

INNOVATION IN NEGLECTED DISEASES – LESSONS LEARNED FROM THE PARTNERSHIP FOR DEVELOPMENT OF ANTIMALARIAL COMBINATION THERAPY IN BRAZIL

Vera Lucia Luiza (1); Tayná Marques Torres Barboza (1); Gabriela Costa Chaves (1); Luciana de Paula Barros Gonçalves (2); Carolina Batista (2); Eric Stobbaerts (2)

1 – Center for Pharmaceutical Policies / Sergio Arouca National School of Public Health, Oswaldo Cruz Foundation (NAF/ENSP/Fiocruz)
2 – Drugs for Neglected Diseases initiative – Latin America (DNDi-LA)

Background

Malaria is a major cause of mortality worldwide, leading to the death of 584,000 individuals per year, the majority children under the age of 5. In order to develop affordable and adapted treatments for those in resource-poor settings, a consortium including the public laboratory Farmanguinhos/Fiocruz in Brazil and DNDi was created to develop a fixed dose combination (FDC) of Artesunate+Mefloquine (ASMQ).

Launched in 2008, so far more than 1,000,000 treatments have been made available worldwide, including Brazil, India, Venezuela and Bolivia. Currently, the drug is registered in Brazil, India, Malaysia, Myanmar, Tanzania, Vietnam, Niger, Burkina Faso, Thailand and Cambodia. The development process has been reviewed and lessons learned extracted.

Malaria epidemiological numbers

198 million new cases [1]

584,000 deaths [1]

55,111,095 DALYs [2]

3.3 billion people at risk

[1] In 2013, according to the World Malaria Report 2014

[2] Global Burden of Disease 2012:

http://www.who.int/entity/healthinfo/global_burden_disease/GHE_DALY_WHOREG6_2000_2012.xls

Methodology

In view of the dimensions of access to medicines proposed by Frost & Reich, 2008 (architecture, availability, affordability and adoption capacity and its sub-dimensions), commenced the process of carrying out semi-structured interviews with actors involved in the different stages of the drug development project. Between January and April 2015, there were 25 interviews carried out, mostly face-to-face. Seeking a critical and constructive feedback to understanding the lessons learned from the ASMQ project, the memory registration and accumulated experience dissemination, the interviews addressed the overall strengths, the difficulties, times of stress, forms of coordination and communication between the partners, the project's priority in the respective institutions, the challenges to its sustainability and access issues. Each respondent suggested new names for the interviews and documents that complemented the analysis undertaken by the study.

Interviewed Stakeholders

Institutions

- DNDi
- Farmanguinhos
- Fiocruz
- CIPLA
- International organizations (PAHO; WHO; UNITAID)
- Brazilian Ministry of Health
- Doctors Without Borders (MSF)

Role in the Project

- Decision Maker
- Operational Implementer
- Adoption Implementer

Study Relevance, Objectives and Questions

Study Relevance

- Identify knowledge gaps
- Evaluate public-private partnership coordination
- Disseminate knowledge and experiences
- Critical and constructive review: lessons learned and conclusions

Study Objectives

- General: to analyse ASMQ development process in accordance to Frost & Reich (2008)
- Specific: Map and describe steps taken on the development, from partnership to to registry and technology transfer
- Specific: To map and analyse Project evolution from 2002 to 2014 according to dimensions of access to medicines

Questions

- What were the main achievements, obstacles and facilitators of the Project, considering the key elements of access
- Has the Project reflected the dimensions – advocacy, capacity building and delivery – of DNDi's mission?

Results

On one hand, a quality product and easily adopted by patients was developed and there have been significant gains in institutional learning, political and technical for all partners involved. On the other, the adoption of the product in Latin America continues deficient, which can be attributed to a broader context involving several aspects that are prior to 2008, the date of its release. It should be remembered that it was the first experience for DNDi and a new one for Farmanguinhos, against a landscape of many uncertainties and changes, such as modifications in the registration process, change on the industrial park location, the previous release of other antimalarials and pronounced decline in cases of *P. falciparum* in the world.

Conclusions

This experience shows that there is still a long way towards achieving the expected public health impact and successfully overcoming the barriers of sustainable access for malaria treatments in the region.

An important lesson learned is that innovation efforts are not enough to guarantee access. Access involves a complex series of events and actors that need to be designed and incorporated throughout the process in an architecture that ensures its harmonious interaction and product availability to end users. The strengths and challenges of this partnership encompass valuable lessons for future projects.