



Our position on Technology Transfer and Capacity Building

What is the issue?

Access to medicines and vaccines remains challenging in many communities around the world, particularly in lower income countries. The COVID-19 pandemic has intensified long-standing calls for these countries to be able to domestically manufacture more healthcare products, supported by technology transfer, as a route to enhancing access.

For us, technology transfer represents a mix of resources and know-how transfer. To be commercially sustainable, investment decisions must be appropriate, viable and have a realistic chance of success. This paper sets out our approach to investing in and supporting lower income countries with technology transfer and capacity building, including through skills development and health systems strengthening.

What is GSK's view?

- We understand the goal of lower income country governments to make a greater share of the healthcare products, particularly vaccines, needed for their countries. This will be a long-term endeavour as developing this highly skilled sector, and supporting ecosystems, is a complex task.
- There are many factors that enable the pharmaceutical industry to invest in a country or partner with community members. These include appropriate economic, scientific and market conditions; an efficient regulatory authority; and a robust legal framework. Steps that weaken intellectual property (IP) protection can inhibit technology transfer.
- We consider technology transfer opportunities when they have a realistic chance of success; are practical and appropriate given local conditions; reflect best use of resources; and are sustainable.
- We are involved in several product, “know-how” transfer and/or capacity building programmes into countries where we operate, including voluntary licence arrangements, work with local medical and regulatory professionals, community partnership projects and clinical trial programmes.
- These projects significantly contribute to local scientific, regulatory, medical and manufacturing capacity. They help to build the sustainable infrastructure needed to attract and absorb new technologies.
- Production technology transfer is one of many options available for increasing the availability of vaccines in lower income countries, both as a routine public health tool and to enhance health security. But, expanded vaccination coverage demands more than local production capacity. A robust cold chain, expertise in vaccination and an adequate public health infrastructure are all critical.
- Preparing for the next pandemic needs to start now. But end-to-end manufacturing of pandemic vaccines in every country is not the solution. Instead, by supporting the manufacturing ecosystem for routine immunisation and building capacity across the supply chain, health systems will be better placed to deploy vaccines to their populations during both pandemics and peacetime.
- To support potential technology transfer during the next pandemic, the global community needs to agree now a path forward to easier and faster technology transfer, eg defining common standards for manufacturing inputs, such as vials. This could also be accomplished through

advanced technology transfer arrangements between companies to increase chances of success.

Conditions supporting inward investment and capacity building

We are committed to playing our part in helping to improve people's health and prospects around the world. Our ability to invest in and partner with countries depends upon supportive "in-country" business and scientific environments. The following aspects are particularly important:

- Economic and political stability: Steady economic growth, stable inflation rates, low and stable interest rates, and open and outward looking markets, all support sustainable business.
- Market size and potential: While it is not easy to define the market size or type that will enable viable economic production, it is generally the case that the larger the country or geographic bloc, the greater the market potential and investment appeal.
- Skilled workers: Highly specialised staff are needed to carry out R&D and high-tech manufacturing.
- A supportive regulatory environment: A good registration process for pharmaceuticals and vaccines that enables medicines to meet stringent criteria on quality, safety and efficacy. This will encourage pharmaceutical companies to conduct clinical trials and launch innovative products early.
- A well-developed national infrastructure, public utilities, and land transport, along with a robust legal framework, will all be considered as part of any investment decision.
- IP protection: The existence and enforcement of an IP system in a recipient country is generally a prerequisite for any out-licensing / joint venturing decisions. While a strong Intellectual Property Rights (IPR) system alone will not provide sufficient incentive to transfer IP protected technology, its absence will be a major disincentive.

Although our role in generating many of these conditions is limited, we are open to engaging in discussions about potential additional ways to support capacity building and the manufacturing eco system in lower income countries.

Technology transfer and manufacturing

Calls to improve capacity often focus on local production of medicines and vaccines in a larger number of countries. However, due to reasons of complexity and efficiency, it is often more viable to concentrate manufacturing at a small number of sites/ regions.

Manufacturing medicines is time-consuming, capital intensive and highly regulated. It needs an efficient supply chain and supporting infrastructure of highly qualified staff, and reliable and continuous supplies of water, gas and electricity. The lowest costs will be achieved by concentrating manufacturing operations in large plants that run close to maximum capacity and produce high volumes.

Similarly, there are scientific, regulatory and economic factors that contribute to the cost of, and time required, for making vaccines. Stringent quality and safety processes, often involving complex biological mechanisms, are crucial as vaccines are given to healthy populations. In addition, variable costs are low

– approximately 15% of total cost base¹. This makes the potential labour cost savings in lower income countries less significant compared to other industries and generates strong competitive pressures in a high cost of goods industry.

Successful technology transfer of vaccines goes far beyond the sharing of patent information, requiring a foundation of trust that enables know-how sharing. Moreover, successful vaccination programmes require more than local production capacity. A robust cold chain, expertise in vaccination, adequate public health infrastructure and supportive vaccination policy environment are all critical.

Vaccine manufacture and pandemic preparedness

The COVID-19 pandemic exposed the challenges of discovering, developing and deploying vaccines globally in an emergency. To get ahead of the next pandemic, preparation must start now.

We support the idea of creating a globally coordinated regional manufacturing network to provide infrastructure and capacity for pandemic preparedness. It is not practical or realistic to establish an end-to-end manufacturing solution in every country as this increases costs and creates inefficiencies. Facilities must be useful in the inter-pandemic period too, eg by producing vaccines for routine use. This will help ensure the right capacity and workforces is available when a pandemic comes. Ahead of the next pandemic, we need a path to easier and faster technology transfer, including through agreed standardisation of manufacturing inputs like vials.

More detail is available in our policy position on pandemic preparedness, available on [gsk.com](https://www.gsk.com).

Our capacity building projects

For us, technology transfer represents a mix of resources and know-how transfer. We consider opportunities that have a realistic chance of success; are practical and appropriate given local conditions; reflect best use of resources; and are sustainable.

Manufacturing operations and skills development

By operating global manufacturing sites, we promote the development of skills and technical expertise of the workforce in those countries.

Our programme of technology and product transfer to local manufacturers outsources production as part of a carefully managed cycle. This frees up GSK production capacity for the development of new drugs and vaccines. Transfer of production usually occurs post-patent expiry for products which local operating units consider of strategic and/or commercial importance in local or regional markets.

They remain GSK branded products, sold and marketed by us. However, production is done by a third-party contractor, with the necessary regulatory and technical support from us to ensure compliance with local and international standards.

Joint ventures

We are involved in several joint ventures (JVs), the rationale for which is based on several factors. Careful consideration is given to all aspects of the agreement between GSK and the JV partner, including the rights and liabilities of the contracting parties, confidentiality matters, IP, training



requirements, development needs, respect for Good Manufacturing Practices (GMP), independent quality control or National Control Authorities. External factors such as market size, a favourable climate for foreign direct investment and opportunities for export are also factored in.

Examples of existing projects include:

- Over the last 25 years we have forged a partnership with the Brazilian Government's Fundação Oswaldo Cruz (Fiocruz) delivering technology transfer projects covering several vaccines (polio, meningitis (Hib), MMR, rotavirus, pneumococcal & MMR-V). We also work with the Butantan Institute to produce a DTPa vaccine; and, as part of a 2015 transaction with Novartis, we took over a Technology Transfer Agreement with the Ezequiel Dias Foundation (Funed) to produce a Meningococcal C vaccine.
- In 2021, GSK, PATH, and Bharat Biotech signed a product transfer agreement to help ensure long-term supply of RTS,S/AS01E malaria vaccine. Bharat is an established, innovative biotechnology company based in Hyderabad, India, focused on delivering safe, affordable, and high-quality vaccines and bio-therapeutics against infectious diseases. The agreement includes the transfer of manufacturing of the RTS,S antigen part of the vaccine. GSK will retain the production of the adjuvant of the vaccine (AS01E) and supply it to Bharat.

Clinical trials

We are committed to developing medicines and vaccines for diseases that disproportionately affect lower income countries, such as TB, malaria and HIV. We run clinical trials in countries where such diseases are prevalent. We sponsor investigator Good Clinical Practice (GCP) training workshops in many countries. This is particularly important in markets where experience of conducting global trials is still growing.

GSK also supports African R&D and skills development and health systems strengthening. For example phase III clinical trials for our RTS,S malaria vaccine included a large-scale efficacy and safety trial conducted at 11 research centres in 7 sub-Saharan African countries (Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania).

More information on these programmes is available on [gsk.com](https://www.gsk.com).

ⁱ Salinsky E, Werble C. "The Vaccine Industry: Does it Need a Shot in the Arm?" National Health Policy Forum Background Paper. 25 January 2006.