MARKET & SUPPLY UPDATE

Malaria Vaccine

CONTEXT

• The first malaria vaccine has been piloted as part of Malaria Vaccine Implementation Programme (MVIP) in Ghana, Kenya and Malawi since 2019. In October 2021, the data generated as part of this ongoing pilot helped inform WHO Policy Recommendation on widespread use of the first malaria vaccine.

• Countries can access Gavi support for malaria vaccine and benefit from special time limited Gavi co-financing policy designed to help stimulate demand during the early years of malaria vaccine programme.

• UNICEF’s tender for supply of malaria vaccine covers 2023-2028 period. Overall aim of the tender is to minimize the time between WHO Policy Recommendation and access to malaria vaccine.

• To date, access to all available supply of first malaria vaccine, 18 million doses of RTS,S/AS01 vaccine, secured through the end of 2025, with supply to countries starting from Q4-2023 and first introductions expected during first half of 2024.

• Continued engagement with existing and pipeline manufacturers of malaria vaccine to ensure timely access to sufficient supply to meet countries’ demand and to reduce price of the malaria vaccines as supply availability increases.

SUPPLY & DEMAND

• First malaria vaccine - RTS,S/AS01 vaccine is WHO pre-qualified and recommended for use. Technology Transfer of RTS,S to manufacturer in India is ongoing. Additional supply expected from 2026 and after completion of technology transfer.

• Second malaria vaccine – R21/Matrix-M vaccine currently in Phase III trials. Data for this vaccine will be reviewed by WHO with potential WHO Policy recommendation in Q4-2023. If recommended for use at least in moderate to high transmission areas of perennial as well as seasonal transmission, and if prequalified by WHO by end of 2023, the vaccine will become a second malaria vaccine available through UNICEF, potentially from 2024.

• Until additional supply becomes available through technology transfer of RTS,S/AS01 vaccine and entry of second malaria vaccine, supply availability is constrained and allocated based on Framework of Allocation of Limited Malaria Vaccine, prioritizing areas of greatest need (Category 1 areas).

• 25 million children estimated to live in areas of moderate to high p.falciparum malaria transmission. With 4-dose schedule, this translates to steady state demand of 80-100 million doses annually. Demand estimates are dependent on WHO policy recommendation.

• High interest in introducing malaria vaccine: 17 countries in total, and additional countries applications for Gavi support are underway. However, currently available supply of RTS,S/AS01 vaccine is only sufficient to meet the needs of 9 new countries.

• Steady state demand for DR Congo and Nigeria alone represents approximately 30 million doses annually if used in all areas of moderate to high transmission. Actual demand will be highly dependent on the pace of introduction in these two countries.

ISSUES & CHALLENGES

• It has taken over 30 years for the first malaria vaccine to come to market due to limited resources and complexity in developing vaccine against human parasite, as well as complex lifecycle of the malaria parasite.

• First generation malaria vaccines will be used as part of overall toolbox for malaria control and prevention. Integration of immunization and malaria control programmes at global, regional and country levels is needed for quality implementation.

• Urgent innovation in next generation vaccines that best meet countries programmatic preference and context and vaccine with higher efficacy rates and fewer doses required is needed.

• Flexibility will be needed from the manufacturers in the initial years of malaria vaccine programme as vaccine becomes progressively introduced in countries’ programmes while countries navigate the challenges of competing health priorities and constrained health systems.

LOOKING AHEAD

• Engagement with countries and partners to support timely malaria vaccine introduction as per countries’ plans, within context of competing health priorities and other new vaccine introductions.

• Active engagement in implementing agreed action points of Malaria Vaccine Market Shaping Roadmap.

• Continued engagement with industry to ensure timely access to additional malaria vaccines as they become recommended for use and prequalified by WHO and help reduce malaria vaccine price as production capacity increases and demand stabilizes.

• Engagement with developers to incentivize innovation and development of new malaria vaccines with improved product characteristics and efficacy.

FURTHER QUESTIONS OR ADDITIONAL INFORMATION? PLEASE CONTACT: Olga Kosyak
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