

WHO PREQUALIFIES A SECOND MALARIA VACCINE MANUFACTURED BY SERUM INSTITUTE OF INDIA

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The World Health Organization (WHO) on Thursday added the [R21/Matrix-M malaria vaccine](#), developed by Oxford University and manufactured by Serum Institute of India, to its list of prequalified vaccines.

In October 2023, [WHO had recommended its use](#) for the prevention of malaria in children, following the advice of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization and the Malaria Policy Advisory Group.

The R21 vaccine is the second malaria vaccine prequalified by WHO, following the RTS,S/AS01 vaccine which had obtained prequalification status in July 2022.

“The prequalification means larger access to vaccines as a key tool to prevent malaria in children, with it being a prerequisite for vaccine procurement by UNICEF and funding support for deployment by Gavi, the Vaccine Alliance,” WHO said in its statement. It added that both vaccines have been shown to be safe and effective in clinical trials, for preventing malaria in children.

Malaria, a mosquito-borne disease, places a particularly high burden on children in the African region, where nearly half a million children die from the disease each year. In 2022, there were an estimated 249 million malaria cases in the world, and 6,08,000 malaria deaths across 85 countries.

Rogério Gaspar, director of WHO’s Department of Regulation and Prequalification, said: “Achieving WHO vaccine prequalification ensures that vaccines used in global immunization programmes are safe and effective within their conditions of use in the targeted health systems. WHO evaluates multiple products for prequalification each year, and core to this work is ensuring greater access to safe, effective, and quality health products.”

As part of the prequalification process, WHO applies international standards to comprehensively evaluate and determine whether vaccines are safe, effective, and manufactured to international standards. WHO also ensures the continued safety and efficacy of prequalified vaccines through, for example, regular re-evaluation, site inspection, and targeted testing. Prequalification

supports the specific needs of national immunisation programmes with regards to vaccine characteristics such as potency, thermostability, presentation, labelling, and shipping conditions.

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