

# Malaria Vaccine: Questions and Answers on Vaccine Supply, Price, and Market Shaping Update

UNICEF Supply Division

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## Malaria Vaccine: Questions and Answers on Vaccine Supply, Price, and Market Shaping February 2023

This update provides new information on malaria vaccines supply and availability. It reflects updates regarding Gavi, the Vaccine Alliance's co-financing policy for the malaria vaccine issued in December 2022 and the publication of a summary of the malaria vaccine's market shaping roadmap in January 2023.

This document has been developed by UNICEF in collaboration with partners including the World Health Organization (WHO), Gavi, the Vaccine Alliance (Gavi), and PATH. It provides general information on malaria vaccine supply, price, and the ongoing market shaping efforts to complement information that is publicly available on programmatic elements and Gavi application requirements. The information includes the initial outcome of UNICEF's tender for malaria vaccine based on the extensive evaluation of the proposals received against this tender, in depth negotiations, and continued partner consultations. As market dynamics continue to evolve, this document will be updated with new information in this or another format.

### 1. Supply Situation

#### a. What is the supply situation for the RTS,S/AS01 malaria vaccine over the near and medium term?

- Over the 2023-2025 period, GSK, the developer and manufacturer, expects to produce approximately 18 million doses in total, with 4 million doses being available for supply from late 2023. GSK plans to increase supply availability to 6 million doses in 2024, and 8 million doses in 2025. UNICEF has secured access to these volumes through a contract established between the parties. Additional information on supply beyond 2025 can be found below.

#### b. What is GSK's plan to increase supply and over what period?

##### i. Manufacturing plan

- 2022 is the first year of continuous manufacturing of the RTS,S antigen at GSK's existing manufacturing facility. The facility was restarted in 2019 after having been shut down in 2015 following WHO's recommendation to initially introduce the vaccine through pilot implementations in order to generate critical evidence to inform decision-making about the potential wider use of the vaccine. An innovative financing agreement to guarantee continued production of the RTS,S antigen for the RTS,S/AS01 malaria vaccine in advance of the key decisions regarding its roll out was put in place in 2021 between Gavi, GSK and MedAccess.<sup>1</sup> Following WHO's recommendation for the broader use of the vaccine, and Gavi's malaria vaccine funding decision, both in late 2021, GSK is now increasing production volumes, with a plan to produce 15 million doses annually from 2026 through 2028.

##### ii. Product Transfer of RTS,S/AS01

- To help ensure the RTS,S/AS01 vaccine's long-term sustainable supply, accessibility, and affordability, GSK, Bharat Biotech (BBIL), and PATH announced in January 2021 the signing of a product transfer agreement.<sup>2,3</sup> This includes the transfer of manufacturing the RTS,S antigen part of the vaccine and grants BBIL a license to commercialize and supply the RTS,S/AS01 malaria vaccine. GSK will retain the production of the adjuvant part of the vaccine (AS01) and will supply it to BBIL.
- The technology transfer is already in progress, and all parties expects this to be completed by 2028 at the latest. The product transfer is taking place in a phased manner, with transfer of secondary activities (e.g., filling, freeze-drying, and packaging), initially using GSK-manufactured RTS,S bulk antigen, to be completed prior to the completion of the full product transfer. This may enable BBIL to initiate supply earlier than 2028.
- Parties are making all possible efforts to accelerate the product transfer and to increase vaccine supply.

<sup>1</sup> Gavi, The Vaccine Alliance, [New Financing Agreement Boost for Malaria Vaccine](#), Gavi, The Vaccine Alliance, Geneva, 4<sup>th</sup> August 2021.

<sup>2</sup> Malaria Vaccine Initiative, [GSK, PATH, and Bharat Biotech Sign Product Transfer Agreement to Help Ensure Long-term Supply of RTS,S/AS01E Malaria Vaccine](#), PATH, Seattle, 27<sup>th</sup> January 2021.

<sup>3</sup> Malaria Vaccine Initiative, [Frequently Asked Questions \(FAQs\): Product Transfer for the RTS,S/AS01 Malaria Vaccine](#), PATH, Seattle, 27<sup>th</sup> January 2021.

### iii. Increasing RTS,S/AS01 supply

- The product transfer to BBIL is the pathway towards increased supply of RTS,S/AS01, as UNICEF expects BBIL to have a greater antigen manufacturing capacity than GSK (i.e., greater than 15 million doses per year). Therefore, by accelerating the product transfer, it may result in an increased supply of this vaccine earlier than 2028-2029.
- GSK and BBIL, working jointly with partners including Gavi, PATH, UNICEF and WHO, are exploring ways to accelerate the product transfer by identifying opportunities to shorten timelines. Over time, this could result in additional RTS,S/AS01 supply becoming available, as BBIL aims to scale up antigen capacity beyond 15 million doses annually.
- In a recent announcement, GSK confirmed it will double the production of its AS01 adjuvant for use in the RTS,S/AS01 malaria vaccine from its current commitment of 15 million doses annually.<sup>4</sup> GSK's commitment to supply the AS01 adjuvant currently extends until the end of 2042.
- Parties are making all the possible efforts to accelerate the product transfer and to increase vaccine production.

## 2. Access to malaria vaccines

### a. What other malaria vaccines are expected on the market?

- In addition to the efforts underway to scale up RTS,S/AS01 vaccine supply, there are currently ongoing Phase III clinical trials in four countries in Africa with the R21/Matrix-M vaccine candidate,<sup>5</sup> developed by Oxford University. If Phase III trial results are positive, Serum Institute of India (SII) would manufacture the R21/Matrix-M. The data generated from these trials will inform any WHO policy and regulatory decisions.
- The Phase III trial results will provide documentation on vaccine safety, efficacy, and duration of protection in different malaria transmission settings, and are material for the relevant WHO advisory bodies to review and assess the vaccine. However, dependent on available data, there is a scenario whereby the R21/Matrix-M could be available for use in areas with moderate to high malaria transmission, potentially with an initial limited indication as early as 2024, and for a broader indication of use by 2026/2027. The manufacturer has publicly stated that they plan to have the capacity to manufacture 120-250 million doses per year.
- In addition to R21/Matrix-M vaccine, there are other malaria vaccine candidates in the development pipeline. The vast majority is however in the early stages of pre-clinical development or Phase 1 trials.

### b. When can all countries that want to introduce a malaria vaccine have access to it at sufficient volumes to meet their full demand?

- UNICEF expects malaria vaccine supply constraints to continue for the next two to five years. UNICEF anticipates that the market will have sufficient malaria vaccine supply to meet expected demand sometime between 2026 and 2028, depending on the successful scale-up of the RTS,S/AS01 vaccine, the results of R21/Matrix-M Phase III trials, any subsequent product licensure, prequalification, and production scale-up.

## 3. Price

### a. What is the expected price of the malaria vaccine?

- The RTS,S/AS01 malaria vaccine will cost EUR 9.30 per dose for supply during 2023-2025. This price should be seen in the context of the section on “**Supply Situation**” above. The price reflects the fact that vaccine production is still scaling up and the supply is not yet in a steady state or benefitting from economies of scale. Other new vaccines, like the pneumococcal conjugate vaccine (PCV), supplied through UNICEF from 2010, entered the market through UNICEF initially at a relatively high price. PCV was launched at a price of USD 7.00 per dose supported by an Advance Market Commitment and at higher initial volumes than the malaria vaccine. The price of PCV reduced over time as manufacturing capacity scaled up and an additional manufacturer entering the market, with possible other manufacturers bringing competitive pressure to bear on the PCV market as a whole.

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<sup>4</sup> GSK, [GSK Announces £1 Billion R&D Investment Over Ten Years to Get Ahead of Infectious Diseases in Lower-income Countries](#), GSK, London, 23<sup>rd</sup> June 2022.

<sup>5</sup> Dattoo, Mehreen S, Magloire Natama PhD, Athanse Some MD, et al., [Efficacy of a Low-dose Candidate Malaria Vaccine, R21 in Adjuvant Matrix-M, with Seasonal Administration to Children in Burkina Faso: A Randomised Controlled Trial](#), The Lancet, Volume 397, Issue 10287, 15<sup>th</sup> May 2021, p. 1809-1818.

- GSK has committed to a price not exceeding the cost of manufacturing, plus a financial return of no more than 5 per cent, which would be reinvested into further product development. As an outcome of UNICEF's current tender, this price reflects the anticipated cost of manufacturing and GSK's agreement to supply the vaccine in 2023 at this price without a financial return. Further, as an outcome of negotiated terms, GSK has agreed to revisit the cost of manufacturing and adjust the price downwards should the cost of manufacturing decrease, and to reflect this reduction in a retroactively adjusted vaccine price, with a refund mechanism agreed with UNICEF to the benefit of countries and donors.
- To facilitate implementing countries' and donors' budget planning, the price of EUR 9.30 per dose will be maintained as a ceiling price during the period of the current supply agreement between GSK and UNICEF, which means until the end of 2025.
- At the recommended four-dose schedule, UNICEF acknowledges that the total cost of the four doses of RTS,S/AS01 vaccine, initially reaching EUR 37.20 will present some challenges for many countries. This vaccine will be the most expensive vaccine in the Gavi portfolio requiring co-financing.
- As such, Gavi approved in December 2022 an exceptional and time-limited co-financing modality for malaria vaccines, which would be reviewed no later than end-2027.
  - For initial self-financing countries, this exceptional co-financing modality would entail a country contribution of USD 0.20 per dose.
  - For preparatory transitioning countries, their co-financing of USD 0.20 per dose in the first year would increase by 15 per cent a year.
  - For countries in an accelerated transition phase, their contribution would be of 20 per cent of the price in the first year of introduction and will increase by 10 per cent annually. In addition, they will be eligible for eight years of Gavi support irrespective of when during their accelerated transition phase they apply.
- With the transfer of production of RTS,S/AS01 to BBIL, and the potential entry of a second malaria vaccine into the market in the coming years, countries can expect the weighted average price per dose to decrease over time.

**b. At the initial price, is RTS,S/AS01 a cost-effective vaccine?**

- Modelling groups, including the Imperial College London and the Swiss Tropical and Public Health Institute, working in collaboration with WHO and PATH, have developed models to assess the cost-effectiveness of the RTS,S/AS01 vaccine within defined assumptions and price ranges.<sup>6</sup> The groups reached a consensus about the expected impact on public health and the cost-effectiveness of RTS,S/AS01 when administered to children as per WHO's recommendations.<sup>7</sup> This was based on an assumed vaccine purchase price of USD 2.00, USD 5.00, and USD 10.00 per dose. The models all assessed the vaccine to be cost-effective at all three price ranges. The initial price of the vaccine, while reflecting the higher end of this range, is expected to decrease over time as the cost of vaccine production decreases and reaches economies of scale through higher volumes. In addition, UNICEF expects other malaria vaccines entering the market over time will help reduce prices, with possibly the next malaria vaccine in the pipeline, R21/Matrix-M, being potentially available for procurement through UNICEF sometime between 2024 and 2026.

#### 4. Market Shaping

**a. What is being done to improve the health of the malaria vaccine market?**

- When WHO issued its malaria vaccine recommendation in 2021, it also published its global Market Information for Access to Vaccines (MI4A) market study. The study highlighted the key challenges in this market to help and support the work of partners in market shaping and access.<sup>8</sup>
- Gavi partners developed a market shaping roadmap that outlines how the Gavi Alliance will help to shape and develop the malaria vaccine market into a healthier state, in the short-, medium-, and long-term.
- Guided by the roadmap, Gavi Alliance partners have also been taking actions to improve the health of the market, primarily through UNICEF's tender for malaria vaccines.

<sup>6</sup> Dr Penny Melissa A PhD, Robert Verity PhD, Caitlan A Bever PhD, et al., [Public Health Impact and Cost-effectiveness of the RTS,S/AS01 Malaria Vaccine: A Systematic Comparison of Predictions from Four Mathematical Models](#), The Lancet, Volume 387, Issue 10016, London, 23<sup>rd</sup> January 2016, p. 367-375.

<sup>7</sup> The World Health Organization, [Malaria Vaccine: WHO Position Paper](#), WHO, Geneva, March 2022.

<sup>8</sup> The World Health Organization, [Global Market Study: Malaria Vaccine](#), WHO, Geneva, September 2021.

- In addition, Gavi's agreement with MedAccess and GSK sought to accelerate access to first available supply and ensure the RTS,S antigen's continued production prior to WHO's recommendation and Gavi's approval for the malaria programme.
- Gavi, UNICEF, WHO, and partners are working together to streamline and accelerate key processes to help increase supply, such as regulatory and policy pathways and establishing demand forecasts that are informed by countries, amongst other processes.
- The Gavi Alliance considers addressing the short-term supply constraints as among the highest priority objectives of UNICEF's tender and the Gavi's roadmap.
  - The roadmap's main objective in the short- to medium-term is to increase the availability of supply to meet full country demand, and to significantly reduce the price per dose of malaria vaccines, compared to their 2023 pricing levels. By making malaria vaccine prices more affordable and supply sustainable, it will substantially help to broaden country access to this lifesaving malaria control tool in combination with other malaria control measures such as long-lasting insecticidal nets (LLINs),<sup>9</sup> and Artemisinin-based combination therapy (ACT) and ensure the sustainability of malaria vaccine programmes.
  - The roadmap will also aim to help establish long-term supply security by developing a diversified, competitive, secure, and sustainable supplier base. Key to achieving this goal is to ensure that timely and sustainable demand can be developed, which would provide an important incentive for research and developers to continue product innovation and supply scale up.
  - Gavi and its Alliance partners will implement the roadmap's action plan, of which a high-level summary is included in the roadmap's Public Summary.<sup>10</sup>The roadmap may be updated in 2023 in accordance with how the different vaccine market determinants evolve.

For further questions or additional information, please contact:

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UNICEF issues market and information notes on products and supplies that are essential for the needs of children, and by extension their families. While some products are easily available and affordable, the availability of others can be limited, or in some instances, non-existent in the quality and price required. UNICEF places a strategic focus on these supplies to shape healthy markets. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, competitive market landscapes, and product quality that is fit for purpose and in the right form for children.

<sup>9</sup> UNICEF, [Long-lasting Insecticidal Nets Market and Supply Update](#), UNICEF, Copenhagen, October 2022.

<sup>10</sup> Gavi, the Vaccine Alliance, [Malaria Vaccine Market Shaping Roadmap](#), Gavi, Geneva, January 2023.