Summary Meeting Report

Meeting of Stakeholders for the “Development of a single dose malaria cure of artemether-lumefantrine through a nano-based drug delivery system”

Health R&D Demonstration Project

27 February 2017, Salle M.605, WHO Headquarters, Geneva, Switzerland

BACKGROUND
The above-mentioned demonstration project and the stakeholder meeting are linked to the World Health Assembly (WHA) resolution WHA66.22 and are part of a “strategic workplan” adopted by the resolution in “Follow up of the report of the Consultative Expert Working Group (CEWG) on Research and Development: Financing and Coordination.” The project was chosen for support by WHO Member States and approved as a demonstration project in April 2016. The proponent of the project is the Council for Scientific and Industrial Research in Pretoria, South Africa.

MEETING OBJECTIVES
A WHO-convened meeting of stakeholders held in Geneva on 27 February 2017 aimed to bring together stakeholders of the demonstration project in order to provide feedback and input for developing the final proposal for submission to the Ad-hoc Committee on Health Research and Development. The meeting was designed to offer insight into the project from various perspectives and to facilitate cooperation and support among existing and potential partners and donors. The meeting, which was attended by 16 participants, aimed at achieving the following:

- Introduce the project, including technical details and the innovative aspects it would demonstrate
- Discuss project plans in terms of next steps, resource needs and responsibilities
- Continue to mobilize political and financial support for the project

Prior to the meeting, the first-year workplan and budget proposal of the selected demonstration project was shared with meeting participants in order to allow ample time to review the project proposal and prepare feedback to the proponents.

The list of participants is provided in Annex 1.

STRUCTURE & EXPECTED OUTCOMES
The meeting was composed of short presentations on the selected topics established in the agenda in consideration of the project proponents’ first-year workplan and budget proposal, followed by moderated open discussion. The views and feedback from participants were sought in order to facilitate revisions to the proponents’ full project proposal.

The expected outcomes for the meeting were as follows:
- Stakeholders fully updated on the projects
- Project plans discussed and finalized shortly after the meetings
- Identification of potential financing sources and mechanisms
- Identification of next steps for implementation

The meeting agenda is provided in Annex 2.
**MEETING SUMMARY**

The context and background for the demonstration project as part of an overall “strategic workplan,” as outlined in resolution WHA66.22, was presented along with a brief update on each of the objectives of the workplan. The principles of affordability, effectiveness, efficiency, equity and delinkage were highlighted along with the increasingly important role that Product Development Partnerships (PDPs) play in needs-driven drug development.

**Read more…**

**Session 1 – Overview of global malaria situation**

Dr Pedro Alonso Fernandez, Director of the WHO Global Malaria Programme, outlined progress and trends in the global malaria response. Despite excellent progress, especially in sub-Saharan Africa, significant challenges remain in the prevention, diagnosis and treatment of the disease. In 2015 alone, the global tally of malaria reached 212 million cases and 429 000 deaths. With the majority of the disease burden in 91 countries and territories, continued progress is threatened by vector and parasite resistance to interventions. Greater investments are needed in the development of new vector control interventions, improved diagnostics and more effective medicines.

**Read more…**

**Session 2 – Project overview**

The primary objective of the project is to demonstrate the potential of a single dose (or significantly reduced dose) cure for artemether–lumefantrine by reformulating within a lipophilic drug delivery system to improve the solubility and absorption of the drugs.

**Read more…**

**Session 3 – How will the envisaged new formulation fit in the current treatment landscape?**

An overview of the global portfolio of future antimalarial medicines from lead generation to product regulatory review was provided in relation to newly defined target candidate profiles and target product profiles. There are a number of critical gaps in the current treatment landscape for which antimalarial drug development initiatives must address. Simplified (dosing levels) and/or more effective (solubility, absorption, fast-acting, long-lasting) formulations of existing antimalarials have the potential to contribute to the achievement of the ambitious elimination and eradication targets set by the global malaria community.

**Session 4 – How to ensure access to new treatments?**

Ensuring access to new and innovative treatments is a complex matter in need of a balanced and multi-faceted approach. Such an approach to access of antimalarial products would consider a number of factors including the needed requirements on the basis of geographical location and cultural context, product cost and other financial considerations, as well as the availability of the commodity itself. Furthermore, access to knowledge surrounding the correct management, as well as treatment adherence, of the disease must be facilitated. Therefore, such factors as price, palatability, and ease of treatment administration also represent important criteria for enhancing uptake.

**CONCLUSION & NEXT STEPS**

Each of the four sessions noted in the meeting summary above was followed by rich discussion within the topical area which led to several key points that will serve as the basis for developing the final project proposal. A few key points identified during the discussion are noted below.

- Following on feedback and input from the meeting, project proponents will finalise and re-submit the first-year workplan and budget proposal for review by the Ad-hoc Committee on Health Research and Development
- In order to identify 2-3 of the most appropriate compounds, project proponents will collaborate with partners
- In vivo proof-of-concept of superiority must be demonstrated within 12-15 months
- In order to optimize one-year of funding and strengthen the project for future WHO-CEWG and/or external funding opportunities, realistic, scientific milestones shall be identified
- Defined one-year endpoints should be identified in order to facilitate decision making with regards to whether or not to continue research efforts in this area
Annex 1. List of Participants

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LIST OF PARTICIPANTS

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Annex 2. Meeting Agenda

Meeting of Stakeholders for the “Development of a single dose malaria cure of artemether-lumefantrine through a nano-based drug delivery system”
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AGENDA

08:45-09:00 Registration

09:00-09:30 Welcome remarks
Context and background of CEWG Demonstration Projects and expectations from this meeting

Peter Beyer, Senior Advisor
Innovation, Access & Use (IAU)
Department of Essential Medicines & Health Products, WHO

John Reeder, Director
WHO Special Programme for Research and Training in Tropical Diseases (TDR)

09:30-09:45 Session 1 – Overview of global malaria situation

Pedro Alonso Fernandez, Director
Global Malaria Programme, WHO

09:45-11:15 Session 2 – Project overview
Moderator: Jean-René Kiechel, Senior Pharma Advisor & Product Manager
Drugs for Neglected Diseases initiative (DNDi)

Richard Gordon, Executive Director, Grants Innovation and Product Development
South African Medical Research Council (MRC)
Setting the scene: background and proposal objectives

Avashnee Chetty, Research Group Leader, Polymer Modification & Encapsulation
Council for Scientific and Industrial Research (CSIR)
Proposal summary: Aims, objectives, implementation plan, partners

Lonji Kalombo, Principal Engineer, Material Science and Manufacturing (MSM)
Council for Scientific and Industrial Research (CSIR)
How can nanomedicine be used for drug reformulation?

Discussion
11:15-11:40  Coffee break

11:40-12:30  Session 3 – How will the envisaged new formulation fit in the current treatment landscape?
Moderator: Manica Balasegaram, Director
Global Antibiotic Research and Development Partnership (GARDP)
Drugs for Neglected Diseases initiative (DNDi)

Neil McCarthy, Vice President, Head of External Relations
Medicines for Malaria Venture (MMV)

Discussion

12:30-14:00  Lunch break (sandwiches will be provided)

14:00-15:00  Session 4 – How to ensure access to new treatments?
Moderator: Manica Balasegaram, Director
Global Antibiotic Research and Development Partnership (GARDP)
Drugs for Neglected Diseases initiative (DNDi)

Martin De Smet, Malaria Coordinator, MSF International
Médecins Sans Frontières (MSF)

Discussion

15:00-15:30  Coffee break

15:30-16:00  Discussion

16:00-16:30  Concluding remarks

Peter Beyer, Senior Advisor
Innovation, Access & Use (IAU)
Department of Essential Medicines & Health Products, WHO