

## GLOBAL GOVERNANCE

September 12, 2014

# The Meningitis Vaccine Project Teaching Note

### Case Synopsis

This case follows the vaccine development for meningitis A, a life threatening disease, that routinely caused deadly epidemics in Sub-Saharan Africa. In particular the case explores why such a vaccine had not been developed previously and how the creation of the Meningitis Vaccine Project (MVP), a partnership between the World Health Organization (WHO) and PATH, a non-governmental organization enabled the vaccine to be successfully developed over ten years by creating a novel product development partnership.

### Case Context

This case was written to highlight the global policy issues affecting innovation and access to health technologies in developing countries. Specifically, the case presents issues related to strategic decision-making on the development of new vaccines—in this instance the vaccine for Meningitis A—where there is low ability to pay and where additional incentive mechanisms are necessary to catalyze innovation. In the situation for the development of the Meningitis A vaccine, a product development partnership enabled the development of the vaccine. Students examine why the public private partnership was successful but also consider what made it so difficult and how such a model could be applied to the development of other vaccines and health technologies. Additionally, the case explores the strategies applied by Marc LaForce, the MVP's director and veteran public health advocate, to make the MVP a success. In particular, the case examines the management skills LaForce exercised to during his tenure to not only develop a vaccine but also develop a vaccine that affected African countries could support through their respective health budgets thus making meningitis A prevention a sustainable priority.

The case was written specifically for Innovation, Access to Medicines and Global Governance, graduate level course taught in the spring of 2014 at the Harvard School of Public Health and cross-registered with the Harvard Kennedy School of Government. A key focus of this case is to understand the role that global governance played in both facilitating and at times preventing the development of MenAfriVac. Students consider the role that international actors such as WHO, national governments and agencies as well as other actors including those from the private sector played in this story.

This case would also be of interest to those teaching courses in global governance, global health, and leadership. The following discussion guide assumes a class session of one hour and twenty minutes. However, the case could be discussed in less or more time depending on constraints.

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## Case Learning Objectives

The case's primary learning objectives are to understand:

- The roles of a wide array of global actors in developing vaccines for underserved markets especially in developing countries who lack either resources or traditional incentives for drug development and innovation.
- The pros and cons of a partnership or networked model of innovation especially in comparison to the general market-driven model.
- The leadership and management skills needed to create an environment where many different actors and individuals are able to work successfully towards a common goal.

## Assignment Questions

1. What made the public private partnership described in the case work?
2. What made the public private partnership difficult?
3. What lessons can be applied from the MVP towards the development of other health technologies for developing countries/
4. What strategies did Marc LaForce use to guide the MVP? What did he do well? What could he have done differently?

## Classroom Case Discussion and Facilitation Guide

### Meningitis Context and Treatment (10 minutes)

- What are the impacts of meningitis in Africa prior to 2010?
  - Individual and societal impacts
- How was meningitis traditionally treated in Africa? Why? Advantages? Disadvantages?
  - Polysaccharide vaccines b/c what existed. Advantages = could stop meningitis if treated in time, disadvantages = costly, unable to give to those under two, expensive
- What is the impact of the 1996-1997 epidemics?
  - Appears to provide momentum to start looking for other vaccines
- What happens in 1999?
  - Development of conjugate vaccine
- What are the advantages of conjugate vaccines?
  - Can be given once and lasts for an extended period of time, may also be given to young children
- What was the role of the African countries in the development of the meningitis vaccine?
  - They wanted it – request came from African countries. Not driven by funders or international community.
  - Wanted a vaccine that they could afford.
- Did it matter that Africans initially asked for/wanted to develop a new meningitis vaccine?
  - Pressing national priority, momentum built from within the affected countries rather than being an international agenda pushed onto these African countries.

## Meningitis Vaccine (15 minutes)

- What were the minimum specs needed to develop a successful vaccine?
  - Price / Affordability – needed to be sustainable so could be paid for by African Health budgets
  - A vaccine effective against specific type A found in sub-Saharan Africa
- Why couldn't the multi-nationals produce the vaccine? What were some of the challenges?
  - Scale – manufacturing capacity not there yet.
  - COGs still too high to meet the needed fifty cent price point
  - Opportunity costs for pharmaceuticals – would mean focusing on a low income population and taking away potential production capacity and resources for more profitable populations
- How did the MVP overcome this issue of price?
  - Worked with several different partners but chosen manufacturing partner (SILL) had fewer constraints than traditional pharma, saw meningitis vaccine development as an opportunity to increase manufacturing expertise and facilities
- Split up the manufacturing process among many different partners. What reasons and motivations did each partner have for joining the project?
  - FDA allowed use of novel conjugation technology at token price
  - SILL—participation in project meant access and training in high technology transfer of conjugate technology for future projects, significant capital investment in facilities
- What was the role of non-member states in this process? (Thinking specifically about the Gates Foundation here.)
  - Gates Foundation funding of \$70 million gave the MVP flexibility, leverage and ability to have a long view.

## Understanding the MVP and Strategies (20 minutes)

- What role does WHO play? What advantages does WHO bring? Disadvantages?
  - Advantages
    - WHO cachet – retired executives willing to share knowledge and expertise for token sum
    - Coordination and use of longstanding in-country relationships with MOH staff
    - Prestige
  - Disadvantages
    - Large bureaucracy with many partners that need to be involved makes negotiations difficult and time consuming.
    - Expertise is not in the drug manufacturing business
- What role does PATH play?
  - A technology facilitator with lots of expertise both in drug development and the field.
- What does LaForce do to manage the process?
  - Upon joining the project goes to Africa always accompanied by WHO staff, learns that fifty cents critical.
  - Forms Project Advisory Group which gives African leaders voice and gives them real decision making power in the process.
  - LaForce emphasis on “communication and more communication.”

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- Why were retired executives willing to work with WHO? What was their role?
  - Willing to work with WHO because offered prestige, opportunity to give back and have a significant social impact.
  - They offered significant industry expertise especially around pricing of goods and methods for manufacture.
- What were the political issues around the clinical trials of the vaccine?
  - Africans reluctant to go ahead before WHO prequalified.
- Why do you think that clinical trials were eventually able to go ahead in 2005?
  - African participation on study trial and design.
- What made the development of MenAfriVac unique/unusual?
  - Partnership model
  - Production model –different partners and outside of big Pharma
  - Vaccine created specifically for a poor population

### Reflections Questions (25 minutes)

- What features did MVP have that enabled its success?
  - Many different partners at many different levels
  - Distribution of risk among the partners
  - Able to leverage main strengths of each partner
  - Sense of urgency – many people dying essentially from a curable disease
- What features made the Public Private Partnership of MVP difficult?
  - WHO's bureaucracy especially member state structure – very inclusive is good for transparency but a hindrance in negotiations.
  - WHO did not have product development expertise
  - Public and private entities have different interests
  - Reputational risks for parties involved
- Funds distribution implementation has evolved at the Gates Foundation from lump sum (like MVP) to smaller, short term distributions. What would this mean for the MVP project today?
  - Possible that MVP may not have received funding that gave it the freedom to fail.
- How does the emergence of high-quality manufacturers in the South potentially impact vaccine (and drug) development? What are the opportunities? Are there challenges, if so, what?
  - Possibility that more drugs may be developed more affordably as manufacture and opportunity costs are potentially lower in the South than in the North.
  - Challenges are potentially one of creditability, standards, creating relationships between government regulating authorities such as FDA and Southern manufacturers, oversight.
- What lessons from the MVP are applicable for future projects?
  - Public and private partnerships can be used successfully and creatively.
  - Think beyond traditional resources (i.e. large multi-national pharma)

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- Why was meeting the fifty cent price point so important? What lessons can be learned from this example?
  - The fifty cent price point allowed African countries the opportunity to budget for meningitis vaccines within their own national health budgets rather than depending on international donors. Enabled African countries to make the vaccination campaigns sustainable.
  - In order for vaccination campaigns to be sustainable for the long term must be programs that countries can own and manage realistically themselves both in terms of execution and funding.
- What risks were involved in developing the MenAfriVac vaccine? Who took on which risks and why?
- What critical management decisions did LaForce make throughout the project?
  - Constantly worked to build alliances across WHO at all levels
  - Emphasized the human relationship piece among actors and nurtured these relationships over time to build trust and dialogue.
  - Very patient with the process.
  - Involved African leaders from the beginning – listened to their concerns about implementation, pricing and sustainability.