# **INVITATION TO BID**

# Procurement of medical products for diagnostics and treatment of <u>children</u> with oncological and oncohematological diseases; and for patients in pre- and post-transplant period

For the National Public Health Programme to the Ministry of Health (MoH) in Ukraine

104-2018-UNDP-UKR-ITB-HP

Ukraine



United Nations Development Programme
August 2018

## Section 1. Letter of Invitation



#### 104-2018-UNDP-UKR-ITB-HP

# Procurement of medical products for diagnostics and treatment of children with oncological and oncohematological diseases; and for patients in pre- and post-transplant period

Dear Bidders,

The Government of Ukraine is in urgent need to secure medicines and essential health commodities at affordable prices and in sufficient quantities. Following recently adopted legislation allowing selected international organizations to provide procurement support services, the Ministry of Health of Ukraine has requested the United Nations Development Programme (UNDP) to support the procurement and distribution of a number of 2017 State Programme medicines and other medical products as an emergency measure.

Therefore, the United Nations Development Programme (UNDP) hereby invites you to submit a Bid in response 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

Section 5 – Bid Submission Form

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

Section 7 – Technical Bid Form

Section 8 - Price Schedule Form

Section 9 – Form for Performance Security (may be required from winning entity)

Section 10 - Template of Purchase Order and General Terms and Conditions for Goods

# Your offer, comprising of the Technical and Financial Proposal in one archived file, should be submitted in accordance with Section 2.

You are kindly requested to submit an acknowledgment letter to UNDP to the following address:

United Nations Development Programme in Ukraine health.procurement.ua@undp.org
Attention: Procurement Unit

Mandatory subject of email: 104-2018-UNDP-UKR-ITB-HP Procurement of medical products

The letter should be received by UNDP *preferably* no later than August 24, 2018. The same letter should advise whether your company intends to submit a Bid. 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,

Andra Brige

Ms. Andra Brige, Deputy Country Director (Operations)

Yana Dongs

Procurement Analyst

United Nations Development Programme

#### **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.
- "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 <a href="http://www.undp.org/content/dam/undp/library/corporate/Procurement/english/Procurement%20Fraud%20Notice.pdf">http://www.undp.org/content/undp/library/corporate/Procurement/english/Procurement%20Fraud%20Notice.pdf</a> otice.pdf</a>and <a href="http://www.undp.org/content/undp/en/home/operations/procurement/protestandsanctions/forfull description of the policies">http://www.undp.org/content/undp/en/home/operations/procurement/protestandsanctions/forfull description of the policies</a>)
- 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: <a href="http://www.undp.org/content/dam/undp/documents/procurement/documents/UNDP\_supplier\_code\_of\_cond-uct.pdf">http://www.undp.org/content/dam/undp/documents/procurement/documents/UNDP\_supplier\_code\_of\_cond-uct.pdf</a>

#### **B. CONTENTS OF BID**

#### 9. Sections of Bid

Bidders are required to complete, sign and submit the following documents as 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 in writing, transmitted by electronic means and will transmit copies of the response (including an explanation of the query but without identifying the source of inquiry) to all Bidders who have provided confirmation of their intention to submit a Bid.
- 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

- 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. All prospective Bidders will be notified in writing of all changes/amendments and additional instructions through Supplemental Information to the ITB and 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** (DSnoS.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 licences 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 and the Bid may be rejected by UNDP, 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),
  - c) Original Bid Security is not provided within specified period of time (as per DS #26, 35) or;
  - d) 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 **Data Sheet** (DS no. 15). 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 **Data Sheet** (DS no. 15), 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 6, 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 <u>any</u> 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 <u>not</u> result in disqualification of an interested Bidder. Minutes of the Bidder's conference will be either posted on the UNDP website, or disseminated to the individual firms who have registered or expressed interest with the contract, whether or not they attended the conference. 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 the Price Schedule <u>must</u> be <u>submitted</u> by electronic method of transmission at the Bid submission address indicated in the data sheet.
- 23.2 Bidders must submit their Bid in the manner specified in the **Data Sheet** (DS nos. 22 and 23). When the Bid is expected to be in transit for more than 24 hours, the Bidder must ensure that sufficient lead time has been provided in order to comply with UNDP's deadline for submission. UNDP shall indicate for its record that the official date and time of receiving the Bid is the <u>actual</u> date and time when the said Bid has physically arrived at the UNDP premises indicated in the **Data Sheet** (DS no. 20).
- 23.3 The number of copies required shall be as specified in the **Data Sheet** (DS no. 19). The copy of Bid shall be signed or initialed by the Bidder or person(s) duly authorized to commit the Bidder on every page. The authorization shall be communicated through a document evidencing such authorization issued by the

highest official of the firm, or a Power of Attorney, accompanying the Bid.

23.4 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. Deadline for Submission of Bid and Late Bids

Bid must be received by UNDP at the address and no later than the date and time specified in the **Data Sheet** (DSno.20 and 21).

UNDP shall not consider any Bid that arrives after the deadline for submission of Bid. Any Bid received by UNDP after the deadline for submission of Bid shall be declared late, rejected, and returned unopened to the Bidder.

#### 25. Withdrawal, Substitution, and Modification of Bid

- 25.1 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.
- 25.2 A Bidder may withdraw, substitute or modify its Bid after it has been submitted by sending a written notice in accordance with ITB Clause 23, duly signed by an authorized representative, and shall include a copy of the authorization (or a Power of Attorney). The corresponding substitution or modification of the Bid must accompany the respective written notice. All notices must be received by UNDP prior to the deadline for submission and submitted in accordance with ITB Clause 23 (except that withdrawal notices do not require copies). The respective envelopes shall be clearly marked "WITHDRAWAL," "SUBSTITUTION," or MODIFICATION".
- 25.3 Bid requested to be withdrawn shall be returned unopened to the Bidders.
- 25.4 No Bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of Bid and the expiration of the period of Bid validity specified by the Bidder on the Bid Submission Form or any extension thereof.

#### 26. Bid Opening

UNDP will open the Bid in the presence of an ad-hoc committee formed by UNDP of at least two (2) members. If electronic submission is permitted, any specific electronic Bid opening procedures shall be as specified in the **Data Sheet** (DS no. 23).

The Bidders' names, modifications, withdrawals, the condition of the envelope labels/seals, the number of folders/files and all other such other details as UNDP may consider appropriate, will be announced at the opening. No Bid shall be rejected at the opening stage, except for late submission, for which the Bid shall be returned unopened to the Bidder.

#### 27. 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**

#### 28. 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.

#### 29. Evaluation of Bid

- 29.1 UNDP shall examine the Bid to confirm that all terms and conditions under the UNDP General Terms and Conditions and Special Conditions have been accepted by the Bidder without any deviation or reservation.
- 29.2 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.
- 29.3 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.

#### 30. 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.

#### 31. 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.

#### 32. Nonconformities, Reparable Errors and Omissions

- 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.
- 32.2 Provided that a Bid is substantially responsive, UNDP may request the Bidder to submit the necessary information or documentation, within a reasonable period of time, to rectify nonmaterial nonconformities or omissions in the Bid related to documentation requirements. Such omission shall not be related to any aspect of the price of the Bid. Failure of the Bidder to comply with the request may result in the rejection of its Bid.
- 32.3 Provided that the Bid is substantially responsive, UNDP shall correct arithmetical errors as follows:
  - a) if there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price shall prevail and the line item total shall be corrected, unless in the opinion of UNDP there is an obvious misplacement of the decimal point in the unit price, in which case the line item total as quoted shall govern and the unit price shall be corrected;
  - b) if there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and
  - c) if there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to the above.
- 32.4 If the Bidder does not accept the correction of errors made by UNDP, its Bid shall be rejected.

#### F. AWARD OF CONTRACT

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

- 33.1 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.
- 33.2 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/

#### 34. 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).

#### 35. 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.

#### 36. 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.

#### 37. Performance Security

A performance security, if required, shall be provided in the amount and form provided in Section 10 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.

#### 38. 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).

#### 39. 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/content/undp/en/home/operations/procurement/business/protest-and-sanctions.html

## **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
2		Title of Goods/Services/Work Required:	Procurement of medical products for diagnostics and treatment of children with oncological and oncohematological diseases; and for patients in pre- and post-transplant period in 63 lots, in accordance with the Technical Specifications as per Section 3.
3		Country:	Ukraine
4	C.13	Language of the Bid:	<ul> <li>☑ English</li> <li>As this particular procurement case is subject to review and approval by UNDP HQ Advisory Committee on Procurement, Members of which are English speakers, the Bidders are requested to submit their Bids in English.</li> <li>☑ Ukrainian/Russian</li> </ul>
6	C.20	Conditions for Submitting Bid for Parts or sub-parts of the Total Requirements  Conditions for Submitting	☐ The Bidder may submit Bid for separate Lots/Items  However, Bidders are encouraged to quote for as many Lots/Items as possible.
		Alternative Bid	Shall not be considered
7	C.22	A pre-Bid conference will be held on:	Time: 15:00 hrs local time Date: August 27, 2018 Venue: Conference Room "Alexanyan"; UN Office in Ukraine; 1 Klovskyi descent, Kyiv Companies can participate at pre-bid conference through skype conference as well. Interested companies should send confirmations by email.

8	C.21.1	Period of Bid Validity commencing on the submission date	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  ☐ 60 days ☐ 90 days ☐ 120 days
9	B.9.5 C.15.4 b)	Bid Security	Not required
10	B.9.5	Acceptable forms of Bid Security	N/a
11	B.9.5 C.15.4 a)	Validity of Bid Security	N/a
12		Advanced Payment upon signing of contract	⊠ Not allowed
13		Liquidated Damages	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, up to maximum deduction of 10% of the value of the Purchase Order. Once the maximum is reached, UNDP may consider termination of the PO.
14	F.37	Performance Security	<ul> <li>☑ Will be required from winning entity for all contracts (Purchase Orders) exceeding 300,000 USD OR upon discretion of UNDP as per template provided in the Section 10</li> <li>Amount: 10 % of the contract amount Form: Bank guarantee.</li> </ul>
15	C.17 C.17.2	Preferred Currency of Bid and Method for Currency conversion	☑ United States Dollars (USD) - strongly advised to use as a risk mitigation measure against the impact of the local currency devaluation.  UNDP will execute payments in USD to international suppliers.  Payments to local (Ukrainian) suppliers will be executed either in USD or UAH 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.

			■ Local Currency (UAH)  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)
16	B.10.1	Deadline for submitting requests for clarifications/ questions	5 calendar days before the submission date.
17	B.10.1	Contact Details for submitting clarifications/questions	Focal Person in UNDP: Procurement Unit Tel. No.:+38 044 253 93 63  E-mail address dedicated for this purpose: health.procurement.ua@undp.org
18	B.11.1	Manner of Disseminating Supplemental Information to the ITB and responses/clarifications to queries	☐ Direct communication to prospective Bidders by email, and Posting on the website http://procurement-notices.undp.org/
19	D.23.3	No. of copies of Bid that must be submitted	1 (one)
20	D.23.1 b) D.23.2 D.24	Bid submission address	tenders.ua@undp.org  Please note that bids received through any other address will not be considered.
21	C.21.1 D.24	Deadline of Bid Submission	Date and Time: September 13, 2018 10:00 AM, Kyiv time (UTC +3:00)
22	D.23.2	Manner of Submitting Bid	☑ Electronic submission of Bid for technical and financial offers
23	D.23.2 D.26	Conditions and Procedures for electronic submission and opening, if allowed	<ul> <li>☑ Official Address for e-submission: tenders.ua@undp.org</li> <li>☑ Format: PDF files preferred in ZIP archives only.</li> <li>☑ Max. File Size per transmission: [5 MB]</li> <li>☑ Max. No. of transmission: [10]</li> <li>No. of copies to be transmitted: [1]</li> <li>☑ Mandatory subject of email: 104-2018-UNDP-UKR-ITB-HP Procurement of medical products</li> <li>Bidders MUST indicate clearly in the e-mail for which LOT they</li> </ul>
			are submitting a Bid for.  ☑ Virus Scanning Software to be Used prior to transmission: [Files should not contain any viruses or malware software.] ☑ Time Zone to be Recognized: [UTC +3, Kyiv time]

			☑ Other conditions:
			PLEASE make all efforts to provide your proposal in 1 archived PDF file not exceeding 5 MB size.
			Bidders are solely responsible for ensuring that any and all files sent to UNDP are readable, that is, uncorrupted, in the indicated electronic format, and free from viruses and malware. Failure to provide readable files will result in the Bid being rejected.
			Please take into consideration the fact that emails are delivered within 5-10 mins, therefore avoid last minute submission, which might lead to late submission.
24	D.23.1 c)	Date, time and venue for opening of Bid	Date and Time: September 13, 2018 3:00 PM, Kyiv time (UTC +3:00)
			Any bidder that intends to participate in the public bid opening shall notify UNDP by address <a href="mailto:health.procurement.ua@undp.org">health.procurement.ua@undp.org</a> at least 24 hours in advance.
			Companies can participate at the Bid Opening procedure through skype conference as well. Interested companies should send confirmations by email.
			<b>Venue:</b> UNDP Ukraine CO conference room Address: Alexanian conference hall; UN Office in Ukraine; 1 Klovskyi descent, Kyiv.
25		Evaluation method to be used in selecting the most responsive Bid	As per DS # 32
26	C.15.1	Required Documents that must be Submitted to Establish Qualification of Bidders	☑ Duly filled-in, signed and stamped Sections 4-8.
			☑ 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".
27		Other documents that may be Submitted to Establish Eligibility	N/A
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	October 15, 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:	☑ One Bidder, depending on the following factors: Lowest-priced technically responsive offer per Lot.
			*) 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.
32	F.34	Criteria for the Award and Evaluation of Bid	Award Criteria
			☑ 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"
			AND
			<ul> <li>☑ Lowest price offer of technically qualified/responsive Bid per Lot</li> <li>*) 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.</li> </ul>
33	E.29	Post qualification Actions	<ul> <li>✓ Verification of accuracy, correctness and authenticity of the information provided by the bidder on the legal, technical and financial documents submitted;</li> <li>✓ Validation of extent of compliance to the ITB requirements and evaluation criteria based on what has so far been found by the evaluation team;</li> <li>✓ Inquiry and reference checking with other previous clients on the quality of performance on ongoing or previous contracts completed.</li> </ul>
34		Conditions for Determining Contract Effectivity	☑ Provision of Performance Security (if requested by UNDP)
35		Other Information Related to the ITB	Administrative Requirements:
			Prior to technical evaluation, submitted offers will be reviewed on a "Pass" or "Fail" basis to determine compliance with the below formal criteria/requirements:  ☑ Bids must be submitted within the stipulated deadline; ☑ Bids must meet required Bid Validity;

				_	-			authority
	⊠ Full cor	nplianc	e and ag	greement	t with	UND	P General	terms and
	condition	S	availa	ıble	by	/	the	link:
	http://wv	vw.und	p.org/co	ontent/da	am/u	ndp/c	locument	s/procure
	ment/doo	ument	s/genco	nditionp	urcha	seord	lers.pdf.	
	Other	inf	ormatio	n	is		available	on
	http://wv	vw.ua.u	ındp.org	contengi	t/ukra	aine/e	en/home/	operation
	s/procure	ment.h	<u>tml</u>					
	For	inf	formation	on,		pleas	e	contact
	health.pro	ocurem	ent.ua@	undp.or	g			
		⊠ Full cor condition http://wv ment/doc Other http://wv s/procure For	☐ Full compliance conditions  http://www.und  ment/documents  Other inf  http://www.ua.u s/procurement.h  For inf	☐ Full compliance and ag conditions availant http://www.undp.org/coment/documents/gencoolong of the compliance and ag conditions availant http://www.undp.org/coment/documents/gencoolong of the compliance and ag conditions availant http://www.undp.org/coment.//www.undp.org/coment.html  For information information in the compliance and ag conditions availant http://www.undp.org/coment.html  For information in the compliance and ag conditions availant http://www.undp.org/coment.//w	Full compliance and agreement conditions available http://www.undp.org/content/dament/documents/genconditionpotent/documents/genconditionpotent/documents/genconditionpotent/documents/genconditionpotent/documents/genconditionpotent/genconditi	☐ Full compliance and agreement with conditions available by <a href="http://www.undp.org/content/dam/ument/documents/genconditionpurcha">http://www.undp.org/content/dam/ument/documents/genconditionpurcha</a> Other information is <a href="http://www.ua.undp.org/content/ukras/procurement.html">http://www.ua.undp.org/content/ukras/procurement.html</a>	☐ Full compliance and agreement with UND conditions available by <a href="http://www.undp.org/content/dam/undp/coment/documents/genconditionpurchaseord">http://www.undp.org/content/dam/undp/coment/documents/genconditionpurchaseord</a> Other information is <a href="http://www.ua.undp.org/content/ukraine/ess/procurement.html">http://www.ua.undp.org/content/ukraine/ess/procurement.html</a> For information, please	☐ Full compliance and agreement with UNDP General conditions available by the <a href="http://www.undp.org/content/dam/undp/documentment/documents/genconditionpurchaseorders.pdf">http://www.undp.org/content/dam/undp/documentment/documents/genconditionpurchaseorders.pdf</a> .  Other information is available <a href="http://www.ua.undp.org/content/ukraine/en/home/s/procurement.html">http://www.ua.undp.org/content/ukraine/en/home/s/procurement.html</a> For information, please

#### Section 3:

## **Schedule of Requirements and Technical Specifications**

#### 1. EXECUTIVE SUMMARY

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.

As of now UNDP has signed 2018 CSA for 24 programmes, further 3 programmes are expected to be passed to UNDP.

Under the State budget of 2016, UNDP successfully procured medicines and medical products for 23 state health programs, managing to achieve significant savings.

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.

The main objective of ITB is to source high quality medical supplies from reliable suppliers and in accordance with the value-for-money principle needed to meet the current health crisis. This ITB targets to source medical products for diagnostics and treatment of children with oncological and oncohematological diseases; and for patients in pre- and post-transplant period for the State budget of 2017 year.

#### **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. PRODUCT SPECIFICATION:

Nº	Name of medical product	Presentation	Quantity
Medical p	roducts for diagnostics and treatment of <u>children</u> with oncological and or	ncohematological	diseases
Medical prod			
1	Double-way set Double-lumen pediatric catheter set for catheterization of the central vein 4,2 Fr type Broviac or equivalent	рс	44
2	Double-lumen pediatric catheterway set for catheterization of the central vein 6,6 Fr type Broviac or equivalent	рс	127
3	Double-way lumen pediatric catheter set for catheterization of the central vein 7 Fr type Hickman or equivalent	рс	25
4	Leukocyte Reduction Filter or device for Platelet Concentrate (for bedside application)	рс	2525
5	SAG-M conservation medium, bag with 100 ml solution	рс	298
6	C4L Platelet Set (5-day storage)	set	50
7	Set for collection of Red Blood Cells with filter for Automated Complex Apheresis device MCS+ (for platelet concentrate collection)	Kit	320
8	Dual Needle Extended Life Platelet Set with LRS Chamber for COBE Spectra Apheresis System (or equivalent)	set	150
Reagents an tumors of chi	nd medical devices for immunohistochemical and morphological diagnostics ar ildhood	nd differential diagn	osis of solid
9	CD38 Mouse Monoclonal Antibody CD38	pack	1
10	OST1 Mouse Anti-Human Osteonectin	pack	1
11	Dispenser tips, 300 mcm	pack	5
solid tumors.	, detect micrometastases, minimal residual disease and monitor the effectivene	ss of therapy using	polymerase
chain reactio	on method on Applied Biosystems 7300/7500 Real-Time PCR	viole	2
	Sodium bisulfite	vials	2
chain reaction 12 13	Sodium bisulfite Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA	50 preps/sets	7
12 13 Laboratory i micrometasta	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and seleases, minimal residual disease and monitor the effectiveness of therapy of pacence in situ hybridization (FISH) applying fluorescent microscope	50 preps/sets	7 tegy, detect
12 13 Laboratory micrometasta using fluores 14	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and seleases, minimal residual disease and monitor the effectiveness of therapy of parameters of the process of the studies in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set	50 preps/sets ect treatment stratediatric malignant stratediatric malignatric	7 regy, detect solid tumors
12 13 Laboratory micrometasta using fluores 14 15	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and sele ases, minimal residual disease and monitor the effectiveness of therapy of p scence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set TP53 / CEP 17 FISH Dual Color DNA Probe Kit	50 preps/sets ect treatment stratediatric malignant stratediatric malignant stratediatric makes	7 detect solid tumors 3 4
Laboratory micrometasta using fluores  14  15  16	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and seleases, minimal residual disease and monitor the effectiveness of therapy of percence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit	50 preps/sets ect treatment stratediatric malignant stratediatric malignatric	7 regy, detect solid tumors 3 4 1
12 13 Laboratory micrometasta using fluores 14 15	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and sele ases, minimal residual disease and monitor the effectiveness of therapy of p scence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit PathVysion HER-2 DNA Probe Kit	50 preps/sets ect treatment stratediatric malignant stratediatric malignant stratediatric makes	7 detect solid tumors 3 4
Laboratory micrometasta using fluores  14  15  16  17  18	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and selected asses, minimal residual disease and monitor the effectiveness of therapy of percence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  PathVysion HER-2 DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe	50 preps/sets ect treatment stratediatric malignant st	7 regy, detect solid tumors  3 4 1 5 1
Laboratory micrometasta using fluores  14  15  16  17	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and sele ases, minimal residual disease and monitor the effectiveness of therapy of p scence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit PathVysion HER-2 DNA Probe Kit	50 preps/sets ect treatment stratediatric malignant st	7 deegy, detect solid tumors  3 4 1 5
Laboratory micrometasta using fluores  14  15  16  17  18  19  20	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and selected asses, minimal residual disease and monitor the effectiveness of therapy of parameters in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  PathVysion HER-2 DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI SS18 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI FUS Dual Color Break Apart Rearrangement DNA Probe Kit	50 preps/sets ect treatment stratediatric malignant st	regy, detect solid tumors  3 4 1 5 1 2 1
Laboratory micrometasta using fluores  14  15  16  17  18  19  20  Laboratory relationship in the second se	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and selected asses, minimal residual disease and monitor the effectiveness of therapy of personner in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  PathVysion HER-2 DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI FUS Dual Color Break Apart Rearrangement DNA Probe Kit  eagents for immunocytological diagnosis of oncohematological diseases and indual illness (by method of multiparameter flow cytometry using flow cytofluorom	50 preps/sets  ect treatment stratediatric malignant s	regy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of
Laboratory micrometasta using fluores  14  15  16  17  18  19  20  Laboratory relationship in the second se	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and sele ases, minimal residual disease and monitor the effectiveness of therapy of p scence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  PathVysion HER-2 DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe LSI SS18 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI FUS Dual Color Break Apart Rearrangement DNA Probe Kit eagents for immunocytological diagnosis of oncohematological diseases and ir	50 preps/sets  ect treatment stratediatric malignant s	regy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of
Laboratory reminimal resident	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and selected asses, minimal residual disease and monitor the effectiveness of therapy of personner in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  PathVysion HER-2 DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI FUS Dual Color Break Apart Rearrangement DNA Probe Kit  eagents for immunocytological diagnosis of oncohematological diseases and indual illness (by method of multiparameter flow cytometry using flow cytofluorom	packs	regy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of
chain reaction 12 13 Laboratory in micrometasta using fluores 14 15 16 17 18 19 20 Laboratory reminimal residents	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and selection asses, minimal residual disease and monitor the effectiveness of therapy of paragraphs of paragraphs of the paragra	packs	regy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of
chain reaction 12 13 Laboratory in micrometasta using fluores 14 15 16 17 18 19 20 Laboratory reminimal residents	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and selected asses, minimal residual disease and monitor the effectiveness of therapy of pacence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  PathVysion HER-2 DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe  LSI SS18 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI FUS Dual Color Break Apart Rearrangement DNA Probe Kit  eagents for immunocytological diagnosis of oncohematological diseases and indual illness (by method of multiparameter flow cytometry using flow cytofluorom Monoclonal Antibody to CD2, Fluorochrome FITC, 100 tests  Monoclonal Antibody to CD3, Fluorochrome ECD, 100 tests	packs	acegy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of 1 3
chain reaction 12 13 Laboratory in micrometasta using fluores 14 15 16 17 18 19 20 Laboratory reminimal resident services 21 22 23	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and seleases, minimal residual disease and monitor the effectiveness of therapy of poscence in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  PathVysion HER-2 DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI FUS Dual Color Break Apart Rearrangement DNA Probe Kit  eagents for immunocytological diagnosis of oncohematological diseases and indual illness (by method of multiparameter flow cytometry using flow cytofluorom Monoclonal Antibody to CD2, Fluorochrome FITC, 100 tests  Monoclonal Antibody to CD3, Fluorochrome PC5, 100 tests  Monoclonal Antibody to CD3, Fluorochrome PC5, 100 tests	packs	acegy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of 1 3 10
chain reaction 12 13 Laboratory in micrometasta using fluores 14 15 16 17 18 19 20 Laboratory reminimal resident signification of the micrometasta using fluores 21 22 23 24	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and sele ases, minimal residual disease and monitor the effectiveness of therapy of parameters in situ hybridization (FISH) applying fluorescent microscope  LSI 1p36 / LSI 1q25 and LSI 19q13 / LSI 19p13 Dual Color DNA Probe Set  TP53 / CEP 17 FISH Dual Color DNA Probe Kit  LSI IGH/MYC/CEP 8 Tripple Color DNA Probe Kit  LSI DDIT3 Dual Color Break Apart Rearrangement DNA Probe  LSI SS18 Dual Color Break Apart Rearrangement DNA Probe Kit  LSI FUS Dual Color Break Apart Rearrangement DNA Probe Kit  eagents for immunocytological diagnosis of oncohematological diseases and indual illness (by method of multiparameter flow cytometry using flow cytofluorom Monoclonal Antibody to CD2, Fluorochrome FITC, 100 tests  Monoclonal Antibody to CD3, Fluorochrome PC5, 100 tests  Monoclonal Antibody to CD4, Fluorochrome PC5, 100 tests  Monoclonal Antibody to CD4, Fluorochrome PC5, 100 tests	packs	acegy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of 1 3 10 8
chain reaction 12 13 Laboratory I micrometasta using fluores 14 15 16 17 18 19 20 Laboratory I minimal residual	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and sele asses, minimal residual disease and monitor the effectiveness of therapy of paragraph of paragraph of paragraph of the properties of the properties of the properties of the paragraph of par	packs	7 tegy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of 1 3 10 8 3
chain reaction 12 13 Laboratory in micrometasta using fluores 14 15 16 17 18 19 20 Laboratory reminimal resident signification of the micrometasta using fluores 21 22 23 24 25 26	Sodium bisulfite  Set or extraction of RNA and DNA from paraffin-embedded samples NucleoSpin FFPE RNA/DNA  reagents for molecular cytogenetic studies to confirm diagnosis and sele ases, minimal residual disease and monitor the effectiveness of therapy of paragraph	packs	acegy, detect solid tumors  3 4 1 5 1 2 1 nonitoring of 1 3 10 8 3 1

Nº	Name of medical product	Presentation	Quantity
30	Monoclonal Antibody to CD11b, Fluorochrome PE, 100 tests	vials	1
31	Monoclonal Antibody to CD14, Fluorochrome FITC, 100 tests	vials	1
32	Monoclonal Antibody to CD15, Fluorochrome PE, 100 tests	vials	2
33	Monoclonal Antibody to CD16, Fluorochrome FITC, 100 tests	vials	1
34	Monoclonal Antibody to CD19, Fluorochrome ECD, 100 tests	vials	3
35	Monoclonal Antibody to CD19, Fluorochrome PC5, 100 tests	vials	11
36	Monoclonal Antibody to CD24, Fluorochrome PE, 100 tests	vials	1
37	Monoclonal Antibody to CD33, Fluorochrome PC5, 100 tests	vials	4
38	Monoclonal Antibody to CD38, Fluorochrome PE, 100 tests	vials	2
39	Monoclonal Antibody to CD42a, Fluorochrome FITC, 100 tests	vials	1
40	Monoclonal Antibody to CD42b, Fluorochrome FITC, 100 tests	vials	1
41	Monoclonal Antibody to CD44, Fluorochrome FITC, 100 tests	vials	1
42	Monoclonal Antibody to CD45, Fluorochrome ECD, 100 tests	vials	23
43	Monoclonal Antibody to CD56, Fluorochrome PE, 100 tests	vials	1
44	Monoclonal Antibody to CD56, Fluorochrome PC5, 100 tests	vials	1
45	Monoclonal Antibody to CD58, Fluorochrome FITC, 100 tests	vials	7
46	Monoclonal Antibody to CD59, Fluorochrome PE, 100 tests	vials	1
47	Monoclonal Antibody to CD61, Fluorochrome PE, 100 tests	vials	1
48	Monoclonal Antibody to CD64, Fluorochrome PE, 2 ml	vials	1
49	Monoclonal Antibody to Anti-MPO, Fluorochrome FITC, 100 tests	vials	1
50	Monoclonal Antibody to HLA-DR, Fluorochrome FITC, 100 tests	vials	2
51	Monoclonal Antibody to Anti-TdT, Fluorochrome FITC, 50 tests	vials	3
52	Lysing solution for intracellular antigen analysis IntraPrep, 150 tests or equivalent	packs	6
53	Lysing solution Optilyse, 200 tests or equivalent	vials	25
54	Test Tube, 12X75MM, Blue (250/PK) Analysis tubes, 12 x 75 mm, blue (250 units in a pack)	packs	30
55	Monoclonal Antibody to CD157, Fluorochrome PE, 50 tests	vials	1
56	Monoclonal Antibody to CD15, Fluorochrome PC5, 50 tests	vials	1
Reagents for	molecular genetic studies  TelVysion Probe 21q Spectrum Green (5 µl in a pack), Abbott Molecular,		
57	Inc., or equivalent	sets	2
58	LeukoStrat™ FLT3 Mutation Assay Set for PCR-based detection of FLT3 mutations in agarose gel (33 reactions), Invivoscribe Technologies, Inc. USA, or equivalent	sets	1
59	LSI p53 (17p13.1) Spectrum Orange Probe translocation probe set, Abbott Molecular, Inc., USA, or equivalent	sets	1
60	LSI TCF3 Spectrum Green Probe translocation probe set, Abbott Molecular, Inc., USA, or equivalent	sets	1
61	Vysis LSI MECOM Spectrum Orange FISH Probe, Abbott Molecular, Inc., USA, or equivalent	sets	1
	Medical products for patients in pre- and post-transplant pe	T.	
Nº	Name of medical device	Presentation	Quantity
62	Consumables for dialysis patients who are being prepared to transplantation (dialysis kit with dialyzers, with blood flow lines and the set of fistula needles), 1.3–1.6 m2 dialyzer for Gambro Innova -type devices	pcs	30
63	Consumables for dialysis patients who are being prepared to transplantation (dialysis kit with dialyzers, with blood flow lines and the set of fistula needles), 1.7–2.0 m2 dialyzer for Gambro Innova-type devices	pcs	60

#### 2.1. Special requirements to the Lots 62,63:

Lot 62. Consumables for dialysis patients who are being prepared to transplantation (dialysis kit with dialyzers, with blood flow lines and the set of fistula needles), 1.3–1.6 m2 dialyzer for Gambro Innova-type devices:

- 1.Dialysis kit with the dialyzer of 1.3–1.6 m2 area (synthetic membrane, steam sterilization, clearance at the blood flow rate of 200 ml/min, dialysis solution flow rate 500 ml/min:
  - urea not less than 190 ml/min;
  - creatinine not less than 165 ml/min.
- 2. Blood flow lines and fistula needles (arterial and venous) for Gambro Inova-type devices (or equivalent).
- 3. Consumables must be compatible for the use on Gambro Innova devices.

Lot 63. Consumables for dialysis patients who are being prepared to transplantation (dialysis kit with dialyzers, with blood flow lines and the set of fistula needles), 1.7–2.0 m2 dialyzer for Gambro Innova-type devices:

- 1. Dialysis kit with the dialyzer of 1.7–2.0 m2 area (synthetic membrane, steam sterilization, clearance at the blood flow rate of 200 ml/min, dialysis solution flow rate 500 ml/min:
  - urea not less than 194 ml/min;
  - creatinine not less than 178 ml/min.
- 2. Blood flow lines and fistula needles (arterial and venous) for Gambro Inova-type devices (or equivalent).
- 3. Consumables must be compatible with for Gambro Innova devices.

#### 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 and medical products, 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 medical product only under the following product standards quality criteria (Option 1 or Option 2):

#### **OPTION 1 (1.1.+1.2.)**

1.1.a. Medical products must be authorised/cleared by at least one of the regulatory authorities of founding members of the Global Harmonization Task Force (GHTF), which later became the International Medical Device Regulators Forum (IMDRF)¹. The GHTF founding member countries are Australia, Canada, the European Union (EU), Japan and the United States of America (USA). To comply with this criteria, the bidder must provide at least one of the following pre-market approval(s)/market clearance(s)/registration(s):

- Therapeutic Goods Administration (TGA), Australia: TGA Device Licence for manufacture or TGA Production Quality Assurance Certificate or TGA Full Quality Assurance Certificate or TGA issued ISO 13485 Certificate or TGA Type-Examination Certificate or AUST R Number;
- Health Canada: Medical Device Licence and summary report for a Class IV IVD CMDCAS-issued ISO 13485
   Certificate;
- European Union: EC Full Quality Assurance Certificate or EC Production Quality Assurance Certificate or EC Type-Examination Certificate (CE 93/42/EEC Medical Device Directive (MDD) Mark and respective amendments and

<sup>&</sup>lt;sup>1</sup> The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011, to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and to accelerate international medical device regulatory harmonization and convergence. IMDRF website: <a href="http://www.imdrf.org/about/about.asp">http://www.imdrf.org/about/about.asp</a>

- provisions according to Directive 98/79/EC for in vitro medical devices and Directive 93/68/EEC CE Marking);
- Japan Ministry of Health, Labour and Welfare (JMHLW): JMHLW Device Licence for manufacture or JMHLW Minister's Approval or JMHLW Recognised Foreign Manufacturer;
- US Food and Drug Administration (US FDA): PMA (pre-market approval) letter or BLA license (Biologics License Application) or 510k market clearance issued by US FDA.

OR

- 1.1.b. Medical products must be WHO prequalified<sup>2,3</sup> or recommended by the relevant WHO program<sup>4</sup> (see an example of a programme in the footnote) or recommended by the Global Fund's Expert Review Panel (GF ERP)<sup>5</sup>. To be compliant with this criteria, bidders are requested to provide at least one of the following letters:
  - WHO prequalification award letter, OR;
  - WHO recommendation letter, OR;
  - GF ERP recommendation letter.

#### AND

- 1.2.a. Suppliers and manufacturers must provide an evidence of conformity\* to at least one of the following Quality Management System standards as recognized by GHTF standards:
  - ISO13485 for products classified as medical devices and IVD; or
  - ISO 9001 for other devices, or
  - Equivalent Quality Management System (QMS) recognised by one of the Regulatory Authorities of the Founding Members of GHTF (EU, USA, Japan, Canada, Australia), for instance:
    - United States QS 21 CFR part 820, or
    - Japan QS Standard for medical devices.
- \*) The evidence(s) of conformity shall indicate, as applicable:
  - a) Manufacturer's certified quality management system standard(s),
  - b) Assessment body (name, country), which shall be recognised by one of the Regulatory Authorities of the Founding Members of GHTF (EU, USA, Japan, Canada, Australia),
  - c) Last audit date,
  - d) Expiration date,
  - e) Certificate number.

#### <u>and</u>

**For sterile consumables/renewables**: If not covered in the scope of the QMS certification claimed above, the manufacturer/supplier shall provide additional certificates for all sterile devices in accordance with ISO 11135 and ISO 11137 - Sterilization of health care products (as applicable).

OR

1.2.b. Suppliers/manufacturers shall provide a copy of valid GMP Certificate issued by The Pharmaceutical Inspection Cooperation Scheme (PIC/S) authorities for the manufacturing site(s) of the proposed product(s).

<sup>&</sup>lt;sup>2</sup> WHO list of prequalified in vitro diagnostic products: http://www.who.int/diagnostics\_laboratory/evaluations/PQ\_list/en/

<sup>&</sup>lt;sup>3</sup> WHO Prequalification of Male Circumcision Devices: <a href="http://www.who.int/diagnostics">http://www.who.int/diagnostics</a> laboratory/evaluations/prequalification male circumcision devices/en/

<sup>&</sup>lt;sup>4</sup> Example of WHO programme - TB detection and diagnosis: <a href="http://www.who.int/tb/areas-of-work/laboratory/en/">http://www.who.int/tb/areas-of-work/laboratory/en/</a>

<sup>&</sup>lt;sup>5</sup> GF Sourcing & Management of Health Products: <a href="https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/">https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/</a>

#### **OPTION 2 (2.1. + 2.2.)**

- 2.1. The proposed product(s) must be registered/certified for the use in Ukraine:
  - Registration Certificate issued by the State Administration on Pharmaceutical Products and Drugs Control Service
    of Ukraine and evidence of at least one successfully completed supply of this product in a similar volume in/to
    Ukraine, within the past five years,

OR

- Declaration of Conformity with the requirements of technical regulations issued for the use in Ukraine (Resolution of the Cabinet of Ministers of Ukraine #753, #754, #755<sup>6</sup>) and evidence of at least one successfully completed supply of this product in a similar volume in/to Ukraine within the past five years.

#### **AND**

- 2.2.a. Suppliers and manufacturers must provide an evidence of conformity\* to at least one of the following Quality Management System standards as recognized by GHTF standards:
  - ISO13485 for products classified as medical devices and IVD; or
  - ISO 9001 for other devices, or
  - Equivalent Quality Management System (QMS) recognised by one of the Regulatory Authorities of the Founding Members of GHTF (EU, USA, Japan, Canada, Australia), for instance:
    - United States QS 21 CFR part 820, or
    - Japan QS Standard for medical devices.
- \*) The evidence(s) of conformity shall indicate, as applicable:
  - a) Manufacturer's certified quality management system standard(s),
  - b) Assessment body (name, country), which shall be recognised by one of the Regulatory Authorities of the Founding Members of GHTF (EU, USA, Japan, Canada, Australia),
  - c) Last audit date,
  - d) Expiration date,
  - e) Certificate number.

And

For sterile consumables/renewables: If not covered in the scope of the QMS certification claimed above, the manufacturer/supplier shall provide additional certificates for all sterile devices in accordance with ISO 11135 and ISO 11137 - Sterilization of health care products (as applicable).

OR

2.2.b. Suppliers/manufacturers shall provide a copy of valid GMP Certificate issued by a Pharmaceutical Inspection Cooperation Scheme (PIC/S) authority for the manufacturing site(s) of the proposed product(s).

Bidders shall demonstrate their compliance in the Annex 4 – Compliance of product/s to the requirements.

<sup>&</sup>lt;sup>6</sup> 1. Technical regulations on medical devices approved by the Cabinet of Ministers of Ukraine on 02/10/2013 № 753 (http://zakon3.rada.gov.ua/laws/show/753-2013-%D0%BF);

<sup>2.</sup> Technical regulations on medical products for diagnostics in vitro, approved by the Cabinet of Ministers of Ukraine on 02/10/2013 № 754 (http://zakon1.rada.gov.ua/laws/show/754-2013-%D0%BF);

<sup>3.</sup>Technical regulations on implanted active medical devices approved by the Cabinet of Ministers of Ukraine on 02/10/2013 № 755 (http://zakon1.rada.gov.ua/laws/show/755-2013-%D0%BF).

NB: If branded product is requested and equivalent product is allowed to be proposed as per section "Product List and Technical Specification", the Bidder must provide technical specification of item quoted and statement of deviations from branded product.

#### 4. REGISTRATION / AUTHORIZATION FOR USE IN UKRAINE

Where a medical product has not yet been registered in Ukraine the suppliers of the Goods who wish to provide to, or within Ukraine, must make sure that the Goods comply with the following regulations at the moment of delivery: Declaration of Conformity with the requirements of technical regulations (Resolution of the Cabinet of Ministers of Ukraine #753, #754, #755 dd. 02.10.2013).

UNDP will evaluate offers for both registered and non-registered medical products. Non-registered products must meet quality standards as per OPTION 1. Bidders offering non-registered products that are compliant with quality standards, must start the registration/certification process preferably before, but not later than 5 days after, signing a conditional contract for the supply of product(s). Failure to obtain registration/certification and submit the required documents to UNDP will serve, at no claim to UNDP, as a ground for contract termination, liquidating Bid Security 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.

#### 5. DELIVERY TIMEFRAMES

Early delivery of medicines/medical products to Ukraine is critical therefore we encourage shortest delivery periods. 100% of products total quantity should be delivered within maximum of 4 months at the latest after signing the contract.

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:

	T	-				
Delivery Term	DAP Kyiv, Central Wa	arehouse of the MoH				
[INCOTERMS 2010]	The products shall b	e supplied to the Central Warehouse (State Enterprise) of				
(Pls. link this to price schedule)	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 ownersl					
	right from seller to buyer occurs simultaneously with the transfer of risk of goods					
	loss or damage at the	e moment when the goods are delivered to the named				
	warehouse.					
	Partial delivery is ac	ceptable: maximum 2 consignments under delivery of one				
	Lot/Item.					
Mode of Transport Preferred	⊠AIR	⊠LAND				
	⊠SEA	□OTHER [pls. specify]				
Shipping documents	Commercial inve	oice – 2 originals.				
	• Packing list – 1 o	сору.				
	<ul> <li>Manufacturer's</li> </ul>	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	Central Warehouse (State Enterprise) of MoH appointed by UNDP will act as					
be done by:	importer of record with the condition that goods are shipped to 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.					
	Within 30 calendar days after delivery subject to written acceptance of goods					
Payment Terms	delivery, duly signed and stamped by UNDP/MoH and provision of original					
	invoice.					
	In case testing is required, satisfactory testing results is a prerequisite fo					
	payment release.					
	Progress payments could be provided in case of partial delivery.					

#### 6. SHELF LIFE

Products (Lots 1-61) 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. Consumables for dialysis (Lots 62-63) must have a minimum of 75% of the total product shelf life 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, Registration Certificate with issued by the Ministry of Health of Ukraine, inspection against UNDP specifications, labelling and packaging.
- 2) Medical products 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:

Data loggers should be used for all shipments from primary stores to the first level of intermediate stores, and elsewhere where possible, most particularly shipments of temperature sensitive health products.

The number of dataloggers should be 1 for each 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 45°c, with accuracy +/- 0.5°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;
- Special instructions for storage;
- J. Name of manufacturer;
- K. Carton numbering e.g. carton 1/40;
- L. Any additional cautionary statements.

4) Labelling of package at the moment of supply must correspond to the one in the product's state registration record or Declaration of Conformity. The labelling of the product shall meet the requirements described in the regulations of at least one of the GHTF founding members (EU, USA, Japan, Canada, Australia), or at a minimum with SG1-N70:2011: Label and Instructions for Use for Medical Devices. In case of any deviations found, the supplier must provide additional documentation to enable receipt of goods.

For sterile consumables/renewables products, the medical device(s) must be labelled "sterile" (EN 556-2:2003 Sterilization of medical devices: requirements for medical devices to be designated "STERILE"- requirements for aseptically processed medical devices).

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

In case medical products 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 or electronic format at the time of supply.

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.

#### 7) Pre-shipment inspection

When all the goods from a specific purchase order are ready for shipment with their final packing and marking, a preshipment 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 preshipment 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.
- d) The supplier is responsible for notifying UNDP of any variation or extention in the company file or in the product registration files, within fourteen days since the event occurred. Those include changes that have a significant impact on the quality, safety or efficacy of a medicinal product and/or that fundamentally alter the terms of current product approvals/registrations. Failure by the manufacturer/supplier in notifying the MoH PIU team about any of the aforementioned changes or similar ones may result in sanctions applied by UNDP Ukraine.
- 9) Stipulations concerning complaints and Recalls: The bidder must notify UNDP of any issue or concern related to the product qualified, which is identified by the manufacturer itself or raised by any other stakeholder. This comprises any complaint or product recall related to the product qualified, which can lead to safety issues for patients. 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 fulfill 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
Comp	liance of Bid	der with Qualifications Requirements			
Minimum 3 years of experience in nature and minimum 2 similar confulfilled 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 years shall equal to no less than total amount to be contracted  Compliance of product/quoted wi product quoted)	75% of the	3. Latest Audited Financial Statement (Income Statement and Balance Sheet) including Auditor's Report for the past 2 years andards and requirements (please com	plete	checkl	ist for each
1.1.a. Medical products must be must be authorised/cleared by at least one of the regulatory authorities of founding members of the Global Harmonization Task Force (GHTF), which later became the International Medical Device Regulators Forum (IMDRF). In order to be compliant with this criteria bidders will be requested to provide one of the following pre-market approval(s) / market clearance(s) (please refer for details to Section 3 of ITB).	summary rep ISO 13485 Ce EC Full Qualit Production Co Type-Examin Medical Devi respective ar to Directive Sand Directive TGA Producti TGA Type-Exa Quality Assur for manufact Certificate or	cy Assurance Certificate or EC quality Assurance Certificate or EC ation Certificate (CE 93/42/EEC ce Directive (MDD) Mark and mendments and provisions according 08/79/EC for in vitro medical devices e 93/68/EEC - CE Marking), OR ion Quality Assurance Certificate or amination Certificate or TGA Full rance Certificate or TGA Device Licence ure or TGA issued ISO 13485 a AUST R Number, OR ce Licence for manufacture or JMHLW proval or JMHLW Recognised Foreign			

Award Criteria	Corresponding document	Yes	No	Reference
	PMA (pre-market approval) letter or BLA license			
	(Biologics License Application) or 510k market			
	clearence issued by US FDA			
1.1.b. Medical products must be	WHO prequalification award letter, OR			
WHO prequalified, or				
recommended by the relevant				
WHO program, or	WHO recommendation letter, OR			
recommended by the Global				
Fund's Expert Review Panel (GF				
ERP). To be compliant with this	GF ERP recommendation letter			
criteria, bidders are requested				
to provide at least one of the				
following letters:				
2.1. The proposed product(s)	Registration Certificate issued by the State			
must have registered/certified	Administration on Pharmaceutical Products and			
for the use in Ukraine (please	Drugs Service of Ukraine, OR			
refer for details to Section 3 of	Declaration of Conformity with the requirements			
ITB)	of technical regulations issued for the use in			
	Ukraine (Resolution of the Cabinet of Ministers of			
	Ukraine #753, #754, #755)			
	AND			
	Evidence of at least one successfully completed			
	supply of this product in a similar volume in/to			
	Ukraine within the past five years			
1.2.a./2.2.a. Suppliers and	ISO13485 – for products classified as medical			
manufacturers must provide an	devices and IVD; ISO 9001 – or other devices, or			
evidence of conformity* to at	United States QS 21 CFR part 820, OR			
least one of the following	Japan QS Standard for medical devices, OR			
Quality Management System	Other QMS recognized by one of the Regulatory			
standards as recognized by GHTF standards	Authorities of the Founding Members of GHTF			
GHIF Standards	ISO 11135 and ISO 11137 – for Sterile health care			
	products (if applicable)			
1.2.b./2.2.b. Suppliers and	A copy of valid GMP Certificate issued by PIC/S			
manufacturers must provide an	authorities for the manufacturing site(s) of the			
evidence of GMP certification of	proposed product(s)			
manufacturing site by PIC/S				
authorities				
Availability of valid	Option A: A copy of a valid registration certificate			
registration/certification in	for every medicinal product quoted issued by the			
Ukraine at the time of supply as	Ministry of Health of Ukraine			
defined in Section 3, (if, at the	AND/OR			
moment of the bid submission,	Declaration of Conformity with the requirements			
the quoted medical products	of technical regulations (Resolution of the Cabinet			
are not registered in Ukraine	of Ministers of Ukraine #753, #754, #755 dd.			
but comply with the quality	02.10.2013)			

Award Criteria	Corresponding document	Yes	No	Reference
requirements of this ITB	Option B: If, at the moment of the bid submission,			
(OPTION 1), a Commitment	the quoted medicinal products are not			
letter shall be provided)	registered/certified 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 registration/certification procedure			
	(see Section 3, para #3 Registration/Authorization			
	for use in Ukraine for details) .			
	By submitting the Bid, the Bidder automatically			
	agrees to maintain and renew			
	registration/certification for these products until			
	their shelf life expiration.			
Compliance with shelf life,	Please provide Information on shelf life in the Form			
packing and labelling	7 Technical Bid Form			
requirements (please refer for				
details to Section 3 of ITB).				
Acceptability of the	Please provide Information on delivery schedule in			
Transportation/Delivery	the Form 7 Technical Bid Form			
Schedule (please refer for				
details to Section 3 of ITB)				

List of other documents required for evaluation of Offeror		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			
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 use in accordance with the legislation of Ukraine. In case quoted			
medicinal products are not registered/certified in Ukraine, instructions for the use in			
the original language shall be provided. Instructions should also include clear			
recommendations for storage and transport (temperature and humidity).			

Complete Technical specification of product quoted, including claimed intended use		
Material Safety data sheet (MSDS) of the product, including section 14: Transport information (as applicable)		
If applicable: product equivalence confirmation; installation and training material; service and maintenance instructions; and list of all supporting items/devices required, but not supplied		
Patent Registration Certificate/s (if applicable), or relevant license/s (if available)		

#### Annex 1

#### **BRIEF SUMMARY**

# 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: <a href="http://zakon2.rada.gov.ua/laws/show/2755-17/page45">http://zakon2.rada.gov.ua/laws/show/2755-17/page45</a>
- 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 Performance Security amount and either awarding the next qualified Bidder or initiating a new bidding process.

## **Commitment letter**

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

Insert: Location

Го:	Insert: Dat [insert: Name and Address of UNDP focal point]
Dear S	ir/Madam:
ocu. c	We, the undersigned, hereby offer to supply the goods required for [insert: title of goods and services required as per ITB] i
accord	ance with your Invitation to Bid dated .
	We hereby commit to register the below listed products with Ukrainian registration authorities as the current legislatio
equir	es.
•	Products:
	1
	2
	3
-	ation and submission, registration fees and that UNDP will in no case be responsible or liable for those costs, regardless of the ct or outcome of the evaluation.  We remain,
	Yours sincerely,
	Authorized Signature [In full and initials]:
_	Name of Firm:
Conta	t 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. 3. .... For and on behalf of Manufacturer or Producer: Yours sincerely, Authorized Signature [In full and initials]: Name and Title of Signatory: \_\_\_\_\_\_ Contact Details:

## Section 5: Bid Submission Form<sup>7</sup>

# (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,

lame and Title of Signatory:	
Name of Firm:	
Details:	

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

<sup>&</sup>lt;sup>7</sup>No deletion or modification may be made in this form. Any such deletion or modification may lead to the rejection of the Bid.

## **Section 6:**

# **Documents Establishing the Eligibility and Qualifications of the Bidder**

## Bidder Information Form<sup>8</sup>

Date: [insert date (as day, month and year] of Bid Submission]
ITB No.: [insert number of bidding process]

Page

of

pages

		101 11011			
1. Bidder's Legal Name [insert Bidder's legal name]					
2. In case of Joint Venture (JV), legal name of each party: [insert legal name of each party in JV]					
3. Actual or intended Country/ies of	Registration/Operation: [insert act	tual or intended Country of Registration]			
4. Year of Registration in its Location	: [insert Bidder's year of registratio	n]			
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	f Registration/Operation:[insert Bid	der's legal address in country of registration]			
9. Value and Description of Top three	e (3) Biggest Contract for the past fi	ve (5) years			
10. Latest Credit Rating (Score and S	ource, 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: [insert Authorized Representative's name]					
Address: [insert Authorized Representative's Address]					
Telephone/Fax numbers: [insert Authorized Representative's telephone/fax numbers]					
Email Address: [insert Authorized Representative's email address]					
13. Are you in the UNPD List 1267.1989 or UN Ineligibility List? ☐ YES or ☐ NO					
14. Attached are copies of original documents of:					
□All eligibility document requirements listed in the Data Sheet					
☐ 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					
□ If case of Government corporation or Government-owned/controlled entity, documents establishing legal and financial					
autonomy and compliance	with commercial law.				

<sup>&</sup>lt;sup>8</sup>The Bidder shall fill in this Form in accordance with the instructions. Apart from providing additional information, no alterations to its format shall be permitted and no substitutions shall be accepted.

# Joint Venture Partner Information Form (if Registered)9

Date: [insert date (as day, month and year) of Bid Submission]
ITB No.: [insert number of bidding process]

		Page	of	pages		
Bidder's Legal Name: [insert Bidder's legal name]						
2. JV's Party legal name: [insert JV	/'s Party legal name]					
3. JV's Party Country of Registrati	on: [insert JV's Party country of regi	stration]				
4. Year of Registration: [insert Party	's year of registration]					
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	f Registration/Operation: [insert Par	ty's legal address in country of reg	gistration]			
9. Value and Description of Top thre	e (3) Biggest Contract for the past fiv	re (5) years				
10. Latest Credit Rating (if any): Clic	ck here to enter text.					
Brief description of litigation his resolved. Click here to enter	istory (disputes, arbitration, claims, eer text.	tc.), indicating current status and	outcomes, if ali	ready		
13. JV's Party Authorized Represer	13. JV's Party Authorized Representative Information					
14. Attached are copies of original of	documents of: [check the box(es) of	the attached original documents	1			
□All eligibility document requireme	nts listed in the Data Sheet					
☐Articles of Incorporation or Regist						
□In case of government owned ent law.	ity, documents establishing legal and	financial autonomy and complia	nce with comme	ercial		

<sup>&</sup>lt;sup>9</sup>The Bidder shall fill in this Form in accordance with the instructions. Apart from providing additional information, **n**o alterations to its format shall be permitted and no substitutions shall be accepted.

## Section 7: Technical Bid Form<sup>10</sup>

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

INSERT TITLE OF THE ITB

#### **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.

<u>2.1. Scope of Supply</u>: 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 shall be provided both in excel and PDF format);

.

<sup>&</sup>lt;sup>10</sup>Technical Bids not submitted in this format may be rejected.

describe how the organization/firm will supply the goods and any related services, keeping in mind the appropriateness to local conditions and project environment.

- <u>2.1.1 Please describe the Freight Forwarder details and Arrangements.</u> 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, unless partial shipment is requested by UNDP. In case partial delivery is proposed, please provide suggested time schedule.

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

- <u>2.2. Technical Quality Assurance Mechanisms</u>: 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
- <u>2.3 Statement of Full Disclosure</u>: 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**

- <u>3.1 Management Structure</u>: Describe the overall management approach toward planning and implementing the contract. Include an organization chart for the management of the contract, if awarded.
- <u>3.2 Staff Time Allocation</u>: 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).
- <u>3.3 Qualifications of Key Personnel.</u> 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:					
<b>Countries of Relevant Work Expe</b>	rience:				
Language Skills:					
<b>Education and other Qualification</b>	ns:				
Summary of Experience: Highlight	ght experience	in the region and on simila	r projects.		
Relevant Experience (From most	recent):				
Period: From – To Name of acti		vity/ Project/ funding , if applicable:	Job Title and Activities undertaken/Description of actual role performed:		
e.g. June 2010-January 2011					
Etc.					
Etc.					
References (minimum of 3):  Name Designation Organization Contact Infor		mation – Address; Phone; E	'mail; etc.		
Declaration:					
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.  Signature of the Nominated Team Leader/Member  Date Signed					

## **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 5 (excel sheet) with the Price Schedule Form.

Annex 5 shall be provided both in Excel and PDF format.

## **Section 9: 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.)

То:	UNDP [Insert contact information as provided in Data Sheet]
of Cont Contra	WHEREAS [name and address of Contractor] (hereinafter called "the Contractor") has undertaken, in pursuance ract No
	AND WHEREAS it has been stipulated by you in the said Contract that the Contractor shall furnish you with a Bank tee by a recognized bank for the sum specified therein as security for compliance with his obligations in accordance e Contract:
	AND WHEREAS we have agreed to give the Contractor such a Bank Guarantee:
currence withou	NOW THEREFORE we hereby affirm that we are the Guarantor and responsible to you, on behalf of the Contractor, total of [amount of guarantee] [in words and numbers], such sum being payable in the types and proportions of cies in which the Contract Price is payable, and we undertake to pay you, upon your first written demand and t cavil or argument, any sum or sums within the limits of [amount of guarantee as aforesaid] without your needing e or to show grounds or reasons for your demand for the sum specified therein.
perforr	This guarantee shall be valid until a date 30 days from the date of issue by UNDP of a certificate of satisfactory nance and full completion of services by the Contractor.
	SIGNATURE AND SEAL OF THE GUARANTOR BANK
Date	
Name (	of Bank
Addres	S

# Section 10: Template of Purchase Order and General Terms and Conditions for Goods

#### Purchase Order Dispatch via Print PO Number Date Page UKR10-000003 Ukraine Freight / INCOTERMS Payment Terms Ship Via Immediate Common UNDP Office in Ukraine 1 Klovsky Uzviz Str Kyiv 30 01021 Buver Phone Currency Tel: Ukraine Fax: Approver Fax: Vendor: 00000 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 Quantity UOM Due Date Unit Price Description Line Total

EJ

PO Text:

Contractor: [please add]

tel./fax : [please add] bank account [please add] Contact names: [please add]

gsm: [please add]

1-1

2. Purchaser: United Nations Development Programme in Ukraine, legal and actual address: 1, Klovsky Uzviz Str., Kyiv, 01021, Ukraine,

tel: +380 44 253 93 63, fax: +380 44 253 26 07,

#### Contact names:

3. Specifications and quantities of goods:

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

Pack size:

Quantity of units/packs:

Registration Certificate in Ukraine: valid till

Shelf life: 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.

Delivery terms: [to be added]

4. Delivery terms and address: DAP-Kyiv, Ukraine.

State Enterprise "[to be added]" of the Ministry Health of Ukraine,

Address of warehouse: [to be added]

Consignee: United Nations Development Programme in Ukraine.

5. Required shipping documents:

Commercial invoice - 2 originals.

Packing list – 1 copy.

Manufacturer's Certificate of Analysis for each batch – copies certified with the stamp of the Supplier.

Batch Release for each batch – copies certified with the stamp of the Supplier.

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 45°c, with accuracy +/- 0.5°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. Primary packaging must preserve quality, safety and stability of the product it contains. The entire package must be duly sealed and protected from spoiling. 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.

- 8. 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.
- 9. 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/MoH 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 shall furnish a Performance Security to UNDP in the amount of 10% of the Purchase Order Value. The Performance Security shall be valid for 30 days longer than the entire contract period, including (but not limited to) manufacture, delivery and warranty obligations. Performance Security shall be provided by Supplier within 2 (two) calendar weeks.
- 13. 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).
- http://www.undp.org/content/dam/undp/documents/procurement/documents/genconditionpurchaseorders.pdf.

14. This Purchase Order is signed with the purpose to fulfill the dd, between the United Nations Development
Programme and the Ministry of Health of Ukraine, for the procurement of medicines under national programs in health
sector for (Budget Program 2301400 "Ensuring hospital measures of separate state programs and complex measures
of programmable nature", Centralized procurement of).
The medicines are procured according to the Decree of the Cabinet of Ministers "On the list of medicines and medical
products subject to be procured pursuant to the procurement agreement with specialized organizations, conducting
public procurement for the State Funds".

### **General Terms and Conditions for Goods**

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.
- 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:

- 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.
- 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:**

- 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.
- 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.
- 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 <a href="www.undp.org">www.undp.org</a> or at <a href="http://www.undp.org/content/undp/en/home/operations/procurement/business/">http://www.undp.org/content/undp/en/home/operations/procurement/business/</a>. 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 any services under the Contract. For these purposes, sexual activity with any person less than eighteen years of age, regardless of any laws relating to consent, shall constitute the sexual exploitation and abuse of such person. In addition, the Contractor shall refrain from, and shall take all reasonable and appropriate measures to prohibit its employees or other persons engaged and controlled by it from exchanging any money, goods, services, or other things of value, for sexual favors or activities, or from engaging any sexual activities that are exploitive or degrading to any person.
- **35.3** UNDP shall not apply the foregoing standard relating to age in any case in which the Contractor's personnel or any other person who may be engaged by the Contractor to perform any services under the Contract is married to the person less than the age of eighteen years with whom sexual activity has occurred and in which such marriage is recognized as

valid under the laws of the country of citizenship of such Contractor's personnel or such other person who may be engaged by the Contractor to perform any services under the Contract.

**36. ANTI-TERRORISM:** The Contractor agrees to undertake all reasonable efforts to ensure that none of the UNDP funds received under the Contract is used to provide support to individuals or entities associated with terrorism and that recipients of any amounts provided by UNDP hereunder do not appear on the list maintained by the Security Council Committee established pursuant to Resolution 1267 (1999). The list can be accessed via <a href="https://www.un.org/sc/suborg/en/sanctions/1267/aq sanctions list">https://www.un.org/sc/suborg/en/sanctions/1267/aq sanctions list</a>. This provision must be included in all subcontracts or sub-agreements entered into under the Contract.