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INVITATION TO PRE-QUALIFICATION OF PROCUREMENT AGENCIES FOR THE SUPPLY OF HEALTH PRODUCTS

Ref: HIST-01-2018

United Nations Development Programme

June 2018

1. 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.

The Bureau for Policy and Programme Support (BPPS) has the responsibility for developing all relevant policy and guidance to support the results of UNDP's Strategic Plan. BPPS's staff provides technical advice to Country Offices; advocates for UNDP corporate messages, represents UNDP at multi-stakeholder fora including public-private dialogues, government and civil society dialogues, South-South and Triangular cooperation initiatives, and engages in UN inter-agency coordination in specific thematic areas. BPPS works closely with UNDP's Crisis Response Unit (CRU) to support emergency and crisis response. BPPS ensures that issues of risk are fully integrated into UNDP's development programmes. BPPS assists UNDP and partners to achieve higher quality development results through an integrated approach that links results based management and performance monitoring with more effective and new ways of working. BPPS supports UNDP and partners to be more innovative, knowledge and data driven including in its programme support efforts.

BPPS supports UNDP's 2018-2021 Strategic Plan. UNDP's commitment to HIV and other major health challenges is based on the principles that health is both a driver and outcome of development, and that actions across a wide range of development sectors have a significant impact on health outcomes.

UNDP's work in HIV and health contributes to the Sustainable Development Goals by addressing the social, economic and environmental determinants of health, health-related inequalities and governance for health. UNDP's work in these areas is outlined in its HIV, Health and Development Strategy 2016-2021.

The strategy encompasses three inter-related action areas, each of which includes three priorities:

Action Area 1: Reducing inequalities and social exclusion that drive HIV and poor health.
Action Area 2: Promoting effective and inclusive governance for health.
Action Area 3: Building resilient and sustainable systems for health.

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 initiating for the first time the Pre-Qualification[1] exercise to identify potential Procurement Agencies[2] of pharmaceuticals and other health products for infectious diseases and more particularly for the treatment of Non-Communicable Diseases[3] or new emerging diseases such as Hepatitis C.

"Health products" include: medicines, medical devices, pesticides used in public health and chemical reagents.

UNDP currently has multiple Long-Term Agreement (LTAs) holders for medicines and medical devices. This prequalification process is not meant to invalidate these LTAs, unless UNDP advices 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.

2. Purpose of the Pre-Qualification Process

UNDP has recently decided to develop a new Quality Assurance Policy for health products procured by the organisation in line with WHO norms and standards for health products.

The objective of UNDP's new QA requrements is to ensure sourcing of high quality health products from reliable sources, efficient utilization of public funds at 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 according to the new UNDP quality requirements based on the WHO Model Quality Assurance for Procurement Agencies[4] (WHO MQAS). This prequalification process is to select/confirm for UNDP procurement the PA meeting the new quality requirements defined by the organization for the supply of health 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 on selecting Procurement Agencies through several evaluation stages. Pre-qualification application and on site visit assessments 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.

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1 Prequalification is, according to WHO MQAS, the activities undertaken in defining a service need and assessing the service offered against the standards of the WHO. Prequalification is required for all organizations that purchase, store and supply pharmaceutical products.

2 Procurement Agencies, in this document, refered to the suppliers (distributors, wholesalers, traders, consolidators etc.) of pharmaceutical products and medical devices but not the manufacturers. According to WHO definition, a procurement agency is defined as "any organization purchasing pharmaceutical products, vaccines , or other health products or otherwise involved in their selection, purchasing, storage and distribution".

3 The main types of NCDs are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructive pulmonary disease and asthma) and diabetes. http://www.who.int/en/news-room/fact-sheets/detail/noncommunicable-diseases

4 WHO Technical Report Series 986 – Annex 3

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

3. Evaluation Stages

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

Stage I: Prequalification Questionnaire
At this stage, UNDP will conduct assessment based on the submitted Procurement Agency Information File (PAIF) application as per **Annex I.** The assessment of the applications[5] will be based on their completeness and sufficient evidences provided in response to the questionnaire in the Pre-Qualification document. Please note there are number of questions with mandatory requirement and non-submission of the supporting documents on those questions 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 sufficient to proof about potential capability of an applicant to supply health products they indicated in their application.

Stage II: **On-site Assessment/Verification**
After preliminary selection of the applicants, upon completion of applications evaluation, UNDP will conduct on site assessment to maximum up to 10 (ten) selected applicants that submitted complete applications with sufficient proofs. On site assessment will be conducted by UNDP staff (pharmacists specialized in health products as the leaders with procurement specialists/analysts 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) that is available at http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex4.pdf). The results of the site visits will be used for reconciliation with submitted pre-qualification applications and will remain valid for 3 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, UNDP will conduct a "gap analysis" to identify whether the capacity of the current Long-Term Agreements (LTAs) may be sufficient to meet the expected future demands of health projects. Based on the results of the "gap analysis" UNDP will either initiate new procurement process with the aim to establish additional LTAs (or expand the scope of the current LTAs, in case they are recommended for award) or will establish a Roster of Prequalified companies with the aim to conduct competition among them. The tender/s (ITB/RFP) will be send to pre-qualified applicants only within specific area (i.e. pharmaceuticals, medical devices, etc.) for specific product categories. At the final stage, UNDP will request Procurement Agencies' commercial offerings for the procurement service to be offered when supplying health products proposed in **Annex II.** UNDP reserve the right to split the contract award based on the list of products offered among the suppliers.

5 Application in this document refers to the Pre-Qualification application submited by a Procuremetn Agency.

4. Tender Process & Multiple Procurement Agencies

4.1 Tender Process

Tender document will be send to maximum up to 10 (ten) pre-qualified suppliers on supply of health products.

Indicative evaluation criteria in the tender could include but not limited to:

- acceptance of UNDP General Terms and Conditions for Contract;
- origin of product, marketing status (SRA[6] or non-SRA);
- Manufacturing licenses and GMP certifications; and
- additional info as needed both for health products.

The tender processes will be evaluated based on several commercial parameters;

a. The unit prices of the goods/services to be procured.
b. Procurement/management fees charged by vendors
c. Other associated and indirect costs e.g. after sales services (e.g. medical/lab equipment)

4.2 Multiple Procurement Agencies

UNDP intends to establish a maximum up to 10 (ten) Long Term Agreements (LTAs) with pre-qualified Procurement Agencies to cover a wide range of health products. The duration of the LTAs is intended for three years, subject to supplier's satisfactory performance and need for the health products for UNDP health projects.

The objective is to establish a non-exclusive LTAs with multiple suppliers for the procurement of specified products that are required regularly during the term of the LTA, however UNDP does not guarantee placement of Purchase Orders for any quantities.

In situations where UNDP issues procurement process for the products for which there is presently no or very limited scope of supply at the time of evaluation of offers in response to the tender , UNDP may use the outcome of the procurement processes to increase the number of product/s to be included in the LTAs.

5. Guidance on Secondary Competition

The Procurement Agencies understand that procurement within UNDP is presently mainly decentralized; as such, while UNDP HQ will be signatory of the LTAs with successful suppliers and monitor their usage; secondary bidding will be conducted by UNDP Headquarters and/or UNDP Country Offices with the LTA holders as and when requirements arise.

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[6] According to the WHO, a SRA is a regulatory authority which is:

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

UNDP Headquarters and/or UNDP Country Office(s) will transmit Request for Quotation(s) to LTA holders for the supply of the health products needed as and when required.

In addition to product cost offered in response to the RFQ, adjudication of the secondary bidding will take into consideration the proposed shelf life, lead and/delivery time, best value for money through consolidation potential with other products and/or any others specific requirements. Applicable evaluation and award criteria will be specified in each individual RFQ issued by UNDP. Corresponding SOP will be developed and disseminated among LTA holders by UNDP.

Call-off contracts from the LTAs will be awarded via Purchase Orders issued by UNDP Headquarters and/or UNDP Country Offices to suppliers based on the outcome of the evaluation of each RFQ.

The intended objective of establishing the LTAs is to efficiently source health products to meet the envisaged needs of UNDP managed projects. UNDP reserves the right to issue subsequent open international solicitation process for specific products in the case where resulting LTA holders are a) deemed unable to meet the orders due to insufficient capacity, or b) where a product had no or only one supplier eligible at the time of bid and additional sources achieve as per UNDP QA requirement during the LTA period, or a combination of a) and b) or any other unforeseen exceptional circumstances.

In situations where UNDP needs to purchase the products for which there is presently no or very limited scope of supply at the time of request, UNDP may, for smaller scope, solicit quotes from LTA holders to meet the need of a project.

6. General Information on Pre-Qualification Process

6.1 Clarification, request for additional information and exchange of information

Applicants requiring any clarification of prequalification documents and procedure may send written request for clarification to the following e-mail address: pranisha.bajracharya@undp.org

In response to a clarification request UNDP publishes all the received questions and answers (without indicating the source of query) on UNDP Procurement Notice site.

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.

6.2 Deadline for submission of Applications

Applications shall be emailed to pso.bidtender@undp.org on or before 17:00 (CPH local time), 9 July 2018. 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.

Applications emailed should be free of any viruses and non-corrupted. Applicant can sent maximum of 10 messages as needed, hower, the size of each email should not exceed 5 MB.

Format: PDF files preferred in ZIP archives only.

Mandatory subject of email: “HIST-01-2018 Prequalification OF PROCUREMENT AGENCIES”

Applicants are solely responsible for ensuring that any and all files sent to UNDP are readable, that is, uncorrupted, in the indicated electronic format. Failure to provide readable files might result in the Application being rejected.

Please take into consideration the fact that emails are delivered within 5-10 mins, therefore avoid last minute submission, which might lead to late submission.

The Applicants shall bear all costs associated with the preparation and submission of the Application.

6.3 Period of validity of Applications

Applications must remain valid for a period of at least 6 months after the deadline for submission of applications. Any Application valid for a shorter period might be rejected. In exceptional circumstances, prior to the expiration of the Application validity period, UNDP may request Applicants to extend the period of validity of their applications. The request and the responses shall be made in writing.

6.4 Ethics Clauses

Any attempt by an Applicant to obtain confidential information, enter into unlawful agreements with competitors or influence UNDP evalution committee during the process of examining, clarifying, on the site assessment will lead to the rejection of his application.

6.5 Appeals

As the steward of public funds, UNDP wants to award contracts through fair and effective competition. Applicants believing that they have been harmed by an error or irregularity during the pre-qualification process may petition the UNDP directly. The UNDP will reply within 5 work days of receipt of the complaint.

To be complete, protests must contain the following information:

- The protestor's name, address, telephone number and email, the application reference;
- A detailed statement of all factual and legal grounds for protests, and an explanation of how the protester was prejudiced;
- Copies of relevant documents supporting protester's statement;

Any incomplete protest received by UNDP will not be entertained.

ANNEX I

PROCUREMENT AGENCY INFORMATION FILE (PAIF)

Acronymes

CFR	Code of Federal Regulations (USA)
CPP	Certificate for Pharmaceutical Product
DOC	Declaration Of Conformity
EC	European Conformity
FSC	Free Sales Certificate
GDP	Good Distribution Practice
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practices
IVD	In Vitro Diagnostic
MD	Medical Device
MQAS	Model Quality Assurance System for Procurement agencies
MSDS	Material Safety Data Sheet
OBL	Own Brand Labelling
PAIF	Procurement Agency Information File
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating procedure
SRA	Stringent Regulatory Authority
WHO	World Health Organization

Definitions

Pre-Qualification Application: this process is different from WHO pre-qualification exercise and the applicants should be guided on the submission by this document only.

GHTF countries founding member: *(applies to medical devices)*
USA, Canada, Japan, European Union and Australia

Multisource (generic) products
Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.

Non-Communicable Diseases (NCDs)
Also known as chronic diseases, tend to be of long duration and are the result of a combination of genetic, physiological, environmental and behaviours factors.
The main types of NCDs are cardiovascular diseases, cancers, chronic respiratory diseases (such as chronic obstructive pulmonary disease and asthma) and diabetes.

Recognition: in the context of this UNDP PAIF is defined as the direct endorsement of a decision taken by a third-party (e.g. automatic qualification of a manufacturing site approved by the US FDA or the automatic qualification of WHO prequalified products)

Stringent regulatory authority (SRA*)* *(applies to medicines)*
A regulatory authority which is:

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

Procurement Agency
A procurement agency in the context of this PAIF is defined as any organization/suppliers (distributors, wholesalers, traders, consolidators, etc.) purchasing pharmaceutical products, vaccines, or other health products or otherwise involved in their selection, purchasing, storage and distribution.

APPLICATION SUBMISSION FORM

(*to be printed on company letterhead, signed, dated and stamped*)

Date: [insert day, month, year]
No. UNDP-GFHT-IFP- 2018/01

We, the undersigned, apply to be prequalified as a UNDP Supplier for Pharmaceutical Products and Medical Devices and declare that:

(a) We have examined and have no reservations to the Prequalification Documents, including any Addendum (or Addenda to same effect), issued by the procuring UNDP entity in accordance with instructions to Applicants.

(b) We understand that you may cancel the prequalification process at any time and that you are neither bound to accept any application that you may receive nor to invite the prequalified applicants to bid for the contract subject of this prequalification, without incurring any liability to the Applicants.

(c) We are not associated, or have been associated in the past, directly or indirectly, with a firm or any of its affiliates which have been engaged by the UNDP to provide advice for the preparation of the pre-qualification documents, and other documents to be used for the ITB for commercial offering.

(d) As of the date of this statement of declaration, we are not in the circumstances of disqualification or restriction and we are not in the circumstances that cannot participate in the pre-qualification process and subsequent ITB, if we found to be quaflied. If any change occurs in this case declared, we undertake to notify the UNDP promptly.

(e) Validity of our application is six (6) months.

(f) The following information shall be used by UNDP to notify us:

Name
Title
Address: Tel: Fax:

Best regards,
Signed *[insert signature(s) of an authorized representative(s) of the Applicant]*

Name *[insert full name of person signing the application]*
In the Capacity of *[insert capacity of person signing the application]*
Duly authorized to sign the application for and on behalf of:
Applicant's Name *[insert full name of Applicant]*
Address *[insert street number/town or city/country address]*
Dated on *[insert day number]* day of *[insert month], [insert year]*

General information on the agency

Company Name	
Postal address	
Physical address (*)	
Trade register number	
VAT number	
Telephone	
Fax number	
Web site URL	
Contact email address	

(*) If the premises are not all located in the same physical address, please clearly mention it in the table (one row per address, add as many rows as needed).

Year of establishment	…… ……
Do you purchase the medicines	☐ From the manufacturer ☐ From another Procurement Agency (distributor, wholesaler)
Do you purchase the medical devices	☐ From the manufacturer ☐ From another Procurement Agency (distributor, wholesaler)

1. Regulatory status and certification(s)

1.1 License (Mandatory Requirement)

Is your company licensed/ registered by the National Regulatory Authority? Please attach a valid copy of the license/registration	☐ Yes ☐ No
Please indicate the date of the last inspection by the regulatory authority:	(dd/mo/yyyy)

1.2 Good Distribution Practices – GDP (Mandatory Requirement)

Ability to to provide a proof of compliance with stringent Good Distribution Guidelines or with the WHO Model Quality Assurance System for Procurement Agencies (http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex4.pdf)

Which Good Distribution Practices guidelines do you follow?	……
Are you regularly assessed against GDP guidelines	☐ Yes ☐ No

If "yes", please specificy the name(s) of the authorities[7] that carry out the GDP assessments and the standard/guidelines used.			
Authority	…… …… ……	Standard/guidelines	…… …… ……

[7] The authority can be your National Medicine Authority (NRA) or any other Regulatory Authority

Please attach valid copy (ies) of the certificate/assessment report/letter of approval to the questionnaire

1.3 ISO or other certification

With which harmonized Quality Management System (QMS) standards or international standards do you comply?		
	ISO certification	☐ Yes ☐ No
	Other certification (s)	☐ Yes ☐ No

If "Yes", please attach valid copy(ies) of the certificate(s) to the questionnaire

1.4 Other approvals[8]

Is your Procurement Agency approved by other international organizations? (*check all that applies)*?

☐	DG ECHO	
☐	INTERNATIONAL COMMITTEE OF THE RED CROSS (ICRC)	
☐	MEDECINS SANS FRONTIERES (MSF)	
☐	PAHO	
☐	UNFPA	
☐	UNICEF SUPPLY DIVISION	
☐	USAID/OFDA	
☐	WHO	
☐	Others (please specify)	…… …… …… ……

Please attach a copy of the letter of approval issued by the organizations mentioned above.

If you are not able to provide such a letter of approval please explain why:

……
……
……
……

If requested, would you accept to provide UNDP with a copy of the audit report performed by the organizations mentioned above?

☐ Yes ☐ No

If « no », please explain why :

……
……
……
……

[8] "Approval" in the context of this paragraph means the decision of an International Organization to purchase or to authorize the purchase of health products from a Procurement Agency based on the satisfactory assessment of its QA system

2. Personnel

Total number of employees	
Total number of pharmacists	
Number of employees in QA department	
Number of employees in QC department	

3. a.Financial Turnover (In USD) (Mandatory requirement)

To demonstrate a cumulative financial turnover of 15 million USD for recent 3 years by including latest audited finacial statement (income statement and balance sheet) for the past 3 years

a) Relating to supply of medicines

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

b) Relating to supply of medical devices

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

b.International Experience (Mandatory requirement)

To provide evidence of minimum of 5 years of experience in similar procurement services at international level

4. Range of products

What type of products do you supply to your customers?		
☐	Multi source (generic) medicines	
☐	Medicines marketed in SRA countries	
☐	Australia	
☐	Canada	
☐	European Union	
☐	Japan	
☐	Switzerland	
☐	United Kingdom	
☐	USA	
☐	Other SRA country (please specify)	…… …… ……

What type of products do you supply to your customers?		
☐	Medical Devices including In Vitro Diagnostic Medical Devices (IVDs) and Medical Equiment (X-ray machines, autoclaves, etc.)	
☐	MDs with **NO MARKET CLEARANCE** in one of the countries founding member of the GHTF (USA, Canada, Japan, Australia and European Union)	
	Please list the country of origin of the manufacturers	…… …… ……
	Are these MDs sold to one of the organizations listed in paragraph 1.4 above?	☐ Yes ☐ No
☐	Own Brand Labelling (OBL) Medical Devices	
	Would you agree to share with UNDP the name of the original manufacturers?	☐ Yes ☐ No
☐	Rebranded Medical Devices	
	Would you agree to share with UNDP the name of the original manufacturers?	☐ Yes ☐ No
☐	Medical Devices **NOT MANUFACTURED** in one of the countries founding member of the GHTF **but with a market clearance** in at least one of the countries founding member of the GHTF	
	Are the devices sold on a large scale in at least one of the countries founding member of the GHTF?	☐ Yes ☐ No
	If "yes", please list the countries	…… …… …… ……
	Are the devices sold to one of the organizations listed in paragraph 1.4 above?	☐ Yes ☐ No
	If "yes", please list the names of the organizations	…… …… …… ……
☐	Medical Devices **MANUFACTURED AND SOLD** in at least one of the founding member countries of the GHTF	
☐	Pesticides used in public health (insecticides, mosquito nets, etc.)	
☐	Chemical reagents	
☐	Other products (please specify):	
	……	

Selection of the sources

4.1 Medicines

5.1.1 Multisource (generic) medicines

On what basis does your company select/qualify its manufacturers of multisource (generic) medicines?
You can tick several boxes

☐ **Your own GMP assessment of the manufacturing sites**

Which GMP guidelines do you use for the assessment?	…… ……
Do you assess the manufacturing sites with your own human resources?	☐ Yes ☐ No
Do you appoint external experts to perform the GMP audits?	☐ Yes ☐ No
Could you provide UNDP with a copy of a recent (< 2 years) copy of a GMP audit report?	☐ Yes ☐ No

If "yes", please attach a copy of the report to the questionnaire
If "no", please explain the reasons of the refusal
……
……
……

☐ **You rely on GMP audits performed by third parties**

Please specify which GMP approvals you recognize

☐	WHO PQ
☐	All PIC/S members inspectorates
☐	All European Union member countries
☐	US FDA
☐	UNICEF
☐	UNFPA
☐	ICRC
☐	MSF
☐	PFSCM
☐	Other third parties (please list the names of bodies and organizations below)

……	……
……	……

☐ **Your selection/qualification procedure is based on other criteria or activities**

Please explain
……
……
……

On what basis does your company select/qualify its multisource (generic) medicines?
You may tick several boxes

☐ **Your own assessment of the product technical information**

Do you use your own product questionnaire?	☐ Yes ☐ No
If "yes", please attach a copy of the format to the PAIF	
Do you use the Inter Agency Product Questionnaire[9]?	☐ Yes ☐ No
Do you use the ICH Common Technical Document?	☐ Yes ☐ No
Do you use other support(s) to collect the product information	☐ Yes ☐ No
If « yes », please explain …… …… ……	
If requested, could you share your product dossiers with UNDP?	☐ Yes ☐ No
If « no », please explain …… …… ……	

☐ **You rely on the qualifications/approvals by third parties**

Please specify which qualifications/approvals you recognize (*check all that applies)*

☐	WHO PQ
☐	Marketing authorization in a SRA country
	If "yes", please clarify your definition of "SRA" …… …… ……
☐	Approval for export granted by a SRA country
☐	US FDA tentative approvals
☐	Other qualifications/approvals (please list the names of bodies and organizations below)

……	……
……	……
……	……

☐ **Your selection/qualification procedure is based on other criteria or activities**

Please explain
……
……
……

[9] WHO Technical Series 986 (Annex 3 – MQAS, appendix 6). Here is link: http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex3.pdf?ua=1

Do you maintain a list of qualified/apporved manufacturers of multi-source generic medicines?	☐ Yes ☐ No
If "Yes", could you provide UNDP with a copy of the current list?	☐ Yes ☐ No
Do you maintain a list of qualified/approved multi-source generic medicines?	☐ Yes ☐ No
If "Yes", could you provide UNDP with a copy of the current list?	☐ Yes ☐ No

5.1.2 Medicines registered/marketed in SRA countries

Which proof of registration/marketing in such SRA countries can you provide?	
☐	A copy of the marketing authorization
☐	WHO Model of Certificate for Pharmaceutical Product (CPP)
☐	Other documents?
	Please explain …… …… ……

Do you make a difference between the medicines that are authorized and marketed in the SRA country and those that are only authorized but not marketed (e.g. products "for export only")?	☐ Yes ☐ No
Please explain …… …… ……	

Please explain how can you ensure that the SRA approved products supplied to UNDP will be identical to the ones registered and marketed in the SRA country.
…… …… ……

5.2 Medical Devices (MDs)

5.2.1	**- Medical devices with <u>no market clearance</u> in one of the countries founding member of the GHTF, or** **- Medical devices sold under your own brand (OBL), or** **- Rebranded medical devices, or** **- Medical devices <u>not manufactured but with a market clearance</u> in one of the founding member countries of the GHTF, and currently not widely used in at least one of those countries** **On what basis does your company select/qualify the <u>manufacturers</u> of such medical devices?**

☐	**Your own assessment of the Quality management (QMS) of the manufacturing sites**	
	Do you request of proof of compliance with either ISO 13485 or 21CFR820?	☐ Yes ☐ No
	Do you use your own questionnaire to collect the information on the manufacturing sites?	☐ Yes ☐ No
	If "yes", please attach a copy of the format to the PAIF	
	Do you audit the manufacturing site with your own human resources?	☐ Yes ☐ No
	Do you appoint external experts to perform the audits?	☐ Yes ☐ No
	Could you share with UNDP a copy of a recent (< 2 years) audit report?	☐ Yes ☐ No
	If "yes", please attach a copy of the report to the questionnaire	
	If "no", please explain the reasons of the refusal …… ……	
☐	**You rely on QMS audits performed by third parties**	
	Do you recognize the WHO Pre-qualification?	☐ Yes ☐ No
	If "Yes", please list below the range of medical devices for which you recognize[10] the WHO Pre-Qualification …… ……	
	Do you recognize the asssessment of the manufacturing site made by other agencies?	☐ Yes ☐ No
	If "Yes", please list below the names of the agencies that you recognize …… ……	
☐	**Your selection/qualification procedure is based on other criteria or activities**	
	Please explain …… ……	

[10] "Recognition" means here that you consider that WHO prequalified devices are directly purchasable and do not require any re-assessment.

On what basis does your company assess the technical information and qualify such medical devices (the products)	
☐	**Your own assessment of the product technical information**
	Do you use your own questionnaire? *If "yes", please attach a copy of the format to the PAIF*
	What type of technical information and documentation do you resquest for sterile Medical Devices? …… ……
☐	**You rely on the qualifications/approvals by third parties**
	Please specify which qualifications/approvals you recognize
☐	WHO PQ
☐	Other qualifications/approvals (please list below the names of bodies and organizations) …… …… ……

5.2.2.	**Medical devices <u>with a market clearance</u> in one of the countries founding member of the GHTF**	
	Do you make a difference between MDs used or not used in those countries	☐ Yes ☐ No
	Please explain …… …… ……	
	If the answer is yes: what proof of use in GHTF founding member countries are you requesting from the manufacturer? …… …… ……	
	How can you ensure that the items supplied to UNDP will be identical to the ones marketed in at least one of the GHTF founding members countries? …… …… ……	

For each medical devices, please indicate which documents are available in your data base:	
☐	CE Certificate (CE marked)
☐	Declaration of conformity (DOC) (CE marked)
☐	Free sales cerftificate (FSC)
☐	ISO 13485/ 21CFR820 of the manufacturing site
☐	Proof of market clearance in the country where the device is manufactured
☐	List of countries where the device is currently widely sold/used
☐	Certificate of analyses of each batch
☐	For each lot of IVD Class A (CE marked): Batch release certificate by the notified body
☐	MSDS (Material Safety Data Sheet)
☐	Other documents (please specify)
	…… …… ……

5. Labeling of the products

For each of your products, is the labeling available in:

☐Arabic ☐English ☐French ☐Russian ☐Spanish ☐Portuguese
☐Other (s), please specify: ……

6. Quality control and Inspection

Do you control the quality of your (pre)qualified sources of multi source pharmaceutical products and medical devices?	☐ Yes ☐ No
If "yes", please explain briefly your policy for Quality Control …… …… ……	

7.1. Pre-shipment inspections	
Do you perform pre-shipment inspections in the premises of the manufacturers	☐ Yes ☐ No
If the answer is "yes" do you systematically inspect all the batches before shipment?	☐ Yes ☐ No
If you do not inspect 100% of the batches, please explain in a few words your sampling procedure …… ……	
Please clarify your requirements for the selection of the agency in charge of the inspections …… ……	

7.2. Pre-shipment Quality Control (for medicines only)	
Do you test the quality of the medicines in the premises of the manufacturers?	☐ Yes ☐ No
If the answer is "yes" do you systematically control all the batches before shipment?	☐ Yes ☐ No
If you do not test 100% of the batches, please explain in a few words your sampling procedure …… ……	
Please clarify your requirements for the selection of the QC labs in charge of the inspections …… ……	

7.3. Quality Control at receipt (for medicines only)	
Do you control the quality of incoming medicines (in your premises)?	☐ Yes ☐ No
If the answer is "yes" do you systematically control all incoming batches?	☐ Yes ☐ No
If you do not test 100% of the batches, please explain in a few words your sampling procedure …… ……	
Please clarify your requirements for the selection of the QC labs in charge of the inspections …… ……	

7. Traceability and recall

8.1. Traceability	
Can you ensure the traceability of the batches supplied to your customers	☐ Yes ☐ No
Please briefly outline your traceability system …… …… ……	

8.2. Recalls			
Do you have an SOP for handling the recalls			☐ Yes ☐ No
How quickly can you intitiate a recall? ……			
When was the last batch recall?	Date:	……	
Which product was concerned?	INN:	……	
	Manufacturer:	……	
	Reason for recall:	……	
Do you have provision for "mock" recalls in your QA system?			☐ Yes ☐ No
If "yes", how often do you organize a "mock" recall		……	
When was the last one done?		……	

8. Re-assessment

Please briefly explain your re-assessment procedure for the manufacturing sites of pharmaceutical products?
……
……
……

Please briefly explain your re-assessment procedure for the manufacturing sites of medical devices?
……
……
……

Please briefly explain your re-assessment procedure for your (pre)qualified pharmaceutical products?
……
……
……

Please birefly explain your re-assessment procedure for your (pre)qualified medical devices?
……
……
……

9. Representation of manufacturers

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).

10. Contact details for responsible persons

Responsibility	Name of contact person + qualification	Telephone	E-mail
Quality Assurance manager		Tel: Cell:	
Quality Control manager		Tel: Cell:	
Responsible of the prequalification of medicines		Tel: Cell:	
Responsible of the prequalification of MD		Tel: Cell::	
Regulatory Affairs manager		Tel: Cell:	
Commercial/business and general inquiries		Tel: Cell:	

11. Other documents

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

1. Company brochure
2. Site Master File
3. Organization Chart
4. Quality manual

12. UNDP assessment/site visit

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?

☐Yes ☐ No

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

13. Commitment

I hereby certify that the information given in this questionnaire and the attachments are true and correct.

Positions	Name	Date	Signature
Quality Assurance manager			
Quality Control manager			
Responsible of the prequalification of medicines			
Responsible of the prequalification of MD			
Regulatory Affairs manager			
Commercial/business and general inquiries			

14. List of attached document: check all that applies

☐ Copy of the license/registration (Pt 2.1) – **Mandatory requirement**

☐ Copy of a proof of compliance with stringent Good Distribution Guidelines or with the WHO Model Quality Assurance System for Procurement Agencies/report of inspection to the questionnaire (Pt 1.2) – **Mandatory requirement**

☐ Copy (ies) of the ISO or other QMS certificate(s) (Pt 2.3)

☐ Copy of the letter of approval issued by organizations listed on Pt 2.4

☐ Evidence of minimum of 5 years of experience providing similar procurement services on international level - (Pt 3.A.) – **Mandatory requirement**

☐ Demonstrate a cumulative financial turnover of 15 million USD for recent 3 years by providing financial statement (Pt 3.B) – **Mandatory requirement**

☐ Copy of your own product questionnaire for medicines (Pt 4.1.1)

☐ List of (pre)qualified manufacturers of pharmaceutical products (PT 4.1.1)

☐ List of (pre)qualified pharmaceutical products (PT 4.1.1)

☐ Copy of your own manufacturing site questionnaire for medical devices (Pt 4.2.1)

☐ Copy of your own product questionnaire for medical devices (Pt 4.2.1)

☐ List of manufacturers of medical devices (PT 4.2.1)

☐ Copy of an example of authorization letter issued by a manufacturer in which he (the manufacturer) unequivocally authorizes the Procurement Agency to represent him to UNDP (Pt 9)

☐ Quality Manual (Pt 12.4)

☐ Company brochure (Pt 13)

☐ Site Master File (Pt 13)

☐ Organization Chart (Pt 13)