

Serum Institute's Indigenous HPV Vaccine CERVAVAC Gets WHO Prequalification, Opens Way for UN Procurement

Pune: Serum Institute of India's indigenously developed gender-neutral Quadrivalent Human Papillomavirus (qHPV) vaccine, CERVAVAC, has received prequalification from the World Health Organization (WHO).

The regulatory milestone marks the 32nd WHO prequalification received by Serum Institute of India for its products and biologicals. With CERVAVAC included on the WHO List of Prequalified Vaccines, the vaccine can be procured by United Nations agencies.

CERVAVAC is a recombinant quadrivalent HPV vaccine targeting HPV types 6, 11, 16 and 18. It is indicated for girls and boys aged 9 through 26 years.

Commenting on the development, Adar Poonawalla, Chief Executive Officer, Serum Institute of India, said, “WHO prequalification of CERVAVAC® is an important step in strengthening the global response to HPV. This milestone reflects the effectiveness of the vaccine and creates the opportunity for countries to prevent HPV-related risks. We are pleased to see this indigenously developed vaccine reach this achievement, and look forward to contributing to immunisation coverage, advancing global healthcare”

CERVAVAC was previously approved for use in India by the Drugs Controller General of India (DCGI). The vaccine is indicated for the prevention of diseases caused by HPV types 6, 11, 16 and 18.

In girls and women aged 9 through 26 years, CERVAVAC is indicated for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16 and 18, as well as genital warts caused by HPV types 6 and 11.

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In boys and men aged 9 through 26 years, it is indicated for the prevention of anal cancer caused by HPV types 16 and 18 and genital warts caused by HPV types 6 and 11.

CERVAVAC was developed in collaboration with the Department of Biotechnology (DBT), Biotechnology Industry Research Assistance Council (BIRAC), WHO's International Agency for Research on Cancer (IARC) and the Gates Foundation.

For individuals aged 9 to 14 years, CERVAVAC is administered as a two-dose schedule at 0 and 6 months. Those aged 15 to 26 years receive a three-dose schedule at 0, 2 and 6 months. The vaccine is administered intramuscularly and is available in 0.5 ml single-dose and 1.0 ml two-dose vial presentations.

Serum Institute of India, part of the Cyrus Poonawalla Group, is a vaccine manufacturer headquartered in Pune. The company said it has an annual production capacity of 4 billion doses and supplies vaccines to more than 170 countries.

News Source:

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