



West African Health Organization

Promoting better health through Regional Integration

MPDER-MRH/EOI/19/001-00

WEST AFRICA MEDICINES REGULATION HARMONIZATION INITIATIVE

CALL FOR EXPRESSION OF INTEREST (EOI) FOR REGIONAL JOINT MEDICAL PRODUCTS EVALUATION FOR ANTIMALARIA MEDICINES

INTRODUCTION

The West Africa Medicines Regulation Harmonization (WA-MRH) Project has agreed a single process for regional medical product evaluation to enable the registration of medicinal products in the 15 ECOWAS Member States.

This call is an invitation to manufacturers of anti-malaria medicines to submit Expressions of Interest (EOI) for the Regional Joint Medical Products evaluation for registration under this project.

The invitation is published in accordance with the document titled “*WA-MRH Regional Joint Medical Product Evaluation Procedure for pharmaceutical product dossier*”, which is dated July 2019 and is available on WAHO Website (www.wahooas.org) under the section **Resources**, sub-section **Publications and Research**, sub sub-section **Essential Medicines and Vaccines**” and also under the section **Procurement**.

Assessment of product(s) submitted under this invitation will include evaluation of:

- Product dossiers, which must include product data and information as specified in the guidelines for submission.
- manufacturing sites, which must adhere to good manufacturing practices (GMP)
- Product samples, which must adhere to the requisite specifications.

If an evaluation demonstrates that the above three criteria meet the harmonized ECOWAS Common Technical Document (CTD) standards, it would be eligible for inclusion in the products register of each NMRA in all 15 ECOWAS Member States. Such an inclusion would be effected in a Member State on payment of the applicable registration fee by the Manufacturer to the NMRA of that Member State, but this eligibility for inclusion will lapse after two (2) years from the date of issuance of regional recommendation.



West African Health Organization

Promoting better health through Regional Integration

MEDICINAL PRODUCTS FOR THIS EOI

The aim of this EOI is to evaluate a specific range of medical products available in relation to the management of Malaria. The medicines listed in this invitation have been identified by the Expert Working Group for Medical Product Dossier Evaluation and Registration of the WA-MRH Project as vital to effective treatment of malaria, based on WAHO's assessment of the priority health needs in the region, and WHO's evidenced-based treatment guidelines.

Artemisinin-based fixed dose oral combination formulations

- Artemether/Lumefantrine
 - tablet 20 mg/120 mg
 - tablet 40 mg/240 mg
 - tablet 60 mg/360 mg
 - tablet 80 mg/480 mg
- Artesunate/Amodiaquine
 - tablet 50 mg/135 mg
 - tablet 100 mg/270 mg
- Artesunate/Mefloquine
 - tablet 100 mg/200 mg
- Artesunate/Pyronaridine
 - tablet 60 mg/180 mg
- Dihydroartemisinin/Piperaquine Phosphate
 - tablet 40 mg/320 mg
 - tablet 60 mg/480 mg
 - tablet (scored) 80 mg/640 mg

Artemisinin-based fixed dose combination, oral paediatric formulations, preferably dispersible

- Artemether/Lumefantrine, tablet 20 mg/120 mg
- Artesunate/Amodiaquine, tablet 25 mg/67.5 mg
- Artesunate/Mefloquine, tablet 25 mg/50 mg
- Artesunate/Pyronaridine tablet 20 mg/60 mg
- Dihydroartemisinin/Piperaquine, phosphate, tablet 20 mg/160 mg (scored) tablet 30 mg/240 mg tablet 40 mg/320 mg

Artemisinin-based single-ingredient formulations

- Artemether, oily injection 20 mg/ml; 40 mg/ml; 80 mg/ml; 100 mg/ml
- Artesunate, powder for injection 30 mg; 60 mg; 120 mg (vial)
- Artesunate, suppositories 50 mg; 100 mg; 200mg



West African Health Organization

Promoting better health through Regional Integration

HOW TO SUBMIT AN EOI

The Lead Coordinating NMRA for this invitation for EOI is the NMRA of Ghana, the Food and Drug Authority (<http://www.fda Ghana.gov.gh>).

In order to submit an expression of interest for product evaluation, the applicant must do the following:

1. The applicant will pay the management fees of US\$ 500 for the lead coordinating NMRA (FDA-Ghana) for reception, screening, file management and communication when submitting the file. The Bank account details are as follows:

Food and Drugs Authority

Bank of Ghana

Account No: 1018631529507

Swift Code: BAGHGHAC.

2. The applicant should download and complete the Market Authorization application (MA) file in accordance with the harmonized Common Technical Document (CTD) format on WAHO Website (www.wahooas.org) under the section **Resources**, sub-section **Publications and Research**, sub sub-section **Essential Medicines and Vaccines** and also under the section **Procurement**. The completed application MA file should be submitted electronically to the lead coordinating NMRA (fda@fdaghana.gov.gh) with a hard copy sent to Room 316, FDA Head Office, 17 Indian Ocean Street, off Nelson Mandela Avenue, South Legon Commercial Area, Shishie, Accra, GHANA (telephone: +233554456478).
3. The applicant should provide samples of the medical product and reference substances. The sample size shall be in line with the quantity defined by the EWG for Quality Control and published under the **Essential Medicines and Vaccines** section and also under the section **Procurement** on the WAHO website. The samples should be submitted together with the Dossiers to the lead coordinating NMRA (FDA-Ghana).
4. After screening, a certificate of eligibility or non-eligibility for full evaluation will be sent to the applicant by the lead coordinating NMRA. On receipt of a certificate of eligibility the applicant should pay the full evaluation fee within 30 calendar days to the WA-MRH secretariat bank account specified in the certificate:-the applicable fee for the processing of the application.

a) Certificate of Eligibility

- Applicants in the West Africa Region will pay US\$ 8,000
- Applicants in other regions of Africa will pay US\$ 10,000
- Applicants outside Africa will pay US\$ 12,000



West African Health Organization

Promoting better health through Regional Integration

The full fees for a product evaluation is US\$ 23,750 but WAHO, as the WA-MRH Secretariat, has undertaken to absorb the difference in cost in the initial stages of this project. The full fees may therefore be implemented in future EOIs at a later date.

b) Certificate of Non-Eligibility

In the event of an applicant receiving a certificate of non-eligibility, the applicant may resubmit another Market Authorization (MA) application file for screening and pay the management fee of US\$ 500 to the lead coordinating NMRA upon resubmission.

QUALITY CONTROL ASSESSMENT AFTER SUBMISSION OF AN EOI BY AN APPLICANT

As part of the full evaluation for Market Authorization, quality control assessment of a product will be undertaken to ensure that it meets international quality requirements and is manufactured in compliance with good manufacturing practices (GMP).

The procedure for quality control assessment incorporates:

- General understanding of the production and quality control activities of the manufacturer;
- Assessment of product data and information on safety, efficacy and quality submitted by the manufacturer, including product formulation, manufacture and test data and results;
- Assessment of the manufacturing site's adherence to GMP, and its consistency in production and quality control of starting materials, with specific emphasis on active pharmaceutical ingredients and the finished product;
- Assessment of quality control units for compliance with good laboratory practices, as appropriate;
- Testing of product samples submitted.

Previous evaluation conducted by a National Medicines Regulatory Authority (NMRA) within the region may be taken into account during the evaluation conducted by WAHO.

REFERENCES AND FURTHER INFORMATION

For further information on the WA-MRH regional Joint Medical Product Dossier Evaluation and Registration, please visit WAHO website at <https://www.wahooas.org> under the section **Resources**, sub-section **Publications and Research**, sub sub-section **Essential Medicines and Vaccines**.

Deadline for the submission of medicines dossiers to the Lead Coordinating NMRA (FDA-GH) is **Monday, 30 September, 2019 at 23:59 GMT**.