INVITATION TO PRE-QUALIFICATION of MANUFACTURERS for the supply of
oral COVID-19 antiviral medicines
(Molnupiravir and Nirmatrelvir/ritonavir)

**Background**

2020 marked the beginning of a Decade of Action towards the Sustainable Development Goals (SDGs). But with the COVID-19 pandemic, the global context for development has fundamentally changed. The world faces the greatest socio-economic shock in a generation, coming at a time of acute inequality, ecological fragility and growing distrust within and amongst societies. This pandemic is a health crisis. But not just a health crisis. Tackling COVID-19 is also a humanitarian and development crisis that is threatening to leave deep social, economic and political scars for years to come, particularly in countries already weighed down by fragility, poverty and conflict. The solidarity that brought the global community together to create the Global Goals is needed more than ever. From building strong institutions to creating jobs to ensuring education and healthcare for all, the SDGs and the pledge to leave no one behind work best when tackled in an integrated manner.

UNDP is fully operational in 170 countries and territories and focused on COVID-19 response. UNDP is mobilizing all its assets to respond to this unprecedented challenge. UNDP transitioned all critical operations to digital and virtual platforms, enabling its teams to continue delivering effectively despite restrictions on movement and physical interaction.

UNDP is streamlining policies and procedures for greater agility, increasing its flexibility to receive and deliver private sector and other financing, and taking steps to ensure UNDP frontline staff are well supported and cared for as they help countries through this crisis.

**Purpose**

The purpose of the Invitation To Pre-qualification exercise is to identify potential manufacturers of oral COVID-19 antiviral medicines (Molnupiravir and Nirmatrelvir/ritonavir) meeting the WHO norms and standards and UNDP QA Policy requirements. The UNDP Quality Assurance Policy for health products procured by the organisation is developed in line with WHO norms and standards for health products. The objective of UNDP QA Policy is to ensure sourcing of high quality medicines and medical products from a reliable sources, efficient utilization of public funds at the best interest of the patients, to obtain the best health care outcomes.

The invitation will result establishment of a roster with pre-qualified manufacturers. The ITP will contribute to the understanding of the potential availability of bulk and final product, and commercialization issues of the COVID-19 medicines (Molnupiravir and Nirmatrelvir/ ritonavir). It will 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.

UNDP is taking a careful approach on selecting manufacturers through the below listed evaluation stages. This approach is expected to address the general requirements for completeness of application submission forms; the products pre-qualification status (WHO, SRA or ERP); experience in supplying pharmaceuticals at international level; as well as the documented policies, standards and procedures required to ensure consistency.

It is expected that UNDP will identify qualified manufacturers and/or Voluntary license holders of oral COVID-19 ativiral medicines (Molunipiravir and Nirmatrelvir/ritonavir). Qualified manufacturers are expected to be committed in supplying Molnupiravir and Nirmatrelvir / ritonavir with the best prices to expand access in Low Middle Income Countries.

**Table of Contents**

1 Overview....3
1,1 General Information....3
1,2 Tender Timeline....4
1,3 Response Rules....4
1,4 Terms....4
1,5 Attachments....5
2 Requirements....6
2.1 Section 1. General Provisions....10
2.2 Section 2. Evaluation criteria - Preliminary examination....10
2.3 Section 3. Technical Evaluation Criteria....17

# 1 Overview

## 1,1 General Information

| | |
|---|---|
| **Title** | Invitation to Pre-qualification of Manufacturers (COVID-19) |
| **Contact Point** | Chinara Israilova |
| **E-Mail** | chinara.israilova@undp.org |
| **Reference Number** | GPH3860000 |
| **Beneficiary Country** | Denmark |
| **Introduction** | |

**General Information on Invitation To Pre-qualification**

**1. Clarification, request for additional information and exchange of information**

Applicants requiring any clarification of pre-qualification documents and procedure may send written request for clarification preferably using messaging function through Supplier Portal or alternatively sending an email to following addresses: chinara.israilova@undp.organd cc to hist.procurement@undp.org

The UNDP may make the amendments to the document, at any time but not later than 5 calendar days prior the deadline for submission, that will be published and accessible by the Applicants.

**2. Deadline for submission of Applications**

Applications must be submitted directly in the system following this link: http://supplier.quantum.partneragencies.org using the profile you may have in the portal. In case you have never registered before, follow the https://estm.fa.em2.oraclecloud.com/fscmUI/faces/PrcPosRegisterSupplier?prcBuId=300000127715297&_adf.ctrl-state=azywmctp_1&_afrLoop=6329722925931702&_afrWindowMode=0&_afrWindowId=null&_afrFS=16&_afrMT=screen&_afrMFW=1042&_afrMFH=575&_afrMFDW=1280&_afrMFDH=720&_afrMFC=8&_afrMFCI=0&_afrMFM=0&_afrMFR=144&_afrMFG=0&_afrMFS=0&_afrMFO=0 to register a profile in the system. Do not create a new profile if you already have one. Use the forgotten password feature in case you do not remember the password or the username from previous registration. Follow the instructions in the guide to search the tender, subscribe, and submit response.

Note that system time zone is in EST time zone (NY time).

PLEASE NOTE:

Date and time visible on the main screen of event (on Quantum Supplier Portal) will be final and prevail over any other closing time indicated elsewhere, in case they are different. It is the responsibility of the applicant to make sure applications are submitted within this deadline. UNDP will not accept any applications that is not submitted directly in the system.

Submit your application a day prior or well before the closing time. Do not wait until last minute. If you face any issue submitting your application at the last minute, UNDP may not be able to assist.

The Applications shall be written in English language. Any documents originated in any other language can be attached to the Application so long as they accompanied by English translation.

**Submission files.**

§ Format: PDF, word, excel files only.

§ File names must be maximum 60 characters long and must not contain any letter or special character other than from Latin alphabet/keyboard.

All files must be free of viruses and not corrupted. Applicants are solely responsible for ensuring that any and all files sent to UNDP are readable, that is, not corrupted, in the indicated electronic format, and free from viruses and malware. Failure to provide readable files will result in the submission being rejected

## 1,2 Tender Timeline

| | |
|---|---|
| **Preview Date** | |
| **Open Date** | 24-03-22 14:50 |
| **Close Date** | 25-04-22 08:00 |
| **Time Zone** | Eastern Standard Time |

## 1,3 Response Rules

*This negotiation is governed by all the rules displayed below.*

| | Rule |
|---|---|
| ☑ | Suppliers are allowed to revise their submitted response |

## 1,4 Terms

**Negotiation Currency** USD (US Dollar)

## 1,5 Attachments

| File Name or URL | Type | Description |
|---|---|---|
| General Instructions | File | |
| Annex 1 | File | Product information |
| Annex 2 | File | Guidance on competitive exercise |
| Annex 3 | File | Checklist |
| Form D | File | Eligibility and Qualification Form |
| Form C | File | Joint Venture Information Form |
| Form B | File | Applicant Information Form |
| Form A | File | Application submission Form |

## 2 Requirements

**Response is required*

**Evaluation Stages**

To ensure selection of the suppliers meeting the QA requirements, UNDP will conduct the following Evaluation Stages: preliminary and technical. The preliminary evaluation will evolve around eligibility of the applicant to supply the product, its financial and manufacturing capacity, experience in supply. The technical evaluation will focus QA compliance of the manufacturing site and offered products.

**Stage I: Preliminary evaluation**

The following criteria must be met in order for suppliers to be accepted for further evaluation stages. All applications will be evaluated on a Pass/Fail basis against below listed criteria.

The preliminary evaluation will be based on the screening of documents and completeness of application submission forms:

(a) Submission of Form A of the ITP

(b) Submission of Form B of the ITP

(c) Submission of Form C of the ITP (if applicable)

(d) Submission of Form D of the ITP

(e) Company profile of max. 15 pages

(f) Business registration certificate of the company

(g) Possession of voluntary license (license issued by Medicine Patent Pool or originator)

(h) Evidence with a confirmation of submission of application for WHO pre-qualification or SRA approval or ERP approval

(i) Evidence of minimum of 5 years of experience supplying pharmaceuticals on international level (contracts or purchase orders from previous clients);

(j) The Statements of Satisfactory Performance from the Top 3 (three) Clients or more or the contact details of the clients for UNDP.

(k) Demonstrate a cumulative financial turnover of 5 million USD for recent 3 years by providing audited financial statement.

(l) Confirmation that there was no litigation history for the last 3 years

(m)Confirmation on history of non - performing contracts for the last 3 years

(n) Confirmation of acceptance of UNDP's General Terms and Conditions

During evaluation process, UNDP may inquire additional information for constructive evaluation of the applications. However, UNDP reserves the right to exclude the application(s) if submitted documents are not found sufficient to proof about potential capability of an applicant to supply oral COVID-19 ativiral medicines (Molnupiravir and Nirmatrelvir and ritonavir) they indicated in the application.

**Stage II**: **Technical compliance**

The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by National Authorities* members of the European Union (EU), UK Medicines and Healthcare products Regulatory Agency (UK MHRA), US Food and Drug Administration (US FDA), Australian Therapeutic Goods Administration (TGA), Health Canada and Swiss Medic.

(*) The selected Suppliers are requested to manufacture products only at manufacturing sites/units/blocks with a valid WHOPIR or GMP certificates issued but the above-mentioned Regulatory Authorities.

NB: GMP certificates and/or WHOPIRs should be provided for all manufacturing sites where product is being produced (incl. manufacturing, packaging, batch release and quality control activities).

The Invitation to Pre-qualification is open to those manufacturers that will be authorized to manufacture and market the medicines by relevant regulatory authorities for the products compliant to the below eligibility and qualification criteria:

**A. Pre-qualified by the WHO Pre-qualification Programme[1]; or**

**B. Authorized for use by a stringent drug regulatory authority[2]; or**

**C. Recommended by the Global Fund's Expert Review Panel for Pharmaceutical Products[3]**

The confirmation of WHO Pre-qualification and/or SRA approval and/or ERP will be a perquisite at the time of the competitive bidding process. Once accepted by UNDP, the pre-qualified manufacturer/s will be allowed to participate in the competitive bidding process limited to roster suppliers.

UNDP will further monitor the market after roster with pre-qualified companies have been established and intends to conduct periodic review and assessment to identify possible additional qualified sources of supply at the time for oral COVID-19 antiviral medicines. Depending on the final scope of the limited competitive exercises conducted among pre-qualified manufacturers offering and based on the demand and forecast, UNDP may consider incorporating additional sources of supply into the roster as an outcome of the cited market review and through the corresponding procurement process/es.

The ITP will result issuance of the Letter of Intent supported with detailed SOPs with all pre-qualified manufacturers for supply of COVID_19 antiviral medicine, the oral antiviral. Recommendation for establishing a roster with pre-qualified manufacturers will be based on the following factors:

- Fulfillment of the preliminary evaluation criteria
- Compliance to the technical criteria
- Acceptance of the UNDP General Terms and Conditions: http://procurement-notices.undp.org/view_file.cfm?doc_id=170154

[1]https://extranet.who.int/prequal/content/prequalified-lists/medicines

[2] SRA definition by the WHO https://www.who.int/medicines/areas/quality_safety/quality_assurance/SRA_QAS17-728Rev1_31082017.pdf?ua=1 In case product is registered by SRA authorities for "export only" (i.e. registered but not marketed on the country of SRA authority), UNDP will conduct additional verification of product's compliance to the products standards.

A regulatory authority which is:

a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or

an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or

a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

[3]https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel

## 2.1 Section 1. General Provisions

1. **General Instructions to Applicants**
   This solicitation process is governed by the General Instructions to manufacturers attached herewith and other information listed herewith. By submitting an application response to this pre-qualification process applicant confirms to have read, understood, and accepted such provisions
   *Target: YES*

*2. Have you submitted Annex 3 Checklist ?
Attachments:

| File Name or URL | Type | Description |
|---|---|---|
| Annex 3_Checklist.xlsx | File | |

*Response attachments are optional.*
*Target: YES*

## 2.2 Section 2. Evaluation criteria - Preliminary examination

*1. **General Conditions of Contract**
Do you accept the General Conditions of Contract (GTCs) as specified herewith.

Select one of the following:-

☐ a. YES

*2. **Form A: Application Submission Form**
Have you submitted signed and stamped Application Submission Form (Form A)?
Attachments:

| File Name or URL | Type | Description |
|---|---|---|
| Form A | File | Application submission Form |

Select one of the following:-

☐ a. YES*(Response attachments are required)*

*3. **Form B: Applicant Information Form**
Have you attached form B with information on the bidder using template herewith attached?
Attachments:

| File Name or URL | Type | Description |
|---|---|---|
| Form B | File | Applicant Information Form |

Select one of the following:-

☐ a. YES*(Response attachments are required)*

4. **Form C: Joint Venture/Consortium/Association Information**
Have you provided information on Joint Venture/Consortium/Association Information using the template and instructions attached?
Choose the applicable answer from options below.

Attachments:

| File Name or URL | Type | Description |
|---|---|---|
| Form C | File | Joint Venture Information Form |

Select one of the following:-

☐ a. Information provided*(Response attachments are required)*

*5. **Form D: Eligibility and Qualification Form**
Have you provided the information required to establish eligibility and qualifications as per form D herewith attached?
**Attach also supporting documentation as applicable.**

Attachments:

| File Name or URL | Type | Description |
|---|---|---|
| Form D | File | Eligibility and Qualification Form |

Select one of the following:-

☐ a. YES*(Response attachments are required)*

*6. **History of non-performing contracts**
Provide history of non-performing contracts that did not occur as a result of contractor default within the last 3 years.
Non-performance, as decided by UNDP, shall include all contracts where (a) non-performance was not challenged by the contractor, including through referral to the dispute resolution mechanism under the respective contract, and (b) contracts that were so challenged but fully settled against the contractor. Non-performance shall not include contracts where Employer's decision was overruled by the dispute resolution mechanism.

Select one of the following:-

☐ a. No history of non-performing contracts
☐ b. Information provided*(Response attachments are required)*

*7. **Legal Registration**

Applicant is a legally registered entity and all relevant information is provided.
Upload scanned copies of legal registration documents according to options listed below and any other relevant document.

Select one of the following:-

☐ a. Certificate of Company Incorporation *(Response attachments are required)*
☐ b. Tax Registration Certificate *(Response attachments are optional)*

*8. **Litigation history**
No consistent history of court/arbitral award decisions against the bidder for the last 3 years.

Select one of the following:-

☐ a. No litigations
☐ b. Litigations history provided*(Response attachments are required)*

*9. **Licence**
Have you provided required licences.
• Copy of Voluntary Licence issued by MPP or originator.

Select one of the following:-

☐ a. Voluntary License provided*(Response attachments are required)*

*10. **Relevant Experience**

Indicate the number of years of relevant experience of the Company.

The company must have at least 5 years of experience supplying pharmaceuticals on the international level

*Response attachments are optional.*

*11. **Financial Standing - Turnover**
Applicant should have cumulative turnover of minimum $5,000,000.00 for the last 3 years.
Provide the cumulative turnover amount for the last 3 years in USD.

*Response attachments are required.*

*12. **Statements of Satisfactory Performance**
Have you submitted the Statements of Satisfactory Performance from the Top 3 (three) Clients or more or the contact details of the clients?

Select one of the following:-

☐ a. Information provided*(Response attachments are required)*

## 2.3 Section 3. Technical Evaluation Criteria

*1. **Manufacturing site requirements**
The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by National Authorities* members of the European Union (EU), UK Medicines and Healthcare products Regulatory Agency (UK MHRA), US Food and Drug Administration (US FDA), Australian Therapeutic Goods Administration (TGA), Health Canada and Swiss Medic.

Have you attached copy of relevant certificate for all manufacturing sites?

Select all that apply:-

☐ a. GMP certificate *(Response attachments are required)*
☐ b. WHOPIR*(Response attachments are required)*

*2. **Product requirements**
The products must be compliant to one of the below eligibility and qualification criteria:

- Pre-qualified by the WHO PQ Programme; or
- Authorized for use by SRA; or
- Recommended by the Global Fund's ERP for Pharmaceutical Products

Select one of the following:-

☐ a. YES, our product is / will be compliant *(Response attachments are optional)*