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Malaria vaccine manufactured by Serum Institute of India receives clearance in Ghana

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The R21/Matrix-M malaria vaccine is a low-dose vaccine that can be manufactured at mass scale and modest cost

The University of Oxford-developed and Serum Institute of India (SII) manufactured and scaled up R21/Matrix-M malaria vaccine, leveraging Novavax's adjuvant technology, has been licensed for use in Ghana by the country's Food and Drugs Authority (FDA).

This marks the first regulatory clearance for the R21/Matrix-M malaria vaccine for use in any country. The successful registration was notified to SII by the FDA Ghana. SII is the manufacturing and commercialisation license holder for the vaccine.

The vaccine has been approved for use in children aged 5 to 36 months, the age group at highest risk of death from malaria. It is hoped that this first crucial step will enable the vaccine to help Ghanaian and African children to effectively combat malaria.

The R21/Matrix-M vaccine has demonstrated high levels of efficacy and safety in Phase II trials, including amongst children who received a booster dose of R21/Matrix-M at one year following a primary three-dose regime.

Adar Poonawalla, CEO, Serum Institute of India, said, "The licensure of the R21/Matrix-M Malaria Vaccine for use in Ghana is a significant milestone in our efforts to combat malaria around the world. We remain steadfast in our commitment to scaling up production of the vaccine to meet the needs of countries with high malaria burden and to support global efforts towards saving lives."