



News digest 32  
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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](mailto:info@meningvax.org) and encourage you to forward this update to friends or colleagues who might be interested in learning about MVP's progress.

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### **Vaccine introduction and communication activities**

- The MVP team has visited Chad and Nigeria in preparation for the second phase of vaccination campaigns that will be held in these countries. A similar visit is planned for Cameroon.
- An epidemiologist and a logistician have been recruited and started work in Chad to prepare for the second phase of the vaccination campaigns that are planned for June 2012.
- The MVP team is preparing country visits to Benin, Ghana, Senegal, and Sudan to start planning the first round of vaccination campaigns that are to be held in these countries toward the end of 2012.

### **Surveillance and epidemic preparedness activities**

- A total of 54.6 million people have been vaccinated with a single dose of MenAfriVac™ in 2010 and 2011; to date there have been no reported cases of group A meningococcal meningitis among vaccinated individuals. Epidemiological surveillance is ongoing in the six countries that introduced MenAfriVac™ at large scale to further assess meningitis activity and vaccine effectiveness.
- At the end of the first quarter of 2012 a total of 11,506 meningitis cases and 1,037 deaths have been notified by the African countries that have an enhanced disease surveillance system. At the end of week 13, *Nm* W135 and *Streptococcus pneumoniae* were the main causal germs identified in alert and epidemic districts. Burkina Faso with 3,630 suspected cases (predominance of *Nm* W135), the Democratic Republic of Congo with 2,554 suspected cases (information on causal germs yet to be confirmed), and Chad with 2,136 suspected cases (predominance of *Nm* A in regions where MenAfriVac™ has not been introduced) pay the heaviest tribute to meningitis this year; while districts in epidemic phase have been reported in a number of other countries, such as Benin, Central African Republic, Ghana, Ivory Coast, and Nigeria.
- A district is considered to be in epidemic phase when there are 10 suspected cases per 100,000 reported in a week. The WHO Intercountry Support Team (IST) in Ouagadougou, Burkina Faso, is supporting a number of countries in developing their laboratory and surveillance capabilities.

### **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 is on schedule. A total of 1,200 infants are enrolled in the study that investigates the safety and immunogenicity of different dosages and schedules of MenAfriVac™ when administered concomitantly with EPI vaccines. Conducted at the Navrongo Health Research Centre in Ghana, the study is scheduled for completion in early 2013.

- The antibody persistence study is on schedule: field activities were completed in Mali and The Gambia in February 2012. A third site in Senegal has started enrolling participants. In this study individuals who participated in the PsA-TT-002 and PsA-TT-003 clinical trials are retraced to measure immune persistence up to 5 years after receiving MenAfriVac™. Overall study results are expected to be available by October 2012.
- A new clinical trial, PsA-TT-007, has started at the Center for Vaccine Development-Mali in Bamako. The study evaluates the immunogenicity and safety of different schedules and formulations of the meningococcal A conjugate vaccine administered concomitantly with local EPI vaccines in healthy infants and toddlers. A total of 1,500 participants will be enrolled. The study started on March 6, 2012, and so far 165 participants have been enrolled. Following the political unrest in Bamako of March 22, enrollment was temporarily suspended. The site has procedures in place to ensure safety and appropriate follow-up of participants as well as to ensure the safety of the study staff.

## Regulatory

On February 7, 2012, the Maharashtra state Food and Drug Administration granted Serum Institute of India Ltd. (SIIL) the marketing license enabling MenAfriVac™ to be manufactured for the domestic market in India as well as for export to all countries. This decision approved an October 2011 request by the Drugs Controller General of India (DCGI)—the national authority that regulates market authorization of vaccines developed in India. The DCGI decision was based on an extensive review of the final study report of the Phase 3 study conducted in India, which SIIL submitted in December 2010 as part of a set of postlicensure required documentation. Marketing permission for MenAfriVac™ export and use in Africa had been granted in January 2010, which together with WHO prequalification granted in June 2010 provided the regulatory basis for using MenAfriVac™ in vaccination campaigns in the meningitis belt.

## Last but not least



On March 1, 2012, Dr. Marie-Pierre Préziosi (center) was appointed Director of the Meningitis Vaccine Project. A member of the MVP team since 2003, Dr. Préziosi most recently served as the Director of Clinical Development for MVP, as part of her role as Medical Officer at WHO.

Acknowledging the huge achievements of the project team and partners under the leadership of her predecessor, Dr. Marc LaForce, Dr. Préziosi said, “I am honored and privileged to serve as MVP’s new director; I welcome the opportunity to continue to work with all the committed partners who have accompanied the project for more than a decade and to lead a public health project for which I have a profound passion. I am confident that we have the quality team that is needed to ensure MVP’s continued momentum and success in the years to come.”

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](mailto: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>.