

Application from Medicines for Malaria Venture for admission into official relations with WHO

1. **Year of establishment of the organization:** 1999

2. (a) **Address of the headquarters of the organization.**

Route de Pré-Bois, 20
1215 Geneva 15
Switzerland

Tel: +41 22 555 0300

(b) **Contact information, name(s) and titles of officer(s) who may speak and correspond authoritatively on behalf of the organization.**

Ms Andrea Lucard
Executive Vice President
External Relations

Mr David Reddy
Chief Executive Officer

Ms Christina do Paço
External Relations Officer

Route de Pré-Bois, 20
1215 Geneva 15
Switzerland

3. **Aims (or purposes, objectives) of the organization as they appear in its constitution, by-laws or equivalent document.** Medicines for Malaria Venture's mission is to reduce the burden of malaria in countries in which the disease is endemic by bringing together the strengths and resources of the public and private sectors. In particular, Medicines for Malaria Venture selects and funds the discovery and development of promising antimalarial medicines and facilitates access to new, effective and affordable medicines in countries in which malaria is endemic. In addition, it seeks commercial partners to ensure the commercialization of antimalarial medicines; puts in place collaboration agreements with multiple partners for research and development and access-related projects; stimulates the dissemination of essential information; and contributes to the mobilization of resources to help achieve Medicines for Malaria Venture's mission and malaria elimination/eradication.

4. **Main fields of work of the organization.** Communicable diseases (malaria); mother, infant and child health; essential medicines and pharmaceuticals; health legislation; and health care professionals, including official representatives from ministries of health of countries in which malaria is endemic.

5. Main types of activities of the organization.¹ Advocacy, conferences, funding/donations, journals/publications/media, and research.

The organization has activities in the following countries: Australia, Austria, Belgium, Benin, Brazil, Burkina Faso, Cambodia, Cameroon, Canada, China, Congo, Costa Rica, Côte d'Ivoire, Democratic People's Republic of Korea, Democratic Republic of the Congo, Denmark, Ethiopia, France, Gabon, Gambia, Germany, Ghana, India, Indonesia, Ireland, Italy, Japan, Kenya, Lao People's Democratic Republic, Malawi, Malaysia, Mali, Mozambique, Netherlands, Nigeria, Norway, Panama, Papua New Guinea, Peru, Philippines, Russian Federation, Senegal, Singapore, South Africa, Spain, Sweden, Switzerland, Thailand, Uganda, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America, Viet Nam, Zambia.

6. Membership information. Medicines for Malaria Venture is a non-membership organization; see section 7 below.

7. Name, composition, function and frequency of meetings of the main, or if applicable, the two main decision-making bodies.

Name:	Board of Directors
Composition:	The Board of Directors is made up of a maximum of 18 members who are chosen for their scientific, medical and public health expertise in malaria and related fields, their research and management competence, and their experience in business, finance and fundraising.
Function:	The Board of Directors is the highest policy- and decision-making body of Medicines for Malaria Venture, and its main duty is to ensure that the management, through the annual budget and work plan, is efficiently executing Medicines for Malaria Venture's objectives. It establishes the policies and principles followed by Medicines for Malaria Venture and appoints the President and Chief Executive Officer. Medicines for Malaria Venture has recently established a Board of Directors for North America.
Frequency of meetings:	At least twice a year.
Name:	Expert Scientific Advisory Committee
Composition:	The Committee consists of experts from both industry and academia and covers the full range of expertise required to assess projects that are engaging in the extremely complex process of drug research and development. They are initially selected for a three-year period, which can be renewed.

¹ For an explanation of the types of activities, please see the Annex to the application.

Function: The Committee helps to identify the best projects worthy of inclusion in the portfolio for research and development and monitors progress through an annual review of all projects.

Frequency of meetings: Twice a year.

8. Human resources of the organization.

Number of paid staff at headquarters/secretariat: 73

Number of volunteer staff at headquarters/secretariat: 0

Number of paid staff worldwide (including staff at headquarters/secretariat): 74

Number of volunteers worldwide (including staff at headquarters/secretariat): 0

9. Financial information on the organization.¹

Annual income and expenditure in the range: More than US\$ 50 million.

10. Formal relations with organizations and bodies in the United Nations system and nongovernmental organizations.

Not applicable.

11. Collaboration with WHO.

(a) Activities carried out jointly with WHO during the working relations period.

Medicines for Malaria Venture was established in 1999 as the first product development partnership to overcome market failure in research for diseases of poverty against a background of a virtually empty antimalarial medicines pipeline and growing resistance to known drugs. Since then, Medicines for Malaria Venture has worked with WHO on malaria projects such as Pyramax Tablet (pyronaridine-artesunate) in 2002, Dacart (chlorproguanil-dapsone-artesunate) in 2003, and the International Drug Purchase Facility (UNITAID) funded project to improve access to injectable artesunate since 2013. WHO is a key partner for Medicines for Malaria Venture in view of its normative role in public health. Medicines for Malaria Venture closely aligns the target product profile of new antimalarial compounds in its product portfolio with input from WHO and also collaborates closely with WHO through the Global Malaria Programme in Geneva and regional and country offices to help ensure a public health impact.

All new antimalarial medicines developed by Medicines for Malaria Venture and its partners are submitted for approval to the WHO prequalification programme. To date, Medicines for Malaria Venture has developed with its partners four new drugs that have been included in the prequalified products list of the prequalification programme.

¹ In order to facilitate comparison, nongovernmental organizations are requested to express their annual income and expenditure in United States dollar equivalents, and to provide estimates of these annual figures in cases where their accounts cover different periods.

Coartem dispersible (co-developed with Novartis), is a child-friendly medicine approved by Swissmedic (regulatory agency of Switzerland) in December 2008 and prequalified by WHO in February 2009. In April 2009, it was added to the WHO Model List of Essential Medicines for Children. As at December 2013, 200 million treatments of Coartem dispersible had been delivered to 50 countries in which malaria was endemic. It is the first WHO-prequalified child-friendly artemisinin-combination therapy and addresses the unmet need for paediatric medicines.

In November 2010, with support from Medicines for Malaria Venture, Guilin Pharmaceutical became the first company to receive prequalification from WHO for Artesun (artesunate injection) for the treatment of severe malaria. Since then, as at the end of 2013, more than 20 million vials had been delivered to countries in which malaria is endemic, saving an additional 130 000 lives in comparison to lives saved with quinine.

Pyramax, co-developed with Shin Poong Pharmaceutical Co. Ltd., is the first artemisinin-combination therapy to receive a positive scientific opinion in accordance with Article 58 of European Medicines Agency Regulation 726/2004 for the treatment of both strains of malaria, *Plasmodium falciparum* and *Plasmodium vivax*, in adults and children over 20 kilograms, and was added to WHO's list of prequalified medicines in 2012.

Eurartesim is a new artemisinin-combination therapy drug class and provides better and longer protection from new malaria infections when compared with other approved artemisinin-combination therapies. Its dossier was submitted to WHO for prequalification in 2012.

In 2012, WHO recommended seasonal malaria chemoprevention for children, using a complete treatment of sulfadoxine-pyrimethamine and amodiaquine once a month for four months during the malaria transmission season. Medicines for Malaria Venture supports this recommendation and is working to enhance the reach of this treatment to populations that need it, including by obtaining prequalification for a corresponding drug and developing user-friendly packaging and patient cards to help ensure correct dispensation by health care workers and proper use by patients. Medicines for Malaria Venture is supporting Guilin Pharmaceutical in its development of a child-friendly formulation of sulfadoxine-pyrimethamine and amodiaquine by field-testing the palatability of the product. In April 2014, Medicines for Malaria Venture launched a seasonal malaria chemoprevention toolkit, developed in consultation with WHO as a practical extension of WHO's field guide, to help plan, implement and monitor this WHO-recommended life-saving intervention for children.

WHO's Global Malaria Programme and Medicines for Malaria Venture launched a new malaria map tool on the occasion of World Malaria Day in April 2013 to allow users to build customized maps free of charge, using data from WHO's *World malaria report*.

Medicines for Malaria Venture is working to obtain prequalification from WHO for one or more rectal artesunate products for use in pre-referral treatment of patients with severe malaria in the context of the UNITAID-funded project "Improving severe malaria outcomes" and to ensure its correct integration alongside injectable artesunate and to understand the policy change requirements needed for the successful uptake of rectal artesunate.

Medicines for Malaria Venture submitted a proposal for a health research and development demonstration project entitled "Exploiting the pathogen box" to the Consultative Expert Working Group on Research and Development: Financing and Coordination in October 2013. The project is an international open-source collaboration aiming to deliver new drug discovery projects for neglected diseases disproportionately affecting developing countries and for which identified research and

development gaps remain unaddressed due to market failure. “Exploiting the pathogen box” was selected to be one of the final demonstration projects.

During the period 2013–2014, Medicines for Malaria Venture has supported the development of the global strategic plan for *Plasmodium vivax* control and elimination, which will form an integral part of the global technical strategy for malaria control and elimination for the period 2016–2025. The draft strategy has been validated during consultative meetings held in each of the six WHO regions. Input received at the meetings has been incorporated and a revised draft will be submitted to the Malaria Policy Advisory Committee in September 2014.

Medicines for Malaria Venture participates in Roll Back Malaria’s annual board meetings and in the activities of its Communication Community of Practice. It also participates in Roll Back Malaria’s Malaria Advocacy Working Group and its research and academia constituency meetings.

(b) Planned collaborative activities with WHO for the coming three-year period.

The plans for joint collaboration for 2015–2017 include the following activities.

Submission of rectal artesunate for prequalification by WHO (2014–2015): there is currently no product of appropriate strength and presentation that has been prequalified by WHO or a stringent regulatory authority. This has hampered widespread availability and use of rectal artesunate for pre-referral treatment programmes funded by international donors. The aim of this project is to deliver a prequalified rectal artesunate for the pre-referral treatment of severe malaria, and this work has already started in 2014.

Medicines for Malaria Venture and WHO are collaborating on glucose-6-phosphate dehydrogenase testing and radical cure for *Plasmodium vivax* malaria during 2014–2017. The aim of the project is to obtain the registration of a glucose-6-phosphate dehydrogenase test and prequalification of a single dose radical cure for *Plasmodium vivax* malaria.

The implementation of Medicines for Malaria Venture’s Consultative Expert Working Group on Research and Development: Financing and Coordination health research and development demonstration project “Exploiting the pathogen box” is expected to take place during 2015–2020, with funding from Member States.

Medicines for Malaria Venture supports WHO-recommended seasonal malaria chemoprevention using a complete treatment of sulfadoxine-pyrimethamine and amodiaquine and is helping its partners to obtain prequalification from WHO for this treatment. This work has started and is part of the planned activities for the period 2015–2017.

In addition, Medicines for Malaria Venture will continue to participate in Roll Back Malaria’s annual board meetings and in the activities of its Communication Community of Practice. It will also participate in Roll Back Malaria’s Malaria Advocacy Working Group and its research and academia constituency meetings, and will communicate with WHO on the latest developments in its work.

ANNEX

EXPLANATION OF TYPES OF ACTIVITIES

Advisory – the organization regularly advises governments, nongovernmental organizations and institutions, intergovernmental bodies, or the media on matters within its competence.

Advocacy – the organization regularly undertakes campaigns, or its main purpose is, to influence decision- or policy-makers, or individual or societal behaviours or attitudes.

Conferences – the organization regularly holds scientific conferences, or other forums, excluding governing body meetings.

Data collection/surveillance – the organization, for example, maintains a register of specific diseases, up-to-date data about the number of people in a particular profession, etc.

Education/training – the organization, or its members, regularly provides educational or training courses for individuals or organizations (governmental and nongovernmental), is an examining or licensing body, or develops curricula.

Funding/donations – the organization funds the work of others and/or donates goods to others, for example, hospital equipment and pharmaceuticals.

Journals/publications/media – the organization regularly publishes a peer-reviewed professional or scientific journal and/or regularly produces and revises books and other media, e.g. CDs and videos, and maintains a publications/resources catalogue.

Research – the organization undertakes commissions or funds research as a regular activity.

Service delivery – the organization provides, commissions or is contracted on a long-term basis to provide services to non-members, for example, child counselling/protection, hospital care, suicide prevention services and delivery of food aid.

Sponsoring – the organization maintains a sponsorship programme, for example, for children, the elderly or young scientists.

Standard-setting – the organization formulates standards, ranging from professional conduct to goods and services.

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