



## **GLOBAL GOVERNANCE**

April 9, 2014

# The Meningitis Vaccine Project Addendum

## The Meningitis Vaccine Project (MVP) in 2014

Reported meningitis cases and related deaths have reduced significantly in the years since MenAfriVac's (MAV) introduction into Africa's Meningitis Belt. In 2011, Burkina Faso, Mali and Niger reported the lowest number of confirmed meningitis A cases ever during an epidemic season. (See **Exhibit 1** for MAV impact.)

In November 2012, efforts were also underway to show that MAV could be effective even when not kept in constant cold storage through a pilot program in Benin. Results of the study were published in 2014 indicating that MAV could remain effective in ambient temperatures up to 102.2 degrees Fahrenheit.<sup>2</sup> Costs to administer the MAV vaccine could drop by as much as fifty percent if the vaccine did not need to be kept in constant cold storage according to a study published in the *Bulletin of the World Health Organization*.<sup>3</sup> Many in the global health community believed that such findings could have impact beyond meningitis treatment. A WHO staff member involved in the study commented, "Finding solutions to reducing the cost and logistical challenges of reaching people living in remote areas would remove a major constraint to achieving universal coverage with vaccines beyond MenAfriVac."<sup>4</sup>

The MVP planned to vaccinate approximately 250 million people over 26 countries in the African Meningitis Belt by 2016.<sup>5</sup>

# **Lessons Learned From the Meningitis Vaccine Project**

With the upfront Gates Foundation funding of \$70 million for the specific purpose to develop a meningitis vaccine, the MVP was considered a successful example of a "push mechanism" for developing new health products. Ultimately the \$70 million was distributed with \$35 million to support clinical research activities, \$6.8 million to facilitate technology transfer and strengthen the Serum Institute of India Ltd.'s (SIIL) conjugate vaccine manufacture capabilities, \$8 million to support other vaccine development partners and the final \$20 million to fund the partnership. After the successful Phase I trials, SIIL also invested an additional \$17 million to build a dedicated manufacturing facility for the new vaccine. The total R&D and innovation costs were approximately \$50 million which are very small compared to general estimates for the costs of vaccine R&D which are generally an order of magnitude more and in the neighborhood of \$500 million.

The MVP was an unusual partnership that consisted of a non-profit developer (PATH), a UN agency (WHO), countries (national governments), a health product regulator in the North (U.S. FDA) and a commercial

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# Addendum: The Meningitis Vaccine Project

manufacturer in the South (SIIL). In addition, rather than depending on one manufacturer for vaccine development, the partnership relied on a consortium: the vaccine raw materials came from one source, the technology transfer and development originated from other sources, and final site of production at scale took place with yet another partner. There was also a Global North-to-South transfer of technology and capacity. This makes the MVP a form of a networked or lattice innovation model. Such an approach has some advantages by building on the particular strengths of different partners and reducing the risk of the overall process as it enables switching among partners for specific deliverables and contributions, which indeed happened when BiosYnth, the original conjugation development and transfer partner, decided to withdraw.

## 2014: Where Are They Now?

#### **Marie-Paule Kieny**

Dr. Marie-Paule Kieny was the first director of the WHO Initiative for Vaccine Research.<sup>10</sup> In addition, to working on the meningitis vaccine, the group also developed and licensed new vaccines for pandemic influenza in developing countries through transfer of technology and expertise. Between 2010 and 2012, Dr. Kieny was the WHO Assistant Director-General for Innovation, Information, Evidence and Research. In 2012 she became the WHO Assistant Director-General for Health Systems and Innovation, a position she continues to hold in 2014.

#### **Marc LaForce**

Dr. Marc LaForce left the MVP in March 2012 and joined SIIL as Director, Technical Services in April 2012. In this position, LaForce continued to follow the introduction of MAV in the African Meningitis Belt. In addition, LaForce was working on the pre-clinical development of a polyvalent meningococcal conjugate vaccine that would not need to be refrigerated. Without the constraint of cold storage, costs for transportation, storage, and delivery would significantly decrease. The hope was that this new vaccine could serve as a follow-on product aimed at ridding Sub-Saharan Africa of all meningococcal epidemics.

#### **Regina Rabinovich**

In 2003 Dr. Regina Rabinovich left her position as the Director of the PATH Malaria Vaccine Initiative to join the Bill & Melinda Gates Foundation where she directed the Infectious Diseases Unit for nine years. During her tenure she oversaw the development and implementation of strategies for the prevention, treatment, and control of diseases such as malaria, pneumonia, diarrhea, and various neglected infectious diseases. In 2012, she became the ExxonMobil Malaria Scholar-in-Residence in the Department of Immunology and Infectious Diseases at the Harvard School of Public Health.<sup>11</sup>

### **Endnotes**

- <sup>1</sup> World Health Organization, "Meningococcal meningitis: Fact Sheet No.141," November 2012, http://www.who.int/mediacentre/factsheets/fs141/en/ accessed April 2014.
- <sup>2</sup> Press Release, "Mass Campaign with First Vaccine Allowed "Outside Cold Chain" in Africa Protects Remotest African Regions from Deadly Meningitis Epidemics," February 19, 2014, http://www.afro.who.int/en/media-centre/pressreleases/item/6296-mass-campaign-with-first-vaccine-allowed-%E2%80%9Coutside-cold-chain%E2%80%9D-in-africa-protects-remotest-african-regions-from-deadly-meningitis-epidemics.html accessed April 2014.
- <sup>3</sup> Press Release, "Mass Campaign with First Vaccine Allowed "Outside Cold Chain" in Africa Protects Remotest African Regions from Deadly Meningitis Epidemics," February 19, 2014, http://www.afro.who.int/en/media-centre/pressreleases/item/6296-mass-campaign-with-first-vaccine-allowed-%E2%80%9Coutside-cold-chain%E2%80%9D-in-africa-protects-remotest-african-regions-from-deadly-meningitis-epidemics.html accessed April 2014.
- <sup>4</sup> Michel Zaffran, coordinator of WHO's Programme on Immunization as quoted in, Press Release, "Mass Campaign with First Vaccine Allowed "Outside Cold Chain" in Africa Protects Remotest African Regions from Deadly Meningitis Epidemics," February 19, 2014, http://www.afro.who.int/en/media-centre/pressreleases/item/6296-mass-campaign-with-first-vaccine-allowed-%E2%80%9Coutside-cold-chain%E2%80%9D-in-africa-protects-remotest-african-regions-from-deadly-meningitis-epidemics.html accessed April 2014.
- <sup>5</sup> The Meningitis Vaccine Project website, http://www.meningvax.org/timeline.php accessed April 2014.
- <sup>6</sup> This paragraph based on James R. Hargreaves, "Making new vaccines affordable: a comparison of financing processes used to develop and deploy new meningococcal and pneumococcal conjugate vaccines," The Lancet, 2011; 378: 1885-93. 
  <sup>7</sup> Project Staff, "Meningitis Vaccine Project Introduces Meningococcal Vaccine for Africa," History of Vaccines Blog website, http://www.historyofvaccines.org/content/blog/meningitis-vaccine-project-introduces-meningococcal-vaccine-africa, December 6, 2010 accessed April 2014.
- <sup>8</sup> Steve Brooke, et. al., "How Public-Private Partnerships Handle Intellectual Property: The PATH Experience," In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, eds. A Krattiger, RT Mahoney, MIHR: Oxford, UK and PIPRA: Davis, USA, www.ipHandbook.org.
- <sup>9</sup> Steve Brooke, et. al., "How Public-Private Partnerships Handle Intellectual Property: The PATH Experience," In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, eds. A Krattiger, RT Mahoney, MIHR: Oxford, UK and PIPRA: Davis, USA, www.ipHandbook.org.
- <sup>10</sup> This section based on information from World Health Organization, "Director-Generale: Marie-Paule Kieny," WHO website, http://www.who.int/dg/adg/kieny/en/ accessed April 2014.
- <sup>11</sup> This section based on information from Harvard School of Public Health, "N. Regina Rabinovich," Harvard School of Public Health website, http://www.hsph.harvard.edu/regina-rabinovich/ accessed April 2014.