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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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### **Special announcement: MVP website updated!**

The MVP website at [www.meningvax.org](http://www.meningvax.org) has been redesigned to offer new material, including sections on vaccine development and vaccine introduction, event announcements, and links to abstracts, scientific publications, posters, and fact sheets. We invite you to explore the site and to share this notice with interested colleagues.

### **Vaccine Development Activities**

- The regulatory process to obtain marketing authorization for the meningococcal A (MenA) conjugate vaccine is on track. Serum Institute of India Ltd. (SIIL) is expected to be able to start manufacturing the vaccine soon for export to Africa.
- The World Health Organization (WHO) prequalification process has been initiated.

### **Clinical Activities**

- The [PsA-TT-001](#) clinical study in India has officially ended.
- The [PsA-TT-002](#) clinical study in Mali and the Gambia has officially ended. The addendum to the study report is being finalized and will be appended to the original report. This two-year-long pivotal Phase 2 study looked at safety and immunogenicity of the MenA conjugate vaccine in 600 12- to 23-month olds (the younger age-group targeted by the mass vaccination campaigns). Study data at four weeks postvaccination showed that the vaccine was safe and that it induced antibody levels almost 20 times higher than those obtained with the unconjugated vaccine. The addendum will provide statistical data on long-term safety and antibody persistence at one and two years postvaccination. Final results will be communicated in a forthcoming scientific publication.
- The [PsA-TT-003](#) clinical study in Mali, Senegal, and the Gambia, and the [PsA-TT-003a](#) clinical study in India have officially ended. One of the two addenda to the clinical study reports has been finalized. The addenda provide data on long-term safety and antibody persistence at one year postvaccination. Both these Phase 2/3 studies looked at safety and immunogenicity of the MenA conjugate vaccine in the age-groups targeted by the mass vaccination campaigns (1–29 years). Final results will be communicated in a forthcoming scientific publication.
- The [PsA-TT-004](#) clinical study at the Navrongo Health Research Centre, Ghana, is going well and proceeding according to schedule. This Phase 2 study evaluates the safety and immunogenicity of different dosages and schedules of the MenA conjugate vaccine in healthy infants when administered concomitantly with Expanded Program on Immunization vaccines.
- Indian authorities have granted MVP permission to launch [PsA-TT-005](#) at Vadu's Shirdi Sai Baba Rural Hospital, a rural division of King Edward Memorial Hospital in Pune. The Phase 3 trial evaluates the consistency of the safety and immunogenicity of consecutive lots of MenA conjugate vaccine administered as a single dose to 830 healthy children ages 5 to 10 years.

- Preparations for PsA-TT-006, a Phase 3 safety study in Africa, are at an advanced stage. A site initiation visit took place in December, and the study is expected to start in the first quarter of 2010 after regulatory clearance has been obtained and all contracts have been signed.

### **Surveillance and Epidemic Preparedness Activities**

- A total of 88,199 suspected cases and 5,352 deaths from meningitis were reported in 2009 in the 14 countries under enhanced surveillance. The countries hardest hit were Nigeria (56,128 cases; 2,488 deaths) and Niger (13,449 cases; 558 deaths). Group A *Neisseria meningitidis* was the principal cause of disease in the region in 2009.
- Representatives from 14 meningitis belt countries and key partners attended the 7<sup>th</sup> Annual Intercountry Review and Planning Meeting on Enhanced Meningococcal Surveillance and Response to Meningitis Epidemics in Africa in Ouagadougou, Burkina Faso, on October 13–14. The meeting provided an opportunity to exchange on lessons learned, challenges, and constraints, and to draw up recommendations and plans for the coming meningitis season.
- The WHO Intercountry Support Team (IST) conducted workshops on the use of Epi-Info and HealthMapper for surveillance and data management staff in Benin and Chad. Both software packages are designed to improve epidemiological and laboratory data analysis and mapping for better decision making for meningitis control.
- The IST team made country visits to Mali, Niger, Nigeria, and Senegal. The main purpose of the visits was to assess the epidemic response in 2009 and provide support to surveillance staff for the next epidemic season (Niger and Nigeria), to communicate on the development of the MenA conjugate vaccine and its future introduction in Africa (Mali and Niger), and to advocate for support from the regional health partners for West Africa based in Dakar (Senegal).
- Meningococcal carriage studies are proceeding in three districts in Burkina Faso under the guidance of the Norwegian Institute of Public Health and the US Centers for Disease Control and Prevention in Atlanta.

### **Vaccine Introduction Strategy and Communication**

- The microplanning tools template for introduction of the MenA conjugate vaccine in Burkina Faso has been finalized and validated. Health personnel will adapt the template as needed at local, provincial, and regional levels.
- On October 15, financial and technical staff from WHO and UNICEF as well as other stakeholders attended a partners meeting on the introduction of the MenA conjugate vaccine in Africa. The meeting resulted in a draft operations plan and recommendations for meningitis epidemics control in Africa.
- On November 17–18, the Direction Générale des Pharmacies du Médicament et des Laboratoires—the Burkina Faso agency in charge of pharmacovigilance in the country—convened a meeting to review the pharmacovigilance protocol in preparation for the introduction of the MenA conjugate vaccine in Burkina Faso. The meeting was attended by local health staff, including medical doctors and pharmacists, as well as by representatives from WHO and Agence de Médecine Préventive.
- On February 10–12, MVP staff and partners will convene in SIIL’s brand new auditorium to attend a scientific forum to review results from MenA conjugate vaccine development. Organized by Fondation Mérieux, WHO, and PATH with contributions from the United States Agency for International Development and the Norwegian Research Council, the meeting will bring together all partners in the pharmaceutical and clinical development to share results and experiences while building capacity and expertise among Indian and African investigators. View the [agenda](#).

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>.