10th Invitation[1] to manufacturers of medicinal products for treatment of neglected tropical diseases, to submit an Expression of Interest (EOI) for product evaluation to the WHO Prequalification Unit

To support national and global efforts to increase access to and the affordability of care and treatment of neglected tropical diseases, WHO invites manufacturers of selected pharmaceutical products to submit Expressions of Interest (EOI) for product evaluation.

1. Procedure for this Invitation to EOI

The current Invitation is published in accordance with the *Procedure for prequalification of pharmaceutical products*, adopted in 2001 by the 37th WHO Expert Committee on Specifications for Pharmaceutical Preparations, and amended subsequently as part of the 45th report of the Committee, published as No. 961 of the WHO Technical Report Series in 2011.

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 (see Procedures & Fees)
- manufacturing sites, which must adhere to good manufacturing practices (GMP)
- clinical sites (if applicable), which must adhere to good clinical practices (GCP).

If evaluation demonstrates that a product and its corresponding manufacturing (and clinical) site(s) meet WHO recommended standards, it will be included in the list of prequalified medicinal products that are considered to be acceptable for procurement by UN organizations and others.

2. Medicinal products included on the 10th Invitation

The aim of this 10th EOI is to ensure the availability of quality assured acoziborole, albendazole, diethylcarbamazine, ivermectin, moxidectin, mebendazole, praziquantel, arpraziquantel, miltefosine, sodium stibogluconate, paromomycin, azithromycin, fexinidazole, liposomal amphotericin B, rifampicin and fixed dose combination of rifampicin and clarithromycin for the treatment of lymphatic filariasis (albendazole, diethylcarbamazine, ivermectin or moxidectin), onchocerciasis (ivermectin, moxidectin) soil-transmitted helminthiasis (STH) (albendazole, mebendazole, ivermectin), scabies (ivermectin), schistosomiasis (praziquantel, arpraziquantel), taeniasis (praziquantel), cutaneous leishmaniasis (miltefosine, sodium stibogluconate), visceral leishmaniasis (miltefosine, sodium stibogluconate, paromomycin sulfate, liposomal amphotericin B), yaws (azithromycin), Human African trypanosomiasis (HAT) (acoziborole, fexinidazole), Buruli ulcer (fixed dose combination of rifampicin and clarithromycin) and leprosy (rifampicin for post-exposure prophylaxis). The recommended active ingredients, dosage forms and strengths listed in this document have been identified by WHO's Neglected Tropical Disease

[1] Additions are in red text

Department for effective treatment of patients suffering from these diseases. These formulations are included either in the WHO Model List of Essential Medicines (EML) 24th list, 2025, under consideration for the next WHO EML (2027) and/or in the WHO technical report series.

They are selected on the basis of disease prevalence, evidence on efficacy and safety and comparative cost-effectiveness.

Products included in the WHO Model List of Essential Medicines or WHO technical report series are selected on the basis of an assessment of the quality of evidence for benefits, harms, costs, and appropriateness for use in a variety of situations, taking into account needs of special populations, and the values and preferences of the groups (professional and patient) using them.

Interested manufacturers are encouraged to submit documentation for the medicinal product as specified below:

Single ingredient medicines to treat lymphatic filariasis, onchocerciasis, soil-transmitted helminthiasis (STH), and schistosomiasis, taeniasis, cutaneous leishmaniasis, visceral leishmaniasis, yaws disease, scabies, leprosy and Human African trypanosomiasis (HAT)

- Diethylcarbamazine citrate 100mg tablet (scored)
- Mebendazole 500mg tablet (chewable*)**
- Albendazole 400mg tablet (chewable*, scored)**
- Praziquantel 600mg tablet (scored)
- Arpraziquantel 150mg and 300mg (scored) dispersible tablet; preferably orodispersible tablet***
- Ivermectin 3mg tablet
- Moxidectin 2mg tablet**
- Miltefosine 10mg and 50mg capsule
- Sodium stibogluconate 10% SB^{5+} (100mg/ml) 30ml or 100ml vial (injectable)
- Paromomycin solution for intramuscular injection of paromomycin base (as the sulfate) 375mg/ml, 2ml ampoule
- Azithromycin 500mg tablet
- Fexinidazole 600mg tablet
- Liposomal amphotericin B powder for injection, 50mg vial****
- Rifampicin 150mg and 300mg capsules*****
- Acoziborole 320mg tablet

Fixed dose combination product to treat Buruli ulcer

- Rifampicin/Clarithromycin tablet 300mg/250mg (scored)

** can be chewed or swallowed whole*
*** The preferred packaging type is a bottle HDPE.*
**** Also known as L-praziquantel or R-(-)-praziquantel*
***** This product is also invited by WHO for treatment of HIV/AIDS related conditions, see EOI for FPPs for HIV/AIDS.*
****** This product is also invited by WHO for treatment of tuberculosis, see EOI for FPPs for tuberculosis.*

Article 3. How to submit an EOI

In order to submit an expression of interest for product evaluation, the manufacturer must send the required documentation, arranged according to the information provided on the WHO Prequalification Unit – Medicines Team website at https://extranet.who.int/prequal.

Article 4. Quality assessment procedure following submission of an EOI by a manufacturer

The quality assessment is undertaken to assess whether the pharmaceutical product being evaluated meets the requirements recommended by WHO, and is manufactured in compliance with good manufacturing practices (GMP).

The procedure established by WHO for quality 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 finished product;
- assessment of clinical testing units or organizations (i.e. parties performing one or more clinical trials with the product) for compliance with good clinical practices and good laboratory practices, as appropriate;
- random sampling and testing of medicines supplied.

Previous evaluation conducted by the relevant National Drug Regulatory Authority (NDRA) may be taken into account during the evaluation conducted by WHO, provided that the NDRA has expertise in the product area. If appropriate, the relevant NDRA may be invited to collaborate with WHO on the quality assessment. Any manufacturer who submits a product for evaluation, is therefore encouraged to authorize its NDRA to discuss relevant product files with WHO representatives, during assessments and inspections, if required (subject to appropriate confidentiality provisions, if necessary).

Once WHO is satisfied that quality assessment has been completed for the manufacturer of the relevant starting materials, the finished pharmaceutical product, and the clinical testing units, and that the product meets WHO recommended standards, the product (as produced at the specified manufacturing site) is added to the WHO List of Prequalified Medicines.

Article 5. References and further information

For further information on the WHO Prequalification Unit – Medicines Team, please visit the PQT website at: https//extranet.who.int/prequal. Should you have any questions relating to the procedure for responding to an EOI, please write to PQT at its email address: prequal@who.int. Your question(s) will be directed to the prequalification team member who can best advise you.