



News digest 24
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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 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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Announcements

MVP would like to welcome [Dr. Godwin Enwere](#) who joined the team in Ferney-Voltaire on March 29. Godwin manages pharmacovigilance activities for all ongoing MVP clinical trials.

Vaccine Development Activities

- On January 21, the Maharashtra state Food and Drug Administration officially granted Serum Institute of India Ltd. (SIIL) the marketing authorization enabling MenAfriVac™, the meningococcal A (MenA) conjugate vaccine, to be exported and used in Africa. This decision approved a December 2009 request by the Drugs Controller General of India (DCGI)—the national authority that regulates market authorization of vaccines developed in India—that MenAfriVac™ be made available for meningitis belt countries in Africa. The DCGI decision was based on an extensive review of the two-part, 13,000-page dossier that had been submitted by SIIL in April/July 2009.
- Following market authorization of MenAfriVac™, SIIL may begin large-scale production. More than 300 million doses will be needed to immunize the target population in the meningitis belt over the next ten years.
- The World Health Organization's (WHO) regulatory inspection of SIIL facilities in Pune took place on March 8–12, and WHO is reviewing the MenAfriVac™ dossier. Although some queries can be expected, prequalification is expected in June/July to allow for vaccine introduction in the fourth quarter of this year.

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. 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. 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. 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). Study results will also 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. A total of 1,200 subjects have been enrolled for this Phase 2 study that evaluates the safety and immunogenicity of different dosages and schedules of the MenA conjugate vaccine in healthy infants when administered concomitantly with EPI vaccines.

- [PsA-TT-005](#) is proceeding within timelines, and over 500 subjects were enrolled at the end of March. This Phase 3 trial is taking place at Vadu's Shirdi Sai Baba Rural Hospital, a rural division of the King Edward Memorial Hospital in Pune. The study 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.
- [PsA-TT-006](#), a Phase 3 safety trial, started on February 22 at the Center for Vaccine Development-Mali in Bamako. Almost 600 subjects were recruited by the end of March. Over the next year a total of 6,000 subjects will be enrolled to evaluate the safety of one dose of the MenA conjugate vaccine administered to healthy subjects aged between 1 and 29 years.

Surveillance and Epidemic Preparedness Activities

- The WHO Intercountry Support Team (IST) reports 7,946 suspected cases of meningitis so far this year in the 14 countries under enhanced meningitis surveillance. Burkina Faso is the hardest-hit country with 2,188 cases and 336 deaths (case-fatality rate: 15.4%). Nigeria and Niger come next with 1,263 cases/120 deaths and 1,091 cases/116 deaths, respectively. Côte d'Ivoire reports a very high case-fatality rate (42.1%), with 32 patients and 16 deaths. Group A *Neisseria meningitidis* remains the principal cause of disease throughout the belt, but some group W135 disease has been identified in Chad, Ghana, and Niger.
- On March 3–4, representatives from the US Centers for Disease Control and Prevention in Atlanta and the Norwegian Institute of Public Health in Oslo gathered at the WHO/IST office in Ouagadougou to evaluate the meningococcal carriage studies that have been conducted in Burkina Faso in 2008 and 2009 and to prepare the second round of studies to be conducted after MenAfriVac™ is introduced. Participants also reviewed the study protocol for case-control studies, and they discussed activities linked to the introduction of MenAfriVac™ in Burkina Faso, including case-based surveillance and pharmacovigilance.
- WHO/IST made country visits to Ghana (March 11–13) and Chad (March 22–30). The main purpose of the visits was to assess epidemic response and to provide training on standard operational procedures for enhanced surveillance of meningitis and laboratory confirmation work. In Ghana WHO/IST also conducted a special workshop on completion of the application forms for accessing the emergency stockpile of polysaccharide vaccines currently managed by the International Coordinating Group on Vaccine Provision for Epidemic Meningitis Control.

Vaccine Introduction Strategy and Communication

- Preparations for vaccine introduction are making progress in Burkina Faso where a MenAfriVac™ introduction technical group consisting of WHO/IST and representatives from the WHO country office now meets on a weekly basis to discuss planning and implementation of all MVP-related activities. Meetings are extended on an *ad hoc* basis to several departments at the Ministry of Health, including pharmacovigilance, disease control, and immunization. Teleconferences are also taking place twice a month between WHO/IST, the WHO country office, WHO AFRO in Brazzaville, and WHO HQ in Geneva.
- A purchase order has been placed for the first 4.7 million doses of vaccine with funds made available by the Michael & Susan Dell Foundation. Additional doses for the Burkina Faso introduction will be purchased by UNICEF following WHO prequalification of the vaccine. Dell funds have also been used to purchase equipment for the introduction campaign. The PATH procurement team collaborated with WHO/IST to purchase needed equipment and supplies for vaccine introduction in Burkina Faso. To date, a purchase order has been placed for 13 incinerators to allow for the safe disposal of campaign waste products.
- Over one hundred scientists, public health officials, and experts from Africa, Europe, India, and North America attended a landmark scientific conference on the development of MenAfriVac™ in Pune on February 10–12. A summary of the meeting is provided on page 4 of the [WHO Global Immunization News](#) March issue.

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>.