

# 22<sup>nd</sup> Invitation to Manufacturers and Suppliers of Medicinal Products for HIV Infections and Related Diseases to Submit an Expression of Interest (EOI) for Product Evaluation to the WHO Prequalification Unit – Medicines Team

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To support national and global efforts to increase access to and the affordability of HIV/AIDS-related care and treatment together with UNICEF, UNAIDS and UNITAID, invite applicants for selected pharmaceutical products to submit Expressions of Interest (EOI) for product evaluation. The first Invitation to EOI for products for HIV/AIDS-related care and treatment was published in 2000.

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## 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 37<sup>th</sup> WHO Expert Committee on Specifications for Pharmaceutical Preparations, and amended subsequently as part of the 45<sup>th</sup> report of the Committee, published as [WHO TRS 961](#) 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 [\(Prequalification Procedures and Fees: FPPs, APIs & QCLs | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)\)](#)
- manufacturing sites, which must adhere to [WHO TRS 957](#) and [WHO TRS 986](#) (GMP)
- clinical sites (if applicable), which must adhere to [WHO TRS 850](#) (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 22<sup>nd</sup> Invitation

The aim of this 22<sup>nd</sup> invitation is to review the range of selected products and sources available in relation to the management of HIV/AIDS. The medicines listed in this invitation have been identified by WHO Global HIV, Hepatitis and STI Programmes as vital to effective treatment and prevention of HIV infection in adults, adolescents and children. These products are included either in the [WHO Model Lists of Essential Medicines](#), the [2021 consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring](#), the 2022 WHO guidance on the use of long acting injectable cabotegravir for HIV prevention, the 2025 WHO guidance on the use of lenacapavir for HIV prevention or the 2025 WHO guidance on the use of the dual prevention pill for contraception and HIV prevention.

Products included in the WHO Model Lists of Essential Medicines are those which satisfy the priority health care needs of a population. They are selected on the basis of disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Products included in WHO treatment guidelines 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.

For medicines for children, age-appropriate flexible solid oral dosage forms such as dispersible tablets are preferred.

Interested applicants are encouraged to submit documentation for recommended dosage forms and strengths of the medicinal products listed below which have been identified as priority products. Other antiretroviral medicines and formulations are in a complementary list (Article 3 below). Interested applicants can still submit dossiers for these products, but with the acknowledgement that they are not considered priority products anymore. In both cases, appropriate solid oral dosage formulations should be functionally scored for paediatric use and relevant evidence should be provided to support equal distribution of active ingredients in the scored products, especially in case of fixed-dose combination products.

## **1. Antiretrovirals as single-ingredient formulations for use in adults and adolescents:**

### **1.1. Non-Nucleoside Reverse Transcriptase Inhibitors:**

- Etravirine, tablet, 200mg
- Dapivirine, silicone matrix vaginal ring, 25 mg

### **1.2. Integrase Inhibitors:**

- Dolutegravir, tablet 50mg
- Cabotegravir, suspension for intramuscular injection, 600mg/3ml (200mg/ml)
- Cabotegravir, tablet, 30 mg

### **1.3 Capsid Inhibitors**

- Lenacapavir, solution for subcutaneous injection, 463.5mg/1.5 ml (309mg/ml)
- Lenacapavir, tablet, 300 mg

## **2. Antiretrovirals as single-ingredient formulations for use in children:**

### **2.1. Solid oral dosage formulations of:**

- Abacavir, tablet 60 mg scored and dispersible
- Dolutegravir, tablet 5 mg dispersible or tablet 10 mg scored and dispersible
- Ritonavir, tablet or pellets (heat-stable) 25 mg

### **2.2. Oral liquid or powder for oral liquid:**

- Lamivudine, 50mg/5ml
- Nevirapine, 50mg/5ml
- Zidovudine, 50mg/5ml

**3. Antiretrovirals as fixed-dose combinations (FDC) for adults and adolescents:****3.1. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors:**

- Lamivudine/Abacavir, tablet (preferably scored) 300mg/600mg

**3.2. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors plus Non-nucleoside Reverse Transcriptase Inhibitors:**

- Emtricitabine/Tenofovir disoproxil fumarate/Efavirenz, tablet 200mg/300mg/400mg
- Lamivudine/Tenofovir disoproxil fumarate/Efavirenz, tablet 300mg/300mg/400mg

**3.3. Protease Inhibitors:**

- Atazanavir/Ritonavir, tablet (heat stable) 300mg/100mg
- Darunavir/Ritonavir, tablet (heat stable) 800/100mg, 600/100mg, 300mg/50mg, 400mg/50mg

**3.4. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors plus Integrase Inhibitors:**

- Emtricitabine/Tenofovir disoproxil fumarate/Dolutegravir, tablet 200mg/300mg/50mg
- Lamivudine/Tenofovir disoproxil fumarate/Dolutegravir, tablet 300mg/300mg/50mg

**3.5. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors plus contraceptive Progestin/Estrogen**

- Emtricitabine/Tenofovir disoproxil fumarate/Levonorgestrel/Ethinylestradiol, tablet 200 mg/300 mg/0.15 mg/0.03 mg (21 tablets); co-packaged with Emtricitabine/Tenofovir disoproxil fumarate tablet 200 mg/300 mg (7 tablets)

**4. Antiretrovirals as fixed-dose combinations (FDC) for paediatric use:****4.1. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors:**

- Lamivudine/Abacavir, tablet 60 mg/120 mg scored and dispersible
- Lamivudine/Zidovudine, tablet 30 mg/60 mg scored and dispersible

**4.2. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors plus Protease Inhibitors:**

- Lamivudine/Abacavir, granules/minitables/pellets 15 mg/30 mg co-mixed with Lopinavir/Ritonavir, granules/minitables/pellets (heat stable) 40 mg/10 mg

**4.3. Protease Inhibitors:**

- Darunavir/Ritonavir, tablet (heat-stable), 120 mg/20 mg
- Lopinavir/Ritonavir, tablet (heat-stable) 100 mg/25 mg
- Lopinavir/Ritonavir, granules/mini tablets/pellets (heat stable) 40 mg/10 mg

**4.4. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors plus Integrase Inhibitors:**

- Lamivudine/Abacavir/Dolutegravir, tablet 30 mg/60 mg/5 mg dispersible

**5. Medicines to treat HIV/AIDS related conditions for adults, adolescents and children:****5.1. Antiviral agents:**

- Ganciclovir, injection 500 mg
- Valganciclovir, tablet 450 mg

**5.2. Antibacterial, antiprotozoal and antifungal agents:**

- Amphotericin B, injection vial 50 mg (deoxycholate); 50 mg (liposomal)

- Flucytosine, capsule 250 mg; 500 mg scored tablet; injection 10mg/ml
- Fluconazole, capsule 50 mg; 200 mg; injection 2mg/ml
- Sulfamethoxazole /Trimethoprim /Isoniazid /Pyridoxine, scored tablet 800mg/160 mg /300 mg/ 25 mg; scored tablet 400mg/80 mg /150 mg/12.5 mg

### 3. Complementary list of non-priority ARV products

The ARV drugs and formulations listed below are still recommended in the WHO treatment guidelines and continue to be invited to the WHO Prequalification Unit (PQT) – Medicines Team, but are not considered as priority products for the purposes of this EOI (See Article 2).

#### 1. Antiretrovirals as single-ingredient formulations for use in adults and adolescents:

##### 1.1. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors:

- Abacavir, tablet 300 mg, 600 mg
- Lamivudine, tablet 150 mg
- Tenofovir disoproxil fumarate, tablet 300 mg
- Zidovudine, tablet 300 mg; capsules 250 mg

##### 1.2. Non-Nucleoside Reverse Transcriptase Inhibitors:

- Efavirenz, tablet 600 mg
- Etravirine, tablet 100 mg

##### 1.3. Protease Inhibitors:

- Darunavir, tablet 400mg; 600mg; 800 mg
- Ritonavir, tablet (heat-stable) 100 mg

#### 2. Antiretrovirals as fixed-dose combinations (FDC) for adults and adolescents:

##### 2.1. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors:

- Emtricitabine/Tenofovir disoproxil fumarate, tablet 200 mg/300 mg
- Emtricitabine/Tenofovir alafenamide, tablet 200mg/25mg; tablet 200/10mg
- Lamivudine/Tenofovir disoproxil fumarate, tablet 300 mg/300 mg
- Lamivudine/Tenofovir alafenamide, tablet 300mg/25mg
- Lamivudine/Zidovudine, tablet 150 mg/300 mg; tablet 150 mg/250 mg

##### 2.2. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors plus Non-nucleoside Reverse Transcriptase Inhibitors:

- Emtricitabine/Tenofovir alafenamide/Efavirenz, tablet 200mg/25mg/400mg

##### 2.3. Protease Inhibitors:

- Atazanavir/Ritonavir, tablet (heat stable) 150 mg/50 mg
- Lopinavir/Ritonavir, tablet (heat-stable) 200 mg/50 mg

##### 2.4. Nucleoside/Nucleotide Reverse Transcriptase Inhibitors plus Integrase Inhibitors:

- Emtricitabine/Tenofovir alafenamide/Dolutegravir, tablet 200mg/25mg/50mg

- Lamivudine/Tenofovir alafenamide/Dolutegravir, tablet 300mg/25mg/50mg
- Lamivudine/Abacavir/Dolutegravir, tablet 300mg/600mg/50mg

### **3. Medicines to treat HIV/AIDS related conditions for adults, adolescents and children**

#### **3.1. Antibacterial, antiprotozoal and antifungal agents:**

- Clindamycin, injection 150 mg/ml, capsule 150 mg; 300 mg
- Sulfadiazine, tablet 500 mg
- Sulfamethoxazole /Trimethoprim, scored tablet 400 mg/80 mg; tablet 800 mg/160 mg
- Pyrimethamine, tablet 25 mg

## **4. How to submit an Expression of Interest**

In order to submit an expression of interest for product evaluation, the applicant must send the requested documentation, arranged according to the information provided on the WHO Prequalification Unit (PQT) – Medicines Team website at <https://extranet.who.int/pqweb>

## **5. Quality assessment procedure following submission of an expression of interest by an applicant**

The quality assessment is undertaken to evaluate 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 NDRA has expertise in the product area.

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 Products](#).

## 6. References and further information

For further information on the WHO Prequalification Unit – Medicines Team, please visit PQT website at: <https://extranet.who.int/pqweb>

For further information on the WHO Model List of Essential Medicines, and WHO Expert Committee on the selection and use of Essential Medicine, please visit the Programme's website at:  
<http://www.who.int/medicines/publications/essentialmedicines/en/>  
<https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/24th-eml-expert-committee>

**For further information on WHO treatment guidelines and ARV drug optimization lists, please consult:**

World Health Organization: Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021, available at: <https://www.who.int/publications/i/item/9789240031593>