The Development of Pharmaceutical Products to Fight Tropical Diseases

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December 15th, 2004

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• Tropical Diseases: Definition, Sizing and Current Situation
• Parties Involved: Goals, Interests and Limitations
• Public Private Partnership Example:
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  - Challenges faced in Malaria Vaccine development
  - Malaria Vaccine development: players, processes and results
  - Management challenges and critical success factors
• Future Outlook
Tropical Diseases: Definition, Sizing, Current Situation

- Tropical diseases: neglected infectious diseases that disproportionately affect poor and marginalized populations.
- More than 500 million people - one tenth of the world’s population - suffer from tropical diseases at any one time.
- Malaria alone causes more than 1 million deaths per year, almost all of them in developing countries (90% in sub-Saharan Africa)

Parties Involved: Goals, Interests and Limitations

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<th>Goals and Interests</th>
<th>Limitations</th>
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<td>Pharmaceutical Producers</td>
<td>Sales revenue, PR, Shorter development lifecycle</td>
<td>Commitment, Business Model (pricing, patents, purchasers)</td>
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<td>Non-Government Organizations (NGOs)</td>
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<td>Economic interests</td>
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<td>Recipient Government organizations</td>
<td>Reduce cost of disease burden</td>
<td>Low funding; instability</td>
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Public Private Partnership Example: Malaria Background

- Threatens around 40% of Humanity (2.5 billion people) in 90 countries
- Affects around 600 million people
- Responsible, each year, for more than 1 million deaths.
- The majority of deaths are in children with a mortality rate of 4 children minute or 35,000 children a week
- Huge economic cost of malaria – $12 billion per year for Africa

Challenges faced by Malaria vaccine development

- Emergence of widespread resistance of the to the available, affordable, and previously effective drugs
- Breakdown and inadequacy of health systems
- Lack of resources
- Poverty
**Public Private Partnership Example:**

**Malaria Clinical Trials in Mozambique**

- **MVI** (Bill & Melinda Gates Foundation)
- **GSK**
- **Centro de Investigação em Saúde da Manhiça, Mozambique**
- **Spanish Agency for International Cooperation / Barcelona Hospital Clinics**

**Main Contributions:**
- **MVI:** Identifying candidates for funding
- **GSK:** Founding promising antigen/adjuvant combination
- **Centro de Investigação em Saúde da Manhiça, Mozambique:** Assisted in safety monitoring during trials
- **Spanish Agency for International Cooperation / Barcelona Hospital Clinics:** Critical expertise

**Partners:**
- Mozambique Government
- Public Support

**Challenges Included:**
- Managing a complex partnership
- Planning and contract development
- Managing the expectations of the participating community
- Managerial resources to guide this complex initiative towards the end

**Key Success Factors in the Initiative Included:**
- Trust and goodwill with the participating communities
- Backing of a world class foundation, and access to capable technical experts and managers
- The expertise and strong track record at the International Health Center at HC BCN
- The effectiveness of the GSK antigen-adjuvant
- Community involvement
- Access to a suitable base of operations and qualified staff, situated in Mozambique
- Streamlined communication and data entry processes
Future Outlook

• Improvements offered by public-private partnerships (PPPs) for the development of malaria vaccines:
  ✓ Speed the development process
  ✓ Increased innovation thanks to multiple perspectives

• Advantages of PPPs over public-only or private-only efforts:
  ✓ Often private-only efforts lack the commitment necessary to make a difference when a problem is as complex and widespread as the world malaria burden.
  ✓ Public-only efforts, though sufficiently committed, are often limited by their financial resources.

• Together, public and private organizations can leverage their respective strengths to tackle the most serious health problems facing the world.

THANK YOU FOR YOUR ATTENTION!
The Development of Pharmaceutical Products to Fight Tropical Diseases

The reason why we decided to work on this topic is that recently a story about a successful PPP captured our attention. We were impressed by the impact such an initiative can have to alleviate critical global problems and the need for professional management.

The purpose of this paper is to explore the challenges faced in development of pharmaceutical products to fight tropical diseases as well as look more in detail into a specific example of PPP which lead to significant progress of Malaria Vaccine development.

General Process for Pharmaceutical Development

- **Discovery Phase:**
  - This begins with an understanding of the disease that allows a target to be identified.
  - A lead series of compounds is then identified, i.e. those with the chemical structures that appeared to have the greatest impact on the target.

- **Clinical Trials Phase:**
  - This is the most well known element of drug development.
  - In Phase I the compound is tested on healthy volunteers to assess safety.
  - In Phase II the drug is tested on patients with a particular emphasis on finding the dose that best balances efficacy and safety.
  - In Phase III the drug is tested on large numbers of patients in at least two well controlled trials (usually double blinded and often with an active control to enable a regulatory submission to be made to get the drug approved for sale.)