



West African Health Organization

Promoting better health through Regional Integration

MPDER-MRH/EOI/19/005-00

WEST AFRICA MEDICINES REGULATION HARMONIZATION INITIATIVE

CALL FOR EXPRESSION OF INTEREST (EOI) FOR REGIONAL JOINT MEDICAL PRODUCTS EVALUATION FOR ANTI- TUBERCULOSIS 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 tuberculosis. 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 tuberculosis, based on WAHO's assessment of the priority health needs in the region, and WHO's evidenced-based treatment guidelines.

Single ingredient first-line anti-tuberculosis medicines

- Ethambutol hydrochloride (E), coated tablet/capsule 200mg; 275mg
- Ethambutol hydrochloride, coated tablet (scored)/ capsule 400 mg
- Isoniazid, tablet/capsule 300 mg
- Pyrazinamide (Z), coated tablet/capsule 250mg
- Pyrazinamide, tablet/capsule 400 mg; 500 mg
- Rifampicin, capsule 150 mg; 300 mg
- Rifabutin, capsule 150 mg
- Rifapentine, tablet 150 mg; 300 mg
- Streptomycin, powder for injection 1g (vial)³
- Streptomycin, powder for injection 0.75 g (vial)³

Footnote: '3'- With or without diluent water for injection 5 ml vial.

Fixed dose combination products of first-line anti-tuberculosis medicines

- Isoniazid / Rifampicin,
 - coated tablet / capsule 75 mg / 150 mg;
 - coated tablet / capsule 150 mg / 150 mg
 - coated tablet / capsule 150 / 300 mg
- Ethambutol hydrochloride / Isoniazid,
 - coated tablet /capsule 400 mg / 150 mg
- Ethambutol hydrochloride / Isoniazid / Rifampicin,
 - coated tablet/capsule 275 mg / 75 mg / 150 mg
- Isoniazid / Pyrazinamide / Rifampicin,
 - coated tablet/capsule 150 mg / 500 mg / 150 mg
- Ethambutol hydrochloride / Isoniazid / Pyrazinamide / Rifampicin,
 - coated tablet 275 mg / 75 mg / 400 mg / 150 mg



West African Health Organization

Promoting better health through Regional Integration

- Isoniazid / Pyrazinamide/ Rifampicin,
 - coated tablet/capsule 75 mg / 400 mg / 150 mg
- Isoniazid / Rifapentine,
 - dispersible tablet 150 mg / 150 mg;
 - coated tablet (preferably scored)/capsule 300 mg / 300mg

Single ingredient second-line anti-tuberculosis medicines

- Amikacin, solution injection 500 mg/2 ml vial, amp; powder for injection 1g vial, 3
- Bedaquiline (fumarate), tablet 100 mg
- Capreomycin, powder for injection 1g, vial3
- Capreomycin, powder for injection 500 mg, vial3
- Clofazimine, capsule 50 mg and 100 mg; tablet 100 mg (scored)
- Cycloserine, capsule 250 mg
- Delamanid, tablet 50 mg
- Ethionamide, tablet/capsule 125mg, 250 mg (scored)
- Gatifloxacin, tablet 200 mg; 400 mg (scored)
- Kanamycin, solution for injection 1 g; powder for injection 1g, vial3
- Kanamycin, solution for injection 500 mg; powder for injection 500 mg, vial3
- Levofloxacin, tablet/capsule 250 mg; tablet 500 mg (scored); tablet 750 mg
- Linezolid, coated tablet 600 mg (scored)
- Linezolid, oral powder for suspension (20 mg/ml) 240 ml, bottle.
- Moxifloxacin tablet (scored)/capsule 400 mg
- Prothionamide, tablet/capsule 250 mg
- Para-Aminosalicylic Acid (PAS) sachets, 4 g granules
- PAS Sodium 100 g jar granules, 4g/9.2 g sachets granules; powder for oral solution, sachets
- Terizidone, tablet/capsule, 250 mg; 300 mg.

Solid dosage formulations for children, preferably dispersible or crushable tablets, in fixed dose combination format:

- Rifampicin 75 mg / Isoniazid 50 mg / Pyrazinamide 150 mg
- Rifampicin 75 mg / Isoniazid 50 mg
- Isoniazid 150 mg / Rifapentine 150 mg
- Isoniazid 300 mg / Rifapentine 300 mg

Solid dosage formulation for children, in single dose format:

- Delamanid, tablet 50 mg (dispersible)
- Ethambutol hydrochloride tablet 100 mg (scored and dispersible); 50 mg (scored and dispersible)
- Isoniazid tablet 100 mg (scored and dispersible); 50 mg (scored and dispersible)
- Pyrazinamide tablet 150 mg (scored and dispersible);
- Cycloserine capsule 125 mg;



West African Health Organization

Promoting better health through Regional Integration

- Levofloxacin tablet 100 mg (scored and dispersible);
- Moxifloxacin tablet 100 mg (scored and dispersible);
- Linezolid tablet 150 mg (scored and dispersible);
- Ethionamide tablet 125 mg (scored and dispersible);
- Rifapentine, tablet 150 mg (dispersible)
- Rifapentine, tablet 300 mg (scored and dispersible)

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.fdaghana.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, Shashie, 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-



West African Health Organization

Promoting better health through Regional Integration

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

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.



West African Health Organization

Promoting better health through Regional Integration

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**.