

## **Frequently Asked Questions (FAQs): Product Transfer for the RTS,S/AS01 Malaria Vaccine**

### **1. What does product transfer mean? What is being transferred?**

The RTS,S/AS01 malaria vaccine is comprised of two parts, RTS,S (the antigen) and AS01 (the adjuvant.) Product transfer in this case means that GSK is transferring the technology to manufacture the antigen RTS,S and granting a license on all rights pertaining to the RTS,S/AS01 malaria vaccine to Bharat Biotech (BBIL). The transfer of manufacturing is common in the pharmaceutical industry.

Concretely, it means that BBIL will take over the production activities of RTS,S (excluding the adjuvant which will continued to be manufactured by GSK), over time, and become the vaccine's sole supplier and Marketing Authorization Holder by 2029, at the latest, to help ensure the maintenance of sustainable supply of the vaccine in the long term. Thus, from 2029, BBIL would be responsible for all the activities related to the commercialization and supply of the vaccine, while GSK will maintain ownership of the adjuvant (which is used in other products) and will supply it to BBIL.

### **2. Why is GSK granting the license?**

GSK is transferring the technology to manufacture the antigen RTS,S and granting a license on all rights pertaining to the RTS,S/AS01 malaria vaccine to maintain a sustainable quality supply of RTS,S, with the potential to meet long-term demand. This is a cost-effective solution that is intended to ensure long-term supply of the malaria vaccine beyond the life of the GSK RTS,S manufacturing facility. (It is estimated that the current GSK facility used to manufacture the RTS,S antigen has less than ten years remaining in its life expectancy.) In the meantime, GSK is ramping up production and will invest in due time in manufacturing capacity to ensure that its RTS,S production plant can be used as efficiently as possible through 2028 to meet its existing commitment to malaria vaccine supply, including the donation of 10 million doses for the MVIP.

BBIL is an experienced vaccine manufacturer with three WHO Prequalified vaccines in its portfolio of 17 vaccines that are already in use. Its expertise, capacity, and commitment to global health—as well as previous experience with technology transfer—make it a strong partner for the transfer of GSK's malaria vaccine.

### **3. How exactly does this support sustainability and availability of the vaccine?**

GSK and PATH have determined that the most efficient way to help ensure that demand for this vaccine can be met into the future is to transfer the manufacture and grant a license on all rights pertaining to the RTS,S/AS01 malaria vaccine to BBIL (GSK would retain the manufacture of the AS01 adjuvant). One factor in this determination is that the current GSK manufacturing facility for the RTS,S antigen has less than ten years remaining in its life expectancy. BBIL already has facilities in place to support a supply of at least 15 million doses and is planning further expansion of its vaccine manufacturing capacity, some of which could be used for the RTS,S antigen.

### **4. Will GSK continue to be involved in the Malaria Vaccine Implementation Programme and the supply of the vaccine?**

GSK is, and will continue to be, one of the tripartite partners in the Collaboration Agreement for the Malaria Vaccine Implementation Programme (along with PATH and the World Health Organization), which is expected to conclude in 2023. In agreement with PATH, GSK is donating up to 10 million doses of the RTS,S malaria vaccine for use in the MVIP, but is not involved in the vaccination itself—that is done by the EPI programmes in the pilot implementation countries. If a WHO recommendation and subsequent adoption and financing decisions are positive, GSK is ready to meet its existing commitment to malaria vaccine supply by ensuring that the GSK RTS,S production plant can be used as efficiently as possible through 2028. GSK has also committed to supplying the

vaccine adjuvant, AS01, through 2042. GSK also is committed to continue monitoring vaccine safety, effectiveness, and impact through Phase 4 studies that are part of GSK's regulatory commitments to the European Medicines Agency.

**5. What made BBIL the best choice for transferring? Can consumers be confident in BBIL versus GSK as the manufacturer of the vaccine?**

BBIL was selected through a comprehensive, competitive process undertaken by GSK and PATH, working in consultation with WHO. BBIL is a pioneering, innovative biotechnology company known for its world-class research and development and manufacturing capabilities, and for its commitment to delivering safe, affordable, and high-quality vaccines and bio-therapeutics against infectious diseases. BBIL has a global track record of supplying WHO Prequalified vaccines at affordable prices to Gavi-eligible countries. BBIL currently manufactures 17 licensed vaccines, most of which are distributed in Indian and global markets. Three vaccines—ROTAVAC®, Typbar-TCV®, and BioPolio®—are WHO Prequalified.

**6. How long will this process take? When will BBIL "take over" producing RTS,S?**

Product transfer is a lengthy process with multiple requirements, due to the technical, financial, and regulatory complexities of manufacturing vaccines. Given the lengthy process, the agreement among BBIL, GSK, and PATH is intended to ensure a seamless hand-off and no interruption of supply.

It is expected that by 2029 at the latest, BBIL will be the sole supplier of the vaccine.

**7. How much will BBIL charge for the vaccine? Does your agreement with them stipulate cost? Will the vaccine be cheaper with BBIL?**

Accessibility and affordability are among the desired key outcomes for this product transfer. Once manufacturing at commercial scale is achieved, it will be possible to estimate the potential impact on the vaccine price. BBIL has committed to supply the vaccine to public sector purchasers at an affordable and sustainable price.

Until 2028, GSK has committed to setting the price of the vaccine (up to 15 million doses per year) to be equal to the cost of manufacturing plus

a financial return of no more than 5 percent. GSK has also committed to continue to supply the adjuvant to the new manufacturer and product license holder through 2042 under the same terms (i.e., cost of manufacturing plus a return of no more than 5 percent).

**8. If the outcomes of the MVIP result in WHO recommending broader use of RTS,S/AS01, then will there be sufficient vaccine supply to meet demand?**

GSK has already committed to provide up to 15 million doses of vaccine per year to the end of 2028 (assuming demand), if a WHO recommendation and subsequent adoption and financing decisions are positive. The technology transfer of the antigen (RTS,S) to a manufacturer able to sustain a quality supply of RTS,S should enable long-term vaccine access. WHO played a technical consulting role to GSK and PATH in the recipient selection process to ensure that quality selection criteria were established and met. BBIL has initial capacity to support the transfer and supply of the RTS,S antigen and is planning further expansion of its vaccine manufacturing capacity, some of which could be used for the RTS,S antigen.

Should the RTS,S/AS01 vaccine be recommended by WHO for broader use, further investments will be required to expand manufacturing capacity, over time, for both the antigen and adjuvant components to meet the potential projected demand for the vaccine—currently estimated to exceed 50 million doses annually.

**9. What will be the practical impact of this product transfer for people living in malarial regions of Africa?**

Malaria takes such a toll on African children, health care systems, and economies, that having a vaccine that has proven efficacy against the disease is cause for optimism, given its potential to further reduce malaria illnesses and deaths. There is a critical need for new tools against malaria, given that progress in the fight against the disease has stalled in recent years.

GSK, PATH, and WHO—the partners in the Collaboration Agreement on the Malaria Vaccine Implementation Programme (MVIP) currently underway in regions of Ghana, Kenya, and Malawi—see product transfer of RTS,S/AS01 as critical to ensure access, in terms of long-term

supply and affordability, for the children who need it. The product transfer agreement now in place among BBIL, GSK, and PATH is an important step toward realizing those supply and access goals for the next decades.

#### **10. What are the partners' roles under this agreement?**

GSK and PATH have the complementary experience and expertise needed to implement this product transfer, and BBIL was selected given its expertise and experience as a leading

manufacturer of vaccines against infectious diseases and supplier to Gavi. GSK is extensively involved in transfer of vaccine manufacturing on a regular basis, as well as “know-how” transfer and capacity building programmes. PATH is applying its manufacturing and product development know-how, and regulatory, project management, and market access expertise to help facilitate the process. PATH has worked successfully with numerous vaccine manufacturers, including in low- and middle-income countries, to bring vaccines to the low-income public markets where they are most needed.

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#### **About GSK**

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit [www.gsk.com/about-us](http://www.gsk.com/about-us).

#### **About BBIL**

Bharat Biotech (BBIL) is a pioneering, innovative biotechnology company known for its world-class research and development and manufacturing capabilities, and for its commitment to delivering safe, affordable, and high-quality vaccines and bio-therapeutics against infectious diseases. BBIL has a global track record of supplying WHO pre-qualified vaccines at affordable prices to Gavi-eligible countries.

BBIL currently manufactures 17 licensed vaccines, most of which are distributed in Indian and global markets. Three vaccines—ROTAVAC®, Typbar-TCV®, and BioPolio®—are WHO Prequalified. In early 2019, BBIL purchased GSK's Indian subsidiary, Chiron Behring Vaccines, relaunching its rabies vaccine under the name ChiroRab in November of last year. ChiroRab is also prequalified by WHO. To learn more about Bharat Biotech visit [www.bharatbiotech.com](http://www.bharatbiotech.com).

#### **About PATH**

PATH is a global nonprofit dedicated to ending health inequity. With more than 40 years of experience forging multisector partnerships, and expertise in science, health, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales innovative solutions to the world's most pressing public health challenges. Learn more at [www.path.org](http://www.path.org). Learn more about PATH's malaria vaccine efforts at [www.malariavaccine.org](http://www.malariavaccine.org).