GSK Public policy positions

Addressing Developing World Vaccine Production Technology Transfer

The Issue

An effective response to healthcare challenges in the developing world embraces many elements, including improved infrastructure, increased affordability of products, increased funding, political will and appropriate industrial policy solutions.

Within industrial policy issues, technology transfer by multinational companies to developing countries has been presented in various fora as a part of the solution. The Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement underlines this in Paragraph 66.2: "*Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base".*

The issue also drew the attention of the WHO at the 2008 World Health Assembly with Resolution 61.15: "*The sixty-first World Health Assembly […] requests the Director-General […] to collaborate with international partners and intergovernmental partners in order to provide technical support to expand the number of manufacturers, particularly in developing countries, that can meet the standards required to attain and maintain WHO-prequalification standards*".

Calls for technology transfer have been applied to vaccines for two reasons. First, because of their importance as a public health tool - they are used across whole populations and are in constant supply need; and second, for security issues, in case of epidemics or biological attacks.

This paper uses the term "production technology transfer" in the context where a manufacturer (usually from a multinational company) contributes to developing local production capacity by transferring its expertise in production processes. Not covered are the non-industrial factors that promote capacity-building in a developing country - these include R&D, clinical trials, regulatory and technical expertise sharing, and corporate responsibility programmes.

GSK's Position

– GSK Vaccines is one of the world's leading vaccine innovators and producers. We seek to be a partner in delivering solutions to the world's vaccination needs in a sustainable manner.

– GSK has developed a network of global industrial vaccine operations spanning 13 sites in 10 countries worldwide. These are made up of a combination of primary and secondary production and composed of a blend of our own operations, joint ventures and collaborations.

– We believe production technology transfer is only one of many options that should be considered for increasing the availability of vaccines in the developing world. However, production technology transfer is not a panacea. GSK considers technology transfer opportunities when they can realistically be forecast to succeed, are practical and appropriate given local conditions, reflect best use of resources and are sustainable.

– For production to be economically viable in terms of facilities and assurance of high levels of quality, high capital investments can only be justified for sites producing upwards of 100 million doses in bulk antigen. However, more flexibility exists for secondary operations.

– Many factors contribute toward a conducive environment in which the pharmaceutical industry will invest in a country or partner with community members. These include appropriate economic, scientific and market conditions; quality and safety, since the transfer of complex biological processes is required for the application in healthy individuals; attractive market conditions; an efficient regulatory authority and a robust legal framework. Within the vaccine delivery system, a robust cold chain, expertise in vaccination and an adequate public health infrastructure are critical to achieve vaccination coverage.

– Ultimately, achieving success in vaccination policy requires more than local production capacity; policies are also needed to make it easy for people to be vaccinated with vaccines once licensed.

Background

Conducive Conditions for Production Technology Transfer

Our willingness to invest in and partner with developing countries is heavily dependent upon suitably supportive "in-country" business and scientific environments and the existence of a suitable partner.

– Skilled workers - to carry out R&D and high tech manufacturing, it is necessary to have access to highly specialised staff. The availability of scientific research skills and infrastructure will generally outweigh financial incentives or a low tax climate, although financial factors may be decisive in a choice between two locations with the necessary science base.
– A supportive regulatory environment - a good national registration process that enables vaccines to meet stringent criteria on quality, safety and efficacy is essential, especially since vaccines are used in healthy individuals. Mutual recognition of a given Agency's licence by other regulatory agencies will also support production technology transfer arrangements.
– Strong political will and commitment - there should be political commitment at the highest levels, as demonstrated by prioritisation of immunisation in health budgets, the promotion of partnerships to enable vaccine R&D, and financing and delivery mechanisms.
– Intellectual property (IP) protection - the existence and enforcement of an Intellectual Property Rights (IPR) system in a recipient country is generally a prerequisite for any out-licensing / joint venturing decisions. While a strong IPR system alone will not provide a sufficient incentive to transfer IP protected technology, its absence will undoubtedly constitute a major disincentive.
– A predictable commercial environment - while it is not easy to define the market size or type that will make for viable economic production, it is generally the case that the larger the country or geographic block, the greater the market potential and investment appeal. Indeed, the potential market for a vaccine product is inherently shaped by cohort size.
– An investment commitment from the partner receiving the technology - a production technology transfer arrangement usually requires the receiving partner to undertake a significant initial investment. Initial barriers to entry are high, due to large start-up costs, and the need for both specialised expertise and the construction of specialised and dedicated vaccine production facilities. This investment includes risk from the long time lag before it starts being recouped, since building and validating vaccine production facilities takes several years. Once these costs are extended, major on-going investment is still required to maintain manufacturing quality and regulatory standards and ensure the sustainability of the facilities.

Vaccine Production Challenges

The favourable environment described above is difficult to achieve, due to the economics inherent in vaccine manufacture. Indeed, several scientific, regulatory and economic factors contribute to the cost of and time required for vaccine manufacture:

– As several antigens are combined to produce combination vaccines, the complexity of production increases many fold.
– Vaccines are given to healthy populations, so safety and quality are paramount. Stringent quality processes need to be in place to ensure the safety of these sophisticated products. For example, the production of GSK's 10-valent vaccine against pneumococcal diseases requires 500 quality test steps. Most of these steps control the execution of complex biological processes.
– Variable costs are low – approximately 15% of total cost base[1]. This has a two-fold effect. First, it makes the favourable difference in low labour costs in developing countries less significant compared to potential savings made in other industries where manufacturing is relocated from developed countries. Second, it generates strong competitive pressures in a high cost of goods industry.

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

– Historically, the lack of commitment from countries in forecasting their requirement puts manufacturers in a difficult supply position. Uncertainty in forecasting can lead to oversupply or supply shortages due to the lead times required for vaccine manufacture.

Case Study - A successful production technology transfer arrangement: GSK and Brazil Fiocruz

Production technology transfer has proved a successful strategy for GSK, Fiocruz and the Brazilian public health system in the case of our partnership with Fiocruz Brazil. This is based on long-term collaboration agreements begun in the late 1990's for the production of key paediatric vaccines against diseases affecting Brazil's population - Hib, measles, mumps, rubella, rotavirus and most recently pneumococcal disease and varicella. The programme has been a success due to the favourable economic, legal, scientific and market conditions existing in Brazil. It has also benefited from a partner willing and able to accommodate the production technology transfer, with a vision and philosophy for the collaboration aligned to GSK's.

Conclusion

Vaccine manufacturing tends to be concentrated in a limited number of sites in the world. For GSK, production technology transfer is one of many options that should be considered for increasing availability of vaccines in the developing world. However, this requires certain pre-conditions to be met. Manufacturing vaccines is a complex, time-consuming, capital intensive and highly regulated process requiring an efficient supply chain and supporting infrastructure of highly qualified staff, and reliable and continuous supplies of utilities.

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