

WHO grants approval for safe, effective meningitis A vaccine for infants

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The World Health Organization (WHO) has opened the door to routine immunization of infants in sub-Saharan Africa by approving for use an innovative and affordable vaccine that has all but rid the meningitis belt of a major cause of deadly epidemics.

In the four years since its introduction in Africa, MenAfriVac has had an immediate and dramatic impact in breaking the cycle of meningitis A epidemics, leading the safe, effective technology to be approved by WHO through its prequalification process for use in infants, and paving the way for protecting millions more children at risk of the deadly disease. The announcement was made today by the Meningitis Vaccine Project (MVP)—a partnership between the global health nonprofit PATH and WHO—and Serum Institute of India Ltd (SIIL), which manufactures the MenAfriVac [vaccine](#).

"Initial mass vaccination campaigns with MenAfriVac have been highly effective in reducing the number of meningitis A cases," said Dr. Marie-Pierre Préziosi, director of MVP. "But epidemics will return when rising numbers of unprotected newborns become a larger proportion of the total population over time. Now, with this decision, health officials will be able to ensure that population-wide protection is sustained by routinely immunizing infants."

The WHO decision means that the new, 5 µg dose of the meningitis A vaccine meets international standards of quality, safety, and efficacy and can therefore be administered to children younger than one year of age

in Africa. MenAfriVac had previously been authorized for use in children and young adults, aged 1-29 years.

Before the introduction of MenAfriVac, people living in countries of the meningitis belt, which stretches from Senegal in the west to Ethiopia in the east, were regularly struck by meningitis A epidemics in which sudden onset of symptoms could rapidly lead to death or permanent disability. One of the most devastating outbreaks ever recorded was in 1996-1997, when an epidemic wave infected more than 250,000 people and killed over 25,000 in just a few months. The only existing vaccine was insufficient to break the cycle.

Protection at an affordable price

In 2004, MVP partnered with SIIL to develop an affordable, tailor-made vaccine for use against meningitis A in sub-Saharan Africa. MenAfriVac was developed in record time at less than 1 tenth the cost of a typical new vaccine. Since campaigns started in 2010, MenAfriVac has been administered to over 215 million people in 15 countries of the African meningitis belt: Benin, Burkina Faso, Cameroon, Chad, Côte d'Ivoire, Ethiopia, Ghana, Mali, Niger, Mauritania, Nigeria, Senegal, Sudan, Togo, and The Gambia.

"Developing the MenAfriVac vaccine fit exactly Serum's ingrained philosophy of bringing down prices of vaccines so that under-privileged children of the world are protected," said Dr. Cyrus Poonawalla, CEO of SIIL, headquartered in Pune, India. "We at Serum Institute are extremely proud of being part of an international partnership that brought an end to a public health issue that has been plaguing sub-Saharan Africa for more than a century."

One year after large-scale vaccine introduction in late 2010, for example, [experience from Burkina Faso](#) provided early evidence that

mass vaccination was associated with a significantly reduced risk of meningitis in the targeted population, as well as among the unvaccinated age groups, suggesting MenAfriVac induced "community" protection. Findings were confirmed in a major way [in Chad](#) in 2012 where researchers reported a dramatic reduction in transmission and incidence of meningitis A, a drop of more than 90 percent following vaccination.

Support from Gavi, the Vaccine Alliance; the United Nations Children's Fund (UNICEF); PATH; WHO; and national governments has been crucial for mass vaccination campaigns that are due to continue until 2016 to cover at-risk populations in all 26 countries where disease burden from meningitis A is greatest.

From mass campaigns to routine immunizations

In parallel to the large-scale vaccination campaigns, clinical studies were designed and conducted to determine the safety, immunogenicity, and optimal dosage and immunization schedule for administering MenAfriVac to infants and toddlers alongside other routine childhood vaccines in African meningitis belt countries.

Results from two infant clinical studies in Ghana and Mali and vaccine introduction impact data were presented to the WHO Strategic Advisory Group of Experts on Immunization (SAGE) in October 2014, and these SAGE experts concluded that a one-dose schedule at 9 months of age or older was recommended to achieve sustainable disease control following the initial mass campaigns in 1-29 year olds.

Specifically, the WHO prequalification that was announced today allows United Nations procurement agencies to purchase the vaccine for use in routine immunization programs in meningitis-belt countries while serving as an endorsement of quality for countries interested in adopting it.

WHO is already working with African countries to ensure a smooth transition from mass campaigns to routine immunization and so ensure sustainable disease control in the region. Seven countries (Burkina Faso, Cameroon, Chad, Ghana, Mali, Niger, and Nigeria) are in line to introduce MenAfriVac in their routine systems as early as 2015, while [mass vaccination campaigns](#) will continue in remaining countries.

Created in June 2001 with the goal of eliminating epidemic meningitis as a public health problem in sub-Saharan Africa, MVP was one of the earliest product development partnerships funded by the Bill & Melinda Gates Foundation. MenAfriVac was the first vaccine developed outside "traditional pharma," and the only vaccine developed specifically for people in Africa.

"With MenAfriVac, we created a revolutionary new model for vaccine development and now we stand on the brink of protecting an entire generation, and those to come, from a devastating disease," said Dr. Kathy Neuzil, director of Vaccine Access and Delivery at PATH. "Our efforts began with a request by African leaders to address a major health challenge affecting hundreds of millions of people, and in less than a decade, we proved that a safe, effective vaccine could be developed and deployed across multiple countries at a price that was sustainable."

"The benefits of childhood immunization last a lifetime and the MenAfriVac vaccine is one of the greatest success stories that shows what partners can accomplish when we commit together to a compelling cause," said Chris Elias, president of the Global Development program at the Bill & Melinda Gates Foundation. "Prequalification of the MenAfriVac vaccine for infants clears the way for the routine immunization of every child before his or her first birthday to ensure long-term meningitis control."

"We are more than halfway through with introducing the vaccine in

meningitis-belt countries, and the first introductions have been a stunning success," said Dr. Jean-Marie Okwo-Bele, director of the WHO Department of Immunization, Vaccines and Biologicals. "But we cannot yet declare a win on meningitis epidemics in sub-Saharan Africa. If we rest on our laurels and don't finish the job, meningitis epidemics will return in a major way in the years to come. Elimination of meningitis epidemics will require [meningitis belt](#) countries' political commitment to complete the mass campaigns and introduce the vaccine in the Expanded Programme on Immunization. Then and only then will we win the battle against [meningitis](#)."

Provided by Burness Communications

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