

Dear partners, friends, and colleagues:

The following is a summary of recent, current, and upcoming activities at the Meningitis Vaccine Project (MVP). We welcome your comments and suggestions at info@meningvax.org and encourage you to forward this update to friends or colleagues who might be interested in learning about MVP's progress.

If you wish not to receive this update, simply reply to this email, changing the subject to "unsubscribe MVP news digest."

Vaccine introduction and communication activities

- Benin, Ghana, Senegal, and Sudan became the seventh, eighth, ninth, and tenth countries in the African meningitis belt to introduce MenAfriVac® (a registered trademark of Serum Institute of India Ltd.) at large scale. There have also been mass campaigns in Cameroon, Chad, and Nigeria. First indications are that the 2012 campaigns, which will be evaluated in depth over the next couple of months, have generally been successful.
- MVP is aware of 38 reported adverse events following the MenAfriVac campaign in the Gouro district in Chad on December 11–15. Following an official request from the Chadian Ministry of Health, the World Health Organization (WHO) sent a team of experts to provide the necessary support in the investigation of these events. The outcome of the investigation showed that no causal link was established between the vaccine and the clinical manifestations observed. See the [Chad Ministry of Health report of 21 January 2013](#).
- More than 100 million people have been vaccinated with MenAfriVac since the vaccine was first introduced in Burkina Faso in December 2010. To mark the 100 millionth vaccination milestone in the fight against meningitis epidemics in Africa, the President of Benin, Dr. Thomas Boni Yayi, who is also the current President of the African Union, hosted a celebration in Cotonou on November 15. The festive event was attended by WHO Regional Director for Africa (WHO/AFRO) Dr. Luis Sambo, MVP Director Dr. Marie-Pierre Préziosi, delegates from meningitis-belt countries that have introduced or will introduce MenAfriVac, representatives from partner organizations, and some 4,000 enthusiastic Beninese. The ceremony was broadcast live via satellite throughout Africa, and media outreach surrounding the event resulted in several reports on the success of the meningitis campaigns so far, including a broadcast piece by Radio France Internationale (RFI) and news stories in African media, including *Le Soleil* (Senegal), *L'Essor* (Mali), *Fraternité Matin* (Ivory Coast), the *Daily Observer* (the Gambia), and *AllAfrica*. Read the WHO/AFRO [announcement](#) (in English) and [press release](#) (in French).



Benin President Dr. Boni Yayi shows the vaccination card of the little girl symbolically representing the 100,000,000th MenAfriVac recipient during the Cotonou celebration of 15 November 2012. Photo credit: Rodrigue Barry/WHO.

- The 100 millionth mark was also recognized in early December at the GAVI Alliance Partners' Forum in Dar es Salaam, Tanzania. Read the [press release](#). Drs. Jean-Marie Okwo-Bele (Director, WHO Immunization, Vaccines and Biologicals) and Samba Sow (Director, Center for Vaccine Development-

Mali [CVD-Mali]) participated in an [RFI special program](#) on “the interest of vaccination” that was broadcast from the conference site.

- On October 31, MenAfriVac received final regulatory approval to be kept outside the cold chain for up to four days at up to 40°C, in a controlled temperature chain (CTC). A pilot project using the CTC approach was conducted in Benin in November in collaboration with Optimize—the WHO-PATH collaboration leading the MenAfriVac-related CTC activities—the government of Benin, WHO/AFRO, and partners. MenAfriVac is the first vaccine intended for use in Africa approved for this type of use, potentially setting a regulatory path for other heat-stable vaccines. A CTC announcement that also included new evidence of MenAfriVac effectiveness was made on November 14 at the American Society of Tropical Hygiene and Medicine conference in Atlanta. In addition to news articles in the *New York Times* and the *Financial Times*, major coverage came out of wire stories, including Reuters, Bloomberg, Agence France Presse, and Irin News, leading to media stories in major markets worldwide. Broadcast coverage included pieces on BBC (French and English), Channel Africa Radio, RFI (Spanish), and Voice of America. Read the [press release](#).

Surveillance and epidemic preparedness activities

- To date, not a single case of group A meningococcal meningitis has been reported in the 54 million people who received one dose of MenAfriVac in 2010–2011.
- Chad was hit by a severe group A *Neisseria meningitidis* (*Nm*) outbreak for the fourth consecutive year. No *NmA* cases occurred in areas vaccinated with MenAfriVac, whereas 12 non-vaccinated districts experienced *NmA* outbreaks.
- About 29,000 suspected cases of meningitis were reported in 2012 in the 18 African countries under enhanced meningitis surveillance. The 2012 epidemic season was characterized by *NmW135*, which affected mostly Benin, Ghana, Ivory Coast, Mali, Senegal, and Burkina Faso—the latter ten years after the *NmW135* epidemic of 2002. Observations made in Burkina Faso together with other research suggest that the dynamic of *NmW135* is different from that of *NmA* and that the outbreak response strategy should be revised accordingly.

Clinical activities

- The following six clinical trials related to licensing and prequalification of MenAfriVac for use in 1- to 29-year olds have been successfully completed:
 - Phase 1 [PsA-TT-001](#) study in India.
 - Phase 2 [PsA-TT-002](#) study in Mali and the Gambia.
 - Phase 2/3 [PsA-TT-003](#) study in Mali, Senegal, and the Gambia.
 - Phase 2/3 [PsA-TT-003a](#) study in India.
 - Phase 3 [PsA-TT-005](#) study in India.
 - Phase 3 [PsA-TT-006](#) study in Mali.
- The Phase 2 [PsA-TT-004](#) study was completed in November 2012 at the Navrongo Health Research Centre in Ghana. A total of 1,200 infants were enrolled in the study that investigated the safety and immunogenicity of different dosages and schedules of MenAfriVac when administered concomitantly with EPI vaccines. Work is well underway on the clinical study report that will be part of the regulatory variation dossier to be submitted for the pediatric approval of MenAfriVac. Meetings will be held in early 2013 in Ghana to present project results to health authorities and partners, and to inform communities of the study results and thank them for their contribution.
- The antibody [persistence study](#) that measured immune persistence up to 5 years after receiving MenAfriVac is now completed. Study results are expected to be available in early 2013.
- CVD-Mali completed enrollment for [PsA-TT-007](#). This phase 3 clinical study evaluates the immunogenicity and safety of different schedules and formulations of the meningococcal A conjugate vaccine administered concomitantly with local EPI vaccines in 1,500 healthy infants and toddlers. Thanks to the strong commitment of CVD-Mali staff, no major delays have resulted from the political unrest in the country, and the study is expected to be completed by summer 2013.

That’s all for now from the MVP team. Stay tuned for our next news digest in three months' time.

We look forward to receiving your comments at info@meningvax.org.

Created in 2001, the Meningitis Vaccine Project is a partnership between WHO and PATH. The mission of MVP is to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines.

For more information on MVP, please visit our website at <http://www.meningvax.org>.