

INVITATION TO BID
REF: 94-2018-UNDP-UKR-HP
Procurement of anti-hepatitis C medicines



United Nations Development Programme
March, 2018

Section 1. Letter of Invitation

The United Nations Development Programme (UNDP) hereby invites you to submit a Bid to this Invitation to Bid (ITB) for the above-referenced subject.

This ITB includes the following documents:

Section 1 – This Letter of Invitation

Section 2 – Instructions to Bidders (including Data Sheet)

Section 3 – Schedule of Requirements and Technical Specifications

Section 4 – Criteria for award and checklist of documents required

- *Annex #1 On the simplified procedure of state registration of medicinal products procured with involvement of the international organizations and VAT legislation*
- *Annex #2 Commitment letter to register non-registered products*
- *Annex #3 Certificate of Authorization to act on behalf of the Manufacturer in case the Bidder is not a Manufacturer*

Section 5 – Bid Submission Form

Section 6 – Documents Establishing the Eligibility and Qualifications of the Bidder

Section 7 – Technical Bid Form

- *Annex #4 Technical Information on product/s quoted*
- *Annex #5 Interagency finished product questionnaire*

Section 8 – Price Schedule Form

- *Annex #6 Price Schedule Form*

Section 9 – Form for Bid Security

Section 10 – Form for Performance Security

Section 11 – Contract (Purchase Order) to be Signed, including General Terms and Conditions

Appendix A – Instructions manual for use of the eTendering system by suppliers

Your offer, comprising of a Technical Bid and Price Schedule, should be submitted in accordance with Section 2, through eTendering online system and by the deadline indicated in

<https://etendering.partneragencies.org>

You are kindly requested to indicate whether your company intends to submit a Proposal by clicking on “Accept Invitation” button no later than **March 21, 2018**. If that is not the case, UNDP would appreciate your indicating the reason, for our records

If you have received this ITB through a direct invitation by UNDP, transferring this invitation to another firm requires notifying UNDP accordingly.

Should you require any clarification, kindly communicate with the contact person identified in the attached Data Sheet as the focal point for queries on this ITB.

UNDP looks forward to receiving your Bid and thanks you in advance for your interest in UNDP procurement opportunities.

Yours sincerely,

Mr. Zafar Yuldashev, UNDP Deputy Country Director Operations, a.i.

Section 2: Instruction to Bidders

Definitions

- a) *“Bid”* refers to the Bidder’s response to the Invitation to Bid, including the Bid Submission Form, Technical Bid and Price Schedule and all other documentation attached thereto as required by the ITB.
- b) *“Bidder”* refers to any legal entity that may submit, or has submitted, a Bid for the supply of goods and provision of related services requested by UNDP.
- c) *“Contract”* refers to the legal instrument that will be signed by and between the UNDP and the successful Bidder, all the attached documents thereto, including the General Terms and Conditions (GTC) and the Appendices.
- d) *“Country”* refers to the country indicated in the Data Sheet.
- e) *“Data Sheet”* refers to such part of the Instructions to Bidders used to reflect conditions of the tendering process that are specific for the requirements of the ITB.
- f) *“Day”* refers to calendar day.
- g) *“Goods”* refer to any tangible product, commodity, article, material, wares, equipment, assets or merchandise that UNDP requires under this ITB.
- h) *“Government”* refers to the Government of the country where the goods and related services provided/rendered specified under the Contract will be delivered or undertaken.
- i) *“Instructions to Bidders”* refers to the complete set of documents which provides Bidders with all information needed and procedures to be followed in the course of preparing their Bid.
- j) *“ITB”* refers to the Invitation to Bid consisting of instructions and references prepared by UNDP for purposes of selecting the best supplier or service provider to fulfil the requirement indicated in the Schedule of Requirements and Technical Specifications.
- k) *“LOI”* (Section 1 of the ITB) refers to the Letter of Invitation sent by UNDP to Bidders.
- l) *“Material Deviation”* refers to any contents or characteristics of the bid that is significantly different from an essential aspect or requirement of the ITB, and (i) substantially alters the scope and quality of the requirements; (ii) limits the rights of UNDP and/or the obligations of the offeror; and (iii) adversely impacts the fairness and principles of the procurement process, such as those that compromise the competitive position of other offerors.
- m) *“Schedule of Requirements and Technical Specifications”* refers to the document included in this ITB as Section 3 which lists the goods required by UNDP, their specifications, the related services, activities, tasks to be performed, and other information pertinent to UNDP’s receipt and acceptance of the goods.
- n) *“Services”* refers to the entire scope of tasks related or ancillary to the completion or delivery of the

goods required by UNDP under the ITB.

- o) *“Supplemental Information to the ITB”* refers to a written communication issued by UNDP to prospective Bidders containing clarifications, responses to queries received from prospective Bidders, or changes to be made in the ITB, at any time after the release of the ITB but before the deadline for the submission of Bid.

A. GENERAL

1. UNDP hereby solicits Bids as a response to this Invitation to Bid (ITB). Bidders must strictly adhere to all the requirements of this ITB. No changes, substitutions or other alterations to the rules and provisions stipulated in this ITB may be made or assumed unless it is instructed or approved in writing by UNDP in the form of Supplemental Information to the ITB.
2. Submission of a Bid shall be deemed as an acknowledgement by the Bidder that all obligations stipulated by this ITB will be met and, unless specified otherwise, the Bidder has read, understood and agreed to all the instructions in this ITB.
3. Any Bid submitted will be regarded as an offer by the Bidder and does not constitute or imply the acceptance of any Bid by UNDP. UNDP is under no obligation to award a contract to any Bidder as a result of this ITB.
4. UNDP implements a policy of zero tolerance on proscribed practices, including fraud, corruption, collusion, unethical practices, and obstruction. UNDP is committed to preventing, identifying and addressing all acts of fraud and corrupt practices against UNDP as well as third parties involved in UNDP activities. (See http://www.undp.org/about/transparencypdocs/UNDP_Anti_Fraud_Policy_English_FINAL_june_2011.pdf and http://www.undp.org/content/undp/en/home/operations/procurement/procurement_protest/ for full description of the policies)
5. In responding to this ITB, UNDP requires all Bidders to conduct themselves in a professional, objective and impartial manner, and they must at all times hold UNDP's interests paramount. Bidders must strictly avoid conflicts with other assignments or their own interests, and act without consideration for future work. All Bidders found to have a conflict of interest shall be disqualified. Without limitation on the generality of the above, Bidders, and any of their affiliates, shall be considered to have a conflict of interest with one or more parties in this solicitation process, if they:
 - 5.1 Are, or have been associated in the past, with a firm or any of its affiliates which have been engaged UNDP to provide services for the preparation of the design, Schedule of Requirements and Technical Specifications, cost analysis/estimation, and other documents to be used for the procurement of the goods and related services in this selection process;
 - 5.2 Were involved in the preparation and/or design of the programme/project related to the goods and related services requested under this ITB; or
 - 5.3 Are found to be in conflict for any other reason, as may be established by, or at the discretion of, UNDP.

In the event of any uncertainty in the interpretation of what is potentially a conflict of interest, Bidders

must disclose the condition to UNDP and seek UNDP's confirmation on whether or not such conflict exists.

6. Similarly, the following must be disclosed in the Bid :

- 6.1 Bidders who are owners, part-owners, officers, directors, controlling shareholders, or key personnel who are family of UNDP staff involved in the procurement functions and/or the Government of the country or any Implementing Partner receiving the goods and related services under this ITB; and
- 6.2 Others that could potentially lead to actual or perceived conflict of interest, collusion or unfair competition practices.

Failure of such disclosure may result in the rejection of the Bid.

- 7. The eligibility of Bidders that are wholly or partly owned by the Government shall be subject to UNDP's further evaluation and review of various factors such as being registered as an independent entity, the extent of Government ownership/share, receipt of subsidies, mandate, access to information in relation to this ITB, and others that may lead to undue advantage against other Bidders, and the eventual rejection of the Bid.
- 8. All Bidders must adhere to the UNDP Supplier Code of Conduct, which may be found at this link: <http://web.ng.undp.org/procurement/undp-supplier-code-of-conduct.pdf>

B. CONTENTS OF BID

9. Sections of Bid

Bidders are required to complete, sign and submit the following documents:

- 9.1 Criteria for award and checklist of documents required (Section 4);
- 9.2 Bid Submission Cover Letter Form (see ITB Section 5);
- 9.3 Documents Establishing the Eligibility and Qualifications of the Bidder (see ITB Section 6);
- 9.4 Technical Bid (see prescribed form in ITB Section 7);
- 9.5 Price Schedule (see prescribed form in ITB Section 8);
- 9.6 Bid Security, if applicable (if required and as stated in the DS nos. 9-11, see prescribed Form in ITB Section 9). A scanned copy of this document must be attached with your proposal in the system and the original must be sent by mail. Original must arrive no later than within 1 week after the Deadline of Bid Submission (as per DS #21), otherwise the Bid will be rejected;
- 9.7 Any attachments and/or appendices to the Bid (including all those specified under the **Data Sheet**)

10. Clarification of Bid

- 10.1 Bidders may request clarification of any of the ITB documents no later than the number of days indicated in the **Data Sheet** (DS no. 16) prior to the Bid submission date. Any request for clarification must be sent in writing via courier or through electronic means to the UNDP address indicated in the **Data Sheet** (DS no. 17). UNDP will respond by uploading the document with the responses in the system (including an explanation of the query but without identifying the source of inquiry). After which, all Proposers who have accepted in the Invitation will be

automatically alerted that such a clarification has been posted online.

- 10.2 UNDP shall endeavor to provide such responses to clarifications in an expeditious manner, but any delay in such response shall not cause an obligation on the part of UNDP to extend the submission date of the Bid, unless UNDP deems that such an extension is justified and necessary.

11. Amendment of Bid

- 11.1 At any time prior to the deadline for submission of Bid, UNDP may for any reason, such as in response to a clarification requested by a Bidder, modify the ITB in the form of a Supplemental Information to the ITB that will be uploaded in the system and made available to all Invited Bidders. All prospective Bidders (Bidders who have “accepted the Bid Invitation” in the system) will be notified in writing that changes have occurred. through the method specified in the **Data Sheet** (DS No. 18).
- 11.2 In order to afford prospective Bidders reasonable time to consider the amendments in preparing their Bid, UNDP may, at its discretion, extend the deadline for submission of Bid, if the nature of the amendment to the ITB justifies such an extension.

C. PREPARATION OF BID

12. Cost

The Bidder shall bear any and all costs related to the preparation and/or submission of the Bid, regardless of whether its Bid was selected or not. UNDP shall in no case be responsible or liable for those costs, regardless of the conduct or outcome of the procurement process.

13. Language

The Bid, as well as any and all related correspondence exchanged by the Bidder and UNDP, shall be written in the language (s) specified in the **Data Sheet** (DS No. 4). Any printed literature furnished by the Bidder written in a language other than the language indicated in the **Data Sheet**, must be accompanied by a translation in the preferred language indicated in the **Data Sheet**. For purposes of interpretation of the Bid, and in the event of discrepancy or inconsistency in meaning, the version translated into the preferred language shall govern. Upon conclusion of a contract, the language of the contract shall govern the relationship between the contractor and UNDP.

14. Bid Submission Form

The Bidder shall submit the Bid Submission Form using the form provided in Section 5 of this ITB.

15. Technical Bid Format and Content

Unless otherwise stated in the **Data Sheet** (DS no. 28), the Bidder shall structure the Technical Bid as follows:

- 15.1 Expertise of Firm/Organization – this section should provide details regarding management structure of the organization, organizational capability/resources, and experience of organization/firm, the list of projects/contracts (both completed and on-going, both domestic

and international) which are related or similar in nature to the requirements of the ITB, manufacturing capacity of plant if Bidder is a manufacturer, authorization from the manufacturer of the goods if Bidder is not a manufacturer, and proof of financial stability and adequacy of resources to complete the delivery of goods and provision of related services required by the ITB (see ITB Clause 18 and DS No. 26 for further details). The same shall apply to any other entity participating in the ITB as a Joint Venture or Consortium.

- 15.2 Technical Specifications and Implementation Plan – this section should demonstrate the Bidder’s response to the Schedule of Requirements and Technical Specifications by identifying the specific components proposed; how each of the requirements shall be met point by point; providing a detailed specification and description of the goods required, plans and drawings where needed; the essential performance characteristics, identifying the works/portions of the work that will be subcontracted; a list of the major subcontractors, and demonstrating how the bid meets or exceeds the requirements, while ensuring appropriateness of the bid to the local conditions and the rest of the project operating environment during the entire life of the goods provided. Details of technical bid must be laid out and supported by an Implementation Timetable, including Transportation and Delivery Schedule where needed, that is within the duration of the contract as specified in the **Data Sheet** (DS noS. 29 and 30).

Bidders must be fully aware that the goods and related services that UNDP require may be transferred, immediately or eventually, by UNDP to the Government partners, or to an entity nominated by the latter, in accordance with UNDP’s policies and procedures. All bidders are therefore required to submit the following in their bids:

- a) A statement of whether any import or export licenses are required in respect of the goods to be purchased or services to be rendered, including any restrictions in the country of origin, use or dual use nature of the goods or services, including any disposition to end users;
- b) Confirmation that the Bidder has obtained license of this nature in the past, and have an expectation of obtaining all the necessary licenses, should their bid be rendered the most responsive; and
- c) Complete documentation, information and declaration of any goods classified or may be classified as “Dangerous Goods”.

- 15.3 Management Structure and Key Personnel – This section should include the comprehensive curriculum vitae (CVs) of key personnel that will be assigned to support the implementation of the technical bid, clearly defining their roles and responsibilities. CVs should establish competence and demonstrate qualifications in areas relevant to the requirements of this ITB. In complying with this section, the Bidder assures and confirms to UNDP that the personnel being nominated are available to fulfil the demands of the Contract during its stated full term. If any of the key personnel later becomes unavailable, except for unavoidable reasons such as death or medical incapacity, among other possibilities, UNDP reserves the right to render the Bid non-responsive. Any deliberate substitution of personnel arising from unavoidable reasons, including delay in the implementation of the project of programme through no fault of the Bidder, shall be made only with UNDP’s acceptance of the justification for substitution, and UNDP’s approval of the qualification of the replacement who shall be either of equal or superior credentials as the one being replaced.

- 15.4 Where the **Data Sheet** requires the submission of the Bid Security, the Bid Security shall be

included along with the Technical Bid. The Bid Security may be forfeited by UNDP, and reject the Bid, in the event of any or any combination of the following conditions:

- a) If the Bidder withdraws its offer during the period of the Bid Validity specified in the **Data Sheet** (DS no. 11), or;
- b) If the Bid Security amount is found to be less than what is required by UNDP as indicated in the **Data Sheet** (DS no. 9), or;
- c) In the case the successful Bidder fails:
 - i. to sign the Contract after UNDP has awarded it;
 - ii. to comply with UNDP's variation of requirement, as per ITB Clause 35; or
 - iii. to furnish Performance Security, insurances, or other documents that UNDP may require as a condition to rendering effective the contract that may be awarded to the Bidder.

16. Price Schedule

The Price Schedule shall be prepared using the attached standard form (Section 8). It shall list all major cost components associated with the goods and related services, and the detailed breakdown of such costs. All goods and services described in the Technical Bid must be priced separately on a one-to-one correspondence. Any output and activities described in the Technical Bid but not priced in the Price Schedule, shall be assumed to be included in the prices of the items or activities, as well as in the final total price of the bid.

17. Currencies

All prices shall be quoted in the currency indicated in the **Bid Event**. However, where Bids are quoted in different currencies, for the purposes of comparison of all Bid:

- 17.1 UNDP will convert the currency quoted in the Bid into the UNDP preferred currency, in accordance with the prevailing UN operational rate of exchange on the last day of submission of Bid; and
- 17.2 In the event that the Bid found to be the most responsive to the ITB requirement is quoted in another currency different from the preferred currency as per **Bid Event**, then UNDP shall reserve the right to award the contract in the currency of UNDP's preference, using the conversion method specified above.

18. Documents Establishing the Eligibility and Qualifications of the Bidder

18.1 The Bidder shall furnish documentary evidence of its status as an eligible and qualified vendor, using the forms provided under Section 5, Bidder Information Forms. In order to award a contract to a Bidder, its qualifications must be documented to UNDP's satisfactions. These include, but are not limited to the following:

- a) That, in the case of a Bidder offering to supply goods under the Contract which the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the goods' manufacturer or producer to supply the goods in the country of final destination;
- b) That the Bidder has the financial, technical, and production capability necessary to perform the Contract; and

- c) That, to the best of the Bidder's knowledge, it is not included in the UN 1267 List or the UN Ineligibility List, nor in any and all of UNDP's list of suspended and removed vendors.

18.2 Bids submitted by two (2) or more Bidders shall all be rejected by UNDP if they are found to have any of the following:

- a) they have at least one controlling partner, director or shareholder in common; or
- b) any one of them receive or have received any direct or indirect subsidy from the other/s; or
- c) they have the same legal representative for purposes of this ITB; or
- d) they have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about, or influence on the Bid of, another Bidder regarding this ITB process;
- e) they are subcontractors to each other's bid, or a subcontractor to one bid also submits another Bid under its name as lead Bidder; or
- f) an expert proposed to be in the bid of one Bidder participates in more than one Bid received for this ITB process. This condition does not apply to subcontractors being included in more than one Bid.

19. Joint Venture, Consortium or Association

If the Bidder is a group of legal entities that will form or have formed a joint venture, consortium or association at the time of the submission of the Bid, they shall confirm in their Bid that : (i) they have designated one party to act as a lead entity, duly vested with authority to legally bind the members of the joint venture jointly and severally, and this shall be duly evidenced by a duly notarized Agreement among the legal entities, which shall be submitted along with the Bid; and (ii) if they are awarded the contract, the contract shall be entered into, by and between UNDP and the designated lead entity, who shall be acting for and on behalf of all entities that comprise the joint venture.

After the bid has been submitted to UNDP, the lead entity identified to represent the joint venture shall not be altered without the prior written consent of UNDP. Furthermore, neither the lead entity nor the member entities of the joint venture can:

- a) Submit another Bid, either in its own capacity; nor
- b) As a lead entity or a member entity for another joint venture submitting another Bid.

The description of the organization of the joint venture/consortium/association must clearly define the expected role of each of the entity in the joint venture in delivering the requirements of the ITB, both in the bid and in the Joint Venture Agreement. All entities that comprise the joint venture shall be subject to the eligibility and qualification assessment by UNDP.

Where a joint venture is presenting its track record and experience in a similar undertaking as those required in the ITB, it should present such information in the following manner:

- a) Those that were undertaken together by the joint venture; and
- b) Those that were undertaken by the individual entities of the joint venture expected to be involved in the performance of the services defined in the ITB.

Previous contracts completed by individual experts working privately but who are permanently or were temporarily associated with any of the member firms cannot be claimed as the experience of the joint venture or those of its members, but should only be claimed by the individual experts themselves in

their presentation of their individual credentials.

If the Bid of a joint venture is determined by UNDP as the most responsive Bid that offers the best value for money, UNDP shall award the contract to the joint venture, in the name of its designated lead entity, who shall sign the contract for and on behalf of all the member entities.

20. Alternative Bid

Unless otherwise specified in the **Data Sheet** (DS nos. 5 and 6), alternative bid shall not be considered. Where the conditions for its acceptance are met, or justifications are clearly established, UNDP reserves the right to award a contract based on an alternative bid.

21. Validity Period

21.1 Bid shall remain valid for the period specified in the **Data Sheet** (DS no. 8), commencing on the submission deadline date also indicated in the **Data Sheet** (DS no. 21). A Bid valid for a shorter period shall be immediately rejected by UNDP and rendered non-responsive.

21.2 In exceptional circumstances, prior to the expiration of the Bid validity period, UNDP may request Bidders to extend the period of validity of their Bid. The request and the responses shall be made in writing, and shall be considered integral to the Bid.

22. Bidder's Conference

When appropriate, a Bidder's conference will be conducted at the date, time and location specified in the **Data Sheet** (DS no. 7). All Bidders are encouraged to attend. Non-attendance, however, shall not result in disqualification of an interested Bidder. Minutes of the Bidder's conference will be uploaded on the system. No verbal statement made during the conference shall modify the terms and conditions of the ITB unless such statement is specifically written in the Minutes of the Conference, or issued/posted as an amendment in the form of a Supplemental Information to the ITB.

D. SUBMISSION AND OPENING OF BID

23. Submission

23.1 The Technical Bid and all other documents required online in the eTendering system. Bids submitted in any other form will not be accepted unless explicitly authorized by UNDP in advance.

23.2 In the unlikely and exceptional event that the Bidder encounter technical problems when submitting the proposal in the system, then the Bid can be sent via email as instructions in Data Sheet (DSNo. 21). Bidders are however strongly advised to undertake all necessary efforts, including requesting support from UNDP, to submit the Bid through the online system. In all cases, email submissions must be authorized and accepted by UNDP prior to the submission deadline indicated. *Bids submitted via email which **does not have prior authorization** by UNDP will not be accepted .*

23.3 Bidders must be aware that the mere act of submission of a Bid, in and of itself, implies that the Bidder accepts the General Contract Terms and Conditions of UNDP as attached hereto as Section 11.

24. Withdrawal, Substitution, and Modification of Bid

- 24.1 Bidders are expected to have sole responsibility for taking steps to carefully examine in detail the full consistency of its Bid to the requirements of the ITB, keeping in mind that material deficiencies in providing information requested by UNDP, or lack clarity in the description of goods and related services to be provided, may result in the rejection of the Bid. The Bidder shall assume any responsibility regarding erroneous interpretations or conclusions made by the Bidder in the course of understanding the ITB out of the set of information furnished by UNDP.
- 24.2 A Bidder may withdraw, substitute or modify its Bid after it has been submitted by cancelling or editing their bid in the system

25. Confidentiality

Information relating to the examination, evaluation, and comparison of Bid, and the recommendation of contract award, shall not be disclosed to Bidders or any other persons not officially concerned with such process, even after publication of the contract award.

Any effort by a Bidder to influence UNDP in the examination, evaluation and comparison of the Bid or contract award decisions may, at UNDP's decision, result in the rejection of its Bid.

In the event that a Bidder is unsuccessful, the Bidder may seek a meeting with UNDP for a debriefing. The purpose of the debriefing is discussing the strengths and weaknesses of the Bidder's submission, in order to assist the Bidder in improving the bid presented to UNDP. The content of other bid and how they compare to the Bidder's submission shall not be discussed.

E. EVALUATION OF BID

26. Preliminary Examination of Bid

UNDP shall examine the Bid to determine whether they are complete with respect to minimum documentary requirements, whether the documents have been properly signed, whether or not the Bidder is in the UN Security Council 1267/1989 Committee's list of terrorists and terrorist financiers, and in UNDP's list of suspended and removed vendors, and whether the Bid are generally in order, among other indicators that may be used at this stage. UNDP may reject any Bid at this stage.

27. Evaluation of Bid

- 27.1. The evaluation team shall review and evaluate the Bids on the basis of their responsiveness to the Schedule of Requirements and Technical Specifications and other documentation provided, applying the procedure indicated in the Data Sheet (DS No. 25). Absolutely no changes may be made by UNDP in the criteria after all Bids have been received.
- 27.2. UNDP reserves the right to undertake a post-qualification exercise, aimed at determining, to its satisfaction the validity of the information provided by the Bidder. Such post-qualification shall be fully documented and, among those that may be listed in the Data Sheet (DS No.33), may include, but need not be limited to, all or any combination of the following :

- a) Verification of accuracy, correctness and authenticity of the information provided by the bidder on the legal, technical and financial documents submitted;
- b) Validation of extent of compliance to the ITB requirements and evaluation criteria based on what has so far been found by the evaluation team;
- c) Inquiry and reference checking with Government entities with jurisdiction on the bidder, or any other entity that may have done business with the bidder;
- d) Inquiry and reference checking with other previous clients on the quality of performance on on-going or previous contracts completed;
- e) Physical inspection of the bidder's plant, factory, branches or other places where business transpires, with or without notice to the bidder;
- f) Testing and sampling of completed goods similar to the requirements of UNDP, where available; and
- g) Other means that UNDP may deem appropriate, at any stage within the selection process, prior to awarding the contract.

28. Clarification of Bid

To assist in the examination, evaluation and comparison of bids, UNDP may, at its discretion, ask any Bidder to clarify its Bid.

UNDP's request for clarification and the Bidder's response shall be in writing. Notwithstanding the written communication, no change in the prices or substance of the Bid shall be sought, offered, or permitted, except to provide clarification, and confirm the correction of any arithmetic errors discovered by UNDP in the evaluation of the Bid, in accordance with ITB Clause 35.

Any unsolicited clarification submitted by a Bidder in respect to its Bid, which is not a response to a request by UNDP, shall not be considered during the review and evaluation of the Bid.

29. Responsiveness of Bid

UNDP's determination of a Bid's responsiveness will be based on the contents of the Bid itself.

A substantially responsive Bid is one that conforms to all the terms, conditions, and specifications of the ITB without material deviation, reservation, or omission.

If a Bid is not substantially responsive, it shall be rejected by UNDP and may not subsequently be made responsive by the Bidder by correction of the material deviation, reservation, or omission.

30. Nonconformities, Repairable Errors and Omissions

30.1 Provided that a Bid is substantially responsive, UNDP may waive any non-conformities or omissions in the Bid that, in the opinion of UNDP, do not constitute a material deviation.

30.2 In the event when Provided that the Bid is substantially responsive, the system automatically calculates the final bid prices by multiplying the unit price by the quantity.

30.3 The system automatically calculates the final bid prices by multiplying the unit price by the quantity. In the event when the Bidder put a quantity that is different from the quantity required, provided that the Bid is substantially responsive, UNDP will re-calculate the Bidders total price based on the correct quantity and using the unit prices offered by the Bidder. Unit prices cannot

be changed:

30.4 If the Bidder does not accept the correction of errors made by UNDP, its Bid shall be rejected.

F. AWARD OF CONTRACT

31. Right to Accept, Reject, or Render Non-Responsive Any or All Bid

31.1 UNDP reserves the right to accept or reject any Bid, to render any or all of the Bids as non-responsive, and to reject all Bids at any time prior to award of contract, without incurring any liability, or obligation to inform the affected Bidder(s) of the grounds for UNDP's action. Furthermore, UNDP is not obligated to award the contract to the lowest price offer.

31.2 UNDP shall also verify, and immediately reject their respective Bid, if the Bidders are found to appear in the UN's Consolidated List of Individuals and Entities with Association to Terrorist Organizations, in the List of Vendors Suspended or Removed from the UN Secretariat Procurement Division Vendor Roster, the UN Ineligibility List, and other such lists that as may be established or recognized by UNDP policy on Vendor Sanctions. (See http://www.undp.org/content/undp/en/home/operations/procurement/procurement_protest/)

32. Award Criteria

Prior to expiration of the period of Bid validity, UNDP shall award the contract to the qualified and eligible Bidder that is found to be responsive to the requirements of the Schedule of Requirements and Technical Specification, and has offered the lowest price (See DS No. 32).

33. Right to Vary Requirements at the Time of Award

At the time of award of Contract, UNDP reserves the right to vary the quantity of the goods and/or related services, by up to a maximum twenty five per cent (25%) of the total offer, without any change in the unit price or other terms and conditions.

34. Contract Signature

Within fifteen (15) days from the date of receipt of the Contract, the successful Bidder shall sign and date the Contract and return it to UNDP.

Failure of the successful Bidder to comply with the requirement of ITB Section F.3 and this provision shall constitute sufficient grounds for the annulment of the award, and forfeiture of the Bid Security if any, and on which event, UNDP may award the Contract to the Bidder with the second highest rated Bid, or call for new Bid.

35. Performance Security

A performance security, if required, shall be provided in the amount and form provided in Section 9 and by the deadline indicated in the **Data Sheet** (DS no. 14), as applicable. Where a Performance Security will be required, the submission of the said document, and the confirmation of its acceptance by UNDP, shall be a condition for the effectivity of the Contract that will be signed by and between the successful Bidder and UNDP.

36. Bank Guarantee for Advanced Payment

Except when the interests of UNDP so require, it is the UNDP's preference to make no advanced payment(s) on contracts (i.e., payments without having received any outputs).

37. Vendor Protest

UNDP's vendor protest procedure provides an opportunity for appeal to those persons or firms not awarded a purchase order or contract through a competitive procurement process. In the event that a Bidder believes that it was not treated fairly, the following link provides further details regarding UNDP vendor protest procedures: <http://www.undp.org/procurement/protest.shtml>

Instructions to Bidders

DATA SHEET

The following data for the supply of goods and related services shall complement / supplement the provisions in the Instruction to Bidders. In the case of a conflict between the Instruction to Bidders and the Data Sheet, the provisions in the Data Sheet shall prevail.

| DS No. | Cross Ref. to Instructions | Data | Specific Instructions / Requirements |
|--------|----------------------------|--|---|
| 1 | | Project Title: | Procurement Support Services to the Ministry of Health in Ukraine AND Procurement of medicines for treatment of socially significant diseases (Kazakhstan) |
| 2 | | Title of Goods/Services/Work Required: | Procurement of anti-hepatitis C medicines in 6 Lots (6 items), in accordance with the Technical Specifications as per Section 3. |
| 3 | | Country: | Ukraine/Kazakhstan |
| 4 | C.13 | Language of the Bid: | <input checked="" type="checkbox"/> English As this particular procurement case is subject to review and approval by UNDP HQ Advisory Committee on Procurement, English is the preferred language of the bid, with any other language documents where possible translated into English. <input checked="" type="checkbox"/> Russian |
| 5 | C.20 | Conditions for Submitting Bid for Parts or sub-parts of the Total Requirements | <input checked="" type="checkbox"/> The Bidder may submit Bid for separate Lots/Items However, Bidders are encouraged to quote for as many Lots/Items as possible. |
| 6 | C.20 | Conditions for Submitting Alternative Bid | <input checked="" type="checkbox"/> Shall not be considered |
| 7 | C.22 | A pre-Bid conference will be held on: | 1st pre-bid conference: Time: 11:00 hrs local time Date: March 13, 2018 Venue: Lviv meeting room (1st floor); UN Office in Ukraine; |

| DS No. | Cross Ref. to Instructions | Data | Specific Instructions / Requirements |
|--------|----------------------------|--|--|
| | | | <p>1 Klovskyi descent, Kyiv Companies can participate at pre-bid conference through skype conference as well. Interested companies should send confirmations by email. ALREADY CONDUCTED</p> <p>2nd pre-bid conference will be conducted as following:</p> <p>Time: 12:00 hrs local time (Kyiv time) Date: March 22, 2018 Venue: Alexanyan meeting room, Operations building (2nd floor); UN Office in Ukraine; 1 Klovskyi descent, Kyiv</p> <p>Companies can participate at pre-bid conference through skype conference as well. Interested companies should send confirmations by email.</p> <p>The UNDP focal point for the arrangement is: UNDP Procurement Unit Telephone: +38 044 2539363 Facsimile: +38 044 253 2607 E-mail: health.procurement.ua@undp.org</p> |
| 8 | C.21.1 | Period of Bid Validity commencing on the submission date | <input type="checkbox"/> 60 days <input type="checkbox"/> 90 days <input checked="" type="checkbox"/> 120 days |
| 9 | B.9.5 C.15.4 b) | Bid Security | <input checked="" type="checkbox"/> Required Bid security is required in the amount of: USD 10,000 for a bid for one or more lots cumulatively exceeding 200,000.00 USD up to USD 399,999.99 OR USD 20,000 for a bid for one or more lots cumulatively amounting from 400,000.00 to 599,999.99 OR USD 30,000 for a bid for one or more lots cumulatively exceeding 600,000.00 |

| DS No. | Cross Ref. to Instructions | Data | Specific Instructions / Requirements |
|--------|----------------------------|--|--|
| 10 | B.9.5 | Acceptable forms of Bid Security | <input checked="" type="checkbox"/> Bank Guarantee Bid Security shall be submitted in the form of Bank Guarantee as per template provided in the Section 9 |
| 11 | B.9.5 C.15.4 a) | Validity of Bid Security | 150 days from the last day of Bid submission. |
| 12 | | Advanced Payment upon signing of contract | <input checked="" type="checkbox"/> Not allowed |
| 13 | | Liquidated Damages | <input checked="" type="checkbox"/> Will be imposed under the following conditions: If the Supplier fails to supply the specified Goods within the time period(s) stipulated in the individual contract (Purchase Orders), the UNDP may without prejudice to its other remedies under the contract, deduct 0.5% of the complete consignment for each day of delay until actual delivery; and 1% for contracts awarded under 30% option with accelerated delivery schedule ("more superior" bids) up to maximum deduction of 10% of the value of the Purchase Order (this is applicable for lots # 5-6 only). Once the maximum is reached, UNDP may consider termination of the PO |
| 14 | F.37 | Performance Security | <input checked="" type="checkbox"/> Will be required from winning entity for all contracts (Purchase Orders) exceeding 300,000 USD OR upon discretion of UNDP (e.g. product is not registered) as per template provided in the Section 10 Amount: 10 % of the contract amount Form: Bank guarantee |
| 15 | C.17 C.17.2 | Preferred Currency of Bid and Method for Currency conversion | <input checked="" type="checkbox"/> United States Dollars (USD) - strongly advised to use as a risk mitigation measure against the impact of the local currency devaluation. <input checked="" type="checkbox"/> UAH – Ukrainian Hryvna – for lots #1-4 <input checked="" type="checkbox"/> KZT – Kazakhstan Tenge – for lots #5-6 |

| DS No. | Cross Ref. to Instructions | Data | Specific Instructions / Requirements |
|--------|----------------------------|---|---|
| | | | <p>UNDP will execute payments in USD to international suppliers.</p> <p>Payments to the local (Ukrainian or Kazakh) suppliers will be executed either in USD or UAH/KZT based on UN Operational Exchange Rate effective at the date of payment (please refer to treasury.un.org). Please state in the financial bid preferred currency of payment.</p> <p>Prices submitted by Bidders will be evaluated versus each other based on UN Operational exchange rate effective at the closure day of the bid submission (please refer to treasury.un.org)</p> |
| 16 | B.10.1 | Deadline for submitting requests for clarifications/questions | 5 days before the submission date. |
| 17 | B.10.1 | Contact Details for submitting clarifications/questions | <p>Focal Person in UNDP: Procurement Unit</p> <p>Tel. No. :+38 044 253 59 84</p> <p>E-mail address dedicated for this purpose: yana.dovga@undp.org</p> |
| 18 | B.11.1 | Manner of Disseminating Supplemental Information to the ITB and responses/clarifications to queries | Uploaded in the system. It is the responsibility of the Proposers to view the respective changes and clarifications in the system |
| 21 | C.21.1 D.24 | Deadline of Bid Submission | <p>ATTENTION! DEADLINE HAS BEEN EXTENDED</p> <p>Date and Time: As specified in the system (note that time zone indicated in the system is New York Time zone).</p> <p><u>PLEASE NOTE:-</u></p> <ol style="list-style-type: none"> 1. Date and time visible on the main screen of event (on e-tendering portal) will be final and prevail over any other closing time indicated elsewhere, in case they are different. It is the responsibility of the bidder to make sure bids are submitted within this deadline. |

| DS No. | Cross Ref. to Instructions | Data | Specific Instructions / Requirements |
|--------|----------------------------|---|---|
| | | | <p>UNDP will not accept any bid that is not submitted directly in the system.</p> <p>2. Submit your bid a day prior or well before the closing time. Do not wait until last minute. If you face any issue submitting your bid at the last minute, UNDP may not be able to assist.</p> |
| 22 | D.23.2 | Manner of Submitting Bid | <p>Online bidding in Etendering module.</p> <p><input checked="" type="checkbox"/> Electronic submission of Bid</p> |
| 23 | D.23.2 D.26 | Conditions and Procedures for electronic submission and opening, if allowed | Online bidding in Etendering module |
| 24 | D. 23 | Date, time and venue for Public Bid Opening | <p>The Purchaser will present bids received in the system in the presence of Bidders' Representatives who choose to attend, at the time, on the date, and at the place specified below.</p> <p>Date and Time: April 4, 2018 12:00 AM, Kyiv time (UTC +2:00)</p> <p><i>Any bidder that intends to participate in the public bid opening shall notify UNDP by address health.procurement.ua@undp.org at least 24 hours in advance.</i></p> <p><i>Companies can participate at the Bid Opening procedure through skype conference as well. Interested companies should send confirmations by email.</i></p> <p>Venue: Alexanyan meeting room, Operations building (2nd floor); UN Office in Ukraine; 1 Klovskyi descent, Kyiv</p> |
| 25 | | Evaluation method to be used in selecting the most responsive Bid | <p><input checked="" type="checkbox"/> Non-Discretionary "Pass/Fail" Criteria on the Technical Requirements; and</p> <p><input checked="" type="checkbox"/> Lowest price offer of technically qualified/responsive Bid <u>per LOT</u></p> |
| 26 | C.15.1 | Required Documents that must be Submitted to Establish Qualification of | <p><input checked="" type="checkbox"/> Duly filled-in, signed and stamped Sections 4-8.</p> <p><input checked="" type="checkbox"/> Copy of properly furnished Bid Security (as per DS #9). Please use template provided in the Section 9.</p> |

| DS No. | Cross Ref. to Instructions | Data | Specific Instructions / Requirements |
|--------|----------------------------|---|--|
| | | <p>Bidders (In “Certified True Copy” form only)</p> <p><i>[check all that apply, delete those that will not be required.]</i></p> | <p>Original should be provided to UNDP within 1 week after the Deadline of Bid Submission (DS #21) to below address, otherwise the bid will be rejected:</p> <p>1 Klovskyi Uzviz, Kyiv, Ukraine 01021 To: UNDP Procurement Unit</p> <p><input checked="" type="checkbox"/> Copies of required documents to establish conformity of Bidder to the qualifications requirements and products quoted to product standards and requirements as per Section 4 “Criteria for award and checklist of documents required”</p> |
| 27 | | Other documents that may be Submitted to Establish Eligibility | NA |
| 28 | C.15 | Structure of the Technical Bid and List of Documents to be Submitted | As per DS #26 |
| 29 | C.15.2 | Latest Expected date for commencement of Contract | May 10, 2018 |
| 30 | C.15.2 | Maximum Expected duration of contract | As per Deadlines described in the Section 3 |
| 31 | | UNDP will award the contract to: | <p><input checked="" type="checkbox"/> One or more Bidders, depending on the following factors: Lowest-priced technically responsive offer <u>per Lot.</u></p> <p><u>*) UNDP might enter into a long-term agreement/s (LTA) with the selected supplier/s as a result of this ITB. The initial Agreement/s shall be concluded for a period of 1 (one) year and may be extended for additional 2 (two) years, subject for satisfactory performance of the supplier/s.</u></p> |
| 32 | F.34 | Criteria for the Award and Evaluation of Bid | <p><input checked="" type="checkbox"/> Non-Discretionary “Pass/Fail” Qualifying Criteria on the requirements listed in the Section 4 “Criteria for award and checklist of documents required” and in the Section 3 “Schedule of Requirements and Technical Specifications”</p> <p>AND</p> |

| DS No. | Cross Ref. to Instructions | Data | Specific Instructions / Requirements |
|--------|----------------------------|---|--|
| | | | <input checked="" type="checkbox"/> Lowest price offer of technically qualified/responsive Bid per Lot *) the discount factor will be considered if such proposed by Bidder for awarding of more than one lot only at the stage of contracting and will not be considered for evaluation purposes |
| 33 | E.29 | Post qualification Actions | <input checked="" type="checkbox"/> Verification of accuracy, correctness and authenticity of the information provided by the bidder on the legal, technical and financial documents submitted; <input checked="" type="checkbox"/> Validation of extent of compliance to the ITB requirements and evaluation criteria based on what has so far been found by the evaluation team; <input checked="" type="checkbox"/> Inquiry and reference checking with Government entities with jurisdiction on the bidder, or any other entity that may have done business with the bidder; <input checked="" type="checkbox"/> Inquiry and reference checking with other previous clients on the quality of performance on ongoing or previous contracts completed; <input checked="" type="checkbox"/> Physical inspection of the bidder's plant, factory, branches or other places where business transpires, with or without notice to the bidder; <input checked="" type="checkbox"/> Testing and sampling of completed goods similar to the requirements of UNDP, where available. |
| 34 | | Conditions for Determining Contract Effectivity | <input checked="" type="checkbox"/> Provision of Performance Security (if requested by UNDP) |
| 35 | | Other Information Related to the ITB | <u>Administrative Requirements:</u> Prior to technical evaluation, submitted offers will be reviewed on a "Pass" or "Fail" basis to determine compliance with the below formal criteria/requirements: <input checked="" type="checkbox"/> Bids must be submitted within the stipulated deadline; <input checked="" type="checkbox"/> Bids must meet required Bid Validity; <input checked="" type="checkbox"/> Bids must include copy of properly furnished <u>Bid Security</u> (as per DS #9). Original should be provided within 1 week after the Deadline of Bid Submission (as per DS #21), otherwise the Bid will be rejected. |

| DS No. | Cross Ref. to Instruction s | Data | Specific Instructions / Requirements |
|-----------|--------------------------------------|------|---|
| | | | <input checked="" type="checkbox"/> Bids have been signed by the proper authority <input checked="" type="checkbox"/> Full compliance and agreement with UNDP General terms and conditions available in the Annex 11 |

Section 3

Schedule of Requirements and Technical Specifications

1. EXECUTIVE SUMMARY

Procurement Support Services to the Ministry of Health in Ukraine

In April 2015, the Ministry of Health of Ukraine approached the UN System in Ukraine to support the procurement and distribution of medicines and other medical products in scope of health state programs as an emergency measure. This new approach to procurement in the public health sector was aimed to prevent corruption and protect the rights of patients in Ukraine to access affordable and quality medicines.

In 2015, UNDP supported the MOH with the procurement and distribution of medicines and other medical products for 8 state health programmes. UNDP support to the Ministry of Health was extended to 23 programmes in 2016.

On July 2017, UNDP signed new agreement with the MoH to procure essential medicines and medical products for 15 health programmes under 2017 State budget. Later in 2017, the MOH allocated 11 more programs to UNDP for procurement of vitally needed health products.

UNDP in Ukraine is fully committed to play its role in resolving the immediate crisis and to support the Ministry of Health of Ukraine in its efforts to reform the procurement and supply management system for it to correspond to the highest standards of transparency, accountability, cost-efficiency, equity and sustainability.

Procurement of medicines for treatment of socially significant diseases (Kazakhstan)

The Ministry of Health of the Republic of Kazakhstan together with "SK-Pharmacy" Limited Liability Partnership (procurement agent of the MOH) approached the UNDP in Kazakhstan to support the procurement of medicines for patients with Hepatitis C as an emergency measure. This new approach to procurement in the public health sector was aimed to protect the rights of patients in Kazakhstan to access affordable and quality medicines.

GENERAL INFORMATION FOR THE BIDDERS

UNDP might enter into a long-term agreements (LTA) with the selected suppliers as a result of this ITB. The initial agreement/s shall be concluded for a period of 1 (one) year and may be extended for additional 2 (two) years, subject for satisfactory performance of the supplier/s.

UNDP plans to place Purchase Orders for the quantities mentioned below (indicated in the Chapter "Products Specification"). The future volumes are expected to remain in the same ranges, however UNDP does not guarantee placement of Purchase Orders for any quantities.

2. PRODUCTS SPECIFICATION*:

| Lot # | International nonproprietary name | Pharmaceutical presentation | Strength | Quantity | Delivery Destination |
|--|-----------------------------------|-----------------------------|---------------|----------|----------------------|
| Procurement Support Services to the Ministry of Health in Ukraine | | | | | |
| 1 | Sofosbuvir | tablets | 400 mg | 62 361 | Ukraine |
| 2 | Sofosbuvir/ Ledipasvir | tablets | 400 mg/90 mg | 170 894 | Ukraine |
| 3 | Daclatasvir | tablets | 60 mg | 52 703 | Ukraine |
| 4 | Sofosbuvir/ Velpatasvir | tablets | 400 mg/100 mg | 49 633 | Ukraine |
| Procurement of medicines for socially significant diseases (Kazakhstan) | | | | | |
| 5 | Sofosbuvir | tablets | 400 mg | 354 144 | Kazakhstan |
| 6 | Daclatasvir | tablets | 60 mg | 354 144 | Kazakhstan |

*) Quantities which are expected to be procured by UNDP with the first order/s.

NB. UNDP reserves the right to vary the quantity of the goods by up to a maximum twenty-five per cent (25%) of the total offer, without any change in the unit price or other terms and conditions.

3. PRODUCT STANDARDS

In view of the specific emergency situation experienced by the country, and the urgency with which UNDP has been requested to procure these medicines, these standards below are specific for this procurement action and in no way constitute an obligation from UNDP to use any of these standards in future procurement actions.

UNDP will procure the medicines only under one the following product standards options:

OPTION 1 [A+E]:

A) **Approved/registered by a Stringent National Medicines Regulatory Authority (SRA) as defined by WHO.** Stringent Drug Regulatory Authority (SRA) means a regulatory authority:

- (a) a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission (in case of the European Union both European Medical Agency (EMA) and European Union member States) and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
- (b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or
- (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

***) 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.**

AND

E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities**

****) The selected Suppliers are requested to manufacture products only at manufacturing sites/units/blocks, which are certified by WHO (WHOPIR) or PIC/S GMP. Respective information would be verified through shipping documents.**

OPTION 2 [B+E]:

B) Prequalified by World Health Organization

AND

E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities**

****) The selected Suppliers are requested to manufacture products only at manufacturing sites/units/blocks, which are certified by WHO (WHOPIR) or PIC/S GMP.**

OPTION 3 [C+E]:

C) Recommended by the WHO Expert Review Panel for the Global Fund (also known as Global Fund ERP)

AND

E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities**

****) The selected Suppliers are requested to manufacture products only at manufacturing sites/units/blocks, which are certified by WHO (WHOPIR) or PIC/S GMP.**

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).

BELOW OPTION 4 IS APPLICABLE FOR LOTS: #2-4 AND 6 ONLY

OPTION 4 [D+E]¹:

D) Medicine's quality will be found compliant with UNDP internal QA policy against WHO norms and standards for pharmaceutical preparations conducted by UNDP after bid submission.

To enable the assessment of medicine Bidder shall provide:

- Filled-in Interagency finished product questionnaire attached as Annex #3 to ITB with copies of requested documents and/or ICH Common Technical Document (CTD)* for the product/s quoted
- AND
- Letter on Acceptance for Assessment for FPP pre-qualification by WHO and/or for FPP registration by SRA registration authorities (if available)
- AND
- List of previous supplies of product/s quoted.

¹ Option 4 is applicable for evaluation of both registered and non-registered products in Kazakhstan and Ukraine which are neither SRA approved nor WHO-prequalified nor GF ERP approved.

Failure to provide above documents might be considered as a ground for disqualification of Bidder.

AND

E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities**

****) The selected Suppliers are requested to manufacture products only at manufacturing sites/units/blocks, which are certified by WHO (WHOPIR) or PIC/S GMP. Respective information would be verified through shipping documents prior delivery.**

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).

4. REGISTRATION / AUTHORIZATION FOR USE IN COUNTRIES OF DESTINATION

UNDP will evaluate offers for both registered and non-registered medicinal products. Non-registered products must meet quality standards as per above OPTIONS.

1) UKRAINE (LOTS #1-4)

By the time of supply, the products must be fully registered with the Ministry of Health confirming their legal use in Ukraine.

Successful Bidders whose product(s) is registered with MOH at time of award will be issued a contract.

Successful Bidder whose product(s) complies with quality standards, but is not registered with MOH at time of award, will sign a conditional contract and will be required to register their products before supply.

Bidders offering non-registered products that are compliant with quality standards, must start the registration process with MOH preferably before, but not later than 5 days after, signing a conditional contract for the supply of product(s). Failure to obtain registration and submit the required documents to UNDP will serve, at no claim to UNDP, as a ground for contract termination, liquidating Bid or Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process. The decision to transfer the award or initiate a new ITB will be at the discretion of UNDP.

Summary on the simplified procedure of state registration of medicinal products procured with involvement of the international organizations provided for reference in the Annex 1.

2) KAZAKHSTAN (LOTS #5-6)

By the time of supply, the products must be either registered with the Ministry of Health of the Republic of Kazakhstan confirming their legal use in Kazakhstan or one-time import permit should be obtained in accordance with Order of the Ministry of Health and Social Development of Kazakhstan #668 dd 17.08.2015². "SK-Pharmacy", LLP will submit the documents for obtaining of one-time import permit, however selected company should provide documents required as per above Order upon request. Failure to obtain registration

² https://online.zakon.kz/Document/?doc_id=36645437#pos=0;0

and submit the required documents for obtaining one-time import permit will serve, at no claim to UNDP, as a ground for contract termination, liquidating Bid or Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process. The decision to transfer the award or initiate a new ITB will be at the discretion of UNDP. While indicating delivery dates in the Bid, timelines required for the registration process or process of obtaining one-time import permission should be considered.

UNDP will evaluate offers for both registered and non-registered medicinal products. Non-registered products must meet **quality standards as per OPTION 1 and/or 2 and/or 3 and/or 5 (for Lot #2).**

5. DELIVERY TIMEFRAMES

1) UKRAINE (LOTS #1-4)

Early delivery of medicines to Ukraine is critical therefore we encourage shortest delivery periods. 100% quantities must be delivered within 4 months at the latest after Purchase Order dispatching. The bids with later delivery dates will be disqualified.

Further to the Schedule of Requirements in the preceding Table, Bidders are requested to take note of the following additional requirements, conditions, and related services pertaining to the fulfillment of the requirements:

| | | |
|---|---|---|
| Delivery Term [INCOTERMS 2010] (Pls. link this to price schedule) | DAP Kyiv, Central Warehouse of the MoH The products shall be supplied to the Central Warehouse (State Enterprise) of MoH or designated by them entity appointed by UNDP. Exact location of the warehouse will be notified at the time of contracting. The transfer of ownership right from seller to buyer occurs simultaneously with the transfer of risk of goods loss or damage at the moment when the goods are delivered to the named warehouse. Partial delivery is acceptable: <u>maximum 3 consignments under delivery of one Lot/Item.</u> | |
| Mode of Transport Preferred | <input checked="" type="checkbox"/> AIR | <input checked="" type="checkbox"/> LAND |
| | <input checked="" type="checkbox"/> SEA | <input type="checkbox"/> OTHER [pls. specify] |
| Shipping documents | <ul style="list-style-type: none"> Commercial invoice – 2 originals. Packing list – 1 copy. Manufacturer's Certificate of Analysis for each batch – copies certified with the stamp of the Supplier. Certificate of Origin, if goods are being imported Air Way Bill (air shipments)/Bill of Lading (sea shipments), if goods are being imported | |
| Customs, if needed, clearing shall be done by: | Central Warehouse (State Enterprise) of MoH appointed by UNDP will act as importer of record with the condition that goods are <u>shipped to</u> the aforesaid State Enterprise. | |
| Pre-shipment inspection | A pre-shipment inspection may be carried out by UNDP or its representative for verification of quality, quantity, packing, labelling, marking and sampling. In cases when pre-shipment inspection is required, the corresponding Purchase Order will specify this condition. | |
| Inspection upon delivery | MoH/UNDP will conduction inspection upon delivery. Quality Control may be required upon discretion of UNDP/MoH. | |

| | |
|---------------|---|
| Payment Terms | <p>Within 30 calendar days after delivery subject to written acceptance of goods delivery, duly signed and stamped by UNDP/MoH and provision of original invoice.</p> <p>In case testing is required, satisfactory testing results is a prerequisite for payment release.</p> <p>Progress payments could be provided in case of partial delivery.</p> |
|---------------|---|

2) KAZAKHSTAN (LOTS # 5-6)

Early delivery of medicines to Kazakhstan is critical therefore Bidders are encouraged to propose shortest delivery timeframes. 100% of required volume shall be delivered within 4 months after signing Purchase Order/s. Bidder is obliged to sign Purchase Order/s within 2 weeks after receipt of Purchase Order/s electronically authorized by UNDP. The bids with later delivery dates will be disqualified.

However bidders can offer different pricing for 30% (1st delivery) and 70% (2nd delivery) or 100 % of the quantities for each lot, where 30% of the total volumes for each procured medicine shall be delivered asap in order to avoid treatment interruption, UNDP reserves the right to award the contract to the responsive bidder that is found to be significantly “more superior” in terms of delivery period even if the price is higher than the lowest priced compliant offer so long as the price is not higher than 20%. In order to evaluate the superiority of bids for 30% option in terms of delivery period UNDP will calculate “evaluated bid prices” using the multipliers below. “Evaluated bid prices” will be used only for evaluation purposes. Evaluated bid price will be calculated by multiplying Bidder’s price proposal (Section 8) with the multiplier corresponding to the bidder’s delivery period, as indicated and committed in Price Schedule Form.

| Proposed delivery period (for 30% option only) | Multiplier |
|--|------------|
| 15 days or less | 0.80 |
| 16-20 days | 0.81 |
| 21-25 days | 0.82 |
| 26-30 days | 0.83 |
| 31-35 days | 0.84 |
| 36-40 days | 0.85 |
| 41-45 days | 0.86 |
| 46-50 days | 0.87 |
| 51-55 days | 0.88 |
| 56-60 days | 0.89 |
| 61-65 days | 0.90 |
| 66-70 days | 0.91 |
| 71-75 days | 0.92 |
| 76-80 days | 0.93 |
| 81-85 days | 0.94 |
| 86-90 days | 0.95 |
| 91-95 days | 0.96 |
| 96-100 days | 0.97 |
| 101-105 days | 0.98 |
| 106-110 days | 0.99 |
| 110-120 days | 0.100 |

Example: This example is provided by using hypothetical figures to provide clarity.

Bidder 1 - ACB:

Delivery date: 4 months

Price: \$100

Evaluated bid price: \$100 x 1.00 = \$100

Bidder 2 - XYZ:

Delivery date: 1 month

Price: \$110

Evaluated bid price: \$110 x 0.83 = \$91.30

In such case, UNDP may consider awarding contract to Bidder 2 for the 30% option even if the price offered by Bidder 2 is higher than that of Bidder 1.

Based on the urgency for the specific product(s) and to ensure best value for money, UNDP reserves the right to award the contract in 30% and 70% proportions to the different companies.

In the event the 30% / 70 % options cannot be sourced, the contract will be awarded to a bidder quoting for 100% of quantities.

Further to the Schedule of Requirements in the preceding Table, Bidders are requested to take note of the following additional requirements, conditions, and related services pertaining to the fulfilment of the requirements:

| | | |
|---|---|---|
| Delivery Term [INCOTERMS 2010] (Pls. link this to price schedule) | For international supplies: DAP, Kazakhstan, Almaty, International Airport of Almaty For local supplies: DAP, Kazakhstan, Almaty, warehouse of "SK-Pharmacy", LLP Partial delivery is acceptable: <u>maximum 3 consignments under delivery of one Lot/Item.</u> | |
| Mode of Transport Preferred | <input checked="" type="checkbox"/> AIR | <input checked="" type="checkbox"/> LAND |
| | <input type="checkbox"/> SEA | <input type="checkbox"/> OTHER [pls. specify] |
| Shipping documents | <ul style="list-style-type: none"> • Commercial invoice – 2 originals. • Packing list – 2 originals. • Manufacturer's Certificate of Analysis for each batch – copies certified with the stamp of the Supplier. • Certificate of Origin, if goods are being imported – 1 original. • Air Way Bill (air shipments)/Bill of Lading (sea shipments), if goods are being imported – 1 original | |
| Customs, if needed, clearing shall be done by: | "SK-Pharmacy" Limited Liability Partnership | |

| | |
|--------------------------|---|
| Pre-shipment inspection | A pre-shipment inspection may be carried out by UNDP or its representative for verification of quality, quantity, packing, labelling, marking and sampling. In cases when pre-shipment inspection is required, the corresponding Purchase Order will specify this condition. |
| Inspection upon delivery | UNDP and "SK-Pharmacy" Limited Liability Partnership will conduct inspection upon delivery. Quality Control may be required upon discretion of UNDP and "SK-Pharmacy" Limited Liability Partnership. |
| Payment Terms | Within 30 calendar days after delivery subject to written acceptance of goods delivery, duly signed and stamped by UNDP and "SK-Pharmacy", LLP and provision of original invoice. In case testing is required, satisfactory testing results is a prerequisite for payment release. Progress payments could be provided in case of partial delivery. |

6. SHELF LIFE

1) UKRAINE (LOTS #1-4)

Products must have a minimum of 75% of the total product shelf life or should have 15 months' shelf life remaining at the time of delivery and must bear the dates of manufacture and expiry. Shelf life shall be indicated for all products quoted in the offer submitted.

Products must not have been subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect fully comply in all aspects with the Technical Specifications and with the conditions laid down in the Contract.

2) KAZAKHSTAN (LOTS #5-6)

Products must have a minimum of 50% of the total product shelf life if total shelf is below 24 months or should have 12 months' remaining shelf life if total shelf life is equal or above 24 months at the time of delivery and must bear the dates of manufacture and expiry. Shelf life shall be indicated for all products quoted in the offer submitted.

Products must not have been subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect fully comply in all aspects with the Technical Specifications and with the conditions laid down in the Contract.

7. PACKAGING, LABELLING, DELIVERY

1) Upon receipt of an incoming batch, UNDP follow a thorough quality control procedure, which includes review of Certificates of Analysis (CoA) for each batch of finished product to be supplied, inspection against UNDP specifications, labelling and packaging.

2) Pharmaceuticals shall be transported and stored in accordance with the temperature mode specified in the product instruction. All temperature restricted commodities must be shipped with clear marking the corresponding temperature conditions. It is the responsibility of the Bidder to provide complete packing as

required for transportation. Bidders shall explain their capabilities and experience to handle temperature control items where applicable.

3) The individual packages shall be packed in carton boxes. Each carton shall contain only one product and one batch. Packing must be sufficiently strong to withstand rough handling and exposure to extreme temperatures and air moisture. All temperature restricted commodities shall be shipped with a minimum number of data loggers as specified below.

Minimum requirements for dataloggers / for PURCHASE ORDERS:

Shipments of temperature sensitive health products, most particularly medicines and diagnostic products, should be accompanied by dataloggers.

The number of dataloggers should be 1 if shipment has 5 or less boxes, 2 if shipment has more than 5 boxes. If products are shipped in containers, each container should have 2 dataloggers.

Dataloggers should be activated, set up with adequate alarm levels and placed inside a box with the products. The boxes with dataloggers should be clearly identified with bright color stickers (ideally orange).

The minimum technical requirements for dataloggers are as follows:

- Measures temperature (from -30° to 70°c, with accuracy +/- 0.3°c).
- Readings to include time and date
- Single or multiple use
- Direct USB interface, without need for additional cable
- Automatically creates PDF report when connected to computer.
- Rapid data download to graph
- Alarm levels set up before shipping according to manufacturer's storage requirements
- LCD featuring up to 1 decimal point readings
- Alarm indication on LCD screen
- Sampling rate: at least 1 measure per hour
- Push button to activate and stop logging.
- Easy to understand user's guide & instructions

All cases should be marked with/prominently indicate the following:

- A. Shipping marks;
- B. The generic name of the product;
- C. The dosage form (tablet, ampoule, syrup);
- D. Strength/ concentration of the product;
- E. Number of registration certificate
- F. Date of manufacture and expiry (in clear language not code);
- G. Batch number;
- H. Quantity per case;
- I. Special instructions for storage;
- J. Name of manufacturer;
- K. Carton numbering e.g. carton 1/40;
- L. Any additional cautionary statements.

4) Labelling of primary package at the moment of supply must correspond to the one in the product's state registration record (for Lots #1-4: State Register of Medicines in Ukraine, for Lots #5-6: the product's state registration record in Kazakhstan if product is registered). In case of any deviations found, the supplier must provide additional documentation to enable receipt of goods.

5) Primary packaging must preserve quality, safety and stability of the product it contains. The entire package must be duly sealed and protected from spoiling.

- **UKRAINE (LOTS #1-4):**

Each package shall contain instructions for the use of the medicinal product in Ukrainian (preferably) or the original language.

In case medicines are delivered in original packaging with instructions for the use in the original language, Ukrainian translation of instruction for the use shall be provided in the paper format at the time of supply.

Ukrainian translation of instruction shall correspond to one published in the product's state registration record (State Register of Medicines in Ukraine).

In case product is not registered, Ukrainian instruction submitted for registration purposes shall correspond to one approved by SRA authorities (e.i. prescription and indication for the use).

- **KAZAKHSTAN (LOTS #5-6):**

Each package shall contain instructions for the use of the medicinal product in Russian and Kazakh (preferably) or in original language.

In case medicines are delivered in original packaging with instructions for the use in the original language, Russian and Kazakh translation of instruction for the use shall be provided in the electronic format at the time of supply and marking by stickers in Russian and Kazakh might be required.

6) UNDP reserves the right to have at any time the items inspected, tested for quality assurance and rejected if found not in compliance with the requested specifications.

Information about relevant medicines stability studies must be available upon request. UNDP reserve the right to verify conformity of Certificate of Analysis of medicine product to the Drug Master File or a Certificate of Conformity with the European Pharmacopoeia.

7) Pre-shipment inspection

When all the goods from a specific purchase order are ready for shipment with their final packing and marking, a pre-shipment inspection may be carried out by UNDP or its representative for verification of quality, quantity, packing, labelling, marking and sampling.

In cases when pre-shipment inspection is required, the corresponding Purchase Order will indicate this.

For this purpose, the Supplier will have to submit the applicable documentation to UNDP or its representative and allow UNDP or its representative access to all the goods. At least the packing list showing also the batch numbers per product and the full address of inspection should be made available to UNDP or its representative 7 working days before the pre-shipment inspection is requested to be carried out. Inspection/testing by UNDP or its representative in no way relieves the Supplier from the performance of full contractual obligations to UNDP. The cost of the pre-shipment inspection will be borne by UNDP. However, it is the responsibility of the supplier to assure that all facilities, to carry out a proper inspection are made available at their expense, and

the goods for one shipment are presented at one location and on the date requested by UNDP or its representative. Furthermore, UNDP or its representative will charge the Supplier for the repeat, supplementary or abortive inspection visits necessitated by the fault of the supplier. UNDP or its representatives may inspect the production premises and the process of the manufacture to make sure they meet Good Manufacturing Practices (GMP).

In case of the detection of a defective product either in the quality of a product or other defects such as packaging, the Supplier will be requested to replace the complete batch at its own cost within one (1) month. In the event of a dispute by the Supplier, a counter analysis will be carried out by an independent neutral laboratory agreed by both UNDP and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective batch. In the event of the independent analysis confirming the quality of the product, UNDP will meet all costs for such analysis.

8) Stipulations concerning Supplier responsibility for Quality, Packaging and Warranty

- a) UNDP shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Purchase Order. Upon receipt of a written notice from UNDP, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to Purchaser at the final location. The Supplier will be required to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered. If the defective Goods are not removed within 30 days, UNDP will dispose on the Supplier's costs.
- b) The Supplier's responsibility for labelling and quantities of goods for every Purchase Order extends to the point at which the goods are inspected by UNDP or its representative and, if required, a Clean Report of Findings (CRF) is issued by UNDP or its representative, upon delivery, for the specific PO. Where discrepancies are found by UNDP or its representative in labelling and/or quantities, these shall be rectified promptly by the Supplier at its own cost.
- c) The Supplier is responsible for the intrinsic quality of the finished dosage form of each product and for the intrinsic quality of the primary packaging of the product, prior to and after the CRF is issued. The Supplier's responsibility will be according to the Incoterms 2010 standards specified in the PO.

9) Stipulations concerning Recalls: In the event any of the Goods are recalled either by the National Regulatory Authority (NRA) of the country of production, the NRA of the recipient country or the Manufacturer, after the CRF related to the PO(s) covering the same Goods is issued, the Supplier shall notify UNDP within fourteen (14) days, providing full details of the reason for the recall and replace affected goods within one (1) month, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specifications and original PO(s) against which they were supplied, and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfil its recall obligation promptly, UNDP will, at the Supplier's expense, carry out the recall.

10) Quality Assurance

Prior to shipment or upon arrival at the destination, some batches of the product may be tested (randomly) to ensure that the products meet Quality Assurance according to agreed contractual standards and requirements. Such tests might include, using an independent laboratory as service provider and or in-house quality checks and any consignment or batch(es) of goods not meeting the above mentioned standards would be rejected.

SECTION 4

Criteria for award and checklist of documents required

Following documents should be attached to the filled-in sections #4-8

Please ensure that all documents necessary to enable objective evaluation are attached to your response to this ITB:

| Award Criteria | Corresponding document | Yes | No | Reference |
|--|--|-----|----|-----------|
| Compliance of Bidder with Qualifications Requirements | | | | |
| Minimum 3 years of experience in similar nature and minimum 2 similar contracts fulfilled over the past 3 years | 1. Certificate of Registration of the business, including Articles of Incorporation, or equivalent document if Bidder is not a corporation | | | |
| | 2. Statement of Satisfactory Performance (Reference letters) from the Top 3 Clients in terms of Contract Value the past 3 years. Please provide reference letters to prove experience in similar nature of contracts | | | |
| Minimum annual turnover over the past 2 years shall equal to no less than 75% of the total amount to be contracted | 3. Latest Audited Financial Statement (Income Statement and Balance Sheet) including Auditor's Report for the past 2 years | | | |
| Compliance of product/quoted with product standards and requirements (please complete checklist for each product quoted) | | | | |
| <p>The product(s) will be procured on the following options (please refer for details to Section 3, para #2 Product Standards):</p> <p>OPTION 1: A+E A) Approved/registered by a Stringent National Medicines Regulatory Authority (SRA) as defined by WHO AND E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities</p> <p>OR</p> <p>OPTION 2: B+E B) Prequalified by World Health Organization</p> | A) A copy of valid Registration/Approval of Stringent National Medicines Regulatory Authority (SRA) as defined by WHO | | | |
| | B) WHO pre-qualification evidence | | | |
| | C) Approval of the WHO Expert Review Panel for the Global Fund (also known as Global Fund ERP) | | | |
| | D) 1) Filled-in Interagency finished product questionnaire attached as Annex 5 with copies of requested documents, 2) Letter on Acceptance for Assessment for FPP pre-qualification by WHO (if available) and | | | |

| Award Criteria | Corresponding document | Yes | No | Reference |
|--|---|-----|----|-----------|
| <p>AND</p> <p>E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities</p> <p>OPTION 3: C+E</p> <p>C) Recommended by the WHO Expert Review Panel for the Global Fund (also known as Global Fund ERP)</p> <p>AND</p> <p>E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities</p> <p>OPTION 4: D+E (for Lots #2-4 and 6 only)</p> <p>D) Medicine's quality will be found compliant with UNDP internal QA policy against WHO norms and standards for pharmaceutical preparations conducted by UNDP after bid submission</p> <p>AND</p> <p>E) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities</p> | <p>3) list of previous supplies of product/s quoted</p> <p>E) A copy of valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities for the manufacturing site(s) of the proposed product(s)</p> <p>Please provide information manufacturing site, including concrete manufacturing unit/block in the Form 7 Technical Bid Form.</p> | | | |
| <p>FOR LOTS: 1-4 only</p> <p>Availability of valid registration in Ukraine at the time of supply as defined in Section 3, para #3, Registration/Authorization for use in Ukraine (if, at the moment of the bid submission, the quoted medicinal products are not registered in Ukraine but comply with the quality requirements of this ITB, a Commitment letter shall be provided)</p> | <p>Option A: A copy of a valid registration certificate for every medicinal product quoted issued by the Ministry of Health of Ukraine. If a bid is submitted less than 90 days prior to the product's registration expiration date, a letter issued by MoH confirming the application and documents package for renewal by the owner must be provided at the time of the submission as part of the documents package</p> | | | |

| Award Criteria | Corresponding document | Yes | No | Reference |
|--|---|-----|----|-----------|
| | <p>Option B: If, at the moment of the bid submission, the quoted medicinal products are not registered in Ukraine but comply with the quality requirements of this ITB, a Commitment letter (Annex 2) from the bidder acknowledging acceptance of the terms and conditions for undertaking a simplified registration procedure (see Section 3a, para #3 Registration/Authorization for use in Ukraine for details) and confirming the ability to comply with submitting the package of documents for state registration will be required.</p> <p>By submitting the Bid, the Bidder automatically agrees to maintain and renew registration of these products until their shelf life expiration.</p> | | | |
| Compliance with shelf life, packing and labelling requirements (please refer for details to Section 3 of ITB). | Please provide Information on shelf life in the Form 7 Technical Bid Form | | | |
| Acceptability of the Transportation/Delivery Schedule (please refer for details to Section 3 of ITB) | Please provide Information on delivery schedule in the Form 7 Technical Bid Form | | | |

| List of other documents required for evaluation of Offeror | Yes | No | Reference |
|---|-----|----|-----------|
| Company profile (maximum 5 pages) or link to company's web-site | | | |
| List of Shareholders and Other Entities Financially Interested in the Firm owning 5% or more of the stocks and other interests, or its equivalent if Offeror is not a corporation | | | |
| Valid Certificate of Authorization to act on behalf of the Manufacturer in case the Offeror is not a Manufacturer as per template provided in the Annex 3. | | | |
| All information regarding any past and current litigation during the last five (5) years, in which the Offeror is involved, indicating the parties concerned, the subject of the litigation, the amounts involved, and the final resolution if already concluded. | | | |
| Quality Certificate (e.g., ISO, etc.) and/or other similar certificates, accreditations, awards and citations received by the Offeror, if any | | | |

| List of other documents required for evaluation of Offeror | Yes | No | Reference |
|--|-----|----|-----------|
| Environmental Compliance Certificates, Accreditations, Markings/Labels, and other evidences of the Offeror's practices which contributes to the ecological sustainability and reduction of adverse environmental impact (e.g., use of non-toxic substances, recycled raw materials, energy-efficient equipment, reduced carbon emission, etc.), either in its business practices or in the goods it manufactures, if any available | | | |

| List of other documents required for evaluation of product quoted (please complete checklist for each product quoted) | Yes | No | Reference |
|---|-----|----|-----------|
| Instruction for the medical use in accordance with the legislation of Ukraine (lots #1-4), Kazakhstan (lots #5-6). In case quoted medicines are not registered, instructions for the use in the original language shall be provided (which is compliant with one accompanied to SRA approval/registration). | | | |
| A copy of the Certificate of Pharmaceutical Product (COPP) from the national regulatory body in the country of manufacture for each product shall be provided. If available WHO type COPPs for products being imported into the countries within WHO certification Scheme are requested to be provided. | | | |
| The Bidder which applies with the patented product shall inform UNDP and provide respective patent certificate/s. The Bidder which have relevant license/s (for example, voluntary license/s) shall provide them. | | | |
| Every patent case will be assessed by UNDP separately and decision will be made upon additional verification and analysis of existing patent/s and local legislation. | | | |

BRIEF SUMMARY (FOR LOTS #1-4)

1. On the simplified procedure of state registration of medicinal products procured with involvement of the international organizations

The procedure of state registration (re-registration) of medicinal products was approved by the Cabinet of Ministers of Ukraine Resolution No. 376 of 26.05.2005.

State registration of the medicinal products procured by international organizations is provided by the Ministry of Health of Ukraine pursuant to an application and subject to an opinion of the MoH State Expert Centre (hereinafter referred to as the Centre) drawn up on the basis of results of the expert examination of the registration materials for their authenticity, conducted according to the procedure specified by the MoH of Ukraine.

Information on the procedures for state registration may be found under the below links:

1. Law of Ukraine "On Medicines"

<http://zakon2.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80>

2. Decree of the Cabinet of Ministers of Ukraine dated 26.05.2005 № 376

<http://zakon5.rada.gov.ua/laws/show/376-2005-%D0%BF>

3. Decree of MOH of Ukraine dated 03.11.2015 № 721

<http://zakon2.rada.gov.ua/laws/show/z1453-15>

2. On additional relevant information on VAT for bidders. This information is provided for references only and UNDP should not be hold accountable for any details. Bidders are encouraged to check the details with relevant authorities directly.

Operations on supply (transfer) of pharmaceuticals and medical products shall be temporarily, until March 31, 2019, exempt from VAT, if importation and/or supply is done under contracts with specialized procurement organizations listed in the Law of Ukraine 'On Public Procurement', concluded with the objective of implementing agreements between the central executive body of Ukraine in charge of developing and implementing the national health policy and a relevant specialized procurement organization within the framework of budget programmes for implementation of public health action plans and/or comprehensive programme activities in the health sector.

Provided VAT exemption condition may not be applied under the Ukrainian legislation. VAT amount should be clearly indicated in a separate line (if applicable).

For more information on VAT exemption, please refer to the following legislation documents:

1. Tax Code of Ukraine, Chapter #XX Transitional Provisions, Section #2; Paragraph #38 on conditions of temporary VAT exemption of medicines that are procured by specialized organizations for the National Public Health Programme to the Ministry of Health (MoH) in Ukraine:

<http://zakon2.rada.gov.ua/laws/show/2755-17/page45>

2. Decree of the Cabinet of Ministers of Ukraine #1153 dated 02.12.2015 on the procedures of importation, supply and targeted use of medicines, medical devices that are VAT exempted:

<http://zakon3.rada.gov.ua/laws/show/1153-2015-%D0%BF>

Prices specified shall remain firm and not be increased. In case Offeror increase price after awarding contract, UNDP will consider this as a ground for contract termination, liquidating Bid or Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process.

Commitment letter (FOR LOTS #1-4)

(This should be written in the Letterhead of the Bidder. Except for indicated fields, no changes may be made in this template.)

Insert: Location

Insert: Date

To: *[insert: Name and Address of UNDP focal point]*

Dear Sir/Madam:

We, the undersigned, hereby offer to supply the goods required for *[insert: title of goods and services required as per ITB]* in accordance with your Invitation to Bid dated .

We hereby commit to register the below listed products with Ukrainian registration authorities as the current legislation requires.

Products:

1. _____
2. _____
3.

We fully understand and recognize that UNDP is not bound to accept this Bid, that we shall bear all costs associated with its preparation and submission, registration fees and that UNDP will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the evaluation.

We remain,

Yours sincerely,

Authorized Signature *[In full and initials]*: _____

Name and Title of Signatory: _____

Name of Firm: _____

Contact Details: _____

[please mark this letter with your corporate seal, if available]

Certificate of Authorization
to act on behalf of the Manufacturer in case the Bidder is not a Manufacturer

(This should be written in the Letterhead of the Manufacturer. Certificate shall cover all items for which the company is bidding)

Insert: Location
Insert: Date

To: [insert: Name and Address of UNDP focal point]

Dear Sir/Madam:

We, the undersigned, who is established manufacturer or producer of [insert name of products], hereby authorize [name and address of Bidder] to submit a Bid, and subsequently sign and implement the contract, against the [insert: title of goods and services required as per ITB] for the supply of following products:

Products:

- 1. _____
- 2. _____
- 3.

For and on behalf of Manufacturer or Producer:

Yours sincerely,
Authorized Signature [In full and initials]: _____
Name and Title of Signatory: _____
Name of Firm: _____

Contact Details: _____

Section 5

Bid Submission Form

(This should be written in the Letterhead of the Bidder. Except for indicated fields, no changes may be made in this template.)

Insert: Location

Insert: Date

To: [insert: Name and Address of UNDP focal point]

Dear Sir/Madam:

We, the undersigned, hereby offer to supply the goods and related services required for [insert: title of goods and services required as per ITB] in accordance with your Invitation to Bid dated . We are hereby submitting our Bid, which includes the Technical Bid and Price Schedule.

We hereby declare that:

- a) All the information and statements made in this Bid are true and we accept that any misrepresentation contained in it may lead to our disqualification;
- b) We are currently not on the removed or suspended vendor list of the UN or other such lists of other UN agencies, nor are we associated with, any company or individual appearing on the 1267/1989 list of the UN Security Council;
- c) We have no outstanding bankruptcy or pending litigation or any legal action that could impair our operation as a going concern; and
- d) We do not employ, nor anticipate employing, any person who is or was recently employed by the UN or UNDP.

We confirm that we have read, understood and hereby fully accept the Schedule of Requirements and Technical Specifications describing the duties and responsibilities required of us in this ITB, and the General Terms and Conditions of UNDP's Standard Contract for this ITB.

We agree to abide by this Bid for **120 days**.

We undertake, if our Bid is accepted, to initiate the supply of goods and provision of related services not later than the date indicated in the Data Sheet.

We fully understand and recognize that UNDP is not bound to accept this Bid, that we shall bear all costs associated with its preparation and submission, and that UNDP will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the evaluation.

We remain,

Yours sincerely,

Authorized Signature [In full and initials]: _____

Name and Title of Signatory: _____

Name of Firm: _____

Contact Details: _____

[please mark this letter with your corporate seal, if available]

Section 6

Documents Establishing the Eligibility and Qualifications of the Bidder

Bidder Information Form

Date: *[insert date (as day, month and year) of Bid Submission]*

ITB No.: *[insert number of bidding process]*

Page _____ of _____ pages

| | | |
|--|---------------------------------|---------------------------------------|
| 1. Bidder's Legal Name <i>[insert Bidder's legal name]</i> | | |
| 2. In case of Joint Venture (JV), legal name of each party: <i>[insert legal name of each party in JV]</i> | | |
| 3. Actual or intended Country/ies of Registration/Operation: <i>[insert actual or intended Country of Registration]</i> | | |
| 4. Year of Registration in its Location: <i>[insert Bidder's year of registration]</i> | | |
| 5. Countries of Operation | 6. No. of staff in each Country | 7. Years of Operation in each Country |
| 8. Legal Address/es in Country/ies of Registration/Operation: <i>[insert Bidder's legal address in country of registration]</i> | | |
| 9. Value and Description of Top three (3) Biggest Contract for the past five (5) years | | |
| 10. Latest Credit Rating (Score and Source, if any) | | |
| 11. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved. | | |
| 12. Bidder's Authorized Representative Information Name: <i>[insert Authorized Representative's name]</i> Address: <i>[insert Authorized Representative's Address]</i> Telephone/Fax numbers: <i>[insert Authorized Representative's telephone/fax numbers]</i> Email Address: <i>[insert Authorized Representative's email address]</i> | | |
| 13. Are you in the UNPD List 1267.1989 or UN Ineligibility List ? <input type="checkbox"/> YES or <input type="checkbox"/> NO | | |
| 14. Attached are copies of original documents of: <input type="checkbox"/> All eligibility document requirements listed in the Data Sheet <input type="checkbox"/> If Joint Venture/Consortium – copy of the Memorandum of Understanding/Agreement or Letter of Intent to form a JV/Consortium, or Registration of JV/Consortium, if registered <input type="checkbox"/> If case of Government corporation or Government-owned/controlled entity, documents establishing legal and financial autonomy and compliance with commercial law. | | |

Joint Venture Partner Information Form (if Registered)

Date: *[insert date (as day, month and year) of Bid Submission]*

ITB No.: *[insert number of bidding process]*

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| | | |
|--|---------------------------------|---------------------------------------|
| 1. Bidder's Legal Name: <i>[insert Bidder's legal name]</i> | | |
| 2. JV's Party legal name: <i>[insert JV's Party legal name]</i> | | |
| 3. JV's Party Country of Registration: <i>[insert JV's Party country of registration]</i> | | |
| 4. Year of Registration: <i>[insert Party's year of registration]</i> | | |
| 5. Countries of Operation | 6. No. of staff in each Country | 7. Years of Operation in each Country |
| 8. Legal Address/es in Country/ies of Registration/Operation: <i>[insert Party's legal address in country of registration]</i> | | |
| 9. Value and Description of Top three (3) Biggest Contract for the past five (5) years | | |
| 10. Latest Credit Rating (if any) : Click here to enter text. | | |
| 1. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved. Click here to enter text. | | |
| 13. JV's Party Authorized Representative Information Name: <i>[insert name of JV's Party authorized representative]</i> Address: <i>[insert address of JV's Party authorized representative]</i> Telephone/Fax numbers: <i>[insert telephone/fax numbers of JV's Party authorized representative]</i> Email Address: <i>[insert email address of JV's Party authorized representative]</i> | | |
| 14. Attached are copies of original documents of: <i>[check the box(es) of the attached original documents]</i> <input type="checkbox"/> All eligibility document requirements listed in the Data Sheet <input type="checkbox"/> Articles of Incorporation or Registration of firm named in 2. <input type="checkbox"/> In case of government owned entity, documents establishing legal and financial autonomy and compliance with commercial law. | | |

Section 7

Technical Bid Form

INSERT TITLE OF THE ITB

| | |
|---|--|
| Name of Bidding Organization / Firm: | |
| Country of Registration: | |
| Name of Contact Person for this Bid: | |
| Address: | |
| Phone / Fax: | |
| Email: | |

SUBSECTION 3.1: EXPERTISE OF FIRM/ ORGANISATION

This section should fully explain the Bidder's resources in terms of personnel and facilities necessary for the performance of this requirement.

1.1 Brief Description of Bidder as an Entity: Provide a brief description of the organization / firm submitting the Bid, its legal mandates/authorized business activities, the year and country of incorporation, and approximate annual budget, etc. Include reference to reputation, or any history of litigation and arbitration in which the organization / firm has been involved that could adversely affect or impact the delivery of goods and/or performance of related services, indicating the status/result of such litigation/arbitration.

1.2. Financial Capacity: Based on the latest Audited Financial Statement (Income Statement and Balance Sheet) describe the financial capacity (liquidity, stand-by credit lines, etc.) of the bidder to engage into the contract. Include any indication of credit rating, industry rating, etc.

1.3. Track Record and Experiences: Provide the following information regarding corporate experience within at least the last five (5) years which are related or relevant to those required for this Contract.

| Name of project | Client | Contract Value | Period of activity | Types of activities undertaken | Status or Date Completed | References Contact Details (Name, Phone, Email) |
|-----------------|--------|----------------|--------------------|--------------------------------|--------------------------|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

SUBSECTION 3.2 - SCOPE OF SUPPLY, TECHNICAL SPECIFICATIONS, AND RELATED SERVICES

This section should demonstrate the Bidder's responsiveness to the specification by identifying the specific components proposed, addressing the requirements, as specified, point by point; providing a detailed description of the essential performance characteristics proposed; and demonstrating how the proposed bid meets or exceeds the specifications.

2.1. Scope of Supply: Please provide a detailed description of the goods to be supplied, indicating clearly how they comply with the technical specifications required by the ITB (**please see Annex 4 – Annex 4 shall be provided both in excel and PDF format**); describe how the organization/firm will supply the goods and any related services, keeping in mind the appropriateness to local conditions and project environment.

2.1.1 Please describe the Freight Forwarder details and Arrangements. Ability to provide/coordinate necessary shipping services, including air, sea and cold chain delivery (if required)

2.1.2 Please provide the detailed Implementation Schedule.

Delivery lead time is a factor of a crucial importance in this project. Please make all possible efforts to propose supply of all requested quantities within shortest timeframe possible. In case partial delivery is proposed, please provide suggested time schedule.

A supporting document with full details may be annexed to this section.

2.2. Technical Quality Assurance Mechanisms: The bid shall also include details of the Bidder's internal technical and quality assurance review mechanisms, all the appropriate quality certificates, export licenses and other documents attesting to the superiority of the quality of the goods to be supplied as requested by Section 4

2.3 Statement of Full Disclosure: This is intended to disclose any potential conflict in accordance with the definition of "conflict" under Section 5 of this document, if any.

2.4 Other: Any other comments or information regarding the bid and its implementation.

SUBSECTION 3.3: PERSONNEL

3.1 Management Structure: Describe the overall management approach toward planning and implementing the contract. Include an organization chart for the management of the contract, if awarded.

3.2 Staff Time Allocation: Provide a spreadsheet will be included to show the activities of each personnel involved in the implementation of the contract. Where the expertise of the personnel is critical to the success of the contract, UNDP will not allow substitution of personnel whose qualifications had been reviewed and accepted during the bid evaluation. (If substitution of such a personnel is unavoidable, substitution or replacement will be subject to the approval of UNDP. No increase in costs will be considered as a result of any substitution).

3.3 Qualifications of Key Personnel. Provide the CVs for key personnel (Team Leader) that will be provided to support the implementation of this project. CVs should demonstrate qualifications in area of expertise relevant to the Contract. Please use the format below:

| | | |
|---|--|--|
| Name: | | |
| Role in Contract Implementation: | | |
| Nationality: | | |
| Contact information: | | |
| Countries of Relevant Work Experience: | | |
| Language Skills: | | |
| Education and other Qualifications: | | |
| Summary of Experience: <i>Highlight experience in the region and on similar projects.</i> | | |
| Relevant Experience (From most recent): | | |
| Period: From – To | Name of activity/ Project/ funding organization, if applicable: | Job Title and Activities undertaken/Description of actual role performed: |
| <i>e.g. June 2010-January 2011</i> | | |
| <i>Etc.</i> | | |
| <i>Etc.</i> | | |
| References (minimum of 3): | <i>Name</i> <i>Designation</i> <i>Organization</i> <i>Contact Information – Address; Phone; Email; etc.</i> | |
| Declaration: | | |
| <p>I confirm my intention to serve in the stated position and present availability to serve for the term of the proposed contract. I also understand that any willful misstatement described above may lead to my disqualification, before or during my engagement.</p> <p>_____</p> <p>_____</p> | | |
| Signature of the Nominated Team Leader/Member | | Date Signed |

INTER-AGENCY FINISHED PHARMACEUTICAL PRODUCT QUESTIONNAIRE
BASED ON THE MODEL QUALITY ASSURANCE SYSTEM
FOR PROCUREMENT AGENCIES

SECTION 1: ADMINISTRATIVE SECTION

1.1 Product identification

1.1.1 Active pharmaceutical ingredient(s) (use INN if any): _____

1.1.2 Generic name of the product: _____

1.1.3 Trade (proprietary) name (if any): _____

1.1.4 Dosage form:

☐ Tablets ☐ Capsules ☐ Injectable ☐ Syrups/oral liquids

☐ Other: *(Please specify)*

1.1.5 Strength per dosage unit: _____

1.1.6 Route of administration:

☐ Oral ☐ I.M. ☐ I.V. ☐ S.C. ☐ Other

(Please specify)

1.1.7 Please provide the formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients). Please also indicate the standard for each ingredient (e.g. BP, USP, in-house). Mention specifically if the product is a fixed-dose combination (FDC) or co-packaged (Annex A)

1.1.8 Please state inactive ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage

form or per dosage unit (e.g. contains alcohol 10%, paraben.....)

1.2 Packaging

1.2.1 Description and materials used for primary packaging³ and pack size (quantity of dosage-form units per pack): Annex B

1.2.2 Description and materials used for secondary packaging materials and pack size: Annex C

CONTACT DETAILS

1.3 Manufacturer identification

Name, address and activities of the manufacturer and manufacturing site(s) (or contract manufacturer(s):

| Name of manufacturer, contract manufacturer if any | Reference of manufacturing license, date and expiry date, if any | Physical address. Please specify units, block if existing | Telephone number, facsimile number and email contact details | Activity (e.g. packaging) |
|--|--|---|--|---------------------------|
| | | | | |
| | | | | |
| | | | | |

1.4 Supplier identification

(to be filled in if not identical to that indicated in 1.3)

Name of company:_____

Physical address (complete details required):_____

Telephone number:_____

³ For example, HDPE bottle, Alu-Alu strip, neutral glass vial.

Fax: _____

Website: _____

Email: _____

Link with the product

☐ Marketing license holder

☐ Distributor/wholesaler

☐ Manufacturer

☐ Other

1.5 Note for the applicant

Please note that the information in this questionnaire can be shared confidentially among ICRC, MSF, WHO, UNFPA and UNICEF for procurement purposes. If you have any objection, please indicate to the relevant agency that you are dealing with.

Has the dossier been submitted to any of the following agencies (ERP, ICRC, MSF, The Union, WHO procurement center, UNICEF)?

Please provide the date of the submission: _____

1.6 Regulatory (Licensing) status

1.6.1 In the country of manufacture

☐ Product registered and currently marketed – License no.:

Provide a copy in Annex D

☐ Product registered for marketing in the country of manufacturing but not currently marketed – License no.:

☐ Product registered for export only – License no.:

☐ Product not registered (*please clarify*):

➤ Please attach a certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863 in Annex E. An earlier version is not acceptable).

- If a CPP cannot be obtained from the national drug regulatory authority (NDRA), please state the reason and send equivalent document if any.
- Submit recent as well as historical deficiency/acceptance letters issued by the WHO Prequalification Programme (PQP)/SRA in relation to the specific product dossier in Annex F.

1.6.2 In other countries

List other countries where the product is registered and is currently marketed (*please provide registration number*)

1.6.3 WHO prequalification status, if applicable

This product is prequalified by WHO/PQP.⁴

☐ Yes ☐ No

If yes, please attach a copy of the relevant WHO/PQP acceptance letter signed by your company (Annex G)

1.6.4 Submitted for prequalification: indicate date of submission, WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product (Annex H)

1.7 Samples for technical evaluation

1.7.1 Samples of insert information

Please relevant inserts/leaflets. ((Annex I)

1.7.2 Label language (attach a copy): primary packaging

☐ Trilingual English/French/Spanish ☐ Bilingual English/French

☐ English ☐ French ☐ Other (specify)

1.7.3 Label language (attach a copy): secondary packaging

☐ Trilingual English/French/Spanish ☐ Bilingual English/French

☐ English ☐ French ☐ Other (specify)

For oral powder for suspension and powder for injection, in-use periods and storage conditions after reconstitution should be stated on the product label

⁴ WHO Prequalification website link: <http://apps.who.int/prequal/>.

1.7.4 Patient information leaflet (Annex J)

☐ Yes (attach a copy) ☐ No

SECTION 2. ACTIVE PHARMACEUTICAL INGREDIENTS

(In case of more than one active ingredient or more than one manufacturer is used, please replicate this section)

2.1 Details of API used (INN if any):

2.1.1 Manufacturer

Manufacturer (name, physical address + country)/manufacturing site (please list all alternative sources):

GMP certificate from the country of origin: attach a copy of the GMP certificate if available in Annex K

Last inspection of API manufacturing sites performed when available
(please attach GMP certificate or relevant letter) by:

- ☐ Finished product manufacturer
- ☐ WHO Prequalification Programme, Geneva
- ☐ EDQM
- ☐ US FDA
- ☐ PIC/S members
- ☐ Others (specify)
- ☐ None of above

Outcomes and date: _____

Is the API used to manufacture this product is/are WHO-prequalified?

☐ Yes ☐ No

2.1.2 API specifications

API specifications from the FPP manufacturer:

- ☐ BP (EDITION/YEAR):
- ☐ USP (EDITION/YEAR):
- ☐ THE INTERNATIONAL PHARMACOPOEIA (PH.INT.) (EDITION/YEAR)
- ☐ OTHERS (SPECIFY):
- ☐ SPECIFICATIONS ADDITIONAL TO THOSE IN THE PHARMACOPOEIA REFERRED TO ABOVE IF AVAILABLE.

Attach a copy of the FPP manufacturer internal API(s) specifications in Annex L

- If analytical methods are in-house, different from BP, USP and Ph.Int., attach a copy of the analytical method and analytical validation data from the FPP manufacturer in Annex M
- Please provide a copy of the certificate of analysis of the API from API manufacturer and FPP manufacturer (Annex N)

For sterile API,

Please provide the data on validation of the sterile aspects of the product including recent media fill validation data as applicable in Annex O

Describe the method of sterilization used when applicable

2.1.3 Certificate of analysis

Please provide a copy of the certificate of analysis of the API from the API manufacturer as well as from the finished pharmaceutical product (FPP) manufacturer in Annex N

2.1.4 Suitability of monograph for API

Are you in a possession of the following information for APIs?

Certificate of suitability to the European Pharmacopoeia (CEP): please attach a copy of the CEP and its annexes (Annex P)

Certificate No.: _____

Open part of drug master file (DMF) registered in (country):

Technical file (please attach Annex Q):

☐ Yes ☐ No

SECTION 3: FINISHED PRODUCT

3.1 Manufacturing site GMP status

GMP inspections carried out by a NDRA

| | NRA of country of origin | Any other inspection of PIC/s member | |
|---------------------|--------------------------|--------------------------------------|--|
| GMP certificate no. | | | |
| Valid until | | | |
| Country | | | |

Please attach the recent/valid GMP certificates/letter (Annex R)

Other GMP inspections carried out by (complete the table below):

| Agency | Date of audit | Outcome |
|--------------------------------|---------------|---------|
| WHO Prequalification Programme | | |
| UNICEF Supply Division | | |
| MSF International | | |
| ICRC | | |
| UNFPA | | |
| Other (specify) | | |

3.2 Finished product specification

| Standard | Edition | Year published |
|---|-----------------|----------------|
| BP | | |
| USP | | |
| Ph.Int. | | |
| In-house | Year documented | |
| Specifications additional to those in the pharmacopoeia referred to above (e.g. dissolution, syringeability): explain | | |
| Other (specify) | | |

If analytical methods are in-house specifications, different from BP, USP and Ph.Int., attach a copy of the in-house finished product specifications and analytical validation data in the Annex S.”

- Please attach a copy of the certificate of analysis for the three last batches released in Annex T

3.3 Method of manufacture and Process validation:

- Have the manufacturing methods for each standard batch size been validated?

☐ Yes

☐ No

If no, please clarify: _____

If yes, please provide details of validation status in the table below:

| | |
|---|--|
| The batch size of the validated batches | |
| The batch numbers of the validated batches | |
| Manufacturing dates of the validated batches | |
| Reference number for the process validation report | |
| If processes are yet to be validated then reference number for the process validation protocol should be indicated. | |

Provide batch formulae for all proposed batch sizes:

- Please provide in Annex U a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

Additional information for sterile products:

Provide the data on validation of the sterile aspects of the product including recent media fill validation data as applicable in Annex V

Describe the method of sterilization used when applicable

3.4 Stability of finished product

3.4.1 Is stability testing data available?

☐ Yes

☐ No

Please provide the protocol and the report for accelerated and long-term stability testing, including: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of batches involved in the study (minimum three); batch sizes for each lot tested; date of beginning of the study; and study conclusions. (These can be provided in Annex W.)

3.4.2 Was the stability testing done on a product of the same formula, same API source, manufactured on the same site and packed in the same packaging material as the product that will be supplied?

☐ Yes ☐ No

If no, describe the differences: _____

3.4.3 Please specify whether stability studies have been done or are ongoing with all declared API sources

☐ Yes ☐ No

Submit a declaration in Annex X that stability studies have been done or are being done with all declared API sources

If no, explain why: _____

3.4.4 Do you have on going stability data for this product?

☐ Yes ☐ No

Attach status report of any ongoing stability studies in Annex Y

3.4.5 Shelf-life as it appears on packaging

☐ 2 years ☐ 3 years ☐ 4 years ☐ 5 years

Other: (specify)

3.4.6 Specific storage conditions for this product as they appear on the packaging and based on stability studies (e.g. «Do not store above 30 °C – Protect from light»):

| | |
|-----------------|--|
| Temperature | |
| Light | |
| Humidity | |
| Other (specify) | |

3.4.7 Product suitable for use in:

- ☐ Zone I
- ☐ Zone II
- ☐ Zone III
- ☐ Zone IVa
- ☐ Zone IVb
- ☐ Other (specify):

3.4.8 For oral powder for suspension and powder for injection, or injection that may further diluted, or multi dose containers provide in-use stability data and storage condition after reconstitution and /or dilution in Annex Z

Indicate the period until which the product is stable after reconstitution and/or dilution based on the available in-use stability data:

SECTION 4: SAFETY/EFFICACY AND OR THERAPEUTIC EQUIVALENCE

(WHO TECHNICAL REPORT SERIES, NO. 902 ANNEX 11/ TRS 937, ANNEX 7 OR LATER)

4.1 For innovator products

Please attach a summary of pharmacology, toxicology and efficacy of the product

4.2 For generic products: THERAPEUTIC EQUIVALENCE

- ☐ Demonstrated
- ☐ Not demonstrated
- ☐ Not relevant, please explain why: _____
- _____

If demonstrated,

4.2.1 By in vivo bioequivalence studies

Study period (dd/mm/yyyy): from to

Reference product

| | |
|-------------------|--|
| Generic name: | |
| Dosage form: | |
| Strength: | |
| Brand/trade name: | |
| Manufacturer: | |
| Manufacture site: | |
| Batch number: | |
| Expiry date: | |

Study protocol

| | |
|--|--|
| Contract research organization (CRO) name: | |
| Country of study: | |
| Number of volunteers: | |
| Study design (describe in detail): | |

| | |
|-----------------------------|--|
| Bio batch size: | |
| Bio batch number: | |
| Bio batch API(s) source(s): | |
| Study conclusion: | |

Study results

Study conclusion:

4.2.2. By comparative in vitro dissolution tests according to conditions described in WHO BCS classification document (WHO Technical Report Series, No. 937, or later)

☐ Yes

☐ No (explain): _____

Reference product

| | |
|------------------|--|
| Generic name | |
| Dosage form | |
| Strength | |
| Brand/trade name | |
| Manufacturer | |
| Manufacture site | |

| | |
|--------------|--|
| Batch number | |
| Expiry date | |

Name and contact details of laboratory performing tests:

Study results

F2 (similarity factor) value: (Standard 50–100%)

F1 (difference factor) value:

Study conclusion:

4.2.3 By another method (please describe study conclusion briefly):

Attach graphic/pictorial representation of summary study results in Annex AA

4.3 The product used in the therapeutic equivalence study is essentially the same as the one that will be supplied (same materials from the same suppliers, same formula and same manufacturing method)

☐ Yes

☐ No (explain what the differences are and justify that the differences do not have any impact on the bioavailability): _____

- Provide a copy of the protocol and report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, others if any in Annex AB
- For bioequivalence studies indicate the stringent regulatory authority (SRA)/WHO/PIC(S) inspection status of the CRO (if the CRO has ever received inspections in relation to the current or other studies).
- Attach schematic representation of study design

SECTION 5: COMMITMENT AND AUTHORIZATION

5.1 Commitment

I, the undersigned,,
(position in the company, e.g. General Manager, Authorized Person, Responsible Pharmacist), acting as
responsible for the company

..... (name of the company),

certify that the information provided (above) is correct and true,

(if the product is marketed in the country of origin, select the appropriate box below)

☐ and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in (country of origin), including formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information.

☐ and I certify that the product offered is identical to that marketed in
..... (name of country), except:
.....
.....
(e.g. formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the finished product and starting material, packaging, shelf-life, indications, product information)

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible.

Date:

Signature:

.....

5.2 Power of attorney

The manufacturer authorizes a distributor to submit the questionnaire

[SIGNATURE]

Distributor (Signed by Distributor for Manufacturer under power of attorney)

Please provide a copy of the power of attorney (Annex AC)

5.3 Authorization for sharing information with other agency

I, the undersigned confirm that the company has no objection to the information contained herein being shared with the agencies listed on page 2 (1.5) except:

I, the undersigned, certify that the information provided above is accurate, correct, complete, up-to-date and true at the time of submission

Full name: _____

Full title/position in company: _____

Company name: _____

Signature

Date

Company seal/stamp:

SECTION 6: ATTACHMENTS/ANNEXES

Attachments or Annexes to the questionnaire should be in PDF format and should be well indexed to facilitate review

Please ensure that all documents necessary to enable objective evaluation of your product are attached.

This checklist may not be exhaustive.

- ☐ A. Formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients (1.1.7)
- ☐ B. Description and composition of primary packing materials (1.2.1)
- ☐ C. Description and composition of secondary packaging materials (1.2.2)
- ☐ D. Copy of product registered and currently marketed – License no. (1.6.1)
- ☐ E. Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863 in the Annex. Earlier version is not acceptable) (1.6.1)
- ☐ F. Submit recent as well as historical deficiency/acceptance letters issued by PQP/SRA in relation to the specific product dossier.(1.6.1)
- ☐ G. Copy of the relevant WHO Prequalification approval letter signed by your company (1.6.3)
- ☐ H. WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product (1.6.4)
- ☐ I. Package insert/leaflet (1.7.1)
- ☐ J. Patient Information Leaflet (1.7.4)
- ☐ K. GMP certificate from the country of origin (2.1.1)
- ☐ L. Copy of the FPP manufacturer internal API(s) specifications (2.1.2)
- ☐ M. Copy of the FPP manufacturer analytical method and analytical validation data of the API in-house specifications (different from BP, USP and Ph. Int.) (2.1.2)
- ☐ N. Copy of the certificate(s) of analysis of the API from the API manufacturer as well as from the FP manufacturer (2.1.2 and 2.1.3)
- ☐ O. Copy of validation of the sterile aspects of the product including recent media fill validation data for sterile API (2.1.2)
- ☐ P. Copy of the certificate of suitability to the European Pharmacopoeia CEP and its annexes (2.1.4)
- ☐ Q. Open part of drug master file (DMF) (2.1.4)
- ☐ R. Recent/valid GMP certificates/letter (3.1)
- ☐ S. If specifications are in house specifications, different from BP, USP and Ph.Int., attach copy of the

in-house finished product specifications and also validated analytical methods (3.2.1)

- ☐ T. Copy of the certificates of analysis for the three last batches released (3.2.1)
- ☐ U. Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters (3.3)
- ☐ V. Data on validation of the sterile aspects of the product including recent media fill validation data as applicable (3.3)
- ☐ W. Protocol and report for accelerated and real time stability testing (3.4.1)
- ☐ X. Submit a declaration that stability studies have been done or being done with all declared API source (3.4.3)
- ☐ Y. Attach status report of any ongoing stability studies (3.4.4)
- ☐ Z. For oral powder for suspension and powder for injection, provide in-use stability data and storage condition after reconstitution (3.4.8)
- ☐ AA. Attach graphic/pictorial representation of summary study results (4.2.3)
- ☐ AB. Provide a copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, others if any (4.3)
- ☐ AC. Copy of the power of attorney (5.2)

Section 8

Price Schedule Form

The Bidder is required to prepare the Price Schedule as indicated in the Instruction to Bidders.

Please refer to Annex 6 (excel sheet) with the Price Schedule Form.

Annex 6 shall be provided both in Excel and PDF format.

Section 9

FORM FOR BID SECURITY

(This must be finalized using the official letterhead of the Issuing Bank. Except for indicated fields, no changes may be made in this template.)

To: UNDP

WHEREAS (hereinafter called “the Bidder”) has submitted a Bid to UNDP dated , to deliver goods and execute related services for(hereinafter called “the Bid”):

AND WHEREAS it has been stipulated by you that the Bidder shall furnish you with a Bank Guarantee by a recognized bank for the sum specified therein as security in the event that the Bidder:

- a) Fails to sign the Contract after UNDP has awarded it;
- b) Withdraws its Bid after the date of the opening of the Bid;
- c) Fails to comply with UNDP’s variation of requirement, as per ITB Section 3; or
- d) Fails to furnish Performance Security, insurances, or other documents that UNDP may require as a condition to rendering the contract effective.

AND WHEREAS we have agreed to give the Bidder such this Bank Guarantee:

NOW THEREFORE we hereby affirm that we are the Guarantor and responsible to you, on behalf of the Bidder, up to a total of [amount of guarantee] [in words and numbers], such sum being payable in the types and proportions of currencies in which the Price Bid is payable, and we undertake to pay you, upon your first written demand and without cavil or argument, any sum or sums within the limits of [amount of guarantee as aforesaid] without your needing to prove or to show grounds or reasons for your demand for the sum specified therein.

This guarantee shall be valid until 30 days after the date of validity of the bids.

SIGNATURE AND SEAL OF THE GUARANTOR BANK

Date

Name of Bank

Address

Section 10

FORM FOR PERFORMANCE SECURITY

(This must be finalized using the official letterhead of the Issuing Bank. Except for indicated fields, no changes may be made in this template.)

To: UNDP

[Insert contact information as provided in Data Sheet]

WHEREAS *[name and address of Contractor]* (hereinafter called “the Contractor”) has undertaken, in pursuance of Contract No. dated, to deliver the goods and execute related services (hereinafter called “the Contract”):

AND WHEREAS it has been stipulated by you in the said Contract that the Contractor shall furnish you with a Bank Guarantee by a recognized bank for the sum specified therein as security for compliance with his obligations in accordance with the Contract:

AND WHEREAS we have agreed to give the Contractor such a Bank Guarantee:

NOW THEREFORE we hereby affirm that we are the Guarantor and responsible to you, on behalf of the Contractor, up to a total of *[amount of guarantee]* *[in words and numbers]*, such sum being payable in the types and proportions of currencies in which the Contract Price is payable, and we undertake to pay you, upon your first written demand and without cavil or argument, any sum or sums within the limits of *[amount of guarantee as aforesaid]* without your needing to prove or to show grounds or reasons for your demand for the sum specified therein.

This guarantee shall be valid until a date 30 days from the date of issue by UNDP of a certificate of satisfactory performance and full completion of services by the Contractor.

SIGNATURE AND SEAL OF THE GUARANTOR BANK

Date

Name of Bank

Address

Section 11

Template of Purchase Order and General Terms and Conditions for Contracts



Ukraine

UNDP Office in Ukraine
1 Klovsky Uzviz Str
Kyiv 30 01021
Ukraine
Tel:
Fax:

Vendor: 00000

Purchase Order

Dispatch via Print

| | | | |
|----------------------------|----------------------------|-----------------|--------------------|
| PO Number UKR10-00000 | Date | Revision | Page 1 |
| Payment Terms Immediate | Freight / INCOTERMS DAP | | Ship Via Common |
| Ruwer | Phone Tel: Fax: | Currency USD | |
| Approver | | | |

Ship To: UNDP Office in Ukraine
1 Klovsky Uzviz Str
Kyiv 30 01021
Ukraine

Tel:
Fax:

Bill To: UNDP Office in Ukraine
1 Klovsky Uzviz Str
Kyiv 30 01021
Ukraine

Tel:
Fax:

| Ln-Sch Item | Description | Quantity | UOM | Due Date | Unit Price | Line Total |
|-------------|-------------|----------|-----|----------|------------|------------|
|-------------|-------------|----------|-----|----------|------------|------------|

1-1

EU

PO Text:

- Contractor: [please add]
tel./fax : [please add]
bank account [please add]
Contact names: [please add]
gsm: [please add]
- Purchaser: United Nations Development Programme

Contact names:

3. Specifications and quantities of goods:

3.1. [Trade name, INN, pharmaceutical presentation, dosage]

Pack size:

Quantity of units/packs:

Registration Certificate # _____ : valid till

Shelf life:.

Delivery terms: [to be added]

4. Delivery terms and address:

5. Required shipping documents:

6. Pharmaceuticals shall be transported and stored in accordance with the temperature mode

specified in the product instruction. All temperature restricted commodities must be shipped with clear marking of the corresponding temperature conditions. It is the responsibility of the Supplier to provide complete packing as required for transportation.

Shipments should be accompanied by dataloggers. The number of dataloggers should be 1 if shipment has 5 or less boxes, 2 if shipment has more than 5 boxes. If products are shipped in containers, each container should have 2 dataloggers. Dataloggers should be activated, set up with adequate alarm levels and placed inside a box with the products. The boxes with dataloggers should be clearly identified with bright color stickers (ideally orange).

The minimum technical requirements for dataloggers are as follows:

- Measures temperature (from -30° to 70°c, with accuracy +/- 0.3°c).
- Readings to include time and date
- Single or multiple use
- Direct USB interface, without need for additional cable
- Automatically creates PDF report when connected to computer.
- Rapid data download to graph
- Alarm levels set up before shipping according to manufacturer's storage requirements
- LCD featuring up to 1 decimal point readings
- Alarm indication on LCD screen
- Sampling rate: at least 1 measure per hour
- Push button to activate and stop logging.
- Easy to understand user's guide & instructions

7. Liquidated Damages terms: According to UNDP General Terms for Supply of Goods and Solicitation document ref. Invitation to Bid UKR-HP- the liquidated damages for delay shall be 0.5% of the price of the Contract per 1 (one) day of delay. Maximum number of days of delay – 30 (thirty) days, after which UNDP may terminate the contract.

8. UNDP shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Purchase Order. Upon receipt of a written notice from UNDP, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to Purchaser at the final location.

The Supplier will be required to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered. If the defective Goods are not removed within 30 days, UNDP will dispose on the Supplier's costs.

10. Payment terms: within 30 calendar days after delivery subject to written acceptance of goods duly signed and stamped by UNDP and MoH/SK Pharmacy LLP and provision of original invoice. In case testing is required, satisfactory testing results is a prerequisite for payment release.

11. Total amount of the present Purchas Order makes up [to be added]

12. The Supplier must comply with all provisions of the present Purchase Order (PO) and attachments mentioned below which are inalienable part of PO:

13.1. Long Term Agreement # [to be added] signed by both Parties. Not attached herein but acknowledged

and in possession by both parties.

13.2. Solicitation document ref. ITB UKR-HP- dated [to be added] with specification. Not attached herein but acknowledged and in possession by both parties.

13.3. Supplier's bid dated [to be added]. Not attached herein but acknowledged and in possession by both parties.

13.4. UNDP General Terms and Conditions for Goods (Purchase Orders).

General Terms and Conditions for Contracts

This Contract is between the United Nations Development Programme, a subsidiary organ of the United Nations established by the General Assembly of the United Nations (hereinafter “UNDP”), on the one hand, and a company or organization indicated in the Face Sheet of this Contract (hereinafter the “Contractor”), on the other hand.

1. LEGAL STATUS OF THE PARTIES: UNDP and the Contractor shall be referred to as a “Party” or, collectively, “Parties” hereunder, and:

1.1 Pursuant, *inter alia*, to the Charter of the United Nations and the Convention on the Privileges and Immunities of the United Nations, the United Nations, including its subsidiary organs, has full juridical personality and enjoys such privileges and immunities as are necessary for the independent fulfillment of its purposes.

1.2 The Contractor shall have the legal status of an independent contractor *vis-à-vis* UNDP, and nothing contained in or relating to the Contract shall be construed as establishing or creating between the Parties the relationship of employer and employee or of principal and agent. The officials, representatives, employees, or subcontractors of each of the Parties shall not be considered in any respect as being the employees or agents of the other Party, and each Party shall be solely responsible for all claims arising out of or relating to its engagement of such persons or entities.

2. OBLIGATIONS OF THE CONTRACTOR:

2.1 The Contractor shall deliver the goods described in the Technical Specifications for Goods (hereinafter the “Goods”) and/or perform and complete the services described in the Terms of Reference and Schedule of Payments (hereinafter the “Services”), with due diligence and efficiency, and in accordance with this Contract. The Contractor shall also provide all technical and administrative support needed in order to ensure the timely and satisfactory delivery of the Goods and/or performance of the Services.

2.2 To the extent that the Contract involves any purchase of the Goods, the Contractor shall provide UNDP with written evidence of the delivery of the Goods. Such evidence of delivery shall, at the minimum, consist of an invoice, a certification of conformity, and other supporting shipment documentation as may otherwise be specified in the Technical Specifications for Goods.

2.3 The Contractor represents and warrants the accuracy of any information or data provided to UNDP for the purpose of entering into this Contract, as well as the quality of the deliverables and reports foreseen under this Contract, in accordance with the highest industry and professional standards.

2.4 All time limits contained in this Contract shall be deemed to be of the essence in respect of the performance of the delivery of the Goods and/or the provision of the Services.

3. LONG TERM AGREEMENT: If the Contractor is engaged by UNDP on the basis of a long-term agreement (“LTA”) as indicated in the Face Sheet of this Contract, the following conditions shall apply:

3.1 UNDP does not warrant that any quantity of Goods and/or Services shall be ordered during the term of the LTA.

3.2 Any UNDP business unit, including, but not limited to, a Headquarters unit, a Country Office or a Regional Centre, as well as any United Nations entity, may benefit from the retainer and order Goods and/or Services from the Contractor hereunder.

3.3 The Contractor shall provide the Services and/or deliver the Goods, as and when requested by UNDP and reflected in a Purchase Order, which shall be subject to the terms and conditions stipulated in this Contract. For the avoidance of doubt, UNDP shall acquire no legal obligations towards the Contractor unless and until a Purchase Order is issued.

3.4 The Goods and/or Services shall be at the Discount Prices annexed hereto. The prices shall remain in effect for a period of three years from the Starting Date stated in the Face Sheet of this Contract.

3.5 In the event of any advantageous technical changes and/or downward pricing of the Goods and/or Services during the term of the retainer, the Contractor shall notify UNDP immediately. UNDP shall consider the impact of any such event and may request an amendment to the retainer.

3.6 The Contractor shall report semi-annually to UNDP on the Goods delivered and/or Services provided, unless otherwise specified in the Contract. Each report should be submitted to the UNDP Contact Person indicated in as indicated in the Face Sheet hereto, as well as to a UNDP business unit that has placed a Purchase Order for the Goods and/or Services during the reporting period.

3.7 The LTA shall remain in force for the maximum period of two years and may be extended by UNDP for one additional year by mutual agreement of the Parties.

4. PRICE AND PAYMENT:

4.1 FIXED PRICE: If Fixed Price is chosen as a payment method pursuant to the Face Sheet of this Contract, in full consideration for the complete and satisfactory delivery of the Goods and/or provision of the Services, UNDP shall pay the Contractor a fixed amount indicated in the Face Sheet of this Contract.

4.1.1 The amount stated in the Face Sheet of this Contract is not subject to any adjustment or revision because of price or currency fluctuations, or the actual costs incurred by the Contractor in the performance of the Contract.

4.1.2 UNDP shall effect payments to the Contractor in the amounts and pursuant to the schedule of payments set forth in the Terms of Reference and Schedule of Payments, upon completion by the Contractor of the corresponding deliverable(s) and upon acceptance by UNDP of the original invoices submitted by the Contractor to the UNDP Contact Person indicated in the Face Sheet of this Contract, together with whatever supporting documentation that may be required by UNDP:

4.1.3 Invoices shall indicate a deliverable completed and the corresponding amount payable.

4.1.4 Payments effected by UNDP to the Contractor shall be deemed neither to relieve the Contractor of its obligations under this Contract nor as acceptance by UNDP of the Contractor's delivery of the Goods and/or provision of the Services.

4.2 COST REIMBURSEMENT: If Cost Reimbursement is chosen as a payment method pursuant to the Face Sheet of this Contract, in full consideration for the complete and satisfactory delivery of the Goods and/or provision of the Services under this Contract, UNDP shall pay the Contractor an amount not exceeding the total amount stated in the Face Sheet of this Contract.

4.2.1 The said amount is the maximum total amount of reimbursable costs under this Contract. The breakdown of costs contained in the Financial Proposal, referred to in the Face Sheet to this Contract shall specify the maximum amount per each cost category that is reimbursable under this Contract. The Contractor shall specify in its invoices or financial reports (as required by UNDP) the amount of the actual reimbursable costs incurred in the delivery of the Goods and/or the provision of the Services.

4.2.2 The Contractor shall not provide the Services and/or deliver the Goods or equipment, materials and supplies that may result in any costs in excess of the amount stated in the Face Sheet of this Contract, or of the maximum amount per each cost category specified in the breakdown of costs contained in the Financial Proposal, without the prior written agreement of the UNDP Contact Person.

4.2.3 The Contractor shall submit original invoices or financial reports (as required by UNDP) for the Goods delivered in accordance with the Technical Specifications for Goods and/or the Services provided in accordance with the schedule set forth in the Terms of Reference and Schedule of Payments. Such invoices or financial reports shall indicate a deliverable or deliverables completed and the corresponding amount payable. They shall be submitted to the UNDP Contact Person, together with whatever supporting documentation of the actual costs incurred that is required in the Financial Proposal, or may be required by UNDP.

4.2.4 UNDP shall effect payments to the Contractor upon completion by the Contractor of the deliverable(s) indicated in the original invoices or financial reports (as required by UNDP) and upon acceptance of these invoices or financial reports by UNDP. Such payments shall be subject to any specific conditions for reimbursement specified in the breakdown of costs contained in the Financial Proposal.

4.2.5 Payments effected by UNDP to the Contractor shall be deemed neither to relieve the Contractor of its obligations under this Contract nor as acceptance by UNDP of the Contractor's delivery of the Goods and/or performance of the Services.

5. ADVANCE PAYMENT:

5.1 If an advance payment is due to the Contractor pursuant to the Face Sheet of this Contract, the Contractor shall submit an original invoice for the amount of that advance payment upon signature of this Contract by the Parties.

5.2 If an advance payment representing 20% or more of the total contract value, or amounting to US\$30,000 or more, is to be made by UNDP upon signature of the Contract by the Parties, such payment shall be contingent upon receipt and acceptance by UNDP of a bank guarantee or a certified cheque for the full amount of the advance payment, valid for the duration of the Contract, and in a form acceptable to UNDP.

6. SUBMISSION OF INVOICES AND REPORTS:

6.1 All original invoices, financial reports and any other reports and supporting documentation required under this Contract shall be submitted by mail by the Contractor to UNDP Contact Person. Upon request of the Contractor, and subject to approval by UNDP, invoices and

financial reports may be submitted to UNDP by fax or email.

6.2 All reports and invoices shall be submitted by the Contractor to the UNDP Contact Person specified in the Face Sheet of this Contract.

7. TIME AND MANNER OF PAYMENT:

7.1 Invoices shall be paid within thirty (30) days of the date of their acceptance by UNDP. UNDP shall make every effort to accept an original invoice or advise the Contractor of its non-acceptance within a reasonable time from receipt.

7.2 Where the Services are to be provided, in addition to an invoice, the Contractor shall submit to UNDP a report, describing in detail the Services provided under the Contract during the period of time covered in each report.

8. RESPONSIBILITY FOR EMPLOYEES: To the extent that the Contract involves the provision of the Services to UNDP by the Contractor's officials, employees, agents, servants, subcontractors and other representatives (collectively, the Contractor's "personnel"), the following provisions shall apply:

8.1 The Contractor is responsible for and shall assume all risk and liabilities relating to its personnel and property.

8.2 The Contractor shall be responsible for the professional and technical competence of the personnel it assigns to perform work under the Contract and will select reliable and competent individuals who will be able to effectively perform the obligations under the Contract and who, while doing so, will respect the local laws and customs and conform to a high standard of moral and ethical conduct.

8.3 Such Contractor personnel shall be professionally qualified and, if required to work with officials or staff of UNDP, shall be able to do so effectively. The qualifications of any personnel whom the Contractor may assign or may propose to assign to perform any obligations under the Contract shall be substantially the same, or better, as the qualifications of any personnel originally proposed by the Contractor.

8.4 At the option of and in the sole discretion of UNDP:

8.4.1 the qualifications of personnel proposed by the Contractor (*e.g.*, a curriculum vitae) may be reviewed by UNDP prior to such personnel's performing any obligations under the Contract;

8.4.2 any personnel proposed by the Contractor to perform obligations under the Contract may be interviewed by qualified staff or officials of UNDP prior to such personnel's performing any obligations under the Contract; and,

8.4.3 in cases in which, pursuant to Article 8.4.1 or 8.4.2, above, UNDP has reviewed the qualifications of such Contractor's personnel, UNDP may reasonably refuse to accept any such personnel.

8.5 Requirements specified in the Contract regarding the number or qualifications of the Contractor's personnel may change during the course of performance of the Contract. Any such change shall be made only following written notice of such proposed change and upon written agreement between the Parties regarding such change, subject to the following:

8.5.1 UNDP may, at any time, request, in writing, the withdrawal or replacement of any

of the

Contractor's personnel, and such request shall not be unreasonably refused by the Contractor.

8.5.2 Any of the Contractor's personnel assigned to perform obligations under the Contract shall not be withdrawn or replaced without the prior written consent of UNDP, which shall not be unreasonably withheld.

8.5.3 The withdrawal or replacement of the Contractor's personnel shall be carried out as quickly as possible and in a manner that will not adversely affect the performance of obligations under the Contract.

8.5.4 All expenses related to the withdrawal or replacement of the Contractor's personnel shall, in all cases, be borne exclusively by the Contractor.

8.5.5 Any request by UNDP for the withdrawal or replacement of the Contractor's personnel shall not be considered to be a termination, in whole or in part, of the Contract, and UNDP shall not bear any liability in respect of such withdrawn or replaced personnel.

8.5.6 If a request for the withdrawal or replacement of the Contractor's personnel is *not* based upon a default by or failure on the part of the Contractor to perform its obligations in accordance with the Contract, the misconduct of the personnel, or the inability of such personnel to reasonably work together with UNDP officials and staff, then the Contractor shall not be liable by reason of any such request for the withdrawal or replacement of the Contractor's personnel for any delay in the performance by the Contractor of its obligations under the Contract that is substantially the result of such personnel's being withdrawn or replaced.

8.6 Nothing in Articles 8.3, 8.4 and 8.5, above, shall be construed to create any obligations on the part of UNDP with respect to the Contractor's personnel assigned to perform work under the Contract, and such personnel shall remain the sole responsibility of the Contractor.

8.7 The Contractor shall be responsible for requiring that all personnel assigned by it to perform any obligations under the Contract and who may have access to any premises or other property of UNDP shall:

8.7.1 undergo or comply with security screening requirements made known to the Contractor by

UNDP, including but not limited to, a review of any criminal history;

8.7.2 when within UNDP premises or on UNDP property, display such identification as may be approved and furnished by UNDP security officials, and that upon the withdrawal or replacement of any such personnel or upon termination or completion of the Contract, such personnel shall immediately return any such identification to UNDP for cancellation.

8.8 Within one working day after learning that any of Contractor's personnel who have access to any UNDP premises have been charged by law enforcement authorities with an offense other than a minor traffic offense, the Contractor shall provide written notice to inform UNDP about the particulars of the charges then known and shall continue to inform UNDP concerning all substantial developments regarding the disposition of such charges.

8.9 All operations of the Contractor, including without limitation, storage of equipment, materials, supplies and parts, within UNDP premises or on UNDP property shall be

confined to areas authorized or approved by UNDP. The Contractor's personnel shall not enter or pass through and shall not store or dispose of any of its equipment or materials in any areas within UNDP premises or on UNDP property without appropriate authorization from UNDP.

8.10 The Contractor shall (i) put in place an appropriate security plan and maintain the security plan, taking into account the security situation in the country where the Services are being provided; and (ii) assume all risks and liabilities related to the Contractor's security, and the full implementation of the security plan.

8.11 UNDP reserves the right to verify whether such a plan is in place, and to suggest modifications to the plan when necessary. Failure to maintain and implement an appropriate security plan as required hereunder shall be deemed a breach of this contract. Notwithstanding the foregoing, the Contractor shall remain solely responsible for the security of its personnel and for UNDP's property in its custody as set forth in paragraph 8.10 above.

9. ASSIGNMENT:

9.1 Except as provided in Article 9.2, below, the Contractor may not assign, transfer, pledge or make any other disposition of the Contract, of any part of the Contract, or of any of the rights, claims or obligations under the Contract except with the prior written authorization of UNDP. Any such unauthorized assignment, transfer, pledge or other disposition, or any attempt to do so, shall not be binding on UNDP. Except as permitted with respect to any approved subcontractors, the Contractor shall not delegate any of its obligations under this Contract, except with the prior written consent of UNDP. Any such unauthorized delegation, or attempt to do so, shall not be binding on UNDP.

9.2 The Contractor may assign or otherwise transfer the Contract to the surviving entity resulting from a reorganization of the Contractor's operations, *provided that:*

9.2.1 such reorganization is not the result of any bankruptcy, receivership or other similar proceedings; *and,*

9.2.2 such reorganization arises from a sale, merger, or acquisition of all or substantially all of the Contractor's assets or ownership interests; *and,*

9.2.3 the Contractor promptly notifies UNDP about such assignment or transfer at the earliest opportunity; *and,*

9.2.4 the assignee or transferee agrees in writing to be bound by all of the terms and conditions of the Contract, and such writing is promptly provided to UNDP following the assignment or transfer.

10. SUBCONTRACTING: In the event that the Contractor requires the services of subcontractors to perform any obligations under the Contract, the Contractor shall obtain the prior written approval of UNDP. UNDP shall be entitled, in its sole discretion, to review the qualifications of any subcontractors and to reject any proposed subcontractor that UNDP reasonably considers is not qualified to perform obligations under the Contract. UNDP shall have the right to require any subcontractor's removal from UNDP premises without having to give any justification therefor. Any such rejection or request for removal shall not, in

and of itself, entitle the Contractor to claim any delays in the performance, or to assert any excuses for the non-performance, of any of its obligations under the Contract, and the Contractor shall be solely responsible for all services and obligations performed by its subcontractors. The terms of any subcontract shall be subject to, and shall be construed in a manner that is fully in accordance with, all of the terms and conditions of the Contract.

11. PURCHASE OF GOODS: To the extent that the Contract involves any purchase of the Goods, whether in whole or in part, and unless specifically stated otherwise in the Contract, the following conditions shall apply to such purchases under the Contract:

11.1 DELIVERY OF GOODS: The Contractor shall hand over or make available the Goods, and UNDP shall receive the Goods, at the place for the delivery of the Goods and within the time for delivery of the Goods specified in the Contract. The Contractor shall provide to UNDP such shipment documentation (including, without limitation, bills of lading, airway bills, and commercial invoices) as are specified in the Contract or, otherwise, as are customarily utilized in the trade. All manuals, instructions, displays and any other information relevant to the Goods shall be in the English language unless otherwise specified in the Contract. Unless otherwise stated in the Contract (including, but not limited to, in any “INCOTERM” or similar trade term), the entire risk of loss,

damage to, or destruction of the Goods shall be borne exclusively by the Contractor until physical delivery of the Goods to UNDP in accordance with the terms of the Contract. Delivery of the Goods shall not be deemed in itself as constituting acceptance of the Goods by UNDP.

11.2 INSPECTION OF THE GOODS: If the Contract provides that the Goods may be inspected prior to delivery, the Contractor shall notify UNDP when the Goods are ready for pre-delivery inspection. Notwithstanding any pre-delivery inspection, UNDP or its designated inspection agents may also inspect the Goods upon delivery in order to confirm that the Goods conform to applicable specifications or other requirements of the Contract. All reasonable facilities and assistance, including, but not limited to, access to drawings and production data, shall be furnished to UNDP or its designated inspection agents at no charge therefor. Neither the carrying out of any inspections of the Goods nor any failure to undertake any such inspections shall relieve the Contractor of any of its warranties or the performance of any obligations under the Contract.

11.3 PACKAGING OF THE GOODS: The Contractor shall package the Goods for delivery in accordance with the highest standards of export packaging for the type and quantities and modes of transport of the Goods. The Goods shall be packed and marked in a proper manner in accordance with the instructions stipulated in the Contract or, otherwise, as customarily done in the trade, and in accordance with any requirements imposed by applicable law or by the transporters and manufacturers of the Goods. The packing, in particular, shall mark the Contract or Purchase Order number and any other identification information provided by UNDP as well as such other information as is necessary for the correct handling and safe delivery of the Goods. Unless otherwise specified in the Contract, the Contractor shall have no right to any return of the packing materials.

11.4 TRANSPORTATION & FREIGHT: Unless otherwise specified in the Contract (including, but not limited to, in any “INCOTERM” or similar trade term), the Contractor shall be solely liable for making all transport arrangements and for payment of freight and insurance costs for the shipment and delivery of the Goods in accordance with the requirements of

the Contract. The Contractor shall ensure that UNDP receives all necessary transport documents in a timely manner so as to enable UNDP to take delivery of the Goods in accordance with the requirements of the Contract.

11.5 WARRANTIES: Unless otherwise specified in the Contract, in addition to and without limiting any other warranties, remedies or rights of UNDP stated in or arising under the Contract, the Contractor warrants and represents that:

11.5.1 The Goods, including all packaging and packing thereof, conform to the technical specifications, are fit for the purposes for which such Goods are ordinarily used and for any purposes expressly made known in writing in the Contract, and shall be of even quality, free from faults and defects in design, material, manufacturer and workmanship;

11.5.2 If the Contractor is not the original manufacturer of the Goods, the Contractor shall provide UNDP with the benefit of all manufacturers' warranties in addition to any other warranties required to be provided under the Contract;

11.5.3 The Goods are of the quality, quantity and description required by the Contract, including when subjected to conditions prevailing in the place of final destination;

11.5.4 The Goods are free from any right of claim by any third-party, including claims of infringement of any intellectual property rights, including, but not limited to, patents, copyright and trade secrets;

11.5.5 The Goods are new and unused;

11.5.6 All warranties will remain fully valid following any delivery of the Goods and for a period of not less than one (1) year following acceptance of the Goods by UNDP in accordance with the Contract;

11.5.7 During any period in which the Contractor's warranties are effective, upon notice by UNDP that the Goods do not conform to the requirements of the Contract, the Contractor shall promptly and at its own expense correct such non-conformities or, in case of its inability to do so, replace the defective Goods with Goods of the same or better quality or, at its own cost, remove the defective Goods and fully reimburse UNDP for the purchase price paid for the defective Goods; and,

11.5.8 The Contractor shall remain responsive to the needs of UNDP for any services that may be required in connection with any of the Contractor's warranties under the Contract.

11.6 ACCEPTANCE OF GOODS: Under no circumstances shall UNDP be required to accept any Goods that do not conform to the specifications or requirements of the Contract. UNDP may condition its acceptance of the Goods upon the successful completion of acceptance tests as may be specified in the Contract or otherwise agreed in writing by the Parties. In no case shall UNDP be obligated to accept any Goods unless and until UNDP has had a reasonable opportunity to inspect the Goods following delivery. If the Contract specifies that UNDP shall provide a written acceptance of the Goods, the Goods shall not be deemed accepted unless and until UNDP in fact provides such written acceptance. In no case shall payment by UNDP in and of itself constitute acceptance of the Goods.

11.7 REJECTION OF GOODS: Notwithstanding any other rights of, or remedies available to UNDP under the Contract, in case any of the Goods are defective or otherwise do not conform to the specifications or other requirements of the Contract, UNDP, at its sole option,

may reject or refuse to accept the Goods, and within thirty (30) days following receipt of notice from UNDP of such rejection or refusal to accept the Goods, the Contractor shall, in sole option of UNDP:

11.7.1 provide a full refund upon return of the Goods, or a partial refund upon a return of a portion of the Goods, by UNDP; *or*,

11.7.2 repair the Goods in a manner that would enable the Goods to conform to the specifications or other requirements of the Contract; *or*,

11.7.3 replace the Goods with Goods of equal or better quality; *and*,

11.7.4 pay all costs relating to the repair or return of the defective Goods as well as the costs relating to the storage of any such defective Goods and for the delivery of any replacement Goods to UNDP.

11.8 In the event that UNDP elects to return any of the Goods for the reasons specified in Article

11.7, above, UNDP may procure the Goods from another source. In addition to any other rights or remedies available to UNDP under the Contract, including, but not limited to, the right to terminate the Contract, the Contractor shall be liable for any additional cost beyond the balance of the Contract price resulting from any such procurement, including, *inter alia*, the costs of engaging in such procurement, and UNDP shall be entitled to compensation from the Contractor for any reasonable expenses incurred for preserving and storing the Goods for the Contractor's account.

11.9 TITLE: The Contractor warrants and represents that the Goods delivered under the Contract are unencumbered by any third party's title or other property rights, including, but not limited to, any liens or security interests. Unless otherwise expressly provided in the Contract, title in and to the Goods shall pass from the Contractor to UNDP upon delivery of the Goods and their acceptance by UNDP in accordance with the requirements of the Contract.

11.10 EXPORT LICENSING: The Contractor shall be responsible for obtaining any export license required with respect to the Goods, products, or technologies, including software, sold, delivered, licensed or otherwise provided to UNDP under the Contract. The Contractor shall procure any such export license in an expeditious manner. Subject to and without any waiver of the privileges and immunities of UNDP, UNDP shall lend the Contractor all reasonable assistance required for obtaining any such export license. Should any Governmental entity refuse, delay or hinder the Contractor's ability to obtain any such export license, the Contractor shall promptly consult with UNDP to enable UNDP to take appropriate measures to resolve the matter.

12. INDEMNIFICATION:

12.1 The Contractor shall indemnify, defend, and hold and save harmless, UNDP, and its officials, agents and employees, from and against all suits, proceedings, claims, demands, losses and liability of any kind or nature brought by any third party against UNDP, including, but not limited to, all litigation costs and expenses, attorney's fees, settlement payments and damages, based on, arising from, or relating to:

12.1.1 allegations or claims that the possession of or use by UNDP of any patented device, any copyrighted material, or any other goods, property or services provided or

licensed to UNDP under the terms of the Contract, in whole or in part, separately or in a combination contemplated by the Contractor's published specifications therefor, or otherwise specifically approved by the Contractor, constitutes an infringement of any patent, copyright, trademark, or other intellectual property right of any third party; *or*,

12.1.2 any acts or omissions of the Contractor, or of any subcontractor or anyone directly or indirectly employed by them in the performance of the Contract, which give rise to legal liability to anyone not a party to the Contract, including, without limitation, claims and liability in the nature of a claim for workers' compensation.

12.2 The indemnity set forth in Article 12.1.1, above, shall not apply to:

12.2.1 A claim of infringement resulting from the Contractor's compliance with specific written instructions by UNDP directing a change in the specifications for the goods, property, materials, equipment or supplies to be or used, or directing a manner of performance of the Contract or requiring the use of specifications not normally used by the Contractor; *or*

12.2.2 A claim of infringement resulting from additions to or changes in any goods, property, materials equipment, supplies or any components thereof furnished under the Contract if UNDP or another party acting under the direction of UNDP made such changes.

12.3 In addition to the indemnity obligations set forth in this Article 12, the Contractor shall be obligated, at its sole expense, to defend UNDP and its officials, agents and employees, pursuant to this Article 12, regardless of whether the suits, proceedings, claims and demands in question actually give rise to or otherwise result in any loss or liability.

12.4 UNDP shall advise the Contractor about any such suits, proceedings, claims, demands, losses or liability within a reasonable period of time after having received actual notice thereof. The Contractor shall have sole control of the defense of any such suit, proceeding, claim or demand and of all negotiations in connection with the settlement or compromise thereof, except with respect to the assertion or defense of the privileges and immunities of UNDP or any matter relating thereto, for which only UNDP itself is authorized to assert and maintain. UNDP shall have the right, at its own expense, to be represented in any such suit, proceeding, claim or demand by independent counsel of its own choosing.

12.5 In the event the use by UNDP of any Goods, property or Services provided or licensed to UNDP by the Contractor, in whole or in part, in any suit or proceeding, is for any reason enjoined, temporarily or permanently, or is found to infringe any patent, copyright, trademark or other intellectual property right, or in the event of a settlement, is enjoined, limited or otherwise interfered with, then the Contractor, at its sole cost and expense, shall, promptly, either:

12.5.1 procure for UNDP the unrestricted right to continue using such Goods or Services provided to UNDP;

12.5.2 replace or modify the Goods and/or or Services provided to UNDP, or part thereof, with the equivalent or better Goods and/or Services, or part thereof, that is non-infringing; *or*,

12.5.3 refund to UNDP the full price paid by UNDP for the right to have or use such Goods, property or Services, or part thereof.

13. INSURANCE AND LIABILITY:

13.1 The Contractor shall pay UNDP promptly for all loss, destruction, or damage to the property of UNDP caused by the Contractor's personnel or by any of its subcontractors or anyone else directly or indirectly employed by the Contractor or any of its subcontractors in the performance of the Contract.

13.2 Unless otherwise provided in the Contract, prior to commencement of performance of any other obligations under the Contract, and subject to any limits set forth in the Contract, the Contractor shall take out and shall maintain for the entire term of the Contract, for any extension thereof, and for a period following any termination of the Contract reasonably adequate to deal with losses:

13.2.1 insurance against all risks in respect of its property and any equipment used for the performance of the Contract;

13.2.2 workers' compensation insurance, or its equivalent, or employer's liability insurance, or its equivalent, with respect to the Contractor's personnel sufficient to cover all claims for injury, death and disability, or any other benefits required to be paid by law, in connection with the performance of the Contract;

13.2.3 liability insurance in an adequate amount to cover all claims, including, but not limited to, claims for death and bodily injury, products and completed operations liability, loss of or damage to property, and personal and advertising injury, arising from or in connection with the Contractor's performance under the Contract, including, but not limited to, liability arising out of or in connection with the acts or omissions of the Contractor, its personnel, agents, or invitees, or the use, during the performance of the Contract, of any vehicles, boats, airplanes or other transportation vehicles and equipment, whether or not owned by the Contractor; *and*,

13.2.4 such other insurance as may be agreed upon in writing between UNDP and the Contractor.

13.3 The Contractor's liability policies shall also cover subcontractors and all defense costs and shall contain a standard "cross liability" clause.

13.4 The Contractor acknowledges and agrees that UNDP accepts no responsibility for providing life, health, accident, travel or any other insurance coverage which may be necessary or desirable in respect of any personnel performing services for the Contractor in connection with the Contract.

13.5 Except for the workers' compensation insurance or any self-insurance program maintained by the Contractor and approved by UNDP, in its sole discretion, for purposes of fulfilling the Contractor's requirements for providing insurance under the Contract, the insurance policies required under the Contract shall:

13.5.1 name UNDP as an additional insured under the liability policies, including, if required, as a separate endorsement under the policy;

13.5.2 include a waiver of subrogation of the Contractor's insurance carrier's rights against UNDP;

13.5.3 provide that UNDP shall receive written notice from the Contractor's insurance carrier not less than thirty (30) days prior to any cancellation or material change of coverage; *and*,

13.5.4 include a provision for response on a primary and non-contributing basis with respect to any other insurance that may be available to UNDP.

13.6 The Contractor shall be responsible to fund all amounts within any policy deductible or retention.

13.7 Except for any self-insurance program maintained by the Contractor and approved by UNDP for purposes of fulfilling the Contractor's requirements for maintaining insurance under the Contract, the Contractor shall maintain the insurance taken out under the Contract with reputable insurers that are in good financial standing and that are acceptable to UNDP. Prior to the commencement of any obligations under the Contract, the Contractor shall provide UNDP with evidence, in the form of certificate of insurance or such other form as UNDP may reasonably require, that demonstrates that the Contractor has taken out insurance in accordance with the requirements of the Contract. UNDP reserves the right, upon written notice to the Contractor, to obtain copies of any insurance policies or insurance program descriptions required to be maintained by the Contractor under the Contract. Notwithstanding the provisions of Article 13.5.3, above, the Contractor shall promptly notify UNDP concerning any cancellation or material change of insurance coverage required under the Contract.

13.8 The Contractor acknowledges and agrees that neither the requirement for taking out and maintaining insurance as set forth in the Contract nor the amount of any such insurance, including, but not limited to, any deductible or retention relating thereto, shall in any way be construed as limiting the Contractor's liability arising under or relating to the Contract.

14. ENCUMBRANCES AND LIENS: The Contractor shall not cause or permit any lien, attachment or other encumbrance by any person to be placed on file or to remain on file in any public office or on file with UNDP against any monies due to the Contractor or that may become due for any work done or against any goods supplied or materials furnished under the Contract, or by reason of any other claim or demand against the Contractor or UNDP.

15. EQUIPMENT FURNISHED BY UNDP TO THE CONTRACTOR: Title to any equipment and supplies that may be furnished by UNDP to the Contractor for the performance of any obligations under the Contract shall rest with UNDP, and any such equipment shall be returned to UNDP at the conclusion of the Contract or when no longer needed by the Contractor. Such equipment, when returned to UNDP, shall be in the same condition as when delivered to the Contractor, subject to normal wear and tear, and the Contractor shall be liable to compensate UNDP for the actual costs of any loss of, damage to, or degradation of the equipment that is beyond normal wear and tear.

16. COPYRIGHT, PATENTS AND OTHER PROPRIETARY RIGHTS:

16.1 Except as is otherwise expressly provided in writing in the Contract, UNDP shall be entitled to all intellectual property and other proprietary rights including, but not limited to, patents, copyrights, and trademarks, with regard to products, processes, inventions, ideas, know-how, or documents and other materials which the Contractor has developed for UNDP under the Contract and which bear a direct relation to or are produced or prepared or collected in consequence of, or during the course of, the performance of the Contract. The Contractor acknowledges and agrees that such products, documents and other materials constitute works made for hire for UNDP.

16.2 To the extent that any such intellectual property or other proprietary rights consist of any intellectual property or other proprietary rights of the Contractor: (i) that pre-existed the performance by the Contractor of its obligations under the Contract, or (ii) that the Contractor may develop or acquire, or may have developed or acquired, independently of the performance of its obligations under the Contract, UNDP does not and shall not claim any ownership interest thereto, and the Contractor grants to UNDP a perpetual license to use such intellectual property or other proprietary right solely for the purposes of and in accordance with the requirements of the Contract.

16.3 At the request of UNDP, the Contractor shall take all necessary steps, execute all necessary documents and generally assist in securing such proprietary rights and transferring or licensing them to UNDP in compliance with the requirements of the applicable law and of the Contract.

16.4 Subject to the foregoing provisions, all maps, drawings, photographs, mosaics, plans, reports, estimates, recommendations, documents, and all other data compiled by or received by the Contractor under the Contract shall be the property of UNDP, shall be made available for use or inspection by UNDP at reasonable times and in reasonable places, shall be treated as confidential, and shall be delivered only to UNDP authorized officials on completion of work under the Contract.

17. PUBLICITY, AND USE OF THE NAME, EMBLEM OR OFFICIAL SEAL OF UNDP OR THE UNITED NATIONS: The Contractor shall not advertise or otherwise make public for purposes of commercial advantage or goodwill that it has a contractual relationship with UNDP, nor shall the Contractor, in any manner whatsoever use the name, emblem or official seal of UNDP or the United Nations, or any abbreviation of the name of UNDP or the United Nations in connection with its business or otherwise without the written permission of UNDP.

18. CONFIDENTIAL NATURE OF DOCUMENTS AND INFORMATION: Information and data that is considered proprietary by either Party or that is delivered or disclosed by one Party ("Discloser") to the other Party ("Recipient") during the course of performance of the Contract, and that is designated as confidential ("Information"), shall be held in confidence by that Party and shall be handled as follows:

18.1 The Recipient shall:

18.1.1 use the same care and discretion to avoid disclosure, publication or dissemination of the Discloser's Information as it uses with its own similar Information that it does not wish to disclose, publish or disseminate; *and*,

18.1.2 use the Discloser's Information solely for the purpose for which it was disclosed.

18.2 Provided that the Recipient has a written agreement with the following persons or entities requiring them to treat the Information confidential in accordance with the Contract and this Article 18, the Recipient may disclose Information to:

18.2.1 any other party with the Discloser's prior written consent; *and*,

18.2.2 the Recipient's employees, officials, representatives and agents who have a need to know such Information for purposes of performing obligations under the Contract, and employees officials, representatives and agents of any legal entity that it controls, controls it, or with which it is under common control, who have a need to know such

Information for purposes of performing obligations under the Contract, *provided that*, for these purposes a controlled legal entity means:

18.2.2.1 a corporate entity in which the Party owns or otherwise controls, whether directly or indirectly, over fifty percent (50%) of voting shares thereof; *or*,

18.2.2.2 any entity over which the Party exercises effective managerial control; *or*,

18.2.2.3 for the United Nations, a principal or subsidiary organ of the United Nations established in accordance with the Charter of the United Nations.

18.3 The Contractor may disclose Information *to the extent* required by law, *provided that*, subject to and without any waiver of the privileges and immunities of the United Nations, the Contractor will give UNDP sufficient prior notice of a request for the disclosure of Information in order to allow UNDP to have a reasonable opportunity to take protective measures or such other action as may be appropriate before any such disclosure is made.

18.4 UNDP may disclose Information to the extent as required pursuant to the Charter of the United Nations, or pursuant to resolutions or regulations of the General Assembly or rules promulgated thereunder.

18.5 The Recipient shall not be precluded from disclosing Information that is obtained by the Recipient from a third party without restriction, is disclosed by the Discloser to a third party without any obligation of confidentiality, is previously known by the Recipient, or at any time is developed by the Recipient completely independently of any disclosures hereunder.

18.6 These obligations and restrictions of confidentiality shall be effective during the term of the Contract, including any extension thereof, and, unless otherwise provided in the Contract, shall remain effective following any termination of the Contract.

19. FORCE MAJEURE; OTHER CHANGES IN CONDITIONS:

19.1 In the event of and as soon as possible after the occurrence of any cause constituting *force majeure*, the affected Party shall give notice and full particulars in writing to the other Party, of such occurrence or cause if the affected Party is thereby rendered unable, wholly or in part, to perform its obligations and meet its responsibilities under the Contract. The affected Party shall also notify the other Party of any other changes in condition or the occurrence of any event which interferes or threatens to interfere with its performance of the Contract. Not more than fifteen (15) days following the provision of such notice of *force majeure* or other changes in condition or occurrence, the affected Party shall also submit a statement to the other Party of estimated expenditures that will likely be incurred for the duration of the change in condition or the event of *force majeure*. On receipt of the notice or notices required hereunder, the Party not affected by the occurrence of a cause constituting *force majeure* shall take such action as it reasonably considers to be appropriate or necessary in the circumstances, including the granting to the affected Party of a reasonable extension of time in which to perform any obligations under the Contract.

19.2 If the Contractor is rendered unable, wholly or in part, by reason of *force majeure* to perform its obligations and meet its responsibilities under the Contract, UNDP shall have the right to suspend or terminate the Contract on the same terms and conditions as are provided for in Article 20, "Termination," except that the period of notice shall be seven (7) days instead of thirty (30) days. In any case, UNDP shall be entitled to consider the

Contractor permanently unable to perform its obligations under the Contract in case the Contractor is unable to perform its obligations, wholly or in part, by reason of *force majeure* for any period in excess of ninety (90) days.

19.3 *Force majeure* as used herein means any unforeseeable and irresistible act of nature, any act of war (whether declared or not), invasion, revolution, insurrection, terrorism, or any other acts of a similar nature or force, *provided that* such acts arise from causes beyond the control and without the fault or negligence of the Contractor. The Contractor acknowledges and agrees that, with respect to any obligations under the Contract that the Contractor must perform in areas in which UNDP is engaged in, preparing to engage in, or disengaging from any peacekeeping, humanitarian or similar operations, any delays or failure to perform such obligations arising from or relating to harsh conditions within such areas, or to any incidents of civil unrest occurring in such areas, shall not, in and of itself, constitute *force majeure* under the Contract.

20. TERMINATION:

20.1 Either Party may terminate the Contract for cause, in whole or in part, upon thirty (30) day's notice, in writing, to the other Party. The initiation of conciliation or arbitral proceedings in accordance with Article 23 "Settlement of Disputes," below, shall not be deemed to be a "cause" for or otherwise to be in itself a termination of the Contract.

20.2 UNDP may terminate the Contract at any time by providing written notice to the Contractor in any case in which the mandate of UNDP applicable to the performance of the Contract or the funding of UNDP applicable to the Contract is curtailed or terminated, whether in whole or in part. In addition, unless otherwise provided by the Contract, upon sixty (60) day's advance written notice to the Contractor, UNDP may terminate the Contract without having to provide any justification therefor.

20.3 In the event of any termination of the Contract, upon receipt of notice of termination that has been issued by UNDP, the Contractor shall, except as may be directed by UNDP in the notice of termination or otherwise in writing:

20.3.1 take immediate steps to bring the performance of any obligations under the Contract to a close in a prompt and orderly manner, and in doing so, reduce expenses to a minimum;

20.3.2 refrain from undertaking any further or additional commitments under the Contract as of and following the date of receipt of such notice;

20.3.3 place no further subcontracts or orders for materials, services, or facilities, except as UNDP and the Contractor agree in writing are necessary to complete any portion of the Contract that is not terminated;

20.3.4 terminate all subcontracts or orders to the extent they relate to the portion of the Contract terminated;

20.3.5 transfer title and deliver to UNDP the fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the portion of the Contract terminated;

20.3.6 deliver all completed or partially completed plans, drawings, information, and other property that, if the Contract had been completed, would be required to be furnished to UNDP thereunder;

20.3.7 complete performance of the work not terminated; *and*,

20.3.8 take any other action that may be necessary, or that UNDP may direct in writing, for the minimization of losses and for the protection and preservation of any property, whether tangible or intangible, related to the Contract that is in the possession of the Contractor and in which UNDP has or may be reasonably expected to acquire an interest.

20.4 In the event of any termination of the Contract, UNDP shall be entitled to obtain reasonable written accountings from the Contractor concerning all obligations performed or pending in accordance with the Contract. In addition, UNDP shall not be liable to pay the Contractor except for those Goods satisfactorily delivered and/or Services satisfactorily provided to UNDP in accordance with the requirements of the Contract, but only if such Goods or Services were ordered, requested or otherwise provided prior to the Contractor's receipt of notice of termination from UNDP or prior to the Contractor's tendering of notice of termination to UNDP.

20.5 UNDP may, without prejudice to any other right or remedy available to it, terminate the Contract forthwith in the event that:

20.5.1 the Contractor is adjudged bankrupt, or is liquidated, or becomes insolvent, or applies for a moratorium or stay on any payment or repayment obligations, or applies to be declared insolvent;

20.5.2 the Contractor is granted a moratorium or a stay, or is declared insolvent;

20.5.3 the Contractor makes an assignment for the benefit of one or more of its creditors;

20.5.4 a Receiver is appointed on account of the insolvency of the Contractor;

20.5.5 the Contractor offers a settlement in lieu of bankruptcy or receivership; *or*,

20.5.6 UNDP reasonably determines that the Contractor has become subject to a materially adverse change in its financial condition that threatens to substantially affect the ability of the Contractor to perform any of its obligations under the Contract.

20.6 Except as prohibited by law, the Contractor shall be bound to compensate UNDP for all damages and costs, including, but not limited to, all costs incurred by UNDP in any legal or non-legal proceedings, as a result of any of the events specified in Article 20.5, above, and resulting from or relating to a termination of the Contract, even if the Contractor is adjudged bankrupt, or is granted a moratorium or stay or is declared insolvent. The Contractor shall immediately inform UNDP of the occurrence of any of the events specified in Article 20.5, above, and shall provide UNDP with any information pertinent thereto.

20.7 The provisions of this Article 20 are without prejudice to any other rights or remedies of UNDP under the Contract or otherwise.

21. NON-WAIVER OF RIGHTS: The failure by either Party to exercise any rights available to it, whether under the Contract or otherwise, shall not be deemed for any purposes to constitute a waiver by the other Party of any such right or any remedy associated therewith, and shall not relieve the Parties of any of their obligations under the Contract.

22. NON-EXCLUSIVITY: Unless otherwise specified in the Contract, UNDP shall have no obligation to purchase any minimum quantities of goods or services from the

Contractor, and UNDP shall have no limitation on its right to obtain goods or services of the same kind, quality and quantity described in the Contract, from any other source at any time.

23. SETTLEMENT OF DISPUTES:

23.1 AMICABLE SETTLEMENT: The Parties shall use their best efforts to amicably settle any dispute, controversy, or claim arising out of the Contract or the breach, termination, or invalidity thereof. Where the Parties wish to seek such an amicable settlement through conciliation, the conciliation shall take place in accordance with the Conciliation Rules then obtaining of the United Nations Commission on International Trade Law ("UNCITRAL"), or according to such other procedure as may be agreed between the Parties in writing.

23.2 ARBITRATION: Any dispute, controversy, or claim between the Parties arising out of the Contract or the breach, termination, or invalidity thereof, unless settled amicably under Article

23.1, above, within sixty (60) days after receipt by one Party of the other Party's written request for such amicable settlement, shall be referred by either Party to arbitration in accordance with the UNCITRAL Arbitration Rules then obtaining. The decisions of the arbitral tribunal shall be based on general principles of international commercial law. The arbitral tribunal shall be empowered to order the return or destruction of goods or any property, whether tangible or intangible, or of any confidential information provided under the Contract, order the termination of the Contract, or order that any other protective measures be taken with respect to the goods, services or any other property, whether tangible or intangible, or of any confidential information provided under the Contract, as appropriate, all in accordance with the authority of the arbitral tribunal pursuant to Article 26 ("Interim measures") and Article 34 ("Form and effect of the award") of the UNCITRAL Arbitration Rules. The arbitral tribunal shall have no authority to award punitive damages. In addition, unless otherwise expressly provided in the Contract, the arbitral tribunal shall have no authority to award interest in excess of the London Inter-Bank Offered Rate ("LIBOR") then prevailing, and any such interest shall be simple interest only. The Parties shall be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such dispute, controversy, or claim.

24. PRIVILEGES AND IMMUNITIES: Nothing in or relating to the Contract shall be deemed a waiver, express or implied, of any of the privileges and immunities of the United Nations, including its subsidiary organs.

25. TAX EXEMPTION:

25.1 Article II, Section 7, of the Convention on the Privileges and Immunities of the United Nations provides, *inter alia*, that the United Nations, including its subsidiary organs, is exempt from all direct taxes, except charges for public utility services, and is exempt from customs restrictions, duties, and charges of a similar nature in respect of articles imported or exported for its official use. In the event any governmental authority refuses to recognize the exemptions of UNDP from such taxes, restrictions, duties, or charges, the Contractor shall immediately consult with UNDP to determine a mutually acceptable procedure.

25.2 The Contractor authorizes UNDP to deduct from the Contractor's invoices any amount representing such taxes, duties or charges, unless the Contractor has consulted with UNDP before the payment thereof and UNDP has, in each instance, specifically

authorized the Contractor to pay such taxes, duties, or charges under written protest. In that event, the Contractor shall provide UNDP with written evidence that payment of such taxes, duties or charges has been made and appropriately authorized, and UNDP shall reimburse the Contractor for any such taxes, duties, or charges so authorized by UNDP and paid by the Contractor under written protest.

26. MODIFICATIONS:

26.1 No modification or change in this Contract shall be valid and enforceable against UNDP unless executed in writing by the duly authorized representatives of the Parties.

26.2 If the Contract shall be extended for additional periods in accordance with the terms and conditions of the Contract, the terms and conditions applicable to any such extended term of the Contract shall be the same terms and conditions as set forth in the Contract, unless the Parties shall have agreed otherwise pursuant to a valid amendment concluded in accordance with Article 26.1, above.

26.3 The terms or conditions of any supplemental undertakings, licenses, or other forms of agreement concerning any Goods or Services provided under the Contract shall not be valid and enforceable against UNDP nor in any way shall constitute an agreement by UNDP thereto unless any such undertakings, licenses or other forms are the subject of a valid amendment concluded in accordance with Article 26.1, above.

27. AUDITS AND INVESTIGATIONS:

27.1 Each invoice paid by UNDP shall be subject to a post-payment audit by auditors, whether internal or external, of UNDP or by other authorized and qualified agents of UNDP at any time during the term of the Contract and for a period of three (3) years following the expiration or prior termination of the Contract.

27.2 UNDP may conduct investigations relating to any aspect of the Contract or the award thereof, the obligations performed under the Contract, and the operations of the Contractor generally relating to performance of the Contract at any time during the term of the Contract and for a period of three (3) years following the expiration or prior termination of the Contract.

27.3 The Contractor shall provide its full and timely cooperation with any such inspections, post- payment audits or investigations. Such cooperation shall include, but shall not be limited to, the Contractor's obligation to make available its personnel and any relevant documentation for such purposes at reasonable times and on reasonable conditions and to grant to UNDP access to the Contractor's premises at reasonable times and on reasonable conditions in connection with such access to the Contractor's personnel and relevant documentation. The Contractor shall require its agents, including, but not limited to, the Contractor's attorneys, accountants or other advisers, to reasonably cooperate with any inspections, post-payment audits or investigations carried out by UNDP hereunder.

27.4 UNDP shall be entitled to a refund from the Contractor for any amounts shown by such audits or investigations to have been paid by UNDP other than in accordance with the terms and conditions of the Contract. The Contractor also agrees that, where applicable, donors to UNDP whose funding is the source of, in whole or in part, the funding for the procurement of Goods and/or Services which are the subject of this Contract, shall have direct recourse to the Contractor for the recovery of any funds determined by UNDP to have been used in violation of or inconsistent with this Contract.

28. LIMITATION ON ACTIONS:

28.1 Except with respect to any indemnification obligations in Article 12, above, or as are otherwise set forth in the Contract, any arbitral proceedings in accordance with Article 23.2, above, arising out of the Contract must be commenced within three years after the cause of action has accrued.

28.2 The Parties further acknowledge and agree that, for these purposes, a cause of action shall accrue when the breach actually occurs, or, in the case of latent defects, when the injured Party knew or should have known all of the essential elements of the cause of action, or in the case of a breach of warranty, when tender of delivery is made, except that, if a warranty extends to future performance of the goods or any process or system and the discovery of the breach consequently must await the time when such goods or other process or system is ready to perform in accordance with the requirements of the Contract, the cause of action accrues when such time of future performance actually begins.

29. ESSENTIAL TERMS: The Contractor acknowledges and agrees that each of the provisions in Articles 30 to 36 hereof constitutes an essential term of the Contract and that any breach of any of these provisions shall entitle UNDP to terminate the Contract or any other contract with UNDP immediately upon notice to the Contractor, without any liability for termination charges or any other liability of any kind. In addition, nothing herein shall limit the right of UNDP to refer any alleged breach of the said essential terms to the relevant national authorities for appropriate legal action.

30. SOURCE OF INSTRUCTIONS: The Contractor shall neither seek nor accept instructions from any authority external to UNDP in connection with the performance of its obligations under the Contract. Should any authority external to UNDP seek to impose any instructions concerning or restrictions on the Contractor's performance under the Contract, the Contractor shall promptly notify UNDP and provide all reasonable assistance required by UNDP. The Contractor shall not take any action in respect of the performance of its obligations under the Contract that may adversely affect the interests of UNDP or the United Nations, and the Contractor shall perform its obligations under the Contract with the fullest regard to the interests of UNDP.

31. STANDARDS OF CONDUCT: The Contractor warrants that it has not and shall not offer any direct or indirect benefit arising from or related to the performance of the Contract, or the award thereof, to any representative, official, employee or other agent of UNDP. The Contractor shall comply with all laws, ordinances, rules and regulations bearing upon the performance of its obligations under the Contract. In addition, in the performance of the Contract, the Contractor shall comply with the Standards of Conduct set forth in the Secretary General's Bulletin ST/SGB/2002/9 of 18 June 2002, entitled "Regulations Governing the Status, Basic Rights and Duties of Officials other than Secretariat Officials, and Expert on Mission" and ST/SGB/2006/15 of 26 December 2006 on "Post-employment restrictions", and shall also comply with and be subject to the requirements of the following documents then in force at the time of signature of the Contract:

31.1 The UN Supplier Code of Conduct;

31.2 UNDP Policy on Fraud and other Corrupt Practices ("UNDP Anti-fraud Policy");

31.3 UNDP Office of Audit and Investigations (OAI) Investigation Guidelines;

31.4 UNDP Social and Environmental Standards (SES), including the related Accountability Mechanism;

31.5 UNDP Vendor Sanctions Policy; and

31.6 All security directives issued by UNDP.

The Contractor acknowledges and agrees that it has read and is familiar with the requirements of the foregoing documents which are available online at www.undp.org or at <http://www.undp.org/content/undp/en/home/operations/procurement/business/>. In making such acknowledgement, the Contractor represents and warrants that it is in compliance with the requirements of the foregoing, and will remain in compliance throughout the term of this Contract.

32. OBSERVANCE OF THE LAW: The Contractor shall comply with all laws, ordinances, rules, and regulations bearing upon the performance of its obligations under the Contract. In addition, the Contractor shall maintain compliance with all obligations relating to its registration as a qualified vendor of goods or services to UNDP, as such obligations are set forth in UNDP vendor registration procedures.

33. CHILD LABOR: The Contractor represents and warrants that neither it, its parent entities (if any), nor any of the Contractor's subsidiary or affiliated entities (if any) is engaged in any practice inconsistent with the rights set forth in the Convention on the Rights of the Child, including Article 32 thereof, which, *inter alia*, requires that a child shall be protected from performing any work that is likely to be hazardous or to interfere with the child's education, or to be harmful to the child's health or physical, mental, spiritual, moral, or social development.

34. MINES: The Contractor represents and warrants that neither it, its parent entities (if any), nor any of the Contractor's subsidiaries or affiliated entities (if any) is engaged in the sale or manufacture of anti-personnel mines or components utilized in the manufacture of anti-personnel mines.

35. SEXUAL EXPLOITATION:

35.1 In the performance of the Contract, the Contractor shall comply with the Standards of Conduct set forth in the Secretary-General's bulletin ST/SGB/2003/13 of 9 October 2003, concerning "Special measures for protection from sexual exploitation and sexual abuse." In particular, the Contractor shall not engage in any conduct that would constitute sexual exploitation or sexual abuse, as defined in that bulletin.

35.2 The Contractor shall take all appropriate measures to prevent sexual exploitation or abuse of anyone by its employees or any other persons engaged and controlled by the Contractor to perform