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REQUEST FOR QUOTATION (RFQ) for supply of reagents for screening newborns for phenylketonuria, congenital hypothyroidism, cystic fibrosis and adrenogenital syndrome (6 lots) (re-announcement)

RFQ Reference: 020-2021-UNDP-UKR	Date: 25 May 2021

SECTION 1: REQUEST FOR QUOTATION (RFQ)

UNDP Ukraine kindly requests your quotation for the provision of goods as detailed in Section 3 of this RFQ.

This Request for Quotation comprises the following documents:

- Section 1: This request letter
- Section 2: RFQ Instructions and Data
- Section 3: Schedule of requirements
- ANNEX 1. Brief summary on product registration and VAT exemption procedure
- ANNEX 2. Commitment Letter (if product is not registered in Ukraine)
- ANNEX 3. Certificate of Authorization (if bidder is not a manufacturer)
- FORM A: QUOTATION SUBMISSION FORM
- FORM B: TECHNICAL AND FINANCIAL OFFER
- Template of Contract for Goods
- Returnable Bidding Forms / Checklist

When preparing your quotation, please be guided by the RFQ Instructions and Data. Please by quided by Returnable Bidding Forms/Checklist while preparing your Bid. Please note that it is your responsibility to ensure that your quotation is submitted on or before the deadline. Quotations received after the submission deadline, for whatever reason, will not be considered for evaluation.

Thank you and we look forward to receiving your quotations.

Issued by: UNDP Ukraine Country Office

Signature: _____

Name: Ms. Agnes Kochan

Title: Operations Manager United Nations Development Program

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SECTION 2: RFQ INSTRUCTIONS AND DATA

Introduction	Bidders shall adhere to all the requirements of this RFQ, including any amendments made in writing by UNDP. This RFQ is conducted in accordance with the UNDP Programme and Operations Policies and Procedures (POPP) on Contracts and Procurement Any Bid submitted will be regarded as an offer by the Bidder and does not constitute or imply the acceptance of the Bid by UNDP. UNDP is under no obligation to award a contract to any Bidder as a result of this RFQ. UNDP reserves the right to cancel the procurement process at any stage without any liability of any kind for UNDP, upon notice to the bidders or publication of cancellation notice on UNDP website.
Deadline for the Submission of Quotation	8 June 2021, 15:00 Kyiv time If any doubt exists as to the time zone in which the quotation should be submitted, refer to http://www.timeanddate.com/worldclock/.
Method of Submission	Quotations must be submitted as follows: ☐ E-tendering ☒ Dedicated Email Address health.procurement.ua@undp.org ☐ Courier / Hand delivery ☐ Other Click or tap here to enter text. Bid submission address: health.procurement.ua@undp.org ▪ File Format: PDF, Excel, Word, Zip ▪ File names must be maximum 60 characters long and must not contain any letter or special character other than from Latin alphabet/keyboard. ▪ All files must be free of viruses and not corrupted. ▪ Max. File Size per transmission: 10 MB ▪ Mandatory subject of email: RFQ 020-2021 UNDP-UKR ▪ Multiple emails must be clearly identified by indicating in the subject line “email no. X of Y”, and the final “email no. Y of Y. ▪ It is recommended that the entire Quotation be consolidated into as few attachments as possible. ▪ The bidder should receive an email acknowledging email receipt.
Cost of preparation of quotation	UNDP shall not be responsible for any costs associated with a Supplier’s preparation and submission of a quotation, regardless of the outcome or the manner of conducting the selection process.
Supplier Code of Conduct, Fraud, Corruption,	All prospective suppliers must read the United Nations Supplier Code of Conduct and acknowledge that it provides the minimum standards expected of suppliers to the UN. The Code of Conduct, which includes **principles on labour, human rights, environment and ethical conduct** may be found at: https://www.un.org/Depts/ptd/about-us/un-supplier-code-conduct Moreover, UNDP strictly enforces a policy of zero tolerance on proscribed practices, including fraud, corruption, collusion, unethical or unprofessional practices, and obstruction of UNDP vendors and requires all bidders/vendors to observe the highest standard of ethics during the procurement process and contract implementation. UNDP’s Anti-Fraud Policy can be found at http://www.undp.org/content/undp/en/home/operations/accountability/audit/office_of_audit_andinvestigation.html#anti
Gifts and Hospitality	Bidders/vendors shall not offer gifts or hospitality of any kind to UNDP staff members including recreational trips to sporting or cultural events, theme parks or offers of holidays, transportation, or invitations to extravagant lunches, dinners or similar. In pursuance of this policy, UNDP: (a) Shall reject a bid if it determines that the selected bidder has engaged in any corrupt or fraudulent practices in

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	competing for the contract in question; (b) Shall declare a vendor ineligible, either indefinitely or for a stated period, to be awarded a contract if at any time it determines that the vendor has engaged in any corrupt or fraudulent practices in competing for, or in executing a UNDP contract.
Conflict of Interest	UNDP requires every prospective Supplier to avoid and prevent conflicts of interest, by disclosing to UNDP if you, or any of your affiliates or personnel, were involved in the preparation of the requirements, design, specifications, cost estimates, and other information used in this RFQ. Bidders shall strictly avoid conflicts with other assignments or their own interests, and act without consideration for future work. Bidders found to have a conflict of interest shall be disqualified. Bidders must disclose in their Bid their knowledge of the following: a) If the owners, part-owners, officers, directors, controlling shareholders, of the bidding entity or key personnel who are family members of UNDP staff involved in the procurement functions and/or the Government of the country or any Implementing Partner receiving goods and/or services under this RFQ. 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, operated and managed as an independent business entity, the extent of Government ownership/share, receipt of subsidies, mandate and access to information in relation to this RFQ, among others. Conditions that may lead to undue advantage against other Bidders may result in the eventual rejection of the Bid.
General Conditions of Contract	Any Contract that will be issued as a result of this RFQ shall be subject to the General Conditions of Contract Select the applicable GTC: ☒ General Terms and Conditions / Special Conditions for Contract. ☐ General Terms and Conditions for de minimis contracts (services only, less than $50,000) ☐ General Terms and Conditions for Works Applicable Terms and Conditions and other provisions are available at UNDP/How-we-buy
Special Conditions of Contract	☒ Cancellation of Contract if the delivery/completion is delayed by [30 days] ☒ Performance Security will be requested in the amount of 10 % of the contract amount in case product is not registered in the country of destination or at the discretion of UNDP. A performance security, if required in the BDS, shall be provided from available at https://popp.undp.org/_layouts/15/WopiFrame.aspx?sourcedoc=/UNDP_POPP_DOCUMENT_LIBRARY/Public/PSU_Solicitation_Performance%20Guarantee%20Form.docx&action=default within a maximum of fifteen (15) days from the date of the contract signature by both parties.
Eligibility	A vendor who will be engaged by UNDP may not be suspended, debarred, or otherwise identified as ineligible by any UN Organization or the World Bank Group or any other international Organization. Vendors are therefore required to disclose to UNDP whether they are subject to any sanction or temporary suspension imposed by these organizations. Failure to do so may result in termination of any contract or PO subsequently issued to the vendor by UNDP. It is the Bidder's responsibility to ensure that its employees, joint venture members, sub-contractors, service providers, suppliers and/or their employees meet the eligibility requirements as established by UNDP. Bidders must have the legal capacity to enter a binding contract with UNDP and to deliver in the country, or through an authorized representative.
Currency of Quotation	• 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)
Joint Venture, Consortium or	If the Bidder is a group of legal entities that will form or have formed a Joint Venture (JV), Consortium or Association for 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 JV, Consortium or Association jointly and severally, which shall be evidenced by a duly notarized Agreement among the legal entities, and submitted with the Bid; and (ii) if they are awarded the contract, the contract shall be entered into,

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Association	by and between UNDP and the designated lead entity, who shall be acting for and on behalf of all the member entities comprising the joint venture, Consortium or Association. Refer to Clauses 19 – 24 under Solicitation policy for details on the applicable provisions on Joint Ventures, Consortium or Association.
Only one Bid	The Bidder (including the Lead Entity on behalf of the individual members of any Joint Venture, Consortium or Association) shall submit only one Bid, either in its own name or, if a joint venture, Consortium or Association, as the lead entity of such Joint Venture, Consortium or Association. Bids submitted by two (2) or more Bidders shall all be rejected 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 b) they have the same legal representative for purposes of this RFQ; or c) 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 RFQ process; d) 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 e) some key personnel proposed to be in the team of one Bidder participates in more than one Bid received for this RFQ process. This condition relating to the personnel, does not apply to subcontractors being included in more than one Bid.
Duties and taxes	Article II, Section 7, of the Convention on the Privileges and Immunities provides, inter alia, that the United Nations, including UNDP as a subsidiary organ of the General Assembly of the United Nations, is exempt from all direct taxes, except charges for public utility services, and is exempt from customs restrictions, duties, and charges of a similar nature in respect of articles imported or exported for its official use. All quotations shall be submitted net of any direct taxes and any other taxes and duties, unless otherwise specified below: All prices must: ☐ be inclusive of VAT and other applicable indirect taxes ☒ be exclusive of VAT and other applicable indirect taxes (Please refer to Annex 1 - Bidder quotes prices without VAT and VAT separately, if applicable)
Language of quotation	English is preferred. Russian/Ukrainian acceptable
Documents to be submitted	Bidders shall include the following documents in their quotation: ☒ FORM A: QUOTATION SUBMISSION FORM ☒ FORM B: TECHNICAL AND FINANCIAL OFFER (Annex 4 and 5 in Excel and PDF to be included) ☒ Annex 2: Commitment Letter (if product is not registered in Ukraine) ☒ Annex 3. Certificate of Authorization (if bidder is not a manufacturer) ☐ Other Click or tap here to enter text.
Quotation validity period	Quotations shall remain valid for 90 days from the deadline for the Submission of Quotation.
Price variation	No price variation due to escalation, inflation, fluctuation in exchange rates, or any other market factors shall be accepted at any time during the validity of the quotation after the quotation has been received.
Partial Quotes	☐ Not permitted ☒ Permitted. Bidder may submit Bid for separate Lots
Alternative Quotes	☒ Not permitted ☐ Permitted If permitted, an alternative quote may be submitted only if a conforming quote to the RFQ requirements is submitted. Where the conditions for its acceptance are met, or justifications are clearly established, Click or tap here to enter text. reserves the right to award a contract based on an alternative quote. If multiple/alternative quotes are being submitted, they must be clearly marked as "Main Quote" and "Alternative Quote"
Payment Terms	☒ 100% within 30 days after receipt of goods, works and/or services and submission of payment documentation. ☐Other Click or tap here to enter text.

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Conditions for Release of Payment	☐ Passing Inspection [specify method, if possible] Complete Installation ☐ Passing all Testing [specify standard, if possible] ☐ Completion of Training on Operation and Maintenance [specify no. of trainees, and location of training, if possible ☒ Written Acceptance of Goods, Services and Works, based on full compliance with RFQ requirements ☐ Others [pls. specify]
Contact Person for correspondence, notifications and clarifications	E-mail address: olena.synie gubova@undp.org Attention: Quotations shall not be submitted to this address but to the address for quotation submission above. Otherwise, offer shall be disqualified. Any delay in UNDP's response shall be not used as a reason for extending the deadline for submission, unless UNDP determines that such an extension is necessary and communicates a new deadline to the Proposers.
Clarifications	Requests for clarification from bidders will not be accepted any later than 2 days before the submission deadline.
Evaluation method	☒The Contract will be awarded to the lowest price substantially compliant offer ☐ Other Click or tap here to enter text.
Evaluation criteria	☒Full compliance with all requirements as specified in Section 3 ☒Full acceptance of the General Conditions of Contract ☐Comprehensiveness of after-sales services ☐Earliest Delivery /shortest lead time ☐Others Click or tap here to enter text.
Right not to accept any quotation	UNDP is not bound to accept any quotation, nor award a contract or Purchase Order
Right to vary requirement at time of award	At the time of award of Contract, UNDP reserves the right to vary (increase or decrease) the quantity of services and/or 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.
Type of Contract to be awarded	☐ Purchase Order ☒ Contract Face Sheet (Please refer to Template of Contract for Goods along with this RFQ instructions) ☐ Contract for Works ☐ Other Type/s of Contract [pls. specify]
Expected date for contract award.	08 July 2021
Publication of Contract Award	UNDP will publish the contract awards valued at USD 100,000 and more on the websites of the CO and the corporate UNDP Web site.
Policies and procedures	This RFQ is conducted in accordance with UNDP Programme and Operations Policies and Procedures
UNGM registration	Any Contract resulting from this RFQ exercise will be subject to the supplier being registered at the appropriate level on the United Nations Global Marketplace (UNGM) website at www.ungm.org. The Bidder may still submit a quotation even if not registered with the UNGM, however, if the Bidder is selected for Contract award, the Bidder must register on the UNGM prior to contract signature.

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SECTION 3: SCHEDULE OF REQUIREMENTS

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.

During 2017-2019 years UNDP was entrusted for the procurement medicines and other medical products for 26-27 state health programmes under the respective State budget years.
UNDP has signed Agreement for the 2020 State budget with the MOH and has been implementing the procurement accordingly.
UNDP operates on a collaborative spectrum leveraging the technical competence to deliver against four strategic objectives:
•selection of reliable suppliers of quality-assured products;
•procurement of the most cost-effective pharmaceutical products in the right quantities;
•timely delivery; and
•achievement of the lowest possible total cost.
This specific tender focuses on the supply of reagents for screening newborns for phenylketonuria, congenital hypothyroidism, cystic fibrosis and adrenogenital syndrome for the 2019 State budget with reference to letter from MOH dd 10.03.2021

2. PRODUCTS SPECIFICATION*

Lot	Medical Device Name	Size of kit	UOM	Quantity	required delivery schedule
1	Test kit for newborns screening for phenylketonuria in samples of blood dried on filter paper	Please see RFQ Section 3, para 3 and para 4 for details	kit	13	July-2021
2	Test kit for newborn screening for congenital hypothyroidism in samples of blood dried on filter paper	Please see RFQ Section 3, para 3 and para 4 for details	kit	14	July--2021
3	Test kit for newborn screening for cystic fibrosis in samples of blood dried on filter paper	Please see RFQ Section 3, para 3 and para 4 for details	kit	31	July--2021
4	Test kit for newborn screening for adrenogenital syndrome in samples of blood dried on filter paper	Please see RFQ Section 3, para 3 and para 4 for details	kit	24	July--2021
5	Paper test-blanks for blood sampling from newborns	Please see RFQ Section 3, para 3 and para 4 for details	unit	21 000	July--2021
6	Immunoassay plate with U-type bottom	Please see RFQ Section 3, para 3 and para 4 for details	unit	100	July--2021

* 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.

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2.1.Medical products should comply with the requirements of Resolution of the Cabinet of Ministers of Ukraine No. 753 dated October 2, 2013, "On Approval of the Technical Regulations on Medical Products" and Resolution of the Cabinet of Ministers of Ukraine No. 754 dated October 2, 2013, "On Approval of the Technical Regulations for Medical Products for Diagnostics in Vitro" (regarding the positions to which they can be applied), which is confirmed at the time of delivery by a certified copy of the declaration and, if available, a certificate of conformity.

2.2. A copy of the instruction (manual) for operation (application) for the medical product in Ukrainian is required. In the case of approved instruction in the original language, it should be accompanied by a copy of the original translation of the instruction into Ukrainian.

2.3.The transportation and storage of medicinal products should be carried out under the conditions determined by the instructions for their use (temperature, avoiding direct sunlight, etc.).

3.SPECIAL CONDITIONS TO THE MEDICAL PRODUCTS:

General requirements for the newborn screening test kit for phenylketonuria, congenital hypothyroidism, adrenogenital syndrome, and cystic fibrosis in dried blood samples on filter paper.

3.1 Newborn screening test kits for phenylketonuria, congenital hypothyroidism, adrenogenital syndrome, and cystic fibrosis should provide the possibility of quantitative determination of phenylalanine, thyroid-stimulating hormone (TSG), 17-hydroxyprogesterone (17-OHP), immunoreactive trypsin (IRT) in newborns' dried blood samples on filter paper by a microplate analyzer with a fluorometer function, equipped in the facilities of the medical genetic services, which carry out screening of newborns. All laboratories of the Medical Genetic Service conducting newborn screening programs are equipped with multifunctional VICTOR 3TM 1420 Multilabel counter analyzers manufactured by Wallac Oy (Perkin Elmer) Finland for production in 2001–2016. Test kits should be compatible with these analyzers.

3.2 Newborn screening test kits for phenylketonuria, congenital hypothyroidism, adrenogenital syndrome, and cystic fibrosis should provide the ability to test at least 780 newborns.

3.3 Shelf life of the kits at the time of delivery must be at least 6 months or 75% of the total shelf life declared by the manufacturer.

3.4 Ability to deliver goods in small batches at least 2 times a year to ensure the storage temperature of the test kits at the final recipient.

3.5 Test kits must be compatible with the installed software and available testing equipment:
- Phenylalanine assay by fluorescence at 390 nm/485 nm wavelength
- TSH assay by fluorescence at 320 nm/405 nm wavelength
- 17-OHP assay by fluorescence at 340 nm/615 nm wavelength
- IRT assay by fluorescence at 320 nm/405 nm wavelength

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

3.7 Kits should contain calibrators and controls with levels of phenylalanine, TSG, 17-OHP, IRT in areas of values that correspond to their concentration in newborns in normal and pathological conditions. Calibrators and controls should be made on paper of the same quality as sample collection cards for blood sampling.

3.8 It should be possible to obtain results for a single determination of the studied parameters in neonatal blood samples.

3.9 Sensitivity limit/minimum quantity definition:
- Phenylalanine: no more than 0.5 mg/dL
- Thyroid-stimulating hormone: no more than 1.0 mmol/L of blood
- 17-hydroxyprogesterone: no more than 0.5 ng/mL of serum

4. Special requirements for the newborn screening test kit for phenylketonuria, congenital hypothyroidism, adrenogenital syndrome, and cystic fibrosis in dried blood samples on filter paper:
4.1. Composition of a reagent kit for determination of phenylalanine:

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1) Succinate buffer 40 mL – succinic acid, pH (5.8 ± 0.1), containing a preservative
2) L-leucyl-L-alanine 9 mL – L-leucine-L-alanine solution containing 0.05% a preservative
3) Ninhydrin 2 × 10 mL – ninhydrin
4) Copper-based reagent 2 × 125 mL – copper sulfate pentahydrate, potassium sodium tartrate, and sodium carbonate
5) Calibrators, 1 sheet with 5 kits of 6 calibrators in a foil pack containing a moisture absorber – phenylalanine on blood samples dried on filter paper (Class 903 or equivalent)
Calibrator values are specific to each test-system batch.
Calibrators are prepared from human blood samples with 50%–54% hematocrit levels and calibrated according to the Reference Preparation of the International Society for Neonatal Screening (ISNS) for neonatal screening to determine phenylalanine and 17-alpha-hydroxyprogesterone in blood spots.
6) Controls, 1 sheet with 5 kits of 2 controls in a foil pack containing a moisture absorber – phenylalanine on blood samples dried on filter paper (Class 903 or equivalent)
Control values are specific to each test-system batch.
Controls are prepared from human blood samples with 50%–54% hematocrit levels.
Phenylalanine values are measured in gravimetric units (mg/dL = mg/100 mL = mg%).
7) Reaction plates, 10 pcs. Microplates without solid-phase coating
8) Plastic caps, 20 pcs. Plastic caps for plates for incubation and elution
9) Control and calibrator value table — 1 piece in each kit

4.2. Composition of a reagent kit for determination of congenital hypothyroidism:
1) Sorbed microplate — 10 plates
a. Microplate with sorbed antibodies
2) Anti-hTSH-HRP conjugate, 2.5 mL, 100-fold concentrate
a. Hormone peroxidase conjugate and antibodies to TSG containing a preservative
3) Conjugate dilution solution 250 mL
a. Buffered saline solution containing a preservative
4) 4a. HPPA substrate, 4 × 50 mL – 3 (p-hydroxyphenyl) propionic acid in a buffer containing a preservative
4b. Solution for dilution of HPPA substrate, 45 mL – H_2O_2 solution
5) Stopping solution, 150 mL – twofold concentrated glycine buffer
6) Flushing solution, 220 mL – tenfold concentrate, solution of buffer containing a preservative
7) Calibrator A-F, (Paper Class 903 or equivalent), 1 sheet
a. Calibrators ready to use, 5 sets.
b. Calibrator values (µg/l of blood) are specific to each test-system batch.
c. Calibrators are prepared from human blood samples with 50%–55% hematocrit levels and calibrated according to the WHO International Standard for hTSH in accordance with the Reference Preparation of the International Society for Neonatal Screening (ISNS) for neonatal screening to determine thyrotropin, phenylalanine, and 17-alpha-hydroxyprogesterone in blood spots.
8) C1–C2 controls (paper of Class 903 or equivalent), 1 sheet
a. Controls ready to use, 5 sets.
b. Control values (µg/l blood) are specific to each test-systems batch.
9) Plastic caps, 20 pcs. Plastic caps for microplates for incubation
10) Reagent containers – 10 pcs.
11) Control and calibrator value table – 1 piece in each kit.

4.3. Composition of reagent kit for the determination of cystic fibrosis:
1) Sorbed microplate – 10 plates
a. Microplate with sorbed antibodies
2) Anti-IRT1-HRP conjugate, 2.5 mL, 100-fold concentrate
a. Horseradish peroxidase conjugate and Tripsinogen-1 antibodies containing a preservative
3) Conjugate dilution solution 250 mL
a. Buffered saline solution containing a preservative
4) 4a. HPPA substrate, 4 × 50 mL a. 3 (p-hydroxyphenyl) propionic acid in a buffer containing a preservative
4b. Solution for dilution of HPPA substrate, 45 mL a. H_2O_2 solution
5) Stopping solution, 150 mL a. 2-fold concentrated glycine buffer
6) Flushing solution, 250 mL a. 10-fold concentrate, solution of buffer containing a preservative
7) Calibrator A-F, (Paper Class 903 or equivalent), 1 sheet
a. Calibrators ready to use, 5 sets
b. Calibrator values (µg/L of blood) are specific to each test-system batch
8) C1–C2 controls (paper of Class 903 or equivalent), 1 sheet

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a. Controls ready to use, 5 sets
b. Control values (μg/L of blood), specific to each test-system batch
9) Plastic caps, 20 pcs. Plastic caps for microplates for incubation
10) Reagent containers – 10 pcs.
11) Control and calibrator value table – 1 piece in each kit

4.4. Composition of a reagent kit for determination of adrenogenital syndrome:
1) 17-OHP calibrators – 8 filter paper cassettes (Whatman, No. 903), each of which contains 1 set of dried blood spots
2) 17-OHP controls – 6 filter paper cassettes (Whatman, No. 903), each contains 2 sets of dried blood stains
3) The main solution of 17-OHP-Eu label (~ 40 nmol/L), 1 vial
a. The label is in Tris-HCl buffer saline solution (pH 7.8) with bovine albumin and dextran T10
4) Main solution of anti-17-OHP antiserum (Polyclonal rabbit), 2 vials, 2.8 mL
a. Antiserum is in a buffered saline solution of Tris-HCl (pH 7.8) with bovine albumin and <0.1% sodium azide as a preservative
5) Flushing concentrate, 1 vial, 250 mL
a. 25-fold concentrated Tris-HCl buffer saline solution (pH 7.8) with Tween 20; contains Germall II as a preservative
6) Buffer for analysis, 1 vial 250 mL
a. Ready-for-use in buffered saline Tris-HCl (pH 7.8) with bovine albumin, Tween 40, polyethylene glycol 6000, CaCl2, danazol, inert red dye, and <0.1% sodium azide as a preservative
7) Amplifier solution, 1 vial 250 mL
a. Ready-to-use amplifier solution with Triton X-1003, acetic acid and chelate complexes
8) Microplate strips with antirabbit IgG, 8 × 12 wells, coated with rabbit IgG antibodies (derived from goats), 10 plates
9) Additional barcode labels for plates, 3 pcs.
10) Individual certificate of batch quality control, 1 pc.

4.5. Specific requirements for microplates for immunoassay:
1) Microplates should have a 96-well format.
2) Microplates should be made of transparent polystyrene.
3) Microplates should have a U-shaped well bottom.

4.6. Special requirements for the filter paper for collecting and transporting samples of newborn blood stains:
1) Forms for sampling blood stains should be developed for screening newborns, namely tests sampling, their identification, and transportation.
2) The filter paper of the form must belong to Class 903 or 226 or TFN.
3) Forms for sampling blood stains should be prescribed for in-vitro diagnostics.
4) Forms for sampling blood stains should have a cassette format: consist of several pieces tied together, the main of which is a filter paper for sampling blood specimens, and a demographic form that can be filled with information about newborns in Ukrainian or Russian.

5. PRODUCT STANDARDS

These standards below are specific for this procurement action and in no way constitute an obligation from UNDP to use any of these standards in future procurement actions.

UNDP will procure the medicines that comply with UNDP QA policy. In the context of this particular RFQ, to be eligible for procurement and supply, any Medical Device, including in vitro diagnostics (IVDs), must comply with the QA criteria established as follows:

1) **Regulatory Requirements and confirmation of Quality standards**: The Medical Device(s) must qualify for at least **one** of the following options:

   Option 1:
   Medical devices, classified as B, C and D[1] (according to GHTF classification principles[2]), authorised by one of the GHTF founding members (EU, USA, Japan, Canada, Australia): In those cases, the medical device must have a market clearance/approval from at least one of the regulatory authorities of the GHTF founding members

[1] B = Low-moderate hazard, C = Moderate-high hazard, D = High hazard
[2] GHTF/SG1/N77:2012

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mentioned above. To comply with these criteria, the manufacturer/supplier must provide at least **one** of the following pre-market approval(s)/market clearance(s)/registration(s) listed below:

- Australia: TGA Production Quality Assurance Certificate or TGA Type-Examination Certificate or TGA Full Quality Assurance Certificate issued by Therauptic Goods Administration
  OR
- Health Canada: Medical Device Licence and summary report for a Class IV IVD CMDCAS – issued ISO 13485 Certificate.
  OR
- European Union: EC Full Quality Assurance Certificate or EC Production Quality Assurance Certificate or EC Type-Examination Certificate (based on CE 93/42/EEC Medical Device Directive (MDD) Mark and respective amendments and provisions according to Directive 98/79/EC for in vitro medical devices and Directive 93/68/EEC – CE Marking).
  OR
- Japan Ministry of Health, Labour and Welfare (JMHLW): JMHLW Device Licence for manufacture or JMHLW Minister's Approval or JMHLW Recognised Foreign Manufacturer.
  OR
- US Food and Drug Administration (US FDA): PMA (pre-market approval) letter or BLA license (Biologics License Application) or 510k market clearance issued by US FDA.

Option 2:

Medical Device prequalified or recommended by WHO: UNDP also recognises the work of the WHO in the prequalification of products and therefore all IVDs and Male Circumcision Devices (MCD) that appear in the WHO PQ lists can also be qualified by UNDP Ukraine. For this standard to be met the supplier must provide the following requirements, which will be assessed in terms of their validity. Those can also be checked in official sources for confirmation purposes:

- WHO pre-qualification award letter.
  OR
- WHO Recommendation letter for a specific WHO programme.

Option 3:

Medical Device reviewed and recommended by WHO Expert Review Panel (ERP): Medical Devices that received a positive recommendation from the Global Fund's ERP can be procured and supplied by UNDP Ukraine within the period of time specified by the ERP.

2) **Product's registration in Ukraine:** By the time of supply to UNDP Ukraine, the medical devices must be fully registered with the MoH of Ukraine confirming their legal use in Ukraine. Products that comply for the qualification options 1, 2 and 3 but are not registered with the MoH of Ukraine at the time of contract award, will need to sign a conditional contract with UNDP Ukraine and will be required to register their products before import.
   - For this standard to be met the supplier must provide:
     - Registration Certificate issued by the State Administration on Pharmaceutical Products and Drugs Control 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); OR
     - If no registration is available: a commitment letter from the manufacturer/supplier showing accountability in registering their products with the MoH before import.

3) **Packaging (primary, secondary, tertiary), Labelling and Product Instructions:** Photos of packaging, labelling and Product instruction should be provided for review. In case if documents mentioned in this point are performed in original language, then the translations into Ukrainian or English or Russian shall be provided in the electronic format at the time of bid evaluation.

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6. SPECIAL REQUIREMENTS TO THE PROCUREMENT AGENCIES:

WHO definition of "Procurement Agency": "Any organization purchasing pharmaceutical products, vaccines, or other health products or otherwise involved in their prequalification, purchasing, **storage and distribution**".

Procurement Agencies must:

- Be authorized by the National Regulatory Authority (NRA) of the country of location; and
- Comply with WHO (or equivalent: EU EMA, Swiss Medic, Health Canada GDP guidelines are considered as equivalent to the WHO ones) Good Distribution Practices (GDP) guidelines.

Applicants must provide a valid copy of the license issued by the NRA and valid GDP Certificate.

7. DELIVERY TIMEFRAMES

Early delivery of medicines to Ukraine is critical therefore we encourage shortest delivery periods.

Selected Bidder is obliged to sign contract for goods/s within 2 weeks after receipt of Contract for Goods.

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 2020] *(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: maximum 3 consignments under delivery of one Lot/Item.	
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 – one either original or copy certified with the stamp of the Supplier – for each batch of products; • Certificate of origin – 1 original; • Certificate of the product's registration in Ukraine – copy; • Sample of packing & labeling – copy: photo or artwork; • Ukrainian translation of the Product Information Leaflet (in case if products are supplied in original packing).	
Customs clearing , if needed, 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.	

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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 conduct 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.

8. PACKAGING, LABELLING, PUBLIC INFORMATION LEAFLETS (PILs)

1)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.

2)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 Contracts:

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 per each 5 boxes 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 colour stickers (ideally orange).

The minimum technical requirements for dataloggers are as follows:

- Measures temperature (from -30° to +45°C, with accuracy +/- 0.5°c).
- Readings to include time and date
- Single or multiple use
- Direct USB interface, without need for additional cable
- Automatically creates PDF report when connected to computer.
- Rapid data download to graph
- Alarm levels set up before shipping according to manufacturer's storage requirements
- LCD featuring up to 1 decimal point readings
- Alarm indication on LCD screen
- Sampling rate: at least 1 measure per hour
- Push button to activate and stop logging.
- Easy to understand user's guide & instructions

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

A.Shipping marks;

B.The name of the product;

C. Number of registration certificate

D.Date of manufacture and expiry (in clear language not code);

E.Batch number;

F.Quantity per case;

G.Special instructions for storage;

H.Name of manufacturer;

I.Carton numbering e.g. carton 1/40;

J.Any additional cautionary statements.

3)Labelling of primary package now of supply must correspond to the specification approved by UNDP. In case of any deviations found, the Contractor must provide additional documentation to enable receipt of goods.

4)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 medicine in the language of country of destination or the original language.

In case medical devices are delivered in original packaging with instructions for the use in the original language, translation of instruction for the use into the language of country of destination shall be provided in the electronic format at the time of supply.

5)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.

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ANNEX 1

Brief summary on product registration and VAT exeption procedure

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 December 31, 2022, 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: https://zakon.rada.gov.ua/laws/show/2755-17#n12342
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 Bidder increases 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

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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 *[Insert RFQ Reference Number]***.**

We hereby commit to register the below listed products with Ukrainian registration authorities as the current legislation requires. As well we acknowledge acceptance of the requirement for undertaking a registration procedure or providing documents for the obtaining import permission in other countries.

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: _____

[Stamp with official stamp of the Bidder]

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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:

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FORM A: QUOTATION SUBMISSION FORM

Bidders are requested to complete this form, including the Company Profile and Bidder's Declaration, sign it and return it as part of their quotation along with FORM B: Technical and Financial Offer. The Bidder shall fill in this form in accordance with the instructions indicated. No alterations to its format shall be permitted and no substitutions shall be accepted.

Name of Bidder:	Click or tap here to enter text.	
RFQ reference:	Click or tap here to enter text.	Date: Click or tap to enter a date.

Company Profile

Item Description	Detail
Legal name of bidder or Lead entity for JVs	Click or tap here to enter text.
Legal Address, City, Country	Click or tap here to enter text.
Website	Click or tap here to enter text.
Year of Registration	Click or tap here to enter text.
Legal structure	Choose an item.
Are you a UNGM registered vendor?	☐ Yes ☐ No If yes, insert UNGM Vendor Number
Quality Assurance Certification (e.g. ISO 9000 or Equivalent) *(If yes, provide a Copy of the valid Certificate):*	☐ Yes ☐ No
Does your Company hold any accreditation such as ISO 14001 or ISO 14064 or equivalent related to the environment? *(If yes, provide a Copy of the valid Certificate):*	☐ Yes ☐ No
Does your Company have a written Statement of its Environmental Policy? *(If yes, provide a Copy)*	☐ Yes ☐ No
Does your organization demonstrate significant commitment to sustainability through some other means, for example internal company policy documents on women empowerment, renewable energies or membership of trade institutions promoting such issues *(If yes, provide a Copy)*	☐ Yes ☐ No
Is your company a member of the UN Global Compact	☐ Yes ☐ No

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Bank Information	Bank Name: Click or tap here to enter text. Bank Address: Click or tap here to enter text. IBAN: Click or tap here to enter text. SWIFT/BIC: Click or tap here to enter text. Account Currency: Click or tap here to enter text. Bank Account Number: Click or tap here to enter text.

Previous relevant experience: 3 contracts				
Name of previous contracts	**Client & Reference Contact Details including e-mail**	**Contract Value**	**Period of activity**	**Types of activities undertaken**

Bidder's Declaration

Yes	No	
☐	☐	**Requirements and Terms and Conditions:** I/We have read and fully understand the RFQ, including the RFQ Information and Data, Schedule of Requirements, the General Conditions of Contract, and any Special Conditions of Contract. I/we confirm that the Bidder agrees to be bound by them.
☐	☐	I/We confirm that the Bidder has the necessary capacity, capability, and necessary licenses to fully meet or exceed the Requirements and will be available to deliver throughout the relevant Contract period.
☐	☐	**Ethics**: In submitting this Quote I/we warrant that the bidder: has not entered into any improper, illegal, collusive or anti-competitive arrangements with any Competitor; has not directly or indirectly approached any representative of the Buyer (other than the Point of Contact) to lobby or solicit information in relation to the RFQ ;has not attempted to influence, or provide any form of personal inducement, reward or benefit to any representative of the Buyer.
☐	☐	I/We confirm to undertake not to engage in proscribed practices, , or any other unethical practice, with the UN or any other party, and to conduct business in a manner that averts any financial, operational, reputational or other undue risk to the UN and we have read the United Nations Supplier Code of Conduct :https://www.un.org/Depts/ptd/about-us/un-supplier-code-conduct and acknowledge that it provides the minimum standards expected of suppliers to the UN.
☐	☐	**Conflict of interest:** I/We warrant that the bidder has no actual, potential, or perceived Conflict of Interest in submitting this Quote or entering a Contract to deliver the Requirements. Where a Conflict of Interest arises during the RFQ process the bidder will report it immediately to the Procuring Organisation's Point of Contact.
☐	☐	**Prohibitions, Sanctions:** I/We hereby declare that our firm, its affiliates or subsidiaries or employees, including any JV/Consortium members or subcontractors or suppliers for any part of the contract is not under procurement prohibition by the United Nations, including but not limited to prohibitions derived from the Compendium of United Nations Security Council Sanctions Lists and have not been suspended, debarred, sanctioned or otherwise identified as ineligible by any UN Organization or the World Bank Group or any other international Organization.
☐	☐	**Bankruptcy**: I/We have not declared bankruptcy, are not involved in bankruptcy or receivership proceedings, and there is no judgment or pending legal action against them that could impair their operations in the foreseeable future.

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Yes	No	
☐	☐	**Offer Validity Period:** I/We confirm that this Quote, including the price, remains open for acceptance for the Offer Validity.
☐	☐	I/We understand and recognize that you are not bound to accept any Quotation you receive, and we certify that the goods offered in our Quotation are new and unused.
☐	☐	By signing this declaration, the signatory below represents, warrants and agrees that he/she has been authorised by the Organization/s to make this declaration on its/their behalf.

Signature: _____

Name: Click or tap here to enter text.

Title: Click or tap here to enter text.

Date: Click or tap to enter a date.

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FORM B: TECHNICAL AND FINANCIAL OFFER

Bidders are requested to complete this form, sign it and return it as part of their bid along with Annex 4 and Annex 5. The Bidder shall fill in this form in accordance with the instructions indicated. No alterations to its format shall be permitted and no substitutions shall be accepted.

Name of Bidder:	Click or tap here to enter text.	
RFQ reference:	Click or tap here to enter text.	Date: Click or tap to enter a date.

Please provide filled-in Annex 4 and Annex 5 in excel and PDF format (signed version).

Compliance with Requirements

Criteria	Required Document	Yes	Reference
OPTION 1: Medical devices, classified as B, C and D (according to GHTF classification principles), authorised by one of the GHTF founding members (EU, USA, Japan, Canada, Australia) **OPTION 2:** Prequalified by World Health Organization. **OPTION 3:** Recommended by the WHO Expert Review Panel for the Global Fund (also known as WHO ERP).	1) The Medical Device(s) must qualify for at least one of the following routes: -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.	☐	
	2) WHO valid pre-qualification evidence.	☐	
	3) WHO Expert Review approval evidence of the Panel for the Global Fund (also known as Global Fund ERP)	☐	

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Criteria	Required Document	Yes	Reference
Availability of **valid registration in Ukraine at the time of supply** (if, at the moment of the bid submission, the quoted medicinal products are not registered in Ukraine but comply with the quality requirements of this RFQ, a Commitment letter shall be provided)	Registration Certificate issued by the State Administration on Pharmaceutical Products and Drugs Control 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); OR If no registration is available: a commitment letter from the manufacturer/supplier showing accountability in registering their products with the MoH before import (Annex 2).	☐	
Compliance with shelf life (product shelf life remaining at the time of delivery as per Section 3 para 3 and 4), packaging and labelling requirements.	Information on shelf life in the Section 3 para 3 and 4	☐	
Compliance with Packaging, Labeling, Instruction for Use (PILs) requirements	Information in the Section 3 para 8	☐	

I, the undersigned, certify that I am duly authorized to sign this quotation and bind the company below in event that the quotation is accepted.	
Exact name and address of company Company NameClick or tap here to enter text. Address: Click or tap here to enter text. Click or tap here to enter text. Phone No.:Click or tap here to enter text. Email Address:Click or tap here to enter text.	Authorized Signature: Date:Click or tap here to enter text. Name:Click or tap here to enter text. Functional Title of Authorised Signatory:Click or tap here to enter text. Email Address: Click or tap here to enter text.

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Template of Contract for Goods

Contract text may vary from order to order and is not binding until issued, accepted and executed by all Parties. The provisions below are to be understood as typical information that UNDP may include.

Договір на надання Товарів між Програмою розвитку Організації Об'єднаних Націй та XXXXXXXXXX *Empowered lives. Resilient nations.*	**Contract for Goods Between the United Nations Development Programme and XXXXXXXXX** *Empowered lives. Resilient nations.*
1. Країна, у якій будуть постачатись Товари та/або надаватись Послуги: Україна	1. **Country Where Goods Will be Delivered and/or Services Will be Provided**: Ukraine
2. **ПРООН** [X] Запит цін [] Запит пропозиції [] Запрошення на участь у конкурсі [ ] укладення прямих договорів Номер та дата: xxx-2021-UNDP-UKR від xxxx	2. **UNDP** [X] Request for Quotation [] Request for Proposal [] Invitation to Bid [ ] direct contracting Number and Date: xxx-2021-UNDP-UKR dtd xxxx
3. **Посилання на номер договору (напр., номер присудження договору):**	3. **Contract Reference (e.g. Contract Award Number)**:
4. **Довгострокова угода**: Ні	4. **Long Term Agreement**: No
5. **Предмет Договору**: [ ] товари [X] послуги [ ] товари *та* послуги	5. **Subject Matter of the Contract**: [ ] goods [X] services [ ] goods *and* services
6. **Тип Послуг:**	6. **Type of Services:**
7. **Дата початку Договору**: 31 березня 2021 / 8. **Дата завершення Договору**: 31 грудня 2021	7. **Contract Starting Date**: March 31st, 2021 / 8. **Contract Ending Date**: December 31st, 2021
9. **Загальна сума Договору є фіксованою та становить**: XXXX доларів США (XXXXXXXX гривень 00 копійок) ПДВ не передбачено. 9a. **Передплата**: не застосовується	9. **The total amount of the Contract is fixed and is:** USD XXXXXX. (XXXXXXXXXX hryvnas, 00 kopeyks), without VAT 9a. **Advance Payment**: not applicable
10. **Загальна вартість Товарів та/або Послуг:** [ ] **менше 50 000 дол. США (лише Послуги)** – застосовуються Загальні умови ПРООН для базових (незначних) договорів [ ] **менше 50 000 дол. США (Товари *або* Товари та Послуги)** – застосовуються Загальні умови ПРООН для договорів [X] **50 000 дол. США або більше (Товари *та/або* Послуги)** – застосовуються Загальні умови ПРООН для договорів	10. **Total Value of Goods and/or Services**: [ ] **below US$50,000 (Services only)** – UNDP General Terms and Conditions for Institutional (de minimis) Contracts apply [ ] **below US$50,000 (Goods *or* Goods and Services)** – UNDP General Terms and Conditions for Contracts apply [X] **equal to or above US$50,000 (Goods *and/or* Services)** – UNDP General Terms and Conditions for Contracts apply
11. **Метод оплати:** [X] тверда (фіксована) ціна [ ] відшкодування витрат	11. **Payment Method:** [X] fixed price [ ] cost reimbursement
12. **Назва(Ім'я) Підрядника**: XXXXXXXXXXXXXX Юридична адреса: XXXXXXXXXXXXXXXX Поштова адреса: XXXXXXXXXXXXXXXXX Тел.: XXXXXXXXXXXXX Email: XXXXXXXXXXXX	12. **Contractor's Name**: XXXXXXXXXXXXXX Legal address: XXXXXXXXXXXXXXXXX Postal address XXXXXXXXXXXXXXXXX Tel.: XXXXXXXXXXXXXXXXX Email: XXXXXXXXXXXXXXXXXXX
13. **Ім'я контактної особи Підрядника**: XXXXXXXXXXXX Посада: XXXXXXXXXXX Адреса:	13. **Contractor's Contact Person's Name**: XXXXXXXXXXXXXXX Title: XXXXXXXXXXXXXXX Address:

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Тел.: Email:	Tel.: Email:
14. Ім'я контактної особи ПРООН: По комерційним/контрактним питанням: health.procurement.ua@undp.org тел. +380 44 253 93 63, ext. 570 По питанням щодо логістики: health.logistics.ua@undp.org Адреса: Програма розвитку ООН Кловський узвіз, 1, м. Київ, 01021, Україна Тел.: (044) 253 93 63, факс. (044) 253 26 07	14. **UNDP Contact Person's Name**: For commercial/contract issues: health.procurement.ua@undp.org; tel: +380 44 253 93 63, ext. 570 For logistics issues: health.logistics.ua@undp.org Address: United Nations Development Programme 1, Klovsky Uzviz, Kyiv, 01021, Ukraine Telephone number: (044) 253 93 63, факс. (044) 253 26 07
15. **Банківський рахунок Підрядника, на який будуть перераховуватись платежі:** Отримувач: **XXXXXXXXXXXXXXX** п/р XXXXXXXXXXXXXXX в АТ КБ «Приватбанк» МФО XXXXXX ЄДРПОУ XXXXXXXXXXXXX ІПНXXXXXXXXXXXX	15. **Contractor's Bank Account to which payments will be transferred**: Company Name - **XXXXXXXXXXXXXXX** Account number XXXXXXXXXX in JSCB "Pryvatbank" Bank code: XXXXXXXX EDRPOU XXXXXXXXXXXXX ID Code XXXXXXXXXXXX
16. Даний Договір складається з наступних документів, які, у разі виникнення конфлікту між ними, мають перевагу один перед одним у наступному порядку: 1. Дана лицьова сторінка («Лицьова сторінка»). 2. Загальні умови ПРООН для договорів – Додаток 1 3. Технічна специфікація (ТС) та інші умови - Додаток 2. 4. Тендерна заявка Постачальника від XX жовтня 20XX року. Документ не додається до цього Договору, але наявний у Сторін та відомий їм; 5. Тендерний документ xxx 2021 року із специфікацією. Документ не додається до цього Договору, але наявний у Сторін та відомий їм). Даний Договір підписано з метою виконання Договору №№54 від 19.04.2019 року між Програмою Розвитку Організації Об'єднаних Націй та Міністерством охорони здоров'я України для закупівель лікарських засобів національних програм у галузі охорони здоров'я на 2019 рік (бюджетна програма 2301400 «Забезпечення медичних заходів окремих державних програм та комплексних заходів програмного характеру», «Реактиви для проведення масового скринінгу новонароджених на фенілкетонурію, вроджений гіпотиреоз, муковісцидоз та адреногенітальний синдром»). Медичні вироби закуповуються у відповідності до Постанови Кабінету Міністрів України №255 від 13.03.2019 «Про затвердження переліку лікарських засобів та медичних виробів, які закуповуються на підставі угод (договорів) щодо закупівлі із спеціалізованими організаціями, які здійснюють публічні закупівлі за кошти 2019 Державного Бюджету». Все вищезазначене, включене до цього документу за допомогою посилання, містить увесь обсяг домовленостей («Договір») між Сторонами, при цьому усі інші переговори та/або угоди, незалежно від того, виконані вони в усній або ж у письмовій формі, що відносяться до предмету даного Договору, втрачають силу.	16. This Contract consists of the following documents, which in case of conflict shall take precedence over one another in the following order: 1. This face sheet ("Face Sheet"). 2. UNDP General Terms and Conditions for Contracts – Annex 1 3. Techncial Specification (TS) and other requirements – Annex 2. 4. Supplier's bid dated October XX, 20XX. Not attached herein but acknowledged and in possession by both parties. Not attached hereto but known to and in the possession of the Parties, and forming an integral part of this Contract. 5. Solicitation documents ref. xxx 2021 with specification. Not attached hereto but known to and in the possession of the Parties and forming an integral part of this Contract. This Contract is signed with the purpose to fulfil the Agreement # Agreement #54 dd. 19.04.2019, 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 2019 (Budget Program 2301400 "Ensuring hospital measures of separate state programs and complex measures of programmable nature", "Reagents for screening newborns for phenylketonuria, congenital hypothyroidism, cystic fibrosis and adrenogenital syndrome"). The medical products are procured according to the Decree of the Cabinet of Ministers #255 dated 13.03.2019 "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 2019 State Funds" All the above, hereby incorporated by reference, shall form the entire agreement between the Parties (the "Contract"), superseding the contents of any other negotiations and/or agreements, whether oral or in writing, pertaining to the subject of this Contract.

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Даний Договір вступає в силу з дня проставлення належним чином уповноваженими представниками Сторін останнього підпису на Лицьовій сторінці і припиняє свою дію в Дату завершення Договору, яка зазначена на Лицьовій сторінці. Внесення змін та/або доповнень до даного Договору можливе лише у разі оформлення належним чином уповноваженими представниками Сторін письмової угоди. Цей Договір складений українською та англійською мовами в двох примірниках. У разі виникнення суперечностей пріоритет віддається версії англійською мовою. **НА ПОСВІДЧЕННЯ ЧОГО,** нижчепідписані, належним чином уповноважені на це представники Сторін, підписали цей Договір від імені Сторін у місці та в день, що вказані нижче	This Contract shall enter into force on the date of the last signature of the Face Sheet by the duly authorized representatives of the Parties, and terminate on the Contract Ending Date indicated on the Face Sheet. This Contract may be amended only by written agreement between the duly authorized representatives of the Parties. The present Contract is made in Ukrainian and English languages in duplicate. In case of any differences priority is given to English version of the Contract. **IN WITNESS WHEREOF**, the undersigned, being duly authorized thereto, have on behalf of the Parties hereto signed this Contract at the place and on the day set forth below.

Від імені Підрядника / For the Contractor		**Від імені ПРООН / For UNDP**	
Підпис / Signature:		Підпис / Signature:	
Ім'я / Name:	**Пан XXXXXXXXX / Mr. XXXXXXXXXX**	Ім'я / Name:	**Пані Дафіна Герчева / Ms. Dafina Gercheva**
Посада / Title:	**Президент / President**	Посада / Title:	**Постійна представниця ПРООН в Україні / UNDP Ukraine Resident Representative**
who acts in accordance with the Charter. що діє на підставі Статуту		що діє на підставі Угоди між ООН та Урядом України від 06.10.1992 року, та Угоди між Урядом України та ПРООН від 18.06.1993 року / who is acting in accordance with Host Agreement between the UN Organization and the Government of Ukraine dated 06.10.1992 and Agreement between the Government of Ukraine and UNDP dated 18.06.1993б	
EDRPOU/ЄДРПОУ XXXXXXXXXXXX, Account # XXXXXXXXXX at JSCB "Privat", Bank code: XXXXXXXXXX / п/р XXXXXXXX в АТ КБ «Універсал Банк», МФО XXXXXXXXX		EDRPOU/ЄДРПОУ: 000 000 000 Bank account/Банківський рахунок 3752174579; Swift: BOFAUS3N, ABA:111000012; Fed: 026009593; Bank of America, 730 15th Street, N.W. 7th floor, Washington DC 10005, USA / Сполучені Штати Америки	
Дата / Date:		Дата / Date:	

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Returnable Bidding Forms / Checklist

This form serves as a checklist for preparation of your Bid. Please complete the Returnable Bidding Forms in accordance with the instructions in the forms and return them as part of your Bid submission. **No alteration to format of forms shall be permitted and no substitution shall be accepted.**

Technical Bid / Price Schedule:

Have you duly completed all the Returnable Bidding Forms?	
▪ FORM A: QUOTATION SUBMISSION FORM	☐
▪ FORM B: TECHNICAL AND FINANCIAL OFFER	☐
Have you provided the required documents to establish compliance with the evaluation criteria in Form B?	☐
▪ Commitment Letter – Annex 2 (if product is not registered in Ukraine)	☐
▪ Certificate of Authorization – Annex 3 (if bidder is not a manufacturer)	☐
▪ Annex 4: Technical Form in Excel and PDF format (signed version)	☐
▪ Annex 5: Price Schedule Form in Excel and PDF format (signed version)	☐