Invitation to Manufacturers

07 April 2026

Manufacturers of Finished Pharmaceutical Products (FPP) of Lenacapavir for Pre-Exposure Prophylaxis Are Invited to Submit An Expression of Interest For Product Evaluation by the Global Fund Expert Review Panel

Opening Date:	07 April 2026
Closing Date:	Not applicable / Open call
Reference Number:	GF/ERP/Ad-Hoc/04-2026

01 Purpose

As part of its Next Generation Market Shaping approach, the Global Fund is committed to advancing equitable and timely access to quality-assured health products and innovations. This includes accelerating the introduction and scale-up of priority commodities, strengthening market health, and ensuring sustainable and resilient supply to meet country needs.

In this context, manufacturers of FPP of Lenacapavir for Pre-Exposure Prophylaxis are invited to submit an Expression of Interest (EOI) for product dossiers evaluation by the Global Fund Expert Review Panel for key life-saving and innovative health products where demand is high, but market conditions remain constrained[1].

Through this process, the Global Fund along with key partners, including but not limited to: UNITAID, the Gates Foundation, CIFF and CHAI, aims to proactively shape markets by expanding the supplier base, supporting accelerated access pathways, and enabling the rapid, equitable scale-up of innovation.

[1] Including products for which there are fewer than two formulations available globally that are either WHO-prequalified or approved by a stringent or WHO-listed regulatory authority. The invitation for manufacturer may also extend to products with two or more eligible suppliers where access remains limited, such as when products are restricted to distribution in a subset of countries, or where existing manufacturing capacity is insufficient to meet global demand.

02 Product formulations included in the invitation for expression of interest

The recommended active ingredients, dosage forms and strengths ("Formulations") listed in this document are included in the current WHO Model List of Essential Medicines and/or in the most recent WHO standard treatment guidelines for treatment and prevention of the three diseases.

Antiretrovirals formulations included in the invitation for expression of interest are listed in Annex A

03 Eligibility for submission[2]

Requirements under CRITERION-1:

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 or to WHO listed authority, and it has been accepted for review by the stringent regulatory authority or the WHO listed 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 WHO listed authority OR a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)[3].

Requirements under CRITERION-2:

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

- 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 WHO listed authority OR a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S),
- AND it is not listed in the WHO invitation to manufacturers to submit an expression of interest for product evaluation by the WHO Prequalification Programme.

[2] Global Fund, https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/
[3] Pharmaceutical Inspection Cooperation Scheme (https://picscheme.org/en/picscheme)

04 Submission of documents for Expert Review Panel review under CRITERION-1

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 cover letter expressing interest in submitting the product to the Expert Review Panel for review;
2. An acceptance letter from the WHO Prequalification Programme confirming that the submission for the product has been accepted for review, and stating the WHO reference number assigned by WHO to this specific product;
3. 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;
4. A completed Pharmaceutical Product Questionnaire[4] (attached);
5. 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;
6. Good quality photos of the sample: product itself (tablet, capsules, etc.), primary and secondary packaging.

For each product awaiting marketing authorization by a stringent regulatory authority or WHO listed authority:

1. A cover letter expressing interest in submitting the product to the Expert Review Panel for review;
2. An acceptance letter from a stringent regulatory authority or WHO listed authority confirming that the submission for the product has been accepted for review;
3. Certification, issued by a stringent regulatory authority OR a WHO listed 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[4] (attached), and all annexes as applicable;
5. Good quality photos of the sample: product itself (tablet, capsules, etc.), primary and secondary packaging.

[4] As available at the Global Fund website:
https://www.theglobalfund.org/media/4325/psm_interagencyfinishedpharmaceuticalproduct_questionnaire_en.docx

05 Submission of documents for External Review Panel review under CRITERION-2

All manufacturers interested in submitting applications for review by the External Review Panel under *Eligibility Criterion 2* are requested to submit the following information and material for each product under consideration:

1. A covering letter expressing interest in submitting the product to the External Review Panel for review;
2. 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;

and/or

3. Certification, issued by stringent regulatory authority OR a WHO listed 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[5];
5. Good quality photos of the sample: product itself (tablet, capsules, etc.), primary and secondary packaging.

06 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 invitation for expression of interest will be shared with and used by the Global Fund, GDF, Unitaid and the following partners: Médecins sans Frontières, UNICEF, and the United States Agency for International Development (USAID) as the basis for procurement decisions.

07 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.

[5] As available at the Global Fund website:
https://www.theglobalfund.org/media/4325/psm_interagencyfinishedpharmaceuticalproduct_questionnaire_en.docx

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.

08 Instructions for submission

Documentation should be submitted by electronic means ONLY via file transfer (because of new IT policy security, please liaise in advance with the contact address above 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 on page 17 of 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 good photos of the sample of the finished product offered.

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

Annex A - Antiretroviral formulations

Formulations included under eligibility (CRITERION-1):

Medicines to prevent HIV/AIDS:

- Lenacapavir 463.5mg/1.5mL solution for injection, subcutaneous injection
    - Preferably pack of 2 single-dose vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL of lenacapavir; 2 disposable syringes; 2 withdrawal needles; 2 injection needles
    - Preferably pack of 10 single-dose vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL of lenacapavir; 10 injection needles

- Lenacapavir 300mg tablet

END

Additional consulted reference guidelines:

Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis (WHO, 15 July 2025)

Appendix 1

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 Quality Assurance Policy for Pharmaceutical Products ("QA Policy"[6]) defines uniform and stringent quality requirements applicable to antiretrovirals (ARVs), antituberculosis, and antimalarial 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 they meet the following standards:

- prequalified by the WHO Prequalification Programme; **or**
- authorized for marketing in a country with a stringent regulatory authority[7] (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 (EC9 No. 726/2004) or US-FDA tentative approval; **or**
- authorized for use by a World Health Organization Listed Authority (WLA)[8]; **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).

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 Pharmaceutical Products eligible to be procured using the Global Fund resources and Grant Funds, a list of products classified according to the above quality assurance requirements is maintained. The current lists can be downloaded from: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/

[6] https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/
[7] https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/
[8] Evaluating and publicly designating regulatory authorities as WHO listed authorities WHO Policy document – Geneva 2021. https://www.who.int/publications/i/item/9789240023444.