



INVITATION FOR PRE-QUALIFICATION OF PROCUREMENT AGENCIES for the supply of pharmaceuticals

Ref: 404-2022-HIST-IFP-PAs

Background

The United Nations Development Programme (UNDP) is the UN's global development network, advocating for change and connecting countries to knowledge, experience and resources to help people build a better life. We are on the ground in 170 countries and territories, working with governments and people on their own solutions to global and national development challenges to help empower lives and build resilient nations.

As a trusted, long-term partner with extensive operational experience, UNDP supports countries in effective implementation of complex, multilateral and multisectoral health projects, while simultaneously investing in capacity development so that national and local partners can assume these responsibilities over time. The UNDP/Global Fund partnership is an important part of this work, facilitating access to resources for action by countries that face constraints in directly receiving and managing such funding. UNDP partners with countries in crisis/post-crisis situations, those with weak institutional capacity or governance challenges, and countries under sanctions. When requested, UNDP acts as interim Principal Recipient in these settings, working with national partners and the Global Fund to improve management, implementation and oversight of Global Fund grants, while simultaneously developing national capacity for governments or local entities to be able to assume the Principal Recipient role over time. Further, increasingly UNDP is requested to provide PSM related support services in the Health sector, directly by National Governments, under Cost-Sharing agreements. Affordable quality assured health products have the greatest potential for maximizing the impact of these efforts.

In this context UNDP is launching the Pre-Qualification exercise to identify potential Procurement Agencies of pharmaceuticals for the treatment of infectious diseases and more particularly for the treatment of Non-Communicable Diseases or new emerging diseases such as Hepatitis C.

UNDP currently has multiple Long-Term Agreement (LTAs) holders for medicines. This prequalification process is not meant to invalidate these LTAs, unless UNDP advises otherwise after completion of the pre-qualification process. However, current LTA holders are subject to this pre-qualification exercise and need to submit the application in line with the requirements of this document.

Purpose

UNDP has a Quality Assurance Policy for all health products procured by the organisation in line with WHO norms and standards for health products. The objective of this UNDP QA Policy is to ensure sourcing of quality medicines and medical products from a reliable sources, efficient utilization of public funds in the best interest of the patients, to obtain the best health care outcomes.

Therefore, the objective of this Pre-Qualification exercise is to assess the quality assurance system of Procurement Agencies (PAs) according to the UNDP quality requirements based on the WHO Model Quality Assurance for Procurement Agencies (WHO MQAS). This prequalification process is to select/confirm the PAs meeting the quality requirements defined by the organization for the supply of pharmaceutical products necessary for the implementation of Global Fund grants managed by UNDP as well as any requirements sought on behalf of Governments in the implementation of national health-related programmes.



UNDP is taking a careful approach in selecting Procurement Agencies through several evaluation stages. Pre-qualification application, desk review and/or on site visit evaluations as required are core to identify pre-qualified Procurement Agencies before proceeding with commercial offerings. This approach is expected to address the general requirements for quality assurance systems, including physical resources such as premises, equipment and personnel, as well as the documented policies, standards and procedures required to ensure consistency in all the key activities for quality assurance in procurement activities.

It is expected that UNDP will identify multiple Procurement Agencies for pharmaceuticals as per the list of products attached in **Annex II**. Procurement Agencies are expected to be committed in providing the requested pharmaceuticals and other health products at preferential prices to developing countries.



Tender Overview

INVITATION FOR PRE-QUALIFICATION
OF PROCUREMENT AGENCIES FOR THE SUPPLY OF PHARMACEUTICALS
Ref: 404-2022-HIST-IFP-PAs



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1 Overview

1.1 General Information

Title	INVITATION FOR PRE-QUALIFICATION OF PROCUREMENT AGENCIES,PHARMACEUTICALS SUPPLY
Amendment Description	Minutes of Pre-Application conference added, Amendment 1 posted, file 404-2022-HIST-IFP-PAs_Invitation amended as reflected in Amendment 1
Contact Point	Viktor Cherniavskiy
Outcome	
E-Mail	viktor.cherniavskiy@undp.org
Reference Number	GPH4040000
Beneficiary Country	Denmark

Introduction

UNDP has a Quality Assurance Policy for all health products procured by the organisation in line with WHO norms and standards for health products. The objective of this UNDP QA Policy is to ensure sourcing of quality medicines and medical products from a reliable sources, efficient utilization of public funds in the best interest of the patients, to obtain the best health care outcomes.

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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 a written request for clarification preferably using messaging function through Supplier Portal or alternatively sending an email to the following addresses: viktor.cherniavskiy@undp.org and 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 to the deadline for submission, which will be published and accessible by the Applicants.

2. Pre-Application conference

Pre-Application conference will be conducted on Monday, 1st of August 2022 at 2:00 PM CEST via Zoom.

To attend pre-application conference, please confirm your willingness to participate to the e-mail : viktor.cherniavskiy@undp.org and cc to hist.procurement@undp.org with the subject 404-2022-HIST-IFP-PAs for provision of the link.

3. 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 [Supplier Portal Registration Link](#) 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 the previous registration. Follow the instructions in the guide to search the tender, subscribe, and submit response.

Note that the system time zone is in the EDT 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 04/08/22 17:59 PM

Close Date 22/08/22 16:00 PM

Time Zone Coordinated Universal Time

1.3 Response Rules

This negotiation is governed by all the rules displayed below.

	Rule
<input checked="" type="checkbox"/>	Suppliers are allowed to revise their submitted response

1.4 Terms

Negotiation Currency USD ()

1.5 Attachments

File Name or URL	Type	Description
404-2022-HIST-IFP-PAs_Invitation	File	
Minutes of Pre-Qualification conference	File	



File Name or URL	Type	Description
Amendment no.1 to the IFP	File	
Annex 3 - Checklist.xlsx	File	
Form A_Application submission Form	File	
General Instructions to Applicants	File	
Form D_Eligibility and Qualification Form	File	
Form C_Joint Venture Information Form	File	
Form B_Applicant Information Form	File	
ANNEX II - LIST OF PRODUCTS	File	



2 Requirements

**Response is required*



Evaluation Stages

To ensure selection of the suppliers meeting the UNDP QA requirements, UNDP will conduct the following Evaluation Stages:

Stage I: Preliminary evaluation

At this stage, UNDP will conduct evaluation based on the submitted Procurement Agency Information File (PAIF) application as per the answers and documents submitted in the Sections 3-6 of this IFP. The evaluation of the applications[1] will be based on their completeness and sufficient evidence provided in response to the questionnaire in the Pre-Qualification document. Please note that the question on Licensing is a Mandatory Requirement and non-submission of the copy of respective License will lead to application's disqualification. 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 to be sufficient to prove the potential capability of an applicant to supply health products they indicated in their application.

Stage I: Prequalification Questionnaire will consist of the following steps:

1. **Step 1- MQAS Mandatory Requirements (ELIGIBILITY CRITERIA).** Requirements are reflected in the Section 3 of the ITP in Quantum. Answers to all requirements are mandatory.

Qualification requirement for Step 1 – full compliance with the requirements. Only fully compliant applications will be reviewed in the Step 2. Not compliant applications will be rejected.

2. **Step 2 – MQAS Compliance Questionnaire.** Requirements are reflected in the Section 4 of the ITP in Quantum.

Total amount of points that Applicant can get in the Section 4 is 220 points.

Qualification requirement for Step 2 – applicants with the rate of 65% (143 points) and more are considered as qualified and admitted to the Stage II: On-site Assessment/Verification.

3. **Complementary questions for bidders performing prequalification of multisource (generic) products** with no MA from SRAs and NOT WHO prequalified ('multisource') are reflected in Section 5 of the ITP.

Total amount of points that Applicant can get in the Section 5 is 115 points.

Qualification requirement for the Section 5 are as follows:

-RATE 75%: NOT qualified for procurement of 'multisource' (Full IAPQ needs to be established before procurement)

- 75% RATE 95%: The Applicant is required to share the dossier of the 'multisource' FPP offered for UNDP QA assessment or to answer specific questions, based on the weaknesses highlighted during this OPTIONAL STEP, before the source is approved by UNDP

- RATE > 95%: Sources offered are automatically considered approved by UNDP

Stage II: On-site Assessment/Verification

After preliminary selection of the applicants, upon completion of applications evaluation, UNDP will conduct a desk review and/or on-site assessment as required to maximum up to 10 (ten) selected applicants that



submitted complete applications with sufficient proof. On-site assessment will be conducted by UNDP staff (pharmacists specialized in pharmaceuticals as the leaders with procurement specialists as observers) and schedule of visits will be communicated to selected applicants in advance. The on-site assessment will be conducted by using the [WHO guidelines \(MQAS\)](#) Annex 4. The results of the site visits will be used for reconciliation with submitted pre-qualification applications and will remain valid for 4 years. The prequalification exercise will be conducted by UNDP every third year. Any inconsistency discovered during the site visit assessments, on quality assurance practices based on the information previously given in the PAIF, will be accordingly taken into consideration for final inclusion or exclusion of the applicants for invitation to commercial offering through tender process/es (Invitation to Bid (ITB)/Request for Proposal (RFP)).

Stage III: Tender Process(es)

After the review of the documentation provided under Stage I and validation exercise under Stage II, the tender/s (ITB) will be sent to pre-qualified applicants for specific product categories. At the final stage, UNDP will request Procurement Agencies' commercial offerings for the procurement service to be offered when supplying pharmaceutical products proposed in **Annex II**. UNDP reserves the right to split the contract award based on the list of products offered among the suppliers.

[1] Application in this document refers to the Pre-Qualification application submitted by a Procurement Agency.

2.1 Section 1. General Provisions

1. General Instructions to Applicants

This solicitation process is governed by the General Instructions to applicants 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 ?**

Response attachments are required.

Target: YES

2.2 Section 2. Evaluation criteria - Preliminary examination

***1. General Terms and Conditions for Contracts**

Do you accept the General Terms and Conditions for Contracts (GTCs) as specified herewith?



Attachments:

File Name or URL	Type	Description
UNDP GTCs for Contracts (Goods and-or Services)	File	

***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

***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

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

***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

***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.

***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.



***8. Litigation history**

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

***9. 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?

***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.

I-1. Total per section Preliminary examination

2.3 Section 3. Technical Evaluation criteria - PAIF: Step 1 - MQAS Mandatory Requirements (ELIGIBILITY CRITERIA)

***1. Please provide the GSDP for medicines certificate or equivalent issued by the NMRA (mandatory)**

Response attachments are required.

***2. Please provide the authorized and current organization chart indicating the positions, names of responsible persons and reporting lines (mandatory)**

Response attachments are required.

***3. Please provide the name and qualification of the Head of QA department (mandatory)**

Response attachments are optional.

***4. Please provide the following information (mandatory):**

- Total warehouse surface (m²)
- Total pallets storage capacity
- Cold room surface (m², if any)
- Total number of truck bays (for reception and dispatch)

Response attachments are optional.

***5. Please provide the dates of the last temperature mapping performed and report title-reference number (mandatory)**

Response attachments are optional.

***6. Please provide evidence of a minimum of 5 years of experience in procurement of pharmaceuticals at the international level (mandatory)**

Response attachments are optional.

***7. Please demonstrate a financial turnover of 15 million USD relating to the supply of medicines for recent 3 years by including latest audited financial statement (income statement and balance sheet) for the past 3 years (mandatory):**

- Latest fiscal year – 1
- Latest fiscal year – 2
- Latest fiscal year – 3

Response attachments are required.

***8. Please provide the Quality Manual title, reference, version and effective date (mandatory)**

Response attachments are optional.

***9. Please provide the Implemented self-Inspection SOP title, reference and version, effective date, review due date (mandatory)**

Response attachments are optional.

***10. Please provide the Evidence of the self-inspections performed during the last 3 years (copy of the document, e.g. completed self-inspection plan, self-inspections dates and report title-reference**



**numbers)
(mandatory)**

Response attachments are required.

I-1. Total points per Section 3

2.4 Section 4. Technical Evaluation criteria - PAIF: Step 2 - MQAS Compliance Questionnaire

- *1. Please provide the warehouse plan showing areas and products flow (copy of the document) - (5 points)
- *2. Please provide the complete list of SOPs including **(mandatory)** the FULL identification system information (e.g. reference) and related life dates (e.g. implementation date) - (42 points)
- *3. Please provide the complete list of Logbooks and annual plans including **(mandatory)** the FULL identification system information (e.g. reference) and related life dates (e.g. implementation date) - (24 points)
- *4. Please provide an example of training record related to one current SOP - (9 points)
- *5. Please provide the name and qualification of the Responsible Person (if different than Head of QA department) - (no points)
Response attachments are optional.
- *6. How many people are working under the Head of QA department (including deputy/back-up of the Head of QA department, if any)? - (3 points)
Response attachments are optional.
- *7. Please provide the name and qualification of the deputy/back-up of the Head of QA department - (2 points)
Response attachments are optional.
- *8. Please provide the official job description of a storekeeper **(copy of the document)** - (7 points)
Response attachments are optional.
- *9. Please provide the current SOP for writing SOP **(copy of the document)** - (11 points)
- *10. How many complaints from customers have you received in 2021? - (2 points)
Response attachments are optional.
- *11. How many complaints did you send to suppliers in 2021? - (2 points)
Response attachments are optional.
- *12. How many internal deviations have you opened in 2021? - (2 points)
Response attachments are optional.
- *13. Please provide the title and reference of the last recall process performed (real or mock-recall) - (2 points)
Response attachments are optional.
- *14. How many product-manufacturer sources with MA from SRA are approved in your database? - (no points)
Response attachments are optional.
- *15. How many WHO prequalified product-manufacturer sources are approved in your database? - (no points)
Response attachments are optional.
- *16. How many product-manufacturer sources with positive opinion from ERP are approved in your database? - (



- no points)*
Response attachments are optional.
- *17. How many other product-manufacturer multisource (generic) sources are approved in your database? - (*no points*)
Response attachments are optional.
- *18. Please provide the list of prequalified suppliers (Vendor list) title, reference, version, effective date - (*2 points*)
- *19. How many of Quality Agreements/Contracts are established with suppliers? - (*3 points*)
Response attachments are optional.
- *20. How many Quality Agreements/Contracts are established with manufacturers? - (*3 points*)
Response attachments are optional.
- *21. Please provide the list of product' specifications and information uploaded in the Logistic Information System used - (*16 points*)
Response attachments are optional.
- *22. How many people are working on FPP prequalification (documentation review)? Please indicate their qualification and experience - (*3 points*)
Response attachments are optional.
- *23. Please provide the product questionnaire/form for FPP prequalification title, reference, version, review date - (*2 points*)
- *24. Please provide the list of documents and information required (or information obtained from the web) in relation to the FPP prequalification process of sources with MA from SRA - (*10 points*)
- *25. Please provide the list of documents and information required (or information obtained from the web) in relation to the FPP prequalification process of WHO PQ sources - (*2 points*)
- *26. Please provide an example of Purchase Order sent to a supplier (manufacturer or distributor) in March 2021 - (*16 points*)
- *27. Please provide the list of documents required in relation to the Purchase Order from supplier (not directly from manufacturer) - (*7 points*)
Response attachments are optional.
- *28. How many pre-shipment controls did you perform in 2021? - (*no points*)
Response attachments are optional.
- *29. Please list the checks performed within the reception process (and documents used to perform the checks, including those part of a blind check process) - (*26 points*)
Response attachments are optional.
- *30. Please provide the approved temperature record of July 2021 (copy of the document) - (*13 points*)
- *31. How many stock reconciliations (inventories) did you perform in 2021? - (*2 points*)
Response attachments are optional.
- *32. How many stock discrepancies did you identify in 2021? - (*2 points*)
Response attachments are optional.
- *33. Please provide the validation of cold chain boxes report title-reference number - (*2 points*)

Response attachments are optional.

I-1. Total Score for the Section 4

2.5 Section 5. Technical Evaluation criteria - PAIF: Complementary questions for bidders performing prequalification of multisource (generic) products

1. Please provide a copy of the current SOP for the prequalification of multisource (generic) products (with no MA from SRA and NOT WHO prequalified).
In case different SOPs are implemented for the assessment of products, manufacturing sites and suppliers, please provide a copy of each one of them. - (44 points)

Response attachments are optional.

2. Please provide a copy of the questionnaire/form used to collect information and documents needed for the assessment of multisource (generic) FPP with NO MA from SRAs and NOT WHO prequalified. - (2points)
3. Please provide a copy of 3 product questionnaire/form and the corresponding conclusions (e.g. evaluation summary sheet or other according to your internal procedure), selected within the following list of FPP (oral formulations): ALBENDAZOLE, AMITRIPTYLINE, AZITHROMYCIN, BISACODYL, CARBAMAZEPINE, CEFIXIME, CHLORPROMAZINE, CLINDAMYCIN, CLOFAZIMINE, CODEINE phosphate, COTRIMOXAZOLE, DAPSONE, DIAZEPAM, DIGOXIN, ERYTHROMYCIN, FLUOXETINE, FUROSEMIDE, GLIBENCLAMIDE, HALOPERIDOL, HYDRALAZINE, IBUPROFEN, ITRACONAZOLE, CARBIDOPA, MEBENDAZOLE, NIFEDIPINE, SALBUTAMOL, TRAMADOL, VALPROATE SODIUM, VERAPAMIL. - (5 points)
4. Are the criteria used to select/qualify evaluators (external or internal) of finished pharmaceutical product' (FPP) dossiers described in a SOP? Please indicate the SOP title, reference, version, date.
Please indicate the requirements (qualification, years of experience, type of experience etc.) to qualify as FPP' dossier evaluator for your company. - (6 points)

Response attachments are optional.

5. Do you have a list of FPP' dossier evaluators performing dossier review for your company (formal or informal list of experts contacted in case of need)?
Please indicate:
-how many evaluators are part of the list
-their experience (e.g. number of years in pharmaceutical industry, as QP, as national authority inspector, as dossier evaluator etc.)?
-if they are internal or external (consultants). - (17 points)

Response attachments are optional.

6. Are the criteria used to select/qualify GMP auditors (external or internal) described in a SOP? Please indicate the SOP title, reference, version, date.
Please indicate the requirements (qualification, years of experience, type of experience etc.) for a GMP expert to be considered part of your list/pool of experts. - (6 points)

Response attachments are optional.

7. Are the criteria used to select/qualify bioequivalence experts (external or internal) described in a SOP? Please indicate the SOP title, reference, version, date.
Please indicate the requirements (qualification, years of experience, type of experience etc.) for a bioequivalence expert to be considered part of your list/pool of experts. - (6 points)

Response attachments are optional.



8. Do you have a list of GMP experts performing manufacturing site audits for your company (formal or informal list of experts contacted in case of need)? (Y/N)

Please indicate:

- how many experts are part of the list
- their experience (e.g. number of years in pharmaceutical industry, as QP, as national authority inspector etc.)?
- if they are internal or external (consultants). (16 points)

Response attachments are optional.

9. Do you have a list of bioequivalence experts performing review of bioequivalence studies for your company (formal or informal list of experts contacted in case of need)? (Y/N)

Please indicate:

- how many experts are part of the list
- their qualification and experience (e.g. number of years in industry, as national authority inspector, as bioequivalence consultant etc.)? - (13 points)

Response attachments are optional.

I-1. Total for the Section 5

2.6 Section 6. Other PAIF requirements

*1.

Procurement Agencies are authorized to represent manufacturers to participate to UNDP tenders or to express their interest for a pre-qualification of their products by UNDP.

They will in that case be requested to submit a letter issued by each manufacturer in which he (the manufacturer) unequivocally authorizes the Procurement Agency to represent him to UNDP.

Please provide UNDP with a few examples of authorization letter(s).

*2. Please provide the contact details for responsible persons

Attachments:

File Name or URL	Type	Description
Contact details for responsible persons	File	

*3.

If available, please attach the following documents to the PAIF:

1. Company brochure
2. Site Master File



3. Quality manual
4. Organization Chart

Response attachments are optional.

*4.

The verification of the compliance with WHO GDP and the WHO MQAS is part of UNDP Quality Assurance Policy. Regardless of the authorization by the regulatory authority or by any other body, UNDP may conduct an on-site visit of your premises. On-site visit is an integral part of the Pre-Qualification Process.

Does your company accept the principle of such on-site visit and do you commit to facilitate the access of UNDP experts to your premises?

Non-acceptance of on site visit request will disqualify an applicant from the evaluation.

Target: Yes

*5. Please provide the commitment signed as per the format attached.

Attachments:

File Name or URL	Type	Description
Commitment	File	

Response attachments are required.

