# THE GLOBAL FUND

## List Of Covid-19 Pharmaceutical Products
## classified according to the GF QA Policy and the Interim Quality Assurance Requirements for the Procurement of COVID-19 Pharmaceutical Products

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The list is an overview of pharmaceutical products subject to the Global Fund Quality Assurance Policy that are listed in National and/or WHO standard treatment guidelines and classified according to the various options (A, B, and ERP reviewed) defined in the Global Fund Quality Assurance Policy (July 2009, amended in December 2010). The list is developed as a tool to assist Principal Recipients (PR) of Global Fund grants to identify the status of finished pharmaceutical products according to the Global Fund Quality Assurance Policy.

The pharmaceutical products are classified based on the following information

**A** classified product - Listed on WHO prequalification list;
**B** classified product - Stringent NDRA Registration letter/Marketing Authorization;
**ERP reviewed** product- **Permitted for time-limited procurement** based on advice by the Expert Review Panel (ERP).

**Please note that the list is not an exhaustive list. A PR can procure product(s) not listed in the current list as long as PR demonstrates that the product is compliant with the Global Fund Quality Assurance Policy.**

**The Global Fund list includes the following information:**

**- "Important Notes" for helpful information;**
**- A, B, and ERP reviewed products;**
**- Period validity of the ERP reviewed products;**
**- "+" means combination product, both fixed-dose combination (co-formulated) and co-packaged product ( i.e. co-blister)**
**- [A+B]+C means A and B are in fixed-dose formulation and C is co-packaged**
**YELLOW signifies a new entry; PINK signifies modification of an existing entry.**
**For more information, please look at:**
**https://www.theglobalfund.org/en/sourcing-management/quality-assurance/.**

**Expert Review Panel (ERP): Expert Review Panel is an independent technical body composed of external technical experts, hosted by WHO Department of Essential Medicines and Pharmaceutical Policies, to review the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized and to advise the Global Fund in its decision on whether to allow grant funds to be used to procure FPP. ERP reviewed products can be procured for a limited time (maximum 12 months). However, under certain circumstances, it is possible to extend the recommendation period. Contracts to supplier/manufacturer for an ERP reviewed products should not be longer than the validity period of the recommendation of that product. For detail information on ERP process and Quality Assurance information, please look at https://www.theglobalfund.org/en/sourcing-management/quality-assurance/.**

**Procurement of ERP Reviewed Products: Principal Recipients (PRs) must inform the concerned Fund Portfolio Manager (FPM) at the Global Fund in writing by filling the "Notification Form" ( available on website) if they intend to procure ERP-reviewed product(s). The Global Fund Secretariat will review the notification request and upon issuing a " no objection" letter to the PR for the requested selection, procurement can only proceed.**

**Important Notes**

This List may be used by Principal Recipients of Global Fund grants when considering options with respect to procurement of pharmaceutical products pharmaceutical products subject to the Global Fund Quality Assurance Policy. The list aims at providing countries with information that will assist them in their procurement options. Please note that the list is not designed to be a basis for countries to select medicines to be included in their National Treatment Guidelines or to replace any applicable and legally required procurement processes. The Global Fund requires its grant recipients to comply with applicable procurement laws and provides the list only for the **identification of products/manufacturers that comply with the Global Fund's quality assurance policy**. It is important to note that there is no strict requirement to procure according to the list, as long as the Principal Recipients can ensure that the product selected is compliant with the Quality Assurance policy criteria. Furthermore, the Principal Recipient should not rely solely on the information provided in the list but should obtain evidence of products compliance with the Quality Assurance policy. For the above reasons, **we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.**

**The Lists will be updated regularly based on evidence received by the Global Fund. Interested parties are invited to supply information** and evidence of products meeting the policy criteria on an ongoing basis. For the above reasons, **we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.**

**According to the Global Fund QA policy, if there are two or more A or B classified manufacturers available for any given product AND the product is available from these manufacturers (available-means that the manufacturer can supply the selected product within 90 days after receiving the Purchase Order), then such product must be procured from A or B classified product manufacturers. The PR must notify by writing to the Global Fund Secretariat (Fund Portfolio Manager) and recieve the "No Objection" letter from GF secretariat before procuring any products complying with option " ERP Reviewed".**

**For ease of reference, each "product" with similar formulation and dosage has been identified in this list with a unique "Product reference number" (Column A). Please see examples below.**

However, different dosage forms may be grouped under the same Product Reference Number and therefore will be considered the same type of products when identifying the number of available manufacturers for the application of this policy. These products share the same dosing protocol, target the same population, and there are no significant differences among them regarding interchangeability. For example, within solid forms, some capsules will have same reference number as tablets while within liquids, oral solution and suspension are grouped together. Following the same principles, the entero coated tablet or dispersible tablet will not share the same reference number as a normal tablet.

| Product Ref.No | International Non-proprietary name | Strength | Dosage form | Supplier/Manufacturer* | Global Fund QA Standard | WHO Pre-qualified/ SRA | Manufacturing site* | Country | Material | Pack |
|---|---|---|---|---|---|---|---|---|---|---|
| **C16** | **XYZ** | **50mg** | Tablet | "Pharma Company A" | A - B | Yes | "Pharmaville" | Country A | HDPE bottle | 60 |
| **C17** | | **100mg** | Tablet | "Pharma Company B" | A - B | Yes | "Pharmaville" | Country B | HDPE bottle | 60 |

The example above shows 2 different variants of the same medicine. Because the strength is different, it is considered 2 different products (there are two different reference numbers C16 and C17). If the strength had been the same but the dosage form had been different (i.e. tablet and liquid) it would also have been considered two different "products".

| Product Ref.No | International Non-proprietary name | Strength | Dosage form | Supplier/Manufacturer* | Global Fund QA Standard | WHO Pre-qualified/ SRA | Manufacturing site* | Country | Packaging | |
|---|---|---|---|---|---|---|---|---|---|---|
| **C25** | **ABC** | **150mg** | Tablet | "Pharma Company A" | A - B | Yes | "Pharmaville" | Country A | Blister, HDPE bottle | 10, 60 |
| | | | Capsules | "Pharma Company B" | A - B | Yes | "Pharmaville" | Country B | HDPE Bottle, Blister | 60, 10 |

In this second example both products have same reference number (C25) because both manufacturers are supplying the same strength and the dosage forms are considered similar as per explanation above.

*** See below**

**Disclaimer:**

The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose, including in regard of its safety and/or efficacy in the treatment of HIV/AIDS, HCV,tuberculosis, malaria or Covid-19. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use of treatment of any disease in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.

*** Note that we consider under**

**Supplier / Manufacturer :**
**Marketing authorization/ product authorization or license holder**

**Manufacturing Site:**
**The Site responsible for the release of the FPP**

| Ref.No | International Non-proprietary name | Strength/ Dose | Dosage form | Supplier/ Manufacturer(s) | Global Fund QA Standard | WHO Prequalification/ SRA | Manufacturing site | Country | Material | Pack |
|---|---|---|---|---|---|---|---|---|---|---|
| **C1** | Molnupiravir | 200mg | Capsule | Merck Sharp & Dohme Corp.'s (Merck) | B | US FDA EUA 108 | Patheon Inc.<br>111 Consumers Drive,<br>Whitby, Ontario L1N 5Z5<br>Canada<br><br>MSD International GmbH (Puerto Rico Branch) LLC<br>Pridco Industrial Park,<br>State Road 183,<br>Las Piedras, Puerto Rico 00771,<br>United States | Canada<br><br>USA | Bottle | 1x40 |
| | Molnupiravir | 200mg | Capsule | Hetero Labs Ltd | A | CV008 | Hetero Labs Ltd, Unit 5, Survey No 439, 440, 441 & 458 TSIIC Formulation SEZ, Polepally Village, Jadcherla (M), Mahaboob Nagar District, Telangana, 509 301, India | India | Blister Alu/Alu<br><br>HDPE Bottle | 4x10<br><br>1x40 |
| | Molnupiravir | 200mg | Capsule | Emcure Pharmaceuticals Ltd | A | CV010 | Emcure Pharmaceuticals Ltd, Plot No P-2, ITBT Park, Phase II MIDC, Hinjwadi, Pune, Maharashtra, 411057, India | India | HDPE Bottle | 1x40 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **C2** | Nirmatrelvir + Ritonavir | 150 mg + 100 mg | Film coated Tablets | Pfizer Limited | A<br><br>B | CV007<br><br>MHRA PLGB 00057/1710 | 1. Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Freiburg, Germany (nirmatrelvir tablet manufacturing, co-packaging, testing, release)<br>2. Pfizer Ireland Pharmaceuticals, Newbridge, Ireland (nirmatrelvir tablet manufacturing, co-packaging, testing, release)<br>3. Pfizer Italia S.r.l., Localita Marino Del Tronto, Ascoli Piceno, 63100, Italy (co-packaging, testing, release)<br>4. M/s. Hetero Labs Limited, Unit-III, 22-110, Industrial Development Area, Jeedimetla, Hyderabad-500055, Telangana, India (ritonavir bulk tablet manufacturing) | Germany, Ireland, Itlay and India | Blister; OPA/Al/PVC | 5 blister cards x (4 Nirmatrelvir tablets + 2 Ritonavir tablets) |
| | Nirmatrelvir + Ritonavir | 150 mg + 100 mg | Film coated Tablets | Hetero Labs Ltd | A | CV012 | Hetero Labs Ltd, Unit III, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055, India | India | Blister: Alu-Alu | 5 x (4-Nirmatrelvir Tablets + 2-Ritonavir tablets) |
| **C3** | Remdesivir | 100mg | Powder for concentrate for solution for infusion | Gilead | A | CV011 (a) | Gilead Sciences Ireland UC, IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland | Ireland | Type 1 clear glass vial, an elastomeric closure, and an aluminium overseal with a flip-off cap. | 1 vial |

For futher information on Therapeutics and COVID-19 refer to : https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/therapeutics

End of A or B products list