



# Corporate Responsibility Report 2010

## Contents

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<b>Overview</b>	<b>1</b>	<b>Research practices</b>	<b>69</b>
<b>Corporate responsibility at GSK</b>	<b>5</b>	<b>R&amp;D in 2010</b>	<b>70</b>
Message from our CEO	6	<b>Patient needs and R&amp;D</b>	<b>74</b>
Why responsibility matters to GSK	8	<b>Emerging technologies</b>	<b>75</b>
– Benchmarking	10	– Cloning technologies and stem cell research	76
– Data summary	12	– Genetic research	77
Our Principles	14	<b>Animal research</b>	<b>79</b>
Corporate responsibility governance	16	<b>Human tissue research</b>	<b>84</b>
Stakeholder engagement	18	<b>Maintaining confidentiality of research participants</b>	<b>85</b>
– Engagement in 2010	19	<b>Medical governance</b>	<b>86</b>
Audit and assurance	21	<b>Conducting clinical trials</b>	<b>87</b>
Risk management	22	– Planning and approval	88
About our reporting	24	– Working with healthcare professionals	89
		– Informed consent	90
		– Post-trial treatment	91
		– Clinical trials in the developing world	92
		– Clinical trials in children	93
		– Training and auditing	94
		<b>Public disclosure of clinical research</b>	<b>97</b>
		<b>Patient safety</b>	<b>100</b>
		– Patient safety governance framework	101
		– Collecting and reporting safety data	102
		– Collaborations on patient safety	106
<b>Access to medicines</b>	<b>25</b>		
Our approach	27	<b>Ethical conduct</b>	<b>107</b>
HIV/AIDS and ViiV Healthcare	30	<b>Key policies</b>	<b>109</b>
Research and development	34	– Privacy	112
– Open innovation	36	– Acquisitions and due diligence	113
– Pipeline update	39	<b>Marketing our products</b>	<b>114</b>
Vaccines	42	<b>Grants and donations to healthcare organisations</b>	<b>118</b>
Flexible pricing	47	<b>Payments to healthcare professionals</b>	<b>119</b>
– Least Developed Countries	49	<b>Direct-to-consumer advertising</b>	<b>121</b>
– Middle-income countries	53	<b>Training and awareness</b>	<b>124</b>
– Developed countries	58	– Leading by example	126
Portfolio expansion	62	– Training and awareness performance	127
Advocacy	64	<b>Monitoring and compliance</b>	<b>128</b>
Future plans	67	– Monitoring for sales and marketing	129
		– Reporting channels	130
		– Monitoring and compliance performance	131

<b>Supply chain</b>	<b>133</b>	<b>Our people</b>	<b>196</b>
<b>Supplier standards</b>	<b>135</b>	<b>Inclusion and diversity</b>	<b>197</b>
– Human rights clause	136	<b>Employee engagement</b>	<b>201</b>
– Choosing suppliers	137	<b>Development and training</b>	<b>203</b>
– Monitoring and engagement	139	<b>Developing leaders</b>	<b>204</b>
– Supply chain performance	141	<b>Reward and recognition</b>	<b>205</b>
<b>Supplier diversity</b>	<b>143</b>	<b>Restructuring</b>	<b>206</b>
<b>Sustainable sourcing</b>	<b>145</b>	<b>Health, safety and wellbeing</b>	<b>207</b>
<b>Security of supply</b>	<b>146</b>	– Health and safety culture	208
<b>Counterfeiting</b>	<b>147</b>	– Addressing key health and safety risks	210
		– Health and wellbeing programmes	212
		– Health and safety performance	214
<b>Environmental sustainability</b>	<b>149</b>	<b>Human rights</b>	<b>217</b>
<b>Environmental sustainability strategy</b>	<b>150</b>	<b>Employees</b>	<b>218</b>
<b>Managing environmental sustainability</b>	<b>152</b>	<b>Suppliers</b>	<b>219</b>
– Plans and targets	155	<b>Communities</b>	<b>220</b>
– Stakeholder engagement	157	<b>Society</b>	<b>221</b>
– Awareness and recognition	158	<b>Activities in embargoed countries</b>	<b>222</b>
– Lifecycle assessment and supply chain	160		
<b>Climate change and energy</b>	<b>161</b>	<b>Public policy and patient advocacy</b>	<b>223</b>
– Propellants	163	<b>Our approach to external affairs</b>	<b>224</b>
– Facilities	164	<b>Public policy activity in 2010</b>	<b>226</b>
– Transport and travel	166	– Advocacy on healthcare reform	227
– Climate change and energy performance	168	– Advocacy on healthcare and disease prevention	230
<b>Water</b>	<b>170</b>	– Advocacy on research practices	234
<b>Environmental stewardship</b>	<b>174</b>	– Advocacy on patient safety	236
– Potential hazards	175	– Advocacy on intellectual property rights	238
– Mass efficiency	177	<b>Political contributions and lobbying expenditures</b>	<b>240</b>
– Waste	179	<b>Patient advocacy</b>	<b>241</b>
– Packaging	183	– Transparency	243
– Emissions to air	185	– Understanding patients	244
<b>Data, audit and assurance</b>	<b>188</b>	– Advocacy in 2010	246
– Data summary	189		
– Internal audit	191	<b>Our work with communities</b>	<b>248</b>
– External assurance	192	<b>Global programmes</b>	<b>249</b>
– GSK response to assurance	195	<b>Local programmes</b>	<b>253</b>
		<b>Our community investment</b>	<b>257</b>
		<b>Plans and targets</b>	<b>259</b>

## Overview

Our approach to corporate responsibility and where to find out more on the issues covered in our online 2010 CR Report:

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## Corporate responsibility at GSK

Strong values are central to business success. We place great importance not just on what we achieve but on how we achieve it. Being a responsible business means connecting our business decisions to society's healthcare needs and operating in a way that reflects our values:

- Commit to **transparency**
- Show **respect** for people
- Always demonstrate the highest **integrity** in our conduct
- Be **patient** focused

Our values underpin our Principles which outline the standards which GSK is committed. Our Corporate Responsibility Committee of Non-Executive Directors provides high-level guidance on our approach to CR. Accountability for the responsible management of GSK sits with the CEO and members of the Corporate Executive Team.

We know that the research and development, manufacture and sale of our products can raise ethical issues, and we aim to be open about how we tackle them. We understand it is important to communicate with our stakeholders, seeking to understand their views, being transparent about any setbacks we have experienced as well as the progress we have made.

Read more about our approach in CR at GSK and in the sections below.

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## Access to medicines

Providing access to healthcare is one of society's most pressing social challenges. We want to increase access to our medicines and vaccines to all patients, irrespective of where they live and their ability to pay. We believe it is the right thing to do and know that it will contribute to our business success. By striving to meet society's healthcare needs we build trust in our business, which helps to safeguard our licence to operate in the long term.

Our access strategy focuses on areas where we can make the most difference through our core business activities, skills and resources. In particular this means initiatives to improve affordability and to conduct and encourage more investment in R&D for the developing world.

To achieve this we are:

- Pursuing flexible pricing strategies
- Refocusing our R&D activities to reflect the needs of developing countries
- Seeking innovative partnerships to try to reach people who would otherwise not have access to our medicines and vaccines.

Read more in Access to medicines.

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## Research practices

Investment in R&D into new medicines and vaccines is at the core of our business. We focus our R&D efforts on areas where there is greatest patient need and where advances in science offer the best opportunities to discover new medicines and generate commercial returns. Our aim is for new treatments to provide value over currently available treatments to both patients and to payers.

Patient safety is always our priority and we evaluate the benefits and risks of our medicines at all stages of research and after a new product is approved for sale. We are committed to transparency and to disclosing the results of our clinical research.

It is essential that we meet consistently high quality and ethical standards in all our R&D, in all parts of our business, and in all the markets where we operate. This enables us to protect the safety of clinical trial participants and the patients who use our medicines, to obtain regulatory approval for new medicines and vaccines, and to maintain the trust of patients and healthcare professionals.

We recognise that biomedical research can raise ethical concerns, including those related to animal research, the use of emerging technologies such as stem cell research and clinical trial standards. We aim to address these by being open about our approach and regularly engage with stakeholders on these issues.

[Read more in Research practices .](#)

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## Ethical conduct

We are building a strong ethical culture at GSK. We do this by developing robust policies, recruiting the right people and equipping them with the information they need to make ethical decisions. Putting patients first is the core principle of being an ethical healthcare company.

All employees must understand what we stand for as well as the policies and procedures that underpin our approach. They must comply with our Code of Conduct which sets out our fundamental standards, and follow our Employee Guide to Business Conduct which helps employees make ethical decisions and emphasises our company values.

Our internal compliance systems are designed to support ethical behaviour and decision making by employees, and to identify and address breaches of our codes.

[Read more in Ethical conduct.](#)

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## Supply chain

Patients depend on an uninterrupted supply of medicines, manufactured to the highest quality standards. An effective and responsibly managed supply and distribution system is essential for us to get high quality products to the right place at the right time.

To meet patients' needs we must protect our complex supply and distribution chain from disruption. We must also ensure that products are stored correctly and handled carefully throughout distribution and at their destination.

We aim to source from companies that maintain high standards for quality, labour and the environment, and protect their employees' human rights. Our standards are explained in our Third Party Code of Conduct, and the EHS and human rights clauses in supplier contracts. Our approach also includes regular supplier performance reviews, audits and training.

We put measures in place to detect and prevent counterfeiting of our products, which can endanger patient health and lead to loss of revenue.

[Read more in Supply chain.](#)

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## Environmental sustainability

We are integrating environmental sustainability into our business. We have a responsibility to contribute to meeting environmental challenges, but we also see this as an opportunity.

Our focus is on carbon dioxide and other emissions that contribute to climate change, water use, and environmental stewardship which covers the use of materials and generation of waste. We conduct life cycle assessments of key products to identify and reduce their full environmental footprint.

We have set ambitious environmental sustainability goals to reduce the impact of our own operations and our value chain, from raw materials to product disposal. Our long-term goal is for our value chain to be carbon neutral by 2050. In the shorter term we have set demanding targets for reducing our carbon footprint by 25% and water use by 20% by 2020.

[Read more in Environmental sustainability.](#)

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## Our people

We employ over 90,000 people in 114 countries worldwide. We want GSK to be known as a great place to work and an employer of choice for talented people from all backgrounds.

Our employment practices help us create the right workplace culture in which all GSK employees feel valued, respected, empowered and inspired. Important elements of our approach include our commitment to inclusion and diversity and support for flexible working practices; regular two-way communication with employees; and respectful and fair treatment of employees during changes to the company.

Our leaders set the tone from the top, and all employees have a role to play in maintaining this culture. We ask them to adopt our company values and behaviours in all their work, and in return we aim to provide a great employee experience for everyone at GSK which includes high-quality training and development opportunities and competitive reward packages.

Keeping employees and contractors healthy and safe is a priority. Our rigorous management system reduces the risk of harm to people working at GSK and helps them remain healthy, productive and energised.

[Read more in Our people.](#)

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## Human rights

We work hard to protect human rights within our sphere of influence, which includes employees, suppliers, local communities and society more broadly. We have most direct control over human rights in our own operations.

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.

Maintaining high standards of human rights benefits our business by helping us get the best from our employees, supporting our relationships with communities near our sites, ensuring supplier contracts run smoothly and provide a reliable supply of high-quality products, and by protecting our reputation.

[Read more in Human rights.](#)

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## Public policy and patient advocacy

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 and professional 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 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 exercises inappropriate influence over governments. We publish key elements of our annual public policy activity on this website and report on our trade association memberships and US Federal and EU institution lobbying expenditures. We also publish information on our work with patient groups, including details of the funding we provide. GSK does not make political contributions.

[Read more in Public policy and patient advocacy.](#)

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## Our work with communities

We invest in community partnership programmes that seek to improve access to medicines and healthcare around the world, and create opportunities in education and economic development.

We aim to make a real difference to communities by working with our partners to find innovative solutions to healthcare challenges. Our programmes include global initiatives designed to tackle diseases of the developing world across multiple countries. We also support local programmes that are tailored to the specific needs and challenges of our many different markets. Our support includes donations of time, money, expertise and medicines.

We encourage employees to get involved through our volunteering programmes because this benefits the organisations and charities we support and contributes to employees' personal development.

[Read more in Our work with communities.](#)

## CR at GSK

Strong values are central to business success. We place great importance on what we achieve but also on how we achieve it.

Being a responsible business means operating in a way that reflects our values, including treating our stakeholders with respect and connecting our business decisions to society's healthcare needs. We seek to minimise the negative impacts and maximise the benefits of our business. Our approach is guided by our Corporate Responsibility Principles.

### Our mission and values

Our mission is to 'Improve the quality of human life by enabling people to do more, feel better and live longer'.

We have four values that underpin everything we do:

- Commit to **transparency**
- Show **respect** for people
- Always demonstrate the highest **integrity** in our conduct
- Be **patient** focused

Read more about embedding values and an ethical culture within our organisation in the Our people and Ethical conduct sections.

Our medicines, vaccines and consumer healthcare products improve people's lives and make a valuable contribution to society. However, we know that the research and development, manufacture and sale of these products raise ethical issues, and we aim to be open and transparent about how we tackle them. We seek to understand and respond to the views of our stakeholders on these subjects.

We have established management processes to help advance progress against our CR Principles, and ensure we identify and manage responsibility and reputational risks to our business.

### The cost of disease – why our contribution matters

Ill health is expensive for the individual and for society. It is often a result of poverty and a 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. Disease has a serious effect on social and economic development in the world's poorest countries.

Researching and developing medicines, vaccines and consumer healthcare products that make a real difference to patients' lives is the most important responsibility issue for GSK. We aim to improve the efficiency of our R&D and focus it even more closely on the needs of patients and healthcare payers. We partner with others to accelerate development of new treatments. Enhancing research into neglected tropical diseases is an increasingly important focus area for GSK. The contribution our products make will be limited if they are not accessible and affordable. That's why we are committed to increasing access to our medicines and vaccines.



## Message from our CEO

We are transforming GSK into a more competitive and efficient company. A company built on strong values and a deep commitment to excellence – a company that our employees, our customers and the societies we work in can be proud of.

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Continuing to run our business in a responsible way is central to our transformation. We don't have a separate 'responsible business strategy' because our commitment to responsible, values-based business underlies everything we do. This means being led by our values and principles, being transparent about how we work, responding to the needs of our stakeholders especially by putting patients first in our decision-making, being thoughtful in how we communicate and not compromising our ethical standards. When we do this we generate real value for patients and for our business.

We are building on our strong culture in which all our decisions are guided by our values:

- Commit to **transparency**
- Show **respect** for people
- Always demonstrate the highest **integrity** in our conduct
- Be **patient** focused

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## Access to medicines

We're committed to increasing access to our medicines for patients, irrespective of where they live and their ability to pay. In 2010 we have further embedded a range of flexible pricing models to deliver our medicines and vaccines to as many of the people who need them as possible. Not only is this the right thing to do, it will also contribute to our business success. For example, we've capped the price of our patented medicines in Least Developed Countries at no more than 25% of what we charge in developed countries, and we're introducing more flexible pricing in developing countries.

This is challenging and the work is at an early stage, however the results of some of our initiatives so far are promising, indicating that price reductions are extending access to more patients and providing a sustainable return to GSK.

This year we also created a specific operating unit dedicated to increasing access to medicines in developing countries. Its success will be judged not on profits but on its contribution to increasing access to our medicines.

I believe the approach we are taking will define GSK as a company that healthcare providers and patients can trust. Combined with our commitment to quality and ethical business practices, this will help us to stand out as a business that is truly committed to patients.

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## Neglected tropical diseases

We continue with our significant commitment to work on neglected tropical diseases and our R&D partnerships in this area are progressing well. GSK's RTS,S malaria vaccine candidate is in phase III trials and, if all goes well, this will be the first ever vaccine against malaria, with the potential to save the lives of millions of children in Africa. We have committed to price RTS,S responsibly and will seek to ensure that price will not be a barrier to access. We will set a price which covers our costs and generates a small return of around 5% which we will reinvest in the development of

next generation malaria vaccines or for other products for diseases of the developing world.

We also announced in 2010 that we will donate enough of our albendazole medicine to protect all school-aged children in Africa against intestinal worms. Intestinal worms cause more ill health in school-aged children than any other infection, so this will have a major positive health impact. When added to the albendazole we already donate to the Global Alliance to Eliminate Lymphatic Filariasis, it means we will be donating about one billion tablets a year for five years – a very significant commitment.

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## Environmental sustainability

We have strengthened our commitment to the environment too, setting new ambitious targets. Our goal is to reduce the environmental impact of our value chain, from raw materials to product disposal, becoming carbon neutral by 2050. We have already achieved a reduction of nearly 11% in greenhouse gas emissions since 2006 which, although less than we had hoped, gives us a good foundation to build on in the coming years. We have also reduced the amount of water we use by 16% since 2006, exceeding our 2% annual reduction target.

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## Operating with integrity

We are continuing to work towards resolving a number of long-standing legal matters. In light of these cases we have fundamentally changed our procedures for compliance, marketing and selling in the US. We now have far-reaching policies and procedures in place to guard against inappropriate promotion to healthcare professionals, and to seek to ensure that if breaches of regulations do occur they are reported to the US government.

To truly embed our values we need to be willing to change how we work, to invest resources and to demonstrate leadership. The changes we are making this year to how we reward our US sales teams are just one example of how we are doing this. Historically, sales teams were rewarded according to the volume of prescriptions in their area, a practice common across the industry. Our new incentive system will assess sales representatives on their scientific and business knowledge, feedback from customers in their region, and the overall performance of their business unit.

By focusing on providing the information and support our customers want, rather than generating the next prescription, we will be acting in the best interests of patients. The more we do this, the more healthcare practitioners will see us as a true partner in delivering the best possible care for their patients.

In my view, it is strong values that differentiate great companies from mediocre ones. By living our values we will achieve results that are good for society and good for GSK. As this Report demonstrates, we continue to make important and exciting changes and I look forward to updating you on further progress next year.

Andrew Witty  
Chief Executive Officer

## Why responsibility matters to GSK

Responsible business practices, underpinned by our values and aligned to our Principles are essential for business success. They help us to respond to the concerns of our stakeholders and successfully implement our business strategy.

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### CR and our strategy

Our strategy is focused on three priorities: diversifying our business, delivering more products of value and simplifying our operations. It is designed to help us respond effectively to a challenging business environment, including loss of patent protection for an unprecedented number of products and growing demand from healthcare payers for more cost-effective healthcare. (See our **Annual Report** for more information).

Many elements of responsible business are directly related to the achievement of our strategy. For example, our efforts to increase access to medicines are helping us to create the right conditions for expansion of our business in emerging markets.

Responsible business practices also help us respond to society's changing expectations. Today, stakeholders expect business to play a greater role in tackling the world's social and environmental challenges and to meet ever-higher standards of ethical conduct. This is particularly true for GSK as a healthcare company.

Reflecting this, and in support of our strategy, the culture of our company is evolving to understand and be more responsive to stakeholder needs and more open and transparent about the way we operate. This will help us to build trust in our company and to create products of real value for patients and healthcare payers.

By delivering our strategy responsibly and meeting the changing expectations of our stakeholders, we believe we will be a more effective and successful business.

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### Business case for corporate responsibility

Ultimately we believe that responsible business is good for society and good for GSK. It helps us to operate efficiently, to gain the trust of our stakeholders, to create the products that patients and healthcare payers really need and to foster the right conditions for expansion of our business. Operating and then demonstrating that practices are ethical:

- Supports our licence to operate and thus our ability to improve people's lives through our products
- Builds trust in GSK and our products
- Enhances our ability to attract, retain and motivate talented people. This is increasingly important as fewer young people in our major markets choose science-based careers
- Supports constructive engagement with stakeholders. This helps us to prevent avoidable conflict and identify innovative approaches that benefit GSK and wider society
- Facilitates greater access to markets and the ability to influence healthcare policy through improved relationships with regulators and healthcare payers.
- Working with governments to increase access to medicines and resolve healthcare challenges is particularly important
- Helps us to anticipate and prepare for legislative changes and remain competitive
- Helps maintain support for the intellectual property system by finding innovative ways to increase access to

medicines

- Reduces costs through increased environmental efficiency and more efficient use of resources.

## Our key responsibility issues

We consider the following responsibility issues to be most significant and relevant (material) to GSK:

- The contribution we make to health through research, development, manufacture and sale of medicines, vaccines and consumer healthcare products
- Increasing access to medicines by making our products more accessible and affordable
- Raising ethical standards in research and development and sales and marketing
- Our environmental impact, particularly relating to climate change

A number of factors influence our materiality assessment including: 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 where we operate; existing and proposed legislation; and public opinion and media coverage.

## Benchmarking

GSK received the following ratings from benchmarking organisations:

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### Indexes



**Organisation:** Access to Medicine Index - Access to Medicine Foundation and RiskMetrics

GSK was ranked top in the Access to Medicine Index for the second successive time in June 2010. The Index assessed 20 R&D-based pharmaceutical companies, and seven generics companies, on their performance against seven criteria: management, influence, R&D, pricing, patenting, capability and philanthropy. GSK was ranked highest in six of the seven categories. Read more.



**Organisation:** Dow Jones Sustainability Index

**Rating:** GSK continued as a member of the Dow Jones Sustainability Index, which covers the top 10% of sustainable companies in each sector. GSK was awarded Bronze Class distinction in the 2010 survey published in 2011.



**Organisation:** FTSE4Good

**Rating:** GSK was included in the FTSE4Good Index which benchmarks companies on corporate responsibility parameters including environmental sustainability, stakeholder relationships, human rights, supply chain labour standards and business ethics.



**Organisation:** Business in the Community – CommunityMark

**Rating:** GSK was one of 21 companies and the only manufacturing company to be awarded the new CommunityMark in 2008, following independent assessment, for outstanding community investment. Companies are awarded the Mark for a three-year period and monitored to ensure continued commitment and excellence. GSK retained its CommunityMark in 2010.



**Organisation:** Carbon Trust Standard

**Rating:** GSK achieved global certification in 2010, and was the first company to do so.

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## Reporting

**Organisation:** SustainAbility Global Reporters benchmark

### **Rating:**

Our 2009 report scored 74%, a one percent improvement on the previous year and above the average of 58% for the eight pharmaceutical companies benchmarked by SustainAbility.

Strengths identified included a comprehensive account of GSK strategic priorities and clear alignment of responsibility activities with business strategy, focused reporting on material issues and impacts, a strong commitment to external engagement and collaboration to deliver on strategic priorities and a transparent account of public policy initiatives and relationship with internal strategy.

Areas suggested for improvement included providing further evidence of the business case for CR activities and the development of further metrics and targets.

## Data summary

### Corporate responsibility data summary

#### Access to medicine

Metric	2010	2009	2008	2007	2006
Number of <i>Combivir</i> and <i>Epivir</i> tablets shipped (millions) <sup>1,2</sup>	1.7	33.0	70.0	85.0	86.3
Number of generic ARVs supplied under licence from GSK (millions)	594	439	279	183	120
<i>Combivir</i> not-for-profit price (\$ per day) <sup>1,3</sup>	3	11	34	34	0
Voluntary licences granted to generic manufacturers for GSK ARVs (cumulative total) <sup>1</sup>	11	8	9	9	9
Value of products donated through GSK Patient Assistance Programs in the US (£ millions, 2010-2007 at cost, 2006 at wholesale price (WAC)) <sup>4</sup>	100	80	56	45	200

#### Research and Development

Metric	2010	2009	2008	2007	2006
Expenditure on R&D (£ billions)	4.0	4.1	3.7	3.3	3.5
Number of trials published on the GSK Clinical Study Register (cumulative total)	4,069	3,687	3,273	3,089	2,760

#### Ethical conduct

Metric	2010	2009	2008	2007	2006
Number of employees completing certification to the GSK Code of Conduct	>24,000	>14,000	>14,000	>14,000	>12,000
Number of contacts through our ethics compliance channels <sup>5</sup>	5,258	5,445	3,812	5,265	5,363

#### Employment

Metric	2010	2009	2008	2007	2006
Women in management grades (%)	38	38	38	37	36
Ethnic diversity - people of colour (US, %)	20.5	20.4	20.5	20.1	19.8
Ethnic diversity - ethnic minorities (UK, %)	19.4	19.4	19.2	19.1	18.3
Reportable injury and illness rate (per 100,000 hours worked)	0.40	0.48	0.57	0.68	0.72

#### Environment

Metric	2010	2009	2008	2007	2006
Total climate change impact (thousand tonnes CO <sub>2</sub> -equivalent) <sup>6</sup>	6,931	7633	7248	7801	7424
– Climate change impact from energy for operations and transport	2,011	2159	2214	2231	2246
– Climate change impact from patient use of inhalers	4,647	5171	4747	5200	4685
Energy from operations and transport (million gigajoules)	24.3	26.0	26.7	26.5	26.7

## Environment

Metric	2010	2009	2008	2007	2006
Water use (million cubic metres)	18.7	19.2	19.7	20.8	22.1
Wastewater chemical oxygen demand (COD) (thousand tonnes)	12.0	13.1	14.9	14.3	15.9
Non-hazardous waste disposed (thousand tonnes)	29.5	31.7	33.2	38.0	37.9
Hazardous waste disposed (thousand tonnes)	35.3	48.5	54.0	72.6	71.0
Volatile organic compound emissions (thousand tonnes)	2.7	3.1	3.7	4.3	4.1

## Community investment

Metric	2010	2009	2008	2007	2006
Total community investment expenditure (£ millions, 2010-2007 at cost, 2006 at wholesale price (WAC)) <sup>4</sup>	222	163	124	109	302
Value of albendazole donations (£ millions, 2010 -2007 at cost, 2006 at wholesale price (WAC)) <sup>4</sup>	17	13	12	7	38
Number of albendazole tablets donated for prevention of lymphatic filariasis (millions)	19.4	19.4	19.2	19.1	18.3
Reportable injury and illness rate (per 100,000 hours worked)	556	425	266	150	155

1. 2010 data relate to ViiV Healthcare, 2009-2006 are GSK data.
2. Includes ARVs sold at not-for-profit and discounted prices.
3. Includes freight and delivery costs. The Médecins Sans Frontières pricing report lists the average cost of generic equivalents.
4. 2010, 2009, 2008 and restated 2007 figures reflect value at cost (average cost of goods) rather than wholesale acquisition price (WAC). This is the third 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. 2006 figures remain at WAC.
5. Includes contacts with line managers, compliance officers, our confidential Integrity Helplines or offsite post office box (in the US).
6. 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.



## Our Principles

Our Corporate Responsibility Principles are underpinned by our values and identify our key responsibility issues. They provide guidance for employees on the standards to which GSK is committed:

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**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.

**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.

**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.

**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. Read about our approach to public policy and patient advocacy.

**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.

**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 underserved people in the developed and developing world. Read about our work with communities.

## 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 2010 the Committee members were Sir Christopher Gent (Chair), Dr Stephanie Burns, James Murdoch and Dr Daniel Podolsky.

The Committee meets three times a year to review our policies and progress. 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.

To augment our engagement with stakeholder opinion, Sophia Tickell was appointed as an independent external adviser to the Corporate Responsibility Committee in March 2009. Sophia is the co-founder and Director of Meteos, from which she directs the Pharma Futures series, which aims to align better societal and shareholder value. She also sits on the Expert Review Committee of the Access to Medicine Foundation and is a member of the European Healthcare Innovation Leadership Network.

### Management of corporate responsibility



During 2010 the CRC reviewed GSK's activity in a number of areas under our CR principles, which include:

#### Access to medicines

- Access and pricing of medicines in middle-income and least developed countries

#### Standards of ethical conduct

- Embedding ethical values in the organization

#### Research and innovation

- Policy on use of animals in research and development

- Research integrity and transparency
- Governance of research conducted by external suppliers and collaborators
- R&D on treatments for rare conditions and for diseases of the developing world
- The potential of stem cell science for regenerative medicines

#### **Products and customers**

- Disclosure of payments to healthcare professionals

#### **Caring for the environment**

- Environmental sustainability strategy
- Management of environmental risks in manufacturing

#### **Employment practices**

- Employment practices including diversity and inclusion
- Leading and developing employees
- Employee relations including consultation arrangements
- Realignment of the pay for performance strategy
- Management of health and safety risks in manufacturing

#### **Community investment**

- Community partnerships and investment
- Humanitarian donations

The Committee also reviews and signs off the annual performance information published in this report on our website.

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## **Management structure**

CR covers a diverse range of issues 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.

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## **Measuring performance**

We have established metrics and key performance indicators to track our performance on responsibility issues.

## Stakeholder engagement

Stakeholder engagement and dialogue enables us to keep in touch 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. We provide training to help managers in our markets to communicate with local stakeholders on our approach to responsible business and transparency.

These are some of the ways we engage with stakeholders. More examples are provided throughout this report.

Stakeholder	Engagement methods
Healthcare professionals (HCPs)	<ul style="list-style-type: none"> <li>• Sales representative meetings</li> <li>• Interactions during clinical trials</li> <li>• Engagement with professional organisations</li> </ul>
Patients	<ul style="list-style-type: none"> <li>• Meetings between GSK scientists and patients through our 'Focus on the Patient' initiative</li> <li>• Work with patient advocacy groups</li> <li>• Market research to understand patient needs</li> </ul>
Governments and regulators	<ul style="list-style-type: none"> <li>• Our lobbying and public policy work</li> <li>• Advocacy on key issues such as access to medicines</li> </ul>
Investors	<ul style="list-style-type: none"> <li>• Meetings with investors and responsible investors</li> <li>• Participation in the Carbon Disclosure Project</li> </ul>
Employees	<ul style="list-style-type: none"> <li>• Regular employee surveys</li> <li>• Consultation with employee representatives on changes to the business</li> <li>• Participation in the Carbon Disclosure Project</li> </ul>
Local communities	<ul style="list-style-type: none"> <li>• Interactions at site level on a range of issues</li> <li>• Our community investment programmes</li> </ul>
CR specialists	<ul style="list-style-type: none"> <li>• Our Environment, Health and Safety Stakeholder Panel</li> </ul>
Multilateral agencies	<ul style="list-style-type: none"> <li>• Engagement through our access to medicines and public health</li> </ul>
Non-governmental organisations	<ul style="list-style-type: none"> <li>• Engagement on issues relating to access to medicines , community investment, public policy, and animal welfare</li> </ul>
Scientific community	<ul style="list-style-type: none"> <li>• Participation in academic collaborations</li> <li>• Participation in scientific debates</li> </ul>
Suppliers	<ul style="list-style-type: none"> <li>• Global and regional supplier review meetings</li> <li>• Meetings for diverse suppliers</li> </ul>
Peer companies	<ul style="list-style-type: none"> <li>• Pharmaceutical industry organisation meetings</li> <li>• Joint projects such as the Pharmaceutical supply chain initiative</li> </ul>

## Engagement in 2010

Many of our discussions with stakeholders during 2010 focused on responsibility-related issues. Examples are included below.

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### Engagement with investors

We met with investors and responsible investment (RI) analysts throughout the year and responded to a number of investor surveys. RI analysts also attended briefings as part of our broader investor relations programme.

Responsibility issues raised by investors in 2010 included:

- **Governance:** transparency, remuneration, audit and internal controls, risk management
- **R&D:** animal testing and welfare, clinical trial ethics including trials in developing countries, stem cells, biodiversity, use of genetically modified organisms
- **Ethics and compliance:** sales and marketing codes and ethical issues, healthcare professional payments, supplier contracts and related ethics and environment issues, UK Bribery Act and impact on GSK operations, whistle-blowing procedures and culture, competition policy
- **Access to medicines:** Access to Medicine Index, R&D for developing countries and rare diseases, pricing issues, formation of Developing Countries and Market Access operating unit
- **Environment:** environmental performance, climate change profile of GSK, business travel, transport emissions, alternative propellants, water pollution and treatment and management of related processes, water management, pharmaceuticals in the environment, renewable raw materials, environmental impact of packaging, disposal of drugs
- **Human rights:** human rights policy and systems, activities in embargoed countries
- **Human capital/employees:** restructuring, training and development, collective bargaining
- **Product-related questions include:** *Avandia*, *Seroxat/Paxil*, *Synflorix*, ingredients in GSK products.

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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.

We keep employees informed through our connectGSK intranet site and Spirit, our internal quarterly magazine. In 2010 over 10 articles on responsibility issues were published in Spirit, covering issues such as how ViiV Healthcare is delivering on its commitments to tackle HIV, GSK'S open innovation strategy to increase access to medicines, the launch of a global strategy for inclusion and diversity, and our employee volunteering and Pulse assignment programme. We distributed 25,000 copies of each quarterly edition and an online version is also available on the intranet.

We distributed our 2009 Corporate Responsibility Highlights 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 CR Report.

Read about our approach to embedding an ethical culture at GSK, our biennial employee survey, and how we engage with employees on environmental issues.

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## Engagement on access to medicines

Engagement on issues related to access to medicines during 2010 is covered in the Access to medicines section. We have held a number of formal engagement processes on subjects relating to access to medicines. These are reported in detail in our 2009 and 2007 CR reports.

## Audit and assurance

We assess many aspects of our responsibility performance through our internal and external assurance processes.

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Our Audit and Assurance department has responsibility for independently assessing, on a sample basis, the process and controls in place to comply with laws, regulations and company standards across GSK. Audits are focused on the key business risks areas for GSK.

The Audit function is a centralised department, independent from our business units. This allows the function to take an holistic view of how risks are managed across the company, reporting its findings to the Audit and Risk Committee. This direct reporting line to the Board helps ensure significant issues are escalated in a timely manner.

The Audit department includes approximately 120 audit professionals, across four groups:

- Manufacturing Internal Audit (which includes Environment, Health, Safety and Sustainability)
- Research & Development Internal Audit
- Commercial and Financial Internal Audit
- Information Technology Internal Audit.

Audits range in duration from two weeks for simple activities where the scope is limited, to several months for an audit involving complex or highly technical processes. Audit teams may be supplemented by external experts with specific technical skills, or by the use of guest auditors from the business.

Where issues are identified, the audit team will recommend improvements. GSK managers develop action plans to address the causes of non-compliance and address gaps in internal controls. Our Audit and Assurance department tracks these plans through to completion and reports results to senior management and the Audit and Risk Committee.

To supplement our traditional audit programme, Strategic Risk Evaluations (SRE) are used to quantify strategic and emerging risks and develop appropriate mitigation strategies. The approach is designed to evaluate areas across GSK where there is an incomplete understanding of risk, and enable the development and implementation of appropriate mitigation plans.

Read more about assurance, internal audit and risk management in the Corporate governance section of our 2010 Annual Report.

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## External assurance of the CR Report

Our environment, health and safety reporting has been externally assured by SGS, an independent 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 assurance statement.

We assure one other section of the CR Report every other year. Bureau Veritas provided assurance of the Ethical Conduct section of the 2009 CR Report. Read how we responded to their recommendation in our 2009 CR report

In the 2007 CR Report, information on access to medicines was externally assured. You can read our response in the 2008 CR Report



# Risk management

Non-financial and reputational risks are included in our core risk management processes.

Our Risk Oversight and Compliance Council (ROCC) co-ordinates the management of significant business risks and oversees internal controls to ensure compliance with applicable laws, regulations and GSK policies.

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The ROCC meets regularly to review and assess significant risks and mitigation plans. It is chaired by GSK's Corporate Compliance Officer and includes several Corporate Executive Team (CET) members and heads of departments with internal control risk management, assurance, audit and compliance responsibilities.

CET members are responsible for establishing an appropriate risk management structure within their business unit to identify and mitigate significant risks.

Each business unit must review significant risks at least once a year, including operational risks, legal compliance risks and risks to the achievement of strategic goals and objectives. This ensures that significant risks connected with changes in management direction and the external environment are identified. Business units and corporate functions are required to present their risk management and compliance approach to the ROCC and Audit and Risk Committee annually. They must provide a balanced assessment of the status of internal controls for key risks, and highlight any significant compliance issues.

We allocate audit resources to ensure sufficient attention is paid to areas of highest risk.

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## Our most significant risks

The following are the most significant risks facing GSK:

- Risk that R&D will not deliver commercially successful products
- Intellectual property protection
- Risk of substantial adverse outcome of litigation and government investigations
- Governmental, payer and regulatory controls
- Risk of interruption of product supply
- Taxation and Treasury
- Anti-bribery and corruption
- Risk of concentration of sales to wholesalers
- Global political and economic conditions
- Environmental liabilities
- Accounting standards
- Protection of electronic information and assets
- Alliances and acquisitions
- Attraction and retention
- Implementing GSK's strategic priorities

The Risk Factors section of our Annual Report provides more detail.

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## Alliances and acquisitions - due diligence

We are acquiring new businesses in line with our strategic priority to grow a diversified global business. Growth of the business must not undermine our commitment to high quality, ethical, environmental and workplace standards.

Our due diligence processes are designed to identify any risks posed by new business acquisitions, including ethical, social or environmental risks. Due diligence is usually managed by the relevant manager from our Corporate Development department in conjunction with regional business development managers. Oversight is provided by the Head of Corporate Development or the Chief Strategy Officer. Depending on the nature of the deal, technical and scientific experts may also be involved. We are working to improve the skills of those involved in due diligence processes and share good practices across the business. [Read more](#)

## About our reporting

We report our CR performance annually via this website as part of our commitment to be open and transparent about our business activities.

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This online CR Report includes an Overview section which summarises our approach to key issues covered in the report, useful tools such as a search function and glossary of terms, as well as options to download the report and more in the resource and downloads section.

This year we have also published a 2010 CR Review which provides an overview of our approach and performance on several key responsibility areas.

Information on corporate responsibility is also included in our Annual Report.

Brand names appearing in italics throughout this report are trademarks either owned by and/or licensed to GSK or associated companies.

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## Data

Data relate to worldwide operations for the calendar year 2010, except where stated.

Data in the environment and health and safety sections were independently assured by SGS. More information on our approach to external assurance is provided in the audit and assurance section.

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## Reporting standards

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.

## Access to medicines

Providing access to healthcare is one of society's most pressing social challenges.

Every year millions of the world's poorest people die from curable or preventable infectious diseases or suffer unnecessary ill health because they do not have access to basic healthcare services, including essential medicines or vaccines. The cost of healthcare can also be a barrier to access for patients in the developed world, particularly in the US where many people do not have healthcare insurance.

We want to increase access to our medicines and vaccines in all countries. We believe it is the right thing to do and know that it will contribute to our business success. By striving to meet society's healthcare needs, we build trust in our business, which helps to safeguard our licence to operate in the long term.

As well as pursuing progressive policies for the world's Least Developed Countries (LDCs), we are also focusing on increasing access to medicines in other developing countries. This helps us to build our business in increasingly important commercial markets such as Brazil, China, India, Indonesia and Russia. In the past, the majority of our revenue in these countries came from selling our medicines and vaccines to higher-income sectors of society. To achieve sustainable growth we need to go beyond the high-income sector, and increase access and affordability for patients at lower-income levels in all countries.

### World of GSK – Extending access in the developing world



View short stories on how GSK is extending access to medicines in the developing world and developing innovative pricing strategies in the 'World of GSK', our review of the year.

Our access strategy focuses on areas where we can make the most difference through our core business activities, skills and resources. In particular this means initiatives to improve affordability and to conduct and encourage more investment in R&D for the developing world.

To achieve this we are:

- Pursuing flexible pricing strategies
- Refocusing our R&D activities to reflect the needs of developing countries
- Seeking innovative partnerships to try to reach people who would otherwise not have access to our medicines and vaccines.

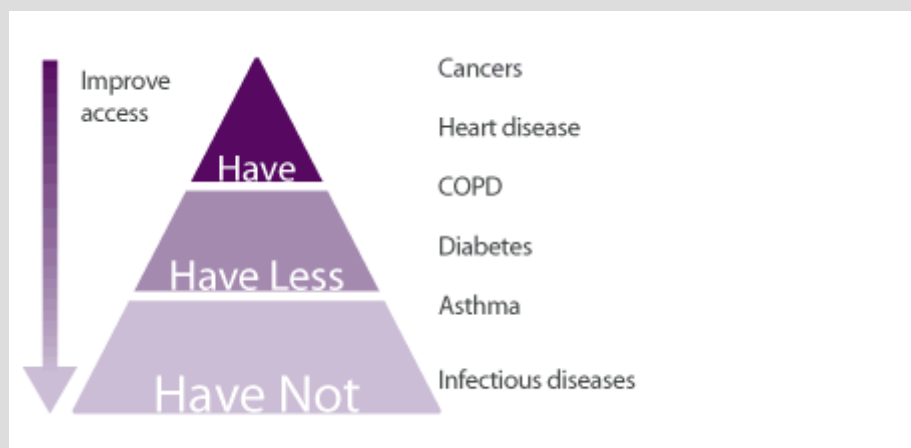
### Leadership in Access to Medicine

GSK was again ranked top in the Access to Medicine (ATM) Index published in 2010, the second time the Index has been published. The Index is produced by the Access to Medicine Foundation and financial analysts RiskMetrics. It provides an independent assessment of company efforts to improve access to medicines. In 2010 the Index assessed 20 R&D-based pharmaceutical companies and seven generics companies. GSK was ranked highest in six of the seven categories. We are pleased that our progress has been recognised but know that there is still more that can be done. We continue to consider the recommendations in the ATM Index carefully when reviewing our approach.

## Our approach

Access to medicines is a global problem that requires global commitment. Barriers to access vary significantly across countries, depending on poverty and income levels, coverage and quality of healthcare infrastructure, political commitment and the resources allocated to healthcare. We tailor our approach to the different needs of Least Developed Countries (LDCs), other developing countries and the developed world, see below for details.

### Expanding access in developing countries



The diagram shows how disease priorities can differ between the poorer and wealthier sectors of society. This is a broad representation - diseases can affect anyone regardless of their economic status. Diseases such as cancer and heart disease do not only affect the affluent. The most urgent healthcare priorities for lower income sectors of society tend to be infectious diseases.

Improving access to medicines is core to GSK's overall strategy and is prioritised from the highest levels of the company. Our CEO, Andrew Witty, is closely involved in our access efforts and has often spoken publicly on our commitments. His views are set out in an article on global health issues published in January 2011 in the leading US journal *Health Affairs* <sup>1</sup>.

The President of GSK's Emerging Markets and Asia Pacific region, leads our access efforts for developing countries. These are reviewed by the Corporate Executive Team, GSK's most senior executive management team, and by the Corporate Responsibility Committee of the Board.

We established a Developing Countries and Market Access (DCMA) operating unit in July 2010 which aims to increase patient access to GSK medicines and vaccines while expanding our presence and helping us to build a sustainable business in developing countries. Country managers for GSK's businesses in LDCs now report into the new unit, enabling us to take a more consistent and integrated approach to increasing access in these countries. The unit is also working with GSK country managers in other developing countries to increase access through flexible pricing and other approaches.

The DCMA unit aims to increase the availability of GSK medicines by broadening our portfolio to make it more relevant to people in these countries, pricing it to increase access and unlock demand, contributing to education and

awareness, and expanding our distribution and supply chain capability.

Wherever possible we work in partnership with companies, governments, international agencies, academic institutions, patient groups, NGOs and communities, providing our expertise, resources, medicines and vaccines to improve healthcare infrastructure and the availability of our medicines. By working together we can achieve more for patients than we can alone. Our DCMA unit is focusing on enhancing our existing partnerships and establishing new collaborations within developing countries to help improve healthcare availability and infrastructure.

In 2010 we conducted a strategic review of our approach to combating malaria. The review was conducted by a cross-functional team which reported directly to our CEO. See case study.

1. Article on global health issues by Andrew Witty - published in the leading US journal Health Affairs.

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## Least Developed Countries (LDCs)

The challenge of increasing access to medicines is particularly difficult in the world's Least Developed Countries. Our approach in these countries includes, investment in R&D for new medicines and vaccines against neglected tropical diseases, encouraging research outside GSK through our open innovation strategy, progressive pricing policies, and encouraging investment in healthcare infrastructure.

Our pricing strategy for LDCs includes capping the prices of our patented medicines, setting not-for-profit prices for HIV/AIDS medicines through ViiV Healthcare, and tiered pricing for our vaccines

We are broadening our portfolio of medicines and vaccines in LDCs and making it more relevant to people in these countries. This includes registering a wider range of GSK medicines in countries where they are not yet available and using partnerships such as those we have with Dr. Reddy's and Aspen to ensure that GSK has a presence in all important therapy areas.

We invest 20% of our profits from sales of our pharmaceutical and consumer healthcare products in LDCs back into projects that strengthen the healthcare infrastructure in those countries, and we support a number of disease prevention and community healthcare programmes. We announced a new five-year commitment in 2010 to expand the donation of our medicine albendazole to treat all school-age children in Africa at risk of intestinal worms (soil-transmitted helminths). Added to our donations to the Global Alliance to Eliminate Lymphatic Filariasis, this will increase our commitment to donate albendazole to around one billion tablets a year. Read more on this and our other community partnership activities in the community investment section of this report.

We currently supply medicines and vaccines directly to around three quarters (37) of the 48 LDCs. We are looking for opportunities to expand our presence into more countries in Africa in partnership with NGOs and UN organisations. For example, we recently relaunched GSK in Angola and have now established a reliable and sustainable supply chain to Somalia.

Our open innovation strategy for R&D into neglected tropical diseases is also focused on the LDCs.

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## Middle-income countries

Middle-income countries (MICs), such as Brazil, China, India, Indonesia and Thailand have a large and affluent middle class, offering significant business opportunities for GSK. However, many MICs 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.

MICs represent increasingly important customers for our industry and also present significant access challenges. In the past, the majority of our revenue in MICs has come from selling our medicines and vaccines to the higher-income sectors of society. To achieve growth we need to go beyond the high-income sector and increase access for patients at lower income levels. We believe our business growth will only be sustainable if it delivers greater access to medicines for these lower-income groups.

MICs will also benefit from our R&D for neglected tropical diseases and open innovation strategy, as well as our

research unit dedicated to making more of our product portfolio better suited for use in developing countries. We are continuing to implement flexible pricing strategies that make our medicines and vaccines more affordable for more segments of society in MICs. As Abbas Hussain, President of GSK's Emerging Markets and Asia Pacific region, has said: "Our aim is to reduce prices at the same time as increasing volumes. We would rather make the same return from supplying our medicines to 1,000 patients at a lower price, than from 200 patients at a higher price. This is better for society and better for GSK. However, this is easier said than done and to make it happen we have to do far more than just reduce our prices."

To this end, we are using in-licensing, joint ventures and acquisitions to expand our portfolio in middle-income countries to better reflect the local disease burden and demographic profile in each market as well as transferring manufacturing and research expertise to key markets.

We also support community programmes in a number of middle-income countries.

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## Developed countries

Even in developed countries some patients cannot afford the medicines they need and healthcare budgets are often under strain. We are developing a range of value and risk-sharing pricing models that reflect our commitment to work with governments and other stakeholders and support efforts to make our medicines and vaccines available to as many people as possible.

### What do we mean by developing countries?

When formulating our pricing and other access policies we tend to use four groupings in which there are some overlaps – Least Developed Countries<sup>1</sup> (LDCs); the countries of sub-Saharan Africa (SSA); low-income countries; and middle-income countries<sup>2</sup>. GSK uses the term 'developing countries' to include all four groupings.

1. We consider LDCs to be the 48 countries identified by the UN
2. For low- and middle-income countries we use the World Bank classifications



## HIV/AIDS & ViiV Healthcare

### Approach

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According to latest estimates, over 33 million people worldwide are living with HIV. Two-thirds of these, and over 90% of all new infections among children, are in sub-Saharan Africa. Although progress is being made there were 1.8 million AIDS-related deaths in 2009, and more than 7,000 new infections every day. Discrimination and stigmatisation remain, and many people still struggle to access the anti-retroviral (ARV) medicines and healthcare support they need. Only one-third of the 15 million people living with HIV who need therapy are receiving it.

GSK has had a significant history of developing medicines to treat HIV, offering its HIV/AIDS medicines at not-for-profit (nfp) prices in 2001 in Least Developed Countries (LDCs) and sub-Saharan Africa. In partnership with Pfizer we launched ViiV Healthcare in 2009; this is the only pharmaceutical company wholly focused on HIV. ViiV Healthcare is a specialist company dedicated to the development of innovative medicines, and partnerships to improve access and care. All GSK and Pfizer HIV medicines are now marketed by ViiV Healthcare.

Through the creation of ViiV Healthcare we intend to accomplish more for people whose lives are affected by HIV than either GSK or Pfizer could have achieved alone, and to bring commercial benefits to both companies.

ViiV Healthcare shares our commitment to increase access to medicines. It has a core objective to address the lack of suitable treatments and formulations for specific groups of people living with HIV such as children. It has taken on, and in some cases expanded, the access policies of the legacy companies.

ViiV Healthcare will publish an update on its approach to increasing access to medicines during 2011. A short summary of its performance in 2010 is provided here.

- Research: ViiV Healthcare is committed to the development of new molecules that target unmet medical needs in HIV including the treatment of children and problems such as drug resistance, complex treatment regimens, ageing with HIV and side effects associated with current treatments
- Pricing: ViiV Healthcare offers its complete ARV portfolio at nfp prices in LDCs, the World Bank's low-income Countries and all of sub-Saharan Africa. This covers 80% of all the people currently living with HIV. It is exploring flexible pricing solutions in middle-income countries that increase access to medicines while also meeting commercial objectives
- Voluntary licences: ViiV Healthcare has extended the voluntary licensing policy it adopted from GSK and now enables generics companies to manufacture and sell versions of its products in 69 countries royalty-free, covering 80% of people currently living with HIV
- Community investment: ViiV Healthcare supports communities impacted by HIV/AIDS through its Positive Action programme, the Positive Action for Children Fund and Positive Action Community Grants.

### Performance

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## Research and development

### Treatment of children with HIV/AIDS

ViiV Healthcare has committed £10 million seed funding to support a public-private partnership into the research and development of new HIV/AIDS medicines and formulations specifically for children. This partnership will also support early detection of HIV and access to therapy for HIV-positive infants and young children.

In 2010 ViiV Healthcare launched a new partnership with TREAT Asia, a Bangkok-based programme run by the American Foundation for AIDS Research (amfAR). ViiV Healthcare will donate \$2 million over two years to help TREAT Asia strengthen its paediatric HIV programme, a collaborative network of clinicians, investigators and healthcare workers providing care and treatment for children affected by HIV. The partnership will focus on research and medical education to identify and share best practices in the treatment of children with HIV.

ViiV Healthcare is also supporting HIV collaborative research trials (CRT) evaluating strategies for the prevention of mother-to-child transmission of HIV and paediatric treatment in resource-poor countries (see below).

### Research into new HIV treatments

Second-generation integrase inhibitors are a promising new class of compounds for the treatment of HIV that may help to address issues such as drug resistance and dosing complexity. The Shionogi-ViiV Healthcare joint venture, following encouraging results in 2010 phase IIb clinical trials of its novel once-daily, unboosted investigational HIV integrase inhibitor (S/GSK1349572, known as '572'), has now taken the compound and a fixed dose combination '572-Trii' ('572+Epzicom/Kivexa) into phase III clinical trials.

See information on GSK's vaccine research for HIV.

### HIV collaborative research trials (CRTs)

ViiV Healthcare is supporting international HIV CRTs in resource-poor settings. These trials are sponsored by external organisations such as WHO, the UK's Medical Research Council and the US National Institutes of Health. They focus on public health-related issues such as prevention of mother-to-child HIV transmission, paediatric and adult treatment strategies, when to start treatment, and HIV-TB co-infection. ViiV Healthcare donates ARVs and/or financial support, as well as scientific input throughout the life of the study.

At the end of 2010, 27 trials were underway and a further nine are planned, involving over 36,000 patients. Twenty-nine of these trials involve one or more African countries and eight are paediatric studies, one of which will provide the first significant clinical data on the efficacy, safety and pharmacokinetics of ViiV Healthcare's NRTI scored tablets in a resource-poor setting.

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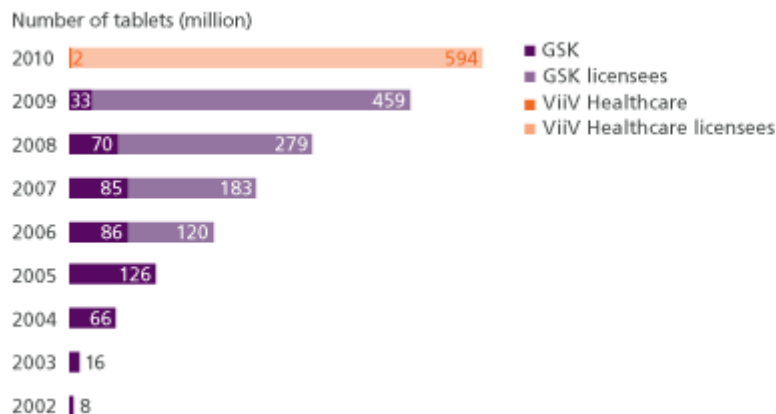
## Not-for-profit pricing

*Combivir*, ViiV Healthcare's leading ARV, now sells at \$197 per patient per year in the Least Developed Countries (LDCs) compared to \$730 in 2001 when we first introduced preferential pricing. Although this is a significant improvement in affordability, no price is affordable for the world's poorest communities without significant additional healthcare resources.

In 2010 ViiV Healthcare shipped 1.73 million tablets of not-for-profit (nfp) *Combivir* and *Epivir* to developing countries, compared with 32.7 million in 2009. The decline in supply of ViiV Healthcare's own ARVs is expected as the number of voluntary licences scale up, and is more than outweighed by the growth of nearly 35% in volumes supplied by its licensees. They supplied over 594 million tablets of their versions of *Epivir* and *Combivir* to African countries in 2010. These figures do not include syrup formulations and are therefore a conservative estimate of the ARV treatments shipped at preferential prices.

ViiV Healthcare will continue to look for new customers for its nfp ARVs and regularly review its nfp prices. However, it may well be that licensees are able to produce first-line ARVs at lower costs and will continue to increase their share of the business.

## Supply of *Combivir* and *Epivir* tablets by ViiV Healthcare and ViiV Healthcare licensees



In the chart above data for 2002 to 2009 relates to GSK. 2010 data relates to ViiV Healthcare. These figures do not include syrup formulations and are therefore a conservative estimate of the ARV treatments shipped at preferential prices

## 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. In total, UNAIDS estimates that 5.2 million people living with HIV in low- and middle-income countries now have access to HIV therapy, a thirteen-fold increase since 2004.

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## Middle-income country pricing

ViiV Healthcare negotiates preferential pricing arrangements for HIV/AIDS medicines with middle-income countries on a case-by-case basis. Prices are lower than those paid by developed countries, but need to be above the not-for-profit prices paid by the Least Developed Countries to make this approach sustainable. This is done bilaterally through dialogue with governments. It also has a number of potential technology transfer agreements under discussion, with countries that have the right local technological capacity.

Read about GSK's approach to pricing in middle-income countries.

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## Voluntary licensing

ViiV Healthcare extended its policy on voluntary licences in 2010. It now considers requests from all genuine partners, on a case-by-case basis, to grant royalty-free voluntary licences for its entire current and future ARV portfolio for use in the 69 countries where 80% of all people with HIV live. This includes all Least Developed Countries, all low-income countries and all of sub-Saharan Africa. This allows licensees to combine ViiV Healthcare's ARVs with those from other companies to which they have rights.

ViiV Healthcare partners, Shire Pharmaceuticals and Shionogi, have agreed to waive their rights to royalty payments for these countries in order to improve access for products developed in collaboration.

ViiV Healthcare has now granted 11 voluntary licences for its ARVs, an increase from eight when the company was formed. Its licensees supplied over 594 million tablets of their versions of *Epivir* and *Combivir* to African countries in 2010. This represents 35% growth over 2009 and ViiV Healthcare welcomes this trend as it gives customers in sub-Saharan Africa greater choice, improves affordability and contributes to better security of supply. Note that these figures do not include syrup formulations and are therefore conservative in giving an estimate of the ARV treatments shipped at preferential prices.

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## Community investment

ViiV Healthcare recognises the significant role that communities play in the response to the HIV/AIDS epidemic and is committed to supporting communities most affected by the disease. Positive Action, established by GSK in 1992, supports communities through grants for vulnerable groups, the new Positive Action for Children Fund, and community grants from local operating companies.

Positive Action projects include research, education, prevention, care and treatment-related activities. Details of current and recent projects may be found on the ViiV Healthcare website.

The Positive Action for Children Fund, established in 2010, has committed £50 million over ten years to support global efforts to virtually eliminate mother-to-child transmission of HIV. Twelve grants were awarded in June 2010, supporting projects in seven African countries and India. A second call for proposals was announced in December 2010, targeting the areas of greatest need around mother-to-child transmission of HIV; as well as support for grassroots community-based organisations and care and support for women affected by gender-based sexual violence in the Democratic Republic of Congo.

ViiV Healthcare has also committed \$2 million over two years to support the Elizabeth Glaser Pediatric AIDS Foundation, which works to increase early detection of HIV and improve access to lifesaving care and treatment for infants and children with HIV/AIDS. The partnership aims to improve HIV testing and care for infants and young children in Lesotho, Malawi and Swaziland.

In 2010 ViiV Healthcare launched the Positive Action US Southern Initiative. This collaborative, community-focused programme is designed to improve care and treatment adherence for African Americans and Latinos living with HIV/AIDS in the states of Alabama, Georgia, Louisiana and Mississippi. In the US, Black Americans and Latinos are disproportionately affected by HIV/AIDS. Compared to Caucasians, the rate of new infections is 6.5 times greater among African American males and 19 times greater among African American females.<sup>1</sup>

1. Hall HI et al. J Acquir Immune Defic Syndr 2008;49:294–297

### The Medicines Patent Pool Foundation

At the end of 2010, the Medicines Patent Pool Foundation was formally established by the board of directors of UNITAID.

The Medicines Patent Pool (MPP) is one of the many international community responses to meet the challenge of improving access to treatment and care for people living with and affected by HIV and AIDS.

Since its establishment, ViiV Healthcare has been in active dialogue with UNITAID and the Medicines Patent Pool Foundation. The Medicines Patent Pool wrote to ViiV Healthcare (and all pharmaceutical companies working in HIV) in early December 2010 asking them to join formal discussions on the pool. ViiV Healthcare met with them in early January 2011 and will continue to lead on discussions with the MPP; any key developments will be communicated by ViiV Healthcare. The MPP has created a section on its website to update on its engagement with companies.

In the meantime, it is important that ViiV Healthcare continues to focus on its many broad and deep approaches to meeting the challenge of access to care for people living with HIV, as set out in the rest of this report.

# Research and development

There is an urgent need for newer and better medicines and vaccines for some neglected tropical diseases. More can also be done to make treatments for other diseases more suitable for use in developing countries.

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We have a long-standing commitment to research and development into diseases of the developing world (DDW). Our R&D portfolio already includes projects for a number of diseases of particular relevance to developing countries including: bacterial meningitis, Chagas disease, chlamydia, dengue fever, HIV/AIDS, human African trypanosomiasis, leishmaniasis, malaria, pandemic flu, pneumococcal disease and TB.

We are ambitious to do more but we recognise that the challenges are too complex to be addressed by any one organisation alone. Partnership is essential and that is why we are pursuing an 'open innovation' approach, working together with industry, academia, NGOs and governments.

Open innovation at GSK includes:

- Sharing our expertise and resources with scientists from around the world through our Tres Cantos Open Lab
- Sharing our intellectual property and know-how through the Pool for Open Innovation against Neglected Tropical Diseases
- Being more open with our data and DDW research to help stimulate research outside GSK.

Each of these is explained in more detail in the following sections.

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## Developing world research units

We aim to integrate research for the developing world into our pharmaceutical and vaccine R&D organisations.

We have a specific R&D group focused on diseases of the developing world, including neglected tropical diseases (NTDs). A significant portion of our developing world drug discovery work takes place at our Tres Cantos site in Spain. This campus links GSK scientists across the organisation including the UK and US. Research decisions are prioritised on their socio-economic and public health benefits rather than on commercial returns. A similar group is active in our vaccines organisation in Belgium.

To complement these discovery efforts, we created a new R&D unit in 2009 with a focus on drug development for patients in emerging markets. This focuses on late stage clinical products that match the needs of patients in emerging markets and aims to champion the needs of these patients throughout GSK's R&D operations. Specifically, the unit is working on:

- Adapting GSK products so that they better meet the needs of patients in emerging markets. This includes regional-specific indications, dose requirements and presentations. The group is looking to develop affordable forms of medicines that will be accessible to more people in more countries
- Creating fixed-dose combinations of generics that offer improved clinical outcomes at an affordable price
- Partnering with research institutes and governments in emerging markets on innovative research and understanding long-term healthcare priorities.

The unit currently has four assets in clinical development across four therapeutic areas (respiratory, dermatology, urology and cardiovascular). Its clinical development portfolio will broaden over the coming year to include infectious diseases, neurology and oncology.

### What's different about research for the developing world?

GSK scientists working in DDW research need to prioritise aspects that will affect access to new medicines from the start of the R&D process. When researching a new DDW treatment we consider factors such as:

- Heat and humidity resistance – the product must be able to survive in a hot climate where refrigeration facilities may not be available
- 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 less expensive to produce.

### Open innovation

New and better medicines and vaccines are urgently needed in the fight against neglected tropical diseases. Given the scale of this task, we need to think differently about how we conduct R&D and find new ways for industry, academia, NGOs and governments to work together.

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We are pursuing an open innovation strategy to help speed up R&D for diseases of the developing world. This includes being more flexible with our intellectual property and providing access to our know-how and resources, and sharing our data with the research community.

For more about our position on intellectual property, read our position paper.

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### Tres Cantos Open Lab

We have created an open laboratory at our Tres Cantos Medicines Development campus in Spain to stimulate research into new treatments for diseases of the developing world. The open lab has space for visiting scientists from universities, not-for-profit partnerships and other research institutes to come to the site, work on projects with us, learn from our expertise and share our world-class facilities.

We have set up a not-for-profit foundation with an initial investment of £5 million to support visiting scientists and their research projects. A governing board of leading scientists within the field is providing strategic direction for the foundation and the research it supports.

All projects supported by the Open Lab Foundation must contribute to research that helps discover new medicines for diseases of the developing world. The projects involve collaboration between the scientists' home laboratory and GSK at Tres Cantos.

Opening up access to our facilities builds on the partnership approach we have always taken at Tres Cantos. Since the site was established in 2001 we have worked closely in public-private partnerships with groups such as the Medicines for Malaria Venture (MMV) and the Global Alliance for TB Drug Development (TB Alliance) on our drug discovery efforts. There are more than 100 scientists working at the centre, and many of these posts are funded by our partners. Some of the results of these collaborations are detailed in the pipeline section. Read more about public-private partnerships below.

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### Pool for Open Innovation against Neglected Tropical Diseases

In 2009 we helped to establish an independent knowledge pool where GSK and others could make available patents and knowledge that may stimulate research into treatments for 16 neglected tropical diseases (NTDs). This is now known as the Pool for Open Innovation against Neglected Tropical Diseases (POINT). Since January 2010 it has been independently administered by BIO Ventures for Global Health (BVGH), a non-profit organisation that aims to accelerate the development of drugs, vaccines and diagnostics to meet global needs.

Under the terms of POINT any medicines or treatments for NTDs developed using the pooled patents and intellectual

property will be available to Least Developed Countries on a royalty-free basis.

We have contributed patents and patent applications to the pool covering small molecules and formulations directed at treatments and delivery technologies for one or more of the 16 NTDs. In response to feedback from the scientific and research community, we have also committed to consider requests for access to our knowledge and experience. For example, we would review requests for information on what we have tried already and what the results were in a specific area, what worked and what did not, and about how we overcame particular challenges.

Several organisations and another company have contributed patents to the pool. They are: the US biotechnology group Alnylam; the Massachusetts Institute of Technology; Medicines for Malaria Venture; University of California, Berkeley; and Caltech. We believe that the creation of POINT and the appointment of BVGH as administrators has helped to foster constructive discussions among groups, including other pharmaceutical companies, in this area.

Organisations which have been granted access to assets in POINT include the Emory Institute for Drug Discovery and iThemba Pharmaceuticals, a company based in South Africa and working on TB with support from the South African government.

For more information about the pool or its administration, visit:

- Pool for Open Innovation against Neglected Tropical Diseases
- BIO Ventures for Global Health website.

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## Sharing research information on DDW

As part of our commitment to open innovation, we have committed to sharing more of our research findings. As a demonstration of this, in May 2010 we published in the leading scientific journal *Nature*<sup>1</sup> research findings that could help identify potential new treatments against malaria.

The research was the result of a year-long screening process in which five GSK scientists reviewed more than two million compounds in GSK's chemical library to seek out those that could inhibit the malaria parasite. Normally a screening can be automated and takes 8–10 weeks, but this process had to be done by hand, given the nature of the screening and the dangers of working with the malaria parasite. The research was co-funded by GSK and the Medicines for Malaria Venture.

This process identified 13,533 compounds that showed greatest activity. More than 80% of these molecules are proprietary to GSK, and this is the first time they have been available to the wider research community.

The data and chemical structures are also available online through the European Bioinformatics Institute (EMBL-EBI), the US National Institutes of Health PubChem resource and Collaborative Drug Discovery. The value of the information is enhanced by the research tools made available on those sites to researchers at no cost.

Many researchers have already accessed and downloaded the data. They are asked to report back their findings to the sites, and thereby create an open worldwide collaboration aimed at expanding our collective knowledge and speeding up development of new medicines.

We hope this will stimulate new research and lead to new anti-malarial therapeutic strategies or new ways of fighting malarial infection.

More information can be viewed online at:

- European Bioinformatics Institute (EMBL-EBI)
- US National Institute of Health PubChem resource and Collaborative Drug Discovery
- [www.collaboratedrug.com](http://www.collaboratedrug.com)

1. Francisco-Javier Gamo et al Thousands of chemical starting points for antimalarial lead identification. *Nature* Vol. 465, issue 7296, pp 305-310, DOI: 10.1038/nature09107



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## Public-private partnerships

Biomedical R&D is a costly, risky and time-consuming activity. There are some diseases which disproportionately affect the developing world but which also affect developing countries where a market for treatments already exists (as with HIV/AIDS). In these cases, we incur all the R&D costs and risks involved, on the expectation that there will be a market in better off countries where we will make a return on our R&D investment.

For other diseases of the developing world, where no such return on investment can be expected, 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. PPPs make this work commercially viable by sharing the risks and costs involved.

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 are becoming increasingly important and they have transformed the landscape for the development of medicines and vaccines for diseases of the developing world.

PPPs can work in many different ways. For example, some of our partnerships are centred on 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. Around half of the scientific posts at Tres Cantos are subsidised by our partner organisations, MMV, the Global Alliance for TB Drug Development and the Drugs for Neglected Diseases initiative.

As compounds move into clinical development, GSK provides the clinical, regulatory and manufacturing expertise and resources through our global R&D and supply network and the clinical trials are conducted with support from our partners.

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.

## Pipeline update

This section contains updates on some of our key research projects for the developing world, covering both medicines and vaccines below.

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GSK is one of the few companies researching new vaccines and treatments for all three of the World Health Organization's priority infectious diseases, HIV/AIDS, malaria and tuberculosis.

Information on HIV/AIDS research is included in the section on ViiV Healthcare.

Read about our developing world research units which integrate research for the developing world into our pharmaceutical and vaccine R&D organisations.

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## Medicines for the developing world

### Malaria

Our work on malaria treatments includes tafenoquine and pyridone GSK932121.

#### Tafenoquine

We are developing tafenoquine, a potential new treatment for the radical cure of *P. vivax* malaria, in partnership with the Medicines for Malaria Venture (MMV). The malaria parasite *P. vivax* causes both an acute infection of red blood cells, as well as a dormant infection in liver cells, which can lead to malaria symptoms recurring at any time. A radical cure would be one that completely eliminates the malaria parasites from the body, including the dormant parasites in the liver. Tafenoquine offers the potential for a one-day treatment course, which is significantly shorter than the current 14-day standard of care course of primaquine.

Tafenoquine, like primaquine, is part of a class of medicines known to cause acute haemolytic anaemia (a condition where red blood cells are destroyed) in some people with an inherited disorder known as glucose-6-phosphate dehydrogenase (G6PD) deficiency. G6PD deficiency is common in areas where malaria is prevalent. As a result of this issue, an initial study is underway to understand the haemolytic risk of tafenoquine in subjects with G6PD deficiency. The study began in 2009 and interim results are expected in 2011. In addition, a phase II clinical study to assess the efficacy and safety of different doses of tafenoquine is scheduled to begin in 2011.

#### Pyridone GSK932121

Pyridones are a new class of compounds with the potential to be highly effective against drug-sensitive and drug-resistant strains of both the *P. falciparum* and *P. vivax* malaria, as well as against the mosquito stages of the parasite. We developed pyridone GSK932121 in partnership with MMV and entered 'first time in human' clinical trials early in 2009. Safety concerns precluded further development of this molecule, but novel inhibitors of the same target are still under investigation.

### Tuberculosis

Our tuberculosis medicines research at Tres Cantos is conducted in partnership with the Global Alliance for TB Drug Development (TB Alliance). Through this partnership, we aim to discover new medicines that can be used in novel combinations for the treatment of susceptible and drug-resistant TB and which may contribute to overall shortening of treatment time.

Our lead TB project is looking at mycobacterium gyrase inhibitors, enzymes which are involved in a key step in the

growth and multiplication of the TB bacterium. Our focus is to develop a suitable compound that can affect the enzyme. We are also researching how to translate preclinical data into potential clinical findings that could help predict at an early stage how TB patients are responding to treatment. This could significantly speed up TB research as currently the effectiveness of a new TB drug cannot be determined until 18-24 months after completion of treatment. We are also collaborating with the European Union Framework and Innovative Medicines Initiative on this issue.

## Visceral leishmaniasis (VL)

Sitamaquine is a compound that has been in development as an affordable, once a day, oral treatment for visceral leishmaniasis (VL), a potentially fatal parasitic disease spread by sand flies.

The rationale for developing sitamaquine was to provide an accessible treatment for patients that represented a significant advance on available therapies. However, phase II studies demonstrated that sitamaquine would be unlikely to offer the significant advance hoped for. After extensive external consultation with policy makers and major stakeholders in endemic countries, we took the decision to discontinue development of sitamaquine on these grounds.

GSK continues to carry out drug discovery efforts into VL treatments through our partnerships with Brazil's Oswaldo Cruz Foundation and the Drugs for Neglected Diseases initiative (DNDi).

## New alliances

We announced a new collaboration with Brazil's Oswaldo Cruz Foundation (Fiocruz) in 2010, directed at developing innovative medicines for malaria, tuberculosis, Chagas disease and leishmaniasis. This alliance, which builds on our vaccines work with Fiocruz, will enable scientists at Fiocruz and GSK's Tres Cantos facility to openly share new research, ideas and know-how. The agreement will initially concentrate on Chagas and leishmaniasis because of the experience of Fiocruz in these areas and the severe burden of unmet medical need for patients living with these diseases.

We are exploring opportunities to join forces with the not-for-profit organisation Drugs for Neglected Diseases initiative (DNDi) in the discovery of new compounds to treat other neglected diseases, including human African trypanosomiasis (sleeping sickness) and Chagas disease.

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# Vaccines for the developing world

## Malaria

GSK has been working on a malaria vaccine for more than two decades. Our candidate vaccine, called RTS,S which we are developing in partnership with the PATH Malaria Vaccine Initiative (MVI) is currently in phase III studies at 11 sites in seven African countries. The trial is on schedule and as of February 2011 had enrolled over 15,000 of the planned 16,000 infants and children. Initial results from the phase III study are expected in late 2011 for the 5-17 month group and late 2012 for the 6-12 week group. The final analysis is expected in late 2014.

RTS,S is the first malaria vaccine candidate designed primarily for Africa and, if effective, it will be the first successful vaccine against a human parasite. Notably, RTS,S is also the first vaccine whose development has been spearheaded by an extended team of researchers and organisations spanning the globe, including GSK, MVI, the Bill & Melinda Gates Foundation and scientists from across Africa, Europe and North America.

Phase II studies showed that RTS,S reduced clinical episodes of malaria by 53% in the 5-17 month age group over an 8-month period following vaccination. In addition, RTS,S was shown to have a promising safety and tolerability profile when used alongside the World Health Organization's (WHO) standard infant vaccines.

We will price the RTS,S vaccine to cover our costs and to generate a small return of around 5% which will be reinvested in research and development for second-generation malaria vaccines, or for other products for diseases of the developing world. See Vaccines for more information.

GSK's Joe Cohen, co-inventor of RTS,S and Vice President and Advisor, Malaria Vaccine Project, commented: "If all goes well, five years from today, a vaccine could start being given to six- to 12-week-old children. It's a fantastic achievement." But as MVI Executive Director Christian Loucq noted: "Development is only half the mission. [The partners] are committed to ensuring this vaccine reaches those who need it most. We hope the international

community will respond by starting to prepare for the day when, if all goes well, this vaccine will be available for distribution and use.”

Under current plans, RTS,S would be submitted to regulatory authorities in 2012, for use in children 5-17 months of age, followed by later submissions for use in infants 6-12 weeks of age, which is the age range when children get their current childhood vaccinations through the Expanded Programme for Immunisation (EPI).

GSK is also collaborating with others to develop next-generation malaria vaccines that build on the success of RTS,S. In 2010 we signed an agreement with Crucell to begin early-stage testing of a malaria vaccine candidate that combines RTS,S with Crucell’s Adenovirus (AdVac) technology. GSK is working with MVI and the US Army on preliminary research for potential vaccines targeted at *P. vivax*, the second most serious malaria-causing parasite

## Tuberculosis

Despite widespread use of the 90-year-old Bacillus Calmette-Guerin (BCG) vaccine, tuberculosis (TB) remains the world’s second leading cause of mortality and morbidity. We work with several partners in our TB vaccine development programme, including the Aeras Global TB Vaccine Foundation and the Tuberculosis Vaccine Initiative. Our M72 TB candidate vaccine has demonstrated positive early results. To date we have conducted phase I and II trials in TB-naïve, TB-infected and BCG-vaccinated adults, as well as HIV positive adults taking a combination of anti-retrovirals. A phase II trial in African infants is ongoing.

## HIV/AIDS

We have been involved in AIDS vaccine research for over two decades. We are now pursuing four separate vaccine strategies. A successful AIDS vaccine might combine several of these approaches

- GSK’s HIV vaccine candidate, F4/AS01, is currently in phase II clinical trials in HIV-infected subjects to evaluate its safety and efficacy.
- The F4/AS01 vaccine candidate will also be combined with a recombinant adenovirus 35 vector in a collaboration with the International AIDS Vaccine Initiative (IAVI).
- GSK is working with the Pasteur Institute in Paris and other partners to develop an AIDS vaccine by fusing genes from the HIV virus onto a measles vaccine vector. A phase I clinical trial has started in 2010.
- A collaborative discovery R&D programme that aims to identify an HIV envelope-based protein vaccine capable of producing broadly neutralising antibodies against HIV infection is being conducted with multiple partners.

## Dengue fever

Our joint R&D initiative with Fiocruz to develop a vaccine for dengue fever continued. Scientists from GSK and Fiocruz are working across facilities in Brazil and Belgium on this partnership which will also enhance Brazilian R&D capacity.

## Vaccines

### Approach

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Vaccines play a major role in preventing disease and have been acknowledged by the World Health Organization (WHO) as being 'among the most cost-effective of health investments'. It is estimated that at least three million deaths are prevented and 750,000 children are saved from disability due to vaccines every year<sup>1</sup>.

GSK is one of the world's largest vaccines producers and growing our vaccines portfolio is a key element of our business strategy. We aim to increase access to vaccines through:

- Investment in vaccine research
- Tiered pricing for developing countries
- Partnerships that help to build local healthcare infrastructure and manufacturing capacity, including technology transfer.

These efforts are needed because vaccines are still under-used in many countries. 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.

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### Tiered pricing for vaccines

For over 20 years we have made our entire 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 the length of a particular supply contract. By selling our vaccines in large volumes through longer-term contracts we are able to significantly reduce the price of each individual dose. For the developing world, prices can be as little as a tenth of those for developed countries. This model works for vaccines because demand is relatively predictable due to centralised bulk purchasing by groups such as UNICEF. We are also introducing flexible pricing for vaccines sold directly to governments and other customers.

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### Strategic alliances

We have a number of joint ventures and technology transfer arrangements for GSK vaccines. These can help to increase the supply and affordability of vaccines while enabling developing countries to develop their research and manufacturing capabilities, and increasing market access for GSK. Read more about our approach to technology transfer in our position paper.

These arrangements include a new agreement signed in 2010 with Binnopharm in Russia that will help Russia to modernise its National Immunisation Calendar, adding additional vaccination against highly prevalent infections such as human papillomavirus (HPV), rotavirus and Streptococcus.

We have partnered with Brazil's Oswaldo Cruz Foundation (Fiocruz) since 1985 to manufacture vaccines for public health priorities in Brazil, including polio, Haemophilus influenzae type b (Hib), measles, mumps, rubella, rotavirus and, most recently, pneumococcal disease. This local manufacturing and technology transfer deal has generated sales for GSK vaccines while helping Brazil strengthen its research and manufacturing capabilities.

In China we have a joint venture with Shenzhen Neptunus to develop and manufacture influenza vaccines and a collaboration agreement with biotech company Walvax to develop and manufacture paediatric vaccines (including a measles, mumps and rubella vaccine).

## Our vaccine portfolio and pipeline

We have over 30 vaccines approved for marketing. These address the medical needs of developing and developed countries and cover most of the leading causes of childhood mortality. Our vaccines protect against the following diseases:

- Cervical cancer
- Chickenpox
- Diphtheria
- Hepatitis A and B
- Haemophilus influenzae type B meningitis (Hib)
- Influenza (seasonal and H1N1)
- Measles
- Meningitis
- Mumps
- Otitis media
- Respiratory pneumococcal disease
- Polio
- Rotavirus
- Rubella
- Tetanus
- Typhoid
- Whooping cough (pertussis)

Over 1,600 scientists work in vaccine research at GSK and our vaccine pipeline has been recognised as the largest in the industry<sup>2</sup> with over 20 potential new vaccines. One-third of vaccines in our pipeline target diseases which are particularly prevalent in the developing world.

1. Ehreth J. The Global Value of Vaccination. *Vaccine* (2003): 21 (7-8): 596-600
2. GSK has received two awards recognising its vaccine pipeline: the SCRIP Awards in 2008 and the 2nd annual Vaccine Industry Excellence Awards in 2009

## Performance

Our vaccines were included in immunisation campaigns in 179 countries worldwide. In 2010, of the 1.4 billion vaccine doses we shipped, just over one billion went to developing countries, including least developed and middle-income countries.

Many of our vaccines are included in government vaccination programmes in developing countries. For example, *Rotarix*, our rotavirus vaccine, is included in government vaccination programmes for new-born babies in Brazil, El Salvador, Mexico, Panama and Venezuela. In 2010 we supplied close to 20 million doses of this vaccine; the vast majority went to developing countries.

In 2009-2010 we also supplied 344 million doses of our pandemic H1N1 influenza vaccines worldwide, including 24 million doses donated to WHO for use in developing countries.

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## Our malaria vaccine candidate

We want to maximise access to all of our vaccines, and there may be cases where tiered pricing is not appropriate so we have to try different approaches. One example is our malaria vaccine candidate known as RTS,S, which is currently in late-stage clinical trials across Africa. If successful, we expect to be in a position to make an initial submission to regulatory authorities in 2012 for approval. This vaccine will be exclusively for African children and there will be no market in developed countries to offset costs. Therefore, unlike virtually every other vaccine, we cannot tier the price, but we will seek to ensure that price will not be a barrier to access.

We have therefore committed to setting a price which covers our costs and makes a small return of around 5%. This will be reinvested fully in R&D for next generation malaria vaccines or for other products for diseases of the developing world.

We have taken this approach in full consultation with our partners such as the Bill & Melinda Gates Foundation and the PATH Malaria Vaccine Initiative. We believe it would not be helpful to launch the first malaria vaccine at a not-for-profit price. This could create an expectation that all following products would have to be similarly priced. This would be a major disincentive to investment in malaria R&D for some organisations and it is essential that we do not do anything that would have such unintended consequences.

We cannot provide guidance on what the actual price will be until we have a better idea of our own cost structure and the likely demand for the vaccine. In addition to the price commitment, we will donate at least 12.5 million doses to the PATH Malaria Vaccine Initiative.

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## Synflorix

In March 2010, GSK became one of the first manufacturers to sign an agreement with the GAVI Alliance to speed access to its pneumococcal vaccine, *Synflorix*.

Respiratory pneumococcal disease is a major global health issue and the leading cause of death in children under five in developing countries. Each year, *Streptococcus pneumoniae* respiratory 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.

Through a new financing mechanism, the Advance Market Commitment (AMC), we will supply up to 300 million doses of *Synflorix* to GAVI-eligible countries. It will be priced at just 10% of the cost in developed markets. This could help to protect up to 100 million children over ten years. The AMC seeks to close the 'vaccine gap' – the 15-20 year delay often experienced between a vaccine launching in the developed world and becoming accessible to developing countries.

*Synflorix* was approved for use in Europe in 2008 and was first introduced in Africa (Kenya) in January 2011.

### *Synflorix* in Uganda

In November 2010, GSK was criticised by the humanitarian organisation Médecins Sans Frontières (MSF), about claims that the company was selling its pneumococcal vaccine *Synflorix* in the private market in Uganda at a price that was unaffordable and not aligned with GSK's stated pricing policies in the Least Developed Countries (LDCs). MSF understood that *Synflorix* was being sold for around \$50 a dose and the claims attracted media attention which resulted in negative articles about GSK. We took this criticism extremely seriously and immediately conducted an internal review.

GSK has a well established tiered pricing policy for its vaccines that is recognised by governments, NGOs and the World Health Organization (WHO). Tiered pricing means that the poorest countries pay a fraction of the cost of developed countries. This is why around 75% of all the vaccines we sell each year go to developing countries.

When it was brought to our attention by MSF that our vaccines prices in the small private market were not always aligned with our wider access strategy in the LDCs to increase access to medicines for people living in these countries, we acknowledged that this was a mistake and conducted a review across all the LDCs to ensure compliance. The company has now brought in a new pricing policy for vaccines in the small private market across all LDCs, setting the price at 25% of the Western European average and has issued clearer guidance to its local operating companies to ensure full compliance.

Under this new policy the maximum retail price for Synflorix in the private market in all these countries was set at \$20 a dose. This will apply provided this price is not below those prices offered to agencies such as the GAVI Alliance and UNICEF which purchase large volumes for the world's poorest children and that are therefore always offered GSK's lowest prices.

In January 2011, the first doses of Synflorix were administered under the Advance Market Commitment (AMC) – a mechanism which means that hundreds of millions of children across Africa will be vaccinated against *Streptococcus pneumoniae* respiratory infections – at a price which is marginally above the cost of goods. We do not expect that African families will have to pay for this vaccine as the vast majority of the funds have been donated by western governments (see details on the AMC above).

GSK recognises the important campaigning role that NGOs such as MSF play and we are grateful for their attention. We meet with them regularly to work through issues such as this. We have responded to all of their concerns in writing and in face to face meetings and will continue to do so.

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## Pilot projects

We are exploring a number of different approaches to increasing access to vaccines in developing countries. These include two projects in Egypt and Mexico to develop a network of new clinics where people can more easily obtain immunisations in their local communities.

For example, in Egypt we have joined forces with the Al Borg chain of private pathology laboratories to find a cost effective way to help more adults access vaccines. The new initiative uses Al Borg's branches, cold chain infrastructure and house-call customer service system to deliver the vaccines. These are offered at reduced prices to make them affordable to more sections of society. The partnership was launched at 30 Al Borg branches in 2009 with the seasonal flu vaccine. It was accompanied by training for 270 branch managers, physicians, technicians, receptionists and call agents. A call centre staffed by specialist agents and a flu hotline for vaccine queries were also established. So far, more than 160,000 people have received the vaccine at the centres and we are looking to expand the programme through partnerships with other laboratory networks in Egypt and elsewhere in Africa.

For *Cervarix*, our vaccine against cervical cancer, we are partnering with a major international non-governmental organisation, using its distribution network in developing countries where most cervical cancer deaths occur. Results from a pilot programme launched in South America in 2009 are encouraging. Read more in the Flexible pricing section.

We are also involved in a project to improve the infrastructure for childhood immunisation programmes in India, where millions of mothers and children do not receive basic immunisations.

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## Strategic alliances

### Russia

We launched a new alliance with Russian company Binnopharm in 2010. GSK will provide technology and expertise to enable Binnopharm to manufacture, fill and pack a number of innovative GSK vaccines in accordance with international current Good Manufacturing Practice standards.

Russia has an efficient system of universal mass vaccination that covers approximately 98% of the population. From 2012 GSK's combined and pneumococcal vaccines will be supplied under Binnopharm's trademark.



## Brazil

Our technology transfer agreement with Fiocruz for our *Rotarix* vaccine which protects against rotavirus, a cause of gastroenteritis, continued this year. Since 2007 GSK (via Fiocruz) has been the sole supplier of more than 33 million doses of rotavirus vaccine in Brazil. The deal has benefited both GSK and Fiocruz and is helping to ensure that around 17 million babies in Brazil will be protected by GSK's *Rotarix* over five years. From 2012 Fiocruz will produce *Rotarix* for the Brazilian domestic market and manufacture *Rotarix* for GSK under contract for export.

GSK is also providing Fiocruz with access to the technology behind its *Synflorix* vaccine which protects against life-threatening infections such as pneumonia, meningitis and bacteraemia. The Brazilian government has incorporated the vaccine into its national immunisation programme.

## Flexible pricing

Pricing is one factor that impacts on access to medicines and vaccines.

We are adopting a range of flexible pricing models that reflect our commitment to work with governments and other stakeholders to deliver our medicines and vaccines to as many of the people who need them as possible.

### World of GSK – An innovative approach to pricing



View short stories on how GSK is extending access to medicines in the developing world and developing innovative pricing strategies in the 'World of GSK', our review of the year.

In the Least Developed Countries (LDCs) we offer substantially reduced pricing for our patented medicines. Through ViiV healthcare, we offer not-for-profit prices for HIV/AIDS medicines in these countries and in sub-Saharan Africa. We offer tiered pricing for GSK vaccines worldwide.

Many of the poorer communities within middle-income countries also face barriers to access to medicines. However, our ability to offer not-for-profit or highly preferential prices in the world's poorest countries is only sustainable if we can continue to make an adequate return on our medicines and vaccines in better-off markets. Many middle-income countries are also growing markets for GSK and represent an important source of future business for our industry. We are exploring a range of pricing approaches that balance our commercial objectives with the need to increase access to medicines for those in these markets who cannot afford to pay. These include: flexible, tiered and preferential pricing models; tailored products; and local sourcing and manufacturing arrangements.

Even in developed countries, some patients lack access to medicines. This is a particular problem for uninsured patients in the US. We seek to price medicines fairly in these countries and at a level that reflects their value to patients and payers. Our US Patient Assistance Programs and discount savings cards provide access to GSK medicines for uninsured patients at no or minimal cost.

### Flexible pricing – the challenges

Pricing is a complex and multi-dimensional issue.

Factors such as new product introductions or the reaction of competitors to our price changes can have an impact on GSK's ability to improve access to our own medicines.

For example, however much we seek to evolve our business model, there will always be companies with a lower cost base which will be able to supply at lower prices than GSK. Our price reductions may lead to competitors

reducing their prices. While this may improve affordability and benefit patients, it could also mean that prices reduce to a point where we cannot make a profit and our business in that market becomes unsustainable.

Reducing the prices of our medicines does not by itself guarantee that more patients will be able to access them or that we will be able to generate the increase in volumes needed to make this sustainable. At the same time as cutting our prices, we also need to increase investment in marketing and distribution.

Other factors include diversion of products sold at lower prices to better-off groups within that country or even to other countries. It is possible that better-off countries may seek the same price reductions even though their ability to pay is greater.

Taking these many factors into account, we will continue to review the prices of our medicines for private and public purchasers in each country to ensure that we are competitive and profitable, and that our medicines are available to the widest number of people who can reasonably afford them.

## Least Developed Countries

### Approach

Since 2009 we have committed to significantly reducing our prices for patented medicines in the Least Developed Countries (LDCs). Our aim is to reduce prices to no more than 25% of their price in the UK (or in France for products not sold in the UK) while ensuring we cover our manufacturing costs so this offer is sustainable. This commitment applies to all patented products where GSK is the sole supplier in that market. In response to feedback from physicians, we have also extended price reductions to some off-patent products.

We have also extended our commitment to all vaccines in the small private market in all LDCs, setting the price at 25% of the Western European average. This will apply provided this price is not below those prices offered to agencies such as the GAVI Alliance and UNICEF which purchase large volumes for the world's poorest children and that are therefore always offered GSK's lowest prices.

We continue to look for opportunities for further price reductions. Country managers for GSK's businesses in LDCs now report into our new Developing Countries and Market Access operating unit, enabling us to take a more consistent and integrated approach to increasing access in these countries. We are also focusing on registering a wider range of products in more LDCs.

Our approach also includes long-established practices such as tiered pricing for vaccines and, through ViiV Healthcare, not-for-profit pricing for HIV/AIDS medicines.

Product diversion, where not-for-profit or preferentially priced medicines are illegally shipped back for sale in better-off countries, denies treatment to patients in poorer countries. There is a particular risk of diversion from LDC markets to better-off countries in East and West Africa because of shared supply chains and a lack of stringent border controls. To reduce this risk we have introduced price reductions in some non-LDC markets.

#### World of GSK – An innovative approach to pricing



View short stories on how GSK is extending access to medicines in the developing world and developing innovative pricing strategies in the 'World of GSK', our review of the year.

# Performance

## Patented products

Since April 2009 we have reduced prices in the Least Developed Countries (LDCs) for 11 GSK patented brands (110 individual product lines and formulations) in the countries where they are registered.

Prices were reduced by an average of 45% and apply to the following brands: *Seretide* (asthma, chronic obstructive pulmonary disease – COPD), *Avamys* (rhinitis), *Flixotide* (asthma), *Malarone* (malaria), *Avodart* (benign prostatic hypertrophy), *Avandia* (type 2 diabetes), *Avandamet* (type 2 diabetes), *Fraxiparine* (anti-coagulant), *Ultiva* (anaesthetic), *Arixtra* (venousthromboembolism – VTE) and *Zeffix* (hepatitis B).

In most cases prices have been reduced to no more than 25% of their price in the UK (or in France for products not sold in the UK). In some cases it is not possible to reduce prices to this level and still cover our manufacturing costs. In these instances we have reduced our prices as much as possible and will look for opportunities to introduce further reductions.

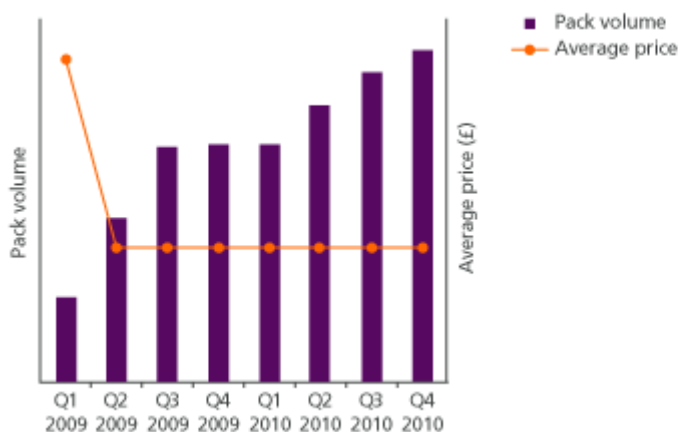
Sales volumes for the majority of products have increased significantly following the price decreases which we believe has increased access for more patients; see charts below.

In 2010 we focused on launching these 11 brands into more LDCs at our reduced prices.

On patent expiry, any price reductions which have been made will continue to apply. When we launch a new GSK patented product in LDCs, they will be priced in line with our reduced pricing policy.

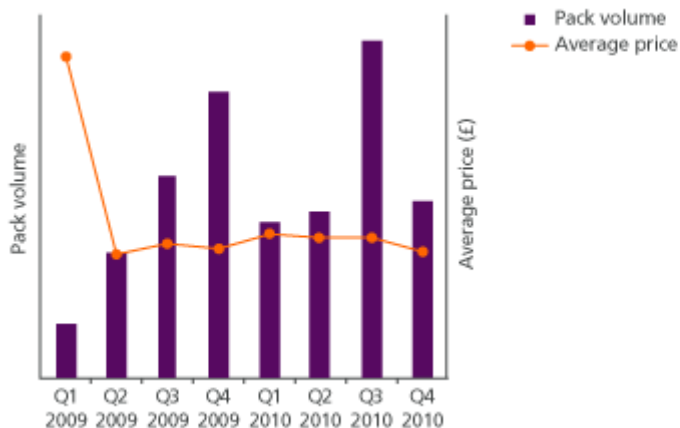
The medicines covered by the price reductions are all products where GSK is the sole supplier. We know that these products may not meet the priority health needs of the general population in LDCs and we are exploring ways to expand access to other GSK products. We are sponsoring research to assess the current reach of GSK respiratory products and to fully understand the barriers to access in 15 different urban areas, ten of which are in LDCs. We will use the findings to form partnerships with NGOs, healthcare providers and professional and patient respiratory groups to tackle these barriers and deliver better treatment.

### Price reductions on GSK branded products in East Africa



The chart above shows the average price to patients and the combined number of packs sold for the following GSK patented products: *Avamys*, *Avandamet*, *Avodart*, *Flixotide*, *Malarone* and *Seretide* in East Africa. Prices were reduced by an average of 69% in the first quarter of 2009 and the number of packs sold increased more than fourfold (320%) by the end of 2010.

### Price reductions on GSK branded products in Francophone West Africa

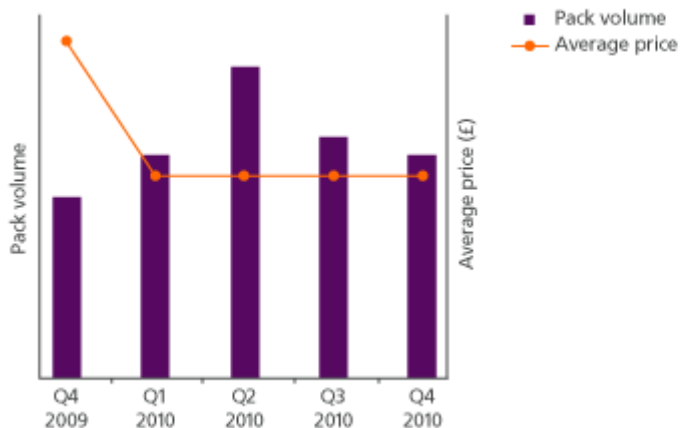


The chart above shows the average price to patients and the combined number of packs sold for the following GSK patented products: *Avamys*, *Avandia*, *Flixonase*, *Flixotide* and *Seretide* in Francophone West Africa. Prices of these products were reduced by an average of 60% in the first quarter of 2009 and the number of packs sold increased fourfold on average (300%) by the end of 2010. Sales growth in this region has been slightly erratic which is due in part to the political climate in some markets and the impact of civil wars or natural disasters which can make it difficult to distribute medicines.

## Reductions on off-patent products

Feedback from local physicians indicated a need for lower-priced antibiotics given the high incidence of infectious diseases. In response, in early 2010, we reduced the cost of *Augmentin* in Francophone West Africa and *Augmentin* and *Zinnat* in East Africa by up to 40% – see details below.

### *Augmentin* price reduction in Francophone West Africa



The chart above shows the average price to patients and the number of packs sold of *Augmentin* in Francophone West Africa. The cost of *Augmentin* was reduced in early 2010 by 30-40%. The number of packs sold increased by two-thirds in the six months following the price reduction and by 35% on average by the end of 2010. We believe the peak in volumes in mid-2010 was in part due to the onset of winter in these markets.

### Price reduction of *Augmentin* and *Zinnat* in East Africa



The chart above shows the average price to patients and the number of packs sold of *Augmentin* and *Zinnat* in East Africa. The prices of *Augmentin* and *Zinnat* were reduced by an average of 22% in East Africa in early 2010, and we have seen a twofold (100%) increase in the number of packs sold by the end of 2010.

Read about our not for profit pricing of ARVs through ViiV Healthcare.

## Ensuring patients benefit

In some countries where there is less government control on mark-ups, there have been cases of middlemen not passing price reductions on to patients. We work with others in the pharmaceutical distribution network to ensure that our price reductions are passed on to patients.

We have been working with governments and the media to ensure patients are aware of and benefit from the reductions and we are beginning to see sales volumes increasing in those countries. We have also received feedback from some physicians indicating that more patients are using these medicines and that patient compliance with the prescribed dose has improved in some cases.

## Middle-income countries

### Approach

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Middle-income countries (MICs) such as Brazil, China, India, Indonesia and Thailand often have a large and affluent middle class, offering significant business opportunities for GSK. But many of these countries also have large numbers of people living in extreme poverty.

Our strategy is to grow our business in MICs by increasing the volume of products we sell and, in doing so, increasing the number of patients from all income levels that receive them. To achieve this, we need to take a flexible approach to pricing our medicines.

In the right circumstances, price reductions enable us to sell more products while significantly increasing access for patients. However, it is not possible to take a single pricing approach in all MICs because of differences in economic status, demography, healthcare infrastructure and pricing regulations.

Our Market Access and Pricing team works with local operating companies to establish the right pricing approach for each of our MIC markets. This includes:

- Optimising our prices so that they reflect the markets' ability to pay, with poorer countries paying less for medicines than better-off countries
- Introducing differential pricing structures within markets to reach new sectors of the population. This includes doing business with public sector organisations in markets where we previously only dealt with the private sector
- Working closely with MIC health authorities and payers to agree innovative pricing programmes for our medicines and other support (for example disease awareness campaigns) that help improve patient access
- Closely monitoring our prices compared to local competition
- Ensuring that price reductions are passed on to patients where appropriate.

Our commercial teams collaborate with our manufacturing organisation to reduce the cost of goods by generating higher sales volumes, improving efficiency, and exploring local sourcing and manufacturing arrangements that can help to reduce prices.

We have established a number of tools and processes to enable our regional and country teams to share information and best practices on market access and to help them maximise opportunities and minimise risks. These include webcasts, online training, virtual tutorials and a dedicated website for best practice sharing.

We are also exploring what can be done to create the right conditions for differential pricing within countries. We expect to commence a number of pilot projects and feasibility studies in 2011.

We work closely with other groups in the distribution chain and the Medicines Transparency Alliance (MeTA) to ensure that price reductions are passed on to patients. We expect to launch the pilot projects in countries where MeTA is active.

Our approach also includes long-established practices such as tiered pricing for vaccines and voluntary licences and preferential pricing for HIV/AIDS medicines.



We are also forming commercial partnerships which give more patients access to medicines by bringing products to countries for the first time.

## Discount cards

We have introduced discount cards in a number of countries such as Ukraine and Vietnam to enable low-income patients with chronic diseases such as asthma to obtain prescription medicines at a discount price.

### World of GSK – An innovative approach to pricing



View short stories on how GSK is extending access to medicines in the developing world and developing innovative pricing strategies in the 'World of GSK', our review of the year.

## Performance

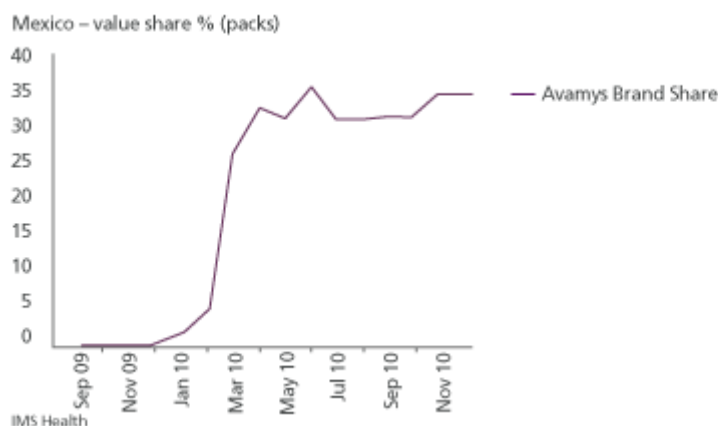
In the first quarter of 2010, we introduced more flexible pricing for some of our innovative medicines and vaccines across MICs. The new reduced prices are more closely linked to a country's gross national income and ability to pay.

This is challenging and the work is at an early stage, however the results of some of our initiatives so far are promising, indicating that price reductions are extending access to more patients and providing a sustainable return to GSK.

## Avamys

Avamys (fluticasone furoate) is our once-daily nasal spray for treating allergic rhinitis. We have reduced the price of Avamys by an average of 45% in over 40 MICs. In countries where Avamys was launched in 2010 or will be launched in future, it will be introduced at a price that is in line with these reductions. Following these reductions we are finding that the increased number of packs sold has off-set the impact of lowering our prices. This means we can treat more patients for the same amount of profit. See chart below.

### Avamys launch in Mexico at reduced price to market leader



The chart above shows the market share of *Avamys* in Mexico since its first launch in January 2010 at a price 30% lower than the market leader. *Avamys* achieved market leadership within three months of launch in a market with five established competitor products, holding 33% market share by number of packs sold at the end of 2010. This illustrates the impact that flexible pricing can have in increasing affordability and choice for patients at the same time as increasing market access for GSK. *Avamys* has maintained its market leadership, despite the previous market leader providing a two-for-one offer following the launch of *Avamys*.

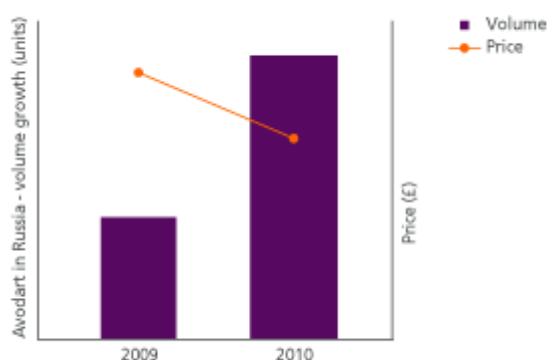
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## Avodart

We have also reduced the price of *Avodart* (dutasteride), our treatment for benign prostatic hyperplasia (BPH), by an average of 27% in MICs, and the number of packs sold has increased significantly.

In Russia, treatment for BPH is not covered by any reimbursement programme. Compliance with treatment is low, with patients often stopping therapy in the first months of treatment. Since reducing the price of *Avodart* in Russia, the volume of packs sold has increased by 130%, suggesting that more patients are initiating and staying on treatment for longer. See chart below

### Avodart price reduction in Russia



The chart above shows the increase in number of packs sold following a 25% price decrease in April 2010. A rapid uptake followed the price decrease, with a 130% increase in pack volumes seen by December 2010.

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## Tyverb

In India, a 32% reduction in the price of our breast cancer treatment *Tyverb* resulted in double the number of new patients receiving the treatment and a 30% increase in the number of units sold in two months. This trend is encouraging and we are confident we will be able to expand access to more patients with the new price.

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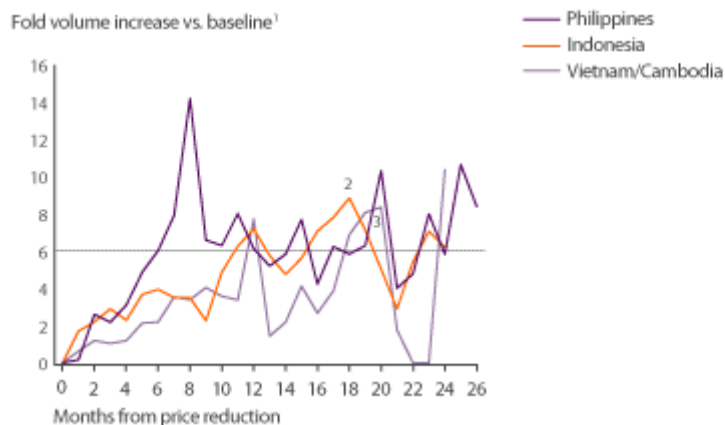
## Cervarix

We have reduced the price of *Cervarix*, our cervical cancer vaccine, by an average of 30% across MICs. This has significantly increased uptake. For example, monthly sales *Cervarix* increased significantly in the Philippines after reducing the price of the vaccine by 60%, settling at around six times the volume of vaccines sold before the price reduction was introduced. Similar results have been achieved in Indonesia and Vietnam with a more than six-fold increase in the numbers of women vaccinated; see chart below.

In many MICs we have introduced other measures alongside price reductions to help increase uptake of *Cervarix* and make sure the vaccine is made available to women. For example, in the Philippines we have supported a number of women's health education programmes and disease awareness activities, including The Tour of Hope a 500km charity bike tour raising money for the Philippine General Hospital which provides low-cost cervical cancer screening. We have also increased access to *Cervarix* for low to middle-income women through alternative channels such as

corporate, institutional and local government programmes and by working with local and provincial governments.

### Cervarix volumes after price reductions in South-East Asia



Notes to chart:

1. Baseline: mean volume in doses 3 months prior to launch of reduced pricing
2. Fasting period in Indonesia when rates of vaccination decline
3. Stock issues in Vietnam from delays in visa renewals

The chart above shows the increase in sales volumes of *Cervarix* after the introduction of price reductions in Philippines and Indonesia and launch in Vietnam at a reduced price. Volumes increased significantly, settling at around six times the volume of vaccines sold before the price reductions were introduced.

These price reductions relate to direct sales to governments and other customers. Read about our tiered pricing system for vaccines distributed via multilateral agencies.

### New centres increase access to *Cervarix* in Mexico

We have found that, on their own, price reductions do not always lead to increased uptake of our medicines and vaccines. In some cases, we need to work with partners to introduce price reductions alongside other measures.

For example, we reduced the price of *Cervarix* by 40% in Mexico, but many women still could not afford the vaccine because of the fees charged by doctors for immunisation.

To tackle this, we joined forces with non-governmental organisations and a leading chain of clinical laboratories to set up new vaccination centres. The centres do not charge a fee for administering the vaccine, meaning women can receive our *Cervarix* vaccine at a more affordable price.

For the initiative to be sustainable it was important that GSK and the vaccination centres could still make a small profit and the NGOs could cover their costs. To achieve this we needed to reduce costs and make sure that a sufficient number of patients attended the clinics.

We worked closely with the NGOs to raise awareness of cervical cancer and to advertise the vaccination centres to the general public. We also reduced costs by introducing a direct delivery system, cutting out middlemen such as wholesalers and distributors. We donated 700 doses of the vaccine to get the initiative started.

During 2010, the first year of the initiative, more than 2,000 women were vaccinated at the centres.

We are also partnering with Al Borg, a chain of laboratories, in Egypt to expand access to vaccines. Read more in the Vaccines section.

## Non-patented products

We are taking steps to establish more competitive private market pricing for our non-patented brands on a country-by-country basis. For example, in Brazil, sales volumes of the antibiotic Augmentin have substantially increased since we reduced the market price for the most prescribed presentations by half in March 2010.

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## Country initiatives

In September 2010, GSK Indonesia introduced 'Sehat Terjangkau', an affordable health initiative which reduces the prices of over half of our medicines by 15-80%. It covers off-patent and patented products for treatment of diseases such as HIV/AIDS, asthma/chronic obstructive pulmonary diseases (COPD), hepatitis B, epilepsy, gastro-intestinal diseases, benign prostatic hyperplasia (BPH) and our antibiotics. This follows the model established by GSK Philippines through its Expanded Access Programme.

We are also looking for ways to reduce barriers to access in countries where patients pay for their full prescription costs or where reimbursement coverage is low. For example, in China, where people are often paid weekly, we launched a smaller seven-day pack of Heptodin, an antiviral used for treatment of hepatitis B, to help patients who otherwise would not be able to access the medicine.

In early 2011, we will extend our Orange Card programme to cover our breast cancer treatment, *Tyverb*, in Ukraine.

## Developed countries

### Approach

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Access to medicines is not only an issue for the developing world.

In developed countries where there is limited public health provision, some patients cannot afford the medicines they need. This is a particular problem in the US where many people do not have health insurance. See below for information on the Patient Assistance Programs (PAPs) and discount savings cards we have developed in the US.

Ageing populations and the rise in incidence of chronic diseases means that healthcare budgets are under strain in many developed countries. Governments must balance the desire for healthcare equality with the need to manage limited financial resources.

We aim to price our medicines fairly in all markets.

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### Pricing new products

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.

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

- Their clinical value to patients in terms of improved efficacy, better safety and fewer side effects
- The value provided to healthcare systems and payers
- The high risks associated with R&D
- The need for a fair return on investment.

National price regulation is often a balancing act between managing public healthcare budgets, enabling patient access and rewarding innovation to ensure continued investment in R&D. 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.

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### Our approach in Europe

In Europe state-funded healthcare systems are experiencing budgetary constraints. To achieve the best results for patients, public budgets and our industry we believe we must work as a genuine partner with governments helping them find solutions that bring value to healthcare systems and support cost-management.

Most countries in Europe require demonstration of the value of a new medicine, for example clinical effectiveness or

cost-effectiveness, before reaching a decision on reimbursement by the government. Wherever possible, we want to demonstrate the full value of our medicines through evidence-based data at the time of introducing a new medicine. This should allow a fair price to be set which reflects a medicine's proven value, one that is affordable to customers and is sustainable for GSK. However, balancing these requirements can be challenging and complex, for example in cases where a level of uncertainty exists in relation to a new medicine. This uncertainty may be over aspects of evidence provided at launch or the expected financial impact of a new medicine.

In some cases innovative approaches to price setting may be needed to support patient access to medicines. GSK is already working with regulators and policy makers on innovative pricing programmes that balance fair reward for GSK with maintaining efficient and fast patient access in several countries.

## Demonstrating value through research

We believe that changes are needed to the current system of drug discovery and development to improve productivity and deliver increased value to medical systems, patients and our shareholders.

GSK is a founding member and active contributor to the European Healthcare Innovation Leadership Network (EHILN), a new collaboration which brings together industry, regulators, health technology assessment organisations, healthcare payers, patient groups, medical associations and academics from across Europe.

The EHILN seeks to improve understanding between the different stakeholder groups as to what constitutes a medicine's value. It is also exploring how the research process can be improved so that it generates the evidence needed to effectively demonstrate a medicine's value.

During 2010 we were also involved in a number of pilot projects that explored whether stakeholder consultation can improve the research process. GSK received advice from a range of stakeholders on one of our pipeline products which offers a potentially new mechanism to help manage diabetes. We found the process very useful and the feedback has been used to shape our development strategy for the product.

Further pilots are planned for 2011 and it is hoped that such consultations may become a routine part of the way drugs are developed in the future.

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## Programmes in the US

Our Patient Assistance Programs (PAPs) and discount savings cards provide prescription medicines to uninsured patients in the US for 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 can now self-enrol to our Bridges to Access using a simple, one-page application or apply by telephone with the help of an advocate.

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 who meet income requirements based on 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 25-40% 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 through an approach called the Triple Solution for a Healthier America that focuses on prevention, intervention and innovation.

# Performance

## Pricing in Europe

We are exploring flexible approaches to pricing, for example:

### Contractual pricing and patient access schemes at launch

When launching our Parkinson's medicine *Requip XR* (extended release), results of trials were not available to show that the extended release form of the product achieved better results than the existing immediate release form of Requip IR. GSK France agreed with the French health authorities to launch *Requip XR* at a lower price than the existing version, so that price would not be a barrier to access for patients. In 2009 we submitted additional study data demonstrating that *Requip XR* was superior to Requip IR. Based on the new clinical data, the French authorities agreed to increase the price. We are exploring a similar solution for our oncology medicine *Arzerra* in France, Italy and Spain.

In 2010 *Votrient* our oncology medicine in the UK was recommended for use on the National Health Service by the UK's National Institute of Health and Clinical Excellence (NICE). In order to make *Votrient* accessible to patients quickly, GSK has offered an innovative patient access scheme, which includes a 12.5% discount on the list price and a potential partial rebate in the future which is linked to the outcome of a head-to-head trial against the current standard of care (sunitinib). The head-to-head study with sunitinib (COMPARZ) is currently underway and is due to report in 2012. As advanced kidney cancer is one of the most difficult to treat malignancies and the side effects of treatment can have a big impact on quality of life, having different treatment options available with different side-effect profiles allows patient and physician choice. Rather than wait until 2012 for the results of the head-to-head trial, GSK has proposed an innovative and flexible approach to pricing to enable patient and clinician choice, and access to *Votrient* as soon as possible. GSK is confident that the evidence from this trial will demonstrate the full value of *Votrient*, but, if it does not, will pay a partial rebate to the NHS.

### World of GSK – An innovative approach to pricing



Hear from the UK General Manager on our innovative patient access scheme for *Votrient* in the UK in the 'World of GSK', our review of the year.

While seeking approval for our breast cancer medicine Tyverb in the UK, GSK offered a patient access programme for patients who are able to receive Tyverb in combination with capecitabine. Under the programme GSK covered the cost of Tyverb for the first 12 weeks of treatment, and the National Health Service paid for treatment beyond 12 weeks for those patients who continue to benefit. In 2010 the UK's National Institute of Health and Clinical Excellence (NICE) concluded that Tyverb did not meet its required cost-effectiveness threshold. While this national process was ongoing, we have worked with a number of local Primary Care Trusts in the UK to set up similar patient access programmes, enabling them to increase patient access to Tyverb.

For our oncology medicine *Arzerra* we have implemented contractual discount schemes in many European countries and are exploring options in France, Italy and Spain.

### Discount cards

We have developed Orange Card schemes in countries such as Bulgaria and Lithuania. These provide discounts to certain groups of patients (such as senior citizens or disabled people) who may not be able to afford the co-payment element of their prescription medicines.

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## Programmes in the US

In 2010 over 452,500 patients received GSK medicines worth \$155 million through our US programmes.

The value of our medicines is calculated using an average cost of goods rather than the wholesale acquisition cost. This approach to valuing medicines more accurately reflects the true cost to GSK and is therefore more transparent. We believe we were the first pharmaceutical company to adopt this practice. When valued at wholesale acquisition cost the value of the medicines would be \$593 million.

This year more than 4,000 patients received over 11,000 30-day prescriptions of GSK medicines through the Together Rx Access programme, giving patients discounts of more than \$450,500. Since its inception in 2002, Together Rx Access has given over two million patients savings totalling \$115 million across a wide range of products.

ViiV Healthcare launched a new patient assistance programme in 2010. This replaces GSK's Bridges to Access programme for HIV medicines and extends coverage to more patients by increasing the household income threshold for enrolment from 250% to 500% of the Federal Poverty Level. ViiV Healthcare is also piloting membership in the Welvista programme, a non-profit programme which facilitates access to HIV medications for individuals currently on the waiting list for the AIDS Drug Assistance Program. Through Welvista, patients can access HIV medicines from several different companies' patient assistance programmes, making it easier to obtain the medicines they need.

ViiV Healthcare will also continue to offer its Patient Savings Card programme for another two years. Together these initiatives, which came into effect in January 2011, will help to maintain access to HIV medicines for low-income patients and those most affected by the economic downturn in the US.

In 2010 we launched a programme to provide our adult vaccines free of charge to eligible, low-income individuals who do not have insurance coverage for vaccines. The GSK Vaccines Access Program enables eligible adults to receive our FDA-approved vaccines for hepatitis A, hepatitis B, tetanus, diphtheria and pertussis. Eligible women aged 19–25 are also able to receive our cervical cancer vaccine. Since the programme started in February 2010 more than 1,000 patients have received assistance.



## Portfolio expansion

Some of our growth in developing countries is achieved through strategic alliances and acquisitions. These deals can also help us to bring a bigger range of affordable and innovative medicines to a wider population.

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Alliances and acquisitions give us access to a high-quality and competitively priced pipeline of branded pharmaceuticals products. They allow us to broaden our product portfolio and make sure it is better suited to the needs of patients in developing countries.

Our focus on quality and our secure supply chain mean these collaborations can provide a reliable and high-quality choice for patients in many countries.

We are also pursuing joint ventures and technology transfer agreements in developing countries. These agreements benefit GSK by giving us access to new markets. They benefit developing countries by expanding the supply of essential medicines and vaccines and supporting the development of local research and manufacturing capabilities. See more in Vaccines.

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## Alliances

Our current alliances include partnerships with:

### Aspen

Since 2008, our licensing collaboration with Aspen, one of Africa's leading healthcare companies, has given us access to a portfolio of low-cost, quality branded products. We can license these products for sale in GSK's Emerging Markets and Asia Pacific regions. In 2009, we combined the commercial activities of GSK and Aspen in sub-Saharan Africa. This collaboration uses GSK's commercial infrastructure to help bring Aspen's extensive product portfolio and pipeline to more patients in the region. GSK also acquired a 19% shareholding in Aspen, demonstrating our commitment to investing in the region.

### Dong-A

In 2010 we signed an alliance with Dong-A, a South Korean company with a portfolio of proprietary and generic pharmaceutical products and leading consumer healthcare brands. This collaboration will help GSK to increase the accessibility of its products to patients in Korea and grow its business in the country, the world's 13th largest pharmaceutical market.

### Dr. Reddy's

Our agreement with Dr. Reddy's Laboratories enables us to license more than 100 branded pharmaceuticals for sale in our Emerging Markets and Asia Pacific regions. The products cover therapy areas such as cardiovascular, diabetes, oncology, gastroenterology and pain management.

### Gilead

We have entered into agreements with Gilead to develop and launch its hepatitis B treatment, Viread, in China, Japan and Saudi Arabia. Together with Gilead, we are committed to increasing access to this medicine for more patients in

Asia, bringing new ways to address the burden of chronic hepatitis B where it is most needed.

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## New product launches

We filed regulatory applications for over 200 products in 2010 through our partnerships with Aspen, Dr. Reddy's and others.

We broadened our product portfolio in 2010 through the launches of 20 products in countries across Africa, Latin America and the Commonwealth of Independent States (CIS) in the anti-infective, cardiovascular and oncology therapy areas.

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## Acquisitions

Acquisitions in 2010 included Laboratorios Phoenix, a leading Argentine pharmaceutical business focused on the development, manufacturing, marketing and sale of branded generic products. Phoenix's broad portfolio will enable us to bring more medicines of value to patients in Argentina, an increasingly important emerging market, and expand our local manufacturing base.

We also acquired Nanjing MeiRui Pharma Company, a leading Chinese pharmaceutical business with a portfolio of urology and allergy products. This will further expand our portfolio and manufacturing base in China, one of the fastest-growing pharmaceutical markets.

See our 2009 CR Report for details of previous acquisitions.

## Advocacy

When appropriate, we lobby governments and policy makers and encourage changes in the policy environment that help to increase access to healthcare sustainably.

In particular we support approaches that encourage: adequate investment in healthcare infrastructure; support for innovation; support for differential pricing; and adequate financing for mechanisms such as GAVI and the Global Fund to Fight AIDS, TB and malaria. All these factors are critical to sustainably improving access for the long term.

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## Advocacy

In 2010 our advocacy 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
- Participating in MMV's Malaria Donor's Forum <sup>1</sup>
- Supporting the UN Secretary General Ban Ki-moon's efforts to develop and launch a 'Global Strategy on Women's and Children's Health' at the 'Millennium Development Goal Summit' in September 2010
- Working with the UK government on global health issues and co-chairing the UK's Industry Government Forum on Access to Medicines<sup>2</sup>
- Presenting at events on access to medicines at the UK Parliament
- Discussing intellectual property, innovation and funding with governments, NGOs, foundations and other stakeholders
- Attending WHO Executive Board meetings and the World Health Assembly
- Presenting at the Commonwealth Health Ministers meeting
- Playing a leading role in major global health initiatives. For example, GSK sits on the Boards of the GAVI Alliance and participates in the Roll Back Malaria Board meetings
- Participating in the Partners Forum of the UK government's Global Health Strategy
- Meeting with the UN Secretary General's Special Envoy for Malaria
- Engaging with the Intergovernmental Meeting on Pandemic Influenza Preparedness
- Participating in meetings on access issues at the European Parliament
- Sponsoring a meeting for 60 businesses and NGOs, attended by the Deputy UN Secretary General Bob Orr and UK Secretary of State for International Development Andrew Mitchell to discuss the role of the private sector in improving maternal and child health.

1. MMV's Malaria Donors Forum
2. UK's Industry Government Forum on Access to Medicines

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### Engaging experts to ensure success – a strategic review of our approach to combating malaria

We believe GSK is uniquely placed to be a key player in the fight against malaria because of our research expertise and facilities, our promising malaria vaccine pipeline, and our extensive operations in many

malaria-endemic countries.

In 2010 we reviewed our approach to combating malaria and developed a comprehensive malaria vision and strategy for the company. Our vision is a world where malaria is no longer a barrier to human health, development and prosperity. The review was conducted by a cross-functional team who reported directly to our CEO. The team consulted with a range of stakeholders, both inside and outside the company, to gain a better understanding of their priorities and their views on current treatment and prevention efforts and GSK's approach. Their feedback has been essential to the development of the new strategy.

The external experts and partners we spoke to included the Medicines for Malaria Venture, the heads of national malaria control programmes in affected countries, the World Health Organization's Global Malaria Programme, the Bill & Melinda Gates Foundation and the Office of Ray Chambers, UN Special Envoy on malaria.

Their feedback covered a range of issues. With respect to our vaccine candidate RTS,S, stakeholders told us that there are gaps in local advocacy expertise which could affect roll-out of the vaccine and they advised us to use health economics data to demonstrate the vaccine's potential impact. They encouraged GSK to focus its discovery efforts on the next generation of medicines beyond artemisinins and to invest in R&D into diagnostics for malaria and G6PD deficiency (a common gene deficiency which can affect the choice of malaria treatment). They suggested that we align our community investment with our malaria R&D by, for example, supporting the use of Rapid Diagnostics Tests and funding diagnostics education and local surveillance efforts that are critical to fighting malaria

The experts within the business included employees involved in R&D for diseases of the developing world. We sought their views on how to maximise the potential of our malaria R&D, what lessons we can learn from development and launch of other products and what we can do to align with the WHO global malaria strategy. They stressed the importance of viewing malaria research as part of core business and of increasing coordination and integration between the different parts of GSK working on malaria.

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## Government relations

GSK aims to support and work constructively with governments in their efforts to strengthen and develop sustainable healthcare systems across the globe. Read examples of our activities in this area.

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## Engaging on the human right to health

Read our response to the review of GSK's policies and practices by the UN Special Rapporteur on the Right to Health in our 2009 CR Report.

### Improving access to medicine – whose responsibility?

Improving access to healthcare in developing countries requires a holistic approach embracing prevention and treatment and efforts to fundamentally strengthen health systems. All stakeholders need to contribute.

Pharmaceutical companies, including GSK, must make their medicines as affordable as possible to people in the world's poorest communities, in a sustainable manner. We must invest in research into diseases of the developing world because new prevention tools and treatments are urgently needed. We must work with others to find innovative solutions to delivering our medicines and vaccines to the people who need them most.

Wealthy nations should continue to be generous in their development assistance and give more where they can. Welcome 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. However, funds are still inadequate and need to be more predictable and sustainable to fund research, strengthen health systems, purchase medicines and vaccines and support disease prevention.

Developing countries should show genuine political commitment to prioritising healthcare in national budgets,

addressing stigma and improving affordability by removing import tariffs on medicines. Middle-income countries can support a tiered pricing approach, based partly on ability to pay, by not seeking the lowest prices that are offered to the world's poorest countries. It is only by making a return in better-off countries that we are able to offer the lowest prices to the poorest countries.

Read our response to the review of GSK's policies and practices by the UN Special Rapporteur on the Right to Health in our 2009 CR Report

# Future plans

Although we are pleased at the progress we have made, we believe there is still more we can contribute to efforts to increase access to medicines. The creation of our Developing Countries & Market Access operating unit will bring increased focus to our efforts to expand access to medicines to people living in the LDCs and will drive our initiatives going forward.

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During 2011 we will continue to deliver on our objective of developing a product portfolio more suited for the disease burden suffered by patients in developing countries.

We will continue with our plans to:

- Introduce flexible pricing strategies and work with others to increase access in middle-income countries
- Seek more partnerships and encourage scientists to work with us at our research centre for diseases of the developing world in Tres Cantos, in Spain
- Encourage others to consider innovative approaches to intellectual property in non-competitive settings, such as contributing to the Pool for Open Innovation against Neglected Tropical Diseases or similar mechanisms
- Seek to further reduce prices for our patented medicines in LDCs
- Continue to reinvest 20% of the profit we make from selling medicines in LDCs to help strengthen healthcare infrastructure in these countries and encourage others to consider similar schemes.

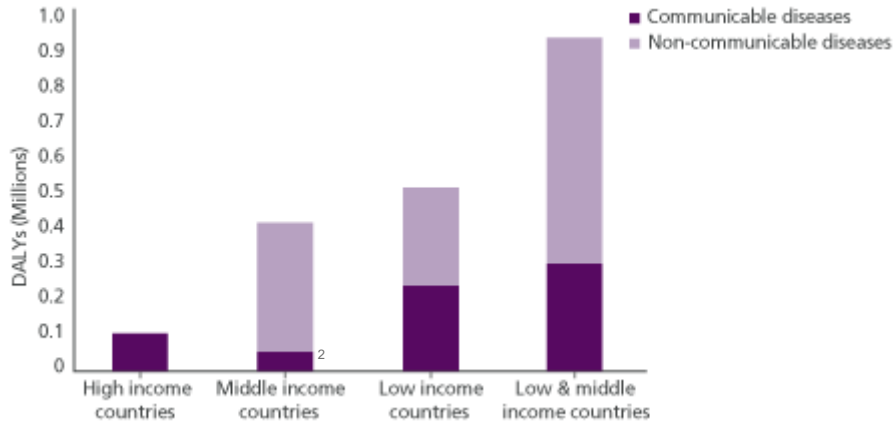
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We will retain our focus on neglected tropical diseases but will also look at ways to increase access to treatments for non-communicable diseases (NCDs) such as diabetes and cancer – which will become more prevalent as improvements are made in tackling childhood and infectious diseases lead to people living longer.

NCDs already represent 65% of the disease burden in developing countries<sup>1</sup> as measured in DALYs. DALYs, or Disability-Adjusted Life Years, are the accepted measure of disease burden, and one DALY is the equivalent of one lost year of 'healthy' life<sup>2</sup>. See chart below. Increasing access to medicines for NCDs can be particularly challenging because of the cost of providing long-term or even life-long care.

In September 2011, the UN General Assembly will hold a Special Session on NCDs and GSK is committed to working with all relevant stakeholders to help tackle this growing problem.

## The global burden of disease



Disability-Adjusted Life Years (DALYs) are the accepted measure of disease burden, and one DALY is the equivalent of one lost year of 'healthy' life

1. WHO Global Burden of Disease Report 2004
2. Disability-Adjusted Life Years

## Research practices

Investment in R&D into new medicines and vaccines is at the core of our business. We focus our efforts on areas where there is greatest need and where advances in science offer the best opportunities to discover new medicines.

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It is essential that we meet consistently high quality and ethical standards in all our R&D in all parts of our business, and in all the markets where we operate. This enables us to protect the safety of clinical trial participants and the patients who use our medicines, to obtain regulatory approval for new medicines and vaccines, and to maintain the trust of patients and healthcare professionals.

Patient safety is always our priority and we evaluate the benefits and risks of our medicines at all stages of research and after a new product is approved for sale. We are committed to transparency and to disclosing the results of our clinical research.

We recognise that biomedical research can raise ethical concerns, including those relating to the use of emerging technologies such as stem cell research; animal research; clinical trial standards; the storage and use of human tissue; and the protection of personal information about research participants. We aim to address any concerns by being open about our approach, participating in discussions on research practices and regularly engaging with academic scientists, regulators, policy makers and other stakeholders on these issues.

To guide our research we must understand what patients need. Our Focus on the Patient programme helps us to do this by bringing patients to GSK sites to speak directly to our R&D teams about their specific healthcare needs.



## R&D in 2010

Despite advances in healthcare, there are still many diseases that have no cure or for which new treatments and vaccines are needed to prevent transmission or help patients better control their symptoms.

We focus our R&D efforts on areas where there is greatest patient need and where advances in science offer the best opportunities to discover new medicines and generate commercial returns. Our aim is for new treatments to provide value over currently available treatments to both patients and to payers.

We make a significant investment in R&D each year, spending £3.96 billion in 2010. Around 75% of this expenditure was in pharmaceutical R&D with the remainder in vaccine and consumer healthcare research. In the UK, we came first in a government ranking of the top 1,000 companies by R&D investment <sup>1</sup>.

### World of GSK – Delivering the next generation of medicines



Hear from the Chairman of R&D on how GSK is delivering the next generation of medicines in the 'World of GSK', our review of the year.

## Our pipeline at a glance

In 2010 our early-stage pharmaceutical research activities focused on:

- Biopharmaceuticals
- Dermatology (through our specialised dermatology company, Stiefel)
- Immuno-inflammatory diseases
- Infectious diseases
- Metabolic pathways
- Neuro-inflammation and degeneration
- Oncology
- Ophthalmology
- Respiratory diseases
- Vaccines
- Rare diseases.

Our late-stage pipeline includes products that target autoimmune disorders, infections, many forms of cancer, metabolic and cardiovascular disease, neurological disease and respiratory disease. At the end of 2010 there were around 30 products in our late-stage development pipeline. More than 20 of these are assets that are not already approved for other indications

Read more about our pipeline progress, product approvals and R&D expenditure in our Annual Report.

As part of our strategy to develop new medicines and improve returns by focusing on areas of science with a higher probability of success, we announced in 2010 the formation of a new standalone unit focusing on treatments for rare diseases (see box below). Research into rare diseases often involves areas of science that can reduce the time to develop new treatments. For instance, the identification of a disease is often very clear as it may be caused by mutation in a single gene, and it can be easier in clinical trials to assess the impact of new treatments.

We also made changes to our early-stage neuroscience research activities, and in 2010 ceased research in selected areas such as depression and pain. We will focus our neurology research efforts on identifying and developing treatments for neurodegenerative and neuro-inflammatory diseases, including Alzheimer's disease, multiple sclerosis and Parkinson's disease, where new treatment options are needed and where the advances in science offer greater prospects for the successful development of new medicines.

#### 1. Department for Business, Innovation and Skills, The 2010 R&D Scoreboard

### Rare diseases

Between 6,000 – 8,000 rare diseases have been identified<sup>2</sup>, of which fewer than 10% are currently treated.<sup>3</sup> This presents a significant unmet medical need in all parts of the world. Despite the rarity of each separate condition, the number of diseases means that, overall, 6–8% of the population<sup>4</sup> may be affected by a rare disease.

With increasing scientific and genetic understanding, researchers are now able to identify which rare diseases are most likely to respond to therapeutic intervention providing a significant impetus to discover and develop new medicines. In 2010 we established GSK Rare Diseases, a group concentrating on finding and delivering new treatments for rare disease. This group is integrated from development through to commercialisation, as we believe this integration suits rare diseases, with its small number of specialist physicians and institutions seeing and treating the relatively small number of patients with rare diseases.

GSK Rare Diseases benefits from dedicated resources, but can also access the cutting-edge science across the entire GSK organisation, exploring how new molecules or platform technology being developed could also be applied to treat one of the thousands of rare diseases. The group will focus on the development of medicines to treat around 200 diseases at any time, selected by factors such as prevalence and severity of disease, the potential for a treatment to help manage a disease and its complications.

The new group is looking at how to bring new treatments to patients both through our own pipeline and with partnerships and licensing deals. Some diseases we are investigating as a result of recent alliances include:

- Duchenne muscular dystrophy, by developing nucleic acid based therapeutics in collaboration with Prosensa
- Hunter syndrome, Fabry disease and Gaucher's disease, through an alliance with JCR Pharmaceuticals, a Japanese developer and manufacturer of bioactive products. We have obtained global rights to several of its enzyme replacement therapies
- ADA Severe Combined Immunodeficiency (also known as 'bubble boy disease') through an exclusive licence with Fondazione Telethon and Fondazione San Raffaele to develop and commercialise an investigational gene therapy, currently in phase III. This alliance also provides for GSK to co-develop six further applications of the technology with the potential to correct genetic abnormalities in a range of rare disorders.



See more about our new Rare Diseases group in the 'World of GSK', our review of the year.

References:

1. [www.orpha.net](http://www.orpha.net); portal for rare diseases and orphan drugs
2. [www.fda.gov](http://www.fda.gov); analysis of approved therapies (249 in the US since 1983) vs. known rare diseases
3. 'Rare Diseases: Understanding this Public Health Priority'. European Organisation for Rare Diseases, November 2005 [www.orpha.net](http://www.orpha.net); portal for rare diseases and orphan drugs

## Collaborative R&D

GSK has a large pool of scientists, but we recognise that we do not have a monopoly on research or on the best science. Therefore we also form alliances with others to accelerate the discovery of new medicines and vaccines as well as to share scientific understanding and ultimately to improve patient care.

Our main areas of collaboration include research into improving drug discovery, biotechnology, neglected tropical diseases, identifying patient safety issues and rare diseases. We also fund basic medical research conducted outside GSK to increase understanding of the human body and the impact of disease. This type of research is frequently the foundation for future advances in the diagnosis, treatment and prevention of disease.

Examples of some new and ongoing collaborations we contributed to in 2010 include:

- An initiative in the UK with the National Institute for Health Research and the University of Manchester to examine the impact of the human biological clock on inflammation in lung diseases such as chronic obstructive pulmonary disease (COPD)
- Our participation as co-chair of the newly established COPD Biomarkers Qualification Consortium (CBQC). This consortium of government agencies, academic institutions and pharmaceutical companies will pool information on Chronic Obstructive Pulmonary Disease (COPD) with the aim of identifying and validating biomarkers for COPD. This should lead to improvements in disease monitoring and expedite developments of new therapies
- We are contributing to the US Environmental Protection Agency (EPA) ToxCast programme, which is developing new laboratory and computer methods to predict compound toxicity in humans. ToxCast is screening 1,000 failed chemicals to see if common factors for toxicity can be identified. GSK and three other pharmaceutical companies have provided information on 111 failed drug candidates. These will enable the EPA to compare ToxCast screening data to human clinical data and other toxicology studies. ToxCast has the potential to identify toxicity issues early in the drug discovery process
- We are involved in the Innovative Medicines Initiative (IMI), a public-private partnership in Europe involving pharmaceutical companies, smaller bioscience companies and academia together with other stakeholders such as regulators and patient groups. The aim of IMI is to develop improved methods for predicting the safety and efficacy of new medicines. We are currently leading on more than five projects and participating in a further 15

Read about further collaborations on patient safety.

We seek to contribute to the body of scientific understanding and the findings from much of this collaborative research are accessible in publicly available scientific journals. In 2010, GSK scientists were listed as co-authors in collaborative research in over 1500 publications.

In forming research alliances, we seek to work with organisations whose principles are aligned with our own. We communicate our policies to our partners and our collaboration agreements include clauses that require partners to comply with our principles.

### Academic collaborations

Much novel and innovative research takes place at academic institutions. In 2010 we agreed over 360 research collaborations with universities and academic institutions globally. This included funding for university research and leading-edge academic research projects.

We also provide support for science students through fellowships and other awards. Our support helps advance scientific understanding and capability, and gives us access to R&D expertise and activity outside the company. It also expands our potential recruitment pool of trained scientists, while our academic collaborators benefit from

technology transfer and access to our research facilities and expertise.

In 2010 we announced a new alliance with the University of Nottingham, UK, to create a chemistry degree module on medicinal chemistry skills for the pharmaceutical industry. Run in collaboration with the University of Nottingham's School of Chemistry, the new module introduces chemistry students to the medicinal chemistry skills the pharmaceutical industry requires while also enhancing knowledge transfer between industry and academia.

The GSK Medicinal Chemistry module was designed as an option for chemistry students in the third year of their 4-year MSci course, allowing the 12 students selected by the university to pursue in the laboratory an active research programme on a molecular target that the pharmaceutical company is developing.

# Patient needs and R&D

To guide our research, it is essential for us to understand what patients need.

Our Focus on the Patient programme brings patients to GSK sites to speak directly to our R&D teams about their specific healthcare needs. This helps us make better medicines, and inspires employees to do more to help improve patients' lives.

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GSK sites hosted nine patient seminars in 2010. Over 5,700 people including GSK employees, healthcare professionals, patients and patient advocacy group representatives came together to discuss a range of topics which included chronic lymphocytic leukaemia, Duchenne muscular dystrophy, lupus, macular degeneration, metastatic melanoma, myasthenia gravis, psoriasis, and sarcopenia. Recordings of these seminars are available on our intranet, enabling more employees to benefit from the discussions.

We also interviewed patients recently diagnosed with rheumatoid arthritis, to expand our knowledge of the condition's impact during its early stages. We aim to use these types of interviews more frequently to inform our drug development programmes.

Read more about our efforts to understand patients, and our work with patient groups in 2010.

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# Emerging technologies

Emerging technologies help to expand the boundaries of scientific understanding and our own research capabilities.

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Stem cell and genetic research provide new opportunities for the discovery of innovative treatments for serious diseases, as well as better ways to evaluate the benefits and risks of the medicines we develop. For example, advances in genetic research are beginning to enable the identification of patients who are more likely to experience certain side effects from use of a medicine.

We use emerging technologies in our research and work with others to develop them further. We recognise that research using emerging technologies can give rise to ethical concerns. Here we outline our approach to the use of cloning technologies and stem cell research, and to genetic research.

# Cloning technologies and stem cell research

## Cloning technologies

GSK uses cloning technologies to replicate molecules and cells for research. These technologies are a fundamental component of medicine discovery and development because they can provide better ways to evaluate compounds, enabling greater insight into the benefits and risks of potential medicines.

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 .

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## Stem cell research

Recent advances in stem cell research have significant potential for producing human tissues for transplantation and for the treatment of diseases including Parkinson's disease, Alzheimer's disease and diabetes, as well as spinal cord injuries. GSK is involved in efforts to identify medicines that activate a patient's own stem cells and regenerate cells that have been lost as the result of disease – for example, pancreas cells in diabetes or brain cells in Parkinson's disease.

The use of adult human stem cells currently forms an integral part of our R&D. In some instances, we also use foetal stem cells and human embryonic stem cells in the discovery of medicines for serious diseases. Such stem cells are only used when their biological properties cannot be reproduced by adult stem cells. Their use is subject to approval by GSK's Chairman of R&D. Our position statement on cloning technologies and stem cell research further outlines our views on the use of stem cells in medical research and sets out the stringent standards we apply.

We collaborate with other research organisations on stem cell research. In 2010, we announced a new strategic alliance with the Italian Fondazione Telethon and Fondazione San Raffaele which specialise in research into rare genetic disorders, to develop novel treatments for such conditions using gene therapy carried out on stem cells taken from a patient's bone marrow. Under this agreement, we will develop an investigational gene therapy for Adenosine Deaminase Deficiency – Severe Combined Immune Deficiency (ADA-SCID), a very rare and life-threatening disorder that affects approximately 350 children worldwide. We will also co-develop further stem cell therapies to treat six other rare disorders. Read more about our new group, GSK Rare Diseases.

Other collaborations include a five-year partnership with the Harvard Stem Cell Institute (HSCI), to support research into neuroscience, heart disease, cancer, diabetes, musculoskeletal diseases and obesity.

We are also a founding member of the Stem Cells for Safer Medicine (SC4SM) initiative in the UK, which brings together pharmaceutical companies and public sector organisations. SC4SM aims to develop a bank of human cell lines for use in early medicine discovery that can help to identify and eliminate potential toxicity issues before medicines are tested in people. In 2010 SC4SM investigations focused on the use of stem cells to generate cardiac and liver cells.

### 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 develop, how fast they progress and how they respond to drugs.

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Recent breakthroughs in DNA analysis have led to the discovery of a variety of genetic markers that make people susceptible to common diseases. Through collaborations with academic groups, GSK has contributed to the identification of susceptibility genes for a variety of conditions including Alzheimer's disease, asthma, coronary artery disease, diabetes, hypertension and sleep disorders. These findings have significant potential for diagnosis of common diseases and the future discovery of innovative medicines. We anticipate further breakthroughs as a result of novel technologies that allow large-scale sequencing of the human genome.

Rare diseases are often caused by genetic defects. In 2010 GSK established a group dedicated to the research, development and commercialisation of innovative therapies for patients with rare diseases. Genetic research forms a significant part of the new unit's activities. Read more about GSK Rare Diseases.

Genetic variation also affects how patients respond to a variety of medicines. GSK scientists are using emerging genetic information, particularly in the field of oncology, to study how medicines can be differentiated to suit groups of patients with different genetic characteristics, and to understand why some patients experience side effects and others do not.

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### Genetic research collaborations

We collaborate with academic partners, regulatory agencies and other pharmaceutical companies to share genetic research information. For example:

- We are co-sponsors of the international Serious Adverse Events Consortium (iSAEC), which aims to improve patient safety through genetic research
- We share research data through the dbGaP, a US National Institutes of Health database which contains the results of studies exploring the association between specific genes and various medical conditions that have a genetic component, such as Alzheimer's disease
- We share genetic research findings with selected academic organisations (including Cambridge, Imperial and Oxford universities in the UK, and Michigan University and the University of North Carolina in the US) and collaborate with them to analyse the results or to develop new statistical methods for genetic analyses
- In 2010 we began a collaboration to develop novel stem cell treatments for rare genetic disorders. Read more about stem cell research and our work on rare diseases.

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### Responding to concerns about genetic research

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 undertaken as part of GSK clinical trials is only done after seeking and obtaining informed consent from the participant. This procedure includes providing information on the purpose and scope of the research



and who has access to the genetic research data. Read more about informed consent.

To inform our genetic research activities, we refer to guidance from national and international groups 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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## Animal research

### Approach

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Animal studies remain a small but vital part of our research. In many cases, they are the only method that can be used to demonstrate the effects of a potential new medicine in a living body before it is tested in humans. Animal research can also 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 evaluated in clinical trials. Some vaccines must be tested on animals each time a new batch is produced, but for our most recent vaccines, *Cervarix*, *Rotarix* and *Synflorix*, we have developed alternative approaches that do not use animals and have been accepted by EU regulators.

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. We revised and strengthened our policy on the care, welfare and treatment of animals in 2010 (see performance for details).

### Our approach

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Ultimately GSK would like to see the important benefits of research being achieved and applied to humans without the need for animal testing. 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. Our senior management reviews our strategy for working with animals on an annual basis.

Our Animal Quality Council oversees the effective application of high quality and welfare standards in all GSK animal testing. Our Worldwide Head, Animal Research Responsibility develops and embeds a co-ordinated strategy across all GSK's business units to finding non-animal alternatives, improve animal welfare (the 3Rs – see below) and ensure progress on these goals. Our Chief of Animal Welfare and Veterinary Medicine, a position created in 2010, is responsible for overseeing the humane and responsible use of animals in pharmaceutical R&D, helping develop relevant policies and responding to stakeholder questions.

GSK has animal research laboratories in Europe, Asia and North America. Some animal research is conducted by external contractors on our behalf, representing around 8% of our total animal use.

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, and goats; together these non-rodents account for just under 2% of the number of animals used and are listed in order of magnitude of use in 2010.

### The 3Rs

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Our scientists apply the 3Rs – principles for finding non-animal alternatives and improving animal welfare – to all our biomedical research:

- Replacing research using animals with non-animal alternatives or species of the lowest possible phylogenetic order
- Reducing the number of animals used while still providing information of a given amount and precision, for example still obtaining the same information as in a larger study
- Refining techniques to minimise pain and distress and maximise the welfare of animals.

Before animal research can proceed, proposed studies must undergo both a scientific and an ethical review which assess study design and incorporation of the 3Rs. Ethical reviews are conducted by an independent internal committee based at the site or in the country where the research will take place. Ethical review committees include at least one veterinarian, at least one scientist and at least one person without a scientific background. They may also include specialists in laboratory animal science.

We engage with regulators to help ensure that regulatory-required animal testing incorporates 3Rs developments.

We encourage a 3Rs culture at GSK through:

- Regular training for staff involved in the care and use of animals
- Raising awareness and encouraging best practice by communicating advances in 3Rs across GSK's medicine discovery and development teams
- Recognising employees who have made outstanding advances in implementing the 3Rs through our Animal Welfare Awards

Read more about recent GSK advances in replacing, reducing and refining animal use.

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## Non-human primates

Less than 0.5% of the animals we use are non-human primates. We have made a voluntary commitment to no longer perform research on great apes. The most common non-human primate species used in research are macaques. We only use non-human primates if no other species is appropriate for the study. For example, in some instances only human and non-human primates will be affected by, or respond to, a potential medicine or vaccine.

Read more in our position statement on the use of non-human primates in research.

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## Ensuring high standards in research facilities

We are committed to high standards of animal welfare in all animal studies carried out by us or on our behalf. All GSK facilities and contracted external laboratories must follow our core principles for the ethical care, welfare and treatment of laboratory animals, and all legal and regulatory requirements. We engage external experts to refine and improve our programmes for animal care.

Our goal is for all GSK-owned animal facilities to be 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. To achieve and maintain AAALACi accreditation, an organisation must follow the National Academy of Sciences' Guide for the Care and Use of Laboratory Animals, revised in 2010, and go through a rigorous review of all aspects of animal care and use including policies, animal housing and management by members of the AAALACi Council and other trained professional staff, every three years.

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## 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 to be transparent about what we do.

We engage regularly with animal welfare experts and our investors, as well as contributing to the public debate. Our

laboratories host visits from external groups including animal welfare organisations, investment groups and politicians. Our scientists also go to schools to talk with pupils about the role of animals in pharmaceutical research.

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## 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.

## Performance

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### Policy revision

In 2010 we revised and strengthened our policy on the care, welfare and treatment of animals by GSK, to clarify that:

- We do not conduct, contract, sponsor or support animal studies using great apes
  - We only conduct animal testing for products that are used primarily for their medical or healthcare benefits. We do not conduct, contract, sponsor or support testing in animals for products designed primarily to improve the appearance of individuals (that is, aesthetic or beautifying purposes)
  - For products with both aesthetic and healthcare uses and /or which are classified as cosmetics by regulators, animal testing is only permitted when it is required by regulators, and when the primary use and marketing claim relates to its healthcare benefits
  - For other products or ingredients (for example nutritional products) animal testing is only permitted when it is required by regulators in order to make a marketing claim related to a health benefit.
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### Progress in the 3Rs

We have developed a central database which is regularly updated to track the different types of animal studies conducted at GSK. This is designed to help GSK researchers worldwide share their experiences in refining animal use and care. The information collected in this database during 2010 will provide a baseline from which we can measure our future progress in the 3Rs.

In 2010 our progress in the 3Rs included:

- Refining blood sampling techniques to enable multiple samples to be taken from a single mouse, reducing the total number of mice required for certain studies
  - Reducing the number of mice required for some carcinogenicity testing, by updating the methodology
  - Refining a rodent model of Experimental Autoimmune Ouveoretinitis (used to represent human sight-threatening inflammatory eye diseases) by using a mouse strain that develops a milder form of the disease, reducing pain and distress
  - Adapting a rodent model of influenza to enable researchers to anticipate findings before the disease becomes apparent in the trial animals, reducing pain and distress
  - Reviewing and refining a model of inflammation in rats. This allowed us to use some historical data, reducing the number of rats required, and to anticipate findings while symptoms are relatively mild.
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### Number of animals

In 2010 the number of animals used in our laboratories was almost 25% lower than in 1994 while R&D activity has increased significantly in the same period. This reduction in use is due to various factors including changing research

priorities, fewer batches of vaccines requiring testing on animals before their release and continued focus on 3Rs initiatives.

Compared with 2009, we are using 10% fewer animals. This decrease is due to a combination of our application of 3Rs principles, our closure of animal research programmes in Croatia and Italy, and our decision to stop neuroscience research in the UK. Following ethical review, animals used in the terminated research programmes were either housed until completion of the ongoing study, transferred to new sites or companies for research use or, if neither of these was possible, euthanased.

We estimate that the proportion of animals used for GSK research conducted by external contractors was 8% in 2010, compared with 8.4% in 2009.

Animals used by GSK in 2010 (%)*	
Mice	74.5
Rats	17.8
Guinea pigs	5.6
Other rodents	0.4
Rabbits	0.6
Others	1.1

\* This does not include animals used by external contractors on our behalf. Of the animals used by external contractors on our behalf in 2010, 92 per cent were rodents and rabbits.

### Change in R&D activity compared to change in number of animals used by GSK (figures normalised to 1994 levels)

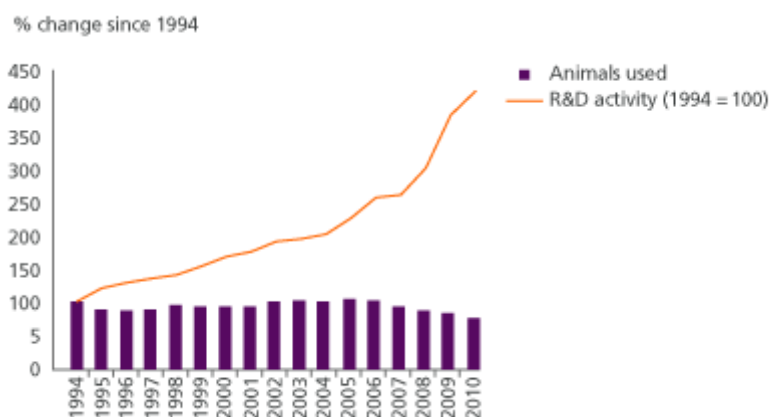


Chart data do not include animal research conducted by external contractors on our behalf. R&D activity combines our R&D budget and our vaccine sales, the two main drivers of animal use. We use 1994 as our baseline year for comparison as this is the year from which we can start to compare data for GSK and its legacy companies, GlaxoWellcome and SmithKline Beecham.

## Animal welfare

We are reviewing the size of animal enclosures in our locations around the world to ensure all our sites are aligned with best practice principles in animal housing and welfare. Following our 2009 review of housing for dogs, in 2010 we worked with external primate behaviour experts to refine our housing strategy for macaque monkeys. The new housing provides the macaques with greater comfort and stimulation, including increased foraging opportunities and more human-animal interactions.

In 2010 we began to review the training offered to all those who work with animals to ensure it is of a consistent standard across all sites, and have appointed two full-time training managers. We will complete the review in 2011 and enhance the training curriculum as necessary.

We are also analysing how ethical review of proposed animal studies is performed across the company. In 2011 we will publish internal guidance to ensure reviews are consistent across all sites worldwide.

### GSK Animal Welfare Award 2010

Our internal Animal Welfare Award recognises advances in the 3Rs that make a real difference to how animal experimentation is conducted at GSK or how animals are routinely cared for. Awards are given to employees who have gone above and beyond the high standards we expect from everyone at GSK involved in animal testing.

In 2010 we gave the award to a research group which adapted a method originally developed for humans to take bile samples from dogs. In the past, bile was collected from dogs through invasive surgery, with the potential for discomfort and complications. The new method involves the dog swallowing a string which absorbs bile from the animal's intestine and can then be withdrawn through the animal's mouth. Switching to this technique has significantly reduced the number of dogs that need to undergo surgery.

## Engagement

We collaborate with others to promote use of the 3Rs. For example, in 2010 we:

- Encouraged the European Partnership for Alternative Approaches to Animal Testing (EPAA), which traditionally advocates the replacement of animals in research, to also focus on reduction and refinement – subsequently adopted as EPAA's theme for the year
- Planned, supported and initiated collaborative experiments to refine methodology for a potential alternative to ocular irritancy testing on rabbits as currently required by regulatory agencies. We conducted this research in collaboration with a contracted research organisation, the European Centre for the Validation of Alternative Methods (ECVAM), and the US Interagency Coordinating Committee on Validation of Alternative Methods (ICCVAM)
- Led an educational seminar to update the US Food and Drug Administration and presented to the Safety Working Party of the European Medicines Agency on the use of Dried Blood Spot (DBS) technology – a method that reduces the amount needed for analysis, so reducing the number of animals required
- In the UK, participated in several working groups run by the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs).

In the US we also sit on the National Academy of Science's Council for the Institute for Laboratory Animal Research, and serve on the Boards of Americans for Medical Progress, the National Association for Biomedical Research, and the Scientists Center for Animal Welfare.

In 2010 the EU revised its legislation on the use of animals in research. Read our position on the new directive.

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## AAALACi accreditation

In 2010 our accredited facilities covered 90% of the animals housed in GSK laboratories. Our accredited facilities are in Belgium, Canada, Spain, the UK and the US.

We are working to extend this accreditation in 2011 to small facilities we have in France, Hungary and the US.

We also conduct animal research in small facilities in China. At present we use leased facilities, but are planning a new building of our own, to be occupied from 2013 and designed to obtain AAALACi accreditation. In the interim we are confident that the standards within leased facilities are comparable to those of our other facilities.

# Human tissue research

Research using human tissue or human biological samples is fundamental to the discovery, development and safety monitoring of GSK medicines and vaccines. We are committed to conducting this research in a manner that respects the rights of research participants and meets legal and ethical obligations.

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Our global policy is to gain appropriate consent or ethical approval for human tissue research conducted, sponsored, supported or funded by GSK. This ensures that we comply in the UK with the Human Tissue Act 2004, and also that we apply ethical requirements for research using human biological samples wherever it takes place.

In 2010 we established a Global Human Biological Sample Management Governance Board to provide a unified governance approach and consistent oversight across GSK's businesses that undertake research using human biological samples.

[Read about our approach to stem cell research.](#)

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# Maintaining the confidentiality of research participants

Medical information collected during research must be protected to maintain the confidentiality of individual participants.

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We use a variety of procedures to protect the confidentiality of research participants' data. For example, we use data coding and encryption, restrict access to research databases, and require third parties handling research data on our behalf to comply with relevant data protection legislation and standards.

We only collect and retain information about individuals that is relevant to the research study. This includes medical information such as health status, medical conditions (including, on occasion, genetic data), treatment of conditions and ethnic origin. We inform research participants about the medical information that will be collected as part of a study, explain why we are collecting it, and describe the types of third parties we work with to perform the study. Participants can withdraw their consent to future collection of medical information at any time. Read about the informed consent process.

In the vast majority of cases, we do not collect or store information that can directly identify individuals such as initials, names, addresses or personal identification number. Information that can identify individuals is only used in very specific instances required by law and regulations, such as those relating to pharmacovigilance. It is used to ensure accuracy of reporting and facilitate follow-up with participants.

We retain medical research data only for the duration reasonably necessary to meet regulatory, legal or research needs.

Read about our global privacy principles.



## Medical governance

Medical governance is our system of principles, policies and accountabilities that ensures we apply recognised principles of good medical science, integrity, ethics and standards to the discovery, development and marketing of GSK products.

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It protects patients' interests by ensuring that:

- Patient safety is GSK's fundamental operating principle ahead of commercial or other interests
- Our research is conducted in an objective, scientific and ethical manner that protects and informs patients, prescribers and payers
- Promotional practices and all the information we provide on our products are ethical, accurate and balanced; meet our legal, regulatory and ethical obligations; and support appropriate use of our products to maximise benefits and minimise risks for patients.

Medical governance also ensures that any safety, ethical or compliance issues identified with our clinical research, marketed products, medical information or promotional practices are dealt with quickly and effectively and, wherever possible, that steps are taken to correct the root cause of the issue.

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## Medical governance framework

Our medical governance framework applies across GSK and focuses in particular on: clinical research involving human subjects, the safety of patient and clinical trial participants, the information we provide about our products and clinical trials, and our promotional activities.

Overall responsibility for medical governance sits with our Chief Medical Officer (CMO, the most senior physician at GSK). The CMO is supported by the Medical Governance Executive Committee (MGEC), which establishes medical governance policies, ensures that medical governance systems are standardised across GSK and identifies new risks.

In 2010 we established Medical Governance Boards, reporting to the MGEC, to ensure the consistent, effective and efficient operation of our medical governance model within all our businesses and in all markets. The boards are also responsible for educating employees involved with human subject research and reporting our medical governance policies, approach and framework.

We require external collaborators to adhere to the same medical governance standards as GSK.

Read about our patient safety governance framework.

### Medical governance training

In 2010 we developed a training programme designed to educate employees about our medical governance framework, policies and best practices, including guidance on what employees should do if they have questions or concerns about medical governance.

By the end of 2010, over 5,000 employees involved with clinical trials, safety and communication about products and trial findings had received this training. We will continue to raise awareness about medical governance in 2011 to ensure that all employees understand their individual responsibility to act with integrity, apply high ethical standards and report any safety concerns.

# Conducting clinical trials

Clinical trials in healthy volunteers and patients enable us to assess a compound's potential to become a new medicine or, once a medicine has been approved for marketing, to further evaluate the effect of the medicine for the approved use, to assess other potential uses, or to obtain additional safety data.

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We conduct clinical trials in accordance with 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). All trial protocols are reviewed by an ethics committee that is independent of GSK.

GSK-sponsored clinical trials are conducted to the same ethical standards irrespective of where they take place. Read about our conduct of clinical trials in the developing world.

Any contract research organisation (CRO), contracted to carry out trial-related activities on our behalf, for example, monitoring of study centres, or data quality management, are required to apply the same high standards of study conduct. Read about the auditing of CROs

Successful clinical trial programmes usually have three or four phases. During a trial, the effect of a potential medicine will often be compared with currently available medicines or, in some cases, an inactive substance known as a placebo. The ethics of conducting placebo-controlled trials are sometimes questioned because one patient group receives a placebo which will not provide active treatment. Placebo-controlled trials are carried out only where there are compelling and scientifically sound methodological reasons, where the risks are minimised and reasonable in relation to the knowledge gains, and where patients who receive a placebo are not subject to any additional risk of serious or irreversible harm.

The safety of clinical trial participants is of paramount importance, and we evaluate safety throughout each phase of a clinical trial programme. Before each trial begins, GSK works with ethics committees and investigators to establish an informed consent process that explains to research participants details of the study and its benefits and risks.

All GSK employees involved in conducting trials receive training on regulatory requirements and GSK policies.

Trials may be audited by our internal audit department and by external regulators. Read more about our clinical trials process.

# Planning and approval

For each clinical trial, we develop a protocol that sets out the purpose of the research and explains how the trial will be conducted and the results analysed.

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It includes details of the dosage supplied, the duration of treatment, and the number of participants required. It also defines the measurements that will be used to evaluate the medicine's safety and efficacy, and describes procedures that should be followed if participants wish to withdraw from the study.

All protocols are reviewed by an ethical review committee that is independent of GSK and is made up of lay people, medical professionals and scientists, and which has the power to reject or stop a clinical trial. These committees also review and approve other materials relating to a trial, including the information to be provided during the informed consent process.

In some instances, trial protocols may also be reviewed by government regulatory agencies.

# Working with healthcare professionals

GSK conducts clinical research in partnership with healthcare professionals who possess the unique medical insight and knowledge that are critical for the development of new medicines and vaccines. We take care to ensure that our interactions are conducted ethically and reflect the best interests of patients and clinical trial participants.

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Our policies governing interactions between GSK R&D staff and healthcare practitioners require that:

- All clinical trial investigators are 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 as a trial investigator
- Payments to practitioners are governed by contracts and any compensation reflects fair market value for the work performed and the services provided
- No payments are offered or made to influence their judgement on whether to enrol or maintain a research participant in a clinical study
- Gifts are not permissible to healthcare professionals involved in research projects for GSK.

We have made a commitment to disclose research payments made to healthcare professionals and their institutions. This will commence with payments made in 2010 to US healthcare professionals and their institutions for research studies that begin from January 2010 onwards. This first annual disclosure will be made in the first half of 2011 and will capture payments for all phases of medicine discovery and development, including clinical trials.

Outside the US, we will continue to work towards disclosure of individual payments. We will disclose payments to healthcare professionals and their research institutions on an aggregate basis, commencing with the publication in 2013 of payments made during 2012.

Read further about the payments we make to healthcare professionals and organisations.

# Informed consent

Potential clinical trial participants must voluntarily confirm their willingness to participate, after being informed about the study and its benefits and risks. This is known as informed consent.

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Informed consent for a clinical trial involves more than just reading and signing a consent form. It is part of a wider process for communicating essential information about the trial, including:

- Its purpose
- Treatment procedures
- Potential benefits and risks
- Alternatives to participation
- Provisions for data protection (confidentiality)
- Participants' rights – including the voluntary nature of participation and the right to end participation.

We aim to provide information for potential trial participants in a non-technical style that a lay person can understand. As well as written documents there are opportunities for face-to-face conversations between potential participants and members of the research team to discuss the trial and answer any questions. We use feedback from patient groups to improve the information we provide.

If a prospective participant 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 necessary information was accurately explained, and that the potential participant was able to ask questions and gave consent voluntarily.

Informed consent is an ongoing and interactive process. If a person decides to participate in a trial, the research team will update them on any new information that may affect whether they want to continue, such as potential new side effects. Participants have the opportunity to ask questions and raise concerns before, during and after a trial.

There may be special cases where obtaining informed consent is not possible. For instance, if a potential participant is below the age of legal consent, we seek consent from someone who is allowed to provide it under local laws and regulations.

# Post-trial treatment

We recognise that continued treatment of clinical trial participants with nationally licensed medicines at the end of a trial is often required for the continued care of patients.

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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 until the patient no longer derives a medical benefit.

There may be circumstances in which there is a compelling medical rationale for patients to continue to receive a GSK investigational medicine after the clinical trial. In this case, post-trial treatment may be provided through a further clinical trial as part of 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.

# Clinical trials in the developing world

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

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In some Least Developed Countries we may need to take additional steps to ensure that trials are conducted according to the Good Clinical Practice (GCP) guidelines. It may be necessary to match the objectives of informed consent to local culture, for instance by involving local leaders or family members.

GSK provides training to ensure healthcare professionals have the necessary skills and knowledge to conduct clinical trials on our behalf. As well as benefiting GSK, enhancing the skills of healthcare professionals in this way brings lasting benefits to communities.

We do not conduct clinical trials in countries when we know at the outset that we do not intend to pursue registration and make the product available for use in that country.

Read our position statement on Clinical trials in the developing world.

# Clinical trials in children

Children have a number of important physiological differences from adults which means they can respond differently to medicines. Clinical trials in children are vital to develop safe and effective medicines for children.

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At present there is a lack of medicines approved for children. We are committed to the development of medicines for children and consider children's needs in all our new medicine development programmes. Read more in our public policy on paediatric medicines.

Conducting clinical trials in children carries practical and ethical challenges. For example, it can be difficult to recruit trial participants, and there are fewer speciality centres in paediatric research compared to those for adults. Extra steps will often be needed to obtain the informed consent of parents or legal representative as well as the children.

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## Children in care

Very occasionally, it may be necessary to recruit children in care to clinical trials. For example, many children with HIV/AIDS in the developing world have lost both their parents to the disease and may be in care.

Trials involving children in care present further ethical concerns because, without parental protection, these children may be more vulnerable. We take additional steps to ensure high ethical standards are followed.

Approval must be obtained from our Chief Medical Officer before children in care can be recruited for a GSK clinical trial. The institutional review board or ethics committee overseeing the trial must also give explicit approval for the inclusion of these children.



## Training and auditing

### Training for clinical trials

All employees involved in designing, conducting, recording and reporting GSK-sponsored clinical research studies receive training on 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 employee training records which are routinely requested by regulatory authorities when inspecting GSK clinical research trials. We work with regulators and other organisations to continually improve the quality and compliance of clinical trials, and provide training to clinical researchers who conduct clinical trials on behalf of GSK and other sponsors.

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### Auditing for clinical trials

Our risk management and compliance framework includes independent audit and assessment of the conduct of clinical trials. Audits and assessments cover GSK systems and processes, as well as external clinical research organisations (CROs) and investigators conducting clinical research on our behalf.

We are conducting more trials in Asia and Latin America, reflecting our business growth in these regions. In 2010 we reorganised our quality assurance management structure to provide additional audit and compliance support in these regions.

Trials are selected for audit and assessment 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. We report audit results 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.

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, where clear breaches of policy have occurred, appropriate disciplinary action will be taken, up to and including dismissal.

For external investigators, GSK may retrain the investigator or stop working with them. Where significant non-compliance (that may impact patient safety or the integrity of data) is identified at an investigative site, we will report trial data to regulators both including and excluding that site and provide a rationale for exclusion.

For CROs, GSK may require the CRO to conduct additional training of its personnel or to enhance its clinical and/or quality assurance systems. Where significant non-compliance is identified, GSK will either promptly secure compliance or discontinue its association with the CRO.

We consider available site inspection reports published by regulatory agencies and information on debarments, disqualifications, warning letters or other disciplinary actions they have issued to investigators, to help us avoid or stop using investigators who don't meet our quality standards.

For the first time in 2010 we began auditing the New Drug Application (NDA) reports that we submit to the US Food and Drug Administration (FDA) as part of the drug approval process. This helps us confirm that the safety data in

these reports, including information from clinical trials, are complete.

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## Third-party audits

Regulatory authorities carry out independent inspections of GSK and the investigators and the clinical research organisations (CROs) we use to conduct clinical trials. They also inspect the independent ethics committees and institutional review boards that ensure the safety of trial participants, the quality of data and conduct of trials according to Good Clinical Practice guidelines.

Third-party audits are occurring with increasing frequency, and with a growing focus on clinical trials in emerging markets. In some markets, for example in Africa and Latin America, authorities have begun conducting audits for the first time.

The standards set by regulatory authorities are also becoming more stringent. It is essential that we maintain sufficient oversight of all clinical trials conducted on our behalf, and have systems in place to ensure quality and safety.

## Training for clinical trials

In 2010 there were 88,377 training activities related to Good Clinical Practice (GCP). Each of these represents a successful completion of an e-learning module or instructor-led course related to GCP by one of our employees or contractors.

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## Auditing for clinical trials

In 2010 we conducted 233 audits and assessments. These focused on:

- 168 investigator sites conducting GSK-sponsored trials. This represents approximately 5% of investigator sites participating in pivotal clinical trials (these are trials which provide the primary data on which regulatory approval is based)
- 8 GSK systems and processes
- 21 clinical research organisations carrying out clinical trials on GSK's behalf
- 8 GSK local operating companies involved in clinical research activities
- 28 New Drug Application (NDA) reports submitted to the FDA.

In addition, 22 investigations were conducted in response to suspected irregularities at investigator sites. We have fully investigated (or are in the process of investigating) any concerns or issues identified and have taken appropriate corrective action (see box).

Regulatory authorities also performed 83 inspections of GSK and the investigators we use to conduct clinical trials in 2010.

### Working with research organisations to ensure compliance

In 2010 we made a routine visit to a research organisation that is conducting a clinical trial on our behalf. In the course of the visit, we became aware of several areas of non-compliance with regulations and our own requirements, including deficiencies in the contractor's monitoring and quality assurance processes.

We informed the organisation about our findings immediately, and it acknowledged the serious nature of the issue. Together, we identified and implemented actions to correct the situation and ensure it never happens again.

The research organisation is now developing a more robust quality assurance process. It has agreed to immediately begin conducting more pre-qualification visits of investigator sites, and significantly increase the number and frequency of routine monitoring visits to sites. These measures will greatly improve the organisation's

ability to verify and demonstrate its compliance with our requirements and standards. Our auditors will follow up with the organisation to check that progress is made within agreed timeframes.

## Public disclosure of clinical research

### Approach

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Pharmaceutical companies are legally required to disclose relevant data from clinical trials to the appropriate regulatory authorities when seeking approval for a new medicine, and to provide updated safety information from clinical trials after approval. Read more about patient safety.

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

GSK is committed to public disclosure of all our clinical research, irrespective of whether the results are perceived to be positive or negative for our medicines. We believe this is fundamental for advancing medical science and informing prescribers and patients about scientific findings relating to our medicines.

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### Our Clinical Study Register

Our Clinical Study Register website, launched in 2004, serves as a resource for researchers, medical professionals and the public to access data from GSK-sponsored clinical trials. It supplements locally approved prescribing information and publications in the scientific literature. Our figures at the end 2010 indicate that the site receives around 10,350 visitors a month.

The register includes:

- Protocol summaries for ongoing studies
- Summaries of results from completed clinical studies into compounds that subsequently became marketed medicines
- Summaries of results of observational research (studies of medicines used in normal medical practice) and meta-analyses (which combine and analyse the results from two or more previously conducted studies) that evaluate our medicines
- Summaries of results from studies of terminated medicines (compounds that are no longer being developed). This helps to inform the scientific community about non-productive areas of research and reduce unnecessary exposure of study participants to similar compounds in clinical trials
- The names of principal investigators who participate in our clinical research.

We aim to disclose trial results summaries for all new medicinal products on our register at the time of first approval or within 12 months of terminating development of a medicine. If trials are completed after a product is approved for marketing, we aim to disclose the results within one year of trial completion.

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### Publication in journals

We believe we are the only pharmaceutical company that has made a commitment to seek publication of the results of

all clinical trials as full papers in scientific journals. Journals undergo independent peer review and provide context and interpretation of research data.

GSK's policy prohibits 'ghost writing' of journal manuscripts by requiring authorship and acknowledgements for scientific publications consistent with the requirements of the International Committee of Medical Journal Editors (ICMJE).

To help meet our commitment to journal publication, Publication Practices were established in 2010 that will further embed our requirements for GSK scientific publications to be of medical or scientific significance, to be the responsibility of project physicians, scientist and external authors, and for there to be no involvement of GSK commercial staff. Read more on our ways of working to clearly separate non-promotional scientific dialogue and legitimate commercial promotional activity to support licensed products.

When studies are not published in journals (for example if they are not perceived by the journal to be of sufficient interest to the journal's readers), we provide context and interpretation of results on our Clinical Study Register to help users interpret the data.

Read our position statement on disclosure of clinical trial information.

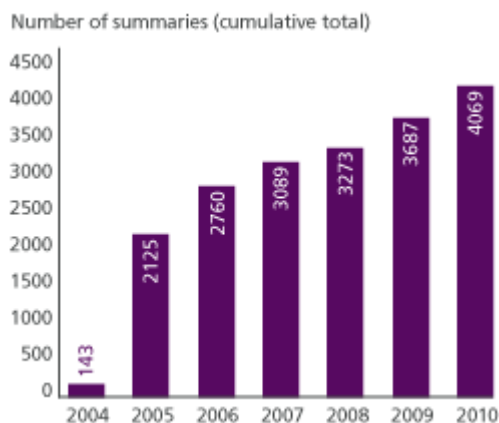
Read about our principles for working with healthcare professionals for the conduct of research.

## Performance

By the end of 2010 the Clinical Study Register included protocol summaries of all actively recruiting GSK clinical trials of medicines, 353 in total.

We posted 382 new results summaries to the Clinical Study Register during the year, bringing the total to 4069 (see chart). Less than 2% of studies were not posted by our own internal target timelines.

### Number of results summaries of GSK clinical trials on the GSK Clinical Study Register



### Medical Publishing Insights and Practices initiative makes progress

GSK is a founding member of the Medical Publishing Insights and Practices (MPIP) initiative. MPIP brings together pharmaceutical industry members and a medical publication professional society to promote trust and transparency in publishing industry-sponsored research. The MPIP helps to: improve understanding of the issues and challenges faced by journals in publishing industry research; identify potential solutions and promote more effective partnership to raise standards and expand access to data.

In 2010 MPIP made significant progress and was recognised with the Communiqué Trust and Reputation Award issued by pharmaceutical industry communications specialists, the PM Group. The award recognises

pharmaceutical initiatives that enhance industry trust and reputation in line with the Association of the British Pharmaceutical Industry's trust initiative.

In 2010 MPIP published 'The Authors' Submission Toolkit: A Practical Guide to Getting Your Research Published' in the journal Current Medical Research and Opinion. The toolkit aims to help raise standards and improve efficiency in medical publishing and highlights best practice in manuscript development and submission. The toolkit was developed through a collaboration between MPIP co-sponsors and editors and publishers of leading journals. After it was introduced at the 6th Annual Meeting of the International Society for Medical Publication Professionals, MPIP rolled out the toolkit at a series of industry training sessions.

In November 2010, MPIP hosted a roundtable event with journal editors that focused on why editors sometimes do not view industry-sponsored research papers as credible with the goal of closing the credibility gap. The output of the meeting was a set of ten recommendations to enhance the credibility of industry research. These include:

- Ensuring clinical studies and publications address clinical – not business – questions
- Publishing all data, including negative results and all adverse events
- Improving disclosure of who the authors are, and any conflicts of interest.

# 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.

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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 (possible side effects) may only be detected 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 whose specific role is to monitor and communicate safety issues to regulatory authorities. We also work with government officials, industry partners and policy makers to enhance safety systems for medicines and vaccines.

Read about our patient safety governance framework and how we collect and report safety data.

## Patient safety governance framework

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

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The GSB's remit is to ensure that safety is a focus throughout product development, and to review the safety of GSK products once they have gone to market. All its decisions are guided by the need to ensure that our medicines and vaccines have a favourable benefit-risk profile.

Its activities include:

- Overseeing the safety of all investigational and marketed medicines, vaccines and consumer healthcare products
- Approving the first administration of investigational medicines to humans
- Defining the conditions for use of medicines and vaccines to minimise safety risks. This includes any special safety monitoring and doses and durations of treatments that are considered safe
- Approving the progression of investigational medicines into pivotal trials (these are trials which provide the primary data on which regulatory approval is based)
- Assessing any issues related to patient safety that arise during product development or marketing.

Three 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 Agency (EMA). These are:

- Global Clinical Safety and Pharmacovigilance team (GCSP), part of our research organisation, 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 Code of Conduct.

Read about our medical governance.

### Benefit-risk management

We assess the balance between the benefits and risks of a particular medicine throughout its life cycle – from early development, during clinical trials and after 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 risks. We review and update plans regularly during clinical development and for a period after a product is approved for marketing.



## Collecting and reporting safety data

### Requirements

We receive information on adverse events (possible side effects) from several sources, including:

- Unsolicited reports from healthcare 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.

Every GSK employee is required to report any adverse event they become aware of, and this is outlined in our policy on adverse event reporting. As part of our annual business ethics certification programme, over 24,000 employees confirmed their compliance with the policy. We have added an adverse event reporting button to the front page of our intranet site, to make reporting easier for employees.

All adverse events reported to GSK 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 regularly.

Regulators in some countries also publish 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 (MHRA). Some safety data are also available in Canada, while in the US the Food and Drug Administration (FDA) has made the information in its database more accessible to the public by publishing a quarterly report of potential safety issues it is investigating.

Read about medical governance at GSK and see our position statement on pharmacovigilance.

#### Responding to adverse events

Adverse events can 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 and establishing specific methods to minimise risk, for example highlighting a warning in the prescribing information. 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 our medicinal products and ensure this is updated when appropriate.

Read our responses to questions about our diabetes product *Avandia* and our products containing long acting beta2 agonists (LABAs).

### Improvements and innovation

We continue to improve our patient safety systems, safety databases and monitoring processes. For example, in 2010 we:

- Further developed SÆfetyWorks® a software tool that enables rapid review of safety information from observational data sources

- Partnered with regulatory agencies and the Observational Medical Outcomes Partnership (OMOP) to understand how best to detect safety issues associated with our products using observational databases
- Enhanced our processes to identify and manage safety signals. For example, we established a system that provides us with real time alerts of sudden changes in the number of adverse event reports received each month for a particular product
- Adapted our system for collating adverse event reports to facilitate the electronic upload of adverse event reports in compliance with international regulatory standards. This allows us a more efficient way to process the safety data.

Read about further collaborations on patient safety.

## New capabilities in the science of benefit and risk evaluation of medicines

To further enhance our approach to patient safety we are establishing a new Clinical Sciences Evaluation team. The specialist team of physicians and scientists will focus on increasing our expertise for the evaluation of the safety and efficacy of our medicines, both in development and once they are approved for use by patients.

The team will draw on the latest research in areas such as population science and clinical medicine to help us assess in greater detail how patients respond to our medicines. Ultimately it will enable us to provide more detailed information to patients and physicians on the benefits and risks of our medicines.

We also aim to establish a network of external experts with whom GSK may collaborate to further develop the science of benefit and risk assessment and new scientific and regulatory standards.

The activities will be lead by a recent appointee to GSK who is an expert in the field of population science and health outcomes research, and a former Chair of a leading American medical school. This senior role will report directly to the Chair of R&D and join our Global Safety Board.

# Responding to questions about *Avandia*

*Avandia* (rosiglitazone) is a treatment for type 2 diabetes which has been the subject of a debate about whether it is associated with an increased risk of myocardial infarction.

The European Medicines Agency (EMA) and the FDA each took individual regulatory decisions and actions in September 2010 following a review of *Avandia*:

- In the European Union, the EMA suspended the marketing authorisation for all rosiglitazone-containing medicines (*Avandia*, *Avandamet* and *Avaglim*). The EMA has stated that the suspension will remain in place unless convincing data are provided that identify a group of patients in whom the benefits of the medicine outweigh its risks.
- In the US, all rosiglitazone-containing medicines (*Avandia*, *Avandamet* and *Avandaryl*) will remain available with additional safety labelling and restrictions for use. The FDA will also require a Risk Evaluation and Mitigation Strategy (REMS) programme with additional measures to ensure the safe use of the medicine. The FDA suspended the operation of the TIDE trial.

Our primary concern continues to be patients with type 2 diabetes. Following these decisions we have worked to ensure that physicians in Europe and the US have the information they need to help them understand how these regulatory decisions affect them and their patients. We have revised the US labels and medication guides for rosiglitazone-containing medicines and have withdrawn the products from all EU markets governed by EMA.

We continue to believe that *Avandia* is an important treatment for patients with type 2 diabetes. We are working with the FDA to implement the remaining FDA requirements for a Risk Evaluation and Mitigation Strategy (REMS) programme to ensure doctors and their patients are aware of restrictions and an independent re-adjudication of the endpoints reported in the cardiovascular safety study, RECORD. We are also working closely with other regulatory agencies to comply with any decisions made by them regarding rosiglitazone-containing medicines.

GSK has voluntarily ceased promotion of *Avandia* in all the countries in which it operates and continues to respond to requests for information and support from healthcare professionals and patients.

Please see the *Avandia* Resource Centre for the latest information.

Home : Research practices : Patient safety : Collecting and reporting safety data : Developments concerning the safety of our products containing long acting beta2 agonists (LABAs)

# Developments concerning the safety of our products containing long acting beta2 agonists (LABAs)

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 June 2010, after a long period of regulatory review (including Advisory Committee meetings) focusing on the issue of potentially increased risk of asthma-related death or other serious outcomes, GSK implemented updated labelling for its LABA-containing products in accordance with the FDA's directions for all LABA-containing products indicated for use in treating asthma. The updated labelling includes strengthened risk information and recommendations intended to promote safe use in patients with asthma.

The FDA has approved a new risk evaluation and management strategy for *Serevent* and for *Advair*; both include a medication guide for use by patients and a GSK communications plan to educate prescribers about the strengthened risk information and recommendations intended to promote safe use in patients with asthma.

The FDA has also required further clinical research; potential approaches were explored at a March 2010 Advisory Committee meeting and consultations with the FDA about appropriate trial design are continuing.

# Collaborations on patient safety

We work with government officials, industry partners and policy makers to enhance safety systems for medicines and vaccines.

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We are co-founders of the international Serious Adverse Events Consortium (iSAEC), a non-profit collaboration of over 20 partners including pharmaceutical companies, academic institutions and regulatory bodies which is working to improve patient safety by identifying genetic variants that predict adverse events. GSK scientists co-chair the iSAEC scientific management committee and have a seat on the board of directors.

iSAEC's initial research has focused on two reactions which are considered serious enough to discontinue medication: drug-induced liver injury and drug-induced serious skin rashes (Stevens-Johnson Syndrome and toxic epidermal necrolysis). GSK contributes patient samples and scientific expertise to these studies.

In Europe, GSK is the industry lead in the patient safety project of the Innovative Medicines Initiative (project PROTECT), a public-private partnership that aims to improve processes for the assessment of the benefit-risk profile of new medicines.

In the US, we partner with the US Food and Drug Administration (FDA), other pharmaceutical companies, healthcare professionals and academia to develop new systems for the detection of adverse events and explore how to more effectively communicate written information about medicines to patients. For example, we participate in the FDA's initiative to improve patient medication information.

We participate in the Critical Path Institute's Predictive Safety Testing Consortium (an independent, non-profit organisation) that brings together scientists from industry and academia to share and validate their safety testing methods under the guidance of the FDA and the European Medicines Agency (EMA).

We are also a member of the executive and scientific oversight committees of the Cardiac Safety Research Consortium, (launched in 2006 through an FDA Critical Path Initiative - Memorandum of Understanding with Duke University in the US) which uses the principles of the Critical Path Initiative and focuses on improving evaluation of cardiac safety during the development of new medicines.

Read about more collaborations to ensure improvements and innovation in collecting and reporting safety data.

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## Ethical conduct

We are building on our strong ethical culture at GSK by developing robust policies, recruiting the right people and equipping them with the information they need to make ethical decisions. Putting patients first is the core principle of being an ethical healthcare company.

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.

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Our Code of Conduct sets out fundamental standards for all employees. It is supported by the Employee Guide to Business Conduct which helps employees make ethical decisions and emphasises GSK's key values:

- Commit to **transparency**
- Show **respect** for people
- Always demonstrate the highest **integrity** in our conduct.
- Be **patient** focused

We stress our commitment to performance with integrity. This means that all employees must understand our values and what we stand for as well as the policies and procedures that underpin our approach.

Our internal compliance systems are designed to identify and address breaches of our codes and reinforce GSK's values. There is continual external pressure to enhance these systems and our compliance oversight and audits are helping to drive this change. We fully investigate suspected breaches and take appropriate disciplinary action, up to and including dismissal.

Ethical risks are also reviewed as part of our due diligence process for acquisitions.

In 2009, Bureau Veritas assured the Ethical Conduct section of our CR Report and made recommendations for how we could improve our approach and reporting. We have taken these recommendations into account in the improvements we made to our policies and processes during 2010.

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### Our 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 policies 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 guidance and to keep asking questions until they are certain that they are making the right choice.

## Key policies

### Code of Conduct

The GSK Code of Conduct applies to our employees and contractors. It states that we will:

- 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.

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## Employee Guide to Business Conduct

Our Employee Guide to Business Conduct builds on the Code and explains what employees must do to meet its requirements. It contains policies and guidance to ensure that we operate according to the law and maintain high standards of ethical business behaviour. The guide emphasises that good ethical conduct is essential to our continued business growth and ability to improve quality of life for patients.

Our Employee Guide is available in 17 languages and helps employees understand how each of our policies is aligned with our values. It includes real-life scenarios.

### Sample questions from our Employee Guide to Business Conduct

**Question:** A vendor offers to pay for a weekend at a resort for my wife, to compensate for all the time I have spent over the last month evaluating the vendor's product. Since I have finished the assessment, and the trip is only for her, can she accept?

**Answer:** Think of how this would look if your wife took the trip. Other people would certainly see this as a reward or pay-off to you for picking that vendor. This is an unacceptable offer that should be politely and firmly refused.

**Question:** Information about a competitor mysteriously appears in my office mail, with no return address or indication of where it came from. The information includes the competitor's plans for a price increase. What should I do with this information?

**Answer:** You should not review the material. Place it in a sealed envelope and immediately contact the GSK Legal Department for guidance. We respect other companies' proprietary or confidential information and would not permit any use of this information. In addition, because the information you received relates to a competitor's future prices, there could be a risk to GSK under competition laws.



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## Third Party Code of Conduct

In 2010 we introduced a Third Party Code of Conduct for GSK suppliers. This sets out the standards we expect suppliers to meet and covers ethical conduct; labour practices and environmental, health and safety standards; and management. We are making existing suppliers aware of the Code during our routine interactions. We require new suppliers to sign a statement confirming that they comply with the principles of the Code before they can do business with GSK.

To help suppliers understand how to interact appropriately with GSK staff, the Code includes key principles from our Employee Guide to Business Conduct such as our policy on receiving gifts.

In the US, suppliers and agents engaging in activities that may be subject to GSK's Commercial Practice Policies (which govern our sales and marketing activities) are now contractually required to read and certify compliance with our ethics policies before initiating any services for GSK. Policies and updates are available to suppliers online.

Read more about GSK's supply chain.

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## Anti-competitive behaviour policy

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. Corrupt and anti-competitive behaviour undermines fair competition, inhibits economic development and is bad for economies, business and people.

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.

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## Preventing bribery and corruption

In 2010 we reviewed and strengthened our approach to preventing, detecting and addressing bribery and corruption. Our Preventing Corrupt Practices policy was updated and we launched a dedicated anti-bribery and corruption unit which will ensure we take a consistent approach across the company.

GSK requires compliance with the highest ethical standards and all anti-corruption laws applicable in the conduct of its business. We value integrity and transparency and have zero tolerance for corrupt activities of any kind, whether committed by GSK employees or by third parties acting for or on behalf of GSK. Unauthorised payments, or acts that create the appearance of promising, offering, giving or authorising payments prohibited by this policy, are not tolerated.

Mandatory risk assessment and due diligence procedures have now been implemented to assess bribery and corruption risks related to relationships with third parties and business development transactions. Contract templates have been updated to include our anti-bribery and corruption policies. These changes are being applied to new contracts and to existing contracts as they are renewed.

### Applying our policies in practice

To comply with our anti-bribery and corruption policy, GSK employees will carry out appropriate checks before engaging suppliers and other third parties. Additional due diligence is required for high-risk third parties including agents, external-facing consultants, distributors, third parties interacting with government officials and those operating in high-risk markets.

This due diligence process helps us reduce the risk of our business partners breaching our anti-bribery and corruption policies. The assessment is based in part on due diligence reports provided by a dedicated in-house team, using licensed research tools and databases supplied by external vendors. It looks for any evidence of negative news reports, warnings or sanctions involving the potential business partner, as well as any association

with politically exposed persons, which may present an increased risk of bribery and corruption.

If the reports raise any concerns, the employee must discuss them with their local compliance officer or legal representative before commissioning the supplier. In some cases, this may mean not progressing with the relationship or third party transaction.

Employees can read our anti-bribery policies and access our anti-bribery handbook and e-learning module via our intranet. The training is mandatory for all managers and additional face-to-face training has also been developed for employees involved in the selection, payment and oversight of third parties, in business development and in interactions with government officials.

To improve detection of bribery and corruption we have commissioned Ernst and Young to work with our anti-bribery and corruption unit to develop a risk-based auditing and monitoring methodology. This will use a combination of data analytics, traditional auditing and forensic accounting techniques.

These changes and the introduction of our Third Party Code of Conduct will support our compliance with the new UK Bribery Act, the US Foreign Corrupt Practices Act and other anti-corruption laws.

### An example of corruption prevention training

Our anti-corruption training, introduced in November 2010, is designed to help employees understand and comply with our anti-bribery and corruption policies.

This e-learning module includes examples of scenarios that employees could encounter in their work. For example, being asked to make a facilitation payment to expedite the processing of a visa application. It explains how they should deal with such situations, including how to report a potential problem.

The course is available in 18 languages and completing it is mandatory for all GSK managers. Employees working in functions such as Legal or in regions where there is a higher risk of corruption must also take the course.

# Privacy

We collect and use personal data from a number of groups of people in the course of our business, including employees, consumers, customers and participants in our clinical research.

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We aim to be open and transparent about the personal information we collect, how we use it and whether it is shared with any third parties. Where required or practical, we will provide such processing information to individuals. We will obtain an individual's informed and voluntary consent to process their personal data in cases where it is necessary or appropriate to do so.

We have developed a set of global privacy principles to ensure that all personal data are collected, used, processed, transferred and stored securely and appropriately, in line with legal requirements. This helps to maintain trust in GSK.

We established a data privacy centre of excellence and Global Privacy office to oversee our privacy processes and communicate best practices throughout GSK.

To raise awareness among GSK employees, we launched a campaign during 2010 reminding them of the importance of protecting personal information. We also refreshed and relaunched our Global Privacy Policy to ensure it reflects key legal requirements and GSK's values. We have developed and deployed data privacy training to support our global privacy programme, and we continue to develop more in-depth training for employees involved in handling personal data on a regular basis.

# Acquisitions and due diligence

GSK is expanding its presence in emerging markets, acquiring new businesses and entering new joint ventures in these regions.

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When entering into a joint venture or acquiring a new business, we look for organisations that share our values. Our due diligence process for potential acquisitions takes account of ethical risks and we integrate our ethics and compliance requirements as standard practice in newly acquired businesses.

We work to embed our values and policies, risk management analysis and internal communications framework within the first six months of any new acquisition.

The integration process for new businesses includes:

- Comparing the new company's compliance programme with our own, identifying areas of non-alignment and developing action plans to address them
- Rolling out our global anti-corruption policy and employee training
- Implementing our code of conduct and compliance training
- Aligning with GSK transparency initiatives such as our disclosure of grants and payments to healthcare professionals
- Implementing key compliance controls and monitoring processes
- Delivering our Performance with Integrity training.

During 2010 we looked at a number of companies for possible collaborations, joint ventures or acquisitions. In some cases we chose not to pursue the deals because our due diligence processes raised concerns about the difference between ethical standards at these companies and standards at GSK. The types of issues identified included insufficient regulatory data to support the claims made for marketed products and sales of products that would not meet GSK's ethical and safety standards. In certain cases, once we have concluded an acquisition, we have discontinued sales of some products for safety or ethical reasons or introduced significant relabelling.

# Marketing our products

We market our prescription medicines and vaccines to healthcare professionals, 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.

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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.

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 global marketing code forbids these practices and other unethical conduct. We provide regular training for sales teams and monitor compliance.

It is very important that GSK is actively engaged in scientific debate and communication outside the company. This enables us to participate fully in the development of scientific understanding, to benefit from the knowledge of leading external scientists, practitioners and patients, and to apply the best science to the development of our medicines and vaccines. We must avoid activities which could be construed as promotion of a product or a new use of a product before we have authorisation to market it. To support this we are implementing clear standards for the way we work, to emphasise the distinction between non-promotional scientific dialogue and legitimate promotional activity to support licensed products.

The new standards will apply to all scientific and medical interactions with any external groups, including healthcare practitioners, payers, governments, patient groups and the media. Our view is that if our scientific activities appear in any way to be promotional, our credibility will be undermined and we will lose the trust of our stakeholders. These standards will therefore support our role as a trusted and valued scientific partner in developing medicines and vaccines that enhance patient care.

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## Marketing Codes of Practice

The sale and promotion of pharmaceutical products is highly regulated by governments and medical agencies. In addition, our GSK global code on promotional activities and interactions with healthcare professionals and our regional marketing codes set consistent standards for our employees and agents working on our behalf. They commit us to promotional practices that are ethical, responsible, principled and patient-centred. They prohibit kickbacks, bribery or other inducements to healthcare professionals (HCPs) or government officials, and any promotion for unapproved uses of our medicines.

Our regional codes reflect differences in market structures, national healthcare systems and regulations. They are at least as stringent as our global code, and in some regions and countries may be more restrictive.

GSK supports efforts to strengthen marketing standards across the pharmaceutical industry. This benefits patients by supporting their appropriate treatment. It also helps to ensure that companies operating to high ethical standards are not put at a competitive disadvantage and helps to improve the reputation of the pharmaceutical industry as a whole.

## Our Marketing Codes of Practice in summary

- **Information** - Our marketing and promotion is based on valid scientific evidence and must be accurate, balanced, fair, objective, unambiguous and up to date. Information can only be provided on approved uses for a medicine
- **Items for healthcare professionals** - These must be educational, or assist patients in the administration of their treatment or management of their condition, or reflect local customs in accordance with local laws, regulations and industry codes. Items cannot be given as an inducement to prescribe any of our medicines or to medical professionals retained as consultants to GSK
- **Hospitality for meetings** - GSK must not host meetings at venues that could reasonably be perceived as lavish or extravagant for a business meeting. It must be the programme, not the venue or hospitality on offer, that attracts delegates to attend. GSK will not invite delegates' guests to accompany them or pay the guest's costs
- **Grants** - decisions about grants for medical education are reviewed by qualified medical or scientific personnel. Our grants, donations or charitable contributions are not an inducement to or reward for the prescription of products.

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## Global practices

All employees who regularly interact with healthcare professionals must now complete our annual Business Ethics certification process, in which they confirm their understanding and compliance with the **Employee Guide to Business Conduct**.

We have updated our policy on engaging public officials to include healthcare professionals acting in this capacity, such as a doctor serving in a ministry of health for a government. The policy generally prohibits GSK employees from sponsoring or funding government officials to attend educational meetings or congresses and generally prohibits gifts to government officials.

We implemented additional controls to prevent market research with HCPs being used to disguise promotion of pharmaceutical products. Market research studies must now be reviewed and approved by our Medical Governance department.

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## United States

We are continuing to work towards resolving a number of long-standing legal matters. In light of these cases we have fundamentally changed our procedures for compliance, marketing and selling in the US. We now have far-reaching policies and procedures in place to guard against inappropriate promotion to HCPs, and to seek to ensure that if breaches of regulations do occur they are reported to the US government.

We have strengthened our training and compliance programmes, we have eliminated past practices and have adopted new measures so that our relationships with HCPs enhance the practice of medicine. This approach reflects GSK's commitment to honesty and integrity, and to focus on the best interests of patients.

We have updated our US Commercial Practices Policies (CPPs), which support our marketing code to make sure they are fully aligned to our values. The language used in the policies has been simplified to make them easier for employees to understand. Our US sales and marketing practices meet or exceed the US PhRMA Code on interactions with healthcare professionals and comply with the applicable Federal healthcare programme and FDA requirements.

In addition to the requirements of our global code, in the US our policies and practices also include:

- A state reporting system for payments to healthcare professionals (HCPs), in line with legislative requirements in several US states
- A requirement that GSK grants to healthcare-related groups, including patient advocacy groups and physician associations cannot exceed 25 per cent of the group's annual income
- A speaker evaluation process for HCPs sponsored by GSK. Our compliance teams and an external supplier evaluate high-frequency speakers, and provide feedback to them on their effectiveness and compliance with our Speaker

Programmes policy. In 2010 they conducted over 700 speaker evaluations

- All questions from doctors on off-label uses for our products must be referred to our medical information department. The number and type of referrals made by individual sales representatives are monitored to help ensure that representatives are not promoting off-label uses.

### **Sales force remuneration**

To reinforce the requirement for the behaviour of our field sales staff to be consistent with our values, we are changing the way we incentivise our representatives. To date, the variable part of their pay has been dependent on the volume of prescriptions for GSK products in their sales territory.

During 2011 we are putting in place a system which reflects three factors in representatives' bonus pay: an assessment of their scientific and business knowledge; feedback from customers in their region, including demonstration of GSK's values; and overall performance of the business unit they support. This will shift the focus from generating the next prescription to providing the information and support our customers want. This programme will be fully implemented in July 2011.

### **Continuing medical education grants**

In 2010 we implemented new standards on funding continuing medical education. These are educational activities that help HCPs to maintain, develop or increase their knowledge, skills and professional performance. We have reduced the number of education providers we support and have restricted our funding to academic medical centres and professional medical associations only. We no longer fund medical education programmes offered by commercial medical education providers.

Our new approach will help us focus our support on the education programmes with the greatest potential to improve patient health.

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## **Europe**

We updated our European Marketing Code in 2010, to clarify the provisions on gifts. It now states that the only items that can be provided for use at GSK-sponsored medical and educational meetings are pens and paper pads and these must only be branded with the GSK logo, not one of our product-specific brand logos. Medical and educational items are permitted if they enhance the responsible use of medicines in GSK therapy areas, carry no product branding and are not more than €10 in value.

In Europe our code of practice on interactions with HCPs reflects the European Federation of Pharmaceutical Industries and Associations' Code of Promotion. It specifies that:

- **Use of consultants** - GSK employees responsible for selecting consultants must have the expertise and authority to evaluate whether the consultant is suitable to meet the identified business need and is providing a service of real value to GSK. Consultants are required to declare their consultancy arrangements with GSK when speaking publicly on a related issue.
- **Samples** - Product samples are to be given only in limited numbers and for a limited time, by reference to local standards, so HCPs can familiarise themselves with a new product.
- **Grants and donations** - When making grants and financial donations to health organisations we must not be involved in how a grant or donation is used and must receive no service in return. Grants and donations:
  - May only be given 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
  - Are only permitted to health organisations rather than individuals.
- **Phase IV clinical studies** - When conducting phase IV studies (studies conducted after a medicine has been approved for marketing) we use the following principles:
  - Studies must not be commissioned as an inducement to prescribe, supply or recommend medicines. They must have a clear scientific or healthcare research purpose
  - There must be a contract with the institution undertaking the research
  - Studies must be conducted in accordance with GSK R&D policies
  - Study results will be distributed to investigators and in line with our publications policy.

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## Asia Pacific, Japan and Emerging Markets

Our revised Promotion and Marketing Code for these regions was implemented in 2010. Its requirements include:

- **HCP fees** - Each country must set an annual maximum limit (cap) for the fees that can be paid to an individual HCP within their country.
- **Grants or donations** - These may only be provided in response to unsolicited requests from HCPs or institutions. They must not be provided or offered in exchange for prescribing medicines or for a commitment to continue prescribing medicines. Grants or donations should be given to institutions, associations or hospitals, rather than to individual HCPs. GSK must be assured there is a valid purpose for any grant or donation but should not get involved in the details of how they are used and must receive no service in return.
- **Samples** - Samples must not be provided as an inducement to prescribe. The maximum number of samples per HCP and the maximum time period is set by national codes or defined in a local Standard Operating Procedure.
- **Market research** - Market research collection methods must be unbiased and non-promotional, although the subsequent use of the statistics or information may be promotional. Local guidance must be available for the development of market research materials, based on the Code. Where there is doubt, the materials must be reviewed by the medical department to ensure that the research process does not constitute promotion or a clinical study. Market research studies must be clearly identified as such to potential participants.
- **Medical education** - When most HCPs invited to attend a GSK medical education event are from one country, the meeting should be held in that country unless there are clear and compelling reasons for holding it in another location. GSK may not invite a guest to accompany the invitee or pay any costs associated with individuals accompanying an invited HCP.



# Grants and donations to healthcare organisations

GSK is regularly asked to make grants and donations to healthcare organisations to support a range of activities. By healthcare organisation we mean a private or public sector organisation or association that is made up of healthcare professionals (HCPs) or patients and which supports research or provides information to HCPs or patients.

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Grants are monetary contributions given to an organisation. These may fund the attendance of the organisation's HCPs at a medical or scientific meeting by covering their expenses. Grants may also be provided to support research where GSK is not directly involved in the activity, and support for independent medical education programmes.

Donations are defined by GSK as non-monetary contributions. For example we may provide equipment such as a bone densitometer or medical textbooks, for the benefit of patients and the healthcare organisation. GSK assigns a monetary value to donations in order to track this activity. Separately we make community investment grants and product donations which are included in our disclosure of community investments.

GSK does not solicit requests for grants and donations, and cannot be involved in the detail of how a grant or donation is used. However, we must be assured that there is a valid purpose for any grant or donation, to benefit patients and public health.

Standards in our marketing codes set out requirements for making a grant or donation which include:

- They cannot be made to individual HCPs.
- The purpose must be for healthcare or research
- GSK must not receive a service in return
- They cannot be given on the understanding that the recipient will prescribe or recommend our products

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## Publishing grants and donations

Grants made to patient advocacy organisations are covered in the section on patient advocacy. Charitable donations are included in our disclosure of community investments.

We started to publish quarterly reports of the grants and donations we make in the US in February 2009.

Achieving this for all countries is challenging because we do not have the systems in place to uniquely identify each healthcare organisation, and to collate data across multiple markets and currencies. We also need to get written permission from the recipient organisations to disclose the purpose and value of the grant or donation. We will continue to work towards disclosure of individual healthcare organisation grants and donations and we will publish aggregate 2010 payments made by our commercial operations (Pharmaceuticals and Consumer Healthcare) outside the US by the end of 2011.

# Payments to healthcare professionals

Healthcare professionals bring expert knowledge and perspectives from their clinical and healthcare management experience which they share with healthcare companies such as GSK, and with other healthcare professionals, to support improvements in patient care. These services are valuable to improving patients' health, and GSK believes these professionals should be fairly compensated if they provide services and expertise to us.

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GSK makes payments to healthcare professionals (HCPs) in the following circumstances:

- Sponsorship - financial support may be provided to healthcare professionals to participate at scientific conferences. Support will be limited to the payment of registration fees, reasonable travel, meals and accommodation.
- Speaker services - we pay HCPs to speak at meetings and conferences about GSK products and disease or therapy areas relevant to us. Any payment made to the HCP must be reasonable and reflect the time they spend speaking on GSK's behalf.
- Advisory panels - we convene advisory panels with HCPs to, for example, learn about unmet medical needs, improve science and develop new therapies.

Conduct of research - read how we engage with healthcare professionals who conduct medical research on our behalf

We have clear standards which set out how we work with HCPs and how much we pay. Support provided will never be an inducement or reward for prescribing our products. It is in our interest that the external healthcare professionals we work with do not receive excessive funding from GSK. Their work for us should not detract significantly from the time they spend with patients or conducting research. This could reduce their professional credibility and their value as independent sources of current medical expertise.

Payments to healthcare professionals must be at fair market value and take into account the individual's speciality area, level of expertise and the amount of time he or she spends in providing these professional services. We have a standard schedule of fees for HCPs that vary according to speciality, and whether the HCP is a local, regional or international expert. These fees have been determined using research based on information from several national wage surveys.

We are introducing policies that state speakers must be transparent about GSK's support for their attendance at conferences and that the content of education programmes must not be influenced by GSK.

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## Publishing payments to HCPs for speaking and advisory services

We have committed to publishing the payments we make to HCPs and we already do so in the US. Achieving this in all countries is challenging because the systems in each country need to be aligned to help us to uniquely identify each HCP, and to collate data across multiple currencies. Also, this is personal information and we need to obtain permission from HCPs to disclose it.

We will continue to work towards disclosure of individual healthcare professional payments as we do in the US, taking into the account the complexities and cultural challenges that publication of these payments presents in each country. GSK is therefore implementing data-gathering systems that should enable the reporting of fees consistently across the

company. As part of this process, the company is amending contracts with HCPs to include clauses that allow individual data closure.

In the US, we publish quarterly reports to show the payments made to HCPs for speaking and advisory services. These are available on our US website.

In January 2010, we reduced the limit on payments to HCPs in the US. Speaker and advisory fees are now restricted to a maximum of \$100,000 a year for an individual HCP, from \$150,000 in 2009. Most US HCP consultants receive fees that total less than \$10,000 per year.

We will continue to work towards disclosure of payments made to individual HCPs and we will publish aggregate 2010 payments made by our commercial organisation (Pharmaceuticals and Consumer Healthcare) outside the US by the end of 2011.

## Direct-to-consumer advertising

### Approach

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In the US it is legal to advertise prescription medicines to consumers through television and print advertisements. This is known as direct-to-consumer (DTC) advertising.

New Zealand, Bangladesh and South Korea also allow limited DTC advertising and some other markets allow limited advertising for some vaccines. 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.

Patients must still consult with their physicians about their condition and the appropriateness of a prescription medicine, and obtain his or her consent before receiving such medicines.

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### 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. We have trained US marketing employees on our DTC policy.

New DTC television advertisements are submitted to the US Food and Drug Administration (FDA) for review and comment prior to 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.

#### Our principles for DTC advertising in the US

Our policy requires us to commit an appropriate amount of time to educating healthcare professionals on new medicines or indications before launching DTC advertising. It states that DTC advertising should:

- Be designed to educate the public 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.

## 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.

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## Disease-awareness campaigns

In many markets we fund disease-awareness campaigns which are designed to increase understanding of a disease but do not promote a specific GSK product. These campaigns can take place to coincide with the launch of a new product or once it is on the market. Raising awareness about disease can have a positive impact on public health and can create commercial benefits for GSK.

Disease-awareness campaigns take the form of 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.

We have policies in place to ensure that all our disease-awareness campaigns are conducted to high ethical standards. For example, campaigns in the US are governed by our DTC policy. Campaign materials are branded to indicate that they have been produced by GSK.

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## 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.

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## Performance

In 2010 our US Pharmaceuticals business received three 'notices of violation' from the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) and one DDMAC response expressing concerns about draft promotional materials submitted to them for review. In each case of violation we immediately reviewed and withdrew the material. Retraining was provided to employees involved in developing the material

In April 2010, DDMAC wrote to Astellas Pharma Inc. regarding a VESICare website. GSK, as a co-promotion partner for VESICare, was copied on the letter. DDMAC found the website to be false and misleading and to contain

unsubstantiated superiority claims and overstatements about the efficacy of VESICare. The VESICare website was immediately suspended while amendments were made and employees were alerted not to use other VESICare promotional materials while these were reviewed.

In April 2010, GSK received a warning letter regarding a journal advertisement for *Arzerra*. DDMAC found that while the advertisement did not mention *Arzerra* by name, it clearly pointed to the product. It found the advertisement to be false and misleading because it omitted important information about the safety and effectiveness of *Arzerra*. The letter also stated that GSK had failed to submit a copy of the advertisement to the FDA for review. GSK had not taken this step since we had deemed the advertisement to be unbranded. All *Arzerra* materials in use were promptly reviewed and employees were instructed to discontinue using related *Arzerra* advertising

Also in April 2010, DDMAC wrote to GSK regarding promotional material for *Altabax*. It found that the material contained misleading information that broadened the indication of *Altabax*, made unsubstantiated superiority claims and minimised important risk information. The *Altabax* response team promptly reviewed all active materials and instructed sales representatives and speakers to stop using them. We also wrote to the healthcare professionals (HCPs) who had received the promotional materials and provided them with corrective information on the issues raised in DDMAC's warning letter.

We take the directions provided to us by the FDA very seriously and are developing new standard operating procedures that will help to ensure that FDA requirements are reflected in all our future advertising.

There were no violations in other countries in which GSK uses DTC advertising.

# Training and awareness

Training and awareness programmes help employees understand the importance of ethical conduct and apply our policies in practice.

Before hiring new recruits we carry out pre-employment checks to ensure they share GSK's values. We include questions on ethics and integrity in our guides that are used during employee interviews.

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We expect all employees to live up to the GSK values and this is reinforced through our Employee Guide to Business Conduct and by senior leaders during meetings and employee broadcasts. Communication and training is used to help employees understand how to apply our values in the decision-making process. Key ethics and integrity messages include:

- Profits without principles are short lived
- 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
- When faced with difficult ethical situations, refer to the ethical decision-making model.

Our Corporate Ethics and Compliance intranet community contains links to all company policies, ethics and compliance training for new recruits, our ethical decision-making model, an ethics quiz, useful examples, connections to key training programmes (such as Anti-Bribery and Corruption, Third Party Oversight, Audit and Assurance), contact details for compliance officers, and the freephone numbers for our Global Confidential Reporting line and US Integrity Helpline.

Employees can also get advice and guidance from their manager, human resources and legal departments, and their local compliance officers and champions. Read more about reporting channels for ethical issues.

New employees complete induction training on the GSK Code of Conduct, which is available on our intranet site. We train new general managers and site directors on their compliance responsibilities and our monitoring and compliance arrangements. Our annual business ethics certification programme requires managers, and employees who interact with healthcare professionals, to confirm that they comply with our ethics policies. Managers can access three e-learning modules on ethical leadership on the company intranet.

Specialised training is provided for employees working in R&D, manufacturing, and sales and marketing, where there are additional regulatory requirements. 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 through our Risk Management and Compliance Boards on the types of unethical conduct detected and disciplinary actions taken.

We provide extra training and guidance for employees committing minor breaches to prevent them committing more serious breaches in future.

## Ethics training in practice

Ethics training helps employees make the right decisions and apply our policies in practice. We run ethical decision-making training for employees and leaders that explores ethical dilemmas they may face in their work and provides guidance to help them understand the appropriate response. This is one example of an ethical dilemma:

A start-up company approaches you to work on a small project as a consultant. The work could be done during weekends and evenings. You could use the extra money, and you have the time available to do the work.

Should you:

- (a) Accept the offer, as you know that what occurs outside the workplace is considered personal
- (b) Talk to your manager, a compliance officer or the GSK Legal Department about the offer before deciding what to do
- (c) Reject the offer, as taking a second job creates a conflict of interest.

The best answer is (b). Each situation is different and you should discuss all the implications before making a decision.



# 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.

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This is reinforced annually by a formal Business Ethics certification in which managers confirm their understanding and compliance with the company policies contained in the Employee Guide to Business Conduct. The programme covers over 14,000 managers worldwide and was extended in 2010 to include employees who regularly interact with healthcare professionals, bringing the total to over 24,000 employees.

Our annual Business Ethics certification promotes awareness of GSK's ethical standards and company policies. It emphasises the important role managers play in embedding an ethical culture and ensuring that all employees understand and apply our policies.

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), Standards of Conduct (STD-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. 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.

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 programme 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. I understand that if I fail to do so, or if the Company finds that I have otherwise acted unethically, this will be dealt with in accordance with the relevant local or national disciplinary policies and procedures. This may result in action being taken against me up to and including termination of my employment.

For Belgium, France and Germany, the Business Ethics certification wording is adjusted to comply with local laws.

## Training and awareness performance

Training and awareness activity in 2010 included:

- Refresher training on our promotion and marketing codes for all US Pharmaceuticals sales and marketing staff
- Performing and Leading with Integrity training for new employees in the UK and US to communicate GSK's values, describe our ethical decision-making model and provide information on how to get help from our Corporate Ethics and Compliance department.
- Employee communications on updates to our policies. These explain why the changes have been made and how they reflect GSK values.
- Compliance refresher training for 6,300 employees and contractors in the US. Employees were presented with a variety of scenarios customised to their business areas and asked to discuss which response would best reflect GSK's values.
- Over 14,000 managers and 10,000 other employees completed our self-certification process.
- We reviewed our 'Acceptance of gifts and entertainment policy' and supplemented it with more real-life examples to help employees understand its requirements.

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### United States

In our US Pharmaceuticals business, we also appointed around 60 Integrity Champions to help raise awareness about compliance and embed the GSK values. These manager-level employees are selected because they have demonstrated an ability to consistently apply our values. Each quarter they are provided with training materials to help them promote discussion of compliance-related topics in their part of the business.

In 2009–2010 all US Pharmaceuticals marketing employees completed a half-day workshop on 'Delivering Growth through Good Decisions' to help them apply the ethical decision-making model in their work. The workshop was facilitated by the Ethics & Compliance department and marketing management team.

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### Europe

Our European Pharmaceuticals business launched a new compliance programme, called 'How Do We Know?', which includes a number of different initiatives:

- New training, to help employees improve their awareness and understanding of our policies and guidelines.
- A new senior management team, led by commercial senior vice presidents, which regularly reviews audit and compliance results, to help us learn from any mistakes.
- An information pack for compliance officers to help them understand and focus on the priority issues for the business.
- A regular 'How Do We Know?' bulletin with information and updates on current compliance initiatives.
- Face-to-face discussions between the compliance team and our general managers and regional heads to discuss our approach to ethical issues.

During the division's annual management meetings, the President of Pharmaceuticals Europe restated the business's commitment to performance with integrity and encouraged employees to report any concerns without fear of recrimination.

# Monitoring and compliance

All managers must ensure compliance with company policies in their areas of responsibility. They are overseen by and can seek advice from our Corporate Ethics and Compliance department, which promotes effective compliance programmes, addresses compliance issues, and reports problems and progress to senior management and the Board.

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Our Corporate Ethics and Compliance department monitors and tracks allegations and suspected legal, ethical or policy infractions. It ensures that all allegations are appropriately investigated. Disciplinary action, up to and including dismissal and reporting to the relevant external authorities, is taken where necessary. Serious violations of our policies are reported to the Audit and Risk Committee of the Board.

Compliance officers are senior managers with direct access to GSK's Corporate Executive Team. 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. We have a dedicated compliance officer for each of our business units – R&D, Manufacturing, Biologicals (vaccines), Pharmaceuticals Europe, Pharmaceuticals Emerging Markets, Asia Pacific and Japan, Consumer Healthcare, Corporate, North America Pharmaceuticals – and additional compliance representatives in some markets. We also have full-time regional compliance directors in the Commonwealth of Independent States (CIS; includes Russia), Latin America, Middle East-North Africa, Asia Pacific, China and sub-Saharan Africa and South Asia (includes India).

In 2010 we appointed four deputy compliance officers to support our compliance officers and help drive a values-based culture within GSK. They consult with GSK's brand and sales teams and also with R&D centres to ensure compliance is embedded in the business and integrated into core processes such as the development of marketing plans.

We enhanced integration between our compliance and audit and assurance functions. Compliance officers contribute to, oversee and comment on the business unit assurance reports delivered to the Audit and Risk Committee of the Board of Directors. These highlight significant risks and associated risk mitigation plans.

To further integrate compliance in our US business, we have established a senior compliance committee, co-chaired by the President of our North American Pharmaceuticals division and North American compliance officer. The committee reports monthly to the Commercial Leadership Team (CLT) in 2010. A Compliance Action Committee of senior representatives from each business unit has also been established to assist with risk management and communication.

## Risk management

Our Risk Oversight and Compliance Council (ROCC), 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 chairs the ROCC and regularly reports on significant risks to the CET and the Audit and Risk 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 teams and individual sales representatives.

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In the US, for example, we monitor a number of activities to identify and prevent off-label promotion. These include:

- Monitoring of sales representatives who receive enquiries from physicians about off-label uses of GSK products. Representatives must not solicit off-label questions and must refer them to our medical information department, which responds to enquiries via a medical information letter. Frequent medical information letter requests by a sales representative could indicate that an employee is promoting off-label uses
- Monitoring of sales representatives providing product information or samples to inappropriate healthcare professionals. For example, providing information or samples to a paediatrician for a GSK product with no approved use in minors would indicate off-label promotion which would be stopped
- Monitoring the sales call notes made by sales representatives during visits to healthcare representatives.

# 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 US Integrity Helpline.

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The Global Confidential Reporting Line is available globally in 70 different languages. It can be used for reporting any concerns employees may have relating to compliance with our policies and the Code of Conduct. Employees can report anonymously and leave a message in their native language which is then translated into English. Our US Integrity Helpline provides advice to callers from both within and outside the company, as well as being a reporting channel. 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. We also raise awareness about the Global Confidential Reporting Line through the company intranet which provides clear access to key information and linkages to related functions.

We are committed to protecting all employees who raise concerns in good faith. Any form of retaliation is prohibited. We will take disciplinary action up to and including termination for any manager, supervisor or employee who engages in retaliation, retribution or harassment of an employee who reports a compliance concern in good faith.

When an employee reports a concern we remind them of our commitment to protect them from retaliation. During the investigation process, interviewed people are reminded of GSK's zero tolerance for retaliation. We do not share the complainant's name with other employees during the investigation unless absolutely necessary. Usually, whistleblowers receive a note from the Compliance Officer or Business Unit Head, thanking them for raising their concerns and reminding them of GSK's non-retaliation policy.

In 2010 we settled the longstanding legal issue relating to the investigation of the company's former manufacturing facility in Cidra, Puerto Rico. This included a settlement with a former employee who worked briefly at the Cidra plant. GSK strongly rejected the initial claim that the former employee had been fired for whistle blowing, and this claim was subsequently dropped from the lawsuit.

## Monitoring and compliance performance

In 2010 there were 5,258 contacts made through our ethics and compliance channels. These included enquiries and requests for information or guidance as well as allegations of misconduct made via line managers, compliance officers, our confidential Integrity Helplines and offsite post office box (in the US).

### Addressing misconduct

In 2010:

- 1,124 employees were disciplined for policy violations
- Of these, 246 were dismissed or agreed to leave the company voluntarily (known as separations)
- Other disciplinary actions included 878 documented warnings
- The 1,124 disciplinary actions included 169 cases of employees breaching sales and marketing codes
- These 169 cases resulted in 9 dismissals or separations from the company. All the other 160 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/distribution practices
- Falsification of documents
- Travel and expenses claims
- Code of Conduct issues.

The increase in the number of policy violations to 1,124 during 2010, compared with 972 in 2009, may be due to tightening controls for addressing Code of Conduct issues, good manufacturing practices and the use of company resources.

#### Communicating our requirements to suppliers

Sometimes breaches of our policies involve suppliers to GSK as well as our own employees.

One of the cases we identified in 2010 involved a GSK manager accepting excessive hospitality from a vendor, including a holiday for him and his wife. One of the manager's colleagues reported the situation through our confidential reporting line.

As well as disciplining the GSK manager we also met with senior legal and compliance representatives from our vendor. We reminded them of GSK's policy on accepting entertainment and gifts and required them to train their staff on our policy. We also required them to change their account team for GSK.

GSK does not accept gifts of more than nominal value, or overnight travel or entertainment. Our reputation and the respect of those who deal with GSK must not be put at risk by staff acceptance of any entertainment, gifts or

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## Breaches of external codes

We now collect information centrally on breaches of external industry or government promotional codes. A breach is defined as a sales or marketing infraction or violation of a law, obligation, code or standard resulting in a fine or censure of GSK by a government agency or industry association.

We aim to continually improve our processes to ensure compliance with industry codes and government regulations. We were found to be in breach of external codes 36 times in 2009 and 29 times in 2010. This decrease may be attributable to changes made to strengthen our policies and further align them with our commitment to focus on the patient.

We fully investigate every breach of an external code and take steps to prevent a reoccurrence. This may include retraining or other corrective action, including disciplinary action.

## Plans for 2011

In 2011 we will review our Internal Control Framework and Compliance programme and assess any opportunities for improvement.

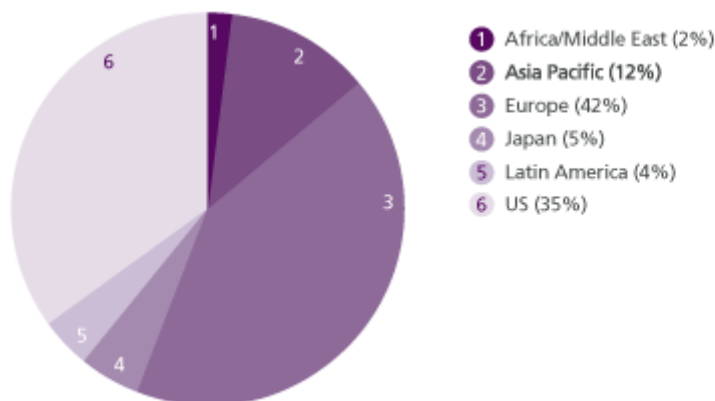
## Supply chain

Patients rely on us to provide an uninterrupted supply of medicines, manufactured to the highest-quality standards. An effective and responsibly managed supply and distribution system is essential for us to get high-quality products to the right place at the right time.

Our supply and distribution chain is complex. It encompasses the materials and services we buy and the suppliers we buy them from. It includes manufacturing, warehousing and distribution, as well as wholesalers, retailers, hospitals, government agencies and other third-party payers.

GSK spends a total of around £9 billion with external suppliers, and around £2 billion of this is spent on active ingredients, chemical intermediates, packaging components and other materials that are directly required for the manufacture of our products. This is spent with 6,000 suppliers in 73 countries worldwide.

### Regional distribution of total spend with external suppliers



The ingredients and materials we purchase from third-party suppliers feed into our network of 79 manufacturing sites in 33 countries. We manufacture 28,000 different GSK presentations and produce four billion packages annually, including tablets, creams, ointments, inhalers, injections and liquids. Over 27,000 people work for our Global Manufacturing and Supply (GMS) division. We also outsource just over 10% (in terms of production costs) of product manufacturing to third-party manufacturers which provide us with finished or part-finished product.

To meet patients' needs, it is also vital for us to protect our supply chain and distribution system from disruption. We establish and maintain contingency stock of both active pharmaceutical ingredients and finished product for our most important products, and especially for medically critical products. Additionally, we periodically assess supply chain risks and, where appropriate, ensure we can obtain key raw materials and ingredients from alternative suppliers if necessary.

Once products are ready, we work with distribution companies to ship them to customers in 150 countries. Products must be stored correctly and handled carefully throughout distribution and at their destination. This ensures patients benefit and it protects our reputation as a provider of high-quality, effective medicines and vaccines. This includes appropriate cold storage facilities for products such as vaccines and biopharmaceutical products. In addition we have to plan for unexpected disruption. When the air transport system was affected by the volcanic ash cloud, and during episodes of extreme weather during 2010, GSK product which had already left our warehouses was temporarily stored



in secure, controlled facilities which were fully compliant with Good Distribution Practices (GDP) requirements.

In this section we focus on our relationships with third-party suppliers and explain the standards we set for them. We aim to source from companies that maintain high standards for quality, labour and the environment, and protect their employees' human rights. Our standards are explained in our quality, EHS and human rights clauses in supplier contracts.

We also report here on our efforts to maintain product quality and security of supply, and our anti-counterfeiting programmes.

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## Manufacturing quality at the Cidra plant in Puerto Rico

In 2010 we settled the longstanding legal issue relating to the investigation of the company's former manufacturing facility in Cidra, Puerto Rico. We regret that we operated this facility in a manner that was inconsistent with current Good Manufacturing Practice (cGMP) requirements and with GSK's commitment to manufacturing quality.

GSK's manufacturing division has a strong track record of quality and compliance with current GMP requirements. We average more than 100 inspections each year at over 80 sites located in over 30 countries. These manufacturing issues were at one facility and took place nearly ten years ago. Our commitment to compliance with cGMP is demonstrated by the fact that we have not received an FDA warning letter for cGMP issues at any plant since the Cidra facility was cited in July 2002. GSK resolved fully the manufacturing issues at the Cidra facility and at the time of its closure in 2009, due to declining demand for the medicines made there, the site had an acceptable compliance status with the FDA.

We are committed to continuous improvement in our manufacturing processes. Since 2002 we have improved our quality systems throughout the GSK manufacturing network, we have improved our self-inspection process to find and resolve potential issues, and we have mandated that site directors and quality directors are totally transparent about issues so we can bring to bear the resources of the company and resolve any potential issues. We spend \$600 million a year updating and improving our equipment to ensure it is 'state of the art'. The patient comes first and we put quality at the top of our priority list.

# Supplier standards

Our supplier standards for ethical conduct, labour practices and protection of human rights, EHS management systems, and interactions with GSK employees are defined in our new Third Party Code of Conduct launched in March 2010. The Code is aligned to the Pharmaceutical Supply Chain Initiative's (PSCI) Pharmaceutical Industry Principles for Responsible Supply Chain Management.

We are rolling out the new Code across GSK and all the businesses in our global supply chain. We require new suppliers to sign a statement confirming that they comply with the principles of the Code before they can do business with GSK. Our procurement teams are engaging with existing suppliers to raise awareness about the Code and reinforce the ethical principles it contains.

GSK procurement contract templates contain EHS requirements based on our global EHS standards and a human rights clause based on the International Labour Organization conventions and the UN's Universal Declaration of Human Rights. Companies must agree to our requirements before they can be included as a supplier.

We train all new procurement employees in our standards and requirements for EHS and human rights, and emphasise the importance of their role in promoting supplier compliance. Key procurement employees, including procurement managers, receive ongoing training on these topics.

Maintaining the quality of the products we make and the materials we buy is also essential. This impacts the safety of patients and the success of our business.

We agree specifications for our product ingredients and packaging materials with suppliers, and conduct quality audits at relevant supplier sites. We use a risk-based approach to determine the frequency of audits.

Read more about our efforts to improve the environmental performance of our suppliers.

### Focusing on critical suppliers

We focus the majority of our engagement and monitoring efforts on our critical suppliers. These include contract manufacturers and suppliers that are pivotal to our business. Critical suppliers represent approximately 30% of our supplier spend.

We consider the following factors when defining critical suppliers who may present a high risk to GSK:

- Regulatory compliance and requirements
- Relevance to the supply of essential medicines
- Threats to continuity of supply
- The value of affected products to GSK
- 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.

# Human rights clause

Our supplier contracts contain a human rights clause (below) which is based on the International Labour Organization's 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.

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## 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 the 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.

## Choosing suppliers

Critical suppliers must meet our minimum standards before we will work with them. Before selecting critical suppliers, we conduct an audit of their environment, health and safety (EHS) performance, and human rights record. In addition, we conduct an audit of quality standards for all new suppliers.

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### Environment, health and safety

We assess potential new critical suppliers against our EHS standards, and they must meet certain criteria if they are to join our supply chain. This provides assurance that they are managing basic EHS risks, reducing the likelihood of significant incidents that could harm people or the environment or disrupt the supply of essential medicines.

Potential new suppliers that do not meet our requirements receive feedback and are encouraged to develop and implement improvement plans. In many cases we offer advice and support to help them improve. We will not put in place supply agreements with potential suppliers until they achieve minimum GSK EHS standards.

In addition to audits of critical suppliers, we conduct pre-audit assessments of potential suppliers in emerging markets. This is because a large number of companies in these countries fail to meet our minimum standards. Pre-audit assessments enable us to identify the suppliers that are more likely to meet our standards if subjected to a full audit, as well as suppliers that – though unlikely to initially meet our standards – have the capability to improve. Suppliers that are unlikely to meet our standards are given feedback so that they can make the necessary improvements.

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### Human rights

Our audit tools also include questions that help us assess potential suppliers' performance against the human rights clauses included in supplier contracts. We ask suppliers 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.

An inadequate response to these questions may be a reason not to progress business with a supplier and may result in GSK informing appropriate authorities of our findings.

Read about our audit programme which ensures compliance with quality standards.

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### Quality

We conduct quality audits of all potential suppliers as part of our pre-qualification process. This enables us to identify companies that meet our standards as well as those we can work with to make the necessary improvements.

We have dedicated quality teams in over 20 countries, including emerging markets such as Brazil, China, India,

Pakistan and South Africa. They are responsible for ensuring our standards are applied consistently, and their local knowledge helps us meet the challenges associated with GSK's growth in these regions. All team members can share information via our global quality database.

In 2010 for example, we collaborated with a supplier in China to improve product quality so they could supply GSK. Despite having failed to meet our minimum quality standards during pre-qualification, the supplier showed it had potential to improve its standards and meet our needs. Our Chinese quality team educated the supplier about good manufacturing practice, and showed how to improve product and process quality. At a follow-up visit six weeks later, the supplier proved it had met our standards and was subsequently approved to supply GSK. Since then it has passed quality inspections from the European Union and US Food and Drug Administration.

We have developed an education programme for ingredient and packaging suppliers in emerging markets, to raise awareness about issues ranging from good manufacturing practice to contamination control. In 2010 we ran workshops for suppliers in China, India and Malaysia and provided participants with training materials for use at their own sites. We plan to run further workshops in more markets, including Indonesia and some African markets in 2011.

## Monitoring and engagement

Our procurement, quality and EHS staff monitor performance against our standards through their routine interactions with suppliers. This includes global and regional supplier review meetings where senior GSK managers interact with suppliers on key issues.

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## Environment, health and safety

We conduct periodic audits of existing critical suppliers to check they continue to meet our standards and that EHS risks and impacts are managed ethically and effectively by GSK and our suppliers. Audits of critical suppliers are conducted by our internal Audit and Assurance function, which is independent of our Global Manufacturing and Supply (GMS) function.

Our audits evaluate supplier facilities against our EHS standards, and they must meet certain criteria to demonstrate acceptable performance and continue to supply GSK.

If audits identify any gaps in EHS performance or breaches of our human rights clause, suppliers must immediately develop and implement improvement plans to completion dates agreed with GSK. We follow up with them to monitor progress and will terminate the supplier's contract if the improvement plans do not address gaps within the agreed timeframe.

In 2010 we introduced issue-specific audits which look in depth at a particular, high-risk issue. These audits are conducted with our larger critical suppliers to provide additional assurance that they manage significant risks effectively. Resulting improvement plans enable suppliers to understand and manage EHS risks better, and help ensure security of supply. The audits also help us build closer relationships with these suppliers. We conducted pilot audits in 2010 (see box), and will extend this approach to more suppliers from 2011.

We encourage suppliers to review and audit the ethical standards and EHS and human rights performance of companies in their own supply chains.

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### Raising awareness about EHS risks

We provide contract manufacturers with information on the EHS risks associated with the GSK materials they are producing or handling. Our supplier booklet 'How to Work with GSK, a Production Supplier Guide' reiterates GSK's expectation for suppliers to operate to the highest ethical standards, act responsibly and comply with the law and industry guidelines.

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## Quality

We use a risk-based approach to determine the frequency of audits for quality standards. When we receive batches of ingredients and packaging materials at GSK sites, we take samples and test them against our quality specification. Additional measures to maintain quality in our supply chain and prevent contamination include the use of dedicated transport and tamper-evident seals.

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## Working with others to improve the supply chain

We are collaborating with others in our industry, for example through the Pharmaceutical Supply Chain Initiative (PSCI), to give suppliers the information they need to meet industry expectations about labour, ethics and EHS management systems. Together we are investigating opportunities for PSCI member companies to adopt a shared audit programme. This would enable greater oversight of the pharmaceutical supply chain without an increased resource burden on each individual pharmaceutical company. It would also reduce the amount of time suppliers must spend on duplicate audit activity, enabling them to operate more efficiently.

GSK is also part of Rx-360, an industry consortium that in 2010 agreed industry-wide standards for quality audits of product ingredient suppliers. This will make it easier for suppliers to understand the expectations of the industry, rather than every company having their own standards.

The long-term goal is to move towards a shared quality audit model for lower-risk suppliers. Suppliers used by a number of companies would be audited once rather than multiple times and the results shared between the purchasing companies. The consortium will begin auditing suppliers on behalf of its members in 2011, to increase the efficiency of the audit process.

Also in 2011, members of Rx-360 will work to agree common standards for auditing packaging material suppliers.

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### Fair treatment of suppliers

We foster good supplier relationships that are characterised by mutual trust and respect, and we aim to treat all our suppliers fairly. GSK supports impartiality in all phases of the procurement cycle. Our standard payment term for all suppliers is a minimum of 60 days from receipt of invoice.

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## Supply chain performance

### Environment, health and safety audit

We audited 39 existing and potential suppliers in 2010. Around 75% of these audits assessed suppliers in Asia.

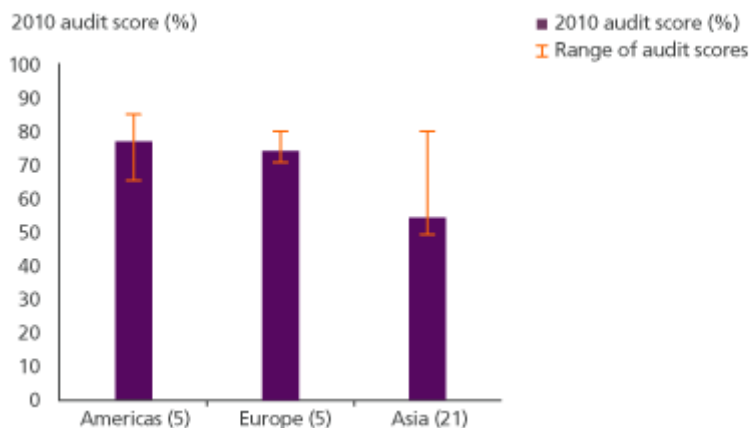
#### Supplier audits 2006-2010 (existing and potential suppliers)

	2010	2009	2008	2007	2006
Americas	5	11	6	10	0
Europe	5	13	18	8	13
Asia	29	46	28	37	18
Africa	0	0	1	0	1
Total number of audits	39	70	53	55	32

#### Number and types of supplier audited in 2010 (existing and potential suppliers)

Type of supplier	Americas	Europe	Asia	Total
Primary (raw materials, intermediates and active pharmaceutical ingredients)	3	5	21	29
Contract Manufacturing (Pharmaceutical (formulations))	2	0	0	2
Consumer healthcare (excipients, actives, raw materials)	0	0	8	8

#### 2010 EHS audit scores of key suppliers (existing suppliers)





The higher average scores in the Americas and Europe, in contrast to the lower average scores in Asia, are largely related to the maturity of EHS management systems and the supporting legislative framework and its enforcement in these regions.

There is a broad range of scores in the Asia region. The upper scores reflect higher-performing suppliers where there has generally been long-term intervention from GSK. The lower scores, by contrast, relate to suppliers where we have undertaken initial audits and found significant deficiencies in EHS management and risk control.

The most significant audit findings for current and potential suppliers occurred mainly in developing markets and included:

- Poor fire risk management and emergency response capabilities
- Absence of fundamental risk controls for process safety
- Poor control of exposure to hazardous substances
- Poor waste management and environmental controls
- Gaps in compliance with regulations.

We did not need to terminate any supplier contracts as a result of audit findings in 2010. In some cases, where we deemed supplier performance to be a risk to security of supply, we brought in additional suppliers as back up.

Based on an analysis of audit findings, we continue to develop information to assist suppliers in understanding GSK EHS requirements and to help them better understand the most common significant issues and how they can improve their EHS management systems.

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## Potential suppliers

In 2010 seven out of 15 potential suppliers we audited failed to meet our minimum requirements. Through pre-audit assessments we identified a further three potential suppliers that were unlikely to meet minimum requirements. If we believe a potential supplier has the capability and commitment to improve, and we still have an interest in using them, we will offer advice and monitor their improvement programme. A further audit is undertaken to ensure the supplier meets GSK criteria before establishing any commercial supply.

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## Quality audits

In 2010 we conducted 1,538 quality audits of our ingredient and packaging material suppliers, compared to 885 in 2009, 558 in 2008 and 776 in 2007. This increase is related to our growing activity in emerging markets, where quality standards may not be as high, and to our acquisition of new businesses that have their own sizeable supply chains.

# Supplier diversity

Small companies and those owned by women or people who belong to minority groups are often under-represented in the supply chains of large companies.

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GSK believes that small and diverse businesses have significant potential to meet our procurement needs, and we recognise the value they bring to their communities through job creation and revenue generation. Sourcing from diverse suppliers has benefits for GSK, too. It helps us comply with regulations in markets such as the US, encourages innovation and exposes us to new perspectives and fresh ideas.

We provide opportunities for small and diverse businesses to supply us with goods and services. We also work with them to build their capabilities so they can expand their business and compete for global contracts with GSK and other multinational companies.

Our supplier diversity programme is led from the US, with support from our procurement teams worldwide. All US GSK procurement employees are responsible for supporting diverse suppliers where possible, and all are assessed against supplier diversity goals as part of their annual performance evaluations.

In 2010 around 18% of our US supplier spend was with diverse suppliers.

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## Supplier diversity and outsourcing

In 2010 GSK outsourced the management of global facilities and security to three specialised sourcing companies. The objective is to improve efficiency and achieve overall cost reductions.

We require these companies to continue using small and diverse suppliers. Before contracting with them, we checked that they already had their own supplier diversity plan and shared our commitment to supplier inclusion and development. Our own procurement team works closely with third-party sourcing managers to ensure the objectives are implemented correctly and that our relationships with small and diverse suppliers develop and thrive.

In addition, GSK believes the partnerships formed through the outsourced relationship will yield greater returns for diverse suppliers. These relationships offer the diverse suppliers opportunity to gain more exposure with other corporations, which in turn should enable diverse suppliers to build capacity and allow their top lines to grow.

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## US programme

Our supplier diversity team in the US creates opportunities for diverse suppliers to work with GSK. Its activities include:

- Supporting procurement in developing supplier diversity strategies
- Evaluating and developing solutions with key prime suppliers to ensure supplier diversity inclusion
- Providing support that enables diverse business leaders to attend executive programmes at the Tuck School of Business and Kellogg School of Management
- Sponsoring and attending national and local outreach and business conferences
- Hosting workshops to enable diverse suppliers to understand our business requirements

- Organising matchmaking forums and roundtable events (see box) to give diverse suppliers an opportunity to meet key senior executives and buyers within GSK
- Advocating supplier diversity throughout GSK and among our business partners
- Setting supplier diversity goals, and monitoring our spend with diverse suppliers and progress against targets
- Reporting supplier diversity achievements to the US government every year.

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## Roundtable gives small and diverse suppliers the chance to shine

Traditional networking and matchmaking forums are designed to give diverse suppliers an opportunity to showcase their company to key senior executives and buyers within GSK during one-on-one matchmaking sessions. In 2010 our team went beyond the traditional internal networking and matchmaking forums to design roundtable events that provide value to our business as well as to the diverse suppliers.

In 2010 we held a different type of event – known as a roundtable – which helps diverse suppliers win business from GSK and allows us to get more value from the meetings. Before the event we provided the companies with information to help them tailor their sales pitch, including details of our needs, challenges and concerns about past supplier relationships.

As a result, diverse suppliers were able to provide us with bespoke information, and came to the roundtable prepared to answer questions and demonstrate their ability to form a successful partnership. We have awarded a contract to around 40% of the suppliers that attended the event, and plan to host another in 2011.

“The [roundtable] forum was excellent beyond my expectations. The logistics and procurement team that you provided far exceeded any forum that I have participated in. There was ample time to meet with everyone.”  
Emmett Walker, Walker International, LLC – Valley Stream, NY

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## Outside the US

Our global supplier diversity initiatives outside the US include:

- Sponsorship of the Global Link programme, which helps diverse suppliers around the world develop partnerships with local businesses, expand their capabilities and access new technology
- Membership of the UK Minority Supplier Development Council (MSDUK), which launched in January 2009. The council links multinational corporations and minority businesses, with the aim of increasing procurement and development opportunities. In October 2010 we attended our first MSDUK conference.

## Sustainable sourcing

We aim to purchase raw materials and packaging from sustainable sources. This helps to ensure security of supply for our business and protect the environment.

We are helping GSK procurement teams to understand what we mean by sustainable sourcing and to think about the environmental implications of the products and materials GSK purchases. We have an explanatory video and detailed training guides on our company intranet that explain our position and the link between sustainable sourcing and issues such as climate change and water use.

We are beginning to engage with our suppliers on sustainable sourcing, using presentations and tools to explain our approach and their role. In 2010 we surveyed 200 of our larger suppliers about their resource use and materials sourcing policies, and collated the information to get a better picture of sustainability in our supply chain.

We will continue to develop our sustainable sourcing strategy in 2011. We aim to establish a set of sustainable sourcing targets and to share sustainable sourcing best practice with suppliers.

### Low-carbon blackcurrants boost *Ribena* sustainability

We are working with the growers who produce *Ribena* blackcurrants in the UK to reduce the climate change impacts of fertilising their crops.

Nitrogen fertiliser use accounts for around a third of agricultural greenhouse gas emissions, because it is made using a highly energy-intensive manufacturing process. Once applied, it is subject to losses through leaching or through loss to the atmosphere as nitrous oxide – a greenhouse gas nearly 280 times more potent than CO<sub>2</sub>. This is an issue that affects all fertilised crops.

With our blackcurrant growers we are exploring two approaches for reducing these impacts:

- Use of slow-release fertiliser formulations so that the nutrient supply more closely matches the requirements of the crop. We are evaluating whether it is possible to increase utilisation efficiency, and so produce the same yield using less fertiliser
- Use of legumes which 'fix' their own nitrogen from the atmosphere, growing alongside the blackcurrant bush rows. When the legumes are cut back or ploughed in, the blackcurrants can use the stored nitrogen as a supplementary source of nutrients.

This research is supported by a fund that all GSK blackcurrant growers – as well as GSK – contribute to. In the long term, finding a low carbon solution will help reduce greenhouse gas emissions and, if successful, these techniques could be used for other crops.

# 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.

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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.

GSK's Global Manufacturing & Supply business implements contingency plans for 'medically critical' products. We define products as 'medically critical' if they are life-saving or if, were they not available to patients, there is a 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. For our global suppliers that deliver goods across borders between GSK manufacturing sites and GSK distribution centres we conduct regular high-level operational reviews that include a focus on security. We also include security requirements in contracts with road and air freight carriers that move goods from our distribution centres to the market.

## Counterfeiting

### Approach

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According to the World Health Organization (WHO), less than 1% of pharmaceutical products sold in developed countries are counterfeit, but in the developing world this figure may be higher than 10%, and up to 30% in some countries.

Counterfeiting of medicines, vaccines and healthcare products is a serious crime that causes harm to patients and consumers. The vast majority of counterfeit drugs are not subject to quality control, hygiene standards, testing of ingredients and monitoring of product specifications or equipment. They 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 micro-organisms
- Packaging that falsifies the product description or expiry date.

GSK's global anti-counterfeiting strategy involves investigating suspected incidents of counterfeiting, collaborating with authorities to take legal action and seize counterfeit goods, and forensic analysis of counterfeit products to provide evidence for legal proceedings. Our Corporate Security, Legal, Packaging Design and Technology Security teams are all heavily involved in these activities.

We use the findings of our investigations to build a picture of where counterfeiting is taking place and the distribution routes used by counterfeiters. This enables us to target our efforts on the most problematic regions, and we also provide this information to relevant authorities to support their work.

GSK country managers are required to identify products that are most likely to be counterfeited and to develop training for sales representatives. Our sales representatives worldwide play an important role in helping to discover counterfeit products, as they have constant contact and detailed knowledge of the markets and outlets where counterfeit products are likely to be sold.

We add anti-counterfeiting features to our product packaging. These include holograms, security seals and complex 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.

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, and helps to shape anti-counterfeiting policy among national governments and international organisations.

# Performance

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In 2010 there were 367 reported cases of counterfeiting of GSK products. The increase from 259 cases in 2009 is likely to be due to a number of factors including our improved interactions with customs authorities, greater external and internal awareness and reporting, as well as the economic downturn fuelling demand for counterfeits, particularly for consumer healthcare products.

The 367 reported cases resulted in 96 raids by the authorities, during which 132 suspected counterfeiters were arrested. Of the raids, 61 took place at illegal manufacturing facilities and 35 at wholesale/distribution outlets. The 61 factories represent criminal operations that were capable of mass producing counterfeit medicines and other healthcare products. The raids on these facilities undoubtedly prevented significant amounts of counterfeit product from entering legitimate markets around the world.

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## Anti-counterfeiting in practice

We conducted a number of successful anti-counterfeiting operations in 2010. For example, we:

- Provided information to the Chinese authorities that led to a police raid at an illegal factory in Shenzhen City, Guangdong Province. The authorities seized manufacturing equipment and 700,000 packs of counterfeit *Zentel*, and arrested two suspects. The counterfeit product was destroyed. One counterfeiter was subsequently sentenced to eight months imprisonment, and fines were also imposed.
  - Helped to identify the source of counterfeit *alli* being purchased over the internet by consumers in the US. Tests on samples indicated the presence of a stimulant drug not manufactured by GSK. The US Food and Drug Administration issued a public safety warning and charged two people with illegally importing counterfeit *alli* from China into the US
  - Contributed to an investigation that led to Indian police raiding an illegal factory in Patna, seizing 10,000 counterfeit *Actifed* tablets, manufacturing equipment and raw materials, and arresting two counterfeiters
  - Helped Maltese customs to detain two containers of counterfeit *Aquafresh* toothpaste, containing over 500,000 packs, destined for Algeria.
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### GSK anti-counterfeiting activity

	2010	2009	2008	2007	2006
Number of reported cases of counterfeit	367	259	289	429	248
Number of raids	96	94	94	71	57
Number of arrests	132	129	84	127	94

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## Environmental sustainability

GSK is committed to integrating environmental sustainability into our business. We have a responsibility to contribute to meeting environmental challenges, but we also see this as an opportunity. There is a compelling business case for saving energy, water and materials, and it aligns with GSK's strategic priority of simplification.

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In 2010 we developed a revised environmental sustainability strategy with ambitious goals, not just for our own operations but also for our value chain, from raw materials to product disposal. Our long-term goal is for our value chain to be carbon neutral by 2050. In the short and medium term, we have set demanding targets for reducing our carbon footprint, material use and other impacts, including a 20% reduction in water use across the value chain, and zero waste to landfill by 2020.

We have continued to make progress in all our previous target areas. We have reduced the amount of water we use by 16% since 2006, exceeding our 2% annual reduction target. We also exceeded the five-year targets for wastewater quality, waste, mass efficiency and emissions of volatile organic compounds. We met our 2010 targets for 5% reductions in energy and greenhouse gases. However, missed our cumulative energy and greenhouse gas emissions targets for 2006 to 2010, but the investments made in the early part of the five-year period are now starting to deliver benefits. The final small amounts of ozone-damaging CFCs in a few pieces of cooling and ancillary equipment will be removed in 2011 to meet our goal of 100% elimination. See the Performance pages of this report, the Targets and Progress summary and the summary data table.

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## Highlights in 2010

- We revised our environmental strategy to focus on carbon, water and environmental stewardship across the value chain, with ambitious new targets
- We developed a global carbon footprint the first time for GSK's entire value chain
- We carried out life cycle assessments of several products, technologies and packaging options to identify more sustainable alternatives
- We developed a framework for procurement teams to integrate sustainability and began measuring suppliers' performance
- We announced an important partnership with the Singapore Economic Development Board, committing S\$50 million (£24 million) in funding to support research in **green and sustainable manufacturing**
- GSK became the first company to achieve global certification to the Carbon Trust Standard



# Environmental sustainability strategy

We revised our environmental sustainability strategy in 2010, building on the strategy originally introduced in 2001 and setting ambitious goals for GSK's impact across the entire value chain. Our objective is to significantly benefit the environment, to engage employees in tackling key issues and to benefit GSK financially. We believe we can reduce our annual costs by & £100million by 2020 through reduced energy, materials and distribution costs.

Analysis of GSK's impacts, including the first carbon footprint of our value chain, shows that we need to concentrate on three main areas: carbon dioxide and other emissions that contribute to climate change; water use; and environmental stewardship, which covers the impacts of our products, the use of materials and the generation of waste.

We need to act beyond our own operations because 40% of our carbon footprint results from our supply chain and a further 40% derives from propellants when customers use our inhalers. We will have a much greater impact by working across the life cycle of our products rather than simply concentrating only on our direct impacts.

Our long-term vision is for our operations and products to be carbon neutral by 2050. This very ambitious target means that there will be no net greenhouse gas emissions from manufacturing, distributing, using and disposing of our products, including the sourcing of raw materials.

To support this vision we have set specific goals for key impacts over the next ten years, including a 25% cut in carbon dioxide (CO<sub>2</sub>) emissions by 2020.

We do not have all the answers to how we will achieve these goals but some projects that will contribute to this are already underway, such as the Jurong 'factory of the future' in Singapore (see the feature box below) and the solar power installation in York, Pennsylvania.

### Jurong – factory of the future

A comprehensive environmental sustainability strategy is turning our site at Jurong, Singapore, into a 'factory of the future'. The site's strategic objectives include achieving tangible benefits from investment in 'green chemistry'.

Jurong appointed a Director for Operational Excellence and Sustainability in 2009. He leads the site team, working closely with GSK's Sustainable Manufacturing Centre of Excellence. They are targeting step changes in environmental performance on energy, water, mass efficiency, chemical oxygen demand in wastewater and volatile organic compound releases to air.

The site has already identified major improvements in manufacturing lamivudine, the active ingredient in many HIV combination therapies. A new process will increase mass efficiency, reduce the water used in a solvent recovery operation from 60 to 15 litres per kg of lamivudine, and will cut the chemical oxygen demand in wastewater to less than a third of the previous level.

## Enabling sustainability

The environmental sustainability strategy is led from the Corporate Executive Team (CET), and the Senior Vice President, Human Resources, has overall accountability. From 2011 this is through a new GSK Sustainability Steering Team of senior executives. Each member of the CET will identify a sustainability-related target or include a specific sustainability goal in their business plan.

Our Environmental Sustainability Centre of Excellence supports the businesses in driving improvement. It will work with each business, providing specialist expertise and support for individual programmes as well as identifying step changes that will achieve our sustainability goals. Central funds are available, in addition to normal spending, to increase capability in the businesses and share the financial risk in environmental sustainability investments.

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### Singapore partnership

We created the GSK-Singapore Partnership for Green and Sustainable Manufacture in 2010. This ten-year programme aims to foster innovation in 'green chemistry' and manufacturing. This partnership is part of the S\$50 million fund that GSK has set up with the Singapore Economic Development Board for education and research in green manufacturing and chemistry and public health policy research. In 2010 we awarded the first eight grants to Singaporean researchers. Four grants were awarded in the area of chemical transformations, two in physical transformations and two in the area of biotransformations

## Managing environmental sustainability

In 2010 we reviewed how we organise to achieve our broad environmental sustainability goals as well as continuing to improve direct impacts such as energy and water use.

Our Environmental Sustainability Centre of Excellence (CoE) is responsible for developing strategy, setting standards and providing expert support to the businesses. It will work with executives with responsibility for sustainability in each business, providing expertise and programme and data management and helping to identify step changes towards sustainability.

Each business, as well as R&D and functional areas such as Procurement and Packaging, is responding appropriately to make its own contribution to GSK's goals and sustainability priorities. For example:

- Pharmaceutical manufacturing has set up a Sustainable Manufacturing Centre of Excellence which is providing support and direction to improve sites' processes and reduce waste
- The vaccines business has created a Sustainability Council of senior managers with climate change as its top environmental priority
- R&D has a Platform Technology and Science (PTS) group which has developed a sustainability strategy for R&D
- Consumer Healthcare has developed a 'Bright Green' strategy covering six key environmental sustainability areas
- US Pharmaceuticals is piloting a recycling scheme for our respiratory product inhalers and a similar pilot is starting in the UK in 2011.

## Governance

Overall responsibility for sustainability and environment rests with the Corporate Executive Team (CET) which from 2011 will formally review sustainability performance each year.

A new Sustainability Steering Team of senior executives will oversee GSK's sustainability plans and programmes from 2011. It will meet quarterly to review progress against targets, identify emergent issues and opportunities, prioritise allocation of funding and revise detailed objectives.

Board subcommittees have oversight respectively of risk and compliance, audit, and corporate responsibility and regularly review performance.

## Policy

Environmental sustainability is a key part of our environment, health, safety and sustainability (EHSS) policy, which defines our aspiration to global leadership and excellence. The current policy was approved by the CET in 2008. It covers EHSS fundamentals such as the approach to risk management, our ambition for sustainability and our commitment to transparency.

### **GSK's EHSS Policy**

Our EHSS policy defines our aspiration to global leadership and excellence. It outlines the broad scope of our plans and how they will be achieved. This revised policy was approved by the CET in 2008:

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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## Management systems

GSK has a comprehensive set of internal standards on environment and sustainability issues which are accessible to all operations via the intranet.

We use a management system aligned with recognised international standards such as ISO 14001. It is based on a structured framework building on the vision and policies and supported by standards, guidance materials, tools, training, recognition and audits that help the businesses to manage these issues.

Targets have been set for five-year periods, originally to 2005 and then 2010. We are currently developing detailed targets to support the revised environmental sustainability strategy.

We use internal audit teams to assess systems for managing risks and impacts, compliance with legislation and performance against our standards. Audits also assess whether appropriate management systems are in use.

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## Integration in business processes

Our scientists use the Environment, Health and Safety Milestone Aligned Process (EHS MAP) to integrate sustainability in everyday activity. It helps to identify and address issues during new product development and supply activities. The EHS MAP helps scientists understand the principles and impacts and how to manage them and can identify opportunities to improve EHS impacts.

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## Procurement and acquisitions

GSK procurement activities support our sustainability and environmental goals by choosing energy-efficient equipment and renewable and recycled materials, and working with suppliers to manage sustainability and environmental risks in our supply chain.

Our due diligence process for acquiring and divesting businesses ensures that sustainability and environmental issues are considered in contract negotiations and that adequate management systems are in place. We work with acquired companies to align their sustainability and environmental, health and safety practices with GSK's.

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## 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 in 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 is minimised. Each site conducts an annual review of its internal emergency response programmes and technical capabilities and develops plans to address any areas needing improvement. Find out more on Health and Safety.

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## Compliance

We remain vigilant to stay in full compliance with all environmental laws and regulations but incurred three environmental fines in 2010.

The largest of these was \$16,708 for exceeding acidity limits and failure to notify the local authority in Upper Merion, US, of a sludge discharge associated with new production activities. The other fines were for \$500 and \$250 for sites in the US.

## Plans and targets

### Approach

During 2010 we completed the first five years of our EHS Plan for Excellence, including the five-year targets set in 2006 (see the Performance page).

Our revised strategy, developed during 2010, has an increased focus on sustainability which translates into ambitious goals for the priority areas: carbon footprint, water and environmental stewardship. It also requires measurement of our overall value chain, especially for carbon footprint.

### Targets

In 2011 we will meet our obligations as a downstream user of chemicals registered by suppliers in 2010. This will include reviewing extended safety data sheets and implementing any necessary changes in our risk management measures. Read our public position paper on REACH regulation.

#### Sustainability targets to 2015 and 2020

	Target	2015	2020
Carbon	Reduction in GSK's overall carbon footprint across the value chain	10%	25%
Water	Reduction in GSK's operational water consumption	20%	–
	Reduction in water consumption across the value chain	–	20%
Environmental stewardship	Mass efficiency of new pharmaceutical processes	2.5%	5%
	Reduction in waste to landfill from our operations	25%	100%
	Reduction in waste generated from our operations (hazardous and non-hazardous)	25%	50%
	Paper packaging from sustainable sources	50%	90%

Note: reduction targets are for absolute % change compared to 2010, with the exception of mass efficiency and packaging.

### Performance

The Plan for Excellence included Group-wide targets to improve environmental performance, as shown in the table.

We exceeded the five-year targets for water, wastewater quality, waste, mass efficiency and emissions of volatile organic compounds. We met our annual 2010 targets for a 5% reduction in energy consumption and greenhouse gas emissions but missed our cumulative targets for 2006 to 2010. The final small amounts of ozone-damaging CFCs in a few pieces of cooling and ancillary equipment will be removed in 2011 to meet our goal of 100% elimination.

### Targets and progress 2010

	Group target	Progress in 2010
Energy for operations and transport	20% reduction per unit of sales from 2006 baseline by 2010	Reduced 5.5 % per £ sales. Cumulative 9.1 % since 2006
Climate change impact from energy for operations and transport	20% reduction per unit of sales from 2006 baseline by 2010	Reduced 5.8 % per £ sales. Cumulative 10.7 % since 2006
Mass efficiency of new processes	2% average for transferred products for the period 2006-2010 3% for new products in manufacturing launched between 2007 and 2012	Average mass efficiency of 3.3% achieved by 2010 for transferred products
Water	2% annual reduction from 2006 baseline per unit of sales	Reduced 1.6 % per £ sales. Cumulative 15.7 % since 2006
Wastewater (chemical oxygen demand)	3% annual reduction from 2006 baseline per unit of sales	Reduced 6.9 % per £ sales Cumulative 24.8 % since 2006
Solid waste disposed (non hazardous)	1% annual reduction from 2006 baseline per unit of sales	Reduced 5.9 % per £ sales Cumulative 22.4 % since 2006
Ozone depletion	100% elimination of CFCs from processes and equipment by 2010	Eliminated 99.4% <sup>1</sup>
Air emissions (volatile organic emissions)	2% annual reduction from 2006 baseline per unit of sales	Reduced 12.8 % per £ sales Cumulative 35.8% since 2006
EHS audit scores	Average: 82% by 2010. Minimum: 70% by 2010	Average 81% achieved in 2009 No longer a requirement in 2010 <sup>2</sup>

Table Notes: All figures per unit sales are calculated at constant exchange rates (CER).

1. A few pieces of equipment containing CFC remain in operation but will be replaced during 2011
2. In 2010 we introduced a new Corporate Audit process across GSK including for risks and impacts related to EHSS (see Data, audits and assurance for more information). The new audit process included an approach for providing an overall audit opinion (star rating) based on the adequacy of risk control and related management systems, replacing the previous audit scoring approach.



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# Stakeholder engagement

We have an Environment, Health and Safety Stakeholder Panel in the UK which has provided independent feedback on company-wide plans and performance since 2005.

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The panel is drawn from customers, suppliers, regulators, public interest groups, environmental organisations 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.

We use feedback from the stakeholder panel to inform our environmental sustainability and health and safety programmes. In 2010 the panel reviewed and commented on progress on climate change, water, sustainable procurement and life cycle analysis.

Engagement also takes place nationally and includes the partnership created in 2010 with the Singapore Economic Development Board. We also participate in issue-specific engagement, through the CEO Water Mandate and other initiatives. Many sites engage with stakeholders locally through activities such as open days, newsletters and community projects.



# Awareness and recognition

It is essential for our environmental sustainability goals to engage employees at all levels of the organisation. The new strategy provides a framework through which each individual can clearly see how they can act and make a contribution.

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We provide training and orientation to our business leaders so they understand the issues and how best to respond. Specific sustainability and environmental training is managed by individual sites and is relevant to job roles. Sustainability and environment professionals receive induction training and undertake regular updates to ensure they are aware of the latest technical information in their fields, but we need to continue to upgrade the level of competence of our site environmental staff.

The CEO's Sustainability Award programme (see below) recognises employees who have furthered GSK's environmental sustainability agenda.

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## Awareness

We raise employee awareness of environmental sustainability through the intranet, regular internal publications and events. We publish articles on sustainability and environment in Spirit, our internal magazine, and brief news stories on internal web pages. A number of site bulletins and functional newsletters also carry articles on sustainability. However, this has been passive communication and we need to develop more interactive communications to engage employees.

In 2009 we launched a climate change microsite called Climate Change, GSK and You. The site explains the importance of climate change, why everyone needs to act, what GSK is doing and what individuals can do. It includes items that report action to cut carbon dioxide emissions across the business, and celebrates successes.

Several other areas of the GSK intranet support sustainability and environment, including the Sustainability and Environment Community site. It shares news on sustainability and environmental programmes within the Group, holds supporting materials for the EHSS Framework, such as the policy, standards and guidelines, and for training materials and other documents. We also use it to collect data for measuring performance and reporting results.

Many of our sites celebrate Earthweek to raise awareness of environmental issues and to encourage integrating environmental concerns into the GSK culture and personal lifestyles.

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## Sustainability awards

The CEO's Sustainability Awards programme recognises GSK teams for innovation that creates benefits for society, the environment and our business – creativity that achieves a genuine step change towards sustainability. We publicise the innovative practices that win awards on a dedicated intranet site.

Any team in GSK may be considered for this award, except from the Sustainability and Environment Centre of Excellence which administers the scheme. An internal review committee agrees a shortlist and winners are chosen by a panel that includes experts from academia, government and public interest groups. Each winner receives a trophy and selects a charity to receive a donation from GSK.

In 2010 there were 69 entries from 19 countries and nine projects were honoured. The winners in the three categories

were:

**Sustainable Science & Technology** – R&D Chemical Development at Stevenage in the UK for a project improving the sustainability of darapladib manufacturing.

Developing a new process route for manufacturing this heart disease treatment, currently in development, has achieved a mass efficiency of 6.1% compared to the original 1.7%, saving emissions of about 80,000 tonnes of CO<sub>2</sub> equivalent a year, as well as reducing costs and eliminating hazardous zinc waste streams.

**Environmental Sustainability** – Global Manufacturing and Supply Production Procurement, for embedding sustainability in production procurement ways of working.

The Procurement team developed tools to help staff select suppliers whose production processes are more sustainable. The tool identifies suppliers that are using sustainable materials, are efficient at manufacturing our products, have sustainability at the heart of their organisation and understand the impact of their carbon footprint in relation to the products or processes they use. A training programme has raised awareness and understanding of the issues, stimulating changes to culture, behaviours and perspectives.

**Workforce Sustainability** – Global Manufacturing and Supply in Gurgaon, India for its project Nurturing Life, which achieved substantial improvements in sickness and safety at our *Horlicks* plants. See more in the feature box in the Health, Safety and Wellbeing section.

# Life cycle assessment and supply chain

GSK is committed to introducing sustainability concepts across the full product life cycle from the supply chain to the disposal of the product. We have begun to develop a sustainable supply chain strategy aligning with our new environmental sustainability strategy.

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## Life cycle assessment

GSK is committed to assessing and minimising the cumulative environmental impact or 'footprint' of our activities across the entire life cycle of the product, including the supply chain, use and disposal. In 2010 we carried out life cycle assessments (LCAs) of several key products and a carbon footprint of the entire value chain (see climate and energy) for the first time.

LCA evaluates environmental impacts including climate change, ozone depletion and water pollution, through raw material extraction, manufacturing, transport, product use, and disposal or recycling.

In 2010 we performed several LCAs, including assessing the footprint of products comparing packaging options and technology alternatives. The findings from the studies were integrated into product, device and packaging development to reduce their environmental impacts.

In 2010 we developed packaging and device life cycle tools and simplified our webtool known as Fast Life Cycle Assessment for Synthetic Chemistry (FLASC), to be used by chemists and engineers in GSK.

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## Supply chain

In 2010 we developed a framework for procurement teams to integrate sustainability in line with our objectives for carbon, water and material sourcing. We developed an educational programme for procurement staff and provided new tools, systems and processes. This programme won the CEO's Sustainability Award for Environmental Sustainability in 2010.

We have begun to measure some of our suppliers' performance to identify areas for improvement. Collecting data on the different materials we buy has been challenging, especially for materials that we do not buy directly and for which there are numerous supplier tiers.

All existing and new suppliers will be required to complete a Request for Information that will provide a greater understanding and awareness of the environmental and social impacts of our supply chain, helping to identify potential risks and opportunities for improvement.

In 2010 we surveyed 200 of our larger suppliers, asking about their resource use and material sourcing policies. We have used this information to help us better understand the life cycle impacts associated with several GSK products. In 2011 we aim to establish a set of sustainable sourcing targets and to share sustainable sourcing best practice with suppliers.

We are also examining the environmental footprint of contract manufacturers, initially targeting the manufacture of four outsourced active pharmaceutical ingredients and intermediates. We evaluated their resource consumption and waste generation, which has enabled us to make high-level estimates of the environmental profile of other suppliers where data are not available directly. The estimates will be refined as more information becomes available from the suppliers.

## Climate change and energy

The pharmaceutical industry creates greenhouse gas emissions and must therefore contribute to the increasingly urgent global efforts to counter climate change. GSK supports efforts to agree an international treaty with legally binding targets because this will provide the clarity businesses need.

However, regardless of the outcome of global negotiations we are committed to reducing our own impact and have set challenging energy and carbon reduction targets which will also support our business by cutting energy costs. In 2011 GSK signed up to the UN Caring for Climate initiative, reflecting our commitment to take action on climate change.

The long-term goal included in our new environmental sustainability strategy is for our entire value chain to be carbon neutral by 2050 and the first step will be a 10% reduction in the carbon footprint by 2015.

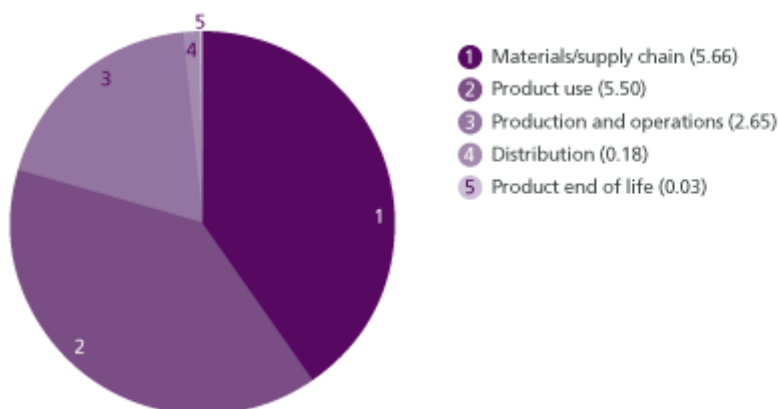
## Value chain carbon footprint

We undertook a high-level, company-wide exercise to identify the main contributors to our carbon footprint by each stage in the value chain using data for 2009. The study estimated our total footprint at about 14 million tonnes of CO<sub>2</sub><sup>1</sup>. The main contributors are the materials we use in our processes and products and propellant releases during inhaler use.

This analysis, together with life cycle assessments of individual products, emphasises that we need to work with suppliers and others beyond our own sites.

1. Throughout this report 'carbon dioxide' and 'CO<sub>2</sub>' refer to all greenhouse gases as CO<sub>2</sub> equivalents unless otherwise specified

### GSK's carbon footprint in 2009 (million tonnes CO<sub>2</sub>e per annum)



We have used the results of this high-level carbon footprint as input to our sustainability strategy to establish priorities and programmes.

In 2011 we plan to refine the carbon footprint of the vaccine business as better estimates of the footprint of the materials used in vaccines production become available. We are also piloting a carbon footprint of selected R&D and manufacturing sites to identify the major opportunities to reduce our operational impacts.

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## Our climate change programme

As well as programmes to reduce the climate change impacts from our propellants and our supply chain, we continue to drive substantial energy and emissions reductions in our own operations.

We expect to achieve substantial energy and emissions reductions by:

- Making our buildings and equipment more energy efficient
- Installing on-site renewable technologies, using biomass, wind turbines and photovoltaic panels (see the feature box below)
- Buying electricity produced from renewable sources
- Reducing the climate impact of travel and transport by switching from air to sea freight and from road to rail
- Encouraging the use of collaborative information technologies to reduce the need for business travel

We have created a central fund to help finance carbon reduction and energy-saving projects. This shares the financial risk with the businesses so we can unlock the greatest potential in energy and carbon-saving opportunities. For example, one of the first renewable energy projects supported by this fund was a rooftop solar array at our IT global data centre in the US. Read more below.

Since we introduced central financial support in 2007, projects supported by the fund have helped to avoid 148,000 tonnes of greenhouse gas emissions.

### Biggest solar roof array in the US at York facility

GSK Consumer Healthcare has installed North America's largest rooftop solar array at its regional distribution centre in York, Pennsylvania. Nearly 11,000 solar panels will generate approximately 3.4 million kWh of energy a year, enough to completely meet the building's energy needs. This will make it the first GSK facility in the world to be powered entirely by solar energy and will save 1,800 tonnes of CO<sub>2</sub> a year.

A number of other renewable energy projects are being investigated by GSK which collectively could save a further 1,400 tonnes CO<sub>2</sub> a year if they are completed.

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## Progress

GSK achieved Carbon Trust Standard Global certification in 2010, the first company to achieve this recognition of global excellence in carbon management.

We met our 2010 targets for a 5% reduction in energy consumption and greenhouse gas emissions. We are still behind our cumulative targets for 2006 to 2010 but the investments made in the early part of the five-year period are now starting to deliver benefits. Energy consumption and greenhouse gas emissions from operations and transport have fallen by 9.1% and 10.7% respectively since 2006 (relative to sales at constant exchange rates), but this is short of the 20% target.

See the Performance page for more information.



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# Propellants

Propellants used in inhalers for asthma and chronic obstructive pulmonary disease represent approximately 40% of our total carbon footprint. Traditionally these products contained either hydrofluoroalkanes (HFAs) or chlorofluorocarbons (CFCs) which are potent greenhouse gases. CFCs also damage the ozone layer.

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We have met our goal of eliminating the use of CFCs in our products by the end of 2010, replacing them with HFAs. This has reduced emissions associated with our inhaler products from 24 million tonnes CO<sub>2</sub>e in 1998 to approximately 4.7 million tonnes in 2010.

We increasingly supply dry powder inhalers which do not use a propellant, however some patients find them difficult to use

Research programmes to find effective ways to further reduce the impacts from these products include:

- Using different valves on metered dose inhalers that require less propellant and therefore release less gas
- Developing all new drug molecules only in dry powder formulations which do not require propellants
- Searching for alternative propellants with a lower global warming potential than HFAs
- Investing in programmes to recycle devices when the patient has finished taking their medication, including recovering residual propellant. Take-back schemes began in the US in 2010 and a pilot scheme will start in the UK in 2011.

## Facilities

We aim to cut energy and emissions in our facilities by becoming more energy-efficient and using more renewable energy.

A central fund has been available since 2007 to help finance energy-saving investments. More than 1,400 projects have been selected. In 2010 we completed almost 200 projects with potential savings of more than 350,000 GJ and more than 52,000 tonnes of CO<sub>2</sub> emissions. This continues the acceleration of investments since 2008, reflected in improved progress towards energy reduction targets.



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### Energy use in manufacturing and supply

Our pharmaceutical and consumer product manufacturing function, Global Manufacturing and Supply (GMS), is the largest emitter of greenhouse gases in the Group and has been targeting a 35% reduction in energy use from 2006 to 2015. GMS has already achieved a 20% reduction.

Some of the most significant improvements come from heating, ventilation and air conditioning. GMS has used 'Kaizen' site-wide continuous improvement campaigns – an approach that originated in Japan – to identify energy efficiency measures. In 2010 GMS completed 17 Kaizen projects, identifying potential energy savings averaging 20%.

Combined heat and power systems, which generate electricity and steam more efficiently than grid supplies of electricity and gas, have been installed at five sites over the past 18 months.

### Memphis cuts energy use by 30% in a year

Our Memphis Consumer Healthcare site in the US cut energy use by 30% in 2010, saving more than 4,000 tonnes of CO<sub>2</sub> and \$500,000 a year. Several projects contributed to this achievement, including improvements to heating, ventilation and air conditioning in the warehouse and lighting throughout the site, and using exhaust heat from air compressors as preheated combustion air for the boiler.

More savings are in the pipeline. Work started towards the end of 2010 on improved air dehumidification for the *Polident* denture cleaner manufacturing process by installing variable speed drives on the site's air conditioning system. Further lighting improvements, including LED lights, will also save energy in 2011 and solar power will be installed during this year.

Appointing a dedicated site energy manager was instrumental in achieving these improvements, supported by energy champions for each product stream. Monthly energy team meetings and frequent communications on progress maintained the drive to cut energy.

Renewable energy is a growing part of the GSK energy and climate programme and includes biomass as well as wind and solar. Even without improved energy efficiency, renewables reduce emissions by replacing fossil fuel sources with

wind or solar power. During 2010 we generated 1,742 GJ from renewables at sites in Belgium, Germany, India, Singapore, South Africa, the UK and the US. Sites in several countries also installed solar water heating systems.

## Solar panels cut emissions from GSK's global data centre

GSK's data centre in Upper Providence, Pennsylvania, will contribute 222 tonnes of CO<sub>2</sub> savings a year, following the installation of solar panels on the roof.

The investment, supported by funding from GSK's Climate Change and Energy Reduction programme and by state and federal grants and tax incentives, generates 492,000 kWh a year. Replacing power from the grid with this solar energy saves the site \$60,000 a year.

The Director of Data Center Operations and Facilities says that making the Upper Providence site as green as possible has been one of the guiding design principles from the beginning, adding: "A large global data centre requires a great deal of energy to power and cool the thousands of computers it contains. The photovoltaic installation is an example of our commitment to designing sustainable operations."

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## Emissions trading

In 2010 13 GSK sites participated in the European Union Emissions Trading Scheme (EU ETS). Collectively, these sites emitted below their specified CO<sub>2</sub> allowances, generating a surplus of carbon credits. Proceeds from the sale of carbon credits are invested in energy-saving projects.

Several UK sites participate in the UK government's voluntary Climate Change Agreement programme which provides discounts on the climate change levy if the sites meet agreed energy-efficiency targets. In 2010 all participating GSK sites complied with their Climate Change Agreements.

GSK will participate in the UK's Carbon Reduction Commitment (CRC) scheme because GSK House in London qualifies for the scheme. This means that all GSK sites in the UK will be affected by the CRC unless they are already regulated under the EU ETS or have Climate Change Agreements in place. In preparation for the CRC, GSK has obtained certification to the Carbon Trust Standard, not just for the UK sites but globally, and has installed continuous energy monitoring equipment at all the sites affected.



# Transport and travel

We estimate that transport of our products, the sales fleet and employees' business air travel accounted for approximately 22% of the direct greenhouse gas emissions from our operations and transport in 2010. They come more or less equally from transporting products from manufacturing plants to distributors, from business air travel and the sales fleet.

## Product transport

In 2010 our logistics group set a target of 9,000 tonnes of CO<sub>2</sub> to be saved from the distribution of products worldwide. We achieved this by:

- Switching transport mode from air to sea where practical (see below)
- Optimising our European road freight network by improving vehicle load configuration to maximise use of the available capacity, resulting in fewer vehicles on the road
- Warehousing improvements
  - Reducing the number of external warehouses, and therefore cutting travel between our sites and the warehouses
  - Installing intelligent lighting controls and energy efficient lighting
  - Consolidation of refrigerated storage units, thereby reducing the amount of electricity used for refrigeration
  - Using energy efficient forklift truck charging units.

We have to use air freight for some of our products because they have a short shelf life, but we are switching others from air to sea freight.

Since 2007 our Air-to-Ocean programme in pharmaceutical and consumer healthcare manufacturing has switched over 140 routes to ocean freight, saving more than 38,000 tonnes of CO<sub>2</sub> emissions. In 2010 we achieved over 9,000 tonnes of savings by changing the transport mode.

We initiated 16 air-to-sea mode changes in 2010. The most significant savings are on the routes from Evreux in France to Japan (almost 1,800 tonnes of CO<sub>2</sub> per annum) and from Zebulon, North Carolina to Australia (almost 2,200 tonnes of CO<sub>2</sub> per annum).



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## 2011 plans

In 2011 our logistics group has a target to save 7,000 tonnes of CO<sub>2</sub>.

A further ten transport switches from air to sea will contribute some of these savings and we will continue to improve the European road distribution network. We will also investigate opportunities to use the European rail network and will benefit from improved pallet loading thanks to product simplification and packaging improvements.

Two major projects looking at efficient distribution will further reduce transport emissions, including a multi market warehouse in our Asia Pacific region which will allow transport mode changes for the majority of the distribution chain

to the markets it will serve.

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## Travel

We have 'green travel plans' at a number of sites to encourage employees to reduce the environmental impact of their travel to work.

We have made a significant investment in videoconferencing systems, with over 500 videoconference rooms in 68 countries. Other technology includes teleconferencing, desktop and personal videoconference units and web conferencing. Staff can select the most appropriate system for their needs, depending on the number of participants and objectives of the meeting.

In 2010, driven by our desire to reduce unnecessary employee travel costs and environmental impacts, there was a 40% increase in the use of videoconferencing compared to 2009. The distance flown fell by more than 200 million km and we used nearly 85,000 fewer single flights compared to 2009. This reduced CO2 emissions by more than 30,000 tonnes, a 25% reduction.

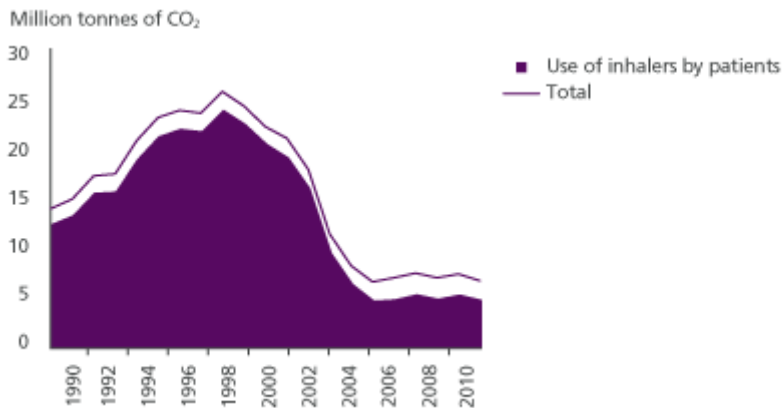


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# Climate change and energy performance

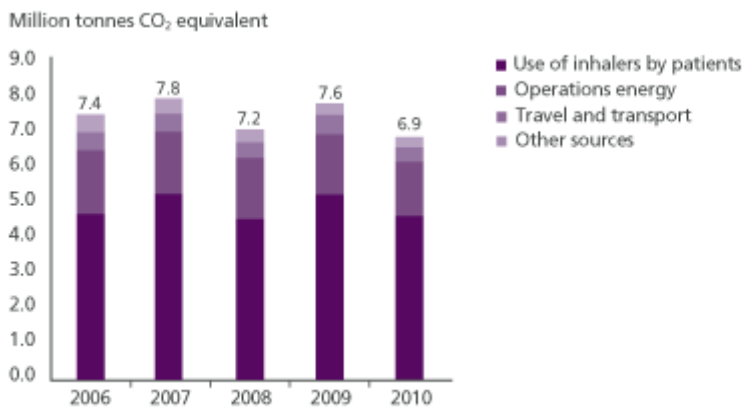
## Total energy and emissions

Global warming potential from energy, transport and inhaler use



Note: Before 2006, emissions from patient use of inhalers are calculated retrospectively from sales data

## Climate change impact from operations, transport and inhaler use



The long-term trend shows a sharp fall in emissions since 1998 when we began replacing CFC gases in metered dose inhalers. Our climate impact levelled out in 2005 but has begun to fall again as energy-saving investments showed positive results.

In 2010 our climate change impact, including operational energy, travel, transport and other direct sources, plus use of inhalers by patients, was 6.9 million tonnes of CO<sub>2</sub>, 9.2% lower than in 2009. This includes 4.6 million tonnes from patient use of inhalers, down by 10.1% from 2009.

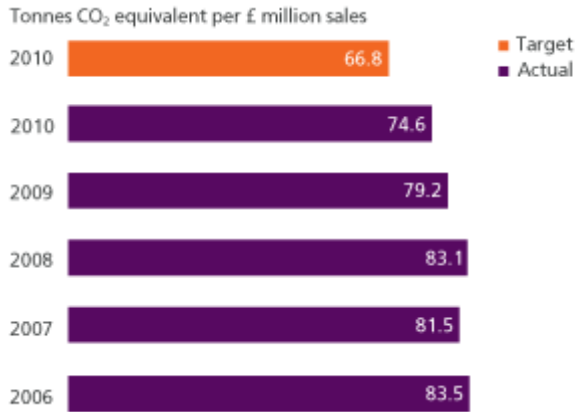
Excluding the manufacture and use of inhalers, our climate change impact from operations energy and transport (the scope of our target) fell from 2.2 million tonnes of CO<sub>2</sub> in 2009 to 2.0 million tonnes in 2010.

The energy use from operations and transport decreased 6.6% from 26.0 million GJ in 2009 to 24.3 million GJ in 2010.

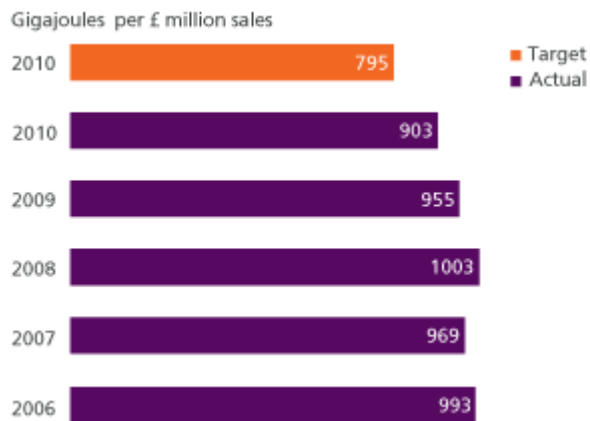
## Sales-related data

Our targets are based on emissions and energy consumption from operations and transport per million £ sales, with sales adjusted at constant exchange rates. In 2010 these normalised emissions decreased by 5.8% while energy use per million £ sales fell by 5.5%. Cumulatively we have cut normalised emissions by 10.7% and energy use by 9.11% since 2006, missing our 20% target for each measure.

### Climate change impact from operations energy and transport



### Energy use for operations and transport



## Explanation for trends

After emissions levelled out from 2005 we launched a new energy programme but initial progress was slow. Performance began to improve in 2009 as investments paid off and over the past two years GSK's climate change emissions have fallen by 9.2% in absolute terms.

We closed a number of facilities in 2010 but this was balanced by acquisitions and growth. The reduction in emissions was mainly driven by investment in projects supported by the climate change programme. In addition there was a decrease in transport emissions caused by reductions in both distance driven by the sales forces and in employee air travel.

The significant acceleration in performance since 2008 demonstrates that we can achieve the ambitious targets in the new environmental sustainability strategy.

Note: All figures, including targets, are restated at constant exchange rates



## Water

### Approach

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Fresh water is a finite and vulnerable resource. The increasing demands on water sources resulting from population growth, rising urbanisation and increasing affluence, together with the effects of climate change, mean that many areas are now water-stressed. By 2025, a third of the world's population is expected to suffer severe and chronic water shortages, damaging ecosystems and the quality of human life.

We recognise the need for a strategic approach to water use that reflects the complex interactions with human population growth, climate change, disease pattern changes and biodiversity stresses. Addressing water issues will help our business by increasing water security, improving manufacturing efficiency and strengthening our reputation and relationships with stakeholders.

Our approach has four elements:

- Continuing reduction in water use and making water quality improvements, maximising water efficiency and minimising risks and impacts
- Assessing both direct and indirect (supply chain) water use
- Collaboratively managing shared water risks with the communities in which we operate
- Reducing human health impacts caused by water scarcity.

We also target reducing the pollution potential of the wastewater our sites discharge, measured using the chemical oxygen demand (COD) – the oxygen required to chemically oxidise the compounds in the water.

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### Direct operations and supply chain

We require clean water mostly for manufacturing (for processes, products, cooling and cleaning), and also for R&D and general site uses such as drinking, food services and sanitation. Action to reduce consumption focuses on sites in areas of water scarcity and on water-intensive products.

We are developing site-specific targets for facilities in areas of water scarcity, which account for less than 10% of all our sites. We identified these sites using the World Business Council for Sustainable Development's Global Water Tool supplemented with local watershed information and intelligence.

Assessments of total water use (direct and indirect) across primary product categories will identify water-intensive products and help to develop product-specific water strategies. Using economic commodity models, we have estimated direct and indirect water use associated with energy, agriculture, chemicals and packaging. For most products, 80-90% of the estimated total water use is embedded in the supply chain.

Recognising that this 'virtual water' associated with the materials we buy represents a major part of our water footprint, we are engaging with suppliers to assess their awareness of, exposure to and plans for mitigating water risks. We will use this information to grade suppliers and drive improvements.

Our target has been to reduce water consumption by 2% per annum per unit of sales from 2006-2010. We only reduced water consumption in 2010 by 1.6% but since 2006 we have exceeded our target, cutting consumption by a total of 15.7%.

These examples show the progress made at pharmaceutical and consumer healthcare manufacturing sites:

- Agbara (Nigeria) saved 81,000m<sup>3</sup> - more than 36% of its overall water consumption by removing old, inefficient washing equipment and improving the inspection and maintenance of water pipelines and sources to minimise losses
- Parma (Italy) saved 67,000m<sup>3</sup> - more than 15% of its overall water consumption – through a water reduction programme focused on cooling water, resin replacement in water softeners and steam discharges from autoclaves
- Zebulon (US) saved 31,000m<sup>3</sup> by using recycled water from a municipal treatment works.

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## Community engagement

Community health and local ecosystems are linked through watersheds. In 2010 we conducted a global assessment of our sites to gauge local awareness of water scarcity, the status of local watersheds and levels of community engagement. We are using the results to develop site communication plans, raising awareness and providing guidance for engaging local communities.

One example is Consumer Healthcare's Turn off the Tap campaign, launched in Italy in 2010 to encourage people to use less water when they brush their teeth. We estimate that 40,000 litres of water will be saved by this education and awareness campaign about the responsible use of water in everyday life.

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## Health impacts - water-borne diseases

GSK addresses water-borne diseases, for example with the *Rotarix* vaccine, as part of our commitment on diseases of the developing world. We also continue to support PHASE, a simple hand-washing programme first launched in 1998, which has taught hundreds of thousands of children how to reduce the spread of infection, in particular diarrhoeal disease.

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## Engagement with governments and other organisations

We endorsed the United Nations CEO Water Mandate in 2009, in line with our support for global health programmes and community initiatives to improve access to medicines. It will guide us in integrating water policy and stewardship into our global healthcare commitments. The strategic elements of the Mandate are the foundation of our approach to water stewardship.

This commitment demonstrates our recognition that water is a valuable natural resource, and that businesses can play a positive role in managing it. By endorsing the mandate, we have pledged to:

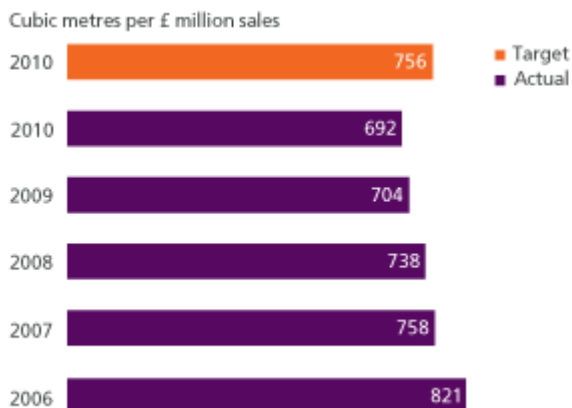
- Improve our water sustainability in direct operations and our supply chain
- Work with other organisations and governments to encourage sustainable policy and practices
- Engage with our sites' local communities in providing education and support on water and sanitation
- Be accurate and transparent in our reporting of water-related issues

This section on water constitutes our Communication on Progress in accordance with the Mandate reporting requirements.

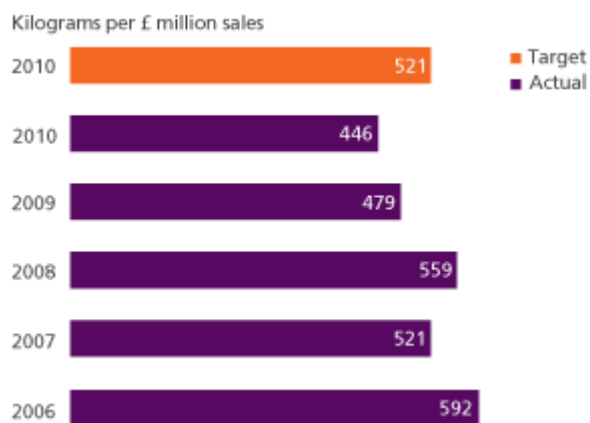
# Performance

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## Water consumption



## Chemical oxygen demand of wastewater



In 2010 GSK's worldwide water use totalled 18.7 billion litres, 0.5 billion litres less than in 2009. Water consumption per unit of sales was 1.6% lower than in 2009. Cumulatively, water use per unit of sales has fallen by 15.7% since 2006, ahead of the 2% annual reduction target.

### Explanation for trend

Water consumption has fallen due to site closures and a range of water saving initiatives across the business. This reduction has been offset through business growth, particularly in Consumer Healthcare, biopharmaceuticals manufacturing and vaccines.

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## Wastewater

We generated 9.9 billion litres of wastewater in 2010, 1.5% higher than 2009 but more than 15.8% below the 2006 baseline.

In 2010 the chemical oxygen demand (COD) of wastewater fell 8%. COD per million £ sales fell 6.9%, reaching a cumulative 24.8% below the 2006 baseline. This puts us ahead of the target to decrease 3% per year.

### Explanation for trend

Wastewater volumes increased because of new and expanded operations, particularly in our vaccines and biopharmaceuticals businesses.

The quality of wastewater discharged, measured in COD, is closely related to the types and amount of materials

produced in the manufacture of our active pharmaceutical ingredients (APIs) and consumer products. The decrease this year is due to lower production from some water-intensive processes in the manufacture of APIs and a number of COD reduction projects. Projects included:

- Segregating and off-site treatment of a high COD waste stream at a pharmaceutical manufacturing site in the UK
- Installing a new effluent treatment plant at our site in Bangladesh
- Introducing a new plant to remove solids at a toothpaste factory in the UK.

Our work to improve manufacturing efficiency should continue to decrease wastewater pollution in the future.

Note: All figures, including targets, are restated at constant exchange rates



SGS Verified



## Environmental stewardship

We aim to operate responsibly, using input materials and packaging efficiently and safely, minimising waste and avoiding harm to humans and the environment.

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Raw materials are typically one of the top contributors to the overall environmental impact of pharmaceutical operations, read more in life cycle assessment. Using materials more sustainably requires changing business processes to consume fewer resources and generate less waste, removing hazardous substances where possible and eliminating waste that is persistent, toxic or bio-accumulative.

We routinely evaluate the environmental footprint of our products and processes to explore ways to minimise their impacts. Our R&D and manufacturing operations use Fast Life cycle Assessment for Synthetic Chemistry (FLASC), a web-based tool that helps to identify the most sustainable processes and materials. We are currently expanding our FLASC assessments to include the eco-footprint of the tablet formulation processes.

In 2010 we launched an enhanced solvent selection guide, doubling the number of solvents covered and including a simplified version for the earliest manufacturing stages. We also began developing a reagent selection guide for different chemical transformations. These two tools will help our R&D scientists to select materials with reduced environmental impacts.

Some of our wastes such as used solvents can be reused in our processes or as a raw material for another industry, achieving what is known as a 'cradle-to-cradle' approach. For instance, sites that manufacture active pharmaceutical ingredients recover some solvents for reuse. Our pilot plants also send solvents such as ethyl acetate and ethanol for external recovery and reuse.

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## Biodiversity

We support efforts to conserve biological diversity, such as the Convention on Biological Diversity. While we use biological materials in developing new medicines and vaccines, and in some production processes, it is unusual for a biological material to be used in its natural form as an active component of a pharmaceutical.

Our operations and those of our suppliers may have an impact on local habitats. GSK's EHSS standards require impact assessments which include impacts on ecosystems that could affect biodiversity. Some sites support protected habitats while others use wastewater to support native species gardens.

Our Procurement group is analysing potential supplier impacts to understand priorities and ensure that biodiversity is covered by our responsible sourcing approach.

We are involved in a number of projects in the UK and the US to remediate sites with land contaminated by past handling practices for chemicals. We have identified five sites in the UK and more than 50 sites<sup>1</sup> in the US that require some remediation. Most of them are waste disposal sites where GSK is one of several responsible parties. GSK and its heritage companies have spent more than £100 million cleaning up sites in the US over the last 20 years and we are involved in continuing work on 25 of them.

1. These figures are not included in the data verification

### Potential hazards

We continuously examine the use of materials of concern across all phases of development to determine which are being used and identify how they can be replaced during development.

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For instance, a new manufacturing route for an epilepsy treatment eliminated the use of a highly hazardous oxidizing agent, peracetic acid, as well as a chlorinated solvent, a highly odorous sulphur reagent and its sulphur waste. Read more about this project which was runner-up in the CEO's Sustainability Science and Technology Awards in 2010.

In 2010 we used 73 metric tonnes of materials of concern (up from 26 tonnes in 2009). The increase was driven by undertaking more manufacturing to support late stage development of products which needs higher volumes of product for clinical trials. Seven solvents accounted for about 80% of this volume. Most of the solvent waste from this production was destroyed by incineration, although some was recycled.

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### Pharmaceuticals in the environment

A portion of active pharmaceutical ingredients (APIs), the substances that make medicines work, eventually enters the environment, mainly through being excreted by the patient but also the disposal of unused medicines and discharges from manufacturing.

The current scientific consensus is that pharmaceutical residues present in the environment do not pose a risk to human health. We are working to identify any potential impacts on the environment, continue to monitor the issue and contribute to working groups and research which will inform all stakeholders.

We have discharge limits for APIs in wastewater from our manufacturing sites, assess process waste concentrations against these levels and treat the wastewater if necessary to achieve safe levels.

For more information read our public position statement about pharmaceuticals in the environment.

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### Genetically modified micro-organisms (GMMs)

We use GMM in the research and development of new therapeutic agents and in the manufacture of certain medical products such as vaccines. We do not produce products that contain viable organisms and do not routinely undertake research and development involving the cultivation of genetically modified plant species.

GMMs help us 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 GMMs, 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 GMMs, such as hepatitis B vaccine.

We manage the use of GMMs through bodies such as site Institutional Biosafety Committees or Genetic Modification Safety Committees in line with national and local regulations.

We require that GMMs are inactive in waste streams to ensure safety to human health and the environment.

In 2010 we published a policy statement on genetically modified micro-organisms and environment, health and safety.

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## Nanomaterials

We are investigating opportunities to use nanomaterials – materials that are on an atomic or molecular scale – in our R&D programmes. We currently have no products on the market that contain deliberately engineered nanomaterials.

Read our public position paper on the use of nanomaterials.

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## REACH

During 2010 compliance activities under the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) requirements were fully embedded in manufacturing, R&D and procurement operations. We continued to implement the REACH legislation by:

- Identifying substances we buy that were required to be registered in 2010 and mitigating risks to supply by requesting confirmation of intent to register from all EU suppliers. Approximately 400 chemicals we purchase had a 2010 registration deadline
- Developing and communicating use conditions and exposure scenarios for substances we buy
- Submitting registration dossiers for two high-volume substances manufactured or imported by GSK that required registration by November 2010 – potassium phenylacetate and 6-aminopenicillanic acid
- Registering one new substance we manufacture or import in volumes greater than one tonne per year
- Reviewing the candidate list of substances of very high concern and implementing substitution plans for two – a phthalate and musk xylene
- Developing procedures at our EU manufacturing sites to meet our responsibilities as a downstream user of chemicals.

In 2011 we will meet our obligations as a downstream user of chemicals registered by suppliers in 2010. This will include reviewing extended safety data sheets and implementing any necessary changes in our risk management measures.

Read our public position paper on REACH regulation

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## Classification and labelling

We met the European Union deadline of December 2010 for implementing the UN's Globally Harmonized System for Classification and Labelling of Chemicals (GHS), which is being adopted as regulation around the world.

Implementation required:

- Updating and publishing on our intranet revised GSK Safety Data Sheets (SDS) in GHS-compliant format
- Reclassifying over 1,000 substances according to GHS criteria
- Submitting classification and labelling information to the European Chemicals Agency inventory for approximately 500 hazardous substances supplied by GSK EU sites or imported into the EU
- Developing e-learning and posters for employee training on new hazard warning symbols and labels introduced as part of GHS
- Producing GHS-compliant hazard labels at manufacturing sites.

We will make further changes to the format of our SDS to comply with the EU REACH Annex II requirements.

## Mass efficiency

### Approach

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The pharmaceutical industry has typically used more than 100 tonnes of material for every tonne of active pharmaceutical ingredient (API) produced. This is because pharmaceutical processes are often complex, usually requiring large amounts of solvents and other raw materials, and it can take several processes to obtain the right pharmaceutical purity. It is also necessary to finalise production processes quickly to avoid delaying drug approval and production.

We originally set a target in 2005 for R&D to double the average mass efficiency of processes for new products, to achieve 2%. In 2009 we increased the target to 2.5% by 2015, an additional 25% increase in efficiency, for new products launched after 2010.

We also set a target for our manufacturing sites to achieve 3% mass efficiency by 2015 for products launched between 2007 and 2012. Our aspiration as part of our new environmental sustainability strategy is to achieve 5% efficiency by 2020.

As well as specific projects to achieve our mass efficiency targets, we launched the GSK-Singapore Partnership for Green and Sustainable Manufacture in 2010.

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### Process design and redesign

Effective process design is essential to minimise environmental impacts. It determines which chemicals and processes are used in manufacturing as well as the impacts from production waste. We have developed a sustainability strategy for R&D to achieve our mass efficiency and sustainability aspirations.

The Operational Sustainability Team works with process development teams to incorporate EHSS considerations into process design and materials sourcing, helping R&D scientists to select materials with the least environmental impacts and identifying potential sustainability and EHSS risks in manufacturing. In 2010 we expanded the solvent selection guide, doubling the number of solvents covered and including a simplified version for the earliest stages in medicinal chemistry. We also simplified our **life cycle assessment tool**.

In 2010 our Operational Sustainability Team was recognised by the American Institute of Chemical Engineers with its Industrial Practice Award in Sustainable Engineering. The Institute cited our work of embedding sustainability into R&D and manufacturing and the Eco-Design Toolkit.

In manufacturing we have assessed potential improvements for new products that are being transferred from R&D as well as existing products. A project at Jurong to redesign a process for one of our existing compounds will improve its mass efficiency from about 2.5% to about 4.5%.

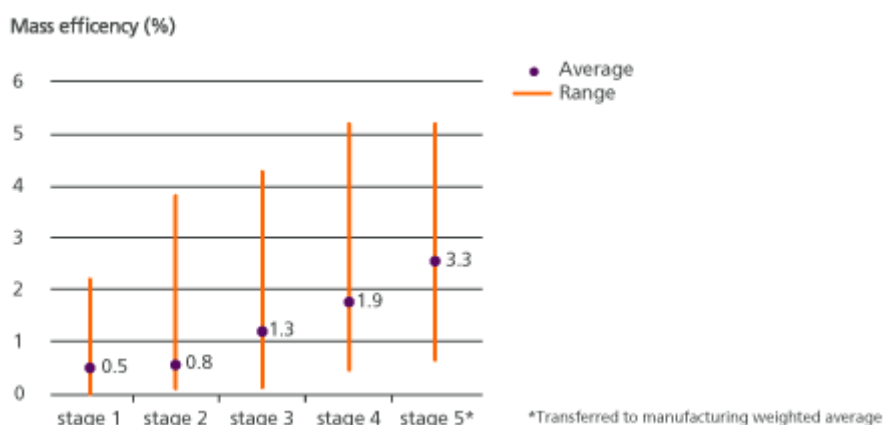
Redesigning a process to save materials and money

Redesigning the manufacturing route for albiglutide, a product in development at Upper Merion in Pennsylvania, improved the overall yield by 24%, reduced water consumption by more than half and increased mass efficiency from 1.7% to 3.9%. These improvements reduce the cost of raw materials by 35%.

This initiative won second place in the CEO's Science and Technology awards in 2010.

## Performance

### Mass efficiency (average 2006-2010)



The chart shows the range of mass efficiency and the average for each process stage while the manufacturing process is being developed in R&D. It demonstrates that we improve mass efficiency as compounds move through development stages. In the early stages many processes achieve less than 1% mass efficiency. By the last stage when the process is transferred from R&D to manufacturing they average 3.3% mass efficiency for the 2006–2010 period.

As well as exceeding our target for the 2006-2010 period, the mass efficiency for new products transferred in 2010 was also within target. In 2011 we will start reporting the mass efficiency performance of new products after they have been transferred into manufacturing.

## Waste

### Approach

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Our production, research and sales activities all produce waste:

- Production – hazardous waste such as solvents and other chemicals, non-hazardous waste including packaging
- 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
- Maintenance – building renovations produce non-routine waste such as obsolete equipment, office furniture and structural materials.

A significant proportion of our waste is classified as hazardous, mainly because it contains solvents and chemicals used to manufacture active pharmaceutical ingredients. Most non-hazardous waste is general material such as office waste paper, kitchen waste and non-hazardous substances used in manufacturing.

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 require disposal contractors to comply with our requirements and local regulations. Sites audit their waste contractors or hire consultants to carry out the audits.

Applying the waste hierarchy to solvents (the main hazardous waste), our work to improve mass efficiency reduces the waste volumes. Our first choice is then to reuse or recycle, and most used solvent is recovered and purified on site. It is then reused in the original manufacturing process and some is sold to commercial reprocessing companies. When reuse or recycling is not possible, solvents are usually incinerated and the energy recovered wherever possible. Regulations vary widely around the world but by working to this hierarchy we manage waste in a way that meets or exceeds regulatory expectations.

Until 2010 our target referred only to non-hazardous waste sent off-site for disposal (see Waste-Performance). From 2011, as part of the new environmental sustainability strategy we have set a target for both hazardous and non-hazardous waste generated. We aim to cut total waste by 25% by 2015 and 50% by 2020, also aiming for zero waste to landfill by 2020.

In 2010 33 GSK sites (excluding offices) did not send any waste to landfill.

#### Cutting waste at source

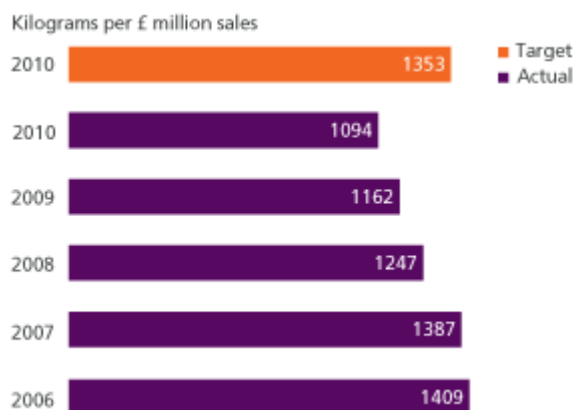
We have significantly reduced waste in supplying clinical trials by tackling waste at source. Through improved planning, a simpler network of distribution depots and optimising the supply chain, we have avoided producing too much of the medicines being tested in trials. This initiative, which began in 2007, has not only reduced excess production of active pharmaceutical ingredients (APIs) and tablets, but also saved the packaging which the excess production would have needed, and avoided the resulting incineration of unused material. We estimate the improvements have saved almost 12,000 tonnes of CO<sub>2</sub> since 2007 through:

- Manufacturing 17.5 tonnes less API, roughly 20% of the previous level
- Making 20 million fewer tablets
- Using 1.8 million fewer plastic bottles to pack the clinical trials materials.

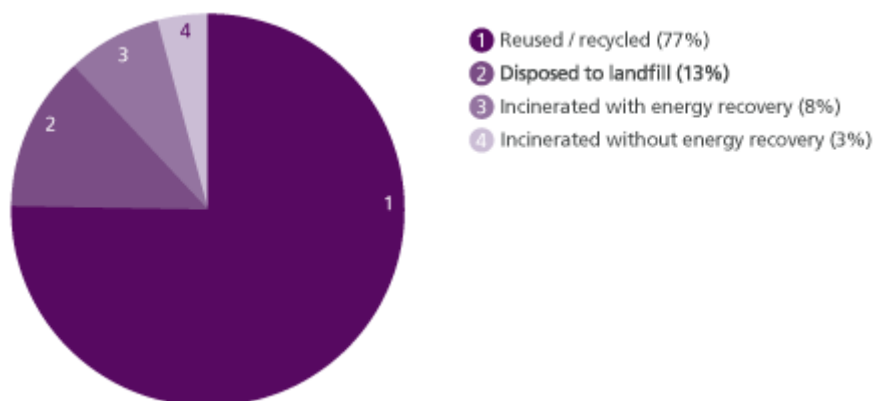
## Performance

### Non-hazardous waste

#### Non-hazardous waste disposed



#### Destination of non-hazardous waste 2010



These data do not include non-routine waste such as construction and demolition rubble and similar material not related to day-to-day operations

In 2010 the amount of non-hazardous waste disposed fell by 7.0% and was 22.2% lower than the 2006 baseline at 29,490 tonnes. Waste per million £ sales was 5.9% lower in the year and more than 22.4% down on 2006. This is substantially beyond our 1% per year improvement target and we will build on this performance with our new ambitious targets.

Our target was specific to non-hazardous waste disposed, but we also measure total non-hazardous waste generated, which includes waste that is recycled. In 2010 we generated 125,700 tonnes of non-hazardous waste, 5.8% higher than the previous year. Of this, 76.5% was recycled and 23.5% was disposed of via landfill or incineration, both figures showing improvements on the 2009 data.

#### Explanation for trend

The increase in non-hazardous waste generated is due to higher production at two of our manufacturing facilities in

Australia and India. However, we managed to increase the percentage of this waste sent for recycling. In particular, the sites in Australia and India which increased their generation of non-hazardous waste were also able to significantly increase the amount of waste they sent for recycling. The site in Australia increased recycling by 45% and the site in India increased recycling by 31%. In addition a site in Nigeria increased the amount of waste recycled by 61%. Overall GSK's total recycling rate increased from 73% to 77%.

Note: All figures, including targets, are restated at constant exchange rates

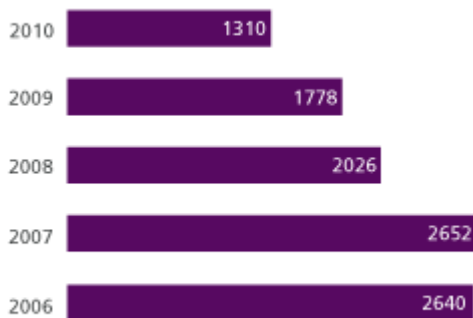


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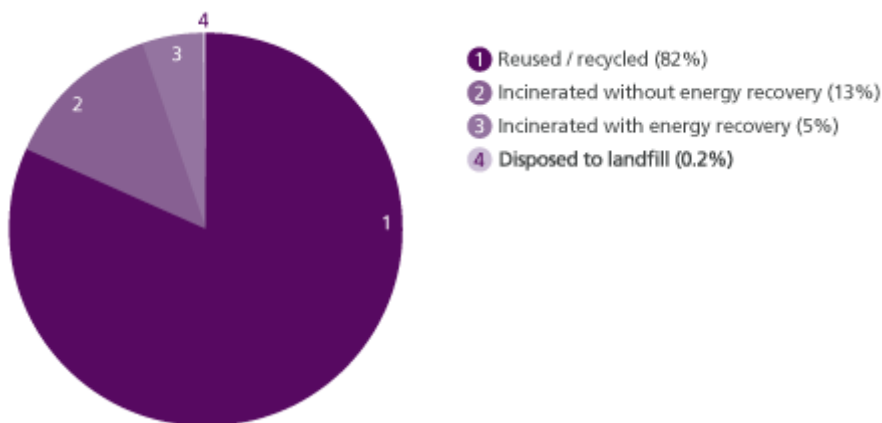
## Hazardous waste

### Hazardous waste disposed

Kilograms per £ million sales



### Destination of hazardous waste 2010



In 2010 we generated 191,470 tonnes of hazardous waste, down from 214,520 in 2009 – a reduction of 10.7%. Of this, 81.6% was recycled and 5.3% was incinerated with energy recovery. Only 0.2% of this waste went to landfill.

Hazardous waste disposed was 35,300 tonnes, 27.2% lower than in 2009. Waste disposed per million £ sales fell by 26.3% and was 50.4% below the 2006 level.

### Explanation for trend

The decrease in hazardous waste disposed is due to continued efforts to manage and recycle it, especially solvents. It



is also due in part to decreased production of some products that used significant quantities of solvent. In 2010 three sites were responsible for 74% of the reduction of all hazardous waste generated. Waste reduced at one of these sites as it scaled down production prior to closure. Actions at the other two sites included the installation of new technology to increase manufacturing efficiency and the installation of an on-site treatment facility which prevented the need to send waste for offsite disposal.

The amount of hazardous waste disposed is related to the types and quantities of products made and the amount of solvent used to manufacture active pharmaceutical ingredients. Solvent waste is 91% of hazardous waste generated. The reduction in hazardous waste generated since 2006 is mainly due to the actions taken at the five main sites which use large quantities of solvents.

Note: All figures, including targets, are restated at constant exchange rates



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## Packaging

We have substantial opportunities to improve our packaging profile and are working to reduce the environmental impact of product packaging. We have set a target to derive 50% of our paper packaging from sustainable sources by 2015, and 90% by 2020.

In 2010 we began to implement the sustainable packaging strategy developed in 2009, based on the '7 Rs' (see table). To support the new strategy, we began to update our Green Packaging Guide. The Guide helps designers and managers to benchmark new and existing packaging designs, taking into account manufacturing impacts, the mass and choice of material, its recyclability and reusability.

We evaluated the eco-footprint of a series of packaging options using life cycle assessment and carbon footprint analysis. The table shows examples:

### Examples of application of the '7 Rs'

Principle	Focus	Example
Reduce	The mass of materials, complexity and the life cycle footprint of packaging	<ul style="list-style-type: none"> <li>The redesigned <i>Ventolin</i> canister will save 125 tonnes of aluminium and 1,200 tonnes of CO2 per year</li> <li>Incoming dry powder inhaler components at Zebulon, US, are now shipped in pallet boxes instead of individual cases, saving 350 tonnes of CO2 and 180 tonnes of material per year</li> </ul>
Remove	Materials with sustainability or EHS issues	<ul style="list-style-type: none"> <li>Removing the PVC tray for <i>Nicoderm</i> saved over 8 tonnes of material and 20 tonnes of CO2 per year</li> </ul>
Reuse	Recycled materials in packaging (subject to regulatory requirements which mean this is a major challenge in pharmaceuticals)	<ul style="list-style-type: none"> <li>Reusing trays, pallets and drums saves plastic and wood</li> </ul>
Recycle	Design for recyclability	<ul style="list-style-type: none"> <li>Moving the desiccant required in <i>Niquitin</i> bottles to the cap means bottles can be recycled</li> <li>Working with suppliers to change a carton material for <i>Aquafresh</i> to a fully recyclable alternative, saving 30 tonnes of material and 250 tonnes of CO2</li> </ul>
Renew	Use materials and energy from renewable sources	<ul style="list-style-type: none"> <li>For paper-based packaging we increasingly buy materials made from recovered fibres.</li> </ul>
Reward	Improve the environmental impact of the total GSK packaging supply chain, meeting the needs of patients, customers and consumers at lower cost	<ul style="list-style-type: none"> <li>Sustainability is a key element in the selection and continued management of suppliers. It forms an integral part of the Procurement framework and general ways of working.</li> </ul>
Respect	Use responsible suppliers	<ul style="list-style-type: none"> <li>We include social and environmental requirements as part of our supplier selection process and we are developing more detailed criteria for specific areas</li> </ul>

Other examples of packaging improvements include:

- The new pack for *Iodex* pain relief ointment, which reduced the material used by 85%
- *Advair* carton and corrugate box materials reduction, which saves 571 tonnes of CO<sub>2</sub> per year
- *Abreva* clamshell packaging, replacing PVC with recycled PET, which saves 25–52 grammes CO<sub>2</sub> per pack
- Moving from glass to polypropylene or PET bottles for *Horlicks*, *Iodex*, and *Crocin* in India, which saves 11,700 tonnes of CO<sub>2</sub> per year
- *Horlicks* carton reduction, which saves 5,000 tonnes of CO<sub>2</sub> per year.

## Emissions to air

### Approach

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The main emissions from GSK sites (apart from greenhouse gases) are gases that damage the ozone layer and volatile organic compounds (VOCs) that cause low-level pollution.

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### Ozone depletion

Ozone-depleting substances (ODSs) damage the ozone layer in the upper atmosphere, exposing people to radiation that can cause skin cancer and other health problems.

Until recently we used CFCs as the propellant gas in most of our metered dose inhalers (MDIs). The gas is released when patients use the inhalers and a small amount escapes during production. We stopped manufacturing CFC inhalers in all GSK sites and our two contract manufacturing sites in 2009.

We still use ODSs in some cooling systems and for other ancillary uses at GSK facilities. They are only released in the event of a leak or during maintenance but we are progressively switching to hydrofluorocarbons (HFCs), ammonia and hydrocarbons. More than 99% of CFCs associated with cooling systems and other ancillary uses were eliminated by 2010 but a few pieces of equipment remain in service. We plan to eliminate the use of CFC associated with the remaining equipment before the end of 2011.

We also plan to eliminate our use of HCFCs from cooling systems and ancillary equipment before the end of 2020. See more in our [public position statement](#).

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### 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.

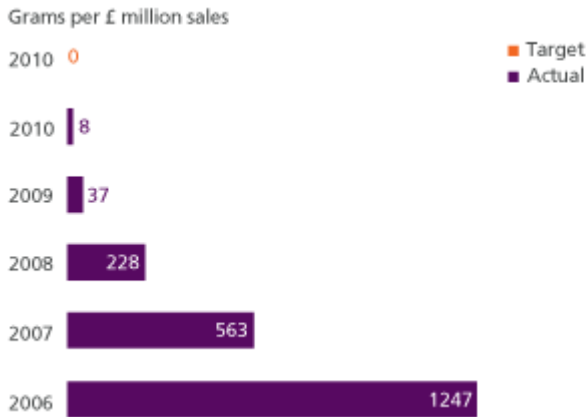
We emit VOCs to the atmosphere mainly from solvents used in the manufacture of our active pharmaceutical ingredients and in R&D pilot manufacturing plants. Our target has been to reduce VOC emissions per unit of sales by 2% per year.

In 2009 we focused on reducing VOCs at the three sites that are responsible for about three-quarters of VOCs released from all our facilities. During 2010 we improved solvent abatement at several sites including those in the UK, Singapore, India and Australia.

# Performance

## Ozone depletion

### Ozone depletion potential from equipment and production (CFC-11 equivalent)



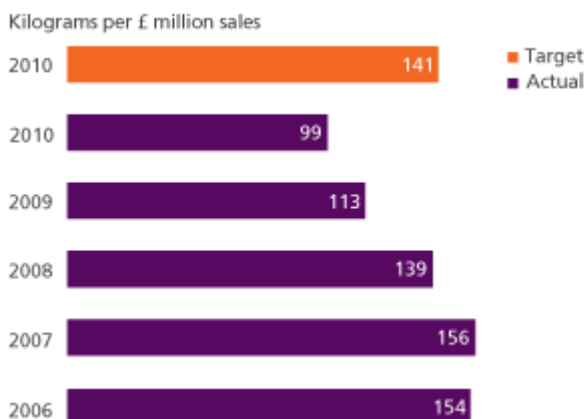
Releases of ozone-depleting substances (ODS) during patient use of inhalers are now eliminated.

In 2010 ODSs from equipment and production losses decreased by 79% to 214 kg, compared to 1,019 kg in 2009. This follows a similarly substantial reduction in 2009 and means we almost met our 2010 target to eliminate losses of CFCs from production and equipment. More than 99% of the CFC which was in service in 2006 is no longer present.

We maintain a register of the significant pieces of equipment that contain refrigerants and use this to track progress. We have 52 pieces of equipment containing more than one kilogram of CFCs, amounting to approximately 4,500 kg in total.

## Volatile organic compounds

### Volatile organic compound emissions



In 2010 volatile organic compound (VOC) emissions decreased 13.8% to 2,660 tonnes. Emissions have now fallen by 35.7% since 2006. VOCs released to air per million £ sales decreased 12.8% in 2010, which means we have achieved our annual target. This continues the trend of reductions from previous years and takes the total reduction per unit sales to 35.8% since 2006.

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## 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.

VOC emissions were once again one of our focus areas in 2010. We concentrated on the top three emitting sites which are in the UK, India and Singapore. The improvements in 2010 were mainly the result of improved solvent abatement at these and other sites. One of our other sites in Australia reduced its VOC emissions by more than 50%.

Note: All figures, including targets, are restated at constant exchange rates



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## Data, audit and assurance

This section summarises key data, providing five-year trends, and contains internal audit and external assurance reports.

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### Basis of reporting

Environmental data are collected from all 76 of our Pharmaceuticals, Consumer Healthcare and Nutritional Healthcare manufacturing sites, 14 vaccines sites, 22 Pharmaceuticals and Consumer Healthcare R&D sites, the UK headquarters building and 60 offices and distribution centres.

Targets and performance are normalised by sales, based on a constant exchange rate, using the rate for 2010. This means that normalised figures for previous years are different to those shown in last year's report.

Data may also vary slightly from earlier reports because any errors found in data from prior years are corrected.

We use the Greenhouse Gas Protocol for all of our calculations of CO<sub>2</sub> emissions from energy use. We use the latest CO<sub>2</sub> country factors for electricity which are published by the International Energy Agency (IEA). 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 pages Geneva, Switzerland, 2007, (chapter eight).

## Data summary

This table is a summary of five years of environmental performance. For a breakdown of the components of each metric and more data, see the detailed data table.

	2010	2009	2008	2007	2006
Energy consumption from operations and transport (million gigajoules)	24.3	26.0	26.7	26.5	26.7
Climate change impacts (thousand tonnes):					
– From operations and transport	2011	2159	2214	2231	2246
– Inhaler use by patients	4647	5170	4747	5200	4685
– Total climate change impacts	6931	7633	7248	7801	7424
Water use (million cubic metres)	18.7	19.2	19.7	20.8	22.1
Wastewater volume (million cubic metres)	9.9	9.8	10.7	10.9	11.8
COD (thousand tonnes)	12.0	13.1	14.9	14.3	15.9
Hazardous waste generated (thousand tonnes)	191.5	214.5	237.1	222.5	241.7
– Disposed (other than recycling)	35.3	48.5	54.0	72.6	71.0
Non-hazardous waste generated (thousand tonnes)	125.7	118.7	109.8	121.5	116.4
– Disposed (other than recycling)	29.5	31.7	33.2	38.0	37.9
Otherwaste generated (thousand tonnes)	43.8	53.1	19.2	37.7	28.1
– Disposed (other than recycling)	2.1	7.4	7.0	14.6	17.0
Volatile organic compounds emissions (thousand tonnes)	2.7	3.1	3.7	4.3	4.1
Ozone depleting substance releases (tonnes):					
– Production and refrigerant releases	0.2	1.0	6.1	15.4	33.5
– Patient use of inhalers	0.0	112.9	87.7	136.5	182.2
– Total ODS	0.2	113.9	93.7	151.9	215.7
Ozone depleting potential of refrigerants in equipment (tonnes)	7.4	12.6	15.9	20.5	23.9

- 2010 values include some estimated data for December when actual data were not available in time for publication, see External assurance and GSK response to assurance.



- Energy and climate change impact for travel and transport by air, land and sea are calculated using the Greenhouse Gas Protocol. The measurement is based on distance travelled, not directly on fuel use. In years before 2006 we did not collect all categories of freight transport or employee business travel. For employee air travel we capture all routes globally for individual bookings but only UK and the USA for group bookings. For product logistics we capture all routes globally by air and sea, but by road we only collect EU, USA and Canada.
- Climate change impact is calculated as CO<sub>2</sub> 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 CO<sub>2</sub> factors and update the data for all years as appropriate.
- We use the factors for climate change emissions and ozone depletion potential from 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).
- Each year we review refrigeration equipment inventories for all years and estimate incomplete data. We calculate the probable releases using a factor from the British Refrigeration Association.
- Since 2006 we have collected inhaler production volumes to allow us to more accurately calculate the climate change and ozone depletion potential impact from their use depletion potential impact from inhaler use before 2006.
- Recycled water is not included in total water consumption.
- 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.
- Chemical oxygen demand (COD), a measure of water pollution, is measured when wastewater leaves our sites following any on-site treatment.
- We focus collection of volatile organic compound emissions on the major contributors; primary manufacturing operations, pilot plants, coating activities and sterile operations.
- 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.



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### Internal audit

We regularly audit our operations, contract manufacturers and key suppliers to assess systems for managing risks and impacts, compliance with legislation and performance against our environment, health, safety and sustainability (EHSS) 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 standard.

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In 2009 the EHSS audit team was integrated into the GSK Audit and Assurance function. This provides an independent audit and assurance capability, separate from the EHSS management organisation.

The EHSS audit team uses the GSK Audit and Assurance function's standardised risk-based audit process to audit the management of environmental risk. The 2010 audit strategy also included audits of 'themes' across several operations, such as the prevention of major releases of the propellant gas HFC 134a (tetrafluoroethane) used in the manufacture of metered dose inhalers.

The frequency of audits across operations is determined by the level of risk and impacts and a site's performance at managing those risks. In 2010 we audited 17 sites, covering key risks and performance against our EHSS standards.

In general, performance relating to the management of environmental risks was good. There were no critical findings that indicate lack of proper management of risks with potentially serious consequences concerning the environment. There were a number of positive performance areas including general management and reduction of environmental impacts. A number of findings were raised, mainly relating to aspects of the management of waste, emissions and containment.

Read more about our supplier audits in the Supply Chain section.

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### Certification

Sites continue to certify to international standards ISO 14001 and OHSAS where they see a potential benefit. This follows a review in 2009 which concluded that certification does not equally benefit all sites and that certification should focus on those that need to make the most significant improvement. All sites are required to have robust management systems, including self-audit systems, and are encouraged to have them certified but this is not a formal requirement. At the end of 2010, 25 sites were certified to ISO 14001.

### External Assurance

This is the fifth year that SGS has reviewed the data in the environment section and the health and safety pages of the Corporate Responsibility Report. Its independent view of our processes has been very valuable and we have adopted its suggestions over the years, improving our processes.

Sites were selected for review from all of the GSK businesses. For the site visits, there was special focus on sites that had been top contributors to environmental emissions the previous year, relatively new sites that had not been visited by SGS for data verification and sites that had difficulty submitting data in a timely manner.

See the SGS Assurance statement below:

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### ASSURANCE STATEMENT



**SGS UNITED KINGDOM LTD'S REPORT ON ENVIRONMENT, HEALTH AND SAFETY DATA IN THE GLAXOSMITHKLINE CORPORATE RESPONSIBILITY REPORT FOR 2010**

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#### NATURE AND SCOPE 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 2010. The scope of the assurance, based on the SGS Sustainability Report Assurance methodology, included 2010 data contained in the following sections of this report:

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**Environmental Sustainability**

- Plans and targets – performance (climate change and energy, water, waste and emissions to air)
- Climate change and energy – CO2 emissions savings
- Climate and energy performance
- Water – performance
- Waste – performance
- Emissions to air – performance
- Data, audit and assurance
- Environmental Data summary

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**Health, safety and wellbeing**

- Safety programmes (Driver safety, Ergonomics and human factors)
- Health and safety performance
- Health and safety data table

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**Detailed Data Table (Environment, Health and Safety)**

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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 with the intention to inform all GSK's stakeholders. Financial data drawn directly from independently audited financial accounts has not been checked back to source as part of this assurance.

This report has been assured at a moderate level of scrutiny using our protocols for evaluation of content veracity. The assurance comprised a combination of interviews with relevant employees; documentation and record review at seven GSK locations during and at the end of the reporting year as follows:

- Interim site visits during October and November 2010 in Australia (Port Fairy), France (Marly-Le-Roi), UK (Coleford, Weybridge), USA (Marietta, Zebulon);
- Interviews with EHS Directors and Management Teams for Global Manufacturing and Supply; Biologicals and Pharma R&D in November 2010;
- End of year site visit during January 2010 in UK (Corporate Health, Safety, Environment & Performance function in London).

The sites selected included those submitting high proportions of key data and all parts of the GSK business.

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**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.

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**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 2010 is reliable and provides a fair and balanced representation of GSK's Environmental, Health and Safety activities in 2010. The assurance team is of the opinion that the Report can be used by the Reporting Organisation's Stakeholders.

**Summary of Findings**

Minor areas for improvement to data collection, submission and manipulation identified during the assurance process 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:

- Due to earlier deadlines for compilation of data some estimated data for the final month of the reporting period requires to be updated with actual figures.
- Some sites have implemented improvements in monitoring and measurements of certain data (such as VOCs and COD), but further improvements in reliability could be considered at sites where emissions data are calculated based on a small number of samples.
- Some cases of known releases of ODS from equipment were not included in the equipment register. The methodology used to collate ODS data in equipment could be amended to enable specific known releases to be included.

In addition good practice was noted in the following areas:

- Increased comments and explanations made by sites inputting data to explain significant changes, estimations and calculations.
- The analysis of data at corporate level has made ongoing improvements including:
  - detailed review of reports illustrating significant changes and anomalous data on a site-by-site basis, including review of conflicting trends and requests to sites for detailed explanations;
  - introduction of graphical display illustrating year-on-year trends for each KPI, including contributions to performance, which is now possible to view by individual site; GSK Business Unit; or GSK Group.
  - introduction of automated report generation to improve evaluation and analysis of submitted data, including generation of reports of double entries, late entries and submissions, and estimated entries.

Recommendations for future data verification process include:

- Interviews with EHS Directors for each GSK Business Unit were found to be an effective method of gaining an overview of expected data trends and projects contributing to achievement of targets. One opportunity for improvement in this process would be to conduct the EHS Director interviews earlier in the reporting cycle to enable direct evaluation of relevant projects to be undertaken as part of the site visits and data verification.

Signed:

For and on behalf of SGS United Kingdom Ltd

Jim Weaver

UK Systems and Services Certification Business Manager

February 2010

WWW.SGS.COM

### GSK response to assurance

We are pleased that most sites improved in submitting complete and accurate data, including comments for the explanation of trends, in a timely fashion. We are committed to continue improving, with the ultimate goal of providing accurate data to the public on the website in real time.

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The data in the Corporate Responsibility Report can be used by sites to improve their management of their environmental programmes and their health and safety programmes. In 2010, in addition to the end-of-year data analysis, we conducted a mid-year evaluation of the data to encourage sites to track their progress and to assist in the management of environment, health, safety and sustainability.

We welcome SGS's findings on good practice and its recognition of the improvements we have made in data collection and analysis. We note that SGS found value in engaging with EHS Directors to discussing the anticipated performance trends for each GSK business. In 2011 we will arrange the EHS Director interviews earlier in the year so that any new EHS projects implemented can be evaluated during the subsequent site visits.

Our responses to specific areas recommended by SGS for improvement are as follows:

- "some estimated data for the final month of the reporting period requires to be updated with actual figures".

The reporting deadline for the sites was brought forward to enable GSK to make the report available to the public as early as possible. For data which is obtained from invoices (such as energy consumption) we are dependent on external suppliers to provide the data in a timely fashion. Where the final data is not available we require sites to provide estimates. We have reviewed all the estimated data and we have ascertained that the estimates are reasonable. We will make sure the data is updated with actual figures by the end of the first quarter of the current year.

- "improvements in reliability could be considered at sites where emissions are calculated on the basis of a small number of samples".

This recommendation relates to sites with a relatively low level of discharges where sampling may be infrequent. In such cases sites may not be required to make measurements by the local regulators, or the local regulators may specify a low frequency of sampling. Nevertheless we will work with these sites to ensure that there is at least one sample for each quarter and if unexpected discharge events occur, that they increase the frequency of sampling until discharges have returned to normal levels.

- "The methodology used to collect ODS data in equipment could be amended to enable specific known releases to be included":

Our register holds information on the ODS content of equipment which we use to calculate fugitive emissions. This does not include any additional losses due to spillages which have to be reported separately. We will introduce a new record in our system to collect any accidental releases of refrigerant gases.

## Our people

GSK employs over 90,000 people in 114 countries worldwide. We want GSK to be known as a great place to work and an employer of choice for talented people from all backgrounds. By attracting and retaining the best people, we can be confident of achieving our mission: to improve the quality of human life by enabling people to do more, feel better and live longer.

Our employment practices are designed to help us create the right workplace culture in which all GSK employees feel valued, respected, empowered and inspired. Important elements of our approach include our values and behaviours; our commitment to **inclusion and diversity** and support for flexible working practices; regular two-way communication with employees; and respectful and fair treatment of employees during changes to the company.

Our leaders set the tone and all employees have a role to play in maintaining this culture. We ask them to adopt our company values and behaviours in all their work (see box). In return, we aim to provide a great employee experience for everyone at GSK. This includes: high-quality training and development opportunities, including focused leadership development for high-potential employees; competitive reward packages; and a commitment to protect employee health, safety and wellbeing.

### Our values and behaviours

We feel strongly that how we realise our achievements is just as important as the achievements themselves.

Our four company values guide GSK employees' conduct in their daily work. We ask them to:

- Commit to **transparency**
- Show **respect** for people
- Always demonstrate the highest **integrity** in their conduct
- Be **patient** focused.

To ensure they contribute to a successful and responsible GSK, employees should: put patients first, be flexible in their thinking, enable change for the better, continually monitor and improve performance, embrace the training and development opportunities on offer, and build strong relationships with customers and each other.

## Inclusion and diversity

### Approach

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We aim to be an inclusive and diverse company. This empowers our employees because it shows that we value and respect their contribution. It is good for business because it brings different knowledge, perspectives, experiences and working styles to GSK.

GSK does not permit harassment or discrimination, whether relating to race, colour, religion or belief, gender, sexual orientation, gender identity or expression, age, national origin, genetic make-up, disability or chronic health conditions. We protect all employees' privacy and confidentiality, and recognise their human rights.

In 2010 we revised our inclusion and diversity strategy to help us create a workforce that reflects our global presence and the communities we serve. It provides a flexible framework that can be adapted to the local culture and legislation of our many different markets. We are communicating the changes to employees and will continue to raise awareness about our approach.

We nominated the President of our European Pharmaceuticals business as the new Corporate Executive Team (CET) sponsor for inclusion and diversity. He is responsible for ensuring that we have the right initiatives in place and for raising awareness among senior management and across the business. He worked with the CET in 2010 to ensure an increased focus on inclusion and diversity in our talent management process and a renewed commitment to equal pay and career opportunities, as well as introducing a new framework for flexible thinking in relation to working practices.

Inclusion and diversity are also supported through our mentoring programme for future leaders which encourages mentors to coach someone with a different background from their own.

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### Global HIV/AIDS policy

We do not discriminate against prospective or current employees based on HIV status and do not require medical testing as a prerequisite for employment. We maintain medical confidentiality at all times.

We provide staff with information and training about HIV/AIDS prevention and how to address problems of stigma relating to the disease. We offer HIV/AIDS testing, voluntary counselling and treatment programmes, including free anti-retrovirals, to employees and their families in countries where these are not easily available via government healthcare programmes.

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### Our approach to disability

We work to ensure that people with disabilities can access the full range of recruitment and career opportunities at GSK.

In the UK, for example, we partner with the Employers' Forum on Disability and aim to be a 'disability confident' organisation. That is, we strive to be a workplace that creates a culture of inclusion, removes barriers to access, and



makes adjustments to enable individuals with disabilities to contribute as employees, customers and partners. We hold the 'Two Ticks' symbol from Jobcentre Plus, which demonstrates our commitment to employing people with disabilities.

Another example is our partnership with SERMES in Spain, a specialist in the integration of disabled people in to the workforce. SERMES has helped us to create employment opportunities for disabled people within our human resources response centre.

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## Flexible thinking in relation to working practices

Thinking flexibly about the way we work can include formal arrangements such as flexible hours, part-time working and job shares, as well as informal arrangements such as working from different locations. This can empower employees, helping them to optimise their effectiveness and better balance their work with other needs and commitments. We encourage flexibility, provided it also meets the broader needs of the business.

In 2010 we developed a new global framework that encourages managers to assess employees and teams on their productivity and performance, rather than simply their presence in the office. The way in which we implement this approach will vary by business and location, according to local needs and cultures.

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## Employee resource groups

Our employee resource groups provide a forum for people with similar interests or backgrounds to meet, discuss shared experiences, and work together to help make GSK a more inclusive workplace. Resource groups also provide GSK managers with views and insights on diversity, and help our media and marketing teams better understand our diverse customers and stakeholders.

GSK employee resource groups include:

- Asian, African American and Hispanic groups
- Cancer support groups
- Gay, lesbian, bisexual and transgender
- Mid-career and beyond
- Multi-faith groups to enhance religious understanding
- Veterans, families and friends
- Young and early career professionals
- Women.

Each group has an executive sponsor who helps to set and achieve goals, obtain resources and champion its objectives.

Most of the groups are based in the US. However, the gay, lesbian, bisexual and transgender group also has a council in the UK, and the young professionals group has councils in several countries including Australia, Brazil, China, India and the UK.

Further information about our commitments relating to employee, customer and stakeholder diversity can be found our website.

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## Performance

## Gender diversity

Despite a continued period of change we have maintained the percentage of women working at all levels of management at GSK. In 2010 38% of all management positions globally were held by women and we are pleased with our steady progress over the last five years.

### Gender diversity in management 2010

	% of positions held by women				
	2010	2009	2008	2007	2006
SVP, VP	25	25	25	22	22
Director	37	36	36	35	34
Manager	42	42	41	40	39
Total	38	38	38	37	36

There are currently two women on our Corporate Executive Team and further changes during 2011 will increase this to three. Two of the roles are leading major commercial operations – the US and the Consumer Healthcare businesses. This is a significant increase since 2008 when women were not represented on the Corporate Executive Team.

## Ethnic diversity

We report ethnic diversity for two markets, the UK and US.

### United Kingdom

Ethnic minorities accounted for 19.4% of UK employees in 2010, the same proportion as recorded in 2009. To put this in context, ethnic minorities accounted for 12.5% of the UK population of England and Wales in 2001, the last UK Census.

Our classification of ethnic minorities is based on the UK Commission for Racial Equality definition, which encompasses anyone who does not identify themselves as White British – including people identified as White Irish, North American and European.

We also measure diversity in the UK by counting the number of employees who define themselves as non-white. In 2010, 12.1% of employees were non-white, compared with 12.2% in 2009, 12.1% in 2008, 11.8% in 2007 and 11.6% in 2006.

### United States

In the US, minorities are defined as Blacks, Hispanics, Asians, Pacific Islanders, American Indians and Alaskan natives. In 2010 minorities comprised 20.5% of our workforce compared with 20.4% in 2009, maintaining the level despite substantial workforce reductions.

Comparing our US workforce data against the North American Industry Classification System (NAICS) for the Pharmaceutical and Medicine Manufacturing industry, we have identified areas to address. While the GSK US workforce of 8.1% African-American is comparable with the NAICS industry figure of 8.5%, the GSK US workforce is 3.7% Latino and 8.4% Asian, compared to the industry figures of 7.3% and 11.6%, respectively.

### Ethnic minorities – UK and US 2010

	% of employees from ethnic minorities				
	2010	2009	2008	2007	2006
UK	19.4	19.4	19.2	19.1	18.3

**% of employees from ethnic minorities**

	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
US	20.5	20.4	20.5	20.1	19.8

## Employee engagement

### Approach

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Our aim is for every GSK employee to feel engaged with their work and their colleagues, and to understand our business objectives and performance.

We communicate regularly with our workforce to provide updates about progress towards our goals and changes to the business, to listen to their feedback, and to stimulate innovative ideas.

We use a variety of communications channels to ensure we reach as many employees as possible. They include:

- Face-to-face communications, including team briefings, company meetings and conferences
- Web broadcasts (live and recorded) to reach large and geographically dispersed teams
- Our global intranet site, connectGSK, which provides updates on company and industry news and acts as a repository of information and resources for employees
- An email cascade system that keeps senior leaders informed of company news, for example about our latest financial results
- Spirit, our internal magazine with news and feature articles about GSK products, people and programmes, available in print and on the intranet
- A biennial employee survey, open to everyone at GSK, as well as separate surveys run by individual business units
- Induction programmes that provide new starters with an overview of GSK and the resources available to employees.

### Communications from senior executives

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Andrew Witty, our CEO, talks regularly to employees through global forums and broadcasts. His CEO Advisory Board comprises employee representatives from across the company, and acts as an informal sounding board for ideas.

On the intranet, the myCEO page gives staff the chance to pose questions to Andrew and other members of the Corporate Executive Team (CET). Many CET members also hold web broadcasts; others have blogs and Q&A pages to keep their teams informed.

### Consultation

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We recognise trade unions for consultation and collective bargaining in many countries worldwide.

In Europe, we have additional mechanisms for consulting employees about significant developments or changes to the business. Our staff and works councils meet regularly, providing employees with the chance to speak directly to company management.

Employee representatives from 28 EU countries also participate in our European Employee Consultation Forum, which

works alongside national consultation processes. The forum meets annually to receive a business update from senior GSK executives, while a sub-committee of six employee representatives meets quarterly with six management representatives to receive updates and discuss any restructuring proposals.

## Performance

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### Engaging online

In 2010 we launched a new intranet portal, connectGSK, which features new social media and networking tools that enable employees to collaborate, share information and keep connected more easily.

We also introduced 'Idea Engine', an online tool which allows employees to submit ideas and recommendations, and vote for or against suggestions from their colleagues. In January 2010 we asked employees for their ideas on how to simplify our company procedures and reduce bureaucracy. Nearly 25,000 employees visited the site, and we received over 1,000 recommendations.

In April we followed this with three, week-long sessions exploring the results from our employee surveys. Employees were asked to comment on why they think responses on specific issues were positive or negative, and to recommend actions that could help us improve. Around 30,000 employees participated. Their feedback has resulted in a number of changes – for example, our increased commitment to think flexibly about working practices.

### Employee survey

Nearly 60,000 employees worldwide took part in our December 2009 workforce survey. The survey asked questions about how well GSK demonstrates its company values, engages its workforce, empowers individuals and develops employees' skills.

Overall, survey results indicate that people are proud to be a part of GSK, clear about what they are accountable for and empowered to do, feel trusted to do their jobs, and understand what constitutes ethical behaviour. Areas identified for improvement include the need for greater transparency, raising further the bar on employee empowerment, and continuing to provide opportunities for personal development.

## Consultation

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In June 2010, we held the annual European Employee Consultation Forum (EECF) in Munich, Germany. Discussions covered topics including:

- Building trust and reputation
- Research and development
- The evolution of the vaccine market and GSK's ambitions for growth
- Our pharmaceutical business in Europe.

# Development and training

We want all employees to have access to high-quality training and development opportunities throughout their career at GSK. The right training and development can help employees improve their performance, feel engaged in their work and make progress in their careers.

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Individuals identify their personal development needs with the support of their manager through our performance appraisal process. We are introducing 360-degree feedback for an increasing number of employees. We also work with specialist external organisations to conduct in-depth assessments of senior leaders and certain other employees including, in 2010, members of our HR department. External experts interview relevant individuals and use the findings to develop a clear picture of his or her experience and capabilities, so that robust personal development plans and the development opportunities can be agreed.

Influential research by the Center for Creative Leadership highlights how adults learn at work. They reported that learning occurs through three key processes:

- 70% on the job development, such as challenging projects
- 20% developmental relationships, such as mentors
- 10% formal development, such as training programmes

With this research in mind, opportunities available to GSK employees include:

- Action Learning Projects which offer employees the opportunity for new challenges, to work with different colleagues and to gain new insights.
- Secondments with other departments within GSK that enable individuals to see how the company works from a different angle
- Work-related training courses, covering subjects from inspirational leadership to financial skills. In 2010 we offered training courses in eight languages to GSK employees in over 18 countries
- Mentoring by senior leaders, which helps employees improve performance, and think about their future career
- Coaching for high-performing employees with the potential to become GSK's future leaders
- Employee volunteering. This helps GSK employees gain new experiences and skills and, in many cases, acquire a deeper understanding of patient needs, at the same time as supporting communities and charities. GSK gives every employee one paid day off each year to volunteer in their community and, through the PULSE programme, offers the chance for employees to spend up to six months working for a non-governmental organisation.

# Developing leaders

Good leadership and good succession planning are vital for the successful and sustainable implementation of our business strategy. We expect leaders to demonstrate our values and behaviours and to inspire their teams to do the same.

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## Succession planning

Effective and robust succession planning ensures we have suitably experienced candidates to fill senior management and other critical roles across GSK. We identify potential future leaders within GSK and develop them so they are equipped with the capabilities needed to run the company. We encourage successors for key roles to gain experience outside their home country, to broaden their outlook and gain new skills.

We measure the readiness of our succession plan twice a year and, where we identify gaps, look to bring in external talent.

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## Enhancing leadership skills

At GSK our senior leaders take part in a 360-degree assessment to receive feedback on their performance from those they supervise as well as colleagues, managers and others. Assessments help leaders to identify areas they can improve.

We provide our existing and future leaders with focused training and development, including assignments and responsibilities designed to stretch and enhance their learning capabilities. In 2010 we provided training to nearly 8,000 GSK leaders worldwide, many of them at the first level of leadership. We have also developed training programmes for future senior leaders and senior executives, which we will implement in 2011.

We also provide leaders with coaching designed to help them reach their personal and business goals. Coaches include managers who are trained in coaching, and internal and approved external coaches.

Under a company-wide mentoring programme, we expected each of our senior leaders to mentor at least one individual in 2010. Mentors have the opportunity to pass on advice and knowledge, and the programme helps employees feel more engaged with management and the company as a whole. We identify employees for mentoring through our talent review process, encourage other employees to set up their own mentoring arrangements, and make resources for both mentors and mentees available through our intranet site. To support our efforts to be an inclusive and diverse company, we encourage mentors to support someone with a different background from their own.

# Reward and recognition

Rewarding employees for their contribution to the company and recognising their achievements help us attract, retain and motivate the best people.

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We offer competitive salaries that are based on industry benchmarks, as well as incentives that acknowledge employees' good performance against annual objectives and actual company performance.

Other benefits include:

- Share ownership schemes, open to GSK managers worldwide and all employees in some markets
- Pension provision
- Healthcare, vacation, childcare support and employee car ownership programmes
- Recognition for specific projects and for demonstrating high performance above and beyond the day job.

Our share ownership schemes help to create a culture of ownership among our employees. GSK managers worldwide are eligible to participate in share programmes as part of their reward package. In countries where all employees have the opportunity to own shares, there is a high level of participation. For example, in the UK 87% of employees participate in our Share Reward Scheme.



# Restructuring

From time to time we undertake restructuring programmes to improve the effectiveness and productivity of our operations and ensure the long-term sustainability of GSK. This can include outsourcing, site closures and staff reductions. At present we are streamlining our operations in developed markets and growing operations in emerging markets, in line with the changing shape of our business.

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We are very conscious of the effect restructuring has on our employees and whenever possible we aim to achieve our organisational and financial goals while preserving jobs. We consult with employees and their representatives before implementing measures that affect our workforce. Where local regulations allow, we always speak to affected employees first and then our works councils, trade unions and other employee representatives as appropriate.

In the event of redundancies, affected employees receive a wide range of support, including a competitive severance package, assistance in finding alternative employment, career counselling and retraining. We also work hard to maintain the morale of other employees at GSK during restructuring.

## Health, safety and wellbeing

Keeping employees and contractors healthy and safe is a business priority and reflects GSK's core value of respect for people. This is an essential part of being a responsible employer and contributes to business performance by improving engagement and productivity and by reducing healthcare, business disruption and insurance costs.

Health and safety are integral parts of a broader environment and workforce sustainability strategy that reduces the risk of harm to employees and helps them remain healthy, productive and energised.

This section reports our focus and performance in 2010.

In 2010 the health and safety aspects of our workforce sustainability strategy focused on:

- improving the health and safety culture
- addressing key health and safety risks
- expanding several high-impact global programmes.

Read about our management of environment, health, safety and sustainability (EHSS).

### Nurturing Life campaign delivers healthy results

A programme called Nurturing Life involved all employees – from the site directors to contractors' staff – at the three Horlicks plants in India, addressing all aspects of healthy working and living. Participants tackled a wide range of issues from machine safety to work culture, including personal health.

It empowered employees to take charge of their health, and we saw tangible improvements: a reduction in sickness absenteeism of more than 30% at two of the sites and greatly improved safety behaviour, especially machine safety.

Our occupational health and safety target has been to reduce reportable injuries and illnesses and ergonomic injuries and illnesses by 5% a year from 2006 to 2010. We have exceeded both annual targets, with annual reductions over the five-year period of 13.7% improvement in the total rate and 18.1% for the musculoskeletal rate. Read more about our performance.

Reduction of reportable injuries and illnesses continues to be an important goal. To drive further reduction GSK will pilot, in 2011, several health and safety indicators that can warn of risks before they result in injury.

# Health and safety culture

We manage health and safety through an integrated environment, health, safety and sustainability (EHSS) management system, which was reviewed and updated in 2009. The system is aligned with recognised international standards such as ISO 14001 and OHSAS 18001. Read more about management of EHSS.

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During 2011 we are conducting a review of our health and safety strategy to ensure it is aligned to GSK's evolving business model. This will ensure GSK continues to have effective and sustainable health and safety governance. The review will enable us to allocate resources in line with health and safety risks and to set new performance targets.

Our occupational health and safety data are independently assured under our EHSS assurance process.

Safety is also built into and maintained at our sites through our:

- Risk assessment and control processes
- Construction contractor safety programme
- Capital project EHS review process
- Emergency response programmes.

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## Monitoring performance through internal audit

In 2010 we conducted integrated EHSS audits at 17 sites to assess systems to manage risks and compliance with legislation, and performance against our global standards.

Overall, we found that many aspects of systems for managing safety and health risks were being implemented. The weakest performance was at newly acquired sites where improvement plans are now addressing gaps and ensuring good levels of risk control. All improvements plans are monitored to ensure timely progress.

Read more about our overall EHSS audits.

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## Living Safety

Our Living Safety programme is designed to embed a strong safety culture throughout GSK. It identifies strengths and gaps in a team's or larger unit's health and safety culture and establishes the behaviours we expect everyone to demonstrate in their everyday work. Three important elements of the programme focus on:

- Behaviours that all employees and contractors should display and which establish everyone's responsibility for the health and safety management system. Everyone is responsible to report any potential risks they encounter and get involved in improving safety performance
- Supervisor behaviours that ensure GSK's health and safety standards are understood, implemented and maintained by their team, including contractors. Supervisors must champion compliance with policies, encourage their team to get involved in improving safety performance and promote risk awareness
- Managers' attitudes and behaviours that set the tone from the top and lead with high health and safety standards,

communicate openly with employees about issues, quickly address any risks they identify and involve others in their efforts to improve safety performance.

Living Safety is currently deployed in the manufacturing and R &D organisations at over 85 GSK sites, with clear business benefit. We will assess the business and health and safety impacts of the programme in 2011.

## Health and safety learning culture

GSK-wide mechanisms for learning from external organisations and events (benchmarking); internal near misses and incidents and internal audits, performance indicators, and reviews all help create a continuously improving health and safety culture.

We have developed a training framework that identifies gaps in employees' knowledge of health and safety and provides in-house and external training courses. We provide global training on personal health risk management, our health and safety standards, as well as programmes such as process safety, chemical exposure protection, identifying risk, auditing and ergonomics. Sites also develop and conduct training based on local needs and capabilities, using our internal learning tools, commercially available programmes or other material.

Our safety and health professionals share knowledge and best practice via teleconferences, intranet communities, training programmes and discussion forums. In November 2009 we launched a new micro site on the GSK intranet for sharing EHS-related training materials.

In 2010 we focused on increasing EHS professionals' skills. Staff at sites have embarked on new qualifications such as the International NEBOSH Diploma (from the National Examination Board in Occupational Safety and Health), and advanced qualifications in both occupational hygiene and environmental management.

In addition to formal training and learning opportunities, we raise awareness about employee health and safety issues through:

- Announcements on the myEHS Community intranet sites
- The CEO's Sustainability Awards programme
- Health and Safety Week celebrations held at site level, to inspire employees to address potential risks at work and at home.

# Addressing key health and safety risks

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## Risk assessment and communication

Understanding the potential hazards posed by the materials we produce or use in research, development and manufacturing is essential to effectively manage health and safety risks and prevent damage to the environment.

Our hazard assessments help us meet regulatory requirements such as the EU Registration, Evaluation and Authorisation of Chemicals (REACH) legislation and the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

We conduct hazard assessments and 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 employees, contractors, contract manufacturers and customers to handle, transport and dispose of materials and products safely.

Our safety data sheets are available in multiple languages via a website which provides health, safety and environmental information for nearly 4,500 GSK materials and key manufacturing and process chemicals.

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## Managing chemical exposure

We have rigorous procedures and controls to protect employees from exposure to chemicals. Each GSK site monitors air quality to assess exposure to hazardous compounds and implements controls to achieve our 'respirator free' goal.

Our goal is to make 80% of existing operations that handle hazardous compounds 'free from respirators' by the end of 2012. 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 situations where it is not possible to be respirator free, employees will remain protected by appropriate respiratory and other equipment. We extended the 'respirator free' target date (which was originally 2010) because we now focus on adapting operations with the highest degree of risk rather than those that will be easiest to adapt. All new facilities will be 'respirator free' from the start.

To date 56% of operations are 'respirator free'.

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## 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 materials through our green chemistry and green technology programmes. Where substitution or elimination is not an option, our engineers use an online system to assess the safety of process and plant designs, develop plant maintenance strategies, and share hazard information and control strategies across GSK.

In 2010 we focused on execution of our long-term plans in the highest risk areas of our business. We also began detailed preparations to implement process safety management principles in other, lower risk, areas of the business from 2011. Oversight of these efforts is maintained through a Process Safety Steering Committee comprising senior operations and EHS management representation from relevant business areas.

There were around 80 process safety incidents in 2010 including a significant overpressure incident at our Thane

manufacturing facility in India. We carried out a full technical and management systems investigation of the incident and are implementing a detailed response plan at Thane with support from staff seconded from other GSK sites. The plan shared across GSK to learn from these incidents, concentrates on risk reduction measures for each of the processes conducted at the site.

A process safety review by an external consultant, to be completed in 2011, is also underway across all other primary technology sites. This includes a desktop review of GSK's Process Safety Management System.

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## Driver safety

Our sales representatives spend significant amounts of time driving and are at risk of being involved in road traffic incidents. Driving accidents have been the most common cause of fatalities since 2002, including one death in 2010. In 2010 16% of the injuries with lost time were due to motor vehicle accidents. See fatalities and serious injuries data in the health and safety performance section.

We aim to reduce the risk of road traffic accidents through our global driver safety programme. This includes instructions and guidelines on driver training, vehicle selection, risk assessment, distractions while driving and accident reporting. We have a motorbike rider safety manual for employees in countries where we provide motorbikes or scooters.

In 2010 we conducted driver safety audits in three higher risk countries – Turkey, India and Egypt. The audits found that there has been progress in implementing the global driver safety programme but we can reduce risks further. For example, we are improving training and maintenance of vehicles in these and other countries.

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## Ergonomics and human factors

Musculoskeletal illnesses and repetitive strain injuries are some of the leading causes of time away from work. Good workplace and job design helps employees to do their jobs effectively while reducing the risk of musculoskeletal illnesses and injuries. Ergonomics and human factors, if applied properly, can reduce illnesses and injuries, as well as work performance errors and lost time.

Seventy cross-disciplinary ergonomic improvement teams work to identify risks, develop solutions and share best practice globally through an ergonomics intranet site. In addition, more than 900 trained facilitators help manage computer-based ergonomic risk assessments. These assessments give employees the opportunity to discuss ways to reduce injury risk.

In 2010 we focused on improving risk assessments and reducing ergonomics-related injury and illness, by:

- Establishing a simplified ergonomics risk assessment for non-office environments for use by site ergonomics teams
- Completely redesigning our ergonomics intranet pages to stimulate interaction and learning between sites via community discussion areas, blogs and feedback
- Continuing to put countermeasures in place for both manufacturing operations and offices, for example to limit injuries from manual lifting and to provide sufficient adjustability of equipment.

As a result of these efforts we have far exceeded our targets and have achieved an average annual reduction in the musculoskeletal-related injury and illness rate of 18% per year between 2006 and 2010. Musculoskeletal injuries and illnesses continue to be a major cause of worker ill health and will continue to be a focus of proactive and reactive systems improvement.

# Health and wellbeing programmes

GSK offers programmes to enhance employee health and wellbeing, sustaining employees' energy and engagement with their work and contributing to improved productivity and performance.

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Our global health programmes focus on preventing and managing the leading causes of employee illness and disability such as depression, non-work-related injuries, heart disease, stroke and respiratory infections. Annual seasonal flu vaccination is offered free to GSK employees in almost all of our markets, and in 2011 all seasonal flu vaccine will be centrally funded, further increasing access. Travel health programmes, including medications and vaccinations, also help keep employees healthy and productive when travelling on business. These are supported by a global network of more than 200 employee health professionals.

As well as global programmes addressing specific issues, support for employee wellbeing includes flexible working options and programmes to improve the health of employees and their families, depending on local needs and healthcare services.

We also assist employees suffering from chronic diseases to support their access to appropriate long-term treatment, help prevent disability and absence from work, and support safe and timely return to work.

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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## Employee Assistance Programme

In 2010 we began introducing a global employee assistance programme (EAP) designed to provide emotional counselling, evaluation and support for employees. By the end of 2010, 15 countries had an EAP in place.

During 2011 it will be introduced in further markets so that every employee in over 100 countries will have access to free, basic mental and emotional healthcare. This will include up to eight sessions of counselling with a qualified health professional for each new life or emotional issue arising during the year. The programme will also provide counselling and emotional support at the time of disasters, crises or site downsizings.

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## Personal and team resilience

The increasing pressure, pace of communication and complexity of global business has put further emphasis on the need to support team and personal energy and resilience under pressure. Resilience is the ability to be successful in a high-pressure, fast-paced and continuously changing work environment. It supports good performance and helps prevent mental illness arising from stress, a leading cause of ill health and disability at work.

We offer workshops for individuals and teams to enhance and build personal resilience and help teams manage the sources of pressure that can lead to ill health or inefficiency.

The personal resilience programme helps people build skills to increase their focus, energy and confidence and reduce tension, anxiety and fatigue. More than 2,500 employees have participated since it started in 2008.

The team resilience programme helps employees and their managers to identify and act on sources of pressure on their teams, such as lack of workplace flexibility or accountability. The programme has been completed by 33,000 employees in 55 countries since it began in 2003. Participants have identified positive outcomes such as more successful team work, more efficient machine operation, increased empowerment and better sales performance. A study of groups engaging with the team resilience programme more than once found reduced perception of workplace pressures along with increased pride in GSK and work motivation. A further study involving interviews with people who had undertaken the team resilience process found a sense of greater control and influence over the team's work, and improved communication.

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## Energy for Performance

High energy levels help employees focus better and work more efficiently. The Energy for Performance (E4P) programme helps employees to build skills to better manage their physical and mental energy more effectively. It helps people develop habits that improve their engagement at work and at home.

In 2010 2,300 employees participated in E4P workshops. In total, over 7,300 employees from 80 countries have attended the programme since 2007. Almost 90% have reported significant improvement in their physical and mental performance and emotional energy. Participants find that improved energy levels last for at least 12 months after the workshop.

Analysis of outcome data for E4P graduates shows increased scores in all six desired GSK behaviours, most notably in developing people, which is key to the empowerment that helps improve wellbeing and performance.

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## Health and business continuity

We have contingency plans in place to protect employees and the business in the event of natural disasters, man-made emergencies, a flu pandemic or other public health emergency.

During the rapid global spread of H1N1 influenza in 2009 and 2010, our pandemic preparations helped us inform and protect more than 435,000 staff, their dependants and key complementary workers in over 127 countries. Universal access to seasonal flu and H1N1 vaccines was provided where legally permitted. Antiviral medicines provided to employees and their dependants gave them quick access to the medication if they became ill with the flu. Increased cleaning, disinfecting of work surfaces, thorough hand washing and rigorous absence procedures helped reduce spread in the workplace.

Based on our experience during the 2009 H1N1 pandemic, we have simplified our strategy for future pandemic response. A dedicated flu information website continues to educate and inform employees. Additionally, a Crisis and Continuity Management website provides information, tools and templates for GSK country and site crisis teams to respond to all types of business disruptions.



# Health and safety performance

## Performance

All performance data are verified by SGS.

### Fines or penalties

There were no safety-related fines or penalties in 2010.

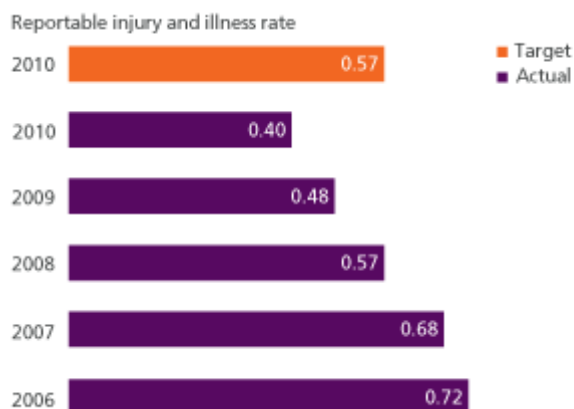
### Injury and illness rates

Our main health and safety measure is the reportable injury and illness rate. This is the number of incidents per 100,000 hours worked. 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.

#### Health and safety targets and progress

Injury and illness target	Progress 2006 to 2010
To reduce the reportable injury and illness rate by 5% each year to the end of 2010	44.8% (average of 13.7% per year)
To reduce the reportable musculoskeletal illness and injury rate by 5% each year to the end of 2010	58.3% (average of 18.1% per year)
To reduce lost time injuries and illnesses by 5% each year to the end of 2010	30.5% (average of 8.5% per year)

#### Reportable injury and illness rate



In 2006 we set a target to reduce our lost time injuries and illnesses by 20% by 2010. Each year we have exceeded our 5% per year target and thus, by 2008, had achieved our 2010 target. We have continued to make good progress and, overall, lost time injuries and illnesses were reduced by 30.5% from 2006.

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## Injury and illness causes

The leading causes of injuries and illnesses continue to be slips, trips and falls, ergonomic injuries (mainly strains and repetitive musculoskeletal injuries) and road traffic incidents.

Mental ill health accounts for only 2% of all illnesses but these cases result in the highest number of days lost, at over 69 days per case on average. This is being addressed by our resilience programme.

### Leading causes of injury and illness

Cause of injury and illness	% of total	
	2010	2009
Slips, trips and falls	22.6	22.3
Ergonomic	18.7	25.9
Road traffic incidents	16.1	13.1
Machinery related	7.1	5.5

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## Fatalities and serious injuries

There was one road traffic accident fatality in 2010 and two amputations to GSK employees who placed their hands into equipment that had not been switched off:

- An employee in India was killed when his motorbike collided with a truck
- An operator was removing a fixed guard while attempting to clear a jam when his finger was cut on the edge of a star wheel, leading to the amputation of his left index finger
- An operator was clearing a foil jam on a packaging machine when a cutter rotated unexpectedly, resulting in the amputation of the middle finger of his right hand.

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## Scope

Data cover GSK employees and contract workers whom we directly supervise. Data for contractors who work on GSK sites but supervise their own staff are incomplete and are therefore not included.

Injury and illness data are collected from 78 of our Pharmaceutical, Consumer Healthcare and nutritional manufacturing sites, 14 Biologicals sites, 31 Pharmaceuticals and Consumer Healthcare R&D sites and the US and UK headquarters sites. We also include 22 offices and sales groups with more than one million hours worked, and 68 of the smaller offices and distribution centres. In 2010 eight sites did not report injury and illness data.



SGS Verified

# Data table

This table is a summary of five years of health and safety performance. For a breakdown of metric components, see the detailed data table.

<b>Injury and illness – GSK employees</b>	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
Hours worked (millions)	208.3	201.0	192.1	196.5	195.4
Fatalities	1	1	2	2	1
Number of injuries with lost time	446	493	520	585	567
Calendar days lost – injuries	7,924	9,915	11,641	11,525	11,311
Number of illnesses with lost time	46	35	64	98	97
Calendar days lost – illnesses	2,248	1,794	1,539	4,181	5,443
Number of injuries without lost time	254	302	325	389	448
Number of illnesses without lost time	78	134	191	264	288
Lost time injury and illness rate	0.24	0.26	0.30	0.35	0.34
Reportable injury and illness rate	0.40	0.48	0.57	0.68	0.72
Ergonomic lost time injury and illness rate	0.05	0.06	0.08	0.09	0.08
Ergonomic reportable injury and illness rate	0.07	0.12	0.16	0.18	0.18
Calendar days lost rate	4.88	5.82	6.86	7.99	8.57

Notes to data:

- The occupational health and safety data cover 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.
- 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.
- All rates are per 100,000 hours worked.
- 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.
- 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.



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## Human rights

GSK is committed to upholding the UN Universal Declaration of Human Rights, the OECD Guidelines for Multinational 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.

Businesses also have responsibilities. We work hard to uphold human rights within our sphere of influence, which includes employees, suppliers, local communities and society more broadly. We have most direct control over human rights in our own operations.

We recognise that our industry has a unique role to play in efforts to improve health worldwide by developing safe and effective treatments for ailments that affect patients' health. We strive to make our medicines and vaccines as widely available as possible while running our business in a sustainable way. Our approach includes research partnerships into diseases of the developing world and flexible pricing to make our products more affordable in developing countries.

We put safeguards in place to ensure that the human rights of people taking part in our clinical research are protected. These include the informed consent process and procedures to protect patient privacy. We are especially careful to protect the rights of any children involved in our clinical trials.

We recognise and support the role that the Convention on Biological Diversity (CBD) plays in providing a framework for the conservation of biological diversity and for protecting the rights of countries and communities to access and share benefits arising from it. Read more about our approach to the CBD and use of biological materials.

Maintaining high standards of human rights benefits our business by:

- Helping us get the best from our employees
- Supporting our relationships with communities near our sites
- Ensuring supplier contracts run smoothly and provide a reliable supply of high-quality products
- Protecting our reputation.

### More information on GSK and human rights

Human rights are relevant to many of the issues covered in this report. This section gives an overview of our approach. For more information:

- See the human rights clause 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 about the informed consent process and our approach to clinical trials involving children
- Read our position statement on the Convention on Biological Diversity

# Employees

Our employment standards on issues such as diversity, equal opportunities and health and safety protect employees' human rights.

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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, a compliance officer or compliance champion, our human resources and legal departments or to our Ethics and Compliance department. They can also use our Global Confidential Reporting line. One call alleging human rights violations was made to the Global Confidential Reporting Line in 2010.

Read more about our employment practices and our policy on inclusion and diversity.

## 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.

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Human rights clauses are included in all supplier contracts. In 2010 we introduced a Third Party Code of Conduct which applies to all our suppliers and outlines the standards we expect them to meet. New suppliers are required to sign a statement confirming that they comply with the principles of the Code before they can do business with GSK. Existing suppliers are required to comply with the Terms and Conditions of our contracts which include elements similar to the Third Party Code of Conduct. We also highlight the stand alone Third Party Code of Conduct during routine engagements with existing suppliers to make them aware of the Code and reinforce the ethical principles it contains. If any issues arise, we will work with the suppliers to close any gaps.

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). Environmental, health and safety (EHS) audits of potential new and existing critical suppliers also include questions which help us identify potential breaches of our human rights clauses. 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
- Rights for workers to organise and recognition of worker organisations.

We will not knowingly use suppliers who are responsible for human rights infringements. Where we identify human rights issues we make recommendations for how the supplier can improve performance. We require the supplier to submit regular progress reports and undertake further site visits to ensure they improve their performance.

We are members of the Pharmaceutical Supply Chain Initiative (PSCI), an industry collaboration that has set out guiding principles and standards for suppliers that cover human rights and labour issues. The PSCI is looking at ways to improve supplier standards, especially in emerging markets.

[Read more about our supply chain.](#)

## Communities

We respect and promote the rights of people in the communities near our operations and, through our efforts to improve access to medicines, work to help society more broadly fulfil its right to health.

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### 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.

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### 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, including those used in the research and development of new medicines and vaccines. GSK supports the CBD's role.

Given the diversity of biological materials and the many ways in which they are used in research and development, it is not possible to generalise the role they play in biomedical research or the fundamental value of any material to a particular project or product. Careful consideration is therefore needed when seeking to define, implement and monitor appropriate access to genetic resources and the sharing of benefits arising from their use.

GSK participated in recent discussions on an international Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. The end result, agreed by the Conference of the Parties to the CBD in Nagoya in October 2010 is recognised as a compromise agreement, which leaves several issues open to interpretation at the national implementation stage. Our hope is that implementation at the local level will ensure that pharmaceutical companies can continue to search for new compounds that might treat and cure disease, while at the same time protecting the interests of the countries and communities from where the genetic resources are sourced.

GSK is not currently involved in any product development using genetic resources collected since the CBD was ratified, nor are we currently looking for any such resources (known as bioprospecting). As a result, we have no access and benefit-sharing agreements in place.

It is possible that in the 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.

# 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”.

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Improving healthcare is one of society's greatest challenges, particularly in the developing world. GSK contributes to healthcare worldwide by discovering new treatments and vaccines. We make a wide range of our products more affordable in developing countries through preferential pricing and voluntary licence agreements with generic manufacturers. We are also making a contribution in the Least Developed Countries through community investment projects that contribute to improvements in healthcare infrastructure. Our Patient Assistance Programs improve access for thousands of uninsured patients in the US.

We engage with governments, multilateral agencies, NGOs and other pharmaceutical companies to help improve access to medicines. Read more about our approach to Access to medicines and our work with communities.



# Activities in embargoed countries

Some stakeholders are concerned about GSK's business activity in countries that are subject to a trade embargo, such as Burma (Myanmar), North Korea, Iran and Sudan. We share the UN's belief that people should not be denied access to medicines because of the regime operating in their country.

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We aim to provide medicines and vaccines in all countries that need and wish to purchase them, while observing any sanctions or trading controls which apply to those countries.

In many nations our long-standing commitment and presence pre-date the introduction of measures such as trade embargoes. During periods of government-imposed trade embargoes, we have ensured continuity of supply (subject to any specific legal restrictions) due to the demand for our products.

In embargoed countries, as in all countries where we do business, 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.

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# Public policy and patient advocacy

The pharmaceutical industry is highly regulated. Government policy, legislation and regulations 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 and professional 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 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 exercises inappropriate influence over governments. We publish key elements of our public policy activity during the year on this website and report on our trade association memberships and US federal and EU institution lobbying expenditures. We also publish information on our work with patient groups, including details of the funding we provide GSK does not make political contributions.

We provide information on our approach to working with healthcare professionals in the Research practices and Ethical conduct sections of this report.

## 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, regulatory authorities and other stakeholders in a constructive way
- Communication: we give our views and we take into account the concerns of 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 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.

External affairs teams in our major regions and business units monitor proposed legislative reforms, policy developments and stakeholder concerns. They meet regularly with government officials and other stakeholders, such as multilateral organisations and NGOs, to explain our views on 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 is always fully consistent with GSK policies and 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 and consumer healthcare industry is sometimes conducted through trade associations. We may also hire professional lobbyists to support our public policy work.

### Trade associations

GSK is a member of many trade and industry organisations, including:

- Association of the British Pharmaceutical Industry (ABPI)
- Association of the European Self-Medication Industry (AESGP)
- BioIndustry Association (BIA)
- Biotechnology Industry Organization (BIO)
- British Pharma Group (BPG)
- Confederation of British Industry (CBI)
- European Brands Association (AIM)
- European Cosmetics Association (COLIPA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Intellectual Property Owners Association (IPO)
- International Chamber of Commerce (ICC)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Japan Pharmaceutical Manufacturers Association (JPMA)
- National Association of Manufacturers (NAM)
- Organization for International Investment (OFII)
- Organisation of Pharmaceutical Producers of India (OPPI)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- R&D-based Pharmaceutical Association Committee (RDPAC)

It is important that lobbying conducted through trade associations reflects our policies and values. We work with other members to set policies and may also attend industry association 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.

## Public policy activity in 2010

We engage with governments and other stakeholders on the wide range of issues that affect our industry.

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We publish our position on key issues relating to corporate responsibility, including:

- Access to medicines
- Ethical conduct of research and development
- Intellectual property
- The environment
- Public health
- Competitiveness
- Pricing, reimbursement and market access
- Counterfeiting of healthcare products.

These are some of the key issues we engaged on in 2010:

- Healthcare reform
- Access to healthcare and disease prevention
- Regulations relating to research practices
- Patient safety intellectual property

## Advocacy on healthcare reform

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### US activity

In March 2010, US President Obama signed into law the Patient Protection and Affordable Care Act (ACA), which significantly changes access to, and funding for, healthcare services in the US. GSK supported the efforts of Congress and the Obama Administration to increase access, improve quality and reduce cost growth in the US health system. While the new law presents the pharmaceutical industry with some financial challenges in the form of expanded rebates and new fees, it also offers opportunities to move the US health system in a direction that that embodies the three-part approach we advocate to achieving lower-cost, higher-quality healthcare: increasing prevention, improving treatment and accelerating research into better treatments for chronic disease – the Triple Solution for a Healthier America.

In 2010 we focused on the interpretation and implementation of the ACA (see below). Our priority is to ensure that the legislation is implemented in ways that reflect the best interests of patients while preserving an environment that values medical research, development and innovation. We believe reforms should improve quality of care and save costs by focusing on prevention and personal responsibility, removing barriers to access, coordinating care, and improving the management of chronic disease. Our health reform position paper offers an outline of where GSK stands on issues related to health reform.

Read more about our advocacy for increased investment in chronic disease prevention and treatment in the US. and the Triple Solution for a Healthier America

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### Increasing access and expanding discounts

**Organisations engaged:** US Congress, the White House

**Industry associations involved:** PhRMA, BIO

**GSK position:** The ACA included an expansion of rebates and discounts for medicines purchased through the government's Medicare and Medicaid programmes. GSK is committed to these changes which will help increase access to medicines for US citizens participating in these programmes and began implementing them in 2010.

Previously, patients eligible for Medicare Part D paid the full costs of their medication once their costs reached a certain amount and before they became eligible for further assistance. Along with other members of PhRMA, beginning in 2011 GSK is providing a 50 per cent discount for branded medications in this coverage gap as required by the ACA. The US government will pay a further 25 per cent, leaving patients to pay the remaining 25 per cent when the law is fully implemented. Our industry also supported provisions of the ACA that help cover the costs of increases and expansions in Medicaid, a government programme that pays for health insurance, including prescription drugs, for children and low-income individuals. The pharmaceutical industry is also contributing to a newly established 'health fund' as stipulated in the ACA that helps offset the costs associated with healthcare reform.

Approximately 32 million US citizens are expected to gain health insurance coverage by the time the ACA is fully implemented, as a result of these and other provisions that seek to improve access to and the affordability of healthcare.

Read more about GSK's work on increasing access to medicines.

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## A regulatory pathway for FDA approval of biosimilars

**Organisations engaged:** US Congress, the White House

**Industry associations involved:** BIO, PhRMA

**GSK position:** The ACA created a regulatory pathway for the US Food and Drug Administration (FDA) to approve biosimilars (versions of biological medicines or vaccines, also called 'follow-on biologics', that are similar to the innovator products). GSK supports the development of a responsible approval pathway for biosimilars.

Biologics are derived from living organisms and include vaccines and human insulin. Biologics are effective and targeted therapies that tackle some of the most costly and complex diseases.

The ACA recognises the importance of medical innovation and includes 12 years of data exclusivity from the date of licence for the innovator product. This encourages an appropriate balance between the desire for enhanced competition and preserving incentives for innovation.

GSK is encouraging the FDA to require all companies using the new regulatory pathway to:

- Provide clinical data to show that the safety and efficacy of a biosimilar are sufficiently similar to that of the innovator product.
- Establish a pharmacovigilance framework for identifying, evaluating and minimising any safety issues before and after regulatory approval.

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## The future of health reform

Implementation of the ACA will take many years. In 2011 and beyond, we will continue to support efforts to address rising healthcare costs through an approach called the Triple Solution for a Healthier America that focuses on prevention, intervention and innovation

We will also focus on three areas with the potential to dramatically change the way healthcare is funded and delivered, especially when considered together:

- Comparative effectiveness research (CER) – the comparison of two or more treatment options or healthcare delivery strategies .
- Health information technology (HIT) – the use of technology to manage individual and group patient data.
- Quality standards – measures of healthcare quality based on nationally recognised practice guidelines.

We believe that implementation of payment and delivery system reform should consider the full spectrum of healthcare services and costs. It should not place limits on expenditure in one area if this could result in increased patient morbidity or mortality, or increased health costs in another area. We will continue to demonstrate the value of expenditure on prescription drugs, supported by numerous studies which show that improving adherence to medication reduces overall healthcare costs

Read about our previous advocacy on CER in our 2009 Corporate Responsibility report.

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## Activity in Asia

### Healthcare reform in China

**Organisations engaged:** Chinese government; the pharmaceutical industry and other businesses in China; US and EU member state governments; European Commission; academics; Chinese think tanks

**Industry associations involved:** BPG, EFPIA, RDPAC, PhRMA, US-China Business Council, China Pharmaceutical

Enterprises Association CPEA, Chinese Pharmaceutical Association (CPA), China Medical Doctor Association (CMDA)

**GSK position:** The Chinese government is investing RMB 850 billion (\$125 billion, or around three per cent of GDP) between 2009 and 2011 to improve the country's healthcare system and narrow the current rural-urban healthcare gap.

Plans for healthcare reforms include expanding basic medical insurance to cover 90 per cent of the population by 2011, establishing a network of local clinics and improving services in public hospitals. The government has also established an essential drug system which requires healthcare institutions to purchase certain medicines to ensure they are available to the public in appropriate dosage forms, at an affordable price.

GSK welcomes the ongoing healthcare reforms, which should help to ensure better access to medicines and vaccines for Chinese patients, particularly those in rural areas. We are committed to working with Chinese authorities to meet these objectives and are reflecting this in our pricing and market access policies to ensure better access to our innovative medicines and vaccines across China.

We are increasing our investment in China, including expanding our R&D activities. R&D China was established in 2007 with a commitment to 'Discover medicines in China'. We are currently conducting research for severe disorders such as multiple sclerosis, Parkinson's disease and Alzheimer's disease. In 2010 we established an innovation centre in Beijing through a subsidiary of GSK in China, Sino-American Tianjin Smith Kline and French Laboratories (TSKF), to ensure that our products are increasingly tailored to the needs of Chinese patients. GSK China has established clinical research centres, with more than 200 development projects being conducted in collaboration with over 30 medical schools and hospitals.

GSK is also speeding up partnerships with domestic biopharmaceutical companies to locally produce flu vaccines and paediatric vaccines. Our investments should help to improve Chinese patients' access to innovative drugs and vaccines.

GSK is engaged in several partnerships in China to improve access to vaccines. In 2010 we launched a website to give information to families on vaccines with China Preventive Medicine Association (CPMA) and a Value of Vaccines public education project with CCDC and CPMA. We are also partnering with the Ministry of Health to improve treatment for hepatitis B and with UNICEF to provide essential vaccines to children in rural and poor areas.

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## Faster patient access to new medicines in Taiwan

**Organisations engaged:** Taiwanese government, Department of Health (DOH), Taiwan Food and Drug Administration (TFDA), Bureau of National Health Insurance (BNHI), the pharmaceutical industry

**Industry associations involved:** International Research-based Pharmaceutical Manufacturers Association (IRPMA), European Chamber of Commerce Taipei (ECCT), American Chamber of Commerce in Taipei (AmCham)

**GSK position:** GSK is working with regulatory and health authorities in Taiwan to encourage changes to the registration and reimbursement system for new medicines.

Currently, reimbursement applications can only be made after a product has been approved for marketing. This delays patients' access to new medicines. GSK advocates either an overlapping or a parallel review process, whereby the TFDA and BNHI evaluate innovative medicines at the same time. This would reduce the time span between marketing approval and decisions about national coverage and payment, accelerating patients' access to new medicines while also creating incentives for investment by reducing the time to return on investment.

We worked with the ECCT to file a position paper, and led the IRPMA in its stakeholder engagement on this issue. GSK Taiwan also worked with the local American Chamber of Commerce in Taipei, which supported GSK's position when meeting with various authorities.



## Advocacy on healthcare and disease prevention

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### Global activity

#### Safeguarding timely and unrestricted access to influenza viruses

**Organisations engaged:** World Health Organization (WHO), developed and developing country governments, EU institutions

**Industry associations involved:** EFPIA European Vaccine Manufacturers (EVM), IFPMA Influenza Vaccines (IVS), PhRMA

**GSK position:** The influenza virus is very unstable and can mutate quickly. Governments need to remain vigilant to the emergence of new strains of the virus and must share them freely with other governments to enable the development of vaccines. A framework for the sharing of influenza viruses and benefits, established at the Intergovernmental Meeting (IGM) on Pandemic Influenza Preparedness (PIP), has been running for three years.

In 2007, Indonesia stopped sharing influenza viruses with WHO, insisting on 'benefits' in exchange for access to viruses. In response the international community – including the vaccine industry – mapped out a way to help developing countries prepare for a pandemic. Their response included product donations, technology transfer and tiered pricing.

During 2010 discussions continued around the nature of the benefits which industry should be providing in return for access to viruses, and whether these should be mandatory or voluntary. GSK and other vaccine manufacturers supported the principle of voluntary benefits, chosen by the individual vaccine manufacturer according to its capabilities.

In preparation for a meeting of the PIP/IGM in December 2010, vaccine manufacturers made individual benefit-sharing commitments via the IFPMA. At the meeting, while some progress was made, in that participants appeared to agree to limit the PIP agreement to pandemic influenza viruses and vaccines (excluding seasonal influenza or other viruses), benefit sharing was not discussed. The co-chairs of PIP/IGM will instead discuss possible benefits directly with manufacturers prior to the next meeting in April 2011.

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#### Innovation for diseases of the developing world

**Organisations engaged:** World Health Organization, UK government (Department for International Development, Department for Health, Intellectual Property Office), EU Commission, various other governments and NGOs

**Industry Organisations Involved:** IFPMA, PhRMA, EFPIA, ABPI, BPG, BIO

**GSK position:** In 2009, we contributed to the development of a Global Strategy and Plan of Action (GSPOA) for research and development relevant to diseases that affect developing countries disproportionately. This was agreed by consensus at the World Health Assembly in May 2009. Read our 2009 CR report for more details

In 2010 GSK continued to pursue an approach on developing world healthcare that is aligned with the GSPOA in areas such as working with Product Development Partnerships (PDPs), setting up a patent pool, sharing our compound library and differential pricing. See Access to medicines for more information.

The GSPOA called for the creation of an Expert Working Group (EWG) to look at financing for R&D for the developing world. We provided input to the work of the EWG and supported its report which was presented to the World Health

Assembly in May 2010. This meeting also created a new Consultative Expert Working Group, to progress the work of the EWG and review other options. The membership of this group was agreed by the WHO's Executive Board in January 2011. GSK will seek to constructively engage with this new group directly, and through the IFPMA, as appropriate.

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## Securing financing and establishing a delivery framework for malaria vaccines

**Organisations engaged over time:** African health ministers, Roll Back Malaria (RBM), UK Department for International Development (DfID), UK Parliament's All Party Malaria Group, UN Special Envoy for Malaria

**GSK's position:** RTS,S, GSK's candidate malaria vaccine, is the candidate furthest advanced through clinical development and likely to be the first available malaria vaccine. Read more in the Access to medicines section of this report. This development happens in full partnership with PATH-MVI. If all goes well, the general introduction of RTS,S for infants aged 6-12 weeks should be possible within five years and the vaccine could be filed for young children aged 5-17 months as early as 2012.

In 2010 GSK stated that we will make this vaccine available at a price which covers our costs and generates a small return of around 5%. We have committed to reinvesting any profits back into R&D for next generation malaria vaccines or for other products for diseases of the developing world for second generation vaccines for malaria or other neglected tropical diseases.

We are working with multilateral partners, NGOs, foundations and other stakeholders to create a supportive policy environment for introduction of the vaccine and to ensure that adequate financing is in place. Our goal is to help healthcare systems and others prepare and invest in the necessary capacity and infrastructure, so as part of a comprehensive programme to control and eventually eliminate malaria, implementation can start as soon as the vaccine is approved for use by WHO.

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## US activity

### Investment in chronic disease prevention and treatment

**Organisations engaged:** US Department of Health and Human Services, US Congress, White House, state legislators, governors&rsquo; offices, various state health agencies, The Partnership to Fight Chronic Disease.

**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 to be reformed to better encourage and reward medical research into improved treatments for costly, unmet medical needs such as Alzheimer&rsquo;s disease. Preventing and better managing chronic diseases will reduce overall healthcare costs in the long term.

[Read about the Triple Solution for a Healthier America](#)

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## European activity

### Supporting governments in tackling obesity

**Organisations engaged:** EU national governments, European Commission/European Parliament, World Health Organization

**Industry associations involved:** European Self-Medication Industry (AESGP), Pharmaceutical Group of the European Union (PGEU), Standing Committee of European Doctors (CPME) and national associations

**GSK position:** European health ministers and the European Commission have set a target to reverse the increasing number of overweight and obese people in Europe by 2015.

Promoting healthy diets and physical activity can help prevent people from becoming overweight or obese, and can reduce the associated social, economic and public health impact.

GSK believes that additional, complementary approaches – including over-the-counter weight loss medicines such as alli - must also be considered by policy makers if they are to reach the 2015 target and ensure that overweight and obese people have the support required to manage their weight and live healthy lives. Read more about our over-the-counter weight loss medicines.

We urge policy makers to consider:

How healthcare professionals – including doctors, pharmacists and nurses – who come into contact with overweight and obese individuals can best support sustained, healthy weight loss.

- How to review the market for weight loss products and better enforce EU and national laws, to give consumers confidence that such products have the appropriate scientifically robust evidence-based safety and efficacy profile
- How to ensure consumers have the information and the tools they need to manage their weight successfully.

Our advocacy work also includes campaigns and events to raise awareness and help change public perceptions and influence policy and funding decisions. In 2010 this included sponsorship of the first-ever European Obesity Day. Events included an awareness-raising picnic and cooperation with the Red Cross, which ran obesity and healthy lifestyle information points in several cities. An online petition was set up for EU citizens to express their support for the Obesity Day Charter and encourage the European Commission to take action.

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## Tobacco dependence and cessation

**Organisations engaged:** European Commission, EU Member States, European Parliament, WHO, the Tobacco Control Community

**Industry associations involved:** Association of the European Self-Medication Industry (AESGP), Pharmaceutical Group of the European Union (PGEU), Standing Committee of European Doctors (CPME) and national associations

**GSK's position:** Many EU Member States are introducing legislation that requires indoor environments to be smoke-free. We believe that this alone will not help people stop smoking, and encourage governments to ensure their national smoking cessation strategies provide smokers with greater support and motivation to stop.

We support the World Health Organization's Framework Convention on Tobacco Control (FCTC) which includes guidelines for promoting smoking cessation and treating tobacco dependence.

Our advocacy event on smoking cessation, held in the European Parliament in November 2010, brought together the tobacco control community, policy makers, scientists and the pharmaceutical industry to discuss how the new guidelines could be turned into practice.

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## Activity in Asia

Engaging with governments and religious leaders on the use of our products by the Muslim community

**Organisations engaged:** Governments of Indonesia, European Union, United States (Embassy), UK (Embassy), Belgium (Embassy), Indonesian Islamic Council (MUI), Indonesian Halal Certification Agency (LPPOM MUI), Nahdlatul Ulama (NU), and academic and research institutes.

**Industry associations involved:** IFPMA, PhRMA, EFPIA

**GSK position:** In 2009 the Indonesian Islamic Council issued a fatwa that forbade use of our meningitis vaccine, Mencevax, which the Indonesian government had purchased for the mass immunisation of pilgrims to the hajj in Mecca. The fatwa related to the use of pork products &ndash; forbidden for consumption by Muslims &ndash; in the Mencevax production process. This decree posed a threat to public health, because it prevented pilgrims and other Indonesian Muslims from receiving the vaccine.

As a general policy, and in accordance with customers' needs, GSK is in the process of changing, whenever possible, to the use of synthetic or non-animal origin materials for the production of its vaccines, including Mencevax. As part of this process, a new seed lot system has been developed for the production of meningococcus polysaccharides that is based on the use of culture media free from animal&ndash;derived materials, including free from bovine and porcine materials.

In 2010 GSK began to work with the Indonesian government, as well as the governments of EU Member States and the US, to ensure the Muslim community in Indonesia is comfortable using Mencevax. We invited Muslim leaders, government representatives, health experts and scientists to visit our manufacturing sites, and provided them with documentation on our R&D and manufacturing processes to confirm that the vaccine does not contain any traces of pork products.

Our efforts in Indonesia have been successful, and the country's largest Muslim community organisation, Nahdlatul Ulama (NU), has issued a Halal decree on our meningitis vaccine.

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## Advocacy on research practices

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### European activity

European Commission review of the Clinical Trials Directive.

**Organisations engaged:** European Commission, European Parliament, EU Member States, national regulatory agencies

**Industry associations involved:** EFPIA European Vaccine Manufacturers (EVM), European Association for Bioindustries (EuropaBio), national trade associations

**GSK position:** The EU Clinical Trials Directive (2001/20/EC) outlines the procedures that clinical trial investigators in the EU must follow. The European Commission began a review to assess the success of the Directive 's implementation in 2008 and plans to publish its findings, and proposals for revising the Directive, in 2012.

We advocate revisions to the Directive that facilitate high-quality clinical research. Achieving this requires:

- A clear legal framework that avoids duplication of regulatory effort and unnecessary bureaucracy
- High-quality scientific regulatory review and approval processes
- Rapid and reliable review and approval timelines
- Harmonised requirements and implementation across all Member States

Read more about our conduct of clinical trials.

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### Advocacy on the revision of EU Variations Regulations

**Organisations engaged:** European Commission, European Parliament, EU Member States, national regulatory agencies, European Medicines Agency

**Industry associations involved:** EFPIA, EVM, EuropaBio, national trade associations

**GSK position:** Once a medicinal product has been approved for marketing, all changes (for example in the manufacturing processes, or prescribing information) are considered as variations and must be handled according to a complex regulatory framework defined in EU law by the Variations Regulations. However, for historical reasons a large majority of products fell outside the EU legislation and were subject to divergent national rules and procedures. This lack of harmonisation places a significant administrative burden on industry and national regulatory authorities, and adds unnecessary complexity. The objective of the revision of the Variations Regulations was to simplify the legislative framework and harmonise the rules so that they apply to all medicinal products.

GSK welcomed the revision and has advocated a simpler, clearer and more flexible framework for variations which:

- Reduces the number of regulatory events associated with post-approval changes and the associated regulatory burden
- Enables predictability of variations procedure timelines, in order that beneficial changes can be introduced in a timely manner
- Provides a legislative framework which accommodates 'flexible regulatory approaches' as outlined in the ICH guidelines: ICH Q8 on Pharmaceutical Development; ICH Q9 on Quality Risk Management; and ICH Q10 on

Pharmaceutical Quality System.

- Introduces a science and risk-based approach for managing post-authorisation changes
- Facilitates innovation and continual improvement in pharmaceutical manufacturing.

The European Commission has adopted framework legislation and has recently finalised key supporting guidelines which are intended to ensure implementation in a manner which is consistent with these objectives.

As this new legislation is implemented, GSK will provide the European Commission with feedback on its experience of applying the guidelines rapidly and consistently to all nationally approved products.

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## Advocacy on the European Animal Directive

**Organisations engaged:** European Commission, European Parliament, European Member States

**Industry associations involved:** ABPI, EFPIA, Les Entreprises du médicament, France (LEEM), Association Française des Sciences et Techniques de l'animal de Laboratoire (AFSTAL), Groupe Interprofessionnel de Réflexion et de Communication sur la Recherche (GIRCOR/GRICE), Laboratory Animal Veterinary Association (LAVA), Laboratory Animal Science Association (LASA), Federation of European Laboratory Animal Science Associations (FELASA), UK Home Office Liaison Forum (UK HOLOs)

**GSK position:** The European Animal Directive (Directive 86/609/EEC), 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.

In September 2010, the EU adopted a revised European Animal Directive (Directive 2010/63/EU) which places a greater emphasis on the '3Rs' - replacing, reducing and refining the use of animals in research.

GSK believes that any legislation on animal testing must ensure high animal welfare standards, while supporting an environment that allows research that leads to new medicines and vaccines to meet patients' needs. We welcome the revised Directive and its requirements, many of which are already integrated into our current practices. We are working with trade bodies to ensure consistent transposition into national legislation.

[Read more on our use of animals in research](#)

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## 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 welcomes the new approach to pharmacovigilance regulation in the EU, approved by the European Parliament in September 2010. The new regulation amends the existing EU framework on pharmacovigilance provided in Regulation (EC) No 726/2004 and Directive 2001/83/EC.

When fully implemented in July 2012, the new Regulation should allow pharmaceutical companies and regulators to focus on evaluating product safety rather than on compliance with unclear and complex regulatory demands.

We believe that the following are essential for the legislation's advantages to be fully realised:

- Harmonised implementation across Europe
- The soonest possible launch of a fully functional 'Eudravigilance' database that collates adverse event reports from across Europe, under a single set of rules.

GSK will continue to work through trade associations, and with regulators where appropriate, to facilitate this and to advise on the publication of clear and unambiguous guidance for the pharmaceutical industry on how to comply with the Regulation.

## Advocacy on patient safety

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### 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 into the US unless they have safety and cost savings certifications from the Secretary of Health and Human Services. Periodic legislative attempts to remove the safety and savings certification requirements aim to make 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 programmes in the US

Read about our advocacy on US healthcare reform.

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### European activity

Enhancing patient safety through harmonised serialisation of pharmaceutical products in Europe

**Organisations engaged:** Patient groups, European Commission, European Parliament, EU Member States, wholesalers, pharmacists, health insurers

**Industry associations involved:** EFPIA, local pharmaceutical trade associations, the Association of the European Self-Medication Industry (AESGP), EuropaBio

**GSK position:** The pharmaceutical supply chain in Europe is complex, with millions of packs moving around the region each year via numerous wholesaler intermediaries and traders. This creates a risk that counterfeit products enter the legitimate supply chain and makes detecting and tracing counterfeit medicines difficult. The World Health Organization has identified trade 'involving several intermediaries and free trade zones' as a key driver of counterfeiting activity.

In December 2008, the European Commission introduced a proposal to tighten supervision of the European supply chain and to mandate the introduction of safety features aimed at tracing and authenticating pharmaceutical products. A key outcome of the Commission proposal is likely to be the introduction of 'serialisation', whereby unique product identification codes are applied to prescription medicines to allow tracking and authentication prior to dispensing to the patient.

GSK welcomed the European Commission's plans and during 2010 we worked with others in the industry to ensure that two elements – which we believe are central to enhancing patient safety – are reflected in the final European

framework namely:

- The need for a harmonised approach across Europe:

A standardised approach to identification and verification of medicines across the EU is essential to allow a pharmacist in any EU member state to check whether the pack has been dispensed before (helping them to detect duplicate, counterfeit products in the supply chain), whatever its country of origin. Without standardisation, identification and verification systems will differ between countries, making it more difficult to identify products originating in other countries. Around 150 million packs of medicines are currently parallel traded (bought from pharmaceutical companies in one member state and sold in another) each year within the EU.

A system limited to national schemes would ignore the cross-border nature of counterfeiting and the principle of a single market.

- Support for a serialisation system based on a 2D Data Matrix and GSI Standards:

The 2-D Data Matrix (ECC-200) is currently the most efficient and effective data carrier available, capable of meeting the needs of all stakeholders in the pharmaceutical supply chain. It is highly reliable, can be quickly read and enables a large amount of data to be stored in a small space, as compared to other methods. It is the only data carrier that could be implemented on all products within three to four years at a reasonable cost.

The proposal will be voted on by the European Parliament and Council under the co-decision procedure in the first quarter of 2011. Thereafter, GSK and others in the pharmaceutical industry will continue to advocate the need for harmonised implementation of the proposal across Europe.

[Read our position statement on counterfeiting](#)



# Advocacy on intellectual property rights

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## Global activity

### Access and benefit sharing and a disclosure obligation in patent law

**Organisations engaged:** Secretariat to the Convention on Biological Diversity (CBD), Ad Hoc Working Group on Access and Benefit Sharing, UK Department for Environment, Food and Rural Affairs, DG Trade (European Commission), national European governments, US government, World Intellectual Property Organization and World Trade Organization

**Industry associations involved:** BIO, BPG, EFPIA, ICC, IFPMA, PhRMA

**GSK position:** In October 2010, Parties to the Convention on Biological Diversity (CBD) adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

GSK supports the CBD in its objective 'to provide fair and equitable sharing of the benefits arising from the use of genetic resources'. However, we have always argued that it is not possible to generalise about the role that 'genetic resources' play in biomedical research or the value of any particular material to any particular project or product.

Our view on the Protocol going into the last round of negotiations was that a careful balance needed to be struck, with the interests of all stakeholders taken into account. Go too far one way, and society risks hampering the search for medicines and vaccines to treat and cure diseases such as cancer, HIV/AIDS and malaria. Go too far the other way, and the legitimate interests of countries and communities from where the genetic resources are sourced could be undermined.

The negotiated Protocol is recognised as a compromise agreement, which leaves several issues open to interpretation by governments. We are however pleased that the negotiators did not mandate the introduction of a disclosure obligation, whereby patent applications would have to disclose the origin of genetic resources used in an invention. Such an obligation would have created major legal and commercial uncertainties for researchers and companies developing products using genetic resources, discouraging innovation and ultimately leading to fewer benefits to share.

GSK will work to ensure that the Protocol is implemented in a balanced way by countries that decide to adopt it.

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## 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 Senate has made progress in drafting legislation that provides meaningful patent reform while preserving the incentives necessary to sustain innovation and spur the creation of high-wage, high-value jobs. Thoughtful compromise on key issues, including post-grant review and damages, should allow the bill to move further through the legislative process.

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.

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## European activity

### Creation of a UK Patent Box to stimulate UK-based investment by GSK

**Organisations engaged:** UK government (HM Treasury and the Department for Business, Innovation and Skills)

**Industry associations involved:** Confederation of British Industry (CBI), The Hundred Group, Association of the British Pharmaceutical Industry (ABPI), BioIndustry Association (BIA)

**GSK position:** In December 2009, the Labour government then in power announced that it would introduce a Patent Box in the UK, to provide a 10 per cent tax rate on income attributed to intellectual property that is beneficially owned in the UK. The idea of creating a Patent Box came from GSK, supported by other companies and trade associations, to make the UK a more attractive location for investment in R&D and pharmaceutical manufacturing. In November 2010, the coalition government announced that it will proceed with these plans, with the aim that the Patent Box will take effect from April 2013. Details regarding implementation are being discussed as part of a consultation.

GSK has welcomed the government's proposals to establish a Patent Box. Its successful introduction will enable us to make several new investments in the UK. Read more in our press release .

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### Detention of patent-infringing products as they transit the EU

**Organisations engaged:** European Commission, WTO

**Industry associations involve:** EFPIA, AIM

**GSK position:** In March 2010, the European Commission launched a review of EC Customs Regulation 1383/2003 which, among other provisions, allows European customs officials to detain goods, including those in transit, if they suspect they may infringe an EU patent or trademark.

Implementation of the Regulation has historically been highly controversial because there have been reported incidents of products being detained, and either destroyed or returned to the exporting country, even though they were in transit through the EU and did not infringe any patents in the exporting or importing country. In May 2010, Brazil and India filed complaints with the World Trade Organization that the Regulation contravenes international trading rules by impeding trade in legitimate products.

GSK supports the objective behind EC Regulation 1383/2003, namely to safeguard intellectual property rights, innovation and brand protection. We believe that every effort should be taken to stop counterfeit healthcare products from entering and transiting the EU.

However, we recognise that the public health arguments supporting detention of counterfeit products do not necessarily extend to patent-infringing products. We would not object if the current 'in transit' provisions relating to patents are removed from the EU Regulation, subject to two considerations:

- The Regulation should retain the provision that allows companies to record their patents so customs can respond to suspected patent-infringing products destined for entry into the EU. GSK has not recorded any patents in this way for several years, but we would like to retain the option to protect our European patents from infringement
- Patent and trademark holders should be able to use any information supplied by officials relating to suspect in-transit goods to support infringement proceedings in the importing or exporting country. This would require a change to the Regulation.

# Political contributions and lobbying expenditures

GSK does not make corporate political contributions. Here we disclose voluntary political contributions made by our US employees through a Political Action Committee and our Federal lobbying expenditure costs, as well as costs of lobbying EU institutions.

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## Political Action Committee contributions in the US

The GSK employee Political Action Committee (GSK PAC) facilitates voluntary political contributions by eligible employees, in accordance with the Federal Election Campaign Act

The PAC is not controlled by GSK. It is run by a governing board of participating GSK employees from across the company. 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.

As required by law, PAC contributions are reported to the Federal Elections Commission (FEC) We also report state PAC contributions in line with applicable state laws. In 2010 the GSK employees' PAC contributed \$824,000 – 54 percent to Republicans, 45 percent to Democrats and 1 percent to unaffiliated or other party candidates running for state and federal offices.

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## Lobbying expenditure

### Europe

GSK is a signatory to the European Commission's 'code of conduct for EU lobbyists' and the voluntary 'register of interest representatives'. In the 'register of interest representatives', we declared the costs associated with lobbying of EU institutions to be in the range of €750,000–€800,000 in 2010. This includes running of the Brussels advocacy office, salaries, external events, travel and accommodation, consulting costs 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 \$6,070,000 in federal lobbying activities in the US during 2010. 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.

## Patient advocacy

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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 care-givers' lives. Some carry out vital research into the causes of and potential treatments for specific conditions.

Patient groups are important stakeholders for GSK and we engage with them as part of our commitment to be a patient-focused company. We share their belief that healthcare systems should focus on preventing, treating and managing disease, and that patients should have access to quality medicines, services and information on disease.

Our relationships with patient groups are mutually beneficial. They help us to better understand patient needs and their illnesses, which in turn guides our R&D, while our support helps them to make patients' voices heard in the healthcare debate. Together we strengthen support for patients throughout their illness, from diagnosis to chronic treatment and end-of-life care.

We support patient groups in disease areas such as Alzheimer's disease, asthma, cancer, diabetes, epilepsy, HIV/AIDS and multiple sclerosis by:

- Providing funding to support day-to-day running costs
- One-off donations to help patient groups conduct a specific event or activity, for example a breast cancer awareness day
- Offering educational support
- Training staff in management skills and disease education
- Working together on disease awareness/prevention projects.

Our engagement is not designed to market our products but to support our public policy work.

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## Managing engagement with patient groups

In 2010 we established a new group responsible for sharing best practice patient advocacy across GSK. The new group seeks to ensure consistency in our relationships with patient groups worldwide. We also opened a new US centre of excellence dedicated to coordinating our engagement with patient advocacy groups and professional associations at the national, regional and state levels.

Where our involvement with a patient group involves funding, our relationship is defined by a written agreement specifying how the group will use our contribution to benefit its members.

All GSK employees who work with patient groups, and relevant third parties must follow our patient advocacy guidance and Standard Operating Procedures (SOPs) (see box below), and abide by applicable laws and regulations. In Europe GSK is working within EFPIA helping to update its code for working with patient groups. The revised code will follow many of GSK's own commitments in this area including our move to disclose all funding to patient groups. We provide training so that employees understand our requirements.

Employees in all regions can learn about our patient advocacy activities by accessing a specific part of our company intranet. In Europe, we also publish a newsletter to raise employee awareness about internal and external

developments relating to patient groups.

## Working with patient groups

Our Standard Operating Procedures state that:

- Access to medicines
- 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 some circumstances (see Encouraging independence, below).
- 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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## Encouraging independence

We believe that patient groups should be independent. We encourage them to seek financial support from as wide a range of organisations as possible, and hold workshops on how to make funding applications. 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 or the regional general manager or head of regional government affairs.

# Transparency

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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, Asia Pacific, 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 the majority of industry codes of practice that require at most a list of the groups funded.

In the US, we require any non-profit organisation seeking GSK funds to consider how they will disclose GSK's support. We voluntarily disclose our funding support on our US website and update this information quarterly. We also ensure that our support is in compliance with all applicable laws and regulations, including the guidelines and standards set by the American Medical Association (AMA), US Food & Drug Administration (FDA), the Pharmaceutical Manufacturers of America (PhRMA) Code, as well as other leading medical organisations.

Detailed information for GSK Australia and Canada can be found on their websites.

# Understanding patients

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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.

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 patient advocates together to discuss health policy concerns and develop new skills and/or ways to expand their influence. PALS can also give patient advocates the opportunity to learn about GSK and tell the company how it can better support their work. In 2010 we were involved in running a total of ten summits: four in European countries, one in Japan and five throughout the US (including a national PALS in North Carolina, and four regional PALS in Colorado, Michigan, New England and Texas).

Discussions at the 2010 PALS meetings in Europe and Japan focused on:

- Improving the quality of care (Netherlands)
- Clinical trials and cross-border healthcare (Latvia)
- The value of innovation (Germany)
- Clinical trials, e-health and the relationship between patient groups and the pharma industry (Switzerland)
- Providing more accurate and easy to understand healthcare information (Japan)

In the US, discussions at the 2010 PALS focused on a broad range of issues, including:

- The impact of healthcare reform legislation on the health of people in minority groups
- Implementation of the Patient Protection and Affordable Care Act
- Best practices in mental health, prevention and wellness for military personnel and their families
- Use of social media and other technology to reach more people who are not being served by the current healthcare system in culturally sensitive and appropriate ways.

The US national PALS meeting, held in April, focused health information technology. Over 100 participants from 31 states and 75 patient advocacy groups discussed ways that technology can be used to improve access, engagement and empowerment. Speakers included the President of our North American Pharmaceuticals business, as well as other leading national healthcare issue experts from the US.

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## European Patient Forum

In May 2010 GSK co-sponsored the European Patient Forum's annual conference in Brussels with other healthcare companies Pfizer, Novartis and Amgen. This brought together approximately 70 patient groups and other stakeholders from across Europe to exchange ideas about improving healthcare and increasing the involvement of patient

organisations in the area of health technology assessment (HTA). HTA is a type of policy analysis that examines the medical, economic, social and ethical implications of the value and use of medical technology in healthcare.



## Advocacy in 2010

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Here we describe some of the training and support activities we undertook in 2010 in partnership with patient groups

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### Working with patient groups on clinical trials

We are increasingly working with patient groups to obtain input into GSK clinical trials. Input from patients can help us improve clinical trial design and the informed consent process, and enhance the recruitment process to include a more diverse population. These factors help us to support clinical trial recruitment and retention.

We have been collaborating since 2008 with PatientPartner to improve communication between patients involved in clinical trials and the professionals running these studies.

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### Training and awareness for patient groups

GSK introduced online training modules for patient groups in Italy and Spain in 2010. They help local and national patient groups increase their understanding of a variety of topics ranging from how to access funds to understanding health technology assessment (HTA). We aim to introduce online training in other countries in 2011.

We also began producing a newsletter that provides patient groups in Germany with useful information on healthcare. We plan to do the same in other markets from 2011.

In the US, we have an external website that informs the patient advocacy community about issues, activities and events that affect them.

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### Involvement in EU working parties

In 2010 GSK became a member of three European working parties that aim to strengthen the patient's voice in the healthcare debate:

**Genetic Alliance UK:** an 18-month project to examine how patients and their families perceive the balance between the risks and the benefits of new medicines. We are one of six pharmaceutical companies that has provided funds for the project, and a GSK representative sits on the steering group to give an industry perspective.

**The Innovative Medicines Initiative Joint Undertaking (IMI JU):** a unique, pan-European public-private partnership that aims to foster collaboration between all stake holders, including large and small biopharmaceutical and healthcare companies, regulators, academia and patients. GSK is a member of an EFPIA consortium associated with a proposed education initiative that aims to enhance patient awareness about pharmaceutical. Consortium members will contribute to educational activities and help to govern the project.

**EGAN-EFGCP Patients' Roadmap to Treatment Working Party:** a neutral, pan-European, multi-stakeholder initiative that could help to provide patient organisations with a training syllabus on drug development, with emphasis

on clinical studies, so they can:

- inform their patient colleagues about topics of clinical studies and new treatment development including study results
  - advise the pharmaceutical industry in protocol development, study management and experiences made by patients during clinical studies
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## Improving community awareness in the US

In 2010 we continued to work with US National Football League team the Washington Redskins to help its fans improve their health and raise awareness about the burden of chronic diseases. The programme focused on collaborating with local government, schools and healthcare organisations to prevent childhood obesity, cardiovascular disease in women, and breast cancer. Leading the team and fans was Washington Redskins Quarterback & Health Ambassador Donovan McNabb who provided health messages to tackle chronic diseases, which will help to save lives and lower healthcare costs.

## Our work with communities

We invest in community partnership programmes that seek to improve access to medicines and healthcare around the world. We aim to make a real difference to communities by working with our partners to find innovative solutions to healthcare challenges.

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We believe that business has an important role to play in society and the contribution we make through our community investment is a key element of this. We aim to use our resources to deliver value to both communities and to our business.

Our support includes donations of time, money, expertise and medicines. Most of our investment is made through specialist non-profit organisations, which are best placed to understand local community needs and target resources effectively. We partner with and support organisations whose goals and objectives reflect our mission to improve the quality of human life.

Our programmes include strategic global initiatives, designed to tackle diseases of the developing world across multiple countries. We also support local programmes that are tailored to the specific needs and challenges of our many different markets. These are focused on the issues of health education, access to medicines and science education.

We aim to maximise the benefits of our community investment by selecting projects that are relevant to our business and enable us to use our expertise and resources. As well as benefiting communities, our investment strengthens our business by improving our reputation, boosting employee morale and helping us build relationships based on mutual understanding with a range of stakeholders.

Improving access to healthcare is one of the main priorities for our community investment. We also invest in programmes that create opportunities in education and economic development. Support for science education is particularly important because of the growing shortage of science graduates in some of our markets. Investing in education will help us to ensure the long-term sustainability of our business and our commitment to improve access to medicines and healthcare. We support a small number of arts and environmental initiatives, particularly those with a health focus.

We encourage employees to get involved because this benefits the organisations and charities we support, contributes to employees' personal development and supports our reputation. Every employee at GSK is entitled to one paid day off each year to volunteer in the community. We also run PULSE which enables high-performing employees to share their expertise and learn from our NGO partners through 3–6 month placements.

We want our support to bring long-term sustainable benefits. We set goals for all our projects and ask our partners to report progress against them annually. We also help community organisations to plan for the time when our support finishes and help them win funding from other sources.

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## Global programmes

### Approach

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In developing countries millions of people continue to suffer and die from preventable or treatable diseases. Our global health programmes are designed to improve the health and quality of life for people in these communities through provision of medicines, education and advocacy, and investment in disease prevention and healthcare infrastructure. Our global programmes are long-term commitments, designed to be scaleable, replicable and sustainable.

By working in partnership with NGOs and leading health organisations, we believe it is possible to achieve significant and long-lasting improvements in healthcare. This section profiles one of the most ambitious programmes we are involved in – the Global Alliance to Eliminate Lymphatic Filariasis, a partnership to eliminate a disfiguring and debilitating tropical disease by contributing towards the world's largest-ever drug donation.

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### In focus: the Global Alliance to Eliminate Lymphatic Filariasis – an ambitious partnership

Hija from the village of Uyombo Vituka in Morogoro region of Tanzania completed his primary education in 1983. He couldn't afford to attend secondary school but was able to find work to help support himself and his family. All that changed in 1988 when he contracted lymphatic filariasis (LF).

LF is a debilitating disease which leads to severe swelling of the limbs, breasts and genitals and regular attacks of fever. It made walking very difficult for Hija and left him too ill to work. And then in 2008 a new programme was launched in Morogoro. Hija received two drugs – albendazole made by GSK and Mectizan made by Merck – which were being administered as part of a drug donation programme to eliminate LF in Tanzania. After taking the drugs, Hija's symptoms improved: the swelling reduced and he suffered less fever. He was soon able to walk again and help cultivate the family's land, and earn money to support his family.

LF is a disease that many in the developed world have never heard about. It is a parasitic disease transmitted by mosquitoes, which affects 120 million people in 83 countries. For communities living in tropical countries its effects can be devastating, making it hard to attend school or hold down a job and resulting in stigma and discrimination for many sufferers. Since 2000 the prospects for these communities have improved significantly, thanks to a unique collaboration – the Global Alliance to Eliminate Lymphatic Filariasis. Through the Alliance, GSK and its partners hope to completely rid the world of LF so that millions of people never have to experience the disabling effects of this disease.

Ten years on from the launch of the Alliance, we have donated almost two billion tablets of albendazole and hundreds of millions of people have been treated through mass drug administrations in 54 countries. The effects have been far reaching. Several counties including Egypt, Togo, Zanzibar, Sri Lanka, the Dominican Republic, Comoros and several Pacific Islands have completed treatment programmes and are conducting evaluations to confirm that the transmission of LF has been eliminated in most areas of these countries. Recent research papers show that in the first eight years of the programme, more than ten million cases of LF were prevented and economic benefits equivalent to \$24 billion have been achieved. These include savings to health systems and the avoidance of loss of income due to the disabling effects of LF.

The Global Alliance is built on a partnership approach, bringing together a complex network of Ministries of Health in LF-endemic countries and 40 other organisations from the public and private sectors, academia, government bodies and non-governmental organisations. GSK works particularly closely with the World Health Organization, which is the lead partner in the Alliance and responsible for working with endemic country governments to ensure the drug is delivered safely and effectively through mass administration programmes.

“Partnership has been absolutely critical to the success of this landmark public health programme,” explains David Molyneux, Emeritus Professor at the Liverpool School of Tropical Medicine. “Members of the Alliance have worked together to overcome technical challenges, to exchange experiences and ideas, to obtain the support of governments in endemic countries and to secure financial support from donors around the world.”

At GSK, our work with so many different partners at all stages of delivering the drug has taught us a lot about the wider barriers to healthcare in the developing world, such as poor physical infrastructure, over-stretched hospital networks and a shortage of trained healthcare workers. This has influenced our approach to all our community investment and given rise to a range of programmes designed to overcome these barriers.

Our involvement in the Global Alliance also means a major commitment of resources, manufacturing skills, capacity and logistics. Albendazole is made under world-class manufacturing conditions in dedicated lines at our manufacturing plants in South Africa and in India. Each requires teams of employees working every day to produce, pack and ship the finished product all over the world. Complex transportation arrangements require dedicated staff to organise and track deliveries. And we need to put in place processes for oversight of medical issues that might arise from time to time when the drug is administered.

The GSK factory manager in Cape Town says: “We may be giving away this drug as part of our community programmes, but we treat every batch we manufacture, every box we ship as professionally and to the same high standards as though it was going to a paying customer anywhere in the world.”

And our commitment is growing.

As well as helping to prevent LF, albendazole is also able to treat intestinal worms (known as soil-transmitted helminths). Intestinal worms cause more ill health in school-aged children than any other infection, impeding physical growth and cognitive development, so the LF programme has had an additional positive impact in the community. After discussions with the WHO and other health experts, we have committed to expand our donation of albendazole to enable treatment of all school-aged children in Africa against intestinal worms from 2012 onwards. “The new donation will have a major impact on children’s educational performance, physical wellbeing, school attendance and nutrition,” says David Molyneux.

The new commitments will bring fresh challenges to our manufacturing plants which will need to produce significantly more albendazole – but as our factory says: “What a nice problem to have – just think of the positive impact this will have on the schooling and education of millions of children and the savings in resources it will bring to over-stretched health systems across Africa. My team and I will do everything in our power to make this work.”

The scourge of LF is being tackled head on in Hija’s community, with the prospect of elimination a real possibility by 2020. And those efforts will soon be joined by a new programme to relieve the misery caused among Africa’s school children by intestinal worms.

## Performance

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Highlights from some of our key global programmes during 2010 are outlined below. More information is available on our website, where you can also view our programmes by region using our interactive map.

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## Investing in developing world healthcare infrastructure

### **The issue**

Millions of people in the world's Least Developed Countries (LDCs) lack access to basic healthcare services.

### **What GSK is doing**

In 2009 we announced GSK's commitment to becoming a partner in finding solutions to healthcare delivery by reinvesting 20% of profits (from our medicines and Consumer Healthcare products) in Least Developed Countries (LDCs) into local healthcare infrastructure. This amounts to £5m based on profits made in 2009 and 2010.

### **Results in 2010**

- To date we have committed £1.8m to a number of projects including: support for maternal and child health in Sudan, Ethiopia and the Democratic Republic of Congo, expanding a network of nurse-run clinics to improve access to essential medicines in Rwanda; and improving access to water and sanitation in Cambodia and Burma (Myanmar).
- In January 2011 we announced a global partnership with AMREF, Save the Children and CARE International to build on these initial projects. Our aim is to establish regional Healthcare Infrastructure Partnerships (HIPs) through which the 20% profits will be invested. The goal of the HIP is to strengthen the health workforce in LDCs, with a focus on frontline health workers in the most rural and marginalised communities. Through this structure, new initiatives in Yemen, Niger, Sierra Leone, Angola, Zambia, Mozambique, Bangladesh, Nepal and Cambodia have been prioritised for implementation in 2011.

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## **Personal Hygiene and Sanitation Education programme (PHASE)**

### **The issue**

Every year more than two million people die of diarrhoea-related disease, mostly children in developing countries.

### **What GSK is doing**

We established PHASE in 1998 to reduce diarrhoea-related disease by encouraging school children to wash their hands.

### **Results in 2010**

PHASE reached 1.4 million children in 16 countries, meeting our goal to reach over one million children. Highlights included:

- 'Fit for School', launched in the Philippines combining PHASE with a campaign to promote regular tooth brushing
- Our PHASE partners in India participated in Global Handwashing Day. Over 3,000 families in the Mumbai slums received a visit from school children conveying the importance of hand washing
- PHASE in Uganda was extended to five new districts. So far, it has helped reduce school absence from 24 % to 14 % participating districts.

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## **African Malaria Partnership**

### **The issue**

Every year up to 500 million people are affected by malaria and 800,000 die from it, mostly in sub-Saharan Africa.

### **What GSK is doing**

Our African Malaria Partnership aims to improve access to treatment and prevention of malaria in sub-Saharan Africa through education of communities and training to help community health volunteers diagnose cases of severe malaria.

## Results in 2010

Highlights from our partnership with Save the Children to reduce the risk of malaria outbreaks in communities affected by flooding in north-east Kenya included:

- Training to help 32 health professionals improve malarial case management
  - Indoor residual spraying to control malarial outbreaks in 336 households, 14 schools and one prison
  - Distribution of 5,120 long-lasting insecticide-treated nets
  - Recruiting and training new community health volunteers.
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## Disaster response

### The issue

Natural disasters such as earthquakes, hurricanes and floods have a devastating effect on many communities each year.

### What GSK is doing

We provide humanitarian assistance to those affected by emergencies and natural disasters. We donate cash and supplies of our products via humanitarian aid organisations experienced at responding quickly to such events.

### Results in 2010

- We gave £250,000 to help the British Red Cross provide emergency safe water and sanitation facilities for thousands of people affected by the earthquake in Haiti
  - We gave £170,000 in cash contributions to support communities affected by the earthquake in Pakistan
  - We donated medicines, including 95,000 doses of hepatitis A vaccines, antibiotics, analgesics and more than 6,000 dental hygiene kits to support communities affected by the earthquake in Chile.
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## Local programmes

### Approach

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We support communities in the many different countries in which we operate. Our programmes are aligned with our goal of supporting access to medicines and healthcare and improving education but are designed to fit local circumstances and cultures.

Local priorities vary from community to community and population to population, but there are often common challenges to address. Improving maternal and child health is one such issue, which is relevant to both developed and developing countries. This is a priority issue for GSK because by helping to improve the health of mothers and their families, we can improve the health and economy of whole communities and future generations.

Below, we focus on some of the GSK local programmes aimed at improving maternal and child health. These are aligned with and support the contribution we make in

Our other key local programmes during 2010 are summarised on the performance tab.

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### In focus: improving maternal and child health

“Chester County is one of the wealthiest counties in Pennsylvania. But an assessment conducted after a major obstetrics hospital closed its doors noted that there were real disparities in access to care and health outcomes between white women and black or Hispanic women, with the latter having significantly poorer birth outcomes,” says Pam Breyer, Executive Director of the Maternal and Child Health Consortium that works to improve the health of families in Chester County, US.

The Maternal and Child Health Consortium is a three-time winner of GSK IMPACT awards programmes that recognise local organisations in the UK and US which have measurably improved access to healthcare for disadvantaged groups. Winners receive a grant (£25,000 in the UK and \$40,000 in the US), to help them continue and extend their programmes. “With support from GSK and our other donors, we’ve been able to help thousands of uninsured women obtain health coverage, provide proper nutrition to their families and access mental health services and other support,” says Pam Breyer.

Women and children are often disproportionately affected by poverty and lack of access to healthcare, so improving maternal and child health is a priority shared by many IMPACT award winners. Helping these groups can have knock-on benefits for families and whole communities, contributing to the health and wellbeing of future generations.

One25, an organisation working with street sex workers, is an IMPACT award winner in the UK. Through its drop-in centre, outreach van and mother and baby house in Bristol, One25 provides practical and emotional support to help women break out of the cycle of sex work and substance misuse, and to look after their children.

“Winning the award has been such a morale boost for the whole team and the vulnerable women we support,” says Helen Hill, One25 Senior Fundraising Manager. “One25 is under-funded and yet more and more women are asking for our help. With this award we were able to replenish our financial reserves. The positive media coverage raised



awareness of the needs of the women we serve, and enhanced our credibility with potential funders.”

GSK is committed to giving more than just money, and One25 is one of an increasing number of IMPACT award winners to benefit from our capacity building support. “Our management team received leadership, networking and fundraising skills training, which has been very beneficial,” says Helen Hill.

Capacity building like this is a key component of our approach to community investment, helping to strengthen the organisations we support and give them the skills they need to operate effectively and sustainably. Many of our local programmes help to build skills and capabilities at an individual level too. For example, GSK is supporting the Pro Mujer programme in northern Argentina which works with low-income women who do not have access to affordable financial services or healthcare. Pro Mujer provides training and small loans to help women set up their own businesses and provides them with access to affordable healthcare services. Estela Carmen Cuevas, a mother of five, has been part of Pro Mujer for four years, benefiting from loans of \$965. “During my time with Pro Mujer, I have developed my business and improved my health,” she says. “But my greatest achievement has been personal. I’ve developed myself as a person and built up my confidence.”

Improving maternal and child health was a priority for many of our other local community investment projects during 2010. Several of our current programmes are focused on reducing the number of women and infants who die during childbirth. For example, in Vietnam we are supporting training for birth attendants in rural villages and in Sudan we are funding motorcycle ambulances to take pregnant women experiencing childbirth complications to hospital.

We also worked at a global policy level, supporting efforts to reach the UN’s Millennium Development Goals on child mortality and maternal health by 2015. We contributed to the development of the UN Secretary General’s new Global Strategy on Women’s and Children’s Health that will mobilise resources from the private and public sectors. Our commitment to expand our albendazole donation to help tackle intestinal worms for school children in Africa is a contribution to that strategy.

## Performance

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We have community investment programmes in the majority of the 114 countries we work in. Below is a small selection of the programmes we supported in 2010 that show the breadth and depth of our work. They are grouped by theme, to illustrate some of the goals we work towards through our community investment.

More information is available on the communities section of our website, where you can also view our programmes by region using our interactive map.

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## Investing in skills and building capabilities

To ensure that patients in developed and developing countries receive the best care, there is a need to improve the skills, knowledge and capabilities of people working in the healthcare system. This includes professionals such as doctors and nurses, as well as people like community health workers. These people provide a wide range of services, such as respite and therapeutic treatment for patients, as well as promoting basic health education.

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### Case study: home nursing for children in Greece

#### The issue

Around 270 children in Greece develop cancer every year. In many cases they have to attend hospital each day for medical care and follow-up. This can disrupt school attendance and affect parents’ attendance at work.

#### What GSK is doing

Working with Floga, a parent association for parents of children living with cancer, we have set up the first

home-based nursing programme in Greece to help improve quality of life for children living with cancer.

### Results and progress in 2010

- Specially-trained nurses made over 1,000 home visits, improving treatment for children and reducing the burden on outpatient care
- A public awareness and advocacy campaign helped to secure donations from other companies, including free transportation for the nurses from car hire firm Avis.

### Examples of other programmes we support:

- WellChild – support for sick children and their families across the UK
- Xintu Centre for Health Promotion – a reproductive health education programme for migrants and their families in Shanghai, China
- Hole in the Wall Association – medically based therapeutic camps for children with serious illnesses and life-threatening conditions in Europe and the US.

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## Improving science education

In the UK and US, the numbers of young people choosing to study science subjects are falling, and many students lack proficiency in reading or mathematics. As a result, both countries face a significant skills shortage. GSK has a longstanding history of supporting initiatives that promote science, especially to young people, and help to improve scientific education.

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### Case study: Opportunity Scholarship (US)

#### The issue

It can be difficult for people who experience adversity to continue their education and achieve their potential.

#### What GSK is doing

Our Opportunity Scholarships are for people who have overcome adversity, including physical and sexual abuse, serious illness and personal loss, yet have pursued an education as a means of changing their lives. The scholarships are available in North Carolina and Philadelphia, and provide the financial support to help people continue their education.

### Results and progress in 2010

GSK awarded 11 scholarships in 2010 for a total of more than \$106,000. These recipients who have overcome adversity will seek degrees in public health, nursing engineering, criminal justice, and business

### Examples of other programmes we support:

- Scientists in Sport - inspiring young people into science in the run-up to the London 2012 Olympic Games
- Science in the Summer - a free education programme designed to get young people in Pittsburgh, Pennsylvania, Greater Philadelphia and North Carolina interested in science.
- Read more on our education programmes in the UK and US.

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## Investing in healthcare infrastructure to improve access to medicines

GSK invests in programmes that build and support healthcare infrastructure. We strive to be a catalyst for change, actively seeking new ways of delivering healthcare in some of the world's most challenging environments.

## Case study: improving access to vaccines in Mumbai

### **The issue**

Two thirds of the 16 million people in Mumbai live in slums. Health indicators of adults and children are low and immunisation coverage is poor.

### **What GSK is doing**

We are working with PATH, an NGO, community groups and other partners to improve vaccine coverage for people living in the Mumbai slums. The 18-month project will work within the existing health system to develop a sustainable model for the delivery of immunisations, which can be replicated in other areas. The project results will be carefully evaluated to help identify the key factors for improving immunisation programmes in poor urban environments.

### **Results and progress in 2010**

- The programme was approved and endorsed by the local government for implementation in January 2011. The number of Health Posts - public health service delivery units - has increased from three to five
- Recruitment and training of programme managers and field coordinators to run the project has been completed
- Initiated baseline evaluation to assess current healthcare provision and immunisation practices

### **Examples of other programmes we support:**

- Pittsburgh Mercy Foundation's Operation Safety Net – supporting healthcare outreach for the homeless
  - Travel packs – providing essential medicines and over-the-counter products for physicians assisting some of the world's poorest people.
  - Sabongidda-Ora Vaccine project – a 10-year peer-reviewed project to raise childhood immunisation in Nigeria by providing vaccination services, basic health education and clinical care.
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## Our community investment

Our global community investment was £222 million (\$345million) in 2010 compared with £163 million (\$254 million) in 2009. We value donations at cost (average cost of goods) rather than wholesale acquisition cost (WAC), a measure used by some other companies, as it is a more accurate reflection of the true cost to GSK.

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 benchmarking purposes we also report the WAC value of our donations. The total value of giving in 2010 using WAC for products was £564 million (\$874million) compared with £467 million (\$729 million) in 2009.

Our giving in 2010 was 36% higher than in 2009 due to the expansion of our product donations for the US Patient Assistance Programs, albendazole for Lymphatic Filariasis, and the donation of H1N1 vaccine, plus increased cash grants for HIV and AIDS and the 20% reinvestment initiative for Least Developed Countries.

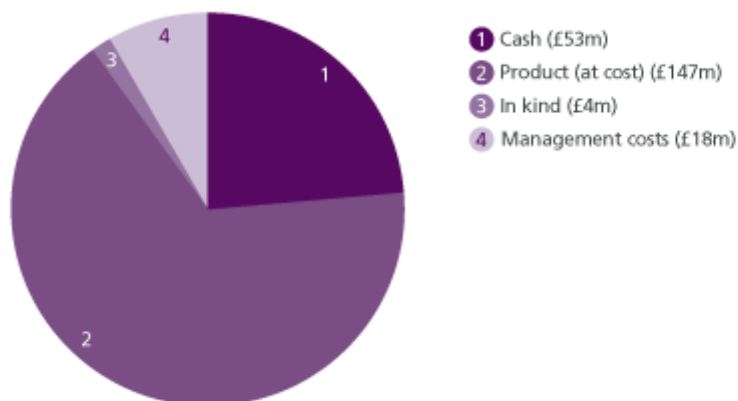
Our product donation figure of £147 million is made through three main programmes (valued at average cost of goods):

- Our Patient Assistance Programs to support low-income patients in the US totalling £100 million
- Our humanitarian product donations totalling £9 million
- Our donation of albendazole tablets for the lymphatic filariasis (LF) elimination programme totalling £17 million

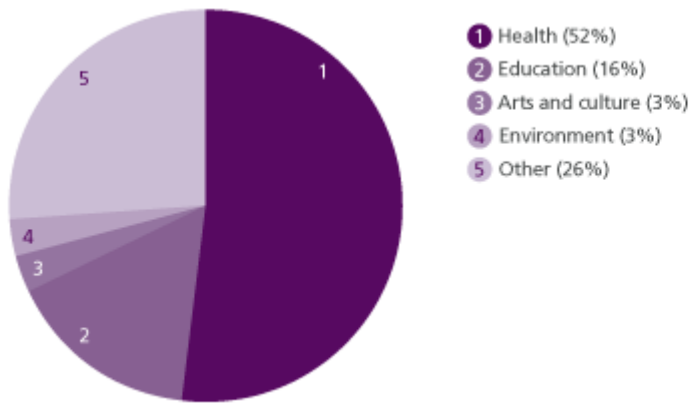
In 2010 our product donation figure also includes the additional cost of donating 24 million doses of our H1N1 vaccine against pandemic flu to the World Health Organization for use in developing countries.

Read our position statement on product donations.

Method of giving (£million)



### Breakdown of cash giving (%)



## Grants

We publish data about our charitable grants made to patient groups in our Europe, Emerging Markets and Asia Pacific business regions and all our charitable grants over £10,000 (\$15,000). Find out more about our grants.

We retained our CommunityMark in 2010 for ongoing work at the local and national level in the UK as well as for our larger international programmes. We were one of the first companies to achieve the Mark in 2008 for outstanding investment in the community. Following independent assessment, CommunityMark companies are awarded for a three-year period and monitored to ensure continued commitment and excellence. The Mark was founded by Business in the Community and is endorsed by UK government and voluntary sector leaders.

### Employee involvement

In 2009, our volunteer initiative was launched to give every GSK employee one paid day off each year to volunteer for a good cause. In 2010 this continued with employees supporting a wide range of charities and projects including work in local schools, shelters for the homeless, community gardens, nursing homes and aiding communities affected by natural disasters.

The GSK PULSE Volunteer Partnership was launched in 2009 and enables GSK employees to make a difference in communities around the world. PULSE volunteers work full-time with one of our partner non-profit or non-governmental organisations (NGOs), using their professional skills and knowledge to facilitate positive, sustainable change for these organisations and the communities they serve. Through this experience, volunteers address a clear NGO need while developing their own leadership capabilities. During 2009 and 2010, 116 PULSE volunteers worked in 33 countries with 42 NGOs. PULSE volunteers continue to receive their full GSK salary during their three to six month PULSE assignment. In 2010, this figure – along with the operating costs for managing the PULSE programme – represented a total in-kind donation of £2.4 million.

More information on our volunteering is available on the communities section of our website.

### Plans and targets

During 2011 we will continue to focus on programmes that help to increase access to healthcare and education.

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Our plans include:

- Expanding our donation of albendazole to treat school-aged children in Africa for soil-transmitted helminths (intestinal worms), in addition to our annual commitment to supply 600 million tablets for use in the Global Programme to Eliminate Lymphatic Filariasis
  - Launching a global partnership with AMREF, Save the Children and Care International to improve healthcare infrastructure in the Least Developed Countries (LDC), as part of our commitment to reinvest 20% of profits made in LDCs from our medicines and Consumer Healthcare products. This will train community healthcare workers and help build the capacity of local healthcare systems
  - Expanding our Personal Hygiene and Sanitation Education programme to include oral healthcare as well as handwashing
  - Rolling out new programmes as part of GSK's partnership of the 2012 Olympic and Paralympic Games. This will include 'Scientists in Sport', an education outreach programme to inspire young people into science, working in partnership with five leading UK universities
  - Continuing our investment in science, technology, engineering and mathematics (STEM) education programs in the US to help ensure the future workforce has necessary qualifications and skills.
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