



# **Our position on** Pricing and Access



## What is the issue?

Over the next 10 years, our ambition is to positively impact the health of more than 2.5 billion people. We will achieve this by making our medicines and vaccines available at responsible prices that are accessible for patients and sustainable for our business through strategic access programmes and partnerships that increase our global impact. We are committed to making a real impact on human health and have an industry-leading track record on ensuring product access for patients.

Around the world, millions of people still lack access to essential medicines and vaccines that could prevent and treat disease; and improve quality of life. The barriers to access to medicines and vaccines are complex and multi-faceted, particularly in lower income countries. At GSK, we believe that these issues are best addressed through partnership between our industry, high income countries and lower income countries, international organisations, civil society and charitable organisations.

This policy position sets out our approach and views on increasing access to our medicines and vaccines through responsible pricing; strategic access programmes and partnerships that are also sustainable for our business. For more information, view our [Pricing and Access Principles](#).

## What is GSK's view?

- **We believe the greatest impact we can make on human health is through our science.** This is where we focus, partnering with others where needed to find sustainable solutions for patient access to our innovation.
- **We develop pricing strategies based on country-specific circumstances** and recognise the need to balance government health budgets. In high-income countries, we apply a value-based approach to price our medicines according to the benefit we bring to patients and health systems, measured by clinical, economic and social outcomes. We collaborate with global health partners to increase our impact in lower income countries.
- **Intellectual property (IP) underpins the system that has led to transformational medical breakthroughs.** IP protections can coexist with mechanisms to improve access to medicines, and the least developed countries are not required to enforce IP rights for medicines before the year 2033. We believe the root cause of healthcare challenges in lower income countries is multifaceted, requiring partnership working to ensure that innovation reaches patients.
- **In some circumstances, technology transfer can play a role in increasing access,** and we are involved in several product transfer and capacity building programmes in countries where we operate. Manufacturing medicines is a complex process with the lowest costs and efficiencies achieved through concentration in large plants in a limited number of locations. It is therefore important to consider technology transfer more broadly than by focussing on local manufacturing alone.
- **We recognise the importance of targeted product donations** in the form of humanitarian assistance or as emergency support in the event of natural disasters. We do not believe that long-term donations are a sustainable approach for creating the capacity and capability needed to manage healthcare challenges faced by many countries.
- **We are renewing our commitment to expand access** to our vaccines and medicines that have the potential to change the trajectory of high-burden diseases in lower income countries. We will



systematically evaluate our pipeline and portfolio, in consultation with global health partners, to focus on opportunities for sustainable impact in lower income countries.

- **Maintaining investment needed for the research, development, manufacture and distribution of new treatments for diseases of lower income countries is extremely challenging.** We need a policy and financing environment where global health discoveries are supported, developed and brought to patients using a model that shares the risk throughout the development lifecycle, and leverages the expertise of different partners involved in delivering healthcare.
- **We recognise the importance of progress towards Universal Health Care (UHC).** A focus on prevention and health system strengthening, and not just on treatment, is essential. Expenditure on health should be seen as an investment rather than solely as a cost.

### GSK's approach to improving access

Our access approach focuses on areas where we can make the most difference through our core business activities, skills and resources. We aim to develop differentiated, best- and first-in-class medicines and vaccines. In doing so, we pursue areas of unmet need and involve the patient in development to ensure that we innovate in ways that are meaningful in the real world. We then partner with others who have the right capability, geographic reach and local knowledge to ensure patients have sustainable access to the innovation that they need.

### Pricing

We have a clear commitment to make a real impact on human health and have an industry-leading track record on ensuring product access for patients. Getting the balance right between responsible pricing and sustainable business is fundamental.

Based on country-specific circumstances, we develop pricing strategies, which recognise the need to balance health budgets. We apply a value-based approach to balance reward for innovation with affordability; and price our medicines according to the benefit they bring to patients and health systems, measured by clinical, economic and social outcomes. To establish the added value of our medicines and vaccines, we compare our offer to what is already available for patients and generate evidence from clinical trials and in real-world settings.

We adjust for the socioeconomic status of a country to ensure affordability and availability. We collaborate with global health partners to increase our reach to patients in lower income countries. For decades, we have worked with partners to strengthen health systems – key to increasing access to medicines in lower income countries. We also recognise health inequities in higher-income countries and help uninsured and underinsured patients navigate healthcare systems, with programmes to increase access and provide financial and disease management support.

ViiV Healthcare, a specialist HIV company - with GSK as majority shareholder – has a flexible pricing approach including non-profit pricing to public health systems in low-income countries (LICs), least developed countries (LDCs) and Sub-Saharan African countries for antiretroviral (ARV) medicines to treat people living with HIV as well as for innovation to prevent HIV transmission. More information on ViiV's approach can be found in their [policy briefing on access to medicines](#).



### *Tiered pricing and access to vaccines*

We have a tiered pricing policy for our vaccines that address public health priorities in low and middle income countries, and are sold through private and public channels. This means that we offer countries prices based on their income levels rather than a single flat rate. Our policy is based on four principles:

- **Availability:** we seek to make our vaccines available, wherever possible, to all countries that need them.
- **Affordability:** we seek to set vaccine prices at levels that allow patients across all income levels to access products.
- **Quality:** we provide the same products at the same quality level no matter where they are supplied.
- **Sustainability:** we aim to operate in a sustainable way that allows the business to continue to develop and supply innovative, high-quality vaccines.

Our tiered pricing model is based on World Bank Gross National Income (GNI) classifications. Price ceilings and price floors exist for each tier, with these decreasing from high to low-income countries. We do not publish specific prices relating to the different tiers due to commercial sensitivities. Countries supported by Gavi, the Vaccine Alliance, have access to our lowest prices for vaccinations in those programmes. As the GNI of countries increase and they transition out of Gavi support, we have committed to a price freeze that ensures they continue to access the lowest price for ten years from the time of transition. More information on our vaccine partnerships is [available on our website](#).

We believe government-led programmes offer the best opportunity for implementing long term and sustainable vaccination programmes. Humanitarian emergencies may limit a government's ability to deliver health services. In these circumstances, we work with partner organisations to help coordinate, manage and respond to vaccine requests from Civil Society Organisations (CSOs). This includes the WHO Humanitarian Mechanism, which facilitates access to affordable vaccines in humanitarian emergencies by CSOs.

### **Intellectual property (IP)**

IP underpins the system that has led to transformational medical breakthroughs in areas including HIV, diabetes, cancer, cardiovascular disease, and COVID-19. IP protections can coexist with mechanisms to improve access to medicines, and the Least Developed Countries (LDCs) are not required to enforce IP rights for medicines before the year 2033. We believe the root cause of healthcare challenges in lower income countries is multifaceted, requiring partnership working and tailored approaches to ensure that innovation reaches patients.

Our approach to filing patents where we are the marketing authorisation holder for medicines on the WHO's list of essential medicines reflects a country's economic maturity:

- We no longer file patents for our medicines, or enforce historic patents, in Least Developed Countries (LDCs) and low income countries (LICs). Generic companies can manufacture and supply generic versions of our medicines in those countries.
- For non-G20 Lower Middle-Income Countries (LMICs), we may file for patents but we are open to offering licences to allow supplies of generic versions of our medicines where we believe this will



enable access. For other countries, our approach to seeking patent protection will be in accordance with our commercial strategy.

- ViiV Healthcare has a description of circumstances in which voluntary licenses will be considered in their policy briefing on access to medicines.

More information on our views on IP and the approach we take to patents and licensing is available in our position on IP available on [gsk.com](https://www.gsk.com).

## **Technology transfer**

In some circumstances, technology transfer can play a role in increasing access when it enables third parties to produce medicines at a lower cost of goods, supporting a sustainable supply. We are involved in several product transfer and capacity building programmes in countries where we operate, including voluntary licence arrangements; work with local medical and regulatory professionals; community partnership projects; and clinical trials programmes. These help to build the sustainable infrastructure necessary to attract and absorb new technologies from other companies and industries.

We are also involved in several manufacturing projects (often referred to as production technology transfer) in lower income countries. However, we believe it is important to consider technology transfer much more broadly than by focussing on local manufacturing alone. Manufacturing medicines is a complex, time-consuming, capital intensive, and highly regulated process. The lowest costs and efficiencies are achieved with high volumes and high-capacity utilisation, via concentration in large plants in a limited number of locations.

More information on our views and approach is available in our public policy position on technology transfer available on [gsk.com](https://www.gsk.com).

## **Product donations**

We are committed to widening access to our products through our approach to pricing and access. We do not believe that long-term donations are a sustainable approach for creating the capacity and capability needed to manage the healthcare challenges faced by many countries. However, we recognise the importance of targeted product donations in the form of humanitarian assistance or as emergency support when disasters hit.

We also believe long term donations can have a role to play where there is an identifiable and achievable end point, such as in disease elimination. GSK is, for example, a key partner in the global programme to eliminate lymphatic filariasis (LF), also known as elephantiasis.

GSK is a member of the Partnership for Quality Medical Donations and operate in line with the [WHO Guidelines for Medicine Donation](#).

## **Improving access in lower income countries**

We are renewing our commitment to expand access to vaccines and medicines from our pipeline and portfolio that have the potential to change the trajectory of high-burden diseases in lower income countries. We will systematically evaluate our pipeline and portfolio, in consultation with global health partners, to focus on opportunities for sustainable impact in lower income countries.



More information on this commitment and how we will achieve it is available on [the responsibility section of gsk.com](#).

We work with partners to understand and address the complex and multi-faceted barriers that can exist to access to medicines and vaccines in lower income countries. These challenges include factors such as ability to pay; under-investment in healthcare infrastructure; supply chain and procurement investments; taxes and tariffs; and cultural factors such as stigma and discrimination. We believe that these issues are best addressed through partnership between the industry, High Income Country (HIC) and lower income country governments, international organisations, civil society and charitable organisations.

### **Building a sustainable business model**

The pharmaceutical business model is based on anticipated return from sales of a new medicine or vaccine. This incentivises companies to take on the lengthy and costly risks associated with research and development. However, for some diseases, such as malaria and tuberculosis (TB), most patients live in countries least able to afford new medicines and vaccines, and where health systems are weaker.

We need to ensure a policy and financing environment where such global health discoveries are supported, developed and brought to patients using a model that shares the risk throughout the development lifecycle, and leverages the expertise of different partners involved in delivering healthcare. Partnerships have been established to share risks in R&D and encourage innovation including Product Development Partnerships (PDPs), such as the Medicines for Malaria Venture (MMV), the TB Alliance and the Drugs for Neglected Diseases initiative (DNDi); and procurement and programme funding partnership organisations like Gavi, the Vaccine Alliance and the Global Fund to Fight AIDS, TB and Malaria.

We are also committed to collaborating with other partners to develop new mechanisms to enable the development, scale up and uptake of innovative products for other infectious diseases and non-communicable diseases.

### **Universal Health Coverage (UHC)**

UHC is the concept that all people should receive the quality health services that they need without experiencing financial hardship as a result. Achieving UHC is one of the targets under the United Nations Sustainable Development Goal (SDG) 3.

We support the concept of UHC and we stand ready to play our part in helping to realise it. Progress towards UHC is linked to reforming health systems financing, governance and delivery infrastructure. Access to medicines is a key component to achieve UHC and a critical driver to achieve health equity. Resilient health systems are the basis for UHC, by enabling availability, affordability, and acceptability to ensure that people can get the right medicines of the right quality at the right price and at the right place.

As every country has a unique health system, tailored approaches and timelines will be required to achieve UHC. A focus on prevention and health system strengthening, and not just on treatment, is essential, and expenditure on health should be seen as an investment rather than a cost.