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Malaria Vaccines:
Questions and Answers on Supply, Price, and Market Shaping

UNICEF Supply Division

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

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UNICEF has to date published four (4) iterations of Malaria Vaccines Questions & Answers on Supply, Price and Market Shaping. This Q&A provides information on malaria vaccines supply, price and availability following WHO Recommendation and pre-qualification of a second malaria vaccine, R21/Matrix-M. It reflects the current outcome of the Malaria Vaccine Tender and highlights current key evolving dynamics in the Malaria Vaccine market.

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 current 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.

1. Supply situation

Two malaria vaccines are currently WHO prequalified and recommended[1] for use to prevent *P. falciparum* malaria in young children, the RTS,S/AS01 vaccine, currently manufactured by GlaxoSmithKline (GSK), and the R21/Matrix-M vaccine, manufactured by Serum Institute of India Pvt (SII).

RTS,S/AS01 and R21/Matrix-M vaccines are shown to be both safe and effective in preventing malaria in children and alongside with seasonal malaria chemoprevention, prevent around 75% of malaria episodes when administered seasonally in areas of highly seasonal transmission[2].

a) What is the overall supply situation for malaria vaccines?

- The WHO prequalification of R21/Matrix-M malaria vaccine in December 2023 allows this second malaria vaccine to complement the ongoing rollout of the RTS,S/AS01 vaccine and will increase access to malaria vaccines and benefit many more children at risk of illness or death from malaria.
- The combined supply availability of RTS,S/AS01 and R21/Matrix-M malaria vaccines is sufficient to meet demand and enables countries that wish to roll out malaria vaccines as per WHO recommendations to do so without supply constraint from mid 2024. However, other constraints may delay malaria vaccine introductions, including competing health priorities at country level, availability of sufficient cold chain capacity and financial considerations. Timely availability of vaccine supply is to a certain degree a function of demand materialization, and it is therefore important that sufficient time is provided to

[1] World Health Organization, Malaria Vaccines: WHO Position Paper, WHO, Geneva, May 2024, p. 234,
[2] World Health Organization, Malaria Vaccines (RTS,S and R21) Questions and Answers, WHO, Geneva, May 2024,

manufacturers in respect to production lead times and necessary quality releases. In addition to the Malaria Vaccine Implementation Programme (MVIP) countries (Ghana, Kenya and Malawi), five countries (Cameroon, Burkina Faso, Benin, Liberia and Sierra Leone) have introduced a malaria vaccine in the first half of 2024. More countries plan to introduce malaria vaccines through 2024.

- In line with its award strategy, UNICEF may consider additional awards to existing and pipeline manufacturers of malaria vaccine, as additional sources of malaria vaccine become available, provided this supports the objectives of the Gavi Market Shaping Roadmap working towards a healthier malaria vaccine market.[3]

b) 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. UNICEF has secured access to these volumes through a supply agreement established between the parties. GSK is working towards increasing production volumes, with a plan to produce 15 million doses annually from 2026 through 2028. As of May 2024, around 4.5 million doses have been delivered since the establishment of the supply agreement to eight countries.
- To ensure long-term sustainable supply, accessibility, and affordability of RTS,S/AS01 vaccine, GSK, Bharat Biotech (BBIL), and PATH announced in January 2021 the signing of a technology transfer agreement which is expected to be completed by 2028. This includes the transfer of manufacturing the RTS,S antigen component of the vaccine and grants BBIL the license to commercialize and supply the RTS,S/AS01. GSK will retain the production of the adjuvant component of the vaccine (AS01) and will supply it to BBIL.
- The technology transfer is underway and taking place in a phased manner, with the transfer of secondary activities (e.g., filling, freeze-drying, and packaging), initially using GSK-manufactured RTS,S bulk antigen prior to the completion of the full technology transfer. This may enable BBIL to initiate supply earlier than 2028.
- The technology transfer to BBIL is expected to increase supply and decrease prices for RTS,S/AS01 vaccine, as UNICEF expects BBIL to have a greater antigen manufacturing capacity at lower manufacturing cost than GSK.
- GSK confirmed it will double the production of its AS01 adjuvant for use in the RTS,S/AS01 malaria vaccine to enable increased production capacity at BBIL. GSK's commitment to supply the AS01 adjuvant currently extends until the end of 2042.

c) What is the supply situation for the R21/Matrix-M malaria vaccine over the near and medium term?

- Following WHO prequalification of R21/Matrix-M vaccine, UNICEF's conditional supply agreement - which secured access to R21/Matrix-M and was signed in October 2023 - went into effect from 1 January 2024.
- Based on current estimated demand from countries, and subject to approximately four (4) months production lead time from confirmed order, UNICEF expects sufficient supply availability to meet countries' needs in 2024 and beyond as per WHO recommendations.
- The first deliveries of R21/Matrix-M vaccine started from end May 2024.

[3] Gavi, the Vaccine Alliance, *Malaria Vaccine Market Shaping Roadmap*, Gavi, Geneva, January 2023.

2. Price

a) What are the prices of malaria vaccines?

- The RTS,S/AS01 malaria vaccine ceiling price is EUR 9.30 per dose for supply during 2023-2025. 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.
- GSK has committed to a price not exceeding the cost of manufacturing, plus a financial return of no more than five 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 country and donor 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.
- R21/Matrix-M malaria vaccine has been secured at an initial price of USD 3.90 per dose, for its two-dose vial presentation. The supply agreement with UNICEF includes tiered pricing and price per dose is expected to be further reduced when certain demand volumes materialize.
- 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, co-financing of USD 0.20 per dose in the first year increases by 15 per cent annually.
    - For countries in an accelerated transition phase, the contribution is 20 per cent of the price in the first year of introduction and increases by 10 per cent annually. In addition, countries are eligible for eight years of Gavi support irrespective of timing of application during their accelerated transition phase.
- With the transfer of production of RTS,S/AS01 to BBIL, and WHO prequalification of R21/Matrix-M vaccine , countries can therefore expect the weighted average price per dose to decrease over time.

3. Summary of key information on malaria vaccines currently recommended for use by WHO:

	RTS,S/AS01	R21/Matrix-M
WHO position **PQ status** **Availability**	- Recommended by WHO in October 2021 - WHO PQ in July 2022 - Available in country from late 2023	- Recommended by WHO in October 2023 - WHO PQ in December 2023 - Available from mid 2024
Indication	- To reduce *P. falciparum* malaria in young children living in areas where malaria is endemic, prioritizing areas of moderate to high transmission	
Schedule	- 4 doses: 3 monthly doses from 5 months of age and a 4th dose provided to prolong protection - A 5th dose may be considered where there is a significant malaria risk remaining in children a year after receiving dose 4	
Presentation	- Two vials clipped together (1 lyophilized, 1 liquid), reconstituted for 2 doses	- Single vial (liquid), 1 or 2 doses per vial (no reconstitution needed)
Shelf life	- 36 months shelf life	- 24 months shelf life
Cold chain	- 2-8°C - 9.92 cm^3 per dose (in secondary packaging)	- 2-8°C - thermostability for 2 weeks at 25°C and 40°C - 7,03 cm^3 per dose (in secondary packaging)
Safe Injection Equipment (SIE)	- Re-use Prevention (RUP) Syringe for reconstitution - Auto Disposable Syringe	- Auto Disposable Syringe

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.[4]
- Gavi and its Alliance 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. Early steps included Gavi's 2021 agreement with MedAccess and GSK, which 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 worked together to streamline regulatory and policy pathways, establish demand forecasts that are informed by countries, and optimize other processes to accelerate access to supply.
- The Alliance's market shaping roadmap, first published in December 2022, includes the following goals:

    - The roadmap's main objective in the short to medium term was to increase the availability of supply to meet full country demand, and to significantly reduce the price per dose of malaria vaccines, compared to the 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),[5] and Artemisinin-based combination therapy (ACT) and ensure the sustainability of malaria vaccine programmes. While supply is now considered sufficient, and pricing is improving, Alliance partners are still focused on reducing the price per dose of malaria vaccines.
    - The roadmap also aims 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 timely and sustainable demand over the short to long term, which will continue to provide an important incentive for research and developers to continue product innovation, including for next generation malaria vaccines and/or localization of vaccine manufacturing.
    - Gavi and its Alliance partners are implementing the roadmap's action plan, of which a high-level summary is included in the roadmap's Public Summary. Roadmaps are reviewed on an annual basis and updated as and when market evolution indicates a new strategic approach may be warranted with the next updated expected in the second half of 2024.

[4] The World Health Organization, *Global Market Study: Malaria Vaccine*, WHO, Geneva, September 2021.
[5] UNICEF, *Long-lasting Insecticidal Nets Market and Supply Update,* UNICEF, Copenhagen, October 2022.

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Other UNICEF market notes can be found at: https://www.unicef.org/supply/market-notes-and-updates

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. Ensuring a sustainable planet for children continues to be a priority for UNICEF, including through its operations and supply management. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, environmental sustainability, and product quality that is 'fit for purpose' and in the right form for children.