



# 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, by developing transformational medicines and vaccines. We make these available at responsible prices that are accessible for patients and sustainable for our business and through strategic access programmes and partnerships that expand our reach. We are committed to making a real impact on human health and have an industry-leading track record on access to reach 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 low- and lower-middle income countries (LLMICs). At GSK, we believe that these issues are best addressed through partnership between our industry, high income country and LLMIC governments, international organisations, civil society and charitable organisations.

This policy position sets our approach and views on increasing access to our medicines and vaccines through responsible pricing that is accessible for patients and sustainable for our business; strategic access programmes; and partnerships.

## 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 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. In lower income countries, we use innovative pricing structures to extend product reach. This includes tiered pricing for vaccines; and non-profit pricing in public markets in low-income countries (LICs), least developed countries (LDCs) and Sub-Saharan African countries for ViiV Healthcare's anti-retroviral (ARV) medicines for people living with HIV.
- **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 LLMICs 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 "know-how" transfer and capacity building programmes in countries where we operate. Manufacturing medicines is a complex process with the lowest costs 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 LLMICs. We are putting a process in place to systematically evaluate our pipeline and portfolio, in consultation with global health partners, to identify which products will benefit LLMICs and develop access plans to reach people that need them.
- **Maintaining investment needed for the research, development, manufacture and distribution of new treatments for diseases of LLMICs 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 then partner with others who have the right capability, geographic reach and local knowledge to ensure patients have sustainable access to our innovation.

### Pricing

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

We develop pricing strategies based on country-specific circumstances and recognise the need to balance health budgets. In high-income countries, we apply a value-based approach to balance reward for innovation with affordability and price our medicines according to the benefit we bring to patients and health systems, measured by clinical, economic and social outcomes.

In lower income countries, we use innovative pricing structures as part of our access strategies to extend product reach. We partner with others who have the right capability, geographic reach and local knowledge to get our innovation to patients. For decades, we have worked with partners to strengthen health systems – key to increasing access to medicines in lower income countries.

ViiV Healthcare, a specialist HIV company - with GSK as majority shareholder – has a flexible pricing approach including non-profit pricing in public markets in low-income countries (LICs), least developed countries (LDCs) and Sub-Saharan African countries for anti-retroviral (ARV) medicines for people living with HIV. 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 sold through public markets. This means that we offer countries prices based on their income levels rather than a single flat rate. Our policy is based on four key 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 GNI (gross national income) 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. 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.

## 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 are not required to enforce IP rights for medicines before the year 2033. We believe the root cause of healthcare challenges in LLMICs 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 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 “know-how” 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 LLMICs. 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, highly regulated process. The lowest costs 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 and/or donations for the treatment of chronic diseases 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 natural disasters hit. Similarly, although we believe government-led programmes offer the best opportunity for achieving stable and sustainable vaccination, we work with partner organisations to help coordinate, manage and respond to vaccine requests from Civil Society Organisations (CSOs) in the event of a humanitarian crisis.

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.

## Improving access in LLMICs

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 LLMICs. We are putting a process in place to systematically evaluate our pipeline and portfolio, in consultation with global health partners, to identify which products will benefit LLMICs (based on factors including a practical treatment pathway and regulatory requirements) and develop access plans to reach people that need them. More information on this commitment and how we will achieve it is available on [the responsibility section of gsk.com](https://www.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 LLMICs. These challenges include factors such as ability to pay; under-investment in healthcare infrastructure; 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 LLMIC 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, 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 and encourage innovation including Product Development Partnerships, such as the Medicines for Malaria Venture (MMV), the TB Alliance and the Drugs for Neglected Diseases initiative (DNDi); and procurement and funding partnership organisations like Gavi and the Global Fund to Fight AIDS, TB and malaria.

We are committed to collaborating with other partners to identifying new mechanisms to enable sustainable development.

### **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, infrastructure, and delivery. 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.