

# Invitation to Manufacturers

9<sup>th</sup> December 2021

## Manufacturers of COVID-19 Pharmaceutical Products

Are Invited to Submit  
An Expression of Interest  
For Product Evaluation by the  
Global Fund Expert Review Panel

Opening Date:	9 <sup>th</sup> December 2021
Closing Date:	Not applicable / Open call
Reference Number:	GF/ERP/Ad-Hoc/12-2021

### 01 Background

#### **Summary of the Global Fund Quality Assurance Policy**

The Global Fund to Fight AIDS, Tuberculosis and Malaria (“Global Fund”) provides grants to support national and global efforts to increase access, care and treatment in approximately 140 countries.

The Global Fund also supports countries to mitigate the impact of COVID-19 on programs to fight HIV, TB and malaria, and initiates urgent improvements in health and community systems through the COVID-19 Response Mechanism (known as C19RM).

The Global Fund Quality Assurance Policy for Pharmaceutical Products (“QA Policy”<sup>1</sup>) defines uniform and stringent quality requirements applicable to antiretrovirals (ARVs), antituberculosis, antimalarial and COVID 19 pharmaceutical products purchased with Global Fund resources. In principle, these pharmaceutical products can be funded using Global Fund resources if they are in compliance with national regulatory standards as applicable and if:

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<sup>1</sup> <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/>

- prequalified by the WHO Prequalification Programme; **and/or**
- authorized for marketing in a country with a stringent regulatory authority<sup>2</sup> (registration "for export only" is not sufficient) or approved/subject to a positive opinion under one of the following schemes: Canada S.C. 2004, c. 23 (Bill C-9) procedures, or Art. 58 of European Union Regulation (EC) No. 726/2004 or US-FDA tentative approval; **or**
- products of which the dossiers were reviewed and permitted for use for a time limited period by an independent panel of technical experts (the Expert Review Panel).

In addition, in the framework of the Covid-19 Response Mechanism and as per the Global Fund interim guidance "Interim Quality Assurance Requirements for the Procurement of COVID-19 Pharmaceutical Products"<sup>3</sup> the Emergency Situation and Related Emergency Procedures is recognized.

Information about the Expert Review Panel mechanism and process for procurement of Expert Review Panel-reviewed products is available at: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/>.

In order to assist Global Fund grant recipients to identify the regulatory status of ARVs, antituberculosis, antimalarial and COVID 19 pharmaceutical products the Global Fund has developed a list of products classified according to the above quality assurance requirements. The current list can be downloaded from: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/>

## 02 Purpose

The purpose of this expression of interest is to invite submissions of product dossiers for review by the Expert Review Panel for which there could be supply bottlenecks, including the cases where there are two or less products of the same formulation available in the global market that are already WHO prequalified or approved by a stringent regulatory authority. This expression of interest may include, as well, some formulations even when there are more than two eligible products in the market, in cases where it has been determined that such products are eligible for distribution to a restricted number of countries only, or when it has been identified that the available production capacity of the qualified products cannot cover the demand.

## 03 Product formulations included in this expression of interest

In line with the Global Fund's Market Shaping Strategy and objective to accelerate access to innovations and new product introduction, in advance of the publication by WHO of treatment guidelines and consequently in advance of country-specific demand, the Global Fund is including promising innovative FPPs in this ERP review process. Note that only products that meet Global Fund Quality Assurance requirements will be eligible for procurement with Global Fund funds.

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<sup>2</sup> <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/>

<sup>3</sup> <https://www.theglobalfund.org/en/covid-19/health-product-supply/quality-assurance/>

The recommended active ingredients, dosage forms and strengths ("Formulations") listed in this document are included in the WHO prequalification 6th invitation- EOI for FPPs for COVID-19 (25 November 2021).

**COVID-19 Pharmaceutical Products included in this expression of interest are listed in Annex A.**

## 04 Eligibility for submission<sup>4</sup>

### **Requirements :**

The following criteria must be met in order for products to be accepted for External Review Panel review:

- the manufacturer of the product has submitted an application of the product to the WHO Prequalification Programme and it has been accepted by WHO for review; OR the manufacturer of the product has submitted an application for marketing authorization to a stringent regulatory authority, and it has been accepted for review by the stringent regulatory authority;
- AND the product is manufactured at a site that is compliant with all standards of good manufacturing practice that apply to the relevant product formulation, as verified after inspection by the WHO Prequalification Programme, OR a stringent regulatory authority, OR a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)<sup>5</sup>.

## 05 ERP Technical advice

For this particular Ad-hoc ERP, The Global Fund would like to offer the opportunity to provide technical and scientific advice to manufacturers in response to questions forwarded by email, or at a meeting. Potential applicants for ERP may forward a request for technical advice to ERP (by emailing [HealthProductQualityAssurance@theglobalfund.org](mailto:HealthProductQualityAssurance@theglobalfund.org)) at any time after the publication of this request for expression of interest, and can expect a response in a few days, depending on the complexity of the question(s).

In addition, the Global Fund will also accept within the same confidentiality framework any technical advice provided by the WHO Prequalification Programme or by any stringent regulatory authorities issued on the same formulation as the one to be submitted for ERP.

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<sup>4</sup> Global Fund, [Quality Assurance Policy for Pharmaceutical Products](#) (as amended and restated on 14 December 2010), Point 13

<sup>5</sup> Pharmaceutical Inspection Cooperation Scheme (<https://picscheme.org/>)

## 06 Submission of documents for Expert Review Panel review

All manufacturers interested in submitting applications for review by the Expert Review Panel are requested to submit the following information and material for each product under consideration:

### **For each product awaiting WHO prequalification:**

1. A covering letter expressing interest in submitting the product to the Expert Review Panel for review;
2. A communication from PQT/MED indicating that the manufacturer has been requested to submit a formal application for prequalification following a pre-submission meeting;
3. A written commitment from the manufacturer to submit an application to PQT/MED;
4. Certification issued by the WHO Prequalification Programme confirming that the site and production line where the product is manufactured comply with all aspects of good manufacturing practice, or a letter describing arrangements made to obtain such certification and stating the date when it will be supplied;
5. A completed Pharmaceutical Product Questionnaire<sup>6</sup> (attached);
6. In lieu of annexes, reference can be made to the dossier submitted for WHO prequalification. Annexes should be submitted in case of any changes or updates;
7. A non-returnable product sample as requested in the Interagency Pharmaceutical Product Questionnaire.

### **For each product awaiting marketing authorization by a stringent regulatory authority:**

1. A covering letter expressing interest in submitting the product to the Expert Review Panel for review;
2. An acceptance letter from a stringent regulatory authority confirming that the submission for the product has been accepted for review;
3. Certification, issued by a stringent regulatory authority OR a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S), confirming that the site and production line where the product is manufactured comply with all aspects of good manufacturing practice, or a letter describing arrangements made to obtain such certification and stating the date when it will be supplied;
4. A completed Pharmaceutical Product Questionnaire<sup>6</sup> (attached), and all annexes as applicable;
5. A non-returnable product sample as requested in the Interagency Pharmaceutical Product Questionnaire.

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<sup>6</sup> As available at the Global Fund website:

[https://www.theglobalfund.org/media/4325/psm\\_interagencyfinishedpharmaceuticalproduct\\_questionnaire\\_en.docx](https://www.theglobalfund.org/media/4325/psm_interagencyfinishedpharmaceuticalproduct_questionnaire_en.docx)

## 07 Confidentiality

All information provided by manufacturers will be received by the Global Fund and shared with the External Review Panel members for the purpose of facilitating their review of the submission and provision of advice to the Global Fund.

Information provided by manufacturers, review findings and advice provided by the External Review Panel in connection with this expression of interest will be shared with and used by the Global Fund, GDF, Unitaïd and the following partners: Médecins sans Frontières, UNICEF, and the United States Agency for International Development (USAID) as the basis for procurement decisions.

Information provided by manufacturers, review findings and advice provided by the External Review Panel can also be shared with National Regulatory Authorities to expedite registration of the ERP approved Pharmaceutical Product. The above information will be shared with the National Regulatory Authorities only after approval received from the manufacturer to expedite registration of the approved ERP Pharmaceutical Product. The NRA will be asked to signed confidentiality agreement as agreed between the parties.

## 08 Eligibility

Completeness of the documents submitted to Global Fund Secretariat for External Review Panel review is determined by the Global Fund quality assurance specialist. All the documents listed in the instructions for submission (in annex) must be included by the applicant. Incomplete submissions will not be forwarded to the External Review Panel.

The eligibility of the submissions for External Review Panel review will not be considered by the Global Fund Secretariat. It is the External Review Panel's responsibility to review and to judge the eligibility and whether or not to perform the risk-benefit assessment of the products submitted.

For any product found not to comply with the required standards during previous External Review Panel review, all documentation requested should be re-submitted in full.

## 09 Instructions for submission

**Documentation should be submitted by electronic means ONLY either via CD, USB key or file transfer (because of new IT policy security, please liaise in advance with the contact address above of this EoI to ensure file transfer software is acceptable to Global Fund).** Files should be named to reflect their content as mentioned in this letter (e.g. "Covering Letter.pdf"). For ease of reference, electronically submitted annexes to the questionnaire should be named according to the letters on the list of annexes included in the questionnaire (e.g. "A.pdf" for information on the formulation of the product). **Please keep the naming of the annexes as short as possible (e.g. "A.pdf").**

**In regards of the technical evaluation, it is mandatory to submit a sample of the finished product offered (one pack of one of the available packaging size is sufficient).**

It is highly recommended that manufacturers send an undertaking with the shipment of sample (sample for technical evaluation) that is sent along with the dossiers, indicating that the samples are sent **for review purpose only**, will not be used on humans or animals have no commercial value and will not be placed in the market. This will ensure smooth passage through customs in the country of origin and in Switzerland.

The deadline for the Submission is : **Not applicable /Open tender.**

Submissions should be sent to the following Address of the TGF QA team:  
**HealthProductQualityAssurance@theglobalfund.org**

Should you have any further questions, please send an e-mail to the following email address: [HealthProductQualityAssurance@theglobalfund.org](mailto:HealthProductQualityAssurance@theglobalfund.org)

## **Annex A - COVID-19 Pharmaceutical Products**

### **Direct-Acting Antiviral Products**

- Molnupiravir 200 mg capsules for oral administration

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