respect human rights. We also include clauses in contracts with all suppliers which specify that upholding human rights is a condition of doing business with GSK.

What are you doing in your supply chain to plan for a flu pandemic?

We have implemented a contingency plan to ensure our operations, and the supply of medically critical products, are not compromised by a flu pandemic. We are now encouraging our critical suppliers to implement their own contingency plans.

You are outsourcing more manufacturing. Will this mean you have less control over your products, increasing risk for patients?

The manufacture of all our medicines and vaccines is closely controlled and subject to the same quality standards, regardless of whether we produce them ourselves or outsource the process to contract manufacturers. Before outsourcing any stage of the manufacturing process, we confirm that the contractor can carry out the required processes to our high standards. All contract manufacturers must also be approved by relevant regulatory authorities, and are subject to inspection by GSK and regulators.

› Home › Responsibility › **Environmental sustainability**

Corporate Responsibility Report 2008

Environmental sustainability

Sustainability has been defined as meeting the needs of today without compromising the ability of future generations to meet their own needs.

GSK is embarking on a journey towards sustainability that we expect to continue for many years. As well as benefiting the environment, our sustainability efforts encourage innovation that provides a better outcome for society and help us to reduce costs.

Our early environmental management programmes focused on controlling emissions and wastes from our operations through treatment and disposal systems. Our approach to sustainability is to change the fundamental process to reduce the amount of resource consumed, avoiding waste at source rather than simply treating the waste and emissions that arise. We have already begun changing our business and developing innovative new manufacturing processes.

We have set initial sustainability goals to:

- Double the average efficiency with which we convert raw materials to finished products for new products by the end of 2010 from a 2005 baseline
- Reduce our energy and climate change impact per unit of sales from 2006 levels by 45 per cent by 2015
- Eliminate CFCs in our products and equipment by the end of 2010

Examples of our sustainability initiatives include

- Reducing the amount of material resources we use such as raw materials and fossil fuels
- Minimising waste and recycling unavoidable waste
- Redesigning production processes to eliminate the production of toxic materials
- Reducing energy consumption and the associated carbon emissions

We manage our Environment, Health, Safety and Sustainability (EHSS) programme according to a framework that sets out consistent standards of employee health and safety, environmental protection and sustainability. This framework acts as an internal regulatory system that reflects our understanding of our risks to ensure our operations comply with laws and regulations. It provides information, tools and training to help everyone at GSK meet our standards. It includes targets as set out in the Plan for Excellence to address our fundamental environmental and sustainability impacts. We also work with our suppliers to help them become more sustainable.

Openness and transparency are fundamental to our sustainability performance and we will continue to engage with stakeholders to share views and dilemmas.

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Corporate Responsibility Report 2008

Plan for excellence

Our EHSS Plan for Excellence sets out our ten-year strategy to improve environment, health, safety and sustainability performance through to 2015.

The details are developed in concert with each business so that the Plan is integrated with business plans and specific actions are identified by each business. The Plan is reviewed every five years and new targets are set. It is designed to support GSK's business plans and consists of three strategic priorities:

- **Environment, health and safety fundamentals embedded in the business** – to produce and sustain high EHS performance we need to combine structured systems with the attitudes and values that create a positive EHS culture. To achieve this we need to embed awareness of environment, health and safety concerns and systems in all GSK activities
- **Environmental sustainability** – to embrace environmental sustainability as a driver for competitive advantage we need to define the principles of environmental sustainability and progressively integrate them into the business, translating them into practical action
- **Open and transparent external relations** – external stakeholders who have a legitimate interest in the company's environment, health, safety and sustainability affairs should have ready access to relevant information and the opportunity for dialogue about issues that concern them. Building open relationships and partnerships can lead to business opportunities, while failure to engage may damage our reputation

Each of these strategic priorities is supported by plans with performance targets in key areas.

GSK has worked with our [External Stakeholder Panel](#) to help set out our plan and to review our annual performance.

Targets

Our EHSS Plan for Excellence includes company targets to improve environment, health, safety and sustainability performance. These are based on site based, practical improvement plans and forecasts from all manufacturing operations.

[Read more about how targets are set and view details of our company targets](#)

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Corporate Responsibility Report 2008

Targets

We set company-wide targets to drive continuous improvement in managing our most significant environment, health, safety and sustainability impacts (see table).

We compare proposals for company targets put forward by operations with benchmarking information and our environment, health and safety professionals, senior managers and management teams throughout the business closely review them and agree on the final target numbers.

We believe it is important to set and achieve targets because lower resource consumption and less waste benefit the environment and GSK. Although we are on track to meet most of our targets, we recognise that some will be difficult to meet within the time we have set ourselves. We explain progress to the targets in the discussions on the individual metrics.

[Read our health and safety targets](#)

Targets and progress 2008

	Target	Progress from 2006 to 2008
Sustainability targets		
Material efficiency of new processes for actives	2% average for the period 2005-2010	Material efficiency of 1.6% achieved by 2008
Energy for operations and transport	20% reduction per unit of sales from 2006 baseline by 2010	Increased less than 1% per £ sales CER
Climate change impact from energy for operations and transport ¹	20% reduction per unit of sales from 2006 baseline by 2010	Increased 2% per £ sales CER
Water	2% annual reduction from 2006 baseline per unit of sales	Reduced 11% per £ sales CER
Fundamental targets		
Wastewater (chemical oxygen demand)	3% annual reduction from 2006 baseline per unit of sales	Reduced 6% per £ sales CER
Solid waste	1% annual reduction from 2006 baseline per unit of sales	Reduced 9% per £ sales CER
Ozone depletion ²	100% elimination by 2010 from 2006	Eliminated 83%
Air emissions (volatile organic emissions)	2% annual reduction from 2006 baseline per unit of sales	Reduced 10% per £ sales CER
EHS audit scores	Average: 82% by 2010 Minimum: 70% by 2010	Average 78% Minimum 62%

1. Climate change impact is measured as CO₂ equivalent emissions

2. Includes ozone depletion potential from production and refrigeration losses Targets and performance normalised by sales are based on a constant exchange rate (CER).



SGS verified

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Corporate Responsibility Report 2008

Journey to sustainability

James Hagan, Vice President, Corporate Environment, Health, Safety and Sustainability, charts GSK's history of environmental management and describes how the company is making the shift towards sustainability.

Sustainability is defined as meeting the needs of today without compromising the ability of future generations to meet their own needs. For GSK to be sustainable, we need to be efficient in the use of resources, including energy, water and raw materials and we need to use renewable resources. As resources become more scarce and expensive, sustainability and cost will be more closely linked. Ultimately, this means that our ability to continue to manufacture affordable medicines requires us to address sustainability.

We have been working towards sustainability since 2001 when GSK was formed. Similar to other industries at that time, the companies that formed GSK started out managing their emissions and waste using treatment and disposal methods and considered management of waste a necessary cost.

We soon recognised that while these 'bolt-on' control measures are essential, they will only ever incrementally improve the impact of waste. To achieve a step-change towards sustainability, we need to make our processes more efficient to prevent waste and emissions being produced in the first place. This fundamental change requires investment in innovative solutions. Through innovation we can create more efficient processes which use less resource and reduce costs. This virtuous circle is completed when we take a portion of our sales and reinvest it in innovation. Sustainability reflects a 'built-in' approach.

To begin guiding our business towards sustainability, we developed a management framework which set out a policy and consistent standards for everyone at GSK to follow. We produced a plan for 2001-2010 which outlined a timetable for achieving the goals set out in the framework and set five-year improvement targets. This plan was refreshed for the period 2006 to 2015.

The plan identified manufacturing efficiency as the first area where we could make significant progress toward sustainability. We used a material balance – a calculation that looks at the amount produced compared to the amounts of raw materials used – to measure our material efficiency and set an improvement target to double the efficiency for our new products. Our Eco-design toolkit supports the development of these more efficient manufacturing processes. Read more about [process design](#). We have already had some success with new medicines and we think we can improve the processes for some of our existing products as well.

Climate change, one of the greatest challenges facing mankind, is a key part of our sustainability strategy. We have set targets to almost halve the amount of energy we use and the CO₂ we produce per unit of sales by 2015.

Our sustainability focus extends beyond manufacturing to all aspects of our business, including R&D, sales and other activities. It also includes environmental product stewardship, the responsibility we have for the environmental impact of our medicines.

Within GSK, sustainability has started to take root. As an example, our Nutritional Healthcare business has a comprehensive sustainability programme, please read this [casestudy](#) for details. They are working with suppliers to examine the lifecycle and biodiversity impacts of raw materials used, developing a 'zero waste to landfill' manufacturing approach, using recycled materials for packaging and developing innovative ways to recover used bottles through reverse vending. Our Consumer Healthcare business has also developed a sustainability strategy called 'Bright Green' which includes packaging, climate change, water use, product stewardship and total supply chain goals.

Although we have made progress in the Nutritionals business and in certain other areas, achieving our fundamental environmental improvement targets and making progress toward sustainability continues to be a challenge. In 2009 we will assess how we can achieve our targets. Of course, we will learn from both success and failure and each year we will explain why we succeeded or failed. We will also continue to broaden our view of what sustainability means to GSK. So far we have focused our attention on sustainability on R&D and manufacturing. Going forward we know we need to broaden that focus to include our sales force and offices.

I realise that we have just begun this journey, and that we will need all our commitment and innovation to succeed. Our internal Sustainability Council composed of senior managers is leading our efforts. We also have an External Stakeholder Panel that gives feedback on our approach and performance and suggests improvement alternatives. I recognise the value that all of our stakeholders can bring so I welcome your views on our approach. Please feel free to let me know your thoughts by emailing me at csr.contact@gsk.com.

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Corporate Responsibility Report 2008

Managing environment, health, safety and sustainability

We manage our environment, health, safety and sustainability issues using a management system aligned with recognised management system standards such as ISO 14001 and OHSAS 18001.

Our management system is based on a structured framework that starts with a vision and policy. The policy is supported by standards, guidance materials, tools, training, recognition and audits that assist the business to manage environment, health, safety and sustainability at their sites throughout key business operations. Systematic audits assess sites' adoption of a management systems approach to manage their risks.

The framework defines our:

- EHSS vision and policy which set out the broad principles we expect our operations to meet
- EHSS standards that outline specific requirements for our company based on our EHSS risks. These meet or exceed applicable laws and regulations and are consistent with the international standards ISO14001 and OHSAS 18001 based on a management systems approach
- EHSS guidelines that support the EHSS standards by providing further information on the requirements of the standards and setting out an approved approach for achieving compliance. They incorporate good practice from both within and outside GSK. A wide range of information supplements the EHSS guidelines. This includes technical information and training materials to help our employees understand and implement our EHSS management system
- Audits that assess the implementation of management systems
- Reward and recognition that recognises teams who have made outstanding progress towards achieving our goals

The framework includes a [Plan for Excellence](#) that sets out our strategy to improve our EHSS performance to 2015.

Improving efficiency through greater integration

Our *Horlicks* manufacturing facility near Delhi, India is certified to the international quality standard ISO9001, the environmental standard ISO14001 and the safety standards ISO22000 and OHSAS18001. In 2008, the site introduced an integrated management system to reduce the burden of complying with these separate standards.

The new system has improved efficiency and cut costs at the plant by reducing the amount of documentation required and the number of audits. Employees can now just use one instruction manual rather than separate documents for each of the four standards.

This project won first place in the 2008 CEO's EHS Excellence Awards, Initiative-Health & Safety category.

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Corporate Responsibility Report 2008

EHSS vision and policy

Vision

GSK's environment, health, safety and sustainability (EHSS) vision is to achieve sustainable competitive business advantage and environmental sustainability through leadership and excellence.

Our EHSS vision supports our mission to help people do more, feel better and live longer.

Policy

Our EHSS policy describes to employees and external stakeholders what we want to accomplish in environment, health, safety and sustainability. It sets out our aspiration of global leadership and excellence and outlines the broad scope of our plans, and how they will be achieved.

A revised policy was approved by the Corporate Executive Team (CET) in 2008:

Leadership and continuous improvement culture

We will be leaders in EHSS performance, protecting the environment and the communities in which we work and enabling healthy motivated employees to be fully engaged with our success. We will maintain a culture of continuous improvement.

EHS fundamentals, risk and impacts

We will embed EHS fundamentals into the fabric of the business by implementing management systems, EHS governance and risk management practices to address risks and impacts from our facilities, processes, contract research and manufacturing organisations, and suppliers.

Sustainability

We will integrate sustainability principles into all aspects of our healthcare business by working with our stakeholders, operating within environmentally sustainable limits, lowering our ecological footprint, enhancing social equity and addressing future issues.

Open EHSS communication

We will be open and transparent with all stakeholders about our efforts to address our EHSS responsibilities and our EHSS performance.

The Corporate Executive Team (CET) will ensure risks are tracked until mitigated and that communication of the more significant risks is escalated within the business management structure, as commensurate with the risks and impacts involved. The CET will ensure effective management and involvement of staff with clearly assigned accountability and responsibility.

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› **Training and awareness**

Corporate Responsibility Report 2008

Training and awareness

We provide detailed guidelines and technical information as part of the framework for managing environment, health, safety and sustainability (EHSS).

Training and awareness programmes, based on the guidelines, inform employees at all levels about risks, to create a culture where EHSS considerations are integral to the way we do business, and to help employees understand the EHSS issues specific to their jobs.

Most EHSS training is managed by the sites and is specific to job roles. EHSS professionals receive induction training and undertake regular training to ensure they are aware of the latest technical information in their fields. Business leaders also receive training so that they understand their responsibilities. In 2008 we reviewed our training programme and found opportunities to improve and standardise EHSS training across GSK in 2009. We will also include EHSS competency as part of the job grading programme for all employees with EHSS responsibilities.

Read more about [health and safety training](#).

We raise employee awareness of environment, health, safety and sustainability and provide training support materials through our intranet, regular internal publications and events.

myEHSS intranet

Our intranet is becoming the primary mechanism to communicate within the company. There are several areas of the GSK intranet that support EHSS including the main site known as myEHSS. myEHSS is the way news about EHSS programmes is shared. It is the source of supporting materials for the framework for managing EHSS such as the policy, standards and guidelines and for training materials and other documents about EHSS. myEHSS is also the basis for the information system with which we collect the data for measuring our EHSS performance and reporting results within GSK and to our external stakeholders. GSK sites use the data to manage their EHSS programmes and risks and to measure their progress.

Publications

Our EHSS publications are available electronically and in print. We publish articles on environment, health, safety and sustainability in Spirit, our internal magazine and brief news stories on internal web pages.

Events

Our sites participate in Earthweek, an annual, voluntary programme to raise awareness of strategic environmental issues and to encourage integrating environmental concerns into the culture. Held in June to coincide with the World Environment Day, Earthweek encourages employees to think about their impact on the environment. In 2008, over 13,000 employees from 48 sites in 24 countries took part in Earthweek. We sent information kits to all sites to help them develop their own activities including tree planting, clearing litter from a local forest and involving local school children in drawing competitions with an environmental theme. In 2009, operations will be encouraged to continue their voluntary environmental activities but they will no longer be organised centrally.

Awards

The CEO's EHS Excellence Award website was a vehicle for sharing the innovative EHS practices of sites or teams that won the annual awards. In 2009 this will be replaced by the website supporting the [CEO's Awards for Sustainability](#).

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› [Audits and compliance](#)

Corporate Responsibility Report 2008

Audits and compliance

Approach

Performance

We regularly audit our operations, contract manufacturers and [key suppliers](#) to assess systems to manage risks and impacts, compliance with legislation and implementation of our environment, health, safety and sustainability standards. Audits also assess whether appropriate management systems are in place to improve performance and maintain compliance. Our internal auditors are certified as lead auditors against the ISO 14001 and OHSAS 18001 standards.

All GSK manufacturing and R&D sites are audited at least once every four years. The actual frequency is determined by the level of risk and impacts and a site's performance at managing those risks. In 2008, we audited 31 sites.

In 2006, we began a four-year programme to certify all GSK pharmaceutical and consumer healthcare manufacturing sites to the international environmental standard ISO 14001 and the health and safety standard OHSAS 18001. In 2008, we certified three more sites, bringing the total to 38 per cent of our pharmaceutical and consumer healthcare manufacturing sites certified to ISO 14001.

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› **Audits & compliance performance**

Corporate Responsibility Report 2008

Audits and compliance

Approach

Performance

In 2008, we audited 31 GSK sites for implementation of our EHS standards and conducted follow up visits for 17 more. The average score was 78 per cent, the same as 2007. The lowest score we consider to be acceptable is 50 per cent. No site scored below this level with the lowest score at 62 per cent in 2008.

Two sites achieved 'leadership' scores above 90 per cent (three in 2007), while a further 11 achieved scores of at least 80 per cent (14 in 2007). High audit scores indicate good management systems and work practices. Sites that achieve audit scores of 90 per cent or higher are considered to be in a leadership category and receive certificates signed by the Chief Executive Officer. Sites that achieve 80 to 89 per cent receive certificates of achievement signed by their business heads.

There were no critical findings related to the environment. These are findings that indicate a high probability of incidents with potentially serious consequences. There were two critical findings related to health and safety. Read about our performance on [health and safety issues](#). The best performance on environmental issues was in waste and water management and sites were generally weakest on assessment of risks for environment, health and safety.

Twenty-six of our 78 Pharmaceuticals and Consumer Healthcare manufacturing sites are now certified to both the ISO 14001 and OHSAS 18001 standards (a further four are certified to ISO 14001 only). One Consumer Healthcare R&D site is certified to both standards and one GSK vaccines site and one Pharmaceuticals R&D site are certified to ISO 14001. A further five sites are confirmed for certification audits in early 2009.

The certified sites are in Argentina, Australia, Brazil, China, Egypt, France, Germany, India, Italy, Japan, Kenya, Mexico, Panama, Philippines, Poland, Saudi Arabia, Spain, Turkey, the US and the UK.

ISO certification is important because it indicates good management systems in place, and sites that have been successfully certified have found the experience beneficial. In order to achieve our 2010 target to certify all pharmaceutical and consumer healthcare manufacturing facilities, we will upgrade the level of management systems implementation. At the same time we will embark on the planned expansion of ISO certification into R&D and vaccines facilities.

Compliance

There were no environmental fines or penalties in 2008, continuing our compliance record from 2006 and 2007. However, we remain vigilant to stay in full compliance with all environmental laws and regulations.

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› **Reward and recognition**

Corporate Responsibility Report 2008

Reward and recognition

The CEO's EHS Excellence Awards recognise and reward GSK sites that show leadership in EHS and sustainability.

They highlight innovation and examples of good practice in EHSS management to share with other sites. Each winner receives a trophy and selects a charity to receive a donation from GSK

Both individuals and teams can enter the competition. A shortlist is drawn up by an internal review committee and winners are chosen by a panel that includes experts from academia, government and public interest groups.

Awards are divided into three categories:

- Green Chemistry/Green Technology – for projects that benefit environment, health and safety through new and efficient chemistry or technology
- Environmental Initiative – for programmes that demonstrate improvements in environmental management or performance
- Occupational Health & Safety Initiatives – for programmes that demonstrate improvements in health and safety management and performance

In 2008 – the seventh year of the awards – there were 89 entries from 23 countries and from all GSK businesses. Honours went to eleven projects from Australia, Belgium, India, the UK and the US.

Read about winning environmental projects throughout this section and about winning [health and safety projects](#) in Our People section.

In 2009, the awards will be upgraded to the CEO's Awards for Sustainability with new categories and new judging criteria supporting increasing focus on sustainability.

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› **Management of EHSS**

Corporate Responsibility Report 2008

Management of EHSS

Overall responsibility for environment, health, safety and sustainability issues rests with the Corporate Executive Team and the Board.

The Chief Executive Officer represents these issues on the Board. The Board Chairman is the champion for GSK's climate change programme. The Chief of Staff has operational management responsibility for EHSS on the Corporate Executive Team. The Vice President, Corporate Environment, Health, Safety and Sustainability (CEHSS) has operational responsibility for EHSS, reports directly to the Chief of Staff and has a dotted line reporting relationship to the President of Global Manufacturing and Supply.

Environment, health, safety and sustainability activities are overseen by the Risk Oversight and Compliance Council, the Corporate Executive Team and the Audit and Corporate Responsibility Committees of the Board of Directors. These committees regularly review EHSS performance, progress toward meeting EHSS targets and results of EHSS audits of GSK operations and suppliers. They consider issues such as sustainability that have social implications.

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Corporate Responsibility Report 2008

Environmental fundamentals

We have been working to reduce the fundamental environmental impacts of our operations for many years.

This involves using treatment and disposal systems to control emissions and wastes from over 80 manufacturing facilities, more than 20 research laboratories, numerous offices and warehouses and a large fleet of vehicles.

Our fundamental emissions include:

- Wastewater
- General solid and hazardous waste
- Ozone depleting substances released from our equipment and production processes and when patients use our inhaler products
- Volatile organic compounds, primarily solvents

We aim to create a culture where fundamental environmental considerations are part of everyday business decisions. While we continue to manage fundamental emissions, we are now moving towards [sustainability](#), changing our production and business processes to avoid waste at source rather than simply treating the waste and emissions that arise.

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Corporate Responsibility Report 2008

Wastewater

Approach

Performance

Most GSK sites discharge wastewater to municipal treatment facilities. Some large sites, especially the sites that manufacture active pharmaceutical ingredients (API), have their own on-site wastewater treatment systems. Some sites are permitted to discharge wastewater direct to the sea. We assess the quality of wastewater by measuring the chemical oxygen demand (COD) – the oxygen required to chemically oxidise compounds in the water. The lower the COD, the cleaner the water.

Our target from 2006 is to improve COD levels by three per cent a year per unit of sales which will give us a reduction of 12 per cent by the end of 2010. The vast majority of COD comes from manufacturing of API. Therefore wastewater from ‘domestic’ activities such as washrooms and canteens is only included when it cannot be separated from manufacturing activities.



SGS verified

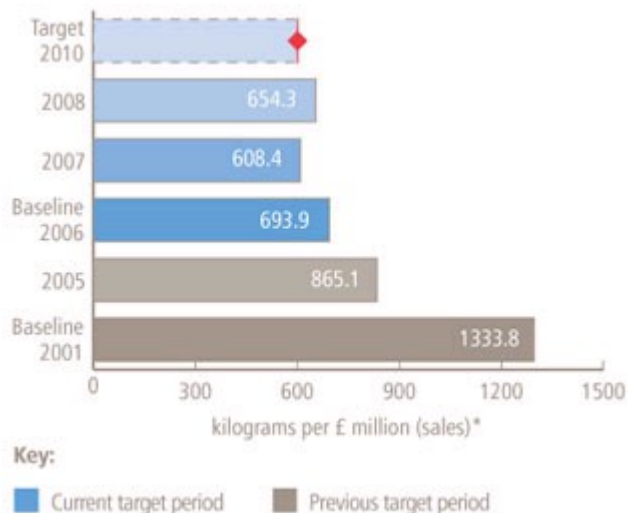
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Corporate Responsibility Report 2008

Wastewater

Approach Performance

Chemical oxygen demand of wastewater



Targets and performance normalised by sales are based on a constant exchange rate. Any errors found in data from prior years are corrected so data may vary slightly from earlier reports

In 2008 our chemical oxygen demand per million £ sales corrected to a constant exchange rate (CER) decreased 5.7 per cent from a 2006 baseline. Absolute chemical oxygen demand decreased 6.5 per cent from a 2006 baseline to 14.9 million kilograms. This decrease is in line with the target to decrease three per cent per year.

Explanation for trend

The quality of wastewater discharged is closely related to the types and amount of materials produced in the manufacture of our active pharmaceutical ingredient. Chemical oxygen demand of wastewater decreased significantly in 2007 with the decrease in production of antibiotic ingredients for that year. In 2008 production of these products increased so chemical oxygen demand increased, although it was still less than in 2006. The site that increased antibiotic production accounts for 21 per cent of the wastewater volume and 55 per cent of the wastewater COD.

We are concerned about the level of pollution in our wastewater because it can cause a burden to local municipal wastewater treatment facilities or to local receiving water bodies. The changes in levels of wastewater pollution from year to year are due to changes in production, waste minimisation and continued improvements in wastewater treatment. For example, we are evaluating wastewater treatment technologies at our pharmaceutical ingredient manufacturing plant in Singapore and we are planning a reverse osmosis system in our pharmaceutical ingredient manufacturing plant in India. In addition, our work to improve manufacturing efficiency should decrease wastewater pollution in the future.

We generated 10.8 million cubic metres of wastewater in 2008 as compared to 10.9 million cubic metres in 2007. The volume of wastewater in 2008 was 1.3 per cent lower than 2007 and 8.1 per cent lower than the 2006 baseline.



SGS verified

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Corporate Responsibility Report 2008

Hazardous and non-hazardous waste

Approach

Performance

Our production, research and sales activities all produce waste:

- Production – hazardous wastes such as solvents and other chemicals
- R&D and quality control laboratories – small amounts of chemicals including products and intermediates, as well as broken glassware and plastics
- Offices – paper and other standard commercial waste
- Building renovations produce non-routine waste such as obsolete equipment, office furniture and structural materials

We classify waste as hazardous, non-hazardous, and non-routine (for waste such as construction and demolition rubble). A significant proportion of our waste is classified as hazardous because it contains solvents and chemicals used to manufacture active pharmaceutical ingredients. Other hazardous waste we produce includes lubricants, fluorescent lights and carcasses of animals used in research. Most non-hazardous waste is general material such as office waste paper, kitchen waste and non-hazardous substances used in manufacturing.

Our approach

We aim to eliminate waste where we can, reduce it if we cannot eliminate it, reuse materials if possible, recycle other waste and dispose of any remaining material sensitively. We separate hazardous wastes into different categories for efficient and appropriate treatment. Regulations vary widely around the world, but our first choice for solvents, which account for most of our hazardous waste, is to reuse or recycle them. Some used solvent is recovered and purified on site and reused in the original manufacturing process and some is sold to commercial reprocessing companies but is still included in our recycling statistics. When reuse or recycling is not possible, solvents are mostly incinerated and the energy recovered wherever possible.

We require disposal contractors to comply with our EHS requirements and local regulations. Sites audit their waste contractors or hire consultants to carry out the audits.

Our target is to reduce non-hazardous waste disposed per unit of sales by one per cent per annum which will give us a reduction of four per cent by the end of 2010. We have not set a target for reduction of hazardous waste but our target to improve [material efficiency](#), the efficiency with which we convert raw materials to finished products, is designed to reduce hazardous waste.

The amount of non-hazardous waste disposed is affected by many factors. The amounts and types of products made in a year can affect not only the amount of waste but also the ability to recycle. In addition to production changes, some sites are actively and aggressively working to recycle as much waste as possible and decrease disposal of waste to minimum levels with focus on eliminating waste sent to landfill.

Disposal of hazardous waste is affected by the way solvents are managed and by the mix of products that are made in the year. Most hazardous waste comes from manufacture of active pharmaceutical ingredients, and this is where we concentrate our efforts. We do not collect hazardous waste data from consumer manufacturing plants, laboratories and offices. We estimate that these sites may generate an additional three per cent of hazardous waste to the amount we report.

Building trust through environmental commitment

In 2008, our manufacturing site in Boronia, Australia, stepped up its environmental efforts. CEO Andrew Witty recognised the site's achievements by awarding it first prize in the environment initiative category of his 2008 Environment, Health and Safety Excellence Awards.

Achievements include:

- Establishing a 'green team' of employee volunteers that has helped to increase involvement in sustainability activities. As a result the site has reduced water use by 20 per cent from 2007 levels, energy use by 5 per cent from 2007 levels and waste, with 34 tonnes diverted from landfill
- A 96 per cent reduction in CO₂ emissions from product transport, the result of switching from air freight to sea freight for imports of raw materials and exports of finished goods. This also saved the facility an estimated \$A2.9 million (1.3 million GBP) in 2008 and we anticipate these savings will increase to over \$A4 million (1.8 million GBP) annually from 2009 onwards
- Introduction of waste-saving measures to the cold chain distribution system, including reusable cool boxes, data loggers and ice bricks. The new cold chain system manages temperature better, even in extreme conditions. This has prevented 12,000 polystyrene cool boxes and temperature alert tags, and 50,000 disposable ice bricks from being sent to landfill. It also saves our customers the trouble of waste disposal – all they have to do is repack the equipment and we collect it from them

This project won first place in the 2008 CEO's EHS Excellence Awards, Initiative-Environment category.

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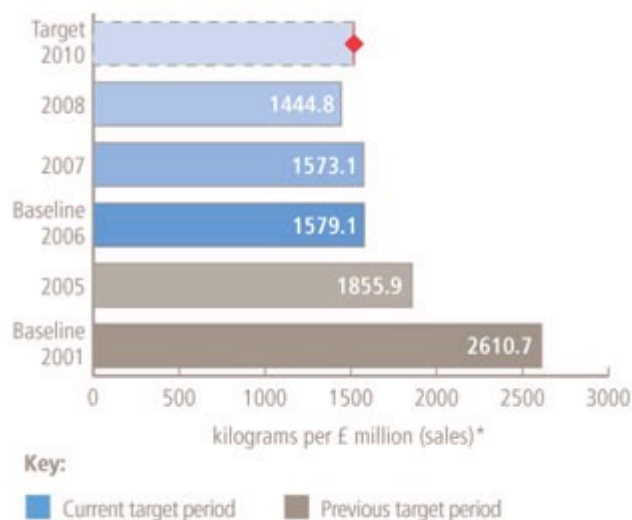
Corporate Responsibility Report 2008

Hazardous and non-hazardous waste

Approach **Performance**

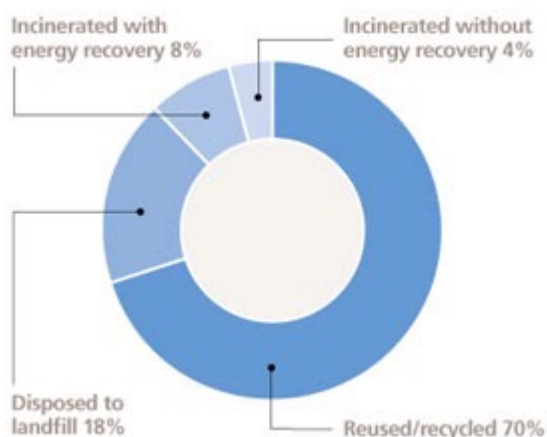
Non-hazardous waste

Non-hazardous waste disposed



Targets and performance normalised by sales are based on a constant exchange rate. Any errors found in data from prior years are corrected so data may vary slightly from earlier reports

Destination of non-hazardous waste 2008



Targets and performance normalised by sales are based on a constant exchange rate.

In 2008 the amount of non-hazardous waste disposed per million £ sales corrected to a constant exchange rate (CER) decreased 8.5 per cent from a 2006 baseline. Absolute non-hazardous waste decreased 9.2 per cent from a 2006 baseline to 32.9 million kilograms. This is significantly better than the one per cent per year improvement target.

Explanation for trend

In 2008 the decrease in non-hazardous waste disposed is at least partially due to continuing efforts to

manage and recycle waste especially in the pharmaceutical and consumer manufacturing operations. It is also due in part to decreased production of some products. This is partially balanced by increasing waste in the vaccines business as it continues to grow.

Our target is specific to non-hazardous waste disposed but we also measure total non-hazardous waste generated which includes both non-hazardous waste disposed and non-hazardous waste recycled. In 2008, we generated 109.4 million kilograms of non-hazardous waste, compared to 120.3 million kilograms in 2007 and 114.7 million kilograms in 2006. Of this, 70 per cent was recycled and 30 per cent was disposed of via landfill or incineration.

We reduced disposal of non-hazardous waste at our pharmaceutical manufacturing sites by 22.1 per cent and by 17.9 per cent at our pharmaceutical R&D sites from 2006. However there was a 72.9 per cent increase in non-hazardous waste disposal in our vaccines business due to continuing expansion. This resulted in the overall 9.2 per cent decrease in the amount of non-hazardous waste disposed in GSK compared to the 2006 baseline.

We have met our non-hazardous waste improvement target. However, to ensure that we maintain this improvement during times of production increases we will review improvement projects to make sure we continue to reduce the amount of waste we dispose. We are particularly committed to reducing the amount of waste sent to landfill because we want to minimise this burden on the environment and society as landfill space becomes harder to find and the cost of sending waste to landfill increases.

These data do not include non-routine waste such as construction and demolition rubble and similar material not related to day-to-day operations.

We continue to look for ways to reduce waste and have undertaken waste management reviews at many sites. Recycling non-hazardous waste such as paper, cardboard, glass, plastic or aluminium usually means sending it for reprocessing so it can be reused to make new products. In addition to these waste reduction measures, the reductions are likely to be due to decreases in the volume of production of certain pharmaceutical and consumer healthcare products.

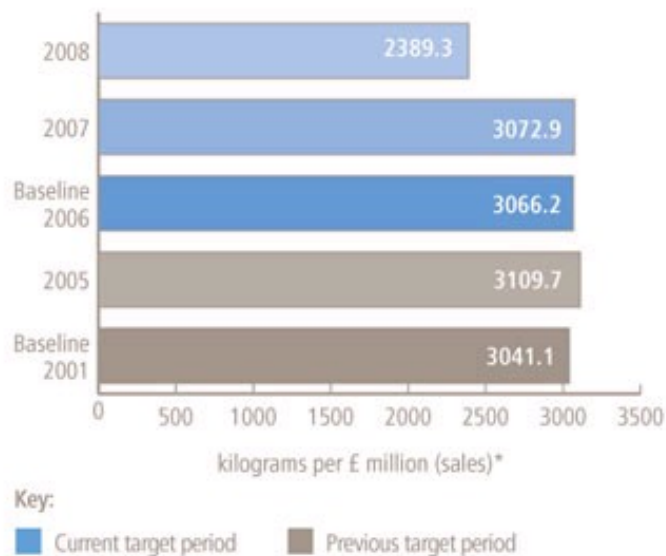
As examples of projects that have reduced non-hazardous waste disposal, two sites in India have stopped putting the coal ash they generate into landfill; instead they sell it as raw material for the production of construction material. In addition, three nutritional drink manufacturing sites send some of their process wastes, such as barley husk, for use in animal food while others recycle canteen waste or effluent treatment plant sludge by converting it into bio-compost.



SGS verified

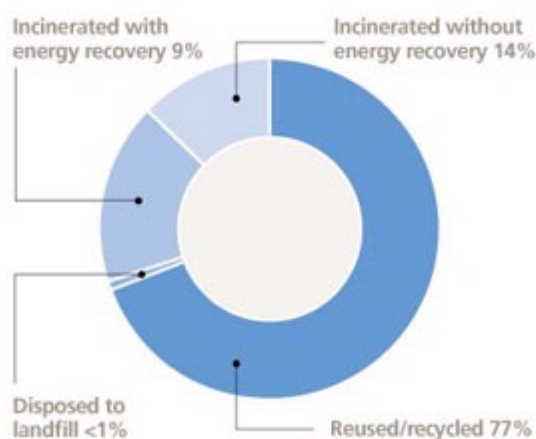
Hazardous waste

Hazardous waste disposed



Targets and performance normalised by sales are based on a constant exchange rate. Any errors found in data from prior years are corrected so data may vary slightly from earlier reports

Destination of hazardous waste 2008



Any errors found in data from prior years are corrected so data may vary slightly from earlier reports

In 2008 the amount of hazardous waste disposed per million £ sales corrected to a constant exchange rate (CER) decreased 22.1 per cent from a 2006 baseline. Absolute hazardous waste decreased 22.7 per cent from a 2006 baseline to 54.4 million kilograms.

Explanation for trend

The decrease in hazardous waste disposed from 2006 to 2008 was due to continued efforts to manage and recycle hazardous waste, especially solvents. It is also due in part to decreased production of some products that used significant quantities of solvent and to outsourcing some production.

The amount of hazardous waste disposed is related to the types and quantities of products made and the amount of solvent used by our factories that manufacture active pharmaceutical ingredients. Solvent waste is 92.4 per cent of hazardous waste generated and 98.6 per cent of hazardous waste recycled. The four largest sites that manufacture active pharmaceutical ingredients together account for over 74 per cent of the solvent waste disposed.

We did not set a target for reducing hazardous waste disposed. Instead we focused our attention on improving manufacturing efficiency because efficiency improvements will mean less material used in the manufacturing process and therefore less waste. However, efficiency improvements will take some time to achieve. In the meantime, because it is important to minimise hazardous waste, we monitor this and improve the way we handle it, for example by recycling solvents.



SGS verified

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› [Contaminated land](#)

Corporate Responsibility Report 2008

Contaminated land

Handling practices for some chemicals, used by industries in the past and now no longer followed, caused contamination to land and groundwater.

Land can also become contaminated due to accidental release of materials.

We are involved in a number of projects in the UK and the US to remediate sites with contaminated land.

We have identified five sites in the UK that require some remediation and more than 50 sites in the US. We work with governments and other parties to effect any necessary remediation. Costs of remediation are shared between the parties involved.

The five UK sites are undergoing remediation and two are being partially or fully decommissioned. GSK and its heritage companies have spent more than £100 million cleaning up more than 50 sites in the US over the last 20 years. We are continuing to clean up 25 of these sites. Most of them are waste disposal sites where GSK is one of several responsible parties. These figures are not included in the data verification.

Explanation for trend

When the heritage companies that formed GSK were confronted with a number of contaminated land sites we undertook actions to avoid similar problems occurring in the future. The first action was to audit commercial hazardous waste treatment and disposal sites for their level of performance and financial solvency to avoid inappropriate disposal. The second action was to minimise solvent use wherever possible as we did by changing from solvent coating to aqueous coating of tablets. The third action was to initiate a project to improve material efficiency and to minimise or eliminate hazardous (persistent, bioaccumulative and toxic) compounds.

We have also reviewed production operations to determine if past practices have contaminated soil or ground water. Where problems were discovered we initiated site remediation.

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Corporate Responsibility Report 2008

Emissions to air

Approach

Performance & plans

Ozone depletion

The ozone layer in the upper atmosphere is essential to human survival because it filters out harmful ultra-violet rays from the sun. It has been damaged by ozone depleting substances (ODSs), mainly chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs) and halons.

The loss of ozone in the upper atmosphere means that more ultraviolet-B radiation reaches the earth's surface. This can affect health, for example by causing skin cancer, skin ageing, eye disorders and suppression of the immune system.

Industrial use of ODSs was common before their negative effects were realised. In the past, we used CFCs as the propellant gas in most of our metered dose inhalers (MDIs). These deliver a precise dose of medication to treat asthma sufferers and people with chronic obstructive pulmonary disease. The gas is released when patients use the inhalers and a small amount escapes during production.

The [Montreal Protocol](#) bans the production of CFCs, but it exempts a number of 'essential uses' which include MDIs. However, in support of its principles we plan to eliminate the use of CFCs from our products by the end of 2010. Less than two per cent of our inhalers now contain CFCs.

We have stopped using CFCs as propellants in inhalers made in the US and the European Union. We offer a selection of alternatives in most other countries and will eliminate all CFCs from our products worldwide by the end of 2010.

The main alternative propellant used is HFA 134a, a hydrofluoroalkane. This does not affect the ozone layer but does have global warming potential, although significantly lower than CFC, contributing to [climate change](#). We have also invested heavily in dry powder delivery systems that do not use propellants such as CFCs or HFA 134a. These are not suitable for all patients, particularly children and the elderly, as they do not contain propellants and rely on a person's lung power for the active ingredients to be administered.

Equipment and production

We also use ODSs in some cooling systems and for other ancillary uses at GSK facilities. These are contained inside the systems and are only released in the event of a leak or during maintenance. We have switched to using hydrofluorocarbons (HFCs), ammonia and hydrocarbons. Ammonia does not contribute to either ozone depletion or climate change and hydrocarbons have a small climate change impact.

We aim to eliminate CFCs and HCFCs from cooling systems. This is the only way to completely eliminate emissions from equipment. We are focusing on removing larger pieces of equipment from service before the end of 2010.

We do not intend to replace equipment containing less than one kilogram of CFCs or HCFCs prior to their planned replacement. This type of equipment tends to be hermetically sealed and is less likely to leak.

Volatile organic compounds

Volatile organic compounds (VOCs) react with nitrogen oxides in the presence of sunlight, creating ozone in the lower atmosphere. This results in smog which is a factor in human respiratory illness. Workplace exposure to certain VOCs can also pose a health risk.

We emit VOCs to the atmosphere mainly from solvents used in our primary manufacturing operations and R&D pilot plants. Solvents are also used to coat some tablets and in cleaning for sterile operations. We use small quantities of solvents in laboratories but do not measure emissions from this use. Our target is to reduce volatile organic compound emissions to air by two per cent per year per unit of sales which will give us a reduction of 8 per cent by the end of 2010.



Corporate Responsibility Report 2008

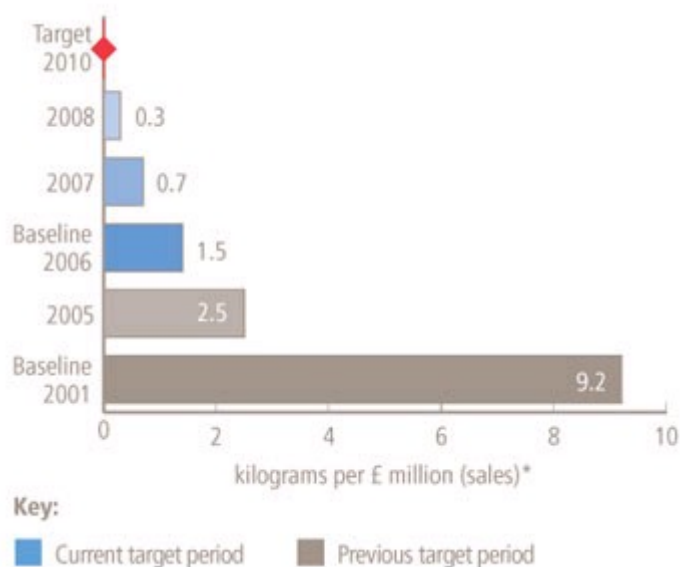
Emissions to air

Approach

Performance & plans

Ozone depletion

Ozone depletion potential (CFC-11 equivalents)



Targets and performance normalised by sales are based on a constant exchange rate
 Any errors found in data from prior years are corrected so data may vary slightly from earlier reports
 CFC-11 has an ozone depletion potential of 1

In 2008 we reviewed the refrigeration equipment inventories for 2006, 2007 and 2008. Where inventories were incomplete they were estimated based on inventories in other years. We also updated the factors for ozone depletion potential and climate change emissions using WMO (World Meteorological Organisation), Scientific Assessment of Ozone Depletion: 2006, Global Ozone Research and Monitoring Project—Report No. 50, 572 pp., Geneva, Switzerland, 2007. (chapter 8).

In 2008, estimated ozone depletion potential (ODP) from equipment and production losses per million £ sales corrected to a constant exchange rate (CER) decreased 82.3 per cent from a 2006 baseline. Absolute ODP from equipment and production losses decreased 82.4 per cent to 5.8 thousand kilograms. This indicates significant progress towards our target to eliminate losses of CFCs and HCFCs from production and equipment.

Explanation for trend

In 2008, 5.4 thousand kilograms of ozone depleting substance were released during production of inhalers and we estimate that less than one thousand kilograms of CFC-11 equivalent were emitted from equipment.

In 2008, 87.7 thousand kilograms of CFC propellant were released when patients used our products. Ozone depletion potential from patient use of metered dose inhalers was 51.9 per cent lower than in 2006. As production of CFC-containing MDIs decreases, the amount of CFC lost during production also declines

We maintain a register of the significant pieces of equipment that contain refrigerants and use this register to track progress towards the target to eliminate CFCs and HCFCs from refrigeration equipment. We have 162 pieces of equipment containing CFCs, amounting to 10,238 kilograms in total. Over 6,774 items of

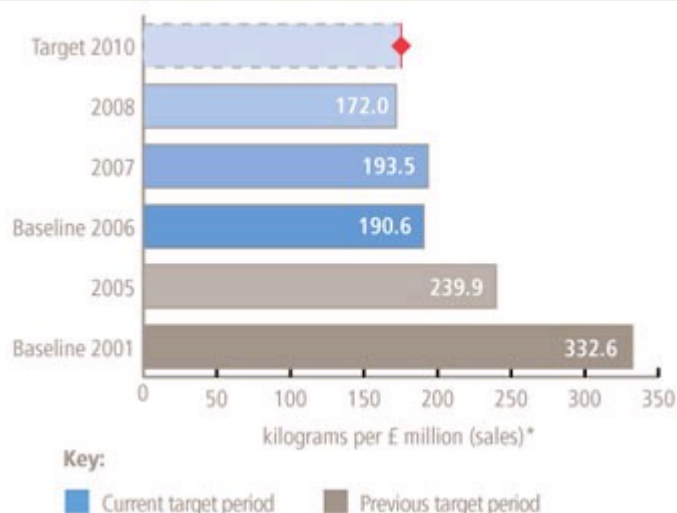
equipment contain other ODSs, with an ODP of 16,468 kilograms of CFC-11 equivalent. We estimate (using an estimation factor of 2.75 per cent from the British Refrigeration Association) that 468 kilograms CFC-11 equivalent were released from equipment in 2008. We are making progress towards our target and expect that we will achieve it.



SGS verified

Volatile organic compounds

Volatile organic compound emissions



Targets and performance normalised by sales are based on a constant exchange rate
 Any errors found in data from prior years are corrected so data may vary slightly from earlier reports

In 2008 the amount of volatile organic compound released to air per million £ sales corrected to a constant exchange rate (CER) decreased 9.7 per cent from a 2006 baseline. Absolute volatile organic compound emissions decreased 10.4 per cent from a 2006 baseline to 3.9 million kilograms. This is better than our two per cent per year target.

Explanation for trend

Emissions of VOC to air are affected by the management of solvents and by the mix of products that are made in the year. In 2008 we decreased production of several products that used significant quantities of solvent and we outsourced several steps of one product.

It is important to reduce emissions of VOC because it benefits the environment, society and GSK. We want to reduce these emissions even in high production years so we continue to identify projects to reduce emissions. In 2008 one site installed a carbon absorption unit to reduce emission of solvents and two more sites have emission reduction projects planned for 2009. We anticipate achieving our target.

Our plans

Our material efficiency projects are expected to reduce the amount of solvent used and we should see the effects of this work in reduced solvent emissions in the future. In the meantime we continue to look for ways to reduce solvent use and increase recycling to achieve our target of a two per cent annual reduction in emissions resulting in eight per cent improvement by the end of 2010. Two of our sites that manufacture active pharmaceutical ingredients have projects planned for 2009 to control emissions.



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› [EHSS in business processes](#)

Corporate Responsibility Report 2008

EHSS in business processes

Here we describe how we are embedding environment, health, safety and sustainability (EHSS) principles into our business processes.

New product development and supply

Our EHSS Milestone Aligned Process helps scientists identify and address environment, health, safety and sustainability issues during new product development and supply activities. It ensures that:

- Scientists understand environment, health, safety and sustainability impacts and how they should be managed throughout a product's life-cycle
- New products and processes are developed that do not harm people, property or the environment
- Opportunities are identified, such as process efficiencies and elimination of waste that reduce environment, health, safety and sustainability impacts and improve product development and supply

Acquisitions and divestitures

Our due diligence process for acquiring and divesting businesses ensures that environment, health, safety and sustainability issues are considered in contract negotiations and that adequate management systems are in place. We work with acquired companies to develop action plans to align their EHSS practices with GSK's.

Emergency response and crisis management

The discovery, development and manufacture of pharmaceutical and consumer products involve the use of hazardous materials and processes. All sites incorporate emergency response and crisis management programmes into their management plans. These programmes ensure that accidents are effectively managed when they occur and that any impact on our business, the local community and the environment are minimised. Each site conducts an annual review of its internal emergency response programmes and technical capabilities and develops action plans to address any areas needing improvement.

Procurement

Our procurement activities support our environment, health, safety and sustainability (EHSS) goals in the following areas:

- Sourcing renewable and recycled materials where appropriate
- Choosing safe and energy-efficient equipment
- Managing EHSS risks in our supply chain

Our capital project technical review process ensures that we consider environment, health, safety, security and loss prevention in the design of new facilities and processes. By identifying EHSS issues early in a project, we can engineer facilities and processes that are efficient and safe for workers and the environment while still being cost effective.

Read more about [EHS and procurement](#).

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Supplier performance

We want to understand the total environmental footprint of the processes used to make our products.

This means measuring the impacts of our suppliers of active pharmaceutical ingredients and packaged products, as well as those from our own operations. Some of our improvements in hazardous waste and air emissions were due to outsourcing of some production processes. Until we can collect data from our suppliers we will not know the full impact of production of our products. In the future we hope to report on the combined environmental impacts of manufacturing at GSK facilities and at our contract manufacturers.

GSK selects suppliers with an appropriate level of EHS management systems control. However, over the past few years it has proved difficult to obtain environment, health and safety performance data from these suppliers just for the products that they manufacture for GSK. In 2007 we surveyed 52 suppliers and received a response from 21 (40 per cent). They indicated that they preferred providing data after the first quarter of the year to give them time to review it. With this input from our suppliers we changed our process. For energy data we will join the Carbon Disclosure Project (CDP) supplier initiative and request energy and climate change data from our large suppliers through the CDP. We will collect 2008 water, waste and injury and illness data from suppliers during the second quarter of 2009 using our electronic system. We published the 2007 data in our 2007 corporate responsibility report and will publish 2008 data in the 2009 report.

Read more about GSK's [supply chain](#).

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Corporate Responsibility Report 2008

Sustainability

Traditional environmental programmes focus on managing wastes after they are generated by business processes.

Sustainable practices change the business processes themselves to consume less natural resource, switch to renewable materials, protect biodiversity, generate less waste, eliminate waste that is persistent, toxic or bioaccumulative and lower costs. This approach benefits the environment, society, GSK and future generations.

Our high priority sustainability issues are:

- Manufacturing efficiency – reducing the amount of raw materials needed to produce a finished product
- Climate change – reducing the climate impacts of our buildings, equipment, transport and products
- Water – reducing the amount of water we use
- Product stewardship – reducing the use of materials of concern and the environmental impacts of our products after use by the patient
- Packaging – reducing the amount of packaging we use and using recyclable and recycled materials

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Corporate Responsibility Report 2008

Materials efficiency

Approach

Performance

We aim to increase the efficiency with which we convert raw materials to finished products. Known as materials efficiency, this helps reduce the resources we use, the waste we generate and the cost of production.

Pharmaceutical processes are often complex, usually requiring large amounts of solvents and other raw materials. Typically, the industry uses more than 100 tonnes of material for every tonne of active pharmaceutical ingredient (API) produced. We have set a target to double the average materials efficiency of manufacturing processes for new products introduced between 2006 and 2010.

Process design

Process design is essential to minimising environmental impacts. It determines which chemicals and processes are used in manufacturing as well as the impacts from production waste. The EHS team works with process development teams to incorporate EHS considerations into process design and materials sourcing, and to identify potential EHS risks in manufacturing.

New manufacturing technique cuts energy and waste

Our R&D facility in North Carolina has developed a novel way to manufacture a diabetes drug, currently in phase II clinical trials, cutting environmental impacts and costs. This replaces a production method that was too resource-intensive to use on a large scale.

The chemical development department found a way to synthesise the molecule more efficiently and then produce it at a yield 37 per cent greater than before. The new process uses fewer raw materials, less than half the energy and 81 per cent less solvent. It also produces around 30 per cent less wastewater.

The new process will save over £110 million each year in raw material and waste disposal costs.

This project won first place in the 2008 CEO's EHS Excellence Awards, Green Chemistry and Technology category

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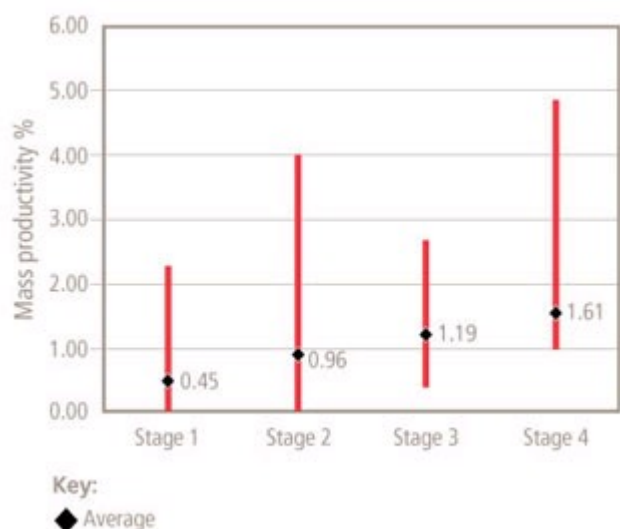
Corporate Responsibility Report 2008

Materials efficiency

Approach

Performance

Mass productivity



The chart shows how we improve materials efficiency as compounds move through development stages. In the early stages almost all compounds are less than one per cent materials efficient. By the last stage most achieve more than two per cent and some are above three per cent, with one process achieving productivity of 4.9 per cent.

Explanation for trend

Improving manufacturing efficiency is one of the most important ways we can address sustainability and meet some of our fundamental environmental targets such as reducing our disposal of waste and emissions to air. This will not be easy because the chemical processes that make our medicines can be complex. In spite of the difficulties, we remain committed to improving efficiency for new products. In 2009 we will review the production processes that are transferred to manufacturing to determine if additional improvements are possible so that we can achieve our target.

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Corporate Responsibility Report 2008

Climate change and energy

Approach

Performance & plans

It is widely acknowledged that human activity, primarily burning fossil fuels to produce energy, is contributing to climate change.

The Intergovernmental Panel on Climate Change (IPCC), the world's leading climate authority, has stated that urgent action is needed to avoid the effects of dangerous climate change, including more frequent extreme weather events such as droughts, floods and hurricanes.

We want to be part of the solution to climate change and are committed to reducing our impact. As well as benefiting the environment, taking action on climate change helps us cut costs, improves our reputation with stakeholders and helps us prepare for future legislation on emissions.

[Read about our energy and climate change position](#)

Our climate change programme

In 2007, following the fourth assessment report of the Intergovernmental Panel on Climate Change, we launched a new climate change programme and committed to new targets.

This includes a commitment to reducing our climate change impact (CO₂ equivalent emissions) and energy use in operations and transport from 2006 levels by 20 per cent per unit of sales (based on a constant exchange rate) by 2010 and by 45 per cent by 2015.

This replaced our 2006 target to reduce energy use by one per cent per year, normalised by sales.

We will achieve our new targets by:

- Making our buildings and equipment more energy efficient
- Installing onsite renewable technologies such as wind turbines and photovoltaic panels
- Buying electricity produced from renewable sources
- Reducing the climate impact of travel and transport by switching from air to sea freight and by transporting more per load to reduce the number of journeys needed

The Corporate Executive Team has approved a central fund to help finance these energy saving projects. The Climate Change and Energy Reduction team consulted with GSK businesses to identify potential energy saving projects. In 2008, 171 projects were completed which are expected to result in a saving of more than 153,000 Kwh (550,800 GJ) of energy per year and more than 40 thousand tonnes of climate change emissions.

Product climate impact

We are also researching ways to minimise the amount of greenhouse gases released when our propellant inhaler products are used by patients for asthma and chronic obstructive pulmonary disease. These account for two-thirds of our climate impact. Propellant inhalers contain either hydrofluoroalkanes (HFAs) or chlorofluorocarbons (CFCs) which ensure a consistent dose but HFAs are 1,400 times more damaging to the climate than CO₂ and some CFCs are more than 10,000 times more damaging to the climate than CO₂. CFCs also [deplete the ozone layer](#).



SGS assurance logo

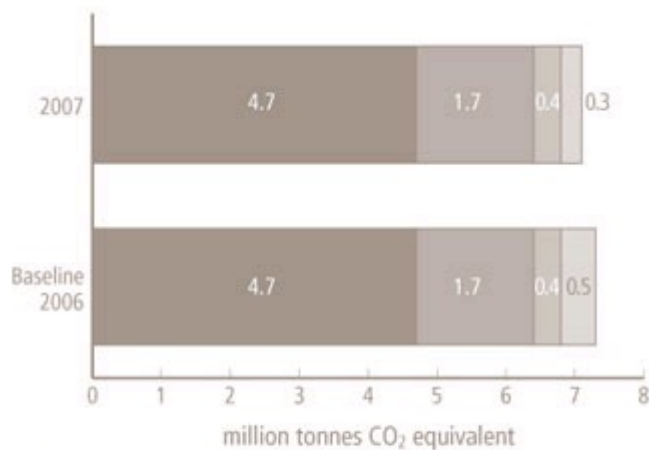
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Climate change and energy

- Approach
- Performance & plans

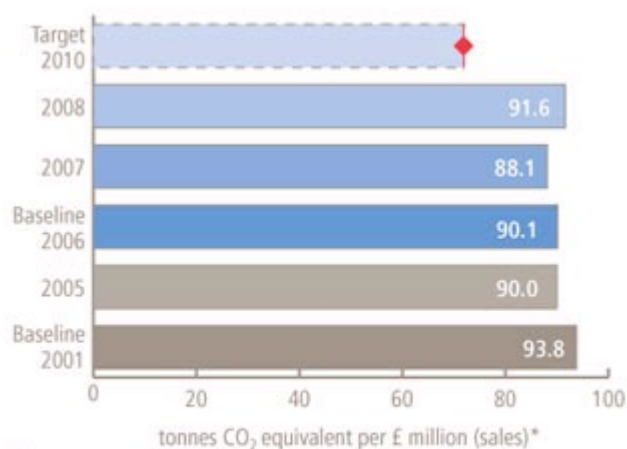
GSK's carbon footprint



- Key:**
- Climate impact from use of inhalers by patient
 - Climate impact from operations energy
 - Climate impact from travel and transport
 - Climate impact from other³

Other includes climate change impact from greenhouse gases released from cooling systems, during the production of inhaler products, from wastewater treatment and other processes. Any errors found in data from prior years are corrected so data may vary slightly from earlier reports

Climate change impact from operations energy and transport



- Key:**
- Current target period
 - Previous target period

Targets and performance normalised by sales are based on a constant exchange rate

Any errors found in data from prior years are corrected so data may vary slightly from earlier reports. We use the Greenhouse Gas Protocol for all of our calculations of CO₂ emissions from energy use. We also updated the factors for climate change emissions from propellants and refrigerants using WMO (World Meteorological Organisation), Scientific Assessment of Ozone Depletion: 2006, Global Ozone Research and Monitoring Project—Report No. 50, 572 pp., Geneva, Switzerland, 2007. (chapter 8)

In 2008, our carbon footprint was equivalent to 7.0 million tonnes of CO₂ compared to 7.3 million tonnes in 2006. The majority of our emissions come from the use of inhalers by patients with respiratory disease. A decrease in the use of CFC inhalers with a simultaneous increase in the use of HFA inhalers meant that our climate change emissions from patient use of inhalers did not change significantly from 2006 to 2008, remaining at 4.7 million metric tonnes of CO₂.

If we exclude the use of inhalers, our carbon footprint reduced from 2.6 million tonnes of CO₂ in 2006 to 2.4 million tonnes in 2008, reflecting emissions of greenhouse gas from inhaler manufacturing which decreased from 0.5 million tonnes in 2006 to 0.3 million tonnes in 2008.

Explanation for trend

We recognise that our products have more of a climate change impact than our energy consumption so our R&D scientists are working to develop alternatives to HFA as a propellant for all candidate inhaled products.

Emissions from operations energy and transport

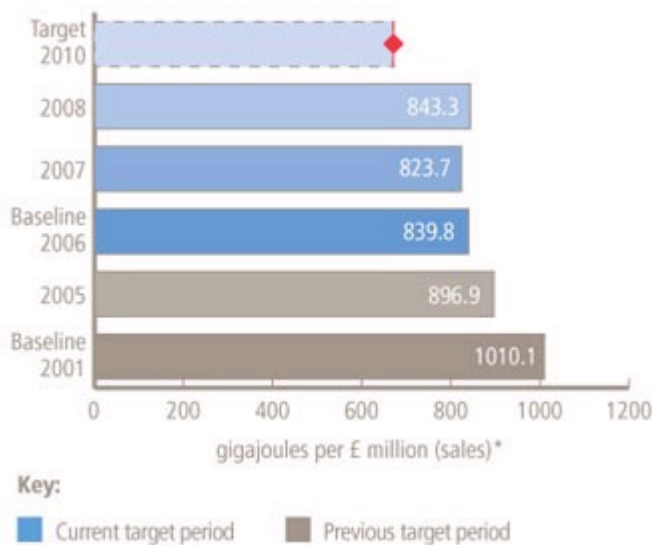
Our CO₂ emissions from operations energy and transport per million £ sales corrected to a constant exchange rate increased 1.6 per cent from a 2006 baseline. Absolute climate change emissions increased less than 1 per cent from a 2006 baseline to 2.1 million tonnes. This was due to increased energy use in the growing vaccines business which overshadowed the energy savings in our pharmaceutical and consumer manufacturing operations, and to an increase in the use of coal in India.

Our energy use from operations and transport on which these CO₂ emissions are based, decreased less than one per cent from 2006 to 2008 to 24.3 million gigajoules.



Energy performance

Energy consumption (facilities and processes)



Targets and performance normalised by sales are based on a constant exchange rate. Any errors found in data from prior years are corrected so data may vary slightly from earlier reports.

Seventy-nine per cent of our energy use is attributed to energy for operations (facilities and processes). In 2008 our energy use per million £ sales corrected to a constant exchange rate (CER) increased less than one per cent from a 2006 baseline. Absolute energy use decreased less than one per cent from a 2006 baseline to 19.2 million gigajoules. This is equivalent to the energy used by over 200,000 UK households.

Explanation for trend

We set aggressive targets to reduce energy use and related climate change emissions and are moving towards these although progress is slower than expected. If we continue on the present course we expect to achieve an improvement of eight per cent per unit sales by 2010. We have taken steps to accelerate the implementation of energy reduction projects such as diverting more engineering resources to support them. We also expect projects initiated in 2008 will begin to deliver energy and carbon savings in 2009 that will then be sustained. In addition, business changes such as site closures resulting in more efficient use of existing facilities may help us achieve the target. We therefore remain committed to the 2015 target of a 45 per cent improvement.

Energy use decreased more than four per cent in the pharmaceutical and consumer manufacturing organisation and the pharmaceutical R&D organisation. However it increased more than 30 per cent in the vaccines organisation due to continuing growth with additional and enlarged buildings and new products. Our pharmaceutical and consumer manufacturing, our vaccines manufacturing and research group and our pharmaceuticals R&D group accounted for 54 per cent, 15 per cent, and 25 per cent of energy use respectively.

Between 2001 and 2006 our energy efficiency programme achieved incremental gains in energy efficiency by focusing on operational changes. These included optimisation of equipment use, resetting thermostats and changing to energy efficient lighting. Since 2006, some parts of our business continued to make incremental gains in energy efficiency but growth in our vaccines business and the associated increases in energy use partially offset these efficiency gains.

In mid-2007 we revised our climate change programme to include more challenging targets covering energy for operations (facilities and processes) and transport of products and employees. A fund was set up to encourage energy projects. More than 400 potential projects were identified for support from this fund in 2007 and in 2008 171 projects were completed with more than £15 million spent. These projects are expected to save 153 million kilowatt hours of energy and 40 thousand metric tonnes of climate change emissions. The majority of projects were completed towards the end of 2008 so the full benefit of these projects will not be realised until 2009. We are currently working on a further 157 projects and a significant proportion of these will be completed during 2009. Around 75 projects that were identified for support in 2007 and 2008 were abandoned following more detailed investigations to determine their business benefit.

Our plans

In 2008 GSK identified more than 600 potential projects for support from our climate change fund and our pharmaceutical and consumer healthcare manufacturing business has created a Centre of Excellence to support the implementation of these projects during 2009. In particular, emphasis will be given to implementing combined heat and power (CHP) projects.

CHP is the simultaneous generation of usable heat and power, usually electricity, in a single process. Typically CHP uses a gas turbine, an engine or a steam turbine to drive an alternator to produce electricity. The heat produced is recovered, usually in a heat recovery boiler, to provide steam, hot water or even cooling with the right equipment. Because CHP systems use the heat produced during the electricity generation process, they can achieve overall efficiencies in excess of 70 per cent at the point of use. Conventional power plants have efficiencies of less than 50 per cent because the excess heat which they generate is normally wasted and additional losses occur during transmission and distribution.

Another key area of focus will be to identify energy saving opportunities associated with heating, ventilation and cooling (HVAC). This equipment is needed to maintain the correct environmental conditions within our production areas so we can manufacture our products. However, it is responsible for more than 50 per cent of the operational energy that we consume.

Energy reduction has also been identified as a key objective for this business and in 2009 the remuneration of senior managers will be linked to the achievement of energy reduction targets. Energy consumption has also been identified as a key business metric that will be tracked throughout 2009 by the Corporate Executive Team.

Using canal water for sustainable cooling

In December 2008, GSK unveiled an energy-saving scheme in partnership with British Waterways, the organisation in charge of the UK's canal network. Under the initiative, GSK House in Brentford will use water from a nearby canal, rather than more energy-intensive air conditioning, to cool its computer data centres.

This will reduce carbon dioxide emissions by around 920 tonnes per year. It will also lower energy bills by £100,000 annually, recovering the costs of the project within five years.

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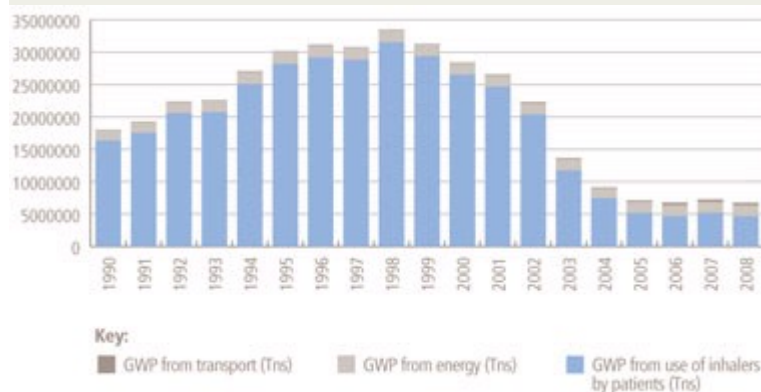
Corporate Responsibility Report 2008

Climate change emissions since 1990

For GSK, climate change emissions from inhaler products are significantly greater than the climate change emissions from operational energy and transport. Our climate change emissions increased 86 per cent from 1990 to 1998 as sales of inhalers with chlorofluorocarbon (CFC) propellants increased. Phase out of CFC propellants began as a result of the Montreal Protocol which aimed to eliminate ozone depleting compounds (CFCs have an impact on both ozone depletion and climate change). As these were replaced with inhalers using hydrofluoroalkane (HFA) propellants or with dry powder inhalers that do not use propellants, climate change emissions improved dramatically because HFAs have much lower climate change impact than CFCs. Currently with 98 per cent of inhalers either using HFA propellants or being dry power propellant-free inhalers, climate change emissions are 64 per cent lower than 1990 levels. These emissions are expected to grow in the coming years as sales of inhalers with HFA propellants continue to grow.

The emissions from inhalers and energy back to 1990 were estimated based on energy and CFC data in public reports back to 1993 for heritage SmithKline Beecham and to 1996 for heritage GlaxoWellcome. Where actual data for inhalers and energy were not available, sales data were used with factors applied to estimate climate change emissions. Climate change emission factors for CFC and HFC have been revised over the years and we used the current factors from the World Meteorological Organisation published in 2007.

Global warming potential from energy, transport and inhaler use



<http://www.epa.gov/ozone/science/ods/classone.html>

WMO (World Meteorological Organisation), Scientific Assessment of Ozone Depletion: 2006, Global Ozone Research and Monitoring Project—Report No. 50, 572 pp., Geneva, Switzerland, 2007. (chapter 8)

Explanation for trend

When the Montreal protocol called for the elimination of CFCs because of their effect on the ozone layer we invested over £1 billion to develop alternatives including devices that use HFA as a replacement propellant. HFA has no ozone depleting potential and it has a lower effect on climate change than CFC. Therefore, as CFC propellants were phased out and HFA phased in, there was a significant decline in the climate change impact from products. We estimated our climate change emissions back to 1990, and calculated an improvement of over 60 per cent by 2008. This compares to the 12.5 per cent reduction that the Kyoto protocol requires for the UK from 1990 to 2012. The Kyoto protocol does not include climate change emissions for CFC but it does include HFA.

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Emissions trading

A number of our UK sites participate in the UK government's voluntary Climate Change Agreement programme which provides companies with energy tax rebates if they meet agreed energy-efficiency targets. In 2008 GSK reported its compliance with these agreements and all participating GSK sites were found to comply with their Climate Change Agreements.

Several GSK sites participated in the European Union Emissions Trading Scheme (EU ETS). Collectively these sites emitted below their specified CO₂ allowances, generating a surplus of carbon credits. Proceeds from the sale of carbon credits are invested in energy-saving projects.

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Transport impact

In 2008, we estimate that transport of our products and employees accounted for 361 million kilograms of CO₂, compared to 363 million kilograms in 2007. This was equivalent to about 17 per cent of our climate change impact from energy.

Our travel-related CO₂ emissions consisted of:

- Business air travel (34 per cent)
- Global sales fleet (32 per cent)
- Transport of products from manufacturing plants to distributors (34 per cent), most of which was by air freight (82 per cent).

Our options for reducing the impact of transporting products include:

- Consolidating freight shipments
- Reducing the number of shipping points
- Making more use of round tripping (managing inbound freight trucks so they do not return empty)
- Switching from air to sea transport where possible

Travelling to work

We have 'green travel plans' at a number of sites to encourage employees to reduce the environmental impact of their travel to work. For example, at GSK House in Brentford, UK, reserved parking spaces are given to car-sharers and drivers of fuel-efficient cars. We provide changing rooms and showers for cyclists, as well as discounts for bicycle equipment and repairs. At our Philadelphia office the cost of public transportation is subsidised.

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Corporate Responsibility Report 2008

Water use

Approach

Performance & plans

Clean water is a valuable resource that needs to be conserved and protected from pollution. We aim to minimise the amount of water we use and the [environmental impact of the water that we discharge](#).

GSK uses water in manufacturing (for processes, products, cooling and cleaning) and for general site uses, including drinking, food services and sanitation. Sites that manufacture active pharmaceutical ingredients use large amounts of water, while R&D sites and offices use less.

Our water standard requires sites to minimise water use, reuse water whenever feasible and ensure that all wastewater is treated and discharged in a way that minimises adverse environmental impacts. Our target is to reduce water consumption by two per cent per annum per unit of sales which will give us an eight per cent water saving by the end of 2010.



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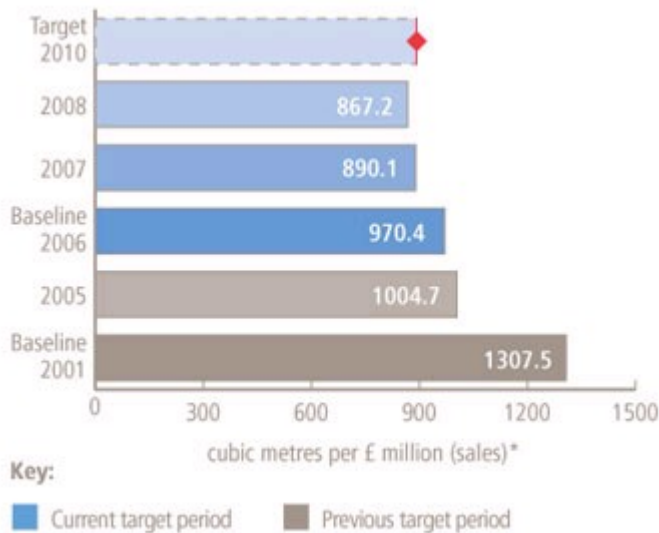
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Water use

- Approach
- Performance & plans

Water consumption



Targets and performance normalised by sales are based on a constant exchange rate. Any errors found in data from prior years are corrected so data may vary slightly from earlier reports.

In 2008 the amount of water used per million £ sales corrected to a constant exchange rate (CER) decreased 10.6 per cent from a 2006 baseline. Absolute water use decreased 11.4 per cent from a 2006 baseline to 19.7 million cubic metres. This is significantly better than the two per cent per year target.

Explanation for trend

Most of this reduction was achieved through maintenance at facilities and process changes. Smaller improvements were achieved through ongoing conservation measures, particularly at water-stressed locations. For example, our pharmaceutical manufacturing plant in Boronia, Australia, located in a water-stressed area, has an ongoing campaign to save water. Since 2001 they have reduced water usage by 33 per cent while increasing production by 22 per cent and staff by 30 per cent, saving an average of 29 million litres of water a year. These water savings are accomplished by recovering wastewater and using it in cooling towers, amenities and maintenance, by capturing storm water and by communicating with employees about saving water. We believe we will achieve our target.

Our plans

GSK has endorsed the UN Global Compact's CEO Water Mandate.

The UN estimates that more than 1 billion people do not have access to clean water and 2.6 billion people lack the basic sanitation necessary for health and well-being. Water stress is expected to worsen in many parts of the world as a result of factors including urbanization and population growth, increasing food production, changing consumption patterns, industrialization, water pollution, and climate change.

We joined the mandate because we recognise that water is an important and valuable resource that needs to be managed responsibly and we are committed to taking action by developing a comprehensive approach in the six areas identified in the mandate: Direct Operations; Supply Chain and Watershed Management;

Collective Action; Public Policy; Community Engagement; and Transparency.

In many of these areas we have already taken some action. For example we have targets for water conservation and we reported water usage from our own operations. We have plans in place to collect and report water usage from a sample of key suppliers. We work with local communities to conserve water and preserve wetlands and we educate our employees in water conservation. We understand the connection between water and public health and have a philanthropic project known as [PHASE](#) to educate people in developing countries about the importance of hand washing. To meet the requirements of the Mandate we will build on these and other existing efforts and manage them under a single programme. During 2009 a Team with representatives from across the business will be formed to determine key priorities and objectives.



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Corporate Responsibility Report 2008

Product stewardship

We take the environment into account across the entire lifecycle of our products.

This begins with [process design](#) and continues through manufacturing to [use by patients](#) and [eventual disposal](#). Some of our wastes such as used solvents can be reused as a raw material for another industry such as paint stripping (cradle to cradle).

In this section we focus on several aspects of product stewardship:

Pharmaceuticals in the environment

Some portion of active pharmaceutical ingredients, the substances that make medicines work, may eventually be excreted by humans and enter the environment. We conduct tests and risk assessments to evaluate the potential effects of our [pharmaceutical products on the environment](#).

Materials of concern

[Materials of concern](#) are chemicals where scientific evidence shows probable serious long-term effects to humans or the environment and for which there is existing or potential future legislation that may restrict use. Our process development teams develop strategies to eliminate or substitute the use of these materials.

Genetically modified organisms

We use [genetically modified organisms](#) (GMOs) in the research and development of new therapeutic agents and in the manufacture of certain medical products such as vaccines. All our work with GMOs is controlled to the strictest national and international regulations, and we apply best practice across all our facilities.

REACH

In 2008, we continued to work to reduce risks to continuity of supply of chemicals presented by the introduction of the [EU's Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) legislation](#).

Global harmonisation

We [continue to prepare](#) for impending changes to classification and labelling of hazards as part of the UN's Globally Harmonised System for Classification and Labelling of Chemicals regulation.

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Corporate Responsibility Report 2008

Pharmaceuticals in the environment

Some portion of active pharmaceutical ingredients (APIs), the substances that make medicines work, may eventually be excreted by humans and enter the environment. Wastewater treatment removes most pharmaceutical residues but small concentrations do end up in rivers or in the sea and very low concentrations of some pharmaceuticals are occasionally found in drinking water. In countries where wastewater is not treated, higher concentrations may enter the environment.

We conduct tests and risk assessments to evaluate the potential effects of our pharmaceutical products on the environment. To date these indicate that our products do not appear to pose a risk for humans or the environment based on current risk assessment methodologies and information.

We conduct retrospective analysis of environmental data to refine our testing methodology and assessment models. We recently revised our material testing strategies to include chronic testing (to determine the impact of our products on the environment over the long term) and mode of action analysis (to identify the most sensitive species), to meet new regulatory guidelines and to improve our understanding of possible environmental effects.

We are committed to transparency about the data we collect and make environmental data publicly available. Assessments and environmental data for individual APIs are provided online in [Safety Data Sheets](#). Data are also available on the Swedish Doctors Prescribing Guide (see below).

We make information about pharmaceuticals in the environment available to the public by publishing the results of our risk assessments in scientific journals. Read our [public position statement about pharmaceuticals in the environment](#).

In the EU and US, environmental risk assessments are part of the approval process for producing and marketing new medicines. They allow regulatory agencies to assess the potential for environmental impacts of drugs pending approval. We work with regulatory agencies to ensure that the potential environmental impacts of our pharmaceuticals are understood and minimised.

We continue to monitor the latest scientific studies and findings to improve our risk assessment methodology. In addition, we conduct and contribute to environmental research in this area. We recently completed a study and submitted a scientific paper assessing the potential impacts on human health from environmental exposures for around 35 APIs included in GSK pharmaceuticals. We are also beginning to study the possible impacts of mixtures of various compounds in household wastewater at extremely low concentrations, which include our pharmaceuticals as well as other pharmaceuticals and household products.

Although the main source of pharmaceuticals in the environment is patients excreting medicines they have taken, GSK has established limits for active pharmaceutical ingredients in wastewater from our manufacturing sites. Based on our studies, we establish safe levels for API, based on a demonstration of no risk. We assess process waste concentrations against these established levels and treat the wastewater if required to ensure that the safe levels are achieved so that there is no subsequent environmental risk.

Industry collaboration

We work with other pharmaceutical companies, universities and research groups on activities around pharmaceuticals in the environment. We also collaborate on joint projects with industry groups and sponsor academic studies. For example, we submit environmental data on our products as part of the Swedish classification system for pharmaceuticals, a collaboration between the Swedish Pharmaceutical Association and the Swedish government. This is a voluntary transparency initiative making information about

environmental risks available to the public, doctors and scientists.

We participate in technical working groups on pharmaceuticals in the environment sponsored by the industry group Pharmaceutical Research and Manufacturers of America (PhRMA). Through PhRMA and the Association of the British Pharmaceutical Industry, we continually engage with regulatory scientists from the US Environmental Protection Agency, the US Food and Drug Administration and the UK Environment Agency.

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Corporate Responsibility Report 2008

Materials of concern, GMOs and nanomaterials

Materials of concern

Materials of concern are chemicals where scientific evidence shows probable serious long-term effects to humans or the environment and for which there is existing or potential future legislation that may restrict use. These compounds include so called PBTs (substances that persist in the environment, bioaccumulate in animals and plants or are toxic to life), carcinogens, mutagens, reproductive toxins, substances known to cause asthma, endocrine disrupting chemicals and ozone depleting substances.

Our EHS team works with our process development teams to help them develop strategies to eliminate or substitute the use of these materials.

Read our [position paper on hazardous chemicals management](#).

Performance

In 2008, we used 56 metric tonnes of materials of concern, 95 per cent of which was accounted for by five solvents. Most of the solvent waste from this production was destroyed by incineration, although some of it was recycled as part of the work in our pilot plants. We also examined the use of materials of concern across all phases of development. This determined which substances are being used and identified how they can be replaced during development.

Genetically modified organisms

We use genetically modified organisms (GMOs) in the research and development of new therapeutic agents and in the manufacture of certain medical products such as vaccines.

We use GMOs to identify the genetic targets and causes of disease and to develop new antibiotics and drugs for conditions such as heart disease, diabetes and depression. We use a number of different GMOs, predominantly harmless organisms such as disabled strains of the bacterium E.coli and eukaryotic cells in culture. We also manufacture a number of products that are derived from genetically modified materials, such as hepatitis B vaccine.

We do not produce or plan to produce any products that are, or contain, viable organisms.

All our work with GMOs is controlled to the strictest national and international regulations, and we apply best practice across all our facilities. Any work with GMOs is subject to full risk assessment, ensuring safe use, storage and disposal. All processes are performed in closed vessels minimising the risk of release. The large-scale fermentation or propagation of GMOs is always undertaken in fully contained systems. Research is performed in containment laboratories appropriate to the risk of the materials handled. Work is controlled by written procedures, and we carry out regular maintenance checks.

We treat all waste from our GMO operations to ensure we do not release viable GMOs from our contained processes into the environment. All GMOs are deactivated prior to disposal by chemical or heat treatment.

We do not routinely undertake research and development involving the cultivation of genetically modified plant species.

Nanomaterials

Nanotechnology is an area of science that involves controlling nanomaterial which are materials that are on an atomic or molecular scale. Nanotechnology may in future be used to develop new medicines.

We have participated in a Responsible Nano Code consultation for the development of a code of conduct for businesses that use nanotechnology. Responsible Nano Code is a collaboration between the Royal Society, Insight Investment and the Nanotechnology Industries Association.

We estimate that we will not begin using nanotechnology until around 2011.

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Corporate Responsibility Report 2008

REACH

In 2008, we continued to work to reduce risks to continuity of supply of chemicals presented by the introduction of the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation. This involved:

- Using site inventories from EU and international sites to identify any chemicals sourced from EU suppliers or imported or manufactured by GSK
- Contacting companies that supply GSK with chemicals covered by REACH to assess their plans for management of potential risks to continuity of supply to GSK. This involved the evaluation of over 1,000 suppliers
- Pre-registering any phase-in material manufactured or imported by GSK in volumes of more than one tonne per year
- Registering any new substances we manufacture or import in volumes of less than one tonne per year

[Read about our position on REACH on gsk.com](#)

Our plans

From 2009 we will start to gather information about use of materials and EHS hazard data required to meet the first REACH registration milestone of November 2010 for phase-in substances. We will also continue to work with our suppliers to ensure that they meet their REACH obligations and will collaborate with other companies via Substance Information Exchange Forums (SIEF) to share any hazard data we have on substances of mutual interest that require REACH registration.

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Corporate Responsibility Report 2008

Global harmonisation

We continue to prepare for impending changes to classification and labelling of hazards as part of the UN's Globally Harmonised System for Classification and Labelling of Chemicals (GHS) regulation.

This includes:

- Changing the way we produce safety data sheets to ensure compliance
- Initiating the process of reclassifying all substances we manufacture or import following GHS rules
- Developing training for employees on new hazard warning symbols and labels introduced as part of GHS

Read our [position paper on hazardous chemicals management](#).

Our plans

During 2009 we will work with GSK operations to evaluate hazard labelling solutions that will facilitate production of GHS compliant labels based upon the revised classifications being developed.

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Corporate Responsibility Report 2008

Packaging

We are working to reduce the environmental impact of packaging for our pharmaceutical and consumer healthcare products.

Our 'green packaging guide' provides guidance for evaluating and selecting packaging. It allows designers and managers to benchmark new and existing packaging designs using five metrics:

- Manufacturing impacts
- Mass of the material
- Biodegradability
- PVC content
- Resource depletion of petrochemical feedstocks

One example of reducing the impact of our packaging is the use of 100 per cent recycled plastic for our *Ribena* bottles, achieved despite the challenge of sourcing sufficient quantities of recycled plastic.

Ribena packaging

Our Nutritionals business has embedded sustainability into every aspect of its business as evidenced by the work done on *Ribena*. We work on biodiversity with the farmers that grow our berries, we work towards a goal of 'zero waste to landfill' from manufacturing *Ribena* and we use 100 per cent recycled materials for our bottles. From these actions we have realised the benefits of sustainability, benefits to the environment, our customers and our business. The work done on bottling is just one example of our approach.

We produce hundreds of millions of bottles of *Ribena* and *Lucozade* a year. The bottles are made from a type of plastic known as PET. We estimate that packaging such as this can form as much as 60 per cent of our Nutritional Healthcare products' environmental impact.

In 2008 we launched the UK and Europe's first 100 per cent recycled and recyclable drinks bottle, for our *Ribena* squash and ready-to-drink products. Previously we had packaged *Ribena* in a bottle made from 40 per cent recycled material.

In 2008 we filled over 125 million of the new bottles with *Ribena*. By using 100 per cent recycled material, we avoided the emission of 8,000 tonnes of CO₂ and prevented a total of 3,500 tonnes of waste from being sent to landfill. The bottles can also be recycled by consumers after use. We are trying to understand what would make people recycle when they are away from home by trialling 'reverse vending machines' at major shopping centres. People can put used drinks bottles into the machines, which crush and compact them ready for collection and recycling.

The new bottles contribute towards our targets for GSK Nutritional Healthcare products to use 25 per cent less packaging, and use packaging made from an average of 50 per cent recycled materials by 2010.

This project won The Vanguard Award in the 2008 CEO's EHS Excellence Awards

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Corporate Responsibility Report 2008

Open and transparent relations

We aim to be transparent and open about the environmental impacts of our products and processes.

This helps us build trust with our stakeholders and provides assurance that we are managing environment, health, safety and sustainability (EHSS) risks.

We report our progress against our EHSS objectives in our annual corporate responsibility report and respond to specific requests for information throughout the year.

We also engage more formally with stakeholders to gather feedback on our approach and performance and to address their concerns.

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› [Stakeholder engagement](#)

Corporate Responsibility Report 2008

Stakeholder engagement

We engage with stakeholders at corporate and local level to inform our plans and approach to managing EHSS and to help identify emerging issues.

This includes *ad hoc* meetings and formalised feedback from our stakeholder panel in the UK (created in 2005) and an EHS stakeholder workshop held in the US for the first time in 2007.

In 2008 we expanded the role of the UK panel to provide input to the Sustainability Council. This Council is composed of senior GSK managers and was formed in 2008 to consider the sustainability issues that are important to GSK and recommend actions. This is a component of GSK's larger effort to address public concerns about how we conduct our business.

We engage with regulators to help them develop controls that protect the environment while safeguarding the development and launch of new medicines.

Read more about [how we engage with stakeholders and the feedback we receive](#).

See how we fare in [benchmarks](#).

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› **EHSS reporting**

Corporate Responsibility Report 2008

EHSS reporting

Our primary objective in collecting EHSS performance data is to help our operations manage EHSS issues.

This is done through EHS Manager, a web-based information management system.

We focus our external reporting on the environmental issues that are most relevant to GSK and of most interest to our stakeholders.

Read about our overall approach to [corporate responsibility reporting](#)

Read about our approach to [health and safety](#) and our health and safety performance

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Corporate Responsibility Report 2008

Assurance

SGS Assurance statement



SGS UNITED KINGDOM LTD'S REPORT ON ENVIRONMENT, HEALTH AND SAFETY DATA IN THE GLAXOSMITHKLINE CORPORATE RESPONSIBILITY REPORT FOR 2008

NATURE AND SCOPE OF THE ASSURANCE

SGS United Kingdom Ltd was commissioned by GlaxoSmithKline (GSK) to conduct an independent assurance of the Environmental, Health and Safety data in their Corporate Responsibility (CR) Report for 2008. The scope of the assurance, based on the SGS Sustainability Report Assurance methodology, included 2008 data contained in the following sections of this report:

Waste water	Injury & illness rates
Waste	Injury & illness causes
Emissions to air	Fatalities and serious injuries
Climate change	Ergonomics
Energy	Driver safety
Transport impact	Health and safety data table
Water use	
Environment data table	

The information in the GSK CR Report and its presentation are the responsibility of the directors and management of GSK. SGS United Kingdom Ltd has not been involved in the preparation of any of the material included in the CR Report. Our responsibility is to express an opinion on the data, graphs and statements within the scope of verification. Financial data drawn directly from independently audited financial accounts has not been checked back to source as part of this assurance process.

The SGS Group has developed a set of protocols for the Assurance of Sustainability Reports based on best practice guidance provided in the Global Reporting Initiative Sustainability Reporting Guidelines (2006) and the AA1000 Assurance Standard (2003). These protocols follow differing levels of Assurance depending the reporting history and capabilities of the Reporting Organisation.

This report has been assured for content veracity. The assurance comprised a combination of interviews with relevant employees; documentation and record review at nineteen GSK locations during and at the end of the reporting year as follows:

- Interim site visits during October 2008 in France (Evreux, Notre Dame de Bondeville, Saint-Amand-Les-Eaux), India (Nabha), Italy (Verona - GMS and R&D), Nigeria (Agbara), UK (Slough, Stevenage R&D, Ware GMS, Worthing) and USA (Clifton, Memphis, Research Triangle Park R&D).
- End of year site visits during January and February 2009 in India (Nashik, Thane), Ireland (Cork) and UK

(Irvine, Ulverston and Corporate CSR function in London).

The sites selected included those submitting high proportions of key data and included all parts of the GSK business.

STATEMENT OF INDEPENDENCE AND COMPETENCE

The SGS Group of companies is the world leader in inspection, testing and verification, operating in more than 140 countries and providing services including management systems and service certification; quality, environmental, social and ethical auditing and training; environmental, social and sustainability report assurance.

SGS United Kingdom Ltd affirm our independence from GSK, being free from bias and conflicts of interest with the organisation, its subsidiaries and stakeholders. The assurance team was assembled based on their knowledge, experience and qualifications for this assignment, and comprised auditors and assurers registered with IRCA, IEMA and EMAS Verifiers.

ASSURANCE OPINION

On the basis of the methodology described and the verification work performed, we are satisfied that the Environmental, Health and Safety data contained within the GSK Corporate Responsibility Report 2008 is reliable and provides a fair and balanced representation of GSK's Environmental, Health and Safety activities in 2008. We believe that GSK has chosen an appropriate level of assurance for this stage in their reporting.

Key areas for improvement to data collection, submission and manipulation were identified during the assurance process and, as far as possible, were addressed to incorporate improvements into this report. These improvement opportunities are outlined below to enable further review to establish the need for system or process changes in future reporting cycles:

- Some data points which are collated centrally at year end were not fully reviewed to identify anomalies leading to an inconsistent approach in estimating missing data.
- Several data points have been calculated using new emissions factors and previous years' data is restated using the same calculation to allow year-on-year comparison. It is important to ensure that any restated information is fully explained and references to factors used remain current.
- Some significant contributors to selected data points failed to submit required information.
- Calculation methodology for ozone depleting substances from patient use of inhalers was updated for one production site but not the remaining sites.
- It was noted that reported data for previous years may change slightly due to obtaining additional data submissions or updating estimates after publication date.
- Some anomalies were identified in data submitted when reviewing site level data and comparing 2008 with previous years' submissions. Some of these included examples where data had been entered twice following a change to the database.
- Improvement opportunities identified from site visits were mainly site specific with the most common observations focussing around the following areas:
 - Manual transfer of data and the opportunity for mistakes and variations in roundings in transfer;
 - Utilising the benefits of improvement in regular review and internal checks of data accuracy and formalising secondary review of manual transfers, rather than end of year checks;
 - Extension of monthly reporting rather than quarterly or annual.

Improvements identified in previous reporting period have started to be implemented as follows:

- Specific reports in EHS manager have begun to be implemented, such as the energy module, to reduce the need for additional data transfer from spreadsheets at site level. There may be additional opportunities to extend this to other areas such as waste data provided by key subcontractor.
- During site visits conducted it was noted that the staff were well prepared and able to provide required

evidence to the auditors in the majority of cases, particularly on sites which had undergone previous visits. In addition required changes were generally made promptly where possible.

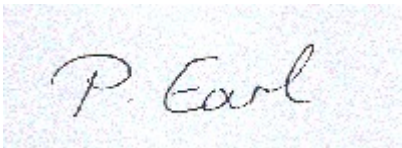
- Data from ancillary services or site activities has started to be included, with explanation provided in the comments section of EHS Manager, however site visits identified that there remain some missing items.
- Review of data submissions indicated an increase in monthly reporting rather than annual or quarterly allowing for more regular review and update of data entries and also indicating discrepancies more clearly.
- The majority of site visits were conducted in the last quarter of 2008 which enabled issues of concern to be identified and dealt with earlier in the assurance process.

Key areas for improvement in data verification process were identified as follows:

- Sites selected for visits should be identified at the earliest opportunity in order to enable visits to be completed alongside ISO14001/OHSAS18001 certification audits where possible.
- Recommended that site visits are completed during the last quarter of 2009 to enable any follow-up required to be completed before end of year verification is performed.
- Recommend selection of key indicators for full review of calculation methodologies across all major contributors, for example VOC and COD emissions and hazardous waste disposal for Primary sites.
- Recommend site visits include detailed review of source evidence for ozone depleting substances from equipment.
- Recommend sites selected for visits include:
 - a sample of sites manufacturing inhalers in order to verify data back to source;
 - a sample of sites with significant contributions that failed to submit data; and
 - a sample of sites where significant changes have occurred which were reflected in data submitted.

Signed:

For and on behalf of SGS United Kingdom Ltd

A rectangular area containing a handwritten signature in black ink that reads "P. Earl". The signature is written in a cursive style.

Pauline Earl
Managing Director
25 February 2008

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› **GSK response to assurance**

Corporate Responsibility Report 2008

GSK response to assurance

GSK response to SGS, March 2009

This is the third year that SGS has reviewed the data in the 'Environment' and the injury and illness data in the 'People' section of the Corporate Responsibility report. Verification is complex due to the large amount of data covered and every year the SGS auditors suggest improvements based on their findings. Their unbiased view of our data and processes has been very valuable and we have adopted their suggestions. As a result the quality of our systems and data has continued to improve over the years.

SGS selects sites for review based on the magnitude of the contribution of the sites to the overall GSK performance, the types of operations and the degree of difficulty the sites seem to have with reporting. We believe their site evaluations are valuable learning experiences for site personnel.

The data included in the corporate responsibility report can be used by the individual sites to monitor and improve their environmental programmes and their health and safety programmes. Therefore, the SGS data verification not only assures the veracity of the data for the corporate responsibility report, it also improves the accuracy and therefore usefulness of data for the sites.

We still find challenges in collecting complete and accurate data in a timely fashion. We are committed to continuing to improve this record so that we reach our goal to be able to provide accurate data to the public on the website in real time.

Responses to specific key areas for improvement for this year:

- Selecting sites so they can be reviewed as part of ISO certification
Sites have already been selected for the 2009 review so they can be verified in combination with any ISO certifications that take place this year
- Site visits to be completed during last quarter of 2009
Sites will be notified of their selection for verification visits in the first quarter of 2009 so visits can take place in the last quarter or in conjunction with ISO certification visits earlier in the year
- Selection of key indicators for full review of calculation methodologies
We will work with our sites that manufacture active pharmaceutical ingredients and are the principal contributors to our VOC and COD emissions and hazardous waste to review their calculation methods over the course of 2009
- Site visits to include detailed review of source evidence for ozone depleting substances from equipment
We will prepare reports of the refrigeration equipment register and SGS will include this in their 2009 site reviews
- Sites selected for visits to include manufacturers of inhalers, sites that failed to submit data and sites that had significant changes after data were submitted
The sites selected for review in 2009 fully represent these groups including some large sales groups that submitted incomplete or late data on injuries and illnesses, and sites from all businesses and regions that made significant data errors

We look forward to the improvements that attention to these areas will bring in 2009.

James Hagan

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Corporate Responsibility Report 2008

Q&As

Here we respond to questions raised by our stakeholders.

Your inhaler products have a large environmental impact. What are you doing about this?

We have been phasing out CFCs from our inhaler products for the last 15 years, replacing these gases with HFAs which have a lower climate change impact (16 per cent that of CFCs). Less than two per cent of our inhalers now contain CFCs and we have committed to a complete phase-out by 2010. As part of our new climate strategy, we are exploring ways to reduce the amount of HFAs released from our inhaler products and we are looking into alternative propellants.

We also offer dry powder inhalers for asthma sufferers which contain no greenhouse gases. These are not suitable for all patients, particularly children and the elderly, as they do not contain propellants and rely on a person's lung power for the active ingredients to be administered.

How can the pharmaceutical manufacturing process be made more efficient?

Making medicines is highly regulated and is complicated due to the number of process steps required. We know that there is more we need to do to improve efficiency and we have set a target to double the average materials efficiency of manufacturing processes for new products introduced between 2006 and 2010.

Are pharmaceutical residues present in drinking water and are they a risk to humans?

Our studies have shown that GSK pharmaceutical products are either not present in watercourses, or are present at low concentrations. Our risk assessments demonstrate that these concentrations do not pose a risk to human health or the environment. But we are not complacent and we continually monitor the latest scientific studies and findings to improve our risk assessment methodology.

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Corporate Responsibility Report 2008

Environmental metrics

Metric	2001	2005	2006	2007	2008
Energy use					
Energy for operations (million gigajoules)	20.7	19.4	19.3	19.3	19.2
Natural gas	9.87	8.78	9.09	9.04	9.15
Fuels	1.40	1.50	1.08	1.06	0.83
Coal	1.04	0.63	0.47	0.51	0.59
Steam imported	0.28	0.21	0.23	0.22	0.19
Electricity imported	8.10	8.30	8.39	8.45	8.43
Energy for transport¹ (million gigajoules)			5.2	5.2	5.1
Sales force			2.1	1.9	1.7
Air travel			1.6	1.6	1.7
Product logistics			1.4	1.7	1.7
Electricity from sustainable sources	0.39	0.14	0.23	0.32	0.26
Climate change impact (CO ₂ equivalents) ²					
Total climate change impact (million kilograms CO₂ equivalent)	3,704.5	2,637.2	7,254.3	7,633.5	7,030.8
CO₂ equivalents from operations energy (million kilograms)	1,798.5	1,717.5	1,704.0	1,701.7	1,722.3
Natural gas	504.0	448.7	464.5	462.6	467.3
Fuels	86.9	98.7	74.5	72.9	59.7
Coal	93.5	56.8	42.6	45.4	53.2
Steam imported	39.1	16.3	15.8	16.3	12.7

Electricity imported	1,074.9	1,096.9	1,106.7	1,104.5	1,129.6
CO ₂ equivalents from transport (million kilograms)	123.0	233.0	363.2	363.0	360.8
Sales force	33.0	102.0	145.4	129.0	114.8
Air travel	71.0	112.0	115.8	112.2	123.5
Product logistics	19.0	19.0	102.0	121.7	122.5
CO ₂ equivalents from other production activities (million kilograms)	1,783.1	686.7	502.3	369.0	282.2
Inhaler production losses	1,578.8	543.4	398.1	289.1	198.6
Equipment containing greater than 1kg refrigerant ³	116.9	46.8	12.8	13.6	12.8
CO ₂ , methane and nitrous oxide from production, waste treatment and other sources	87.4	96.5	91.4	66.2	70.8
CO ₂ equivalents from use of inhalers by patients ⁴ (million kilograms)			4,685	5,200	4,666
CFC-11 inhalers			242	181	116
CFC-12 inhalers			1,083	1,071	688
HFA-134a inhalers			3,360	3,948	3,861
Water use and discharge					
Water (million cubic metres)	26.8	21.8	22.3	20.9	19.7
Municipal	15.20	12.82	12.94	12.23	11.62
Wells or boreholes	11.56	8.59	8.95	9.27	7.78
Other water ⁵	0.04	0.35	0.37	0.35	0.34
Wastewater volume ⁶ (million cubic metres)	20.7	16.6	11.7	10.9	10.8
Wastewater to recycling	1.29	1.04	0.73	0.58	0.52
Wastewater to municipal sewer	9.90	8.12	5.67	5.35	5.44
Wastewater to water bodies	9.48	7.46	5.35	5.01	4.83
COD after on-site treatment ^{6,7} (million kilograms)	27.3	18.7	15.9	14.3	14.9

COD in recycled water	0.06	0.06	0.01	<.01	0.01
COD to municipal sewer	6.04	4.87	4.08	4.05	3.80
COD to water bodies	21.17	13.81	11.83	10.20	11.08

Waste generated and disposed

Hazardous waste generated⁸ (million kilograms)	350.7	261.0	241.1	221.8	237.5
Hazardous waste recycled	288.41	193.62	170.73	149.86	183.11
Hazardous waste disposed	62.31	67.36	70.33	71.98	54.36
Hazardous waste incinerated with energy recovery ⁹	28.69	29.90	30.38	32.72	20.20
Hazardous waste incinerated with no energy recovery	30.25	36.06	39.45	38.68	32.53
Hazardous waste to landfill	3.37	1.40	0.50	0.58	1.64
Non-hazardous waste generated (million kilograms)	132.8	124.0	114.7	120.3	109.4
Non-hazardous waste recycled	79.34	83.82	78.48	83.48	76.55
Non-hazardous waste disposed	53.49	40.20	36.22	36.85	32.87
Non-hazardous waste incinerated with energy recovery ⁹	5.92	9.94	8.69	8.83	8.35
Non-hazardous waste incinerated with no energy recovery	12.05	6.53	4.93	4.87	4.85
Non-hazardous waste to landfill	35.52	23.73	22.60	23.15	19.67
Non-routine waste generated¹⁰ (million kilograms)	25.3	77.9	28.1	37.7	18.9
Non-routine waste recycled	2.29	39.97	11.10	23.04	11.97
Non-routine waste disposed	22.98	37.96	17.00	14.63	6.90
Non-routine waste incinerated with energy recovery	1.55	7.46	2.55	4.21	0.49
Non-routine waste incinerated with no energy recovery	0.24	0.39	0.79	0.82	1.13
Non-routine waste to landfill	21.19	30.12	13.65	9.60	5.29

Volatile organic compound emissions

Volatile organic compound emissions¹¹ (million kilograms)	6.8	5.2	4.4	4.5	3.9
Top six solvents released to air (million kilograms)					
Acetone	1.24	1.15	1.06	0.96	1.03
Dichloromethane	1.74	0.88	0.85	0.75	0.63
Methanol	0.75	0.71	0.46	0.64	0.54
Ethanol	0.36	0.54	0.46	0.57	0.37
Isopropanol	0.39	0.20	0.28	0.18	0.18
Toluene	0.42	0.06	0.09	0.26	0.06

Ozone depleting substances¹²

ODS releases from production (thousand kilograms)	183.5	51.0	32.9	14.9	5.4
CFC-11 releases from production	88.55	14.11	19.35	3.22	1.59
CFC-12 releases from production	94.90	36.86	13.51	11.63	3.82
Ozone depletion potential of refrigerants released from equipment (thousand kilograms CFC-11 equivalent)	4.3	3.0	0.7	0.6	0.5
CFC-11 releases from equipment	0.56	1.62	0.42	0.38	0.26
CFC-12 releases from equipment	0.33	0.21	0.02	0.02	0.03
Other ODS from equipment	3.42	1.15	0.22	0.16	0.19
ODS released from patient use of inhalers¹³		272.5	182.2	136.5	87.7
CFC-11 from patient use		76.15	50.91	38.14	24.49
CFC-12 from patient use		196.38	131.29	98.35	63.16
ODP of refrigerants contained in equipment¹⁴ (thousand kilograms CFC-11 equivalent)			23.9	20.5	16.2

Estimated costs and investments

Operations and maintenance cost (million £)	41.6	39.3	33.9	33.1	31.3
Capital investment (million £)	24.4	12.1	9.7	16.8	12.9

Footnotes

1. Energy and climate change impact for travel and transport by air, land and sea are calculated using the Greenhouse Gas Protocol starting from distance travelled, not directly from fuel use. In years before 2006 we did not collect all categories of freight transport or employee business travel. Some of the transport data are estimated and we may not capture all routes and employee air travel.
2. Climate change impact is calculated as CO₂ equivalent using the Greenhouse Gas Protocol developed by the World Resources Institute and the World Business Council for Sustainable Development. Each year we review the CO₂ factors and update the data for all years as appropriate. The greatest changes are generally in the updated factors for electricity.
3. In 2008 we reviewed the refrigeration equipment inventories for 2006, 2007 and 2008. Where inventories were incomplete they were estimated based on inventories in other years. We also updated the factors for ozone depletion potential and climate change emissions using WMO (World Meteorological Organisation), Scientific Assessment of Ozone Depletion: 2006, Global Ozone Research and Monitoring Project—Report No. 50, 572 pp., Geneva, Switzerland, 2007. (chapter 8). We calculate the probable releases using a factor from the British Refrigeration Association.
4. We did not have enough information to calculate climate change impact from inhaler use before 2006.
5. Water from other sources includes recycled sources
6. We focus collection of wastewater and chemical oxygen demand data primarily on the major contributors; primary manufacturing operations, pilot plants, coating activities and sterile operations. Some sanitary wastewater streams are included if they cannot be separated from production wastewater streams or if they are significant.
7. Chemical oxygen demand (COD), a measure of water pollution, is measured when wastewater leaves our sites following any onsite treatment.
8. We consider a waste to be hazardous if it has any of the properties defined by the 1989 Basel Convention or if it is radioactive, bioengineered or biohazardous. Basel Convention properties include flammability, explosivity, water or air reactivity, corrosivity, oxidising potential, acute or chronic toxicity, ecotoxicity or infection. Biological waste rendered non-hazardous after treatment is considered non-hazardous waste. We focus collection of hazardous waste on the major contributors; primary manufacturing operations, pilot plants, coating activities and sterile operations.
9. Incineration with energy recovery means burning the material and using the resulting energy.
10. Non-routine waste includes construction and demolition rubble and is not included in hazardous or non-hazardous waste calculations.
11. We focus collection of volatile organic compound emissions on the major contributors; primary manufacturing operations, pilot plants, coating activities and sterile operations.
12. We used WMO (World Meteorological Organisation), Scientific Assessment of Ozone Depletion: 2006, Global Ozone Research and Monitoring Project—Report No. 50, 572 pp., Geneva, Switzerland, 2007. (chapter 8) for ozone depletion potential and climate change emissions factors.
13. Before 2006 we did not have information about inhalers produced in Asia so it was not included in ODP or GWP calculations until 2006.
14. Before 2006 we did not have information about the amounts of refrigerants contained in equipment

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Corporate Responsibility Report 2008

Our people

Good employment practices are essential to achieve our business strategy. Our goal is to 'be the best place for the best people to do their best work'.

We employ over 90,000 people in 114 countries across the world. The essential characteristics of a good workplace are integrity, diversity and inclusion, development and creativity.

Integrity is critical in everything we do. The GSK spirit defines the culture and behaviours we expect from our employees. Any failures of integrity risk damaging our long-term success.

Diversity and inclusion in our workforce demonstrate our commitment to equal opportunities, and enhance our business. Diversity and inclusion help us attract the best people in each of the countries in which we operate, give us a wide range of perspectives to draw on and enhance our understanding of local market needs.

Development of our employees means they are more likely to stay with GSK and contribute their best to our success. We encourage our employees to achieve their full potential through training programmes and on-the-job development. We offer a supportive and safe work environment and competitive reward packages.

Creativity is fostered in the best work environments. Our aim is that GSK workplaces empower our people to be creative and innovative in their work, for the benefit of the company, shareholders, customers and patients.

Employment awards

A selection of the employment awards won by GSK in 2008:

UK

- Ranked fourth in the 2008 Britain's Top Employers survey by CRF International and published by Guardian books
- Best in class in Engineering and Science and shortlisted for best Graduate Employer in Target awards, voted for by graduates and post-graduates
- Received The Times Employers of Choice for Research and Development Award, based on results of undergraduate interviews
- Ranked 14th in The Times Top 100 Graduate Employers Survey, a list of organisations that new graduates most want to work for
- First in the Employee Benefits Award for the most effective use of employee financial education in the workplace, awarded by Employee Benefits magazine
- Highly commended in PricewaterhouseCoopers Building Public Trust Awards in 'People reporting' category, based on disclosure and strength in human capital management and employee practices

US

- Awarded a perfect score (100 per cent) for Corporate Equality by the Human Rights Campaign Foundation and listed as one of the best places to work for gay, lesbian, bisexual and transgender equality
- Named one of the 100 best companies by Working Mother magazine, for the 16th consecutive year
- Awarded platinum honours for workplace and lifestyle programmes, by the National Business Group on

Health. Identified as a leader in providing a healthy workplace and promoting a healthy lifestyle for employees and their families

› Home › Responsibility › Our people › **Our culture and behaviours**

Corporate Responsibility Report 2008

Our culture and behaviours

Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

We place great emphasis not only on what we achieve, but also on how we deliver our achievements. Integrity is critical in everything that we do.

The GSK spirit defines the culture and behaviours we expect from all our employees:

Culture

- Passionate people
- Patient-focused
- Performance with integrity

Behaviours

- Innovative thinking
- Engaging and developing others
- Leading people
- Achieving excellence

Our mission and spirit help our employees deal with new challenges and maintain a clear focus. We raise awareness of the GSK spirit and help employees to understand and adopt its principles through workshops, team meetings, presentations and awards.

We are working to individually empower each of our employees. Empowerment means trusting employees and recognising and rewarding them for achieving their objectives. It helps to encourage innovation and entrepreneurship, and is good for employee morale. Empowered employees take responsibility for their tasks, are able to prioritise better and make decisions more quickly and effectively. Achieving a culture of individual empowerment across GSK will motivate our staff, make us more effective and improve our ability to deal with challenges.

Corporate Responsibility Report 2008

Restructuring

In October 2007, we announced a three-year Operational Excellence programme to improve the effectiveness and productivity of our operations. We launched the programme as a response to a more challenging business environment and forecast that it would deliver annual pre-tax savings of up to £700 million by 2010. In February 2009 we announced an expansion to this restructuring programme, to realise increased pre-tax annual savings of £1.7 billion by 2011. In 2009, savings from restructuring will mitigate the decline we expect to our gross margin due to product mix changes with a higher percentage of sales generated from vaccines, Consumer Healthcare and Emerging Markets, and support further investment behind our strategic priorities.

The programme includes initiatives to streamline manufacturing, adapt our selling model and improve efficiency in R&D. We are very conscious of the effect this programme will inevitably have on our employees and if options exist where we can achieve our financial goals and preserve jobs we will do everything we can to do so. We consult with employees and their representatives before we implement measures that affect them, such as outsourcing, site closures and staff reductions. We always speak to affected employees first (except where local regulations do not allow it) and then our works councils, trade unions and other employee representatives as appropriate.

We aim to treat our employees with dignity and respect and offer a wide range of support for all affected employees. This includes a competitive severance package and outplacement support such as assistance in finding alternative employment, career counselling and retraining. We also work hard to maintain the morale of all other employees at GSK.

Corporate Responsibility Report 2008

Consultation

In Europe our staff or works councils and European Employee Consultation Forum meet regularly, providing an opportunity for employees and company management to discuss key issues and developments in the business.

We also recognise trade unions for consultation and collective bargaining in many countries worldwide.

Our European Employee Consultation Forum, which includes employee representatives from 28 EU countries, works alongside national consultation processes and is governed by UK law. There is an Operating Sub-Committee of six employee representatives who meet four times a year with six management representatives to receive updates and review proposals affecting the structure of the business. Extraordinary Operating Sub-Committee meetings can be called should the need arise. The whole of the Forum meets once a year at an Annual Meeting to receive a business update from senior GSK executives. In 2008, Eddie Gray, President of GSK Pharmaceuticals Europe, and other business leaders spoke about the opportunities presented by new products in the R&D pipeline, the challenge of growth within Europe and GSK's vision for developing the Consumer Healthcare business.

We also discuss issues through national consultation forums. For example, the UK Information and Consultation (I&C) Forum which consists of 15 GSK elected employee representatives and seven managers and meets three times a year. In 2008, the I&C Forum reviewed and amended a number of GSK's UK policies including those on driving while on company business, further education and special leave. The Forum also continued to review UK-wide redeployment and selection guidelines for redundancy and proposals to handle pension legislation changes taking effect in April 2010. In 2008, the Forum received presentations on strategy from senior managers within Global Manufacturing and Supply and R&D.

Corporate Responsibility Report 2008

Communication

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Good two-way communication with our employees is vital.

We aim to keep everyone well informed and involved in company activities, and provide opportunities to get their feedback.

Our internal communications channels include:

- Face-to-face communications, for example through ‘town hall’ style meetings, lunches with the Corporate Executive Team, conferences and team meetings
- The GSK Experience programme for new starters. This is a mandatory, two-day induction programme that teaches new employees in the UK and US about GSK. Feedback indicates the programme helps them to feel valued and involved. Other countries arrange their own induction programmes locally
- Spirit, our internal magazine. We print and distribute 33,500 copies throughout the company, four times a year. Spirit is also published on our intranet, myGSK, reaching a broader audience than print alone and allowing our employees to easily give us feedback on articles they have read
- Our global intranet site, myGSK, provides updates on company and industry news, and a large range of information and resources for employees. myGSK has several features for employees including:
 - myCEO, a dedicated part of the intranet where staff can pose questions to our Chief Executive Officer (CEO) and the other members of the Corporate Executive Team. Employees ask approximately 70 questions each month and our CEO’s answers are posted regularly on the site
 - The Ambassador intranet community which provides reference materials, information and tools for employees to use as a reference, including presentations, facts and figures
 - An interactive intranet feature, Your Story, which allows our employees to share stories about what inspires them and how this impacts their work with the company
- An email cascade system where messages are sent to business leaders to share with employees, for example details of our latest financial results
- Surveys that enable us to monitor employee engagement and help us to track the impact of our internal communications

Corporate Responsibility Report 2008

Communication

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Internal communications

Some of the ways that we communicated with our employees in 2008:

CEO communications

- As CEO designate, Andrew Witty held nine employee forums with 250 employees from across the world to help inform his strategic priorities for GSK
- As CEO, Andrew Witty hosted three global employee broadcasts, recorded live in front of an employee audience. These broadcasts are available for employees to view throughout the year as video on demand via our online video library GSKtv
- A CEO Advisory Board has also been established which will act as an informal sounding board for ideas. The Board will be filled by employees from across the company

Communicating with our senior leaders

We held meetings with senior leaders in April and September 2008 to support alignment of the different parts of our business with our new strategic priorities. These were attended by 1000 and 200 leaders respectively.

Online communications

In 2008 we launched several new features on the company intranet, myGSK, including:

- A new myCEO discussion forum, called 'Let's talk', designed to support the transition to a new CEO. This received 176 comments from employees between May and December 2008. Employees also sent 456 questions to the myCEO Q&A facility
- The online version of our employee magazine, Spirit, in September 2008. We also redesigned the magazine and now print it on 100 per cent recycled, chlorine-free paper
- GSKtv, an online multi-media library which allows employees to view and download a range of videos from across the organisation
- A new internal website that provides employees with information about what to do in the event of a flu pandemic. [Read more about GSK's flu pandemic preparedness](#)

Business communications

Our business units communicate directly with employees through the intranet, 'town hall' meetings and other face-to-face meetings, broadcasts and video messages. Many members of the Corporate Executive Team also run live web chats and host Q&A sessions on their intranet communities, ensuring we are aware of areas of concern within regions, business units and functional areas.

Employee surveys

Between 2002 and 2006 we conducted Global Leadership Surveys every two years to track management views on a range of issues. The next survey will be run in 2009 and will measure managers' perceptions of our progress towards achieving our new strategic priorities which were introduced in 2008.

Our plans

We are continually reviewing the effectiveness of our communications and how we can improve them. Employees are encouraged to ask questions and comment on the information we provide and the communication channels we use. As technology is updated, it is easier for us to encourage direct communication and discussion with employees.

In 2009 we will expand our use of technology, such as social media tools, to encourage greater collaboration and communication across GSK, breaking down traditional communication barriers.

Corporate Responsibility Report 2008

Diversity and inclusion

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At GSK, we recognise the value that different perspectives and experiences bring to GSK and we aim to recruit a diverse range of employees to our global workforce.

We respect all our employees and include talented people in the workforce regardless of race, gender, sexuality, age, religion and belief or disability. We do not require medical testing as a prerequisite for employment.

We aim to adopt inclusive work practices that create an environment where employees feel individually and collectively empowered, and can develop and contribute to the business to their full potential.

Being a diverse and inclusive business helps GSK to recruit and retain the best people for the job. It also enables us to understand and meet the needs of diverse patients, customers and consumers.

Global diversity policy

Our commitment is set out in our global diversity policy. Our Corporate Executive Team endorses the policy and related activities such as our annual [Multicultural Marketing and Diversity Awards](#).

All our employees are expected to comply with this policy. Allegations of discrimination are taken extremely seriously, fully investigated and findings acted upon.

Each business has diversity champions, employees that promote diversity issues. In the UK and US we have Diversity & Inclusion (D&I) steering committees, made up of human resources managers and line managers with specific responsibility for diversity and inclusion. The committees run diversity awareness campaigns and training sessions. GSK also monitors and reports on gender diversity in management in the UK and US.

Employee networks

Employee networks are an important element of our diversity and inclusion programme. They support professional growth and provide a forum where people with similar interests or backgrounds can meet, discuss shared experiences and address any problem areas. This helps engage and empower employees.

The networks are an important source of expertise on diversity issues. GSK managers can engage with the networks to improve their understanding of employees from different backgrounds. Networks also help our media and marketing teams understand our diverse customers and stakeholders.

GSK has networks for Asian, African American, Hispanic, gay, lesbian, bisexual and transgender employees. We also have networks for mature employees, employees early in their career, women in leadership and veterans. Each network has an executive sponsor who helps to set and achieve goals, obtain resources and promote the network's objectives among senior management.

Disability

We work to ensure people with disabilities can access the full range of recruitment and career opportunities at GSK. In the UK, we partner with the Employers' Forum on Disability and strive to be a 'disability confident' organisation. Disability confidence is a concept developed by the Employers' Forum to describe companies that create a culture of inclusion, remove barriers to access and make adjustments to enable individuals with disabilities to contribute as employees, customers and partners. We hold the 'Two Ticks' symbol from

JobCentrePlus, which demonstrates GSK's commitment to employing disabled people.

Read more information on our approach to [diversity and inclusion](#).

Positively managing HIV in the workplace

We do not discriminate against prospective and current employees based on HIV status and do not require testing as a prerequisite for employment. We maintain medical confidentiality at all times. We provide information and training to staff on HIV/AIDS prevention and addressing problems of stigma relating to the disease. We provide HIV/AIDS testing, voluntary counselling and treatment programmes to employees and their families in countries where these are not easily available via government healthcare programmes.

We also offer [preferentially priced anti-retrovirals](#) or equivalent not-for-profit arrangements to other employers in Sub-Saharan Africa who have their own workplace clinics

Corporate Responsibility Report 2008

Diversity and inclusion

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Gender diversity

We are pleased that the percentage of women in management has increased incrementally in the last five years. However, there is still a lot of room for improvement.

Gender diversity in management 2008

Per cent positions held by women (worldwide)					
	2004	2005	2006	2007	2008
Corporate Executive Team, senior vice presidents, vice presidents	19	21	22	22	25
Director grade	33	33	34	35	36
Manager grade	38	38	39	40	41
All management positions	35	35	36	37	38

Gender equality in the workplace is affected by many factors, some external to GSK, including the requirements of family life. Our flexible working policies help employees balance the demands of work and home life. They can be particularly beneficial for caring and family responsibilities. For example, we offer part-time working, job sharing and remote working.

Read more about our programmes encouraging women in science: [Women in Science Events and the Scientific Women's Scholarship Programme](#).

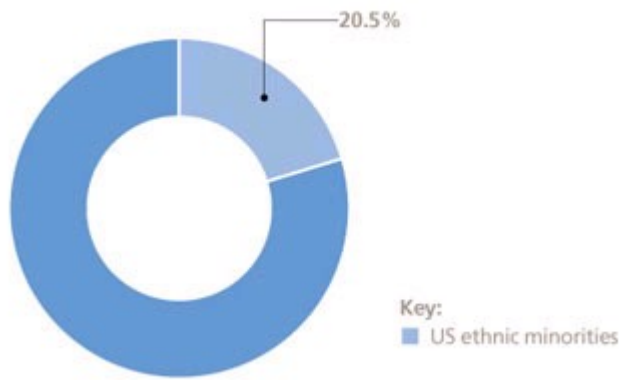
Ethnic diversity

In the US, minorities (defined as Blacks, Hispanics, Asians, Pacific Islanders, American Indians and Alaskan natives) made up 20.5 per cent of our workforce in 2008, compared with 20.1 per cent in 2007, 19.8 per cent in 2006 and 19.6 per cent in 2005.

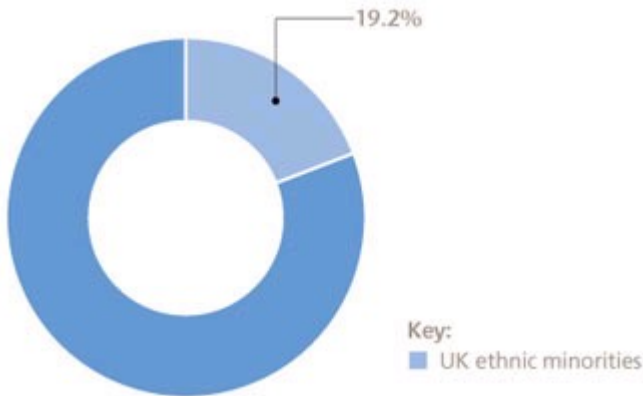
In the UK, ethnic minorities accounted for 19.2 per cent of employees, in 2008 compared with 19.1 per cent in 2007, 18.3 per cent in 2006 and 16.8 per cent in 2005. Ethnic minorities accounted for 12.5 per cent of the UK population of England and Wales in 2001, the last UK Census. We use the UK Commission for Racial Equality definition of ethnic minorities. This includes anyone who does not identify themselves as White British, so this means people identified as White Irish, North American and European are included as minorities.

We also measure diversity in the UK by counting the number of employees that define themselves as non-white. In 2008, 12.1 per cent of employees defined themselves as non-white, compared with 11.8 per cent in 2007, 11.6 per cent in 2006 and 11.0 per cent in 2005.

Ethnic minorities (US)



Ethnic minorities (UK)



Multicultural marketing and diversity awards

Our annual Multicultural Marketing and Diversity Awards aim to inspire employees to find creative ways to reach a broader range of potential employees, customers and communities. Awards are given in categories such as employee attraction, development or retention; multicultural marketing and sales; community outreach; and diversity ambassador.

The 2008 Awards recognised 13 project teams and five individuals. Award-winning projects included:

- An initiative that, over four years, increased the representation of diverse subjects in US clinical trials from just under 20 per cent to 35 per cent, slightly higher than the overall US minority population
- A literacy programme to teach 154 Indian manufacturing employees how to sign their names on official documents instead of using a thumb print

Read more in our [case study](#) on this literacy programme.

Our plans

During 2009 we plan to simplify our approach to diversity and inclusion, ensuring that this maximises employee empowerment.

Corporate Responsibility Report 2008

Training and development

Approach**Performance & plans**

Training and development opportunities help employees feel valued and engaged in their work.

GSK provides work-related training courses for all employees, and leadership training for managers. These focus on providing people with the right behaviours and expertise for their jobs and the skills needed to apply their knowledge effectively.

Our goal is for each individual to achieve their potential and contribute fully to company performance. We conduct regular appraisals to identify training needs and help employees set and achieve development objectives. We operate 360-degree assessments for our top managers to ensure they receive objective feedback on their performance from the employees they manage and colleagues that they work with, as well as their manager.

Training is carried out within each business function and online, for example through our 'myLearning' intranet site in the US and UK. We also offer project secondments to help employees learn new skills.

Leadership development

We identify high-performing employees and potential leaders in each business function through our annual talent management cycle. Managers are accountable for developing talent and successors and this is a top priority for every leader. The process ensures we have the diverse and high-performing talent required to deliver our business strategy and to reflect the global growth of GSK.

Talented people participate in leadership programmes and connect with senior management through programmes such as the Chief Executive Forum. Our leadership framework helps employees fulfil their potential, become leaders in their field and contribute fully to our business performance. Specifically, it helps them to:

- Develop the behaviours that distinguish high-performing leaders. These include innovative thinking, engaging and developing others, leading people and achieving excellence in their work
- Understand their behaviour, take personal responsibility for their actions and continue to perform with integrity
- Enhance their expertise, including technical and functional skills and broader knowledge. These contribute directly to GSK's overall performance and are likely to be unique to the position, role or function of each employee
- Effectively use and apply the processes and practices within GSK

We also provide extensive [health, safety and environment training](#) for our employees.

Corporate Responsibility Report 2008

Training and development

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The majority of our employees receive an annual performance appraisal through our Performance and Development Planning (PDP) programme. Compliance with this requirement is measured at local level, but we know that more than two-thirds of employees received an appraisal in 2008.

The PDP programme assesses how well employees have implemented GSK business principles through their work. The appraisals impact on bonus payments and future career development.

In 2008, we focused on embedding our leadership framework. This included the following training initiatives:

- 'Hot Topics' training which focused on how to lead in times of transformational change. Nearly 1,700 managers and senior leaders attended
- Workshops to teach GSK leaders about the importance of coaching their staff and techniques for doing so effectively; 138 managers took part in the workshops in 2008
- Online development resources available for all English-speaking employees, providing a variety of steps they can take to build leadership skills

We also offered over 3,000 learning programmes to all GSK employees via our online learning management system.

Our plans

During 2009 our Leadership and Organisation Development function will work to support GSK's strategic priorities. Plans include forecasting and delivering the capabilities needed for the future growth and success of GSK. In addition, leadership development will continue as an area of focus, including refining the behaviours necessary for successful leadership and supporting this with prescribed learning and development opportunities and experiences.

Corporate Responsibility Report 2008

Reward and recognition

We offer employees a competitive salary based on industry benchmarks, as well as performance-related incentives and other benefits. This helps us to attract and retain the best people.

We particularly reward employees for innovation and good performance and we reward leaders who empower their staff.

Our pay strategy for managers is based on a programme called TotalReward that helps us recognise good performance and enables managers to share in GSK's success. We use feedback from managers to identify the types of reward that they prefer.

Components of TotalReward include:

- Cash, including salary, bonuses and incentives (including long-term incentives for eligible employees), and recognition awards. Salaries are allocated within defined bands for different employment levels
- Savings choices such as pension provision and share schemes
- Lifestyle benefits, for example healthcare, childcare support and employee car ownership programmes

TotalReward applies to GSK managers around the world, although the component parts of an employee's package will differ by country in accordance with local legislation and best practice.

Share ownership

Our share ownership schemes help to create a culture of ownership among our employees. In countries where share ownership opportunities exist, they are open to all employees and there is a high level of participation. For example, in the UK 67 per cent of employees participate in our ShareSave scheme, and 85 per cent in our ShareReward scheme.

› Home › Responsibility › Our people › [Health, safety and wellbeing](#)

Corporate Responsibility Report 2008

Health, safety and wellbeing

Keeping our employees and contractors healthy and safe is a priority.

Our rigorous management system reduces the risk of harm to our employees and helps them stay healthy. It is part of our broader [environment, health, safety and sustainability \(EHSS\) programme](#). As well as being the right thing to do, this improves business performance by increasing attendance, improving productivity and reducing healthcare and insurance costs.

Corporate Responsibility Report 2008

Health and safety management

We manage health and safety through an integrated environment, health, safety and sustainability (EHSS) management system.

This incorporates our EHS and sustainability vision and policy and associated standards. Our EHSS [Plan for Excellence](#) includes our strategy for improving EHSS performance up to 2015.

We employ health and safety professionals across sites within business units and at the global level to manage health and safety risks across GSK.

Read more about our [EHSS management system](#).

Our occupational health and safety data is [independently assured](#). Assurance does not include personal health and wellbeing programmes and data.

Audits and performance

As part of our overall environment, health, safety and sustainability audit programme, we conduct occupational [health and safety audits](#) at our sites every one to four years. The frequency depends on current risks and past performance. We carry out more frequent visits at some sites, based on the degree of risk at the site, its health and safety performance and the issues raised by previous audits. Audit results are presented to the Audit Committee of the Board of Directors.

Our occupational health and safety target [[link to environmental sustainability/plan for excellence/targets](#)] is to reduce reportable injuries and illnesses by five per cent a year from 2006 to 2010, and to be placed within the top quartile of comparable industry ratings by 2012.

We systematically assess and manage occupational health and safety risks and performance. When incidents do happen we identify root causes and take action to prevent reoccurrence. We believe that addressing the causes of incidents will help eliminate risks and hazards, and prevent future occupational injuries and illnesses.

In 2008 we audited 31 GSK sites for implementation of occupational health and safety standards as part of our overall [environment, health, safety and sustainability audits](#). The average audit score was 78 per cent which compares to our 2010 target of 82 per cent.

Best performance was seen in fire prevention, site management commitment to occupational health and safety, investigation and reporting of injuries and illnesses and emergency planning and response. Sites were generally weakest in resilience and mental wellbeing, control of chemical agents, use of work equipment, risk assessment, permit to work systems, noise control and ergonomics.

Auditors found two 'critical findings', which indicate a high probability of incidents with potentially serious consequences. The first related to deficiencies in controlling the risk of falls during a construction project and the second was related to the risk of fire from inadequate management of highly flammable liquids. These issues are monitored to ensure that appropriate actions have been taken to mitigate risks and ensure ongoing compliance.

In 2008 one of our active pharmaceutical ingredients manufacturing sites was fined £50,000 by the UK regulator, HSE, for a process safety incident that occurred in 2006. A serious explosion occurred at the Irvine, UK site, involving a 'placebo' batch used to test plant conditions and controls. Two operators were injured. The event has been thoroughly investigated, learnings shared and improvements made. This was reported in our [2006 Corporate Responsibility report](#).

In 2008, a site in the US received a fine of \$1,375 from the South Carolina state Occupational Safety and Health Administration (OSHA) for violations of forklift regulations. These concerns have been addressed at the site.

OHSAS 18001 certification

Twenty-six of our 78 Pharmaceuticals and Consumer Healthcare manufacturing sites and one Consumer Healthcare R&D site are certified to the international health and safety standard OHSAS 18001. We have set a goal for all manufacturing sites to be jointly certified to OHSAS 18001 and the environmental standard ISO 14001 by the end of 2010. In 2008, three new sites were certified. The certified sites are in Argentina, Australia, Brazil, China, Egypt, France, Germany, India, Japan, Kenya, Mexico, Panama, Philippines, Poland, Saudi Arabia, Spain, Turkey, the US and the UK.

› Home › Responsibility › Our people › Health safety and wellbeing
› **Hazard assessment and communication**

Corporate Responsibility Report 2008

Hazard assessment and communication

Assessment

Understanding the intrinsic hazards of the materials we produce or use in research, development and manufacturing is an important first step to enable us to effectively manage health and safety risks and prevent damage to the environment.

Our occupational toxicologists and environmental scientists assess materials hazards throughout product development. Increasingly, we use computer-based modelling and in vitro methods instead of animal tests. We use hazard information to assign occupational and environmental exposure limits that help guide the design of systems used to protect our employees' health and to protect the environment from chemical contamination.

Our hazard assessments help us meet regulatory requirements such as the new EU [Registration, Evaluation and Authorisation of Chemicals \(REACH\) legislation](#).

Communication

We provide hazard information to enable our employees, contract manufacturing partners and customers to handle and dispose of our materials and products safely.

We develop safety data sheets for new materials and products as they progress through the development process. This ensures that health and safety information is readily available to our staff before they handle chemicals and to our customers when the product is launched.

We distribute safety data sheets using a web-based system. It provides safety information for nearly 4,500 GSK materials and key manufacturing and process chemicals. It also includes over 2,200 safety data sheets for pharmaceutical, biological and consumer healthcare products. The information is regularly updated and is available in English, French, German, Italian, Portuguese and Spanish.

Safety data sheets for our products are available on our [website](#) and are also communicated directly to our customers via fax on demand, or through customer response centres.

Safe transport of materials

As part of our normal business operations we transport materials that require special handling such as chemicals, biological and radioactive materials, and finished products. We have a network of highly trained employees to oversee transportation-related activities to ensure materials are transported in a safe and effective manner that complies with national and international laws and conventions. This ensures that our employees, the public and the environment are kept safe.

We use two systems that support tracking, classification and emergency information for the transportation of chemical, biological and radioactive materials. The HazClass™ system is available for use by R&D sites. Manufacturing sites use the SAP system to manage transport of their materials and products.

Understanding fire and explosion risks

Our in-house fire and explosion laboratory conducts tests to determine fire and explosion properties of materials handled in research and development and manufacturing. This work is primarily driven by the requirements of the EU regulations on explosive atmospheres (Directive 99/92/EC, ATEX 137). When manufacturing sites receive hazard data from laboratories, they undertake risk assessments to design work practices that eliminate or reduce the risk of fires and dust explosions.

Corporate Responsibility Report 2008

Safety programmes

We operate a number of programmes to keep our employees and contractors safe:

Chemical exposure

We have rigorous procedures and controls in place to ensure employees involved in developing and manufacturing our products are protected from exposure to chemicals.

We have a goal to make 80 per cent of operations involving the handling of hazardous compounds 'respirator free' by 2010. This means employees will not need to wear respiratory protective equipment for routine production tasks. Instead, sites will install technology that prevents the release of hazardous compounds into the work environment. For example, we have installed contained powder transfer systems and glove-box technology at our pilot plant facility in Cork, Ireland, and a special containment system at our new penicillin facility in Pakistan. We have also developed a proprietary manufacturing technology which greatly reduces operator exposure to medicines as they are manufactured.

Each GSK site monitors air quality to assess exposure to hazardous compounds and implements controls to protect employees and achieve our 'respirator free' goal. Our occupational hygienists, employee health staff and engineers work together at site, regional and global levels to reduce employees' exposure to chemicals.

By the end of 2008 over 40 per cent of operations had achieved a 'respirator free' level of engineering control based on at least some occupational hygiene monitoring results. We continue to upgrade engineering controls to achieve 'respirator free' levels of control. For situations where engineering controls are not possible, employees will remain protected by appropriate respiratory and other protective equipment.

Process safety

Many of our products begin with the formulation and processing of hazardous materials such as flammable solvents and combustible powders. Our scientists look for opportunities to eliminate the use of these hazardous materials through our green chemistry and green technology programmes. Where substitution or elimination is not an option, our process safety programme aims to ensure that safety is built into manufacturing, research and development processes, and that employees receive training to understand risks and implement appropriate controls.

Our engineers use an online assessment system to develop safer processes and plant maintenance strategies and to share hazard information and control strategies across GSK.

We have reviewed and updated our process safety strategy after two employees were injured in an explosion at our factory in Irvine, UK, in 2006. Using the results of this review, we are continuing to update and integrate our process safety management system (PSMS) into our EHSS management systems at all GSK sites. This includes:

- A design code containing new engineering standards for process safety
- Assessments against the new engineering standards, with gap analyses
- Upgraded risk assessments and remediation processes
- Process safety indicators
- Steps to embed process safety in the overall safety culture

- New training and competence programmes and process safety tools

We also appointed a new director of process safety.

Safety engineering

Our safety engineering programme focuses on improving construction and plant safety and ensuring effective emergency response systems. We have developed safety engineering guides to managing the risk of fire and explosion and to provide guidance on machine guarding and electrical hazards. These web-based guides provide a standardised approach to managing safety risks across GSK.

We also ensure that safety is built into and maintained at our sites worldwide through the following programmes: Risk Assessment and Control Processes, Construction Contractor Safety Programme, Capital Project EHS Review Process and our Emergency Response Programmes.

Ergonomics

Musculoskeletal illnesses and repetitive strain injuries are some of the leading causes of time away from work. Our Corporate Executive Team has set a target to reduce the number of these illnesses and injuries by five per cent each year through to 2010.

Good workplace and job design, known as ergonomics, helps employees to do their jobs effectively while reducing the risk of musculoskeletal illnesses and injuries.

There are 70 ergonomic improvement teams working across GSK businesses to assess and manage the ergonomic risks of existing operations and planned projects. Teams include members from areas such as manufacturing quality, safety, health and medical services and those that perform the work itself. Teams work together to identify risks, develop solutions and share best practice globally through a dedicated ergonomics community on our intranet.

In addition, over 900 trained facilitators throughout the business help to manage computer-based ergonomic risk assessments for over 30,000 employees. These assessments identify steps to reduce discomfort and injury relating to computer use. Information about ergonomics best practice is also available to employees on our intranet site.

These efforts have contributed to:

- A 4.7 per cent improvement from 2006 to 2008 in ergonomics-related injury and illness. This is short of our target of an annual five percent improvement through to 2010, equivalent to a 10 per cent improvement over 2006 to 2008. In order to meet or exceed our target in 2009, we will increase our effort and resources in this area
- Cost and productivity gains in manufacturing operations. For example, in 2008 at our Nabha site in India, a manual handling task was improved resulting in simplified work process, reduced risk of injury and reduction in the number of employees needed to perform the task from three people to one person. This allowed the two workers to focus on other tasks while reducing the risk of injury for all workers
- Improved audit scores through implementation of ergonomic improvement processes. For example, Kuala Lumpur improved its 'ergonomics management of risks' score from 43 per cent to 80 per cent as a result of implementing an ergonomics improvement process, and improved its overall audit score
- Significant impacts on introduction of new ergonomics improvement teams. For example at our Tianjin facility in China, six major ergonomic improvements initiated by the new team in their first months resulted in a 40 per cent reduction in reports of discomfort/injury and improved morale
- The GSK ergonomic improvement teams were given special recognition in 2008 by the European Safety and Health Council as part of a Europe wide-focus on improving manual handling
- Internal recognition of the global ergonomic community team and process as an example of new ways of working at GSK with shared global resources spanning functions, businesses and cultures. The team won an award in our 2008 'Cross sector multicultural marketing and diversity awards'

Driver safety

Our sales representatives spend significant amounts of time driving and are therefore at risk of being involved in road traffic incidents. We aim to reduce this risk as much as possible through our worldwide driver safety programme.

This includes instructions and guidelines on driver training, vehicle selection, risk assessment and accident reporting. We have a motorbike rider safety manual for employees in countries where we provide motorbikes or scooters.

Around three-quarters of GSK's commercial businesses have extensive driver safety programmes in place, including driving licence checks, guidance on the use of mobile phones, safety training and tracking and reporting incidents. We plan to extend these to our other sites.

The most common cause of fatalities and serious injuries remains driving accidents. In 2008, 15.9 per cent of the injuries with lost time were due to motor vehicle accidents, as were 19.7 per cent of the injuries without lost time.

In 2008, two road traffic accidents caused the death of two of our employees. See '[Fatalities and serious injuries](#)'.

Defibrillator programme

In 2007 and 2008 six people were resuscitated using automated external defibrillators (AEDs). An AED is a safe and easy to use portable medical device that analyses heart rhythm and delivers electric shocks to victims of ventricular fibrillation in order to restore the victim's heart rhythm to normal.

We began expanding the number of sites with AEDs when they were used in saving several lives in the US and UK in 2005 and 2006. Key personnel are trained to use AEDs in emergency situations and the equipment is installed at an estimated 100 GSK sites in Belgium, Brazil, Canada, Egypt, France, Germany, India, Italy, Japan, Mexico, Puerto Rico, Singapore, South Africa, Spain and US.

We used a risk assessment to decide which sites should have AEDs, based on factors including heart disease risks among employees, hazards on site such as chemicals or energised circuits that could cause cardiac arrest, and ambulance response times.

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› **Health and wellbeing programmes**

Corporate Responsibility Report 2008

Health and wellbeing programmes

GSK offers programmes to boost employee health and wellbeing and to create and sustain energy and engagement with their work. This in turn helps improve our business performance.

GSK helps improve employee wellbeing by offering flexible working options and health and wellbeing initiatives. These include health risk appraisals, screening for diabetes and hypertension, smoking control support, fitness and nutritional advice, and immunisations. Our prevention and screening initiatives focus on the leading causes of illness and disability among our employees which include depression, non-work-related injuries, heart disease, stroke and respiratory infections.

Increasingly we are also focusing on ways to encourage team and personal energy and resilience in times of high pressure.

Many of our employee health and wellbeing programmes have won national awards for excellence in 2008, such as the Platinum Awards from the National Business Group on Health (NBGH) in the US and the Health Promotion Board in Singapore for our team resilience programme. We received an award in 2008 from the NBGH for innovation and commitment to providing lifestyle improvement programmes designed to improve healthier lifestyles for our employees.

Energy and resilience

We define resilience to describe the skills and traits necessary for success in a high-pressure working environment. These skills and behaviours also help prevent mental illness due to stress, a leading cause of ill health and disability at work.

Energy for Performance

When employees have energy they can focus better and perform their tasks more efficiently. The Energy for Performance (E4P) programme is designed to boost energy levels and help employees invest energy in the right way, at work and at home.

Uptake was good: 1,626 employees participated in E4P workshops in 2008. Over 3,000 employees from over 30 countries had attended E4P workshops by the end of 2008. Over 80 per cent have reported significant improvement in their physical and mental performance and emotional energy. Participants found that their performance improvements persisted for at least 12 months after the workshop.

Personal resilience

We run workshops for employees who want to enhance and build their personal resilience. Focusing on improving work and home life, the programme aims to help employees increase their focus, energy and confidence while also helping to reduce tension, anxiety and fatigue. Since the programme started in 2007 over 1,100 employees have participated in the programme

Team resilience

Healthy, collaborative and motivated teams are critical to business success. The Team Resilience programme helps employees and their managers to identify sources of pressure on their teams, such as process complexity or lack of workplace flexibility or accountability.

Teams then work together to agree action plans to address their concerns. The programme helps teams take more control of their work, and eliminate or manage the sources of pressure that can lead to ill health or

inefficiency.

Since the programme began in 2003 it has been completed by teams in 51 countries, comprising 26,500 employees by the end of 2008. Participants report an 80 per cent reduction in workplace pressures, 25 per cent drop in work-life conflict and a 21 per cent increase in satisfaction with GSK as an employer.

Wellbeing and work-life balance

GSK offers programmes to improve the health of employees and their families. We find this increases employee commitment and productivity and reduces absenteeism and the cost of ill health. Support varies between countries and according to local needs. Our sites use public health and GSK data to identify high-risk areas and investments that lead to significant health and cost improvements.

Programmes often include benefits such as on-site health and fitness centres, flexible working arrangements, immunisations, regular medical check-ups, assistance to stop smoking, disease screening and management, family support services and health education. We also assist employees suffering from chronic diseases to ensure they have access to the correct long-term treatment and support. Our programmes help local healthcare services by focusing on health education, prevention awareness and management of current conditions. We have created a network of GSK employee health professionals to share health and wellbeing best practice.

GSK also supports key public health efforts such as World AIDS Day, the World Health Organization's Health Day, Tobacco Free Day and Global Handwashing Day.

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Corporate Responsibility Report 2008

Health and business continuity

We have developed contingency plans to protect our employees and business in the event of natural disasters, man-made emergencies or a flu pandemic.

These plans aim to ensure that our business can continue to function and we can continue to supply critical medicines to patients.

We have also developed and implemented programmes to protect more than 435,000 staff, their dependants and key complementary workers in over 130 countries in the event of a pandemic.

We offer employees annual seasonal flu vaccination in 95 per cent of our markets, as well as travel health programmes. We stockpile multiple antiviral medicines that can be used to prevent or treat pandemic flu. From 2009 this will include pre-pandemic vaccines, which can be administered before a pandemic has started, and a pandemic flu vaccine which will be available six months after the exact pandemic flu strain has been identified.

In the event of an outbreak we will implement special rules to prevent the disease spreading among our workforce. For example, non-essential services will close, face-to-face meetings will not be held and special cleaning and personal protective programmes will be implemented. We will restrict business travel and access to GSK sites and employees will be encouraged to work from home. We have developed a special website, accessible on our intranet and externally, that acts as a single source for all global and local flu information across GSK.

Corporate Responsibility Report 2008

Training and awareness

Training helps to create a workplace culture where occupational health and safety is taken seriously. Employees who are responsible for managing occupational health and safety issues at sites and business units receive regular training and in turn instruct employees about safe working.

We give training on our environment, health, safety and sustainability (EHSS) standards, as well as programmes such as process safety, chemical exposure protection, identifying risk, auditing and ergonomics. Sites develop and conduct training based on local needs and capabilities. Some use our internal learning tools, commercially available training programmes or locally available government or university sponsored training programmes.

We have developed a training framework that identifies gaps in employees' knowledge of health and safety and provides in-house and external training courses. Our health and safety professionals share knowledge and best practice via teleconferences, intranet communities, training programmes and discussion forums.

We raise awareness about employee health and safety issues through:

- Employee bulletins
- Announcements on our myEHS Community intranet sites
- The CEO's EHS Excellence awards programme
- Health and Safety Week, held in October to coincide with the European Health and Safety week. The event encourages employees to address potential risks at work and at home. Over 13,000 employees from 76 sites in 26 countries took part in the 2008 Health and Safety week activities.

Read more about [training on environment, health and safety issues](#).

Health and safety: Worthing EHS challenge competition

In 2008, GSK's penicillin manufacturing facility in Worthing, UK, ran four competitions to improve employees' knowledge of EHS issues.

Each month, the EHS team sent five questions to all staff on topics such as fire and evacuation, first aid, how to respond to penicillin exposure and the site's EHS targets. The following month, the questions were posed to five employees from each work unit and points were awarded for correct responses.

The team published a league table each month and every quarter the winning team was awarded £1,000 for the charity of their choice. In total, competition winners gave £4,000 to charity in 2008.

Following its success at Worthing, the competition was introduced at 12 more sites in the UK, France, China and India in 2008.

This project won second place in the 2008 CEO's EHS excellence awards in the Safety Initiative category.

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Corporate Responsibility Report 2008

Performance

Performance

Data table

Injury and illness rates

Our main health and safety measure is the reportable injury and illness rate. We also measure the number of injuries and illnesses that result in lost days, as well as the number of days lost from these injuries and illnesses. This provides an indication of the severity of the incidents, although it is only a rough guide. We have set targets to improve injury and illness rates.

Injury and illness targets

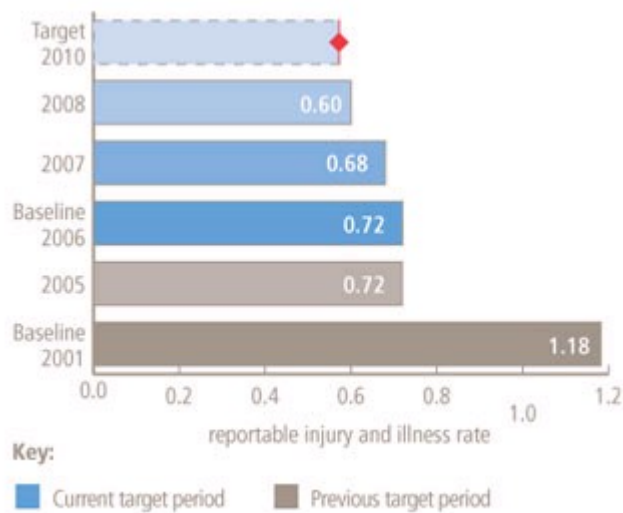
Injury and illness target	Progress 2006 to 2008
To reduce the reportable injury and illness rate by 5 per cent each year to the end of 2010	Improved 16 per cent
To reduce the reportable musculoskeletal illness and injury rate by 5 per cent each year to the end of 2010	Improved 4.7 per cent
To rank in the first quartile of an industry benchmark group	Improved ranking by one place, remaining in third quartile

Data cover GSK employees and contract workers who we directly supervise. We report separately data for contractors who work on GSK sites but supervise their own staff in the [data table](#) . Contractors' data are not externally verified.

Injury and illness data are collected from all 79 of our Pharmaceutical, Consumer Healthcare and Nutritionals manufacturing sites, 14 of our 15 vaccines sites (one site is not yet in operation), 29 of 31 Pharmaceutical and Consumer Healthcare research and development sites (two sites are considered too new to start reporting), the US and UK headquarters sites, eighteen offices and sales groups with more than one million hours worked, and 46 of the smaller offices and distribution centres.

In 2008 some sales and office sites did not report injury and illness data. We estimate that approximately three per cent of the data are missing due to one large sales group that reported injury and illness in 2007 but not in 2008.

Injury and illness rates



The reportable injury and illness rate continues to improve at an average rate of more than five per cent per year across GSK. In 2008 there were 847 injuries and 284 illnesses, a total reportable injury and illness rate of 0.6 reportable injuries and illnesses per 100,000 hours worked. This was an improvement of 16 per cent from the 2006 baseline, exceeding our target.

The reportable ergonomics-related injury and illness rate has improved 4.7 percent from 2006-2008. This is short of our target of an annual five percent improvement through to 2010, equivalent to a 10 per cent improvement over 2006 to 2008. In order to meet or exceed our target in 2009, we will increase our effort and resources in this area.

In our Pharmaceutical and Consumer Healthcare manufacturing organisation, where injury and illness rates are included in managers' objectives, the rate has improved 27 per cent from 2006 to 2008. Machinery safety projects at many manufacturing sites, and projects encouraging employee safety awareness, are examples of initiatives contributing to this improvement.

The rate of lost-time injuries and illnesses has improved only 3.3 per cent from 2006 through 2008 to 0.33 lost-time injuries and illnesses per 100,000 hours worked. However, days lost per 100,000 hours has improved 11.3 per cent indicating a lower number of days lost per incident, possibly an indicator of less severe injuries and illnesses.

In 2006 and 2007 our injury and illness performance places us in the third quartile of a benchmark industry group, which means we need to improve. Our target is to be in the top quartile of comparable industry ratings by 2012.

Read a [case study](#) on how a site has improved safety during shutdown.



SGS verified

Injury and illness causes

The most frequent types of incident overall are ergonomic, mainly musculoskeletal illnesses and repetitive strain injuries, accounting for 27.7 per cent of all injuries and illnesses. We continue to expand our [ergonomics programmes](#) to address this cause of injury and illness

The most frequent reportable injuries are slips, trips and falls, and account for 19.3 per cent of all injuries and illnesses in 2008. A team is being assigned to look into ways to address this type of injury

Injuries due to machinery accounted for 17.5 per cent of all injuries and illnesses. Our manufacturing sites are renewing their focus on machine safety to [continue improvements](#) in this area.

Road traffic accidents accounted for 13.0 per cent of all injuries and illnesses in 2008 and two fatalities detailed below. [Driver safety](#) is a continuing area of focus especially in the sales force.

Mental ill health accounts for 3.8 per cent of all injuries and illnesses but these cases result in the highest number of days lost at over 76 days per case on average or 21.5 per cent of the total number of days lost for all injuries and illnesses. This is being addressed by our [resilience programme](#).



SGS verified

Fatalities and serious injuries

Employee fatalities

Five year trend in employee fatalities

2008	2
2007	2
2006	3
2005	1
2004	2
2003	5
2002	3

In 2008, one of our sales employees was killed in a fatal road traffic accident in the Philippines. Three passengers were also killed in the accident.

One of our sales employees in India was killed in 2008 when he fell from his bicycle into the path of an oncoming motorized three-wheeler when the front tire of his bicycle was punctured.

Two GSK employees were seriously injured in another road traffic accident in India in 2008 when the vehicle in which they were being transported by a contract driver struck another vehicle, killing two people.

In 2008, there were five amputations and a serious finger injury due to accidents with moving machinery. Three employees had amputations of fingers or finger tips, one employee sustained amputation of a foot and one contract worker had an amputation of his forearm.

- An employee in the US was injured when his foot was caught between powered rollers. Reconstructive surgery proved unsuccessful and the foot had to be amputated
- A contract worker in India reached into a clothes dryer while it was rotating to remove an article of clothing, resulting in amputation of his forearm
- An employee in South Africa slipped on a wet floor and grabbed a piece of equipment to keep from falling. His weight caused a valve to close on his hand amputating his finger at the top joint and badly crushing two fingers. The severed finger was re-attached, but the crushed fingers could not be saved and were amputated
- An engineering mechanic in Pakistan placed his hand on an operating piece of machinery. A tube holder struck a finger inflicting severe damage resulting in amputation
- An employee in the US was clearing a jam on an assembly/packing machine and placed her hand on a part of the machine that closed on her finger amputating the finger tip
- A fitter in Australia suffered serious lacerations to his finger while installing a cutter on a blister pack machine. Hospital treatment was required but amputation was avoided

All of these amputations resulted in renewed emphasis on machine guarding programmes at these sites.



SGS verified

Injury and illness milestones

All GSK operations strive to work without experiencing any lost-time injuries or illnesses. We issue certificates signed by business heads to sites that reach one million hours worked without a lost-time injury or illness. Sites that reach two or more million hours worked without a lost-time injury or illness are awarded certificates signed by our Chief Executive Officer.

Small sites that do not attain the level of one million hours worked in a three- year period can obtain a certificate for three or more years worked without a lost-time injury or illness.

Milestones achieved in 2008 for hours worked without a lost time injury or illness:

- 1 million hours: 4 sites
- 2 million hours: 1 site
- 3 million hours: 4 sites
- 4 million hours: 1 site
- 5 million hours: 1 site
- 3 years: 1 site
- 5 years: 2 sites

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Corporate Responsibility Report 2008

Performance

Performance

Data table

Metric	2001	2005	2006	2007	2008
Injury and illness – GSK employees¹					
Hours worked (millions)	191.1	196.6	195.4	196.4	187.7
Fatalities	5	1	3	2	2
Number of injuries with lost time ²	751	552	565	585	522
Calendar days lost – injuries ³	16,268	11,610	11,291	11,412	10,706
Number of illnesses with lost time ²	133	81	98	97	94
Calendar days lost – illnesses ³	5,304	3,034	5,454	4,135	3,564
Number of injuries without lost time ⁴	1,079	464	448	393	325
Number of illnesses without lost time ⁴	315	319	287	260	190
Reportable injury and illness rate	0.72	0.72	0.72	0.68	0.60
Reportable ergonomic injury and illness rate	0.20	0.16	0.18	0.18	0.17
Lost-time injury and illness rate	0.31	.032	0.34	0.35	0.33
Injury and illness – non-GSK employees					
Hours worked (million)	17.0	22.8	22.9	26.1	22.0
Fatalities	0	2	0	2	0
Number of injuries and illnesses with lost time	69	98	89	59	74
Calendar days lost	754	1,575	968	924	708
Number of injuries and illnesses without lost time		275	375	400	208

1. The occupational health and safety data cover both our employees and contract workers who are directly supervised by GSK employees. We report a snapshot of injury and illness performance for the year. Cases may be added after the end of the year so prior years may change

2. Lost-time injuries and illnesses are work-related injuries and illnesses that are serious enough to result in one or more days away from work

3. Lost calendar days are the calendar days, including weekends which employees could not work because of work-related injuries and illnesses. This helps to provide a measure of the severity of injuries and illnesses

4. Reportable injuries and illnesses without lost time are incidents that did not result in time away from work (lost time). They are more serious than first aid but not serious enough to result in lost time



SGS verified

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Corporate Responsibility Report 2008

Case studies

Diversity and inclusion

Women in Science Event

We have created a global programme within GSK R&D which encourages and celebrates women in science, the Women In Science Event (WISE).

The programme started in 2004 in the UK, bringing women scientists together for a day-long event for networking, education and knowledge-sharing opportunities and has since developed in scope and attendance.

In 2007 the annual event was held simultaneously at our sites in Stevenage and North Carolina, with a series of speakers, workshops and simultaneous broadcast of the keynote speaker, an internationally renowned female scientist, to both sites.

In 2008 we held events in the UK and at two US sites in North Carolina and Delaware, with a keynote speaker and networking opportunities. We plan hold a further event in late 2009.

Additional speaking and networking events are arranged throughout the year in the UK and US, featuring leading female scientists from GSK.

Scientific Women's Scholarship programme

The Scientific Women's Scholarship programme has been in place since 1993. This programme has offered a unique combination of scholarships and mentor relationships with professional women scientists. Supported by an endowment fund, the programme is open to 29 US colleges and universities.

In 2008, 58 women scholars were selected to participate in the programme with GSK in Research Triangle Park, North Carolina. Fifty-five GSK mentors worked with the scholars to pass on their dedication, energy and passion for science to this new generation of students.

The scholars are paired with professional women scientists at GSK who serve as their mentors. These women take the scholars under their wing, provide them with expert advice and share their experiences and lessons learned over the years.

GSK volunteer mentors also work to secure internship funding and opportunities for their scholars. The internships offer insight into careers and give the scholars hands-on experience in the pharmaceutical industry.

Supporting adult literacy

Our manufacturing sites in Nabha and Rajamundy, India, are taking action to improve literacy rates among their employees. At the beginning of 2007, around ten per cent of workers could not read or write and had to use a thumb print instead of signing their name.

The sites set a goal for all employees to be able to sign their name. Employees at the Nabha factory took nearly 10,000 hours of training in total, including sessions on how to read and write in Punjabi and English. As a result of the initiative, 154 people learned to read and write and all employees are now able to sign their name.

Sessions also included areas such as family relations, AIDS awareness, good health practices and

domestic safety and budgeting.

The project received an honourable mention in the Employee Attraction, Development and Retention category at the 2008 Multicultural Marketing and Diversity Awards.

Occupational health and safety

Contractor competition improves safety during shutdown

GSK's Slough site, which makes Lucozade and Horlicks powders, holds an annual shutdown to clean and maintain manufacturing equipment.

The site's EHS team developed a programme to reduce the number of accidents occurring during the shutdown, a time of increased risk to employees and contractors when they undertake non-routine engineering activities in a short period of time. The team reviewed the log of accidents and near-misses from previous shutdowns, and held briefing meetings with supervisors and contractors to raise awareness of risks. It then ran a competition to identify and reward contractors with the best safety performance.

The initiative has contributed to a 70% reduction in minor accidents during shutdown, and there have been no reportable incidents since the competition began in 2007.

This project won third place in the 2008 CEO's EHS excellence awards in the Safety Initiative category.

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Corporate Responsibility Report 2008

Q&As

Here we respond to questions raised by our stakeholders.

As you reduce your workforce, how will you ensure that your remaining employees are not faced with additional stress in their jobs?

We recognise that stress at work is an important issue. We have established programmes to help individuals and teams deal with stress, and offer other support such as on-site health and fitness centres, flexible working arrangements, family support services and health education.

GSK aims to simplify its operating model and create a culture of individual empowerment, where each employee takes responsibility for his or her own work. We are simplifying how we work by removing processes and structures. This reduces the amount of work there is to do in some areas, and as a result fewer people are required. Empowering individuals to make decisions and carry out work without layers of bureaucracy will support this.

How will your Operational Excellence programme affect employees?

Regrettably, our Operational Excellence programme will result in job losses. We will do everything that we can to support affected employees including providing a competitive severance package and providing outplacement support such as assistance in identifying alternative employment, career counselling and retraining.

We will also work hard to ensure the programme does not have a negative impact on the morale of other staff. We have produced a guide for managers with information on how to support employees during the uncertainty, anxiety and stress encountered during major organisational change.

Why are there still relatively few women in senior management at GSK?

We are pleased that the percentage of women in management has increased incrementally over the last four years. However, we recognise that there is still room for improvement, especially in senior management positions and in roles within historically male-dominated disciplines such as science and engineering.

We aim to attract more women to GSK and to support the career development of existing employees through our flexible working programmes. These help employees balance the demands of their personal and professional lives. We also have diversity champions in each business unit as well as employee networks which support career development for women and minority groups at GSK.

Your health and safety performance is below the industry average. What needs to improve?

We know we need to improve our performance in this area. In 2008, an assessment project identified ergonomics and attitudes to health and safety in the workplace as among the main causes of injuries and illnesses. We will target our awareness and training programmes based on these results. During the year, we also launched a toolkit to help sites assess their risks and identify interventions. This has been adopted by our Pharmaceutical manufacturing business and behaviour-based safety programmes are now planned in all sites.

What progress have you made toward your 'respirator-free' target?

Results of baseline monitoring of the level of exposure to chemicals in the workplace are being used to define where new and upgraded engineering controls are needed to meet the target for employees in 80% of

operations to be able to work without needing to wear respiratory protection. We have reached 42% of operations that have achieved this level of engineering control pending completion of full verification monitoring. We continue to upgrade engineering controls to achieve 'respirator free' levels of control but for situations where engineering controls are not possible we will make sure appropriate respiratory protective equipment is used.

Corporate Responsibility Report 2008

Human rights

We are committed to upholding the UN Universal Declaration of Human Rights, the OECD Guidelines for Multi-National Enterprises and the core labour standards set out by the International Labour Organization. We are a signatory to the UN Global Compact, a voluntary global standard on human rights, labour, the environment and anti-corruption.

We believe that governments have a responsibility to define and enforce a legal framework for human rights in accordance with international laws and agreements, such as the Universal Declaration of Human Rights.

Businesses also have responsibilities. We work hard to uphold human rights within our sphere of influence, which includes [employees](#), [suppliers](#), [communities](#) and [society](#). We have most direct control over human rights in our own operations and can also influence our supply chain and wider society. As a marketer of medicines, we strive to make them as widely available as possible while running our business in a sustainable way.

High standards of human rights are important to GSK because they:

- Help us get the best from our employees
- Support our relationships with communities near our sites
- Ensure supplier contracts run smoothly and provide a reliable supply of high-quality products
- Protect our reputation

Human rights are relevant to many of the issues covered in this report. This section gives an overview of our approach.

More information on GSK and human rights

See the [human rights clauses](#) included in our contracts with suppliers

Read more about our [supply chain](#)

Read about our efforts to improve [access to medicines](#)

Read about our [investment in local communities](#)

Read about our [employment practices](#)

Read our position statement on the [Convention on Biological Diversity](#)

› Home › Responsibility › Human rights › **Employees**

Corporate Responsibility Report 2008

Employees

Our employment standards on issues such as diversity, equal opportunities and health and safety protect employees' human rights.

As an employer we are:

- Committed to providing a fair salary and good employment conditions
- Committed to providing a healthy, safe and secure workplace for all employees and contractors
- Opposed to discrimination at work and committed to promoting respect for diversity
- Committed to promoting the personal development and dignity of every employee
- Respectful of employees' right to join an independent trade union and freedom of association
- Opposed to all forms of slavery and exploitative child labour and will work with appropriate partners to address this problem responsibly wherever we encounter it.

Employees can report any concerns to their supervisor or line manager, to human resources or to our ethics and compliance office. They can also use our Global Confidential Reporting line.

Read more about our [employment practices](#).

› Home › Responsibility › Human rights › **Suppliers**

Corporate Responsibility Report 2008

Suppliers

As a buyer of raw materials, manufactured goods and services around the world, we require all our suppliers, contractors and business partners to meet the same standards on human rights as GSK.

We will not knowingly use suppliers who are responsible for human rights infringements. We conduct regular audits of existing suppliers and only engage new suppliers that meet our expectations. [Human rights clauses](#) are included in our contracts.

We consider human rights issues during routine interactions with critical suppliers (contract manufacturers and suppliers that present the greatest risk to GSK in one or more key risk areas). [EHS audits](#) of potential new and existing critical suppliers also include questions which help us identify potential breaches of the human rights clauses included in supplier contracts. Suppliers are asked for information on policies and practices relating to:

- Age limits for employees
- Discrimination against employees and the local population
- Prevention of abuse of individuals
- Wages, benefits and working hours (whether they meet the legal minimum)
- Rights for workers to organise and recognition of worker organisations

These questions do not contribute to the EHS audit score, but may be a reason not to progress business with a supplier.

Read more about our [supply chain](#).

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Corporate Responsibility Report 2008

Communities

We respect and promote the rights of all those in the communities near our operations. For example:

Local communities

GSK aims to have good relationships with all the communities around our sites and to operate in ways that do not infringe their human rights. We seek to minimise our impacts on the local environment and operate our sites safely. We aim to bring social and economic benefits to areas where we have a presence. Read more about our [investment in local communities](#)

UN Convention on Biological Diversity (CBD)

The Convention on Biological Diversity provides a framework for the conservation and sustainable use of biodiversity. It also promotes fair and equitable sharing of the benefits arising from the use of genetic resources. GSK supports the CBD's role.

We are not currently involved in any bioprospecting activity. As a result, we have no access and benefit-sharing agreements in place.

It is possible that in future we may undertake development work using natural genetic resources indigenous to a particular country. In that instance, access to those resources would be obtained in accordance with the CBD, as reflected in local laws. We would ensure that relevant parties received agreed benefits from the use of the resources, for example monetary payments.

Read our position statement on the [Convention on Biological Diversity](#)

Read our position on [protecting biodiversity](#).

Corporate Responsibility Report 2008

Society

The UN Declaration of Human Rights states that ‘everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including medical care’.

Improving healthcare is one of the greatest challenges we face, particularly in the developing world. GSK contributes to healthcare in the developing world by discovering new treatments and vaccines. We also make a wide range of our products more affordable in developing countries through preferential pricing and voluntary licence agreements with generic manufacturers.

We engage with governments, multilateral agencies, NGOs and other pharmaceutical companies to help improve access to medicines. Read more about our efforts to improve [access to medicines](#) and our [community investment](#) initiatives.

Corporate Responsibility Report 2008

Activities in sensitive countries

Some stakeholders are concerned about GSK's business activity in countries with poor human rights records, such as Burma (Myanmar), North Korea and Sudan. We share the UN's belief (see box) that people should not be denied access to medicines because of the regime operating in their country.

We aim to provide medicines and vaccines in all countries that need and wish to purchase them. We observe any trading controls required by law in the countries where we operate.

In many nations our long-standing commitment and presence pre-date their oppressive regimes and the subsequent introduction of measures such as trade embargoes. During periods of government-imposed trade embargoes, we have continued operations (subject to any specific legal restrictions) due to the need for our products.

In sensitive countries, as in all countries where we operate, we support and are committed to upholding the Universal Declaration of Human Rights and the core standards set out by the International Labour Organization. We observe all local laws and regulations.

UN statement on the right to the highest attainable standard of health

Paragraphs relating to access to medicines in sensitive countries:

- Paragraph 12: 'Health facilities goods and services must be accessible to everyone without discrimination, within the jurisdiction of the State party.'
- Paragraph 41: 'Parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment. Restrictions on such goods should never be used as an instrument of political and economic pressure'
- Paragraph 42: 'While only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society - individuals, including health professionals, families, local communities, intergovernmental and non-governmental organizations, civil society organizations, as well as the private business sector - have responsibilities regarding the realization of the right to health. State parties should therefore provide an environment which facilitates the discharge of these responsibilities.'

Read the full [UN statement for the right to the highest attainable standard of health](#).

› Home › Responsibility › [Public policy and patient advocacy](#)

Corporate Responsibility Report 2008

Public policy and patient advocacy

The pharmaceutical industry is highly regulated. Government policy and legislation can have a significant impact on our business so it is important that we engage with governments and other stakeholders in the legislative and policy process.

Through our public policy activity we work towards legislation and policy that encourage scientific innovation and balance the interests of business with those of other stakeholders. We also work with [patient groups](#) to help give their members a voice in the healthcare debate.

We believe that we conduct our advocacy work responsibly and make a valuable contribution to the debate on public policy issues that impact our business, particularly those relating to research and development, the use of pharmaceuticals and healthcare.

We aim to increase stakeholder trust in GSK and, by being transparent about our lobbying and public policy work, to address concerns from some stakeholders that the pharmaceutical industry has too strong an influence over governments. We publish our annual public policy activity on this website and report on our memberships of trade associations, our political contributions and US lobbying expenditures. We also publish information on our work with patient groups, including details of the [funding we provide](#).

We provide information on our approach to working with doctors and healthcare professionals in the [Research practices](#) and [Ethical conduct](#) sections of this website.

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Corporate Responsibility Report 2008

Our approach to external affairs

Employees involved in public policy work must abide by our [Employee Guide to Business Conduct](#) which is based on three principles:

- Partnership: we are committed to working with governments and regulatory authorities in a constructive way
- Communication: as well as giving our views, we take on board any concerns from external audiences. This enables us to assess and improve our business practices
- Integrity: we base our public policy work on research, analysis and facts. We respect other opinions and look for constructive solutions. All of our external affairs work must be in line with our [Code of Conduct](#) and other relevant policies including those related to competition law, preventing corrupt practices and political contributions

We have external affairs teams in our major regions who monitor proposed legislative reforms and policy developments. They meet regularly with government officials and other stakeholders, for example multilateral organisations and NGOs, to explain our views on a range of public policy issues. We tailor our approach to suit different cultures and political traditions in the countries where we engage in the public policy process, while ensuring that our position in these discussions is fully consistent with our public policy statements. We ensure that the standards set out in our Guide to Business Conduct are applied globally.

Lobbying on issues affecting the whole pharmaceutical industry is sometimes conducted through trade associations. We may also hire professional lobbyists to support our public policy work.

We have a Political Contributions Policy governing our contributions to political candidates and parties.

Trade associations

GSK is a member of many trade and industry organisations, including:

- Association of the British Pharmaceutical Industry (ABPI)
- BioIndustry Association (BIA)
- Biotechnology Industry Organization (BIO)
- British Pharma Group (BPG)
- Confederation of British Industry (CBI)
- European Federation of Pharmaceutical Industries (EFPIA)
- International Chamber of Commerce (ICC)
- Intellectual Property Owners Association (IPO)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Japan Pharmaceutical Manufacturers Association (JPMA)
- Organisation of Pharmaceutical Producers of India (OPPI)
- Organization For International Investment (OFII)
- Pharmaceutical Research and Manufacturers of America (PhRMA)

It is important that any lobbying conducted through trade associations reflects our policies and values. We work with other members to help set policies and may also attend lobbying meetings with governments and other stakeholders.

Sometimes we do not share the same views on a particular issue as other members of a trade association. If a trade association adopts a public policy position that we do not agree with, we will not participate in advocacy activity related to that subject. Senior GSK managers sit on the boards of the majority of industry trade associations of which we are members and raise any concerns we may have about a particular advocacy position.

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Corporate Responsibility Report 2008

Public policy activity in 2008

We engage with governments and other stakeholders on a wide range of issues that affect our industry.

These are some of the key issues we engaged on during 2008:

- [Access to healthcare and disease prevention](#)
- [Research practices](#)
- [Patient safety](#)
- [Intellectual property](#)
- [Pricing and competitiveness](#)

We [publish our position](#) on key issues relating to corporate responsibility, including:

- Access to medicines in developing countries
- Research and development
- Intellectual property
- The environment
- Public health
- Competitiveness
- Pricing, reimbursement and market access

We are happy to discuss our position on these or any other issues with legitimate parties. Contact our corporate responsibility team at csr.contact@gsk.com.

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Advocacy on healthcare and disease prevention

Global activity

Safeguarding timely and unrestricted access to influenza viruses

Organisations engaged: World Health Organization (WHO), key developed and developing country governments (including countries affected by the H5N1 strain), EU institutions

Industry associations involved: EFPIA (EVM), IFPMA (IVS), PhRMA

GSK position: The influenza virus is very unstable and can mutate quickly. Governments must remain vigilant to the emergence of new strains of the virus and must share virus strains freely with other governments. The free sharing of viruses is in the best interests of global public health as it enables governments to develop vaccines which may prevent an influenza pandemic. The WHO's Global Influenza Surveillance Network recommends the content for influenza vaccines twice a year and will act as a global alert mechanism in the event of a pandemic. The international community should unconditionally support the Network, which relies on receiving information on virus strains from governments.

Despite the importance of timely and unrestricted access to viruses, Indonesia stopped sharing influenza viruses with the WHO in 2007 insisting on 'access and benefits' in exchange for viruses. The international community – including the vaccine industry – spent much of 2008 finding a way to help developing countries prepare for a pandemic. Some progress was made towards agreeing an effective solution at the InterGovernmental Meeting in Geneva in December 2008. GSK is hopeful that a solution that will ensure speedy access to the pandemic virus while assuring developing countries of the support they require to secure access to pre-pandemic and pandemic vaccines will be agreed at the next IGM in May 2009.

US activity

Investment in chronic disease prevention and treatment

Organisations engaged: US Department of Health and Human Services, Office of the First Lady, US Congress, White House, state legislators, Governors' Offices, various state health agencies

Industry associations involved: PhRMA

GSK position: Chronic diseases such as diabetes, heart disease and lung disease account for three-quarters of healthcare spending. Relatively little is invested in prevention even though many chronic diseases and their costly complications are preventable and increasingly manageable. We are advocating a three-part approach to achieving lower-cost, higher-quality healthcare: increasing prevention, improving treatment, and accelerating research into better treatments for chronic disease. Healthcare providers need incentives to promote preventative services that address major causes of chronic disease such as obesity and smoking. Healthcare policy needs reform to better encourage and reward medical research into improved treatments for costly, unmet medical needs such as Alzheimer's disease. Preventing and better managing chronic diseases will reduce overall healthcare costs in the long term.

Supporting a petition to protect Americans from fraudulent weight loss claims

Organisations engaged: US Food and Drug Administration

Industry associations involved: None. See below for the healthcare associations involved.

GSK position: In the US, two-thirds of adults are overweight or obese, increasing their risk of illnesses such as cancer, heart disease and type 2 diabetes.

There are dozens of dietary supplements on the market in the US which manufacturers claim can help people to lose weight. Most of these claims are not reviewed by the Food and Drug Administration (FDA) and are not supported by credible scientific evidence. Ineffective weight loss products can prevent people getting the support they need to lose weight. The US Federal Trade Commission's Consumer Fraud Survey recently highlighted that there were more victims of fraudulent weight-loss products, 4.8 million American consumers, than any of the other frauds covered by the survey.

GSK manufactures *alli*, the only over-the-counter weight loss product that has gained FDA approval for safety and efficacy. In April 2008, GSK and three research and advocacy organisations (the American Dietetic Association, the Obesity Society and Shaping America's Health) submitted a citizen's petition to the FDA, asking it to provide greater protection for Americans from fraudulent weight loss claims.

The petition requests that the FDA treats weight loss claims in the same way as unsubstantiated claims of efficacy against disease, which are not permitted under the Dietary Supplement Health and Education Act. The petition calls for the FDA to require rigorous scientific evidence for any such claims. It also aims to raise awareness and educate the public about the issue of fraudulent weight loss products.

In a separate development, in January 2009 the FDA demanded the recall of a large number of weight-loss supplement products and warned a number of companies that they may be liable for criminal charges. Among the FDA's complaints against 69 supplement products in the US was the illegal inclusion of regulated, unapproved or withdrawn prescription pharmaceuticals, including sibutramine and rimonabant (weight loss), phenytoin (anti-seizure) and phenolphthalein (laxative, previously withdrawn by the FDA due to carcinogenicity). GSK supports and will continue to work with the FDA to help protect the public from false and unsubstantiated weight loss claims and possibly unsafe products.

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Advocacy on research practices

We regularly engage with policy makers and other stakeholders on issues relating to research practices and the research environment. Read more about [research practices](#).

Global activity

Advocacy on revisions to the Declaration of Helsinki

Organisations engaged: World Medical Association, American Medical Association

Industry associations involved: BIO, IFPMA, PhRMA

GSK position: The Declaration of Helsinki sets out the ethical principles for the conduct of research on human subjects. The Declaration was revised in 2008 by the World Medical Association. We urged the World Medical Association to resist changes that make the document more detailed and prescriptive, because we believe they create confusion and conflict with other, more detailed guidance such as ICH guidance on Good Clinical Practice.

Shaping the scope of the International Regime on Access and Benefit Sharing

Organisations engaged: Secretariat to the Convention on Biological Diversity (CBD), Ad Hoc Working Group on Access and Benefit Sharing, UK DEFRA, DG Trade (European Commission), national European governments, US government.

Industry associations involved: BIO, BPG, EFPIA, ICC, IFPMA, PhRMA

GSK position: The Convention on Biological Diversity (CBD) was signed in 1992. It has three main goals, including the fair and equitable sharing of benefits arising from the use of 'genetic resources'. GSK believes that the best way to achieve the CBD's access and benefit-sharing objectives is for countries to introduce national laws governing access to their genetic resources and for mutually agreed contracts to define how any benefits arising from their use should be shared. This approach allows national governments the flexibility to develop guidelines that will best serve their national interests, and enables users of the guidelines to reach agreements that are appropriate to each individual case.

Notwithstanding GSK's support for national legislation we recognise the CBD's mandate to 'elaborate and negotiate an international regime on access and benefit-sharing'. We believe that the resulting regime, currently under discussion within the CBD, should be consistent with the CBD's treaty and objectives. It should create no new obligations for CBD signatories and should not be applied retrospectively. It should provide guidance to governments and other CBD members on how to achieve access and benefit-sharing objectives, rather than prescribing rules. It should adopt a sectoral approach and not seek to enforce a 'one size fits all' solution on all industries. It should apply only to genetic resources as defined in the CBD, not a broader class of materials. It should not extend to human genetic resources, nor to derivatives, or pathogens.

Read our [position statement on the Convention on Biological Diversity](#).

European activity

Advocacy on the European Animal Directive

Organisations engaged: European Commission

Industry associations involved: ABPI, EFPIA

GSK position: The European Animal Directive, originally introduced in 1986, governs the use of animals for experimental or other scientific purposes. It aims to establish a framework for all animal research activities within the EU. The European Commission has published a draft revision of the Directive which controls the use of laboratory animals and sets minimum standards for their housing and care.

GSK welcomes the review of the Directive and recognises the need for it to be revised to reflect advances in animal welfare and science. We welcome many of the recommendations in the draft revision, many of which are already integrated into our current practices. For example, we welcome the rules relating to the replacement, reduction and refinement in the use of animals in research (known as the 3Rs), and the need for a permanent or standing ethic review body in the establishments that use animals in research.

It is essential that any legislative changes achieve high animal welfare standards while supporting an environment that allows research that leads to new medicines and vaccines to meet patients' needs. In this regard we have a number of concerns related to the restrictions on the use of non-human primates to those diseases that are considered life-threatening or seriously debilitating and the reuse of surgically instrumented animals which is likely to result in an increased number of animals where procedures are mild to moderate.

Read our [position statement on use of non-human primates in research](#).

Supporting a new approach to pharmacovigilance in the EU

Organisations engaged: European Commission, European Medicines Agency, UK government

Industry associations involved: ABPI, EFPIA

GSK position: GSK seeks a new approach to pharmacovigilance regulation in the EU that will allow pharmaceutical companies and regulators to focus their resources on safety evaluation activities instead of compliance with unclear and complex regulatory demands.

New pharmacovigilance legislation should contain clear and concise provisions to simplify, strengthen and provide legal certainty to the EU legislative framework for pharmacovigilance. Specifically, it should:

- Contain a single set of simplified rules, and a single reporting point, for adverse drug reactions in the EU
- Require the reporting of all serious cases when an electronic reporting system is implemented
- Contain clear and flexible provisions that allow individual companies to appoint the number Qualified Persons for Pharmacovigilance (QPPVs) they require
- Provide consistent standards for inspections of company pharmacovigilance departments by EMEA and EU member state authorities

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Advocacy on patient safety

US activity

Legislation on prescription medicine imports

Organisations engaged: US Department of Health and Human Services, Food and Drug Administration (FDA), US Congress, state Boards of Pharmacy, state legislators, Governors' Offices

Industry associations involved: BIO, PhRMA

GSK position: Current US law prevents prescription medicines from being imported to the US unless they have safety and cost savings certifications from the Secretary of Health and Human Services. Pending legislation would remove the safety and savings certification requirements, making it easier to legally import medicines. This would undermine the FDA's ability to protect the US distribution system from counterfeit and unsafe medicines that could harm patients. There is also no guarantee that consumers would save any money, as the Department of Health and Human Services has found that third-party payers such as insurance companies are most likely to benefit.

GSK supports safer alternatives to help patients afford their medicines. The Partnership for Prescription Assistance (PPA), for example, gives access to more than 475 public and private patient assistance programmes, for patients who lack prescription drug coverage. Read more about GSK's [Patient Assistance Programs](#).

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Advocacy on intellectual property

US activity

US patent system reform – Federal legislation

Organisations engaged: Patent and Trademark Office (PTO), US Congress

Industry associations involved: BIO, Coalition for 21st Century Patent Reform, PhRMA

GSK position: A patent law framework that provides business certainty over a long period and promotes investment is essential to the research-based pharmaceutical industry and a wide range of other manufacturers that have long lead times from research to market. The US Congress is considering patent reform legislation that could have a negative effect on the current framework. Specifically, the proposals fail to strike an appropriate balance in the areas of restricting abuse of the inequitable conduct doctrine (which encourages infringers to try to prove in litigation that a patent was improperly obtained so that a completely valid patent may be held ‘unenforceable’) and the allocation of damages for infringement. In addition, giving the PTO substantive rule-making authority removes responsibility for establishing substantive patent law from Congress and innovation policy from the public debate.

GSK is working with a coalition of research-based companies, manufacturers, universities and small inventors to promote US patent reform that stimulates investment in research and strengthens the patent system. We support patent reforms that are clear, provide business certainty, improve the quality of patents and remove subjectivity in litigation issues.

Asian activity

Compulsory licensing in Thailand

Organisations engaged: Thai government including the Thai Ministry of Public Health; academics, NGOs and members of the business community in Thailand; World Health Organization; international NGOs; US and EU member state

Industry associations involved: BPG, EFPIA, IFPMA, PhRMA, PReMA

GSK position: In late 2006 the Thai government issued compulsory licences on three pharmaceutical products. Four more compulsory licenses for oncology products were announced just prior to the previously elected government leaving office in early 2008 of which two were implemented. We support the Thai government’s public health goals and want to help improve health outcomes for people in Thailand. Compulsory licences are a legitimate policy option for the Thai government but they should not be used as a routine policy tool or for commercial purposes. Rather than unilaterally using compulsory licences to increase access to medicines, we believe it is more effective to engage in dialogue with industry and other stakeholders to find sustainable ways to address healthcare issues, including access to medicines. We hope to reinforce this dialogue with governments and other stakeholders in the future.

Healthcare and intellectual property in India

Organisations engaged: Relevant agencies in the Indian government; members of the pharmaceutical industry and the wider business community in India; Indian academics and civil society representatives; US and EU member state governments; European Commission

Industry associations involved: BPG, EFPIA, OPPI, PhRMA

GSK position: We believe that India's tremendous strengths in science and pharmaceuticals, coupled with its rapid economic growth, offer the government an opportunity to tackle some fundamental characteristics of its healthcare system and policy base. Further improvements in India's intellectual property (IP) regime to the level provided in the EU and US could further encourage investment in collaborative R&D. Issues of IP rights are not the fundamental barrier to access to healthcare and we believe that reform and increased investment in the Indian healthcare system should be a priority. We want to be active partners in addressing these challenges.

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Advocacy on pricing and competitiveness

European activity

Guiding principles for relative effectiveness assessments and pricing

Organisations engaged: EU member states, the European Commission, stakeholder representatives participating in the EU's High Level Pharmaceutical Forum

Industry associations involved: EFPIA, EuropaBio

GSK position: Government funding decisions are often based on an assessment of a medicine's clinical or cost effectiveness. We believe that these value assessments should be conducted transparently and in a timely manner and all key stakeholders should be able to submit evidence for the assessments. Governments should allow greater pricing flexibility when the long-term value of a medicine is not certain at launch.

GSK, representing EFPIA, strongly supported the Good practice principles for relative effectiveness assessments which were developed within the framework of the EU's High Level Pharmaceutical Forum (HLPF). These were adopted in 2008 along with the Guiding principles for good practices implementing a pricing and reimbursement policy. EFPIA's Health Technology Assessments principles, which the industry has previously adopted and that GSK helped to develop, are aligned with the principles adopted by the HLPF.

Improving regulations that impact on the pharmaceutical industry's competitiveness in the UK

Organisations engaged: UK government and the European Commission

Industry associations involved: ABPI, CBI, Institute of Directors

GSK position: The pharmaceutical industry is one of the most highly regulated industries in Europe. GSK supports strong regulation but has been working with the UK government and the European Commission to propose ways to simplify regulations while achieving the same policy goal. This aligns with the aims of the UK government and European Commission to reduce the regulatory burden placed on industry.

GSK submitted a series of 50 proposals to the UK government for simplification of existing regulations. We also made a similar submission to the Commission, focusing on regulations that originate at a European level.

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› **Political contributions and lobbying expenditures**

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Political contributions and lobbying expenditures

In late December 2008, GSK announced a new global policy to voluntarily stop all corporate political contributions.

Prior to this, GSK made political contributions with corporate funds in countries where they were authorised by law and were culturally appropriate, such as the US and Canada. The new policy ensures that no such contributions will be made in the future.

Contributions to political parties or other political organisations in the European Union were prohibited by GSK policy prior to this change. See the corporate governance section of our [Annual Report](#) for more information.

Prior to this policy change, in 2008 we contributed £347,000 to political organisations in the US and Canada.

In the rest of the world, contributions have been very rare and of low monetary value. These contributions were agreed by local management and approved by GSK's international legal operations and corporate government affairs department. All contributions were made in compliance with local laws and customs.

Contributions in the US

In the US, corporate contributions to party affiliated committees and candidates running for federal office are prohibited by law. State and local political campaigns are financed through a variety of sources including contributions from companies, individuals, NGOs and local campaign committees. By supporting pro business candidates, corporate contributions are an accepted and legal means for corporations to have a voice in the political debate. However, to ensure that there is no implication whatsoever that such contributions provide GSK with any special privileges, the company changed its policy in late December 2008 to prohibit any corporate contributions to political candidates.

Contributions to state candidates

In 2008 prior to the change in policy, GSK donated £319,000 to candidates for state-held offices. Contributions were only made where permitted by law and were not made on the basis of political party.

Contributions were made to candidates who support an environment that appropriately rewards high-risk, high-investment industries and who work to preserve free market principles and intellectual property rights. We made approximately 46 per cent of our contributions to Republican candidates and 54 per cent to Democratic candidates. All states publish information disclosing the names of contributors and the amount of contributions that are at or above an established threshold.

Political Action Committee contributions

In accordance with the Federal Election Campaign Act, GSK established a Political Action Committee (PAC) that facilitates voluntary political contributions by eligible employees.

The PAC is not controlled by GSK. Decisions on the amount and recipients of contributions are made by participating employees exercising their legal right to pool their resources and make political contributions. All PAC contributions are voluntary and contributions are subject to strict limitations. For example, the GSK PAC may not contribute more than \$5,000 per election to an individual candidate for federal office.

The PAC is run by a governing board of participating GSK employees from across the company. As required by law, PAC contributions are reported to the Federal Elections Commission (FEC). In 2008, the GSK employees' PAC contributed £539,359 - 58 per cent to Republicans, 40 per cent to Democrats and two per cent to unaffiliated or other party candidates running for state and federal offices.

Contributions in Canada

In 2008, GSK donated £28,000 in Canada to political candidates in those provinces where it is legal.

Lobbying expenditure

Europe

In December 2008, GSK signed up to the European Commission's new code of conduct and the voluntary register of organisations working to influence European Union institutions. In the 'transparency register of interest', we declared the costs associated with lobbying of the EU institutions to be in the range of €750,000-800,000 in 2008. This includes running of the Brussels advocacy office, salaries, external events and educational materials. This figure takes into account the proportion of employee time spent on interest representation.

US

We report our US lobbying expenditures to the US Congress in accordance with the Lobbying Disclosure Act 1995. We spent \$6.99 million in federal lobbying activities in the US during 2008. This includes the costs of salaries and benefits for all employees registered to lobby the US government; use of lobbying consultants; support for lobbying contacts such as planning activities and research; running the GSK Washington DC government affairs office; support staff; and the portion of trade association fees associated with federal lobbying. We also report our state lobbying expenses, in line with applicable state laws.

Contributions to policy groups

GSK contributes to various groups which provide a forum for policy analysis and debate. This includes think tanks in a number of countries, and '527' organisations in the US.

Corporate Responsibility Report 2008

Patient advocacy

Patient groups are non-profit organisations founded by patients, care-givers, family members and health professionals.

They provide their members with information about their condition and guidance on how to live with their disease. They engage with healthcare providers, governments and the media to promote improved treatment and services for patients and campaign for change on issues that affect patients' and carers' lives. Some carry out vital research into the causes and potential treatments for specific conditions.

GSK works with a wide range of patient groups in disease areas such as cancer, asthma, diabetes, Alzheimer's disease, multiple sclerosis and HIV/AIDS. GSK and patient groups share a common concern that healthcare systems should focus on preventing, treating and managing disease. Both parties believe that patients should have access to quality medicines, services and information on disease.

Patient groups are important stakeholders for GSK and we engage with them as part of our commitment to be a patient focused company. Our relationships with patient groups are mutually beneficial. They help us to better understand patient needs and their illnesses. We work with patient groups to strengthen their support for patients throughout their illness, from diagnosis to chronic treatment and end-of-life care. We also [help these groups give patients the ability to have their voice heard](#) in the healthcare debate, alongside other stakeholders.

Our approach

We support patient groups across the world in a number of different ways. These include:

- Providing core funding to support the day-to-day running of the group
- One-off donations to help patient groups conduct a specific event or activity, for example a breast cancer awareness day
- Educational support
- Training staff in management skills and disease education
- Working together on disease awareness/prevention projects

Our relationship with each patient group is defined by a written agreement specifying how the group will use our funding to benefit its members.

Some stakeholders are concerned that pharmaceutical companies use patient groups as a way of marketing their products. Our support for patient groups is about the bigger agendas that dictate whether or not new medicines are made available to patients, and whether patients have access to the kind of treatments that they need. We are committed to maintaining the highest ethical standards and transparency in this area.

We have developed detailed guidance and Standard Operating Procedures (SOP) for employees in each of our major regions. These policies, used in conjunction with GSK's patient advocacy manual, ensure that GSK employees who work with patient groups comply with applicable laws and regulations and our standards. [Read a summary of our SOP.](#)

All employees, and outside agencies working for GSK that are likely to interact with patient groups, must abide by our guidelines and SOPs. We provide training so that our employees understand our requirements. For example in 2008, around 70 marketing employees in the US attended a webinar on our guidelines and SOPs.

Our patient advocacy teams in Europe and our Asia Pacific, Japan and Emerging Market region coordinate interaction with patient groups and adherence with our policies and global principles. In the US, patient advocacy is decentralised across a number of functions including state government affairs, R&D, communications and marketing, but is coordinated by the state government affairs group.

Employees in all regions can access our patient advocacy resource intranet site. In Europe, we also publish a newsletter to raise employee awareness about internal and external developments relating to patient groups.

In 2007, we conducted a review of departments that have relationships with patient groups in the US. This led to the development of an interactive patient group database that tracks our relationships with patient advocacy groups and the projects we support. This will enable employees to learn about past interactions with patient groups and the type of projects supported. It will help us to allocate resources to patient groups more efficiently. The database will be launched in 2009.

Encouraging independence

We believe that patient groups should be independent and we encourage them to seek financial support from as wide a range of organisations as possible. We ensure that the funding we give to patient groups is appropriate to their size.

Our guidelines state that GSK funding should make up no more than 25 per cent of a group's overall income. In the vast majority of instances the actual percentage is much lower. We allow some exemptions to the 25 per cent cap as some of the groups supported have limited incomes, so a small donation (for example £1,000) would exceed the limit, and because some groups have difficulty attracting funding because of the nature of their activity (for example, providing needle exchange for drug users). These cases must be approved by the general manager of each local operating company. We also encourage patient groups to seek funding from multiple sources and we hold workshops on how to make funding applications.

Corporate Responsibility Report 2008

Transparency

We believe that being transparent about our support for patient groups helps build trust with our stakeholders, including the groups themselves.

We publish information on all our work with patient groups in our Europe and Asia Pacific, Japan and Emerging Markets regions, as well as information on our support for patient groups working globally, including details of the funding received. See details of our [funding for patient organisations](#).

We were the first pharmaceutical company to publish this level of information and it goes beyond industry codes of practice that at most require a list of the groups funded.

Detailed information for GSK [Australia](#) and [Canada](#) can be found on their websites.

In the US, from February 2009 we will report educational and charitable grants provided to health-related organisations, including hospitals, teaching institutions and patient advocacy groups. The report will be updated quarterly.

See details of our [funding for patient organisations](#)

Working with patient groups

Our Standard Operating Procedures state that:

- Any involvement with a patient organisation must be declared and transparent
- GSK must neither seek patient organisation endorsement for its medicines, nor pay patient groups to endorse GSK services
- Medicines must not be promoted to patient organisations
- GSK must not create patient organisations, must not be the sole funding sponsor of a patient organisation, and should not provide more than 25 per cent funding to patient organisations. Exceptions may be allowed in the case of rare disease focus or start-up funding up to 50 per cent. However, must be agreed with directly with the local country or region general manager or head of regional government affairs
- GSK must not seek a direct return on investment from the funding of a patient organisation
- Any information on GSK pipeline compounds must be factual and non-promotional and provided to patient organisations as part of a scientific dialogue
- It is acceptable for GSK clinical trials or medical personnel to work with patient organisations to ensure optimal clinical trial recruitment, and to consult them on clinical trial design and protocols
- GSK must not directly sponsor patient organisation representatives to attend medical congresses, conferences and other healthcare professional events. Exceptions include where the representative is invited to speak at the conference or where the medical congress has a specific workstream designed for patients. GSK may sponsor representatives to attend non-medical congresses
- GSK may pay a modest honorarium or speaker fee to the patient organisation that an advisory board member or speaker represents
- Any third party working for GSK on a given project must be fully transparent about this relationship when interacting with a patient group on the project

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Understanding patients

To help us better understand patient needs we have set up advisory boards in the US and Europe that include representatives from a wide range of patient groups.

The advisory boards have independent chairs, meet regularly and are attended by senior GSK managers. The boards enable the voice of patients to be heard at the highest levels of GSK. They also allow us to access the views of patient groups and we seek feedback on subjects such as clinical trials, pharmacogenetics, information provided to patients and ethical issues.

In all regions we invite speakers from patient groups to meet GSK employees, including scientists, researchers and marketers, to discuss issues affecting their members. As well as improving our understanding of patient needs, it shows GSK employees the difference their work can make to people's lives. Read about how our [Focus on the Patient initiative](#) is helping us to better understand patient needs and develop better medicines.

We also engage with patient groups through Patient Advocacy Leaders' Summits (PALS). These bring groups together to discuss health policy concerns, develop new skills and/or ways to expand their influence. PALS can also give patient groups the opportunity to learn about GSK and tell the company how it can better support their work. In 2008 we were involved in running a total of 33 summits: 14 in nine European countries, one in Japan and 18 throughout the US.

Discussions at the 2008 PALS focused on a broad range of issues, including:

- Efforts to establish patient-centred healthcare (Japan)
- Availability of medicines and the role of patients and patient organisations (Netherlands)
- Clinical trials (Germany)
- Healthcare as a political priority and healthcare funding impacts on patients (Estonia)
- Healthcare system reform and patient rights (Czech Republic)
- Healthcare financing and patient access to healthcare in an economic downturn (Latvia)
- Patient input to the national strategy for cancer (Bulgaria)
- Communications strategies for patient associations (France)
- Importance of innovation, intervention and prevention in health care reform (US)

In 2008, GSK co-sponsored the European Patient Forum's annual conference in Brussels with the pharmaceutical company Pfizer. This brought together approximately 100 patient groups and other stakeholders to exchange ideas about improving healthcare and the role of patient organisations.

We intend to hold a further 20 PALS summits in the US in 2009 and in Europe we will support a similar number of PALS as in 2008. We also plan to have several regional PALS meetings in our Asia Pacific and Emerging Markets regions.

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› **Developing industry standards**

Corporate Responsibility Report 2008

Developing industry standards

We are taking a leadership approach in developing industry standards for engaging with patient groups.

In the US, we are working with the industry trade group PhRMA to develop guidelines for its members on working with patient groups which will be launched in May 2009. We also helped the National Health Council to develop guidelines for patient groups to follow when working with companies. Patient group members of the Council are required to follow the guidelines, which were launched in 2008.

Update August 2009

Since the publication of this report, our work with PhRMA to develop guidelines on working with patient groups has stopped. All companies did not agree on the need to develop industry wide guidelines, however PhRMA supports the National Health Council guidelines for patient groups when working with companies. GSK remains committed to developing industry standards for engaging with patient groups.

In Europe, we were closely involved in the development of the first EFPIA code of practice on relationships with patient organisations, which came into effect in July 2008. The code bears a close resemblance to GSK's policies on working with patient groups, and a senior GSK manager chaired the EFPIA Patient Relations Network that originally developed the code.

The EFPIA code contains many of the requirements of GSK's policies. It states that companies cannot promote their medicines to patient groups, there must be written agreements in place for all interactions with patient groups, and companies must list all patient groups they work with and describe the nature of any support.

We have been involved in training other companies to prepare to implement the code at the European level and locally in countries including Finland and Germany.

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Corporate Responsibility Report 2008

Advocacy activity in 2008

Here we describe some of the advocacy activities we undertook in 2008 in partnership with patient groups.

Global recruitment for lung cancer vaccine clinical trial

We partner with the Global Lung Cancer Coalition (GLCC), a body comprising 23 not-for-profit groups from around the world, that promotes understanding about lung cancer and advocates for patients' right to early detection, better treatment and supportive care. GLCC members are also committed to campaigning for more lung cancer research and an increase in enrolment of patients into clinical trials. As with many other new therapy trials, the GLCC network helped us in the recruitment of patients for the phase III clinical trial of our therapeutic lung cancer vaccine. We raised awareness about the trial through GLCC members who disseminated information to lung cancer patients, calling for those who had recently undergone surgery to ask their doctors about entering the study. We hope that the vaccine, to be given to lung cancer patients after surgery, could help stop tumours returning and reduce the effect of the disease.

Chronic hepatitis B in Asia Pacific

In 2008 we continued our campaign in Asia Pacific to raise awareness about chronic hepatitis B, increase the number of people being tested and diagnosed, and improve compliance with antiviral medication. Around 300 million people in the region live with the disease. GSK and a patient consortium developed a patient engagement programme and created resources to support healthcare professionals and encourage patients to adhere to their treatment regimes, including an SMS service that reminds patients about how to manage their condition. We piloted the programme and resources in Korea in 2008, and will roll them out across ten more countries by World Hepatitis Day in May 2009.

Raising awareness about breast cancer treatment times in Canada

Through our partnership with the Canadian Breast Cancer Network (CBCN), GSK helped raise awareness about unacceptable treatment waiting times and differences in access to breast cancer care across Canada's provinces. In 2008, the CBCN published a report that revealed waiting times of up to five years from the initial application by the manufacturer until patients could access a new breast cancer drug. The report provoked extensive national media coverage and a strong call to action for policy makers, politicians, concerned organisations and individuals to work together to address these issues.

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Corporate Responsibility Report 2008

Q&As

How do you make sure that your lobbying activity doesn't contradict or undermine your corporate responsibility work?

Corporate responsibility is central to our business. We aim to ensure that all our lobbying activity reflects the values set out in this report as well as being sensitive to the views of our stakeholders. Employees involved in public policy must abide by our Employee Guide to Business Conduct which commits them to acting with honesty and integrity.

We have well-established public policy positions. These are developed through wide consultation and are approved by our Corporate Executive Team. Employees who lobby for GSK are closely involved in developing these positions. We believe transparency is key to building trust with our stakeholders and we disclose our [public policy positions](#) on our website.

Does GSK make political contributions through so-called '527' organisations?

Yes, we support a number of '527' organisations such as the New Democratic Network. GSK has no influence over how '527' organisations use GSK contributions; however, our support enables the organisations to develop and advocate policy positions and us to participate in their functions and to debate and discuss important issues for GSK with other organisations, the public and policy makers.

Contributions to '527' organisations are not defined as political contributions and so are not subject to our policy to stop all corporate political contributions.

Isn't your support for patient groups just another marketing tool?

No. GSK neither promotes medicines to patient groups nor would ever ask a patient group to endorse a GSK medicine. We work with patient groups in a number of areas, including improving how clinical trials are run, disease awareness initiatives, and on the bigger agenda of ensuring that all new medicines are made available to patients.

When GSK provides funding, are you trying to 'buy' favours from the patient organisation?

No. We never ask for endorsement of any of our medicines or a return on investment for our support. We are careful that our support for an organisation does not compromise its independence and is based on trust and mutual respect, and complies with the highest standards of our code of conduct.

How do these groups maintain their independence if they receive significant funding from companies such as GSK?

We encourage patient groups to diversify their funding from sources in both the public and the private sector. Patient groups should never become dependent on any one funder from either sector. Our [guidelines](#) state that we should provide no more than 25 per cent of a group's overall income, except in exceptional

» Home » Responsibility » [Our work with communities](#)

Corporate Responsibility Report 2008

Our work with communities

We donate money, time, medicines and equipment to support communities around the world.

Our programmes are long term and focus on addressing healthcare challenges and increasing [access to medicines](#). We also invest in improving education, especially science education, and provide some support for art and environment initiatives.

We believe contributing some of our profits to benefit communities is part of being a responsible company. Community investment also brings us long-term business benefits by improving our reputation, boosting employee morale and helping us build good relations with governments. We do not use community investment as a way of generating sales.

We invest in innovative projects to:

- [prevent disease](#)
- [build the capacity](#) of community organisations
- [promote education](#), particularly in science

We focus our community investment on areas relevant to our business and the skills of our people. This is where we can bring the most benefit to communities and GSK.

Most of our investment is made through non-profit organisations that are experts in healthcare and education. These organisations are best placed to understand local community needs and to target resources effectively. Donations are made at a company level and by individual sites.

Healthcare

We support [major public health initiatives](#) in the developing world. For example:

- We are a founding member of the Global Alliance to Eliminate Lymphatic Filariasis (GAELF). We have committed to donating as many albendazole tablets as are needed to eliminate lymphatic filariasis (elephantiasis), a disabling parasitic disease that threatens 1.3 billion people – one-fifth of the world's population - in over 80 countries
- Our Positive Action programme works with communities to reduce stigma and improve capacity for HIV prevention and treatment
- Our African Malaria Partnership supports Mobilising for Malaria, an advocacy initiative to generate political commitment and funding to combat malaria
- PHASE – Personal Hygiene And Sanitation Education – is our hand-washing programme for children to prevent diarrhoea-related disease and improve school attendance
- We donate essential antibiotics and other medicines for disaster relief to under-served communities around the world, while specific programmes support low-income, uninsured patients in the US

Education

We support education programmes [[link to Supporting science education](#)] in the UK and the US to inspire young people about science, improve their understanding of science and encourage them to pursue a science-related career. Our programmes enable young people to make informed decisions about the

science-related issues they meet in everyday life such as healthy eating, vaccinations and the value of medicines.

Measuring impact

We ask our partner organisations for our larger programmes to report annually on the progress of the projects supported by GSK to ensure that the money we give has the greatest possible impact. We review results with our partners and identify any changes required to achieve the programmes' objectives.

Corporate Responsibility Report 2008

Community investment

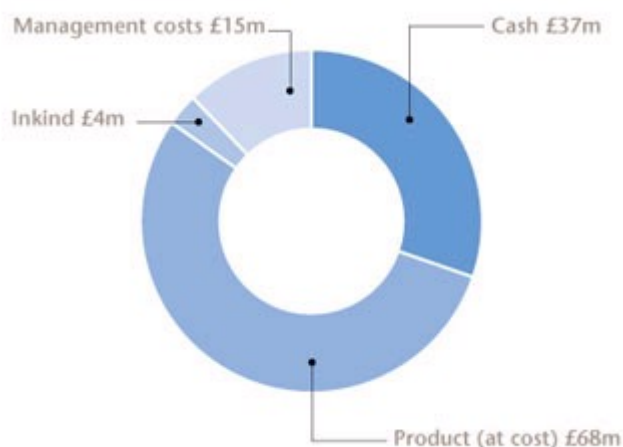
In 2008, our global community investment was £124 million (\$229 million) compared with (restated) £109 (\$219 million) in 2007, an increase of 13 per cent. Just over half of this comprises product donations and this is the first year we have valued donations using cost (average cost of goods) rather than the wholesale acquisition price (WAC).

Our new approach to valuing donations is a more accurate reflection of the true cost to GSK and is therefore more transparent. We believe we are the first pharmaceutical company to adopt this practice. We will continue to also report the WAC value of our donations for benchmarking purposes.

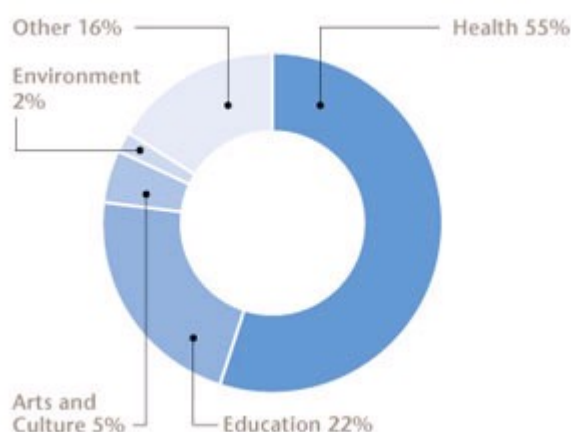
We belong to the UK's London Benchmarking Group (LBG) and the US Committee Encouraging Corporate Philanthropy (CECP). LBG guidelines report product donations at cost, whereas CECP guidelines report product donations at market value. For comparative purposes the total value of giving in 2008 using WAC for products would be £343 million (\$634 million) compared with £282 million (\$564 million) in 2007.

The giving figure is built up in the following way:

Method of giving (£ million)



Breakdown of cash giving (%)



Our product donations are made through three main programmes:

- Our Patient Assistance Programmes to support low-income patients in the US, totalling £56 million (at cost) in 2008
- Humanitarian product donations to under-served communities in 118 countries, including people affected by the natural disasters in Burma and China, totalling £5m (at cost) in 2008
- Donation of 266 million albendazole tablets for the lymphatic filariasis (LF) elimination programme. In 2008 we announced we would double our manufacturing capacity for albendazole tablets to 600 million tablets per year by 2010 from the current 300 million, to meet the growth of the LF programme, especially in India. As a result, our donations of albendazole tablets will increase significantly from 2009 onwards

We already publish data about our charitable grants made to patient groups in our European, Emerging Markets and Asia Pacific regions. We are further increasing transparency by publishing details of all our charitable grants over £10,000 (\$20,000). Find out more about [our grants](#).

GSK was one of 21 companies and the only manufacturing company to be awarded the new CommunityMark, following independent assessment, for outstanding community investment. The Mark, created by Business in the Community, is endorsed by the UK government and voluntary sector leaders. It was given for our work at local and national level in the UK as well as for our larger international programmes.

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Corporate Responsibility Report 2008

Preventing disease

Infectious diseases kill millions of people in the developing world each year.

They cause misery, cost billions of dollars and slow economic growth. Preventing infection is more effective than treatment and can have significant social and economic benefits.

[Our vaccines](#) play a significant role in preventing disease.

GSK supports innovative community approaches to disease prevention that are tailored to local settings and needs. 2008 marked two significant milestones in our support for community disease prevention; it is ten years since we made a commitment to [eliminate lymphatic filariasis \(LF\)](#) worldwide and since we launched our hand-washing programme [PHASE](#), to prevent diarrhoea-related disease.

We also support a wide range of [local programmes](#) to help prevent disease in the communities where we operate.

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› **Eliminating lymphatic filariasis**

Corporate Responsibility Report 2008

Eliminating lymphatic filariasis (LF)

We have committed to donating as many tablets of albendazole, our anti-parasitic drug, as are needed to eliminate LF.

LF is a disfiguring disease prevalent in tropical and sub-tropical countries. Transmitted by mosquitoes, it can lead to severe swelling of the arms, legs, breasts and genitals and thickening of the skin. LF is one of the world's leading causes of permanent disability, with 1.3 billion people in over 80 countries (approximately one-fifth of the world's population) at risk of infection.

In 2008, GSK donated 266 million albendazole treatments to 30 countries. This included 130 million tablets to India, the country with the largest LF burden. The economic cost of LF in India is estimated to exceed US\$840 million due to treatment costs and reduced working time.

Since the programme began we have donated over one billion tablets and over 180 million people have been treated at least once with albendazole. We estimate that to the end of 2007 66 million babies born in the treated regions have been spared the risk of contracting LF. A study published in the journal Public Library of Science on Neglected Tropical Diseases confirmed the progress already made towards eliminating LF.

This year we decided to double our annual manufacturing capacity for albendazole tablets to 600 million tablets per year by 2010 by opening of a new production line in Nashik, western India.

An additional benefit of the albendazole tablets given for the LF programme is that they also treat intestinal worms. These parasites particularly affect children, causing anaemia and malnutrition, and stunting growth. We estimate that since the beginning of the LF programme, over 170 million albendazole treatments have been administered to children and over 140 million to women of child-bearing age. This will have had a positive impact on the overall health of those infected with intestinal worms.

Each country aiming to eliminate LF must treat all at-risk people once a year for at least five years. So far, Egypt, several Pacific Island countries, Sri Lanka and Zanzibar have completed five annual mass drug administrations (MDAs). These countries are monitoring their populations to evaluate the impact of the programme on the disease. Assessments conducted in Egypt and Vanuatu, a Pacific Island nation, showed that LF has been eliminated in most areas of these countries.

Programmes in Tanzania, Madagascar and Burkina Faso have also reported an unexpected benefit of the MDAs, beyond reducing infection rates. In these countries, some patients already infected with LF are describing an alleviation of symptoms after the MDAs, including reduced leg swelling and a reduction in frequency and length of acute attacks (spells of feverishness and loss of energy). Acute attacks are the most incapacitating symptom of LF.

[Read more about our approach to LF and the patients who are living with the disease.](#)

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› **Personal Hygiene and Sanitation Education**

Corporate Responsibility Report 2008

Personal Hygiene And Sanitation Education (PHASE)

Every year more than two million people die of diarrhoea-related disease, mostly children in developing countries. These deaths can often be easily prevented through better hand-washing and sanitation.

PHASE is a school-based programme that helps to reduce diarrhoea-related disease by encouraging school children to wash their hands. We established PHASE in 1998 and since then we have invested over £4 million (\$7 million) in the programme.

PHASE is run in partnership with AMREF, Save the Children and Earth Institute at Columbia University, as well as Ministries of Health and Education in the countries where the programme operates.

The programme has had impressive results. In Bangladesh, for example, in partnership with Save the Children, we introduced PHASE to 127 schools in one of the country's poorest areas, where it is helping to improve the lives of 20,000 young children and their families. In the three-year period of the programme's funding:

- Schools with hand-washing facilities increased from 5 per cent to 97 per cent, leading to an increase in hand washing with soap by schoolchildren from 40 per cent to 75 per cent
- More latrines were made available in schools and a further 1,200 latrines constructed in children's homes, resulting in a marked decrease in open defecation from 75 per cent of the population to 13 per cent
- With healthier children, school attendance rates increased from 53 per cent to 80 per cent over the period 2006 to July 2008

The success of PHASE in Nasirnagar (Bangladesh) led to the decision to expand the programme to include all 950 schools in the Brahmanbaria district. Save the Children is now working with health and education ministers to prepare them for the scale-up.

In 2008, we committed funding of £320,000 over three years to extend the programme into the slum areas of Mumbai in India with our partner Pratham. PHASE now operates in 13 countries and has reached over 500,000 children. Our aim is for the programme to reach over one million children by next year.

Supporting the Millennium Development Goals

In 2000 world leaders agreed the Millennium Development Goals (MDGs) to meet the needs of the world's poorest people. The MDGs include targets to halve extreme poverty and hunger by 2015, and improve education, health, gender equality and environmental sustainability.

We have introduced PHASE to two Millennium Villages in Malawi and Senegal. Millennium Villages are research projects in African communities designed to find practical ways to meet the MDGs

Global Hand-Washing Day

The first Global Hand-Washing Day was held during 2008. This was marked by a week of activities encouraging millions of children and adults around the world to wash their hands, with the aim of improving hygiene and health. PHASE partners arranged a range of activities to promote hand-washing which reached around 300,000 people.

[Read more about PHASE and the Global Hand-Washing Day.](#)

Corporate Responsibility Report 2008

Local programmes

We support a wide range of programmes to help prevent disease in the communities where we operate. We fund these programmes at corporate and local levels. Below are just a few local programme examples.

Australia - helping Aborigines tackle diabetes

Indigenous Australians have poorer health and a life expectancy of about 20 years less than the rest of the Australian population. This is due to the rapid increase in so-called 'lifestyle' diseases, including type 2 diabetes, and could wipe out indigenous populations in 20 years.

GSK is working with the Unity of First People of Australia in the far north of Western Australia on their Diabetes Management and Care Program. The programme aims to arrest the rising incidence of diabetes in Aboriginal communities by encouraging the local people to take on the responsibility for their community's health, because health providers can only do so much without their active support.

UK – improving sexual health services for disabled people

We have donated over £520,000 over three years to Leonard Cheshire Disability to fund a project to give young disabled people better access to sexual health services. The project addresses knowledge and understanding gaps relating to disabled people's sexual health issues. Over the three-year period, the organisation will run focus groups and workshops to identify key issues and will develop a range of materials to support sexual health workers who deal with disabled people.

UK - promoting sport for children

Through our Consumer Healthcare business we support Access Sport, an organisation that encourages young people in the UK to keep fit and participate in sport. In 2008, Access Sport held three 'Sports Jam' events, in Bristol, Bath and London, where more than 3,500 children took part in sporting activities. We provided funding and our employees volunteered their time and held fundraising events. For example, 90 employees raised money by cycling from Land's End to John O'Groats. In future GSK staff will also support Access Sport by volunteering at their local sports clubs during our annual employee volunteering day.

Preventing childhood obesity in the US

In the US we support the Zone Health initiative which helps schools strengthen their policies and programmes on nutrition and physical activity. It aims to improve the health of more than 200,000 children by 2010. Following a successful pilot, Zone Health is being expanded and GSK has announced support for the FitU programme in the Washington DC area, which will benefit more than 600 young people over three years.

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Corporate Responsibility Report 2008

Building community capacity

Lack of healthcare infrastructure – including clinics and trained healthcare professionals – and cultural attitudes are significant barriers to treatment in many developing countries.

Our global programmes such as [Positive Action](#) is working with communities affected by HIV and AIDS, and our [African Malaria Partnership](#) is improving prevention and access to malaria treatment.

We support [local initiatives](#) that help overcome stigma, build the capacity of communities to provide healthcare and combat disease.

We also provide [humanitarian relief](#) in times of emergency and natural disasters.

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› **Combating HIV/AIDS – Positive Action**

Corporate Responsibility Report 2008

Combating HIV/AIDS - Positive Action

Positive Action works with community organisations to build capacity to counter the ignorance and stigma surrounding HIV through outreach, education and advocacy. Since it was established in 1992, it has provided over \$70 million, funding projects in 63 countries across Africa, Asia, Latin America and Eastern Europe.

Through Positive Action, GSK has pioneered support for vulnerable communities, including men who have sex with men, intravenous drug users, sex workers, migrants, young people, orphans and vulnerable children and marginalised poor rural women - groups who have limited human rights or public voice and are thus excluded from playing a role in developing mainstream programming. It is essential to work with these groups if we expect to make a difference to this epidemic.

During 2008, we supported 18 Positive Action programmes in 21 countries. Key projects include:

- Fighting stigma and discrimination in Mexico among vulnerable sectors of the population
- Bringing HIV education to vulnerable women in India through self-help groups
- Helping communities in Asia understand and prepare for treatment programmes
- Improving access to treatment in Kenya by promoting greater understanding and involvement of communities

Update August 2009

In July 2009 we announced the creation of a new Positive Action for Children Fund. The Fund will make £50 million (\$80 million) available over ten years to help prevent mother-to-child transmission of HIV and to support orphans and vulnerable children.

Positive Action programmes involve grass roots organisations that are able to continue to support their communities after the projects have come to an end.

This year we were the principal sponsor of the Global Village (the community space) at the International AIDS2008 conference held in Mexico City. We also hosted community forums to allow delegates to share experience of their fight against HIV/AIDS.

Read more about [Positive Action](#).

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- › **Combating malaria – Africa Malaria Partnership**

Corporate Responsibility Report 2008

Combating malaria – Africa Malaria Partnership

Every year up to 500 million people are affected by malaria and over one million die from it, mostly young children in Africa. But the disease can be prevented by controlling the breeding of mosquitoes and using low-cost measures such as insecticide-treated nets. Malaria can be cured if treated promptly with effective medicines.

We established the African Malaria Partnership in 2001 to improve the prevention and access to treatment of malaria in sub-Saharan Africa. Since then we have invested over \$3 million in initiatives to combat the disease.

2008 was the final year of our three-year grant to support Mobilising for Malaria, an advocacy initiative to generate greater awareness, political commitment and sustained funding for malaria in Europe and Africa. National Coalitions Against Malaria have now been launched in the UK, Belgium, France, Ethiopia and Cameroon bringing together advocates and activists from the public sector, NGOs, the media, the private sector and the political, academic and scientific communities.

Part of this initiative was the award of innovation grants to civil society organisations in Africa to boost advocacy efforts and inspire African civil society organisations and media to become leaders in the fight against malaria in their own countries. Grants were awarded to civil organisations in Nigeria, Tanzania, Ghana, Mozambique, Democratic Republic of Congo and Burkina Faso.

We supported a journalist competition run by the Guardian, a British newspaper, to raise awareness of issues faced by people with malaria and LF. Their global web site attracted 20,000 unique visitors and the winning stories were published in two dedicated supplements.

Read more about our [malaria programmes](#).

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› **Local programmes**

Corporate Responsibility Report 2008

Local programmes

We support a wide range of programmes to build healthcare capacity in the communities where we operate. We fund these programmes at corporate and local levels. Below are just a few local programme examples.

Training midwives in Vietnam

We support a project to train birth attendants to bring maternal healthcare services to rural villages in Vietnam. The project aims to reduce childbirth complications and decrease newborn fatality from the unacceptably high level of 6 per cent. The trainees are housed in a residential training centre built by GSK at Tu Du Hospital, Ho Chi Minh City. Supported by hospital staff, they spend four months gaining practical knowledge of maternal and child healthcare.

During the first phase of the project, between 2004 and 2007, over 520 midwives – representing 38 of Vietnam's 54 ethnic groups – have graduated with a government-recognised qualification. The midwives return to their villages equipped with a medical pack. Some are also provided with a motor scooter to assist access to remote areas.

Phase two of the project was launched in 2008. This involves hospital staff visiting villages to provide additional training to the midwives and to provide basic pregnancy and reproductive health education for community members.

Palliative care for children in Romania

Over the last three years we have been working in partnership with the Hospice Casa Sperentei in Romania on the 'Beacon of Hope' project to improve the level of care available to terminally ill children in the Balkans. Huge progress has been achieved, helping to change attitudes towards dying patients in the region.

The project has received acclaim from the Romanian government, which began a partnership with the hospice in 2007 with a view to creating a national plan for palliative care. Key achievements include the establishment of a children's palliative care unit in Brasov, a mobile nursing team and a network of care providers across the region. The project has developed a regional centre of excellence for the whole of south-eastern Europe that provides palliative care training for health workers and volunteers. As a result, children's palliative care services have been set up in neighbouring Moldova.

New fund for Children's Hospital of Philadelphia

In October 2008 we announced a \$1 million donation to the Children's Hospital of Philadelphia to help young people with cancer in the US. The hospital runs one of the world's largest paediatric cancer programmes. Our contribution, together with a matched donation from the hospital, will form the GlaxoSmithKline Hope for Families Fund. The Fund is a permanent endowment to enable children and young adults suffering from relapsed and hard-to-cure cancers access to innovative therapies. It will help cover the travel and accommodation costs of patients and their families, who often must stay at or near the hospital for extended periods.

Healthcare for the homeless in Pittsburgh

GSK supports Pittsburgh Mercy Foundation's Operation Safety Net 'Street Medicine' outreach programme that enables Pittsburgh's homeless to access free healthcare. The programme includes a mobile medical unit, a drop-in clinic and teams of clinicians and care workers who walk the streets offering medical examinations and treatment to homeless people.

Rewarding community healthcare organisation in the UK

Each year the GSK IMPACT Awards recognise voluntary organisations that have significantly improved the health of their local communities. Ten winning charities receive £25,000 each and the overall winner is awarded an extra £10,000.

In 2008 the UK Impact Awards programme introduced an initiative for the managers of the winning organisations to be trained in leadership, networking and fundraising skills. This will help strengthen small charities that are often unable to afford this vital skills training.

The GSK IMPACT Awards also run in Philadelphia in the US.

Read more about the [GSK IMPACT Awards](#) and the winning organisations.

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› **Responding to disasters around the world**

Corporate Responsibility Report 2008

Responding to disasters around the world

GSK provides humanitarian assistance in the form of cash and product donations in times of emergency and natural disasters. In 2008, as part of our ongoing programme, we provided humanitarian relief to many areas, including China, Burma and Zimbabwe.

Following the cyclone in Burma we worked with AmeriCares, one of our partners specialising in rapid-response delivery, to supply GSK-donated medicines. We also made a donation of £50,000 (\$93,000) to Save the Children, a charity that has an established presence in Burma. Our contribution supported recovery efforts, including the provision of shelter, child protection, food and nutrition and emergency health services for over 100,000 children and their families.

The earthquake which hit Sichuan Province in China in May left over 70,000 dead and 15 million people displaced or homeless. GSK Hong Kong/China gave a cash donation of 10 million Yuan, approximately \$1.4 million, to the China Red Cross, and donated supplies of basic medicines.

We provided funds to the British Red Cross for a Mass Sanitation Module to provide emergency sanitation facilities and hygiene education for up to 20,000 people during times of crisis. This helps to avoid outbreaks of disease and was deployed in December 2008 in Zimbabwe to help stem the cholera outbreak.

We continued our support for communities affected by the 2004 Indian Ocean tsunami, which caused huge damage to coastal areas across South Asia:

- In Sri Lanka, we are helping to establish mobile clinics that increase access to quality healthcare for isolated communities affected by the tsunami and conflict in the country. In 2008, 47 mobile clinics were set up in 13 different locations, providing the only reliable healthcare services in these areas. The clinics treated nearly 10,500 patients and in total gave healthcare education messages to 12,000 patients and the people accompanying them
- We are working with Leonard Cheshire Disability to create an inclusive, barrier-free and rights-based society for people with disabilities who were affected by the 2004 tsunami in Galle, Sri Lanka. A new resource centre will be established to support people with disabilities by providing rehabilitation services, mainstream education and livelihood opportunities.
- We support long-term relief efforts in affected areas of Chennai, India, by providing nursing training to young women from poor villages. As well as boosting healthcare services in the area, the training enables the women to support themselves financially by becoming nursing assistants. Between 2007 and 2009 420 women will be trained.
- In Thailand we are helping to boost the economies of six coastal villages where the local fishing industry was destroyed by the tsunami. With the Raks Thai Foundation we support initiatives that provide business loans and organise youth activities and efforts to improve the local environment. We also gave funding to help NGO Francois Xavier Bagnoud (FXB) to introduce the concept of a 'model village'. This is a low-cost, sustainable, community-based programme that has been successful in helping families to achieve self-sufficiency

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Corporate Responsibility Report 2008

Supporting science education

In the UK and US, the numbers of young people choosing science subjects is falling and many students lack proficiency in either reading or mathematics.

As a result, both countries face a significant skills shortage.

The success of our business relies on us being able to recruit talented individuals, particularly those with science qualifications. We also want young people to make sound decisions about the science-related issues they meet in everyday life.

Our education programmes help make science more relevant to young people in the UK and US, stimulating their interest in science, and supports the training and development of science teachers.

UK

Project ENTHUSE

Half of secondary school science teachers in the UK have had no subject training within the past five years. Project ENTHUSE was launched in 2008 to improve continuing professional development of science teachers and to provide them with the latest techniques to rekindle interest in science.

Teachers, assistants and technicians can apply for an ENTHUSE Award to help them study at the National Science Learning Centre at the University of York. The award will cover course fees, the cost of covering teachers' roles while they are on the course, and travel and accommodation for 2,200 teachers each year. The schools will also receive a small amount of money to help implement ideas back in the classroom.

We have committed £1 million to this initiative helping to create a £30 million fund with support from the UK government, the Wellcome Trust and eight other industry partners.

CREST Star Investigators

After-school clubs help broaden the interests and experiences of young people, but these often focus on sports or arts rather than science. [CREST Star Investigators](#), developed by the British Association for the Advancement of Science and funded by GSK, aims to redress this balance and engage 5 to 12 year olds in science-based activities.

The UK-wide programme offers activity packs to schools and other organisations such as the Brownies and Cubs for use in after-school clubs. The activities encourage children to solve scientific problems through exciting practical investigations. The pack contains activities at three different difficulty levels, and children are awarded a certificate when they complete each stage.

So far almost 3,000 packs have been distributed to nearly 1,500 schools. By 2010, we aim to have 5,000 schools and 55,000 children taking part.

US

Institute for a Competitive Workforce (ICW)

Building on GSK's leadership at state and local levels related to reform and improvement of public schools, GSK led the effort to create the ICW on a national level. The result has been a national movement for business/education partnerships focused on improved academic achievement in our public school system in order to help ensure a qualified workforce for American businesses in the future.

Science in the Summer

We support [Science in the Summer](#), a free education programme designed to get young people in

Pittsburgh, Pennsylvania, Greater Philadelphia and North Carolina interested in science. Classes held in local libraries give children the chance to take part in hands-on experiments and take courses ranging from genetics to oceanography. The programme began in 1986, and in 2008 GSK invested \$575,000 across 162 sites where over 6,000 children participated in the programme.

North Carolina New Schools Project

GSK partners with the North Carolina New Schools Project, an initiative that aims to transform teaching and learning so that high school students graduate ready for college and the workplace. GSK is helping to fund the development of science and technology programmes at ten of North Carolina's low-performing high schools. The initiative aims to improve the schools' test results and graduation rates. GSK also funds a review of state curricula so that the benefits are shared more widely.

Corporate Responsibility Report 2008

Our plans

Volunteering

From 2009, we will expand our volunteering programme so that every GSK employee can spend at least one day a year helping in their community. Employees will select local organisations to support and will undertake a variety of work for them, ranging from manual jobs to fund-raising. This will include supporting employees that wish to visit schools to encourage science education.

We will also be launching an international assignment programme to enable a select number of employees to use their professional skills to support our non-profit partners for extended periods.

Positive Action

We have agreed to extend three of our larger HIV programmes (Zingatia Maisha in Kenya, Vida Digna in Mexico and Reach India) for an additional year to ensure their sustainability.

We will be working with the Ubuntu Education Fund in South Africa to expand a programme called 'Living Positively'. This programme will work with men and older boys in Port Elizabeth township to challenge gender roles that exacerbate HIV infection and exclude men from HIV services.

We will be working with AIDS Action Europe to provide networking for HIV/AIDS NGOs across Eastern Europe and Central Asia for improved HIV policy, advocacy and programming and support for those facing the HIV crisis.

We will be working with the American Foundation for AIDS Research (amfAR) to expand its initiative to provide prevention, care and support services for men who have sex with men in Asia Pacific. We will also work with AIDS patient groups in the Philippines to increase members understanding of health issues.

PHASE

Our partner Pratham will be implementing the PHASE programme in the slum areas of Mumbai, India. We will also extend PHASE to new districts in Uganda and advocate for the incorporation of PHASE into national policy, enabling sustainability and replication of the project nationwide.

LF

We are increasing our manufacturing capacity for albendazole tablets to 600 million tablets per year by 2010. This will enable us to increase fourfold the number of tablets we donated in 2007.

US

We are continuing to provide leadership and support to the Children's Health Fund (CHF) Referral Management Initiative to increase access to specialist healthcare for homeless and uninsured American families. We are also supporting a pilot telemedicine project to help patients access specialist care. CHF's new Memphis Regional Children's Health Project will serve as the pilot site to link approximately 400 rural patients with specialists at Memphis hospital, using state-of-the-art videoconferencing technology.

Europe, Emerging Markets and Asia Pacific regions

Several new programmes are being implemented. For example

- In Greece we are helping to introduce the concept of home-based nursing services for children living with cancer

- In the Netherlands, we are supporting a national programme to promote healthy behaviours among young people, helping them to make informed decisions about what they eat and to encourage regular physical activity
- We will also seek new partnerships to improve community healthcare through social venture and enterprise projects

Preparing for when the funding stops

Most of our programmes run over a number of years, recognising that it takes time to build change. But from the start we plan for what will happen at the end of our funding.

We work hard with community organisations to bring results over the life of a project (usually around three years) and to help organisations win funding from other sources to continue their work.

From the start we require our partners to work to a budget to make sure funding is spent effectively and produces the right results. We also ask our partners to demonstrate achievements by producing an annual progress report. These reports show evidence of success and are a crucial part of attracting new donors.