INVITATION TO BID

Procurement of reagents for screening newborns for phenylketonuria, congenital hypothyroidism, cystic fibrosis and adrenogenital syndrome

Procurement of medical products for patients in pre- and post-transplant period

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

64-2017-UNDP-UKR-ITB-HP

Ukraine

United Nations Development Programme
November 2017

Section 1. Letter of Invitation

Kyiv, Ukraine
November 02, 2017

64-2017-UNDP-UKR-ITB-HP

Procurement of reagents for screening newborns for phenylketonuria, congenital hypothyroidism, cystic fibrosis and adrenogenital syndrome

Procurement of medical products 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 Bid Security
Section 10 – Form for Performance Security *(may be required from winning entity)*
Section 11 – 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: 64-2017-UNDP-UKR-ITB-HP “Procurement of reagents and medical products”

The letter should be received by UNDP *preferably* no later than November 06, 2017. 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,

Ms. Andra Brige, UNDP Deputy Country Director Operations

Section 2: Instruction to Bidders

Definitions

a) *"Bid"* refers to the Bidder's response to the Invitation to Bid, including the Bid Submission Form, Technical Bid and Price Schedule and all other documentation attached thereto as required by the ITB.

b) *"Bidder"* refers to any legal entity that may submit, or has submitted, a Bid for the supply of goods and provision of related services requested by UNDP.

c) *"Contract"* refers to the legal instrument that will be signed by and between the UNDP and the successful Bidder, all the attached documents thereto, including the General Terms and Conditions (GTC) and the Appendices.

d) "*Country"* refers to the country indicated in the Data Sheet.

e) *"Data Sheet"* refers to such part of the Instructions to Bidders used to reflect conditions of the tendering process that are specific for the requirements of the ITB.

f) *"Day"* refers to calendar day.

g) *"Goods"* refer to any tangible product, commodity, article, material, wares, equipment, assets or merchandise that UNDP requires under this ITB.

h) *"Government"* refers to the Government of the country where the goods and related services provided/rendered specified under the Contract will be delivered or undertaken.

i) *"Instructions to Bidders"* refers to the complete set of documents which provides Bidders with all information needed and procedures to be followed in the course of preparing their Bid

j) *"ITB"* refers to the Invitation to Bid consisting of instructions and references prepared by UNDP for purposes of selecting the best supplier or service provider to fulfil the requirement indicated in the Schedule of Requirements and Technical Specifications.

k) *"LOI"* (Section 1 of the ITB) refers to the Letter of Invitation sent by UNDP to Bidders.

l) *"Material Deviation"* refers to any contents or characteristics of the bid that is significantly different from an essential aspect or requirement of the ITB, and (i) substantially alters the scope and quality of the requirements; (ii) limits the rights of UNDP and/or the obligations of the offeror; and (iii) adversely impacts the fairness and principles of the procurement process, such as those that compromise the competitive position of other offerors.

m) *"Schedule of Requirements and Technical Specifications"* refers to the document included in this ITB as Section 3 which lists the goods required by UNDP, their specifications, the related services, activities, tasks to be performed, and other information pertinent to UNDP's receipt and acceptance of the goods.

n) *"Services"* refers to the entire scope of tasks related or ancillary to the completion or delivery of the goods required by UNDP under the ITB.

o) "*Supplemental Information to the ITB"* refers to a written communication issued by UNDP to prospective Bidders containing clarifications, responses to queries received from prospective Bidders, or changes to be made in the

ITB, at any time after the release of the ITB but before the deadline for the submission of Bid.

A. GENERAL

1. UNDP hereby solicits Bids as a response to this Invitation to Bid (ITB). Bidders must strictly adhere to all the requirements of this ITB. No changes, substitutions or other alterations to the rules and provisions stipulated in this ITB may be made or assumed unless it is instructed or approved in writing by UNDP in the form of Supplemental Information to the ITB.

2. Submission of a Bid shall be deemed as an acknowledgement by the Bidder that all obligations stipulated by this ITB will be met and, unless specified otherwise, the Bidder has read, understood and agreed to all the instructions in this ITB.

3. Any Bid submitted will be regarded as an offer by the Bidder and does not constitute or imply the acceptance of any Bid by UNDP. UNDP is under no obligation to award a contract to any Bidder as a result of this ITB.

4. UNDP implements a policy of zero tolerance on proscribed practices, including fraud, corruption, collusion, unethical practices, and obstruction. UNDP is committed to preventing, identifying and addressing all acts of fraud and corrupt practices against UNDP as well as third parties involved in UNDP activities. (See http://www.undp.org/content/dam/undp/library/corporate/Procurement/english/Procurement%20Fraud%20Notice.pdfand http://www.undp.org/content/undp/en/home/operations/procurement/protestandsanctions/for full description of the policies)

5. In responding to this ITB, UNDP requires all Bidders to conduct themselves in a professional, objective and impartial manner, and they must at all times hold UNDP's interests paramount. Bidders must strictly avoid conflicts with other assignments or their own interests, and act without consideration for future work. All Bidders found to have a conflict of interest shall be disqualified. Without limitation on the generality of the above, Bidders, and any of their affiliates, shall be considered to have a conflict of interest with one or more parties in this solicitation process, if they:

   5.1 Are, or have been associated in the past, with a firm or any of its affiliates which have been engaged UNDP to provide services for the preparation of the design, Schedule of Requirements and Technical Specifications, cost analysis/estimation, and other documents to be used for the procurement of the goods and related services in this selection process;
   5.2 Were involved in the preparation and/or design of the programme/project related to the goods and related services requested under this ITB; or
   5.3 Are found to be in conflict for any other reason, as may be established by, or at the discretion of, UNDP.

   In the event of any uncertainty in the interpretation of what is potentially a conflict of interest, Bidders must disclose the condition to UNDP and seek UNDP's confirmation on whether or not such conflict exists.

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

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

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

7. The eligibility of Bidders that are wholly or partly owned by the Government shall be subject to UNDP's further evaluation and review of various factors such as being registered as an independent entity, the extent of Government ownership/share, receipt of subsidies, mandate, access to information in relation to this ITB, and others that may lead to undue advantage against other Bidders, and the eventual rejection of the Bid.

8. All Bidders must adhere to the UNDP Supplier Code of Conduct, which may be found at this link: http://www.undp.org/content/dam/undp/documents/procurement/documents/UNDP_supplier_code_of_conduct.pdf

B. CONTENTS OF BID

9. Sections of Bid

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

11.1 At any time prior to the deadline for submission of Bid, UNDP may for any reason, such as in response to a clarification requested by a Bidder, modify the ITB in the form of a Supplemental Information to the ITB. 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 any of the following:

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

19. Joint Venture, Consortium or Association

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

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

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

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

Where a joint venture is presenting its track record and experience in a similar undertaking as those required in

the ITB, it should present such information in the following manner:

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

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

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

20. Alternative Bid

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

21. Validity Period

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

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

22. Bidder's Conference

When appropriate, a Bidder's conference will be conducted at the date, time and location specified in the **Data Sheet** (DS no. 7). All Bidders are encouraged to attend. Non-attendance, however, shall not result in disqualification of an interested Bidder. Minutes of the Bidder's conference will be 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 **must** be submitted 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 actual 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.

29.1 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

32.3 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.

32.4 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.

32.5 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.

32.6 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 reagents for screening newborns for phenylketonuria, congenital hypothyroidism, cystic fibrosis and adrenogenital syndrome** **Procurement of medical products for patients in pre- and post-transplant period** in 12 Lots, in accordance with the Technical Specifications as per section 3.
3		Country:	Ukraine
4	C.13	Language of the Bid:	☒ English 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. ☒ Ukrainian/Russian
5	C.20	Conditions for Submitting Bid for Parts or sub-parts of the Total Requirements	☒ The Bidder may submit Bid for separate Lots/Items However, Bidders are encouraged to quote for as many Lots/Items as possible.
6	C.20	Conditions for Submitting Alternative Bid	☒ Shall not be considered
7	C.22	A pre-Bid conference will be held on:	Time: 14:00 hrs local time Date: November 7, 2017 Venue: Alexanian conference hall; 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. 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
8	C.21.1	Period of Bid Validity commencing on the submission date	☐ 60 days ☐ 90 days ☒ 120 days
9	B.9.5 C.15.4 b)	Bid Security	☒ Required **Bid security is required for the Lots 1-4 in the amount of:** **USD 10,000** for a bid for one or more lots cumulatively exceeding 200,000.00 USD up to USD 399,999.99 OR **USD 20,000** for a bid for one or more lots cumulatively amounting from 400,000.00 to 599,999.99 OR **USD 30,000** for a bid for one or more lots cumulatively exceeding 600,000.00
10	B.9.5	Acceptable forms of Bid Security	☒ Bank Guarantee Bid Security shall be submitted in the form of Bank Guarantee as per template provided in the Section 9
11	B.9.5 C.15.4 a)	Validity of Bid Security	150 days
12		Advanced Payment upon signing of contract	☒ Not allowed
13		Liquidated Damages	☒Will be imposed under the following conditions: If the Supplier fails to supply the specified Goods within the time period(s) stipulated in the individual contract (Purchase Orders), the UNDP may without prejudice to its other remedies under the contract, deduct 0.5% of the complete consignment for each day of delay until actual delivery, 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	☒ 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 or in Amount: 10 % of the contract amount Form: Bank guarantee.
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+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. ***Any bid sent to the private email addresses of any UNDP staff will not be accepted.***
21	C.21.1 D.24	Deadline of Bid Submission	***Date and Time: December 1, 2017 10:00 AM, Kyiv time (UTC +2:00)***
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	☒ Official Address for e-submission: *tenders.ua@undp.org* ☒ Format: PDF files preferred in **ZIP archives only.** ☒ Max. File Size per transmission: *[5 MB]* ☒ Max. No. of transmission: *[10]* No. of copies to be transmitted: *[1]* ☒ Mandatory subject of email: ***64-2017-UNDP-UKR-ITB-HP "Procurement of reagents and medical products"*** ***Bidders MUST indicate clearly in the e-mail for which LOT they 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 +2, 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.***
z	D.23.1 c)	Date, time and venue for opening of Bid	**Date and Time**: **December 1, 2017 2:00 PM, Kyiv time (UTC +2:00)** ***Any bidder that intends to participate in the public bid opening shall notify UNDP by address health.procurement.ua@undp.org at least 24 hours in advance.***

			Companies can participate at the Bid Opening procedure through skype conference as well. Interested companies should send confirmations by email. **Venue:** 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. ☒ Copy of properly furnished Bid Security (as per DS# 9). Please use template provided in the Section 9 (For the lots 1-4). Original should be provided to UNDP within 1 week after the Deadline of Bid Submission (DS #21) to below address, otherwise the bid will be rejected: 1 Klovskyi Uzviz, Kyiv, Ukraine 01021 To: UNDP Procurement Unit ☒ 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	*January 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 ☒ Lowest price offer of technically qualified/responsive Bid per Lot *) the discount factor will be considered if such proposed by Bidder for awarding of more than one lot only at the stage of contracting and will not be considered for evaluation purposes.
33	E.29	Post qualification Actions	☒ Verification of accuracy, correctness and authenticity of the information provided by the bidder on the legal, technical and financial documents submitted; ☒ Validation of extent of compliance to the ITB requirements and evaluation criteria based on what has so far been found by the evaluation team; ☒ Inquiry and reference checking with other previous clients on the quality of performance on ongoing or previous contracts completed.
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; ☒ Bids must include copy of properly furnished Bid Security for the Lots 1-4 (as per DS 9). Original should be provided within 1 week after the Deadline of Bid Submission (as per DS #21), otherwise the Bid will be rejected. ☒ Bids have been signed by the proper authority ☒ Full compliance and agreement with UNDP General terms and conditions available by the link: http://www.undp.org/content/dam/undp/documents/procurement/documents/genconditionpurchaseorders.pdf. Other information is available on http://www.ua.undp.org/content/ukraine/en/home/operations/procurement.html

			For information, please contact health.procurement.ua@undp.org

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. It is expected that in the nearest future additional programmes would be handled 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 reagents and medical products for Procurement of reagents for screening newborns for phenylketonuria, congenital hypothyroidism, cystic fibrosis and adrenogenital syndrome, medical products for patients in pre- and post-transplant period for the State budget of 2017. Procurement of reagents for screening newborns for phenylketonuria, congenital hypothyroidism (savings accumulated while procuring under the State budget of 2016).

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 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. Medical products must be produced and controlled in accordance with product standards and quality system standards recommended by the World Health Organization (WHO)
AND/OR
the International Medical Devise Regulators Forum (IMDRF) (former Global Harmonization Task Force (GHTF). For more information see http://www.imdrf.org/. The GHTF founding members are Australia, Canada, the European Union (EU), Japan and the United States of America (USA). To be compliant with this criterion bidders are requested to provide at least one of the following pre-market approval(s) / market clearance(s)/registration(s):

- Canada – Medical Device license, OR;
- European Union - EC Full Quality Assurance Certificate or EC Production Quality Assurance Certificate cate or EC Type-Examination Certificate (CE/ Conformité Européenne mark) or / Conformité Européenne 92/42 or CE/ Conformité Européenne 98/79, OR;
- Australia - TGA Production Quality Assurance Certificate or TGA Type-Examination Certificate or TGA Full Quality Assurance Certificate issued by Therauptic Goods Administration, OR;
- Japan – PMDA (Pharmaceuticals and Medical Devices Agency) approval or JMHLW (Japan Ministry of Health, Labour and Welfare) Minister's approval, OR;
- USA – PMA (pre-market approval) letter or BLA license (Biologics License Application) or 510k device letter issued by US Food and Drug Administration.

AND

1.2.a. Suppliers and manufacturers must provide an evidence of conformity* to at least one of the following conformity with the following Quality Management System standards as recognized by GHTF standards:

- ISO13485/ISO 13488, or
- ISO 9001, or
- 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)
c) Last audit date and
d) Expiration date
e) Certificate number

OR

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

OPTION 2 (2.1. + 2.2.)

2.1. The proposed product(s) must have registered/certified for the use in Ukraine:

- Registration Certificate issued by the State Administration on Pharmaceutical Products and Drugs Control Service of Ukraine and at least one successfully completed supply of this product in the similar volume in/to Ukraine within the past five years confirmed by medical institution/diagnostic center/laboratory center (since August 2012), 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[1]) and at least one successfully completed supply of this product in the similar volume in/to Ukraine within the past five years confirmed by medical institution/diagnostic center/laboratory center (since August 2012)

AND

2.2.a. Suppliers and manufacturers must provide an evidence of conformity* to at least one of the following conformity with the following Quality Management System standards as recognized by GHTF standards:

- ISO13485/ISO 13488, or
- ISO 9001, or
- 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)
c) Last audit date and
d) Expiration date
e) Certificate number

OR

2.2.b. Suppliers/manufacturers shall provide a copy of valid GMP Certificate issued by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) authorities 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.

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.

3. 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).

[1] 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);
2. 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);
3.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).

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.

4. PRODUCTS SPECIFICATION *:

Lot	Medical Device Name	Size of kit	UOM	Quantity
1	Test kit for newborns screening for phenylketonuria in samples of blood dried on filter paper	960 tests / kit	kit	616
2	Test kit for newborn screening for congenital hypothyroidism in samples of blood dried on filter paper	960 tests / kit	kit	547
3	Test kit for newborn screening for cystic fibrosis in samples of blood dried on filter paper	960 tests / kit	kit	545
4	Test kit for newborn screening for adrenogenital syndrome in samples of blood dried on filter paper	960 tests / kit	kit	530
5	Paper test-blanks for blood sampling from newborns*	1 pcs	unit	499 419
6	Immunoassay plate with U-type bottom	1 pcs	unit	6 053
7	Diagnostic kits for the determination of cyclosporine A concentration	-	kit	22
8	Diagnostic kits for the determination of Tacrolimus concentration	-	kit	21

Lot	Medical Device Name	Size of kit	UOM	Quantity
9	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 Fresenius 5008-type devices	-	pcs	134
10	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
11	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 Fresenius 5008-type devices	-	pcs	190
12	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	30

* paper brand Watman ™ 903 or equivalent

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

4.1. General requirements to the Lots 1-6:

1. Test kits for screening newborns for phenylketonuria and congenital hypothyroidism should allow the determination of phenylalanine and thyroid stimulating hormone (TSH) in newborns dried blood samples on filter paper in a microplate analyzers with fluorophotometry function available in the medical genetic service carrying out mass screening of newborns.

2. All laboratories of the medical and genetic service carrying out research on the program of mass neonatal screening are equipped with multifunction analyzers VICTOR 3^{TM} 1420 Multilabel counter manufactured by the Wallac Oy (Perkin Elmer) Finland during 2001 - 2016.

3. Test kits for screening newborns for phenylketonuria and congenital hypothyroidism should allow testing not less than 800 children.

4. The shelf life of the kits at the time of delivery shall be not less than 6 months or not less than 75% of the total shelf life as determined by the manufacturer.

5. The possibility to deliver the goods in small quantities at least 2 times a year to ensure temperature conditions of test kits storage at the final recipient's premises.

6. Test kits should be compatible with the software installed and available testing equipment:

- Phenylalanine assay by fluorescence at 390 nm/485 nm wave length;
- TSH assay by fluorescence at 320 nm/405 nm wave length;
- Immunoreactive trypsin assay by fluorescence at 320 nm/405 nm wave length;
- 17-OHP concentration assay by fluorescence at 320 nm/405 nm wave length;

7. All necessary reagents for work should be in the form of solutions or concentrates of solutions ready for use.

8. The kits should have calibrators and controls with the levels of phenylalanine and TSH at the rates that correspond to their concentrations in newborns in normal and pathological conditions. Calibrators and controls should be made on paper of the same quality as the test forms for blood collection.

9. Possibility to obtain results for a single definition of the analyzed blood samples of newborns.

10. Sensitivity/detection limit:

- Phenylalanine: not more than 0.5 mg/dL.
- Thyroid-stimulating hormone: not more than 1.0 mmol/L blood;
- 17-OHP: not more than 0.8 ng/ 1 ml of serum

4.2. Composition of the sets of the reagents:

4.2.1. Composition of the set of reagents for determination of phenylketonuria:

1) Succinic buffer (succinic acid, pH 5,8 ± 0,1, containing 0,05% Bronidox® as an additive) - 40 ml.
2) L-leucyl-L-alanine (a solution of L-leucyl-L-alanine containing 0,05% Bronidox® as an additive) - 9 ml
3) Ninhydrin 2 x 10 ml
4) Copper-containing reagent (pentahydrate copper sulphate, sodium-potassium tartrate and sodium carbonate) - 250 ml
5) Calibrators, 1 sheet of 5 sets of 6 calibrators in foil package containing a desiccant. Values of calibrators are specific to test-systems batch. Calibrators are prepared from human blood levels of hematocrit of 50 - 54% and calibrated according to the 1st Etalon of the International Society for Neonatal Screening (ISNS) for neonatal screening to determine thyrotropin, phenylalanine and 17-alpha-hydroxyprogesterone in spots of blood.
6) Controls, 1 sheet of 5 sets of 2 control in foil package containing a desiccant. Values of controls specific to test-systems batch. Controls prepared from human blood hematocrit level of 50 - 54%. The value of phenylalanine is given in gravimetric units (mg/dL = mg/100 ml = mg%).
7) The reaction plates, 10 pcs. Microplate without solidphase coat.
8) The plastic covers, 20 pcs. Plastic cover for plates for incubation and elution.
9) Table with the data of controls and calibrators - 1 pc. in each set.

4.2.2. Composition of the set of reagents for determination of congenital hypothyroidism:

1) Adsorbed titration microplate (microplate with adsorbed antibodies) - 10 plates
2) Conjugate anti-hTSH-HRP 100-fold concentrate (conjugate Horseradish peroxidase and antibodies to TSH (Thyroid-stimulating hormone) containing Kathon CG® as an additive) – 2.5 ml.
3) Solution for diluting conjugate (buffered saline solution containing Bronidox® as an additive) - 250 ml
4) Substrate HPPA (3- (p-hydroxyphenyl) propionic acid in buffer containing Kathon CG® as an additive) - 4 x 50 ml
5) Solution for diluting substrate HPPA (H_2O_2 solution) – 45 ml
6) Stopping solution (2-x concentrated glycine buffer) - 150 ml
7) Washing solution (10-x concentrate, buffer solution containing Bronidox® as an additive) - 220 ml
8) Calibrators A - F, (paper brand Watman ™ 903 or equivalent), 1 sheet (ready-to-use calibrators, 5 sets). Values (mIU / L blood) of calibrators are specific to test-systems batch. Calibrators are prepared from human blood levels of hematocrit of 50 - 55% and calibrated according to the 1st Etalon of the International Society for Neonatal

Screening (ISNS) for neonatal screening to determine thyrotropin, phenylalanine and 17-alpha-hydroxyprogesterone in spots of blood.

9) Controls C1 - C2 (paper brand Watman ™ 903 or equivalent) 1 sheet (ready-to-use controls, 5 sets). Values (mIU/L blood) controls are specific to test-systems batch.
10) Plastic covers (plastic cover for microplate for incubation) – 20 pcs.
11) Tanks for reagents - 10 pieces.
12) Table with the data of controls and calibrators - 1 pc in each set.

4.2.3. Composition of the set of reagents for determination of cystic fibrosis:

1) Adsorbed titration microplate (microplate with adsorbed antibodies) - 10 plates
2) Conjugate anti- IRT1-HRP 100-fold concentrate (conjugate Horseradish peroxidase and antibodies to Tripsinogen-1 containing Kathon CG® as an additive) – 2.5 ml.
3) Solution for diluting conjugate (buffered saline solution containing Bronidox® as an additive) - 250 ml
4) Substrate HPPA (3- (p-hydroxyphenyl) propionic acid in buffer containing Kathon CG® as an additive) - 4 x 50 ml
5) Solution for diluting substrate HPPA (H_2O_2 solution) – 45 ml.
6) Stopping solution (2-x concentrated glycine buffer) - 150 ml
7) Washing solution (10-x concentrate, buffer solution containing Bronidox® as an additive) - 250 ml
8) Calibrators A - F, (paper brand Watman ™ 903 or equivalent), 1 sheet (ready-to-use calibrators, 5 sets). Values (mcg/L blood) of calibrators are specific to test-systems batch.
9) Controls C1 - C2 (paper brand Watman ™ 903 or equivalent) 1 sheet (ready-to-use controls, 5 sets). Values (mcg/L blood) controls are specific to test-systems batch.
10) Plastic covers (plastic cover for microplate for incubation) – 20 pcs.
11) Tanks for reagents - 10 pieces.
12) Table with the data of controls and calibrators - 1 pc in each set.

4.2.4. Composition of the set of reagents for adrenogenital syndrome:

1) Adsorbed titration microplate (microplate with adsorbed antibodies) - 10 plates
2) Conjugate ant i- OHP-HRP (100-fold concentrate of 17-OH progesterone conjugated with Horseradish peroxidase containing N- methylisothiazolinone as an additive) – 2.4 ml.
3) Solution for diluting conjugate (buffered saline solution containing Bronidox® as an additive) - 250 ml
4) Substrate HPPA (3- (p-hydroxyphenyl) propionic acid in buffer containing Kathon CG® as an additive) - 4 x 50 ml
5) Solution for diluting substrate HPPA (H_2O_2 solution) – 45 ml
6) Stopping solution (2-x concentrated glycine buffer) - 150 ml
7) Washing solution (10-x concentrate, buffer solution containing Bronidox® as an additive) - 220 ml
8) Calibrators A - F, (paper brand Watman ™ 903 or equivalent), 1 sheet (ready-to-use calibrators, 5 sets). Values (ng / ml of serum) of calibrators are specific to test-systems batch. Calibrators are prepared from human blood levels of hematocrit of 50 - 55% and calibrated according to the 1st Etalon of the International Society for Neonatal Screening (ISNS) for neonatal screening to determine thyrotropin, phenylalanine and 17-alpha-hydroxyprogesterone in spots of blood.
9) Controls C1 - C2 (paper brand Watman ™ 903 or equivalent) 1 sheet (ready-to-use controls, 5 sets). Values (ng/ml of serum) controls are specific to test-systems batch.
10) Plastic covers (plastic cover for microplate for incubation) – 20 pcs.
11) Tanks for reagents - 10 pieces.
12) Table with the data of controls and calibrators - 1 pc in each set.

4.3. Special requirements to paper test-blanks for blood collection of newborns:

1) Test-blank for blood samples collection must be designed for newborn screening, namely samples collection, its identification and transportation.

2) Blank Filtering paper should refer to a class 903 or 226 or TFN.
3) Test-blank should refer to a medical device “in-vitro” safety class.
4) Test-blank must have cassette format: consist of several parts fastened together, the main ones are filtering paper for samples collection and demographic form that could be filled with data on newborn in Ukrainian or Russian.

4.4. Special requirements to plates immunoassay, 96 holes, transparent, with U-shape bottom

1. Plates must have 96-holes format.
2. Plates must be made of transparent polystyrene.
3. Plates must have U-shape bottom.

4.5. General requirements to the Lots 7-12:

- The products must be compatible for the use on automated chemiluminescent immunoassay analyzers of closed type (module immunochemical analyzer to test the concentration of immunosuppressive agents in the blood) under the trade name ARCHITECT (Lots 7-8).
- Products must have a minimum of 75% of the total product shelf life or should have 6 months’ shelf life remaining at the time of delivery (Lots 7-8).
- Products must have a minimum of 75% of the total product shelf life remaining at the time of delivery (Lots 9-12)

4.5.1. Diagnostic kits for the determination of cyclosporine A concentration:

- The on-board stability of the kits for testing cyclosporine must be at least 30 days after opening.
- The test range for the cyclosporine kit should be within 30.0–1,500.0 ng/ml (without dilution of samples).
- The reproducibility, CV (coefficient of reproducibility) for the cyclosporine kit should be not more than 15%.
- The functional sensitivity for the cyclosporine kit should be not more than 30.0 ng/mL.
- The specificity (cross reactivity) for the cyclosporine kit with AM1 metabolite should be not more than 1.7%, and with AM9 metabolite — not more than 1.9%.

4.5.2. Diagnostic kits for the determination of Tacrolimus concentration:

- The on-board stability of the kits for testing Tacrolimus must be at least 30 days after opening.
- The test range for the Tacrolimus kit should be within 2–30 ng/ml (without dilution of samples).
- The reproducibility, CV (coefficient of reproducibility) for the Tacrolimus kit should be not more than 10%.
- The functional sensitivity for the Tacrolimus kit should be not more than 2 ng/mL.
- The specificity (cross reactivity) for the Tacrolimus kit with M I metabolite should be not more than 8%.

4.5.3. Special requirements to the Lots 7-8:

Composition of the Lot 7 (Diagnostic kits for the determination of cyclosporine A concentration):

Architect Cyclosporine Reagent Kit - 100 tests
Architect Cyclo Whole Blood Precipitation Reagent — 1 pcs.
Architect Cyclosporine Calibrators — 1 pcs.
Abbot Immunosuppressant-MCC– 1 pcs.
Architect Concentrated Wash Buffer — 1 package.
Pre-Trigger Solution — 1 package.
Trigger Solution — 1 package.
Architect Probe Conditioning Solution — 0.25 package.
Transplant Pretreatment Tubes — 2 packages.

X-Systems Centrifuge tubes — 1 package.
Septums — 1 package.
Replacement Caps — 1 package.
Sample Cups — 1 package.
Reaction Vessels — 1 package.

Composition of the Lot 8 (Diagnostic kits for the determination of Tacrolimus concentration):

Architect Tacrolimus Reagent Kit - 100 tests
Architect Tacrolimus Whole Blood Precipitation Reagent — 1 pcs.
Architect Tacrolimus Calibrators — 1 pcs.
Abbot Immunosuppressant-MCC– 1 pcs.
Architect Concentrated Wash Buffer — 1 package.
Pre-Trigger Solution — 1 package.
Trigger Solution — 1 package.
Architect Probe Conditioning Solution — 0.25 package.
Transplant Pretreatment Tubes — 2 packages.
X-Systems Centrifuge tubes — 1 package.
Septums — 1 package.
Replacement Caps — 1 package.
Sample Cups — 1 package.
Reaction Vessels — 1 package.

4.5.3. Special requirements to the Lots 9-12:

Lot 9. 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 Fresenius 5008-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 186 ml/min;
- creatinine not less than 173 ml/min.
2. Blood flow lines and fistula needles (arterial and venous) for Fresenius 5008-type devices (or equivalent).
3. Consumables must be compatible for the use on Fresenius 5008 devices.

Lot 10. 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 11. 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 Fresenius 5008-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 188 ml/min;
- creatinine not less than 175 ml/min.
2. Blood flow lines and fistula needles (arterial and venous) to devices of Fresenius 5008 type (or equivalent).
3. Consumables must be compatible for the use on Fresenius 5008 devices.

Lot 12. 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.

13) DELIVERY TIMEFRAMES

Early delivery of medicines/medical products to Ukraine is critical therefore we encourage shortest delivery periods. Products must be delivered within 4 months at the latest after signing the contract.

For the Lots 1-6 the Bidder must ensure delivery of the goods in partial quantities at least 2 times a year to ensure temperature conditions of test kits storage at the final recipient's premises. Proposed delivery schedule has to be described in the Annex 4.

The products under “Diagnostic kits for the determination of cyclosporine A and Tacrolimus concentration” (Lots 7-8) have to be delivered in two lots with the interval between the deliveries at least 2-3 months – last delivery should be arranged before/on May 15, 2018. Proposed delivery schedule has to be described in the Annex 4.

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

Delivery Term [INCOTERMS 2010] *(Pls. link this to price schedule)*	DAP Kyiv, Central Warehouse of the MoH The products shall be supplied to the Central Warehouse (State Enterprise) of MoH or designated by them entity appointed by UNDP. Exact location of the warehouse will be notified at the time of contracting. The transfer of ownership right from seller to buyer occurs simultaneously with the transfer of risk of goods loss or damage at the moment when the goods are delivered to the named warehouse. Partial delivery is acceptable: <u>maximum 3 consignments under delivery of one Lot/Item.</u>	
Mode of Transport Preferred	☒AIR	☒LAND
	☒SEA	☐OTHER *[pls. specify]*

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. • Certificate of Origin, if goods are being imported • Air Way Bill (air shipments)/Bill of Lading (sea shipments), if goods are being imported
Customs, if needed, clearing shall be done by:	Central Warehouse (State Enterprise) of MoH appointed by UNDP will act as importer of record with the condition that goods are 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.
Payment Terms	Within 30 calendar days after delivery subject to written acceptance of goods delivery, duly signed and stamped by UNDP/MoH and provision of original invoice. In case testing is required, satisfactory testing results is a prerequisite for payment release. Progress payments could be provided in case of partial delivery.

14) SHELF LIFE

Products (Lots 1-8) must have a minimum of 75% of the total product shelf life or should have 6 months' shelf life remaining at the time of delivery and must bear the dates of manufacture and expiry. Consumables for dialysis (Lots 9-12) 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.

15) 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:

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

The minimum technical requirements for dataloggers are as follows:

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

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

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

4) Labelling of package at the moment of supply must correspond to the one in the product's state registration record or Declaration of Conformity. In case of any deviations found, the supplier must provide additional documentation to enable receipt of goods.

5). Primary packaging must preserve quality, safety and stability of the product it contains. The entire package must be duly sealed and protected from spoiling. 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 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 pre-shipment inspection may be carried out by UNDP or its representative for verification of quality, quantity, packing, labelling, marking and sampling.

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

For this purpose, the Supplier will have to submit the applicable documentation to UNDP or its representative and allow UNDP or its representative access to all the goods. At least the packing list showing also the batch numbers per product and the full address of inspection should be made available to UNDP or its representative 7 working days before the pre-shipment inspection is requested to be carried out. Inspection/testing by UNDP or its representative in no way relieves the Supplier from the performance of full contractual obligations to UNDP. The cost of the pre-shipment inspection will be borne by UNDP. However, it is the responsibility of the supplier to assure that all facilities, to carry out a proper inspection are made available at their expense, and the goods for one shipment are presented at one location and on the date requested by UNDP or its representative. Furthermore, UNDP or its representative will charge the Supplier for the repeat, supplementary or abortive inspection visits necessitated by the fault of the supplier. UNDP or its representatives may inspect the production premises and the process of the manufacture to make sure they meet Good Manufacturing Practices (GMP).

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

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

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

c) The Supplier is responsible for the intrinsic quality of the finished dosage form of each product and for the intrinsic quality of the primary packaging of the product, prior to and after the CRF is issued. The Supplier's responsibility will be according to the Incoterms 2010 standards specified in the PO.

9) Stipulations concerning Recalls: In the event any of the Goods are recalled either by the National Regulatory Authority (NRA) of the country of production, the NRA of the recipient country or the Manufacturer, after the CRF related to the PO(s) covering the same Goods is issued, the Supplier shall notify UNDP within fourteen (14) days, providing full details of the reason for the recall and replace affected goods within one (1) month, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specifications and original PO(s) against which they were supplied, and arrange for collection or destruction of any defective Goods. If the Supplier fails to 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
Compliance of Bidder with Qualifications Requirements				
Minimum 3 years of experience in similar nature and minimum 2 similar contracts fulfilled over the past 3 years	1. Certificate of Registration of the business, including Articles of Incorporation, or equivalent document if Bidder is not a corporation			
	2. Statement of Satisfactory Performance (Reference letters) from the Top 3 Clients in terms of Contract Value the past 3 years. Please provide reference letters to prove experience in similar nature of contracts			
Minimum annual turnover over the past 2 years shall equal to no less than 75% of the total amount to be contracted	3. Latest Audited Financial Statement (Income Statement and Balance Sheet) including Auditor's Report for the past 2 years			
Compliance of product/quoted with product standards and requirements (please complete checklist for each product quoted)				
1.1. Medical products must be produced and controlled in accordance with product standards and quality system standards recommended by the World Health Organization (WHO) AND/OR the International Medical Devise Regulators Forum (IMDRF) (former Global Harmonization Task Force (GHTF). In order to be compliant with this criterion 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).	Medical Device license (Canada), OR			
	EC Full Quality Assurance Certificate or EC Production Quality Assurance Certificate cate or EC Type-Examination Certificate (CE/ Conformité Européenne mark) or / Conformité Européenne 92/42 or CE/ Conformité Européenne 98/79, OR			
	TGA Production Quality Assurance Certificate or TGA Type-Examination Certificate or TGA Full Quality Assurance Certificate issued by Therauptic Goods Administration), OR			
	PMDA (Pharmaceuticals and Medical Devices Agency) approval or JMHLW (Japan Ministry of Health, Labour and Welfare) Minister's approval, OR			
	PMA (pre-market approval) letter or BLA license (Biologics License Application) or 510k device letter issued by US Food and Drug Administration			

Award Criteria	Corresponding document	Yes	No	Reference
2.1. The proposed product(s) must have registered/certified for the use in Ukraine (please refer for details to Section 3 of ITB)	Registration Certificate issued by the State Administration on Pharmaceutical Products and Drugs Service of Ukraine, 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)			
	AND			
	Evidence of at least one successfully completed supply of this product in the similar volume in/to Ukraine within the past five years confirmed by medical institution/diagnostic center/laboratory center (since August 2012)			
1.2.a./2.2.a. Suppliers and manufacturers must provide an evidence of conformity* to at least one of the following conformity with the following Quality Management System standards as recognized by GHTF standard	ISO 13485, OR			
	ISO 9001, OR			
	United States QS (21 CFR part 820), OR			
	Japan QS Standard for medical devices			
1.2.b./2.2.b. Suppliers and manufacturers must provide an evidence of GMP certification of manufacturing site by PIC/S authorities	A copy of valid GMP Certificate issued by PIC/S authorities for the manufacturing site(s) of the proposed product(s))			
Availability of valid registration/certification in Ukraine at the time of supply as defined in Section 3, (if, at the moment of the bid submission, the quoted medical products are not registered in Ukraine but comply with the quality requirements of this ITB (OPTION 1), a Commitment letter shall be provided)	Option A: A copy of a valid registration certificate for every medicinal product quoted issued by the Ministry of Health of Ukraine AND/OR Declaration of Conformity with the requirements of technical regulations (Resolution of the Cabinet of Ministers of Ukraine #753, #754, #755 dd. 02.10.2013)			
	Option B: If, at the moment of the bid submission, the quoted medicinal products are not 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.			

Award Criteria	Corresponding document	Yes	No	Reference
Compliance with shelf life, packing and labelling requirements (please refer for details to Section 3 of ITB).	Please provide Information on shelf life in the Form 7 Technical Bid Form			
Acceptability of the Transportation/Delivery Schedule (please refer for details to Section 3 of ITB)	Please provide Information on delivery schedule in the Form 7 Technical Bid Form			

List of other documents required for evaluation of Offeror	Yes	No	Reference
Company profile (maximum 5 pages) or link to company's web-site			
List of Shareholders and Other Entities Financially Interested in the Firm owning 5% or more of the stocks and other interests, or its equivalent if Offeror is not a corporation			
Valid Certificate of Authorization to act on behalf of the Manufacturer in case the Offeror is not a Manufacturer as per template provided in the Annex 3.			
All information regarding any past and current litigation during the last five (5) years, in which the Offeror is involved, indicating the parties concerned, the subject of the litigation, the amounts involved, and the final resolution if already concluded.			
Quality Certificate (e.g., ISO, etc.) and/or other similar certificates, accreditations, awards and citations received by the Offeror, if any			
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.			
Technicalspecification of product quoted			
Safety data sheet (SDS) of the product			
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: http://zakon2.rada.gov.ua/laws/show/2755-17/page45

2. Decree of the Cabinet of Ministers of Ukraine #1153 dated 02.12.2015 on the procedures of importation, supply and targeted use of medicines, medical devices that are VAT exempted:
http://zakon3.rada.gov.ua/laws/show/1153-2015-%D0%BF

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

Annex 2.

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
Insert: Date

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

Dear Sir/Madam:

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

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

Products:

1. _____
2. _____
3. ….

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

We remain,
Yours sincerely,

Authorized Signature [*In full and initials*]: _____
Name and Title of Signatory: _____
Name of Firm: _____
Contact Details:_____

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

Annex 3

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

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

Insert: Location
Insert: Date

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

Dear Sir/Madam:

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

Products:

1. _____
2. _____
3. ….

For and on behalf of Manufacturer or Producer:

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

Contact Details:_____

Section 5: Bid Submission Form[2]

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

Insert: Location
Insert: Date

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

Dear Sir/Madam:

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

We hereby declare that:

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

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

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

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

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

We remain,
Yours sincerely,

Authorized Signature [*In full and initials*]: _____
Name and Title of Signatory: _____
Name of Firm: _____
Contact Details: _____

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

[2] *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[3]

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

Page _____of _____ pages

1. Bidder's Legal Name *[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 actual or intended Country of Registration]*		
4. Year of Registration in its Location: *[insert Bidder'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 Registration/Operation:*[insert Bidder's legal address in country of registration]*		
9. Value and Description of Top three (3) Biggest Contract for the past five (5) years		
10. Latest Credit Rating (Score and Source, if any)		
11. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved.		
12. Bidder's Authorized Representative Information Name: *[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.		

[3] *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)[4]

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

Page _____ of_____pages

1. Bidder's Legal Name: *[insert Bidder's legal name]*		
2. JV's Party legal name: *[insert JV's Party legal name]*		
3. JV's Party Country of Registration: *[insert JV's Party country of registration]*		
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 Registration/Operation: *[insert Party's legal address in country of registration]*		
9. Value and Description of Top three (3) Biggest Contract for the past five (5) years		
10. Latest Credit Rating (if any): Click here to enter text.		
1. Brief description of litigation history (disputes, arbitration, claims, etc.), indicating current status and outcomes, if already resolved. Click here to enter text.		
13. JV's Party Authorized Representative Information Name: *[insert name of JV's Party authorized representative]* Address: *[insert address of JV's Party authorized representative]* Telephone/Fax numbers: *[insert telephone/fax numbers of JV's Party authorized representative]* Email Address: *[insert email address of JV's Party authorized representative]*		
14. Attached are copies of original documents of: *[check the box(es) of the attached original documents]* ☐All eligibility document requirements listed in the Data Sheet ☐Articles of Incorporation or Registration of firm named in 2. ☐In case of government owned entity, documents establishing legal and financial autonomy and compliance with commercial law.		

[4]*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.*

Section 7: Technical Bid Form[5]

INSERT TITLE OF THE ITB

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

SUBSECTION 3.1: EXPERTISE OF FIRM/ ORGANISATION

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

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

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

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

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

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

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

2.1. Scope of Supply: Please provide a detailed description of the goods to be supplied, indicating clearly how they comply with

[5] *Technical Bids not submitted in this format may be rejected.*

the technical specifications required by the ITB **(please see Annex 4. – Annex shall be provided both in excel and PDF format)**; describe how the organization/firm will supply the goods and any related services, keeping in mind the appropriateness to local conditions and project environment.

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

2.1.2 Please provide the detailed Implementation Schedule.

Delivery lead time is a factor of a crucial importance in this project. Please make all possible efforts to propose supply of all requested quantities within shortest timeframe possible, 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.

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

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

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

SUBSECTION 3.3: PERSONNEL

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

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

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

Name:		
Role in Contract Implementation:		
Nationality:		
Contact information:		
Countries of Relevant Work Experience:		
Language Skills:		
Education and other Qualifications:		
Summary of Experience: *Highlight experience in the region and on similar projects.*		
Relevant Experience (From most recent):		
Period: From – To	**Name of activity/ Project/ funding organization, if applicable:**	**Job Title and Activities undertaken/Description of actual role performed:**
e.g. June 2010-January 2011		
Etc.		
Etc.		
References (minimum of 3):	*Name* *Designation* *Organization* *Contact Information – Address; Phone; Email; 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 BID SECURITY

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

To: UNDP

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

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

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

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

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

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

SIGNATURE AND SEAL OF THE GUARANTOR BANK

Date

Name of Bank

Address

Section 10: FORM FOR PERFORMANCE SECURITY

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

To: UNDP
[Insert contact information as provided in Data Sheet]

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

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

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

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

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

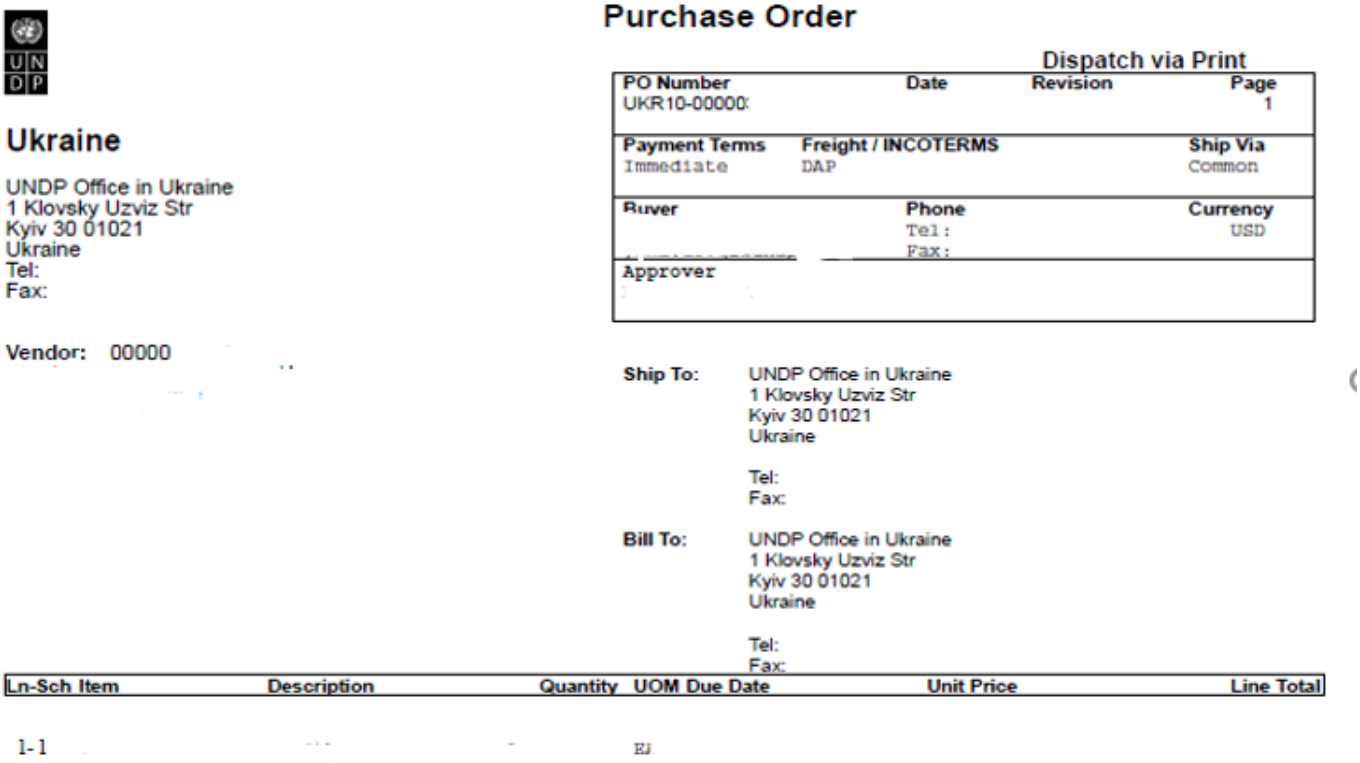
SIGNATURE AND SEAL OF THE GUARANTOR BANK

Date .....

Name of Bank .....

Address .....

Section 11: Template of Purchase Order and General Terms and Conditions for Goods



Purchase Order

Dispatch via Print

PO Number	Date	Revision	Page
UKR10-00000			1

Payment Terms	Freight / INCOTERMS	Ship Via
Immediate	DAP	Common

Buyer	Phone	Currency
	Tel:	USD
	Fax:	

Approver

Ukraine

UNDP Office in Ukraine
1 Klovsky Uzviz Str
Kyiv 30 01021
Ukraine
Tel:
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	Description	Quantity	UOM	Due Date	Unit Price	Line Total
1-1			EJ			

PO Text:

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

7. 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

1. ACCEPTANCE OF THE PURCHASE ORDER

This Purchase Order may only be accepted by the Supplier's signing and returning an acknowledgement copy of it or by timely delivery of the goods in accordance with the terms of this Purchase Order, as herein specified. Acceptance of this Purchase Order shall effect a contract between the Parties under which the rights and obligations of the Parties shall be governed solely by the terms and conditions of this Purchase Order, including these General Conditions. No additional or inconsistent provisions proposed by the Supplier shall bind UNDP unless agreed to in writing by a duly authorized official of UNDP.

2. PAYMENT

2.1.1 UNDP shall, on fulfillment of the Delivery Terms, unless otherwise provided in this Purchase Order, make payment within 30 days of receipt of the Supplier's invoice for the goods and copies of the shipping documents specified in this Purchase Order.

2.1.2 Payment against the invoice referred to above will reflect any discount shown under the payment terms of this Purchase Order, provided payment is made within the period required by such payment terms.

2.1.3 Unless authorized by UNDP, the Supplier shall submit one invoice in respect of this Purchase Order, and such invoice must indicate the Purchase Order's identification number.

2.1.4 The prices shown in this Purchase Order may not be increased except by express written agreement of UNDP.

3. TAX EXEMPTION

3.1 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 utilities services, and is exempt from customs 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 UNDP's exemption from such taxes, duties or charges, the Supplier shall immediately consult with UNDP to determine a mutually acceptable procedure.

3.2 Accordingly, the Supplier authorizes UNDP to deduct from the Supplier's invoice any amount representing such taxes, duties or charges, unless the Supplier has consulted with UNDP before the payment thereof and UNDP has, in each instance, specifically authorized the Supplier to pay such taxes, duties or charges under protest. In that event, the Supplier shall provide UNDP with written evidence that payment of such taxes, duties or charges has been made and appropriately authorized.

4. RISK OF LOSS

Risk of loss, damage to or destruction of the goods shall be governed in accordance with DDU Incoterms 2000, unless otherwise agreed upon by the Parties on the front side of this Purchase Order.

5. EXPORT LICENCES

Notwithstanding any INCOTERM 2000 used in this Purchase Order, the Supplier shall obtain any export licenses required for the goods.

6. FITNESS OF GOODS/PACKAGING

The Supplier warrants that the goods, including packaging, conform to the specifications for the goods ordered under this Purchase Order and are fit for the purposes for which such goods are ordinarily used and for purposes expressly made known to the Supplier by UNDP, and are free from defects in workmanship and materials. The Supplier also warrants that the goods are contained or packaged adequately to protect the goods.

7. INSPECTION

1. UNDP shall have a reasonable time after delivery of the goods to inspect them and to reject and refuse acceptance of goods not conforming to this Purchase Order; payment for goods pursuant to this Purchase Order shall not be deemed an acceptance of the goods.

2. Inspection prior to shipment does not relieve the Supplier from any of its contractual obligations.

8. INTELLECTUAL PROPERTY INFRINGEMENT

The Supplier warrants that the use or supply by UNDP of the goods sold under this Purchase Order does not infringe any patent, design, trade-name or trade-mark. In addition, the Supplier shall, pursuant to this warranty, indemnify, defend and hold UNDP and the United Nations harmless from any actions or claims brought against UNDP or the United Nations pertaining to the alleged infringement of a patent, design, trade-name or trade-mark arising in connection with the goods sold under this Purchase Order.

9. RIGHTS OF UNDP

In case of failure by the Supplier to fulfil its obligations under the terms and conditions of this Purchase Order, including but not limited to failure to obtain necessary export licenses, or to make delivery of all or part of the goods by the agreed delivery date or dates, UNDP may, after giving the Supplier reasonable notice to perform and without prejudice to any other rights or remedies, exercise one or more of the following rights:

a) Procure all or part of the goods from other sources, in which event UNDP may hold the Supplier responsible for any excess cost occasioned thereby.
b) Refuse to accept delivery of all or part of the goods.
c) Cancel this Purchase Order without any liability for termination charges or any other liability of any kind of UNDP.

10. LATE DELIVERY

Without limiting any other rights or obligations of the parties hereunder, if the Supplier will be unable to deliver the goods by the delivery date(s) stipulated in this Purchase Order, the Supplier shall (i) immediately consult with UNDP to determine the most expeditious means for delivering the goods and (ii) use an expedited means of delivery, at the Supplier's cost (unless the delay is due to Force Majeure), if reasonably so requested by UNDP.

11. ASSIGNMENT AND INSOLVENCY

11.1. The Supplier shall not, except after obtaining the written consent of UNDP, assign, transfer, pledge or make other disposition of this Purchase Order, or any part thereof, or any of the Supplier's rights or obligations under this Purchase Order.

11.2. Should the Supplier become insolvent or should control of the Supplier change by virtue of insolvency, UNDP may, without prejudice to any other rights or remedies, immediately terminate this Purchase Order by giving the Supplier written notice of termination.

12. USE OF UNDP OR UNITED NATIONS NAME OR EMBLEM

The Supplier shall not use the name, emblem or official seal of UNDP or the United Nations for any purpose.

13. PROHIBITION ON ADVERTISING

The Supplier shall not advertise or otherwise make public that it is furnishing goods or services to UNDP without specific permission of UNDP in each instance.

14. CHILD LABOUR

The Supplier represents and warrants that neither it nor any of its affiliates 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.

Any breach of this representation and warranty shall entitle UNDP to terminate this Purchase Order immediately upon notice to the Supplier, without any liability for termination charges or any other liability of any kind of UNDP.

15. MINES

The Supplier represents and warrants that neither it nor any of its affiliates is actively and directly engaged in patent activities, development, assembly, production, trade or manufacture of mines or in such activities in respect of components primarily utilized in the manufacture of Mines. The term "Mines" means those devices defined in Article 2, Paragraphs 1, 4 and 5 of Protocol II annexed to the Convention on Prohibitions and Restrictions on the Use of Certain Conventional Weapons Which May Be Deemed to Be Excessively Injurious or to Have Indiscriminate Effects of 1980.

Any breach of this representation and warranty shall entitle UNDP to terminate this Purchase Order immediately upon notice to the Supplier, without any liability for termination charges or any other liability of any kind of UNDP.

16. SETTLEMENT OF DISPUTES

16.1 Amicable Settlement

The Parties shall use their best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to this Purchase Order 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 UNCITRAL Conciliation Rules then obtaining, or according to such other procedure as may be agreed between the Parties.

16.2 Arbitration

Unless, any such dispute, controversy or claim between the Parties arising out of or relating to this Purchase Order or the breach, termination or invalidity thereof is settled amicably under the preceding paragraph of this Section within sixty (60) days after receipt by one Party of the other Party's request for such amicable settlement, such dispute, controversy or claim shall be referred by either Party to arbitration in accordance with the UNCITRAL Arbitration Rules

then obtaining, including its provisions on applicable law. The arbitral tribunal shall have no authority to award punitive damages. The Parties shall be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such controversy, claim or dispute.

17. PRIVILEGES AND IMMUNITIES

Nothing in or related to these General Terms and Conditions or this Purchase Order shall be deemed a waiver of any of the privileges and immunities of the United Nations, including its subsidiary organs.

18. SEXUAL EXPLOITATION:

18.1 The Contractor shall take all appropriate measures to prevent sexual exploitation or abuse of anyone by it or by any of its employees or any other persons who may be engaged 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 appropriate measures to prohibit its employees or other persons engaged by it from, exchanging any money, goods, services, offers of employment or other things of value, for sexual favors or activities, or from engaging in any sexual activities that are exploitive or degrading to any person. The Contractor acknowledges and agrees that the provisions hereof constitute an essential term of the Contract and that any breach of this representation and warranty shall entitle UNDP to terminate the Contract immediately upon notice to the Contractor, without any liability for termination charges or any other liability of any kind.

18.2 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.

19.0 OFFICIALS NOT TO BENEFIT:

The Contractor warrants that no official of UNDP or the United Nations has received or will be offered by the Contractor any direct or indirect benefit arising from this Contract or the award thereof. The Contractor agrees that breach of this provision is a breach of an essential term of this Contract.

20. AUTHORITY TO MODIFY:

Pursuant to the Financial Regulations and Rules of UNDP, only the UNDP Authorized Official possess the authority to agree on behalf of UNDP to any modification of or change in this Agreement, to a waiver of any of its provisions or to any additional contractual relationship of any kind with the Contractor. Accordingly, no modification or change in this Contract shall be valid and enforceable against UNDP unless provided by an amendment to this Agreement signed by the Contractor and jointly by the UNDP Authorized Official.