



## REQUEST FOR QUOTATION (RFQ) (Goods)

DATE: September 30, 2020
REFERENCE: RFQ No. 010-2020-UNDP-UKR

Dear Sir / Madam:

We kindly request you to submit your quotation for medicines for patients with Viral Hepatitis B and C, medicines for treatment of adults/children with hemophilia A or B or von Willebrand disease, medicines for children with primary (congenital) immunodeficiencies and medicines for children with mental disorders and behavior from the spectrum of autism, with schizophrenia, affective disorders, hyperkinetic disorders as detailed in Annex 1 of this RFQ. When preparing your quotation, please be guided by the form attached hereto as Annex 2.

Quotations may be submitted on or before October 12, 2020 via ☒e-mail to the address below:

**United Nations Development Programme**  
1 Klovsky Uzviz, Kyiv, Ukraine 01021  
***health.procurement.ua@undp.org***

Quotations submitted by email must be limited to a maximum of 5 MB, virus-free and no more than one email transmissions. They must be free from any form of virus or corrupted contents, or the quotations shall be rejected.

It shall remain your responsibility to ensure that your quotation will reach the address above on or before the deadline. Quotations that are received by UNDP after the deadline indicated above, for whatever reason, shall not be considered for evaluation. If you are submitting your quotation by email, kindly ensure that they are signed and in the .pdf format, and free from any virus or corrupted files.

Please take note of the following requirements and conditions pertaining to the supply of the abovementioned good/s:

Delivery Terms [INCOTERMS 2010] (Pls. link this to price schedule)	<input type="checkbox"/> FCA <input type="checkbox"/> CPT <input type="checkbox"/> CIP <input checked="" type="checkbox"/> DAP <input type="checkbox"/> Other [pls. specify]	
Customs clearance <sup>1</sup> , if needed, shall be done by:	<input checked="" type="checkbox"/> UNDP <input type="checkbox"/> Supplier/Offeror <input type="checkbox"/> Freight Forwarder	
Exact Address/es of Delivery Location/s (identify all, if multiple)	DAP – Kyiv region, 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.	
Distribution of shipping documents (if using freight forwarder)	health.logistics.ua@undp.org eduard.kovalov@undp.org	
Latest Expected Delivery Date and Time (if delivery time exceeds this, quote may be rejected by UNDP)	<input checked="" type="checkbox"/> 60 days from the issuance of the Purchase Order (PO) Date. <input type="checkbox"/> As per Delivery Schedule attached [if delivery will be staggered]	
Delivery Schedule	<input checked="" type="checkbox"/> Required if applicable <input type="checkbox"/> Not Required	
Packing Requirements	As per cl. 5 Annex 1	
Mode of Transport	<input checked="" type="checkbox"/> AIR <input type="checkbox"/> SEA	<input checked="" type="checkbox"/> LAND <input type="checkbox"/> OTHER [pls. specify]
Shipping documents	<ul style="list-style-type: none"> <li>• Commercial invoice – 2 originals;</li> <li>• Packing list – 1 copy;</li> <li>• Manufacturer's Certificate of Analysis – one either original or copy certified with the stamp of the Supplier – for each batch of products;</li> <li>• Batch release certificate - one either original or copy certified with the stamp of the Supplier – for each batch of products;</li> <li>• Certificate of origin – 1 original;</li> <li>• Certificate of the product's registration in Ukraine – copy;</li> <li>• Sample of packing &amp; labeling – copy: photo or artwork;</li> <li>• Ukrainian translation of the Product Information Leaflet (in case if products are supplied in original packing).</li> </ul>	
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.	

<sup>1</sup> Must be linked to INCO Terms chosen.

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.
Preferred Currency of Quotation	<input checked="" type="checkbox"/> United States Dollars <input type="checkbox"/> Euro <input type="checkbox"/> Local Currency: <i>[pls. specify]</i>
Value Added Tax on Price Quotation <sup>2</sup>	<input type="checkbox"/> Must be inclusive of VAT and other applicable indirect taxes <input checked="" type="checkbox"/> Must be exclusive of VAT and other applicable indirect taxes (please refer to Annex 4 of this BDS)
Deadline for the Submission of Quotation	<i>Monday, October 12, 2020, 13:00 Kyiv time (+2 GMT)</i>
All documentations, including catalogs, instructions and operating manuals, shall be in this language	<input checked="" type="checkbox"/> English <input type="checkbox"/> French <input type="checkbox"/> Spanish <input checked="" type="checkbox"/> Others Ukrainian
Documents to be submitted	<input checked="" type="checkbox"/> Duly Accomplished Forms: <ul style="list-style-type: none"> <li>Form A: Bid Submission Form</li> <li>Form B: Bidder Information Form</li> <li>Form C: Certificate of Authorization - Manufacturer's Authorization of the Company as a Sales Agent (if Supplier is not the manufacturer)</li> <li>Form D: Supportive documents to Table 1: Technical Form (GMP certificates, Registration Certificates etc.)</li> </ul> <u>UNDP will procure the medicines, which meets product standards, described in Annex 1 to BDS</u>  <input checked="" type="checkbox"/> Duly Accomplished Tables in accordance with the list of requirements in Bid submission instructions: <ul style="list-style-type: none"> <li>Table 1. Technical Information on product/s</li> <li>Table 2. Price Schedule Form</li> </ul> <input checked="" type="checkbox"/> Latest Business Registration Certificate; <input checked="" type="checkbox"/> Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List; <input type="checkbox"/> Others <i>[pls. specify as many as required]</i>
Period of Validity of Quotes starting the Submission Date	<input type="checkbox"/> 60 days <input type="checkbox"/> 90 days <input checked="" type="checkbox"/> 120 days

<sup>2</sup> This must be reconciled with the INCO Terms required by the RFQ. Furthermore, VAT exemption status varies from one country to another. Pls. tick whatever is applicable to the UNDP CO/BU requiring the goods.

	In exceptional circumstances, UNDP may request the Vendor to extend the validity of the Quotation beyond what has been initially indicated in this RFQ. The Proposal shall then confirm the extension in writing, without any modification whatsoever on the Quotation.
Partial Quotes	<input checked="" type="checkbox"/> Not permitted <input type="checkbox"/> Permitted <i>[pls. provide conditions for partial quotes, and ensure that requirements are properly listed to allow partial quotes (e.g., in lots, etc.)]</i>
Payment Terms <sup>3</sup>	<input checked="" type="checkbox"/> 100% upon complete delivery of goods within 30 days <input type="checkbox"/> Others <i>[pls. specify]</i>
Liquidated Damages	<input type="checkbox"/> Will not be imposed <input checked="" type="checkbox"/> Will be imposed under the following conditions: Percentage of contract price per day of delay: 0.5% Max. no. of days of delay: 30 (thirty) calendar days After which UNDP may terminate the contract.
Evaluation Criteria <i>[check as many as applicable]</i>	<input checked="" type="checkbox"/> Technical responsiveness/Full compliance to requirements and lowest price <sup>4</sup> <input checked="" type="checkbox"/> Full acceptance of the PO/Contract General Terms and Conditions <i>[this is a mandatory criteria and cannot be deleted regardless of the nature of services required]</i> <input checked="" type="checkbox"/> Earliest Delivery / Shortest Lead Time <sup>5</sup> <input type="checkbox"/> Others <i>[pls. specify]</i>
UNDP will award to:	<input checked="" type="checkbox"/> One and only one supplier (for each lot) <input type="checkbox"/> One or more Supplier, depending on the following factors:
Type of Contract to be Signed	<input checked="" type="checkbox"/> Purchase Order <input type="checkbox"/> Contract Face Sheet (Goods and-or Services) UNDP (this template is also utilized for Long-Term Agreement <sup>6</sup> and <i>if LTA will be signed, specify the document that will trigger the call-off. E.g., PO, etc.)</i> <input type="checkbox"/> Other Type/s of Contract <i>[pls. specify]</i>
Contract General Terms and Conditions	<input checked="" type="checkbox"/> General Terms and Conditions for contracts (goods and/or services) <input type="checkbox"/> General Terms and Conditions for de minimis contracts (services only, less than \$50,000)

<sup>3</sup> UNDP preference is not to pay advanced amount upon signing of contract. If vendor strictly requires advanced payment, it will be limited only up to 20% of the total price quoted. For any higher percentage, or advanced payment of \$30,000 or higher, UNDP shall require the vendor to submit a bank guarantee or bank cheque payable to UNDP, in the same amount as the advanced payment made by UNDP to the vendor.

<sup>4</sup> UNDP reserves the right not to award the contract to the lowest priced offer, if the second lowest price among the responsive offer is found to be significantly more superior, and the price is higher than the lowest priced compliant offer by not more than 10%, and the budget can sufficiently cover the price difference. The term "more superior" as used in this provision shall refer to offers that have exceeded the pre-determined requirements established in the specifications.

<sup>5</sup> This shall be used for time-critical and/or exigent requirements (e.g., post-crisis emergencies, elections, etc.).

<sup>6</sup> Minimum of one (1) year period and may be extended up to a maximum of three (3) years subject to satisfactory performance evaluation

	Applicable Terms and Conditions are available at <a href="http://www.undp.org/content/undp/en/home/procurement/business/how-we-buy.html">http://www.undp.org/content/undp/en/home/procurement/business/how-we-buy.html</a>
Special conditions of Contract	<input checked="" type="checkbox"/> Cancellation of PO/Contract if the delivery/completion is delayed by 15 (fifteen) calendar days <input type="checkbox"/> Others <i>[pls. specify]</i>
Conditions for Release of Payment	<input checked="" type="checkbox"/> Written Acceptance of Goods based on full compliance with RFQ requirements <input type="checkbox"/> Others <i>[pls. specify]</i>
Annexes to this RFQ <sup>7</sup>	<input checked="" type="checkbox"/> Specifications of the Goods Required (Annex 1) <input checked="" type="checkbox"/> Form for Submission of Quotation (Annex 2) <input checked="" type="checkbox"/> General Terms and Conditions / Special Conditions: <a href="http://www.undp.org/content/undp/en/home/procurement/business/how-we-buy.html">http://www.undp.org/content/undp/en/home/procurement/business/how-we-buy.html</a> <input type="checkbox"/> Others <i>[pls. specify, if any]</i>  Non-acceptance of the terms of the General Terms and Conditions (GTC) shall be grounds for disqualification from this procurement process.
Contact Person for Inquiries (Written inquiries only) <sup>8</sup>	<i>Procurement Unit</i> <i>Health.procurement.ua@undp.org</i> <i>Eduard Kovalov</i> <i>Procurement and Administrative Associate</i> <i>eduard.kovalov@undp.org</i> 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.

Goods offered shall be reviewed based on completeness and compliance of the quotation with the minimum specifications described above and any other annexes providing details of UNDP requirements.

The quotation that complies with all of the specifications, requirements and offers the lowest price, as well as all other evaluation criteria indicated, shall be selected. Any offer that does not meet the requirements shall be rejected.

Any discrepancy between the unit price and the total price (obtained by multiplying the unit price and quantity) shall be re-computed by UNDP. The unit price shall prevail and the total price shall be corrected. If the supplier does not accept the final price based on UNDP's re-computation and correction of errors, its quotation will be rejected.

<sup>7</sup> Where the information is available in the web, a URL for the information may simply be provided.

<sup>8</sup> This contact person and address is officially designated by UNDP. If inquiries are sent to other person/s or address/es, even if they are UNDP staff, UNDP shall have no obligation to respond nor can UNDP confirm that the query was received.

After UNDP has identified the lowest price offer, UNDP reserves the right to award the contract based only on the prices of the goods in the event that the transportation cost (freight and insurance) is found to be higher than UNDP's own estimated cost if sourced from its own freight forwarder and insurance provider.

At any time during the validity of the quotation, no price variation due to escalation, inflation, fluctuation in exchange rates, or any other market factors shall be accepted by UNDP after it has received the quotation. At the time of award of Contract or Purchase Order, 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.

Any Purchase Order that will be issued as a result of this RFQ shall be subject to the General Terms and Conditions attached hereto. The mere act of submission of a quotation implies that the vendor accepts without question the General Terms and Conditions of UNDP indicated above - <http://www.undp.org/content/undp/en/home/procurement/business/how-we-buy.html>.

UNDP is not bound to accept any quotation, nor award a contract/Purchase Order, nor 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.

Please be advised that UNDP's vendor protest procedure is intended to afford an opportunity to appeal for persons or firms not awarded a purchase order or contract in a competitive procurement process. **In the event that** you believe you have not been fairly treated, you can find detailed information about vendor protest procedures in the following link:  
<http://www.undp.org/content/undp/en/home/operations/procurement/protestandsanctions/>

**UNDP encourages every prospective Vendor 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.

UNDP implements a zero tolerance on fraud and other proscribed practices, and is committed to identifying and addressing all such acts and practices against UNDP, as well as third parties involved in UNDP activities. UNDP expects its suppliers to adhere to the UN Supplier Code of Conduct found in this link : [http://www.un.org/depts/ptd/pdf/conduct\\_english.pdf](http://www.un.org/depts/ptd/pdf/conduct_english.pdf)

**Thank you and we look forward to receiving your quotation.**

**Sincerely yours,**



**Sergei Mostovoy**  
**Operations Manager a.i.**  
**United Nations Development Program**

## Annex 1

### Technical Specifications

Lot #	Description / Specifications of Goods			TOTAL Q-TY required*	Latest Delivery Date**
	International Non-Proprietary Name	Presentation Form	Dosage		
1	Tenofovir	tablets, capsules, pills	300 mg	260,160	60 days from the issuance of the Purchase Order (PO) Date
2	Desmopressin	ampules, vials, syringes	15 µg/ml, 1 ml	345	60 days from the issuance of the Purchase Order (PO) Date
3	Desmopressin (child prescription)	ampules, vials, syringes	15 µg/ml, 1 ml	105	60 days from the issuance of the Purchase Order (PO) Date
4	Voriconazole	tablets	50 mg	755	60 days from the issuance of the Purchase Order (PO) Date
5	Aripiprazole	oral solution	1 mg/mL	10,184	60 days from the issuance of the Purchase Order (PO) Date
6	Fluoxetine	oral solution	20 mg/5 mL	2,393	60 days from the issuance of the Purchase Order (PO) Date
7	Valproic acid salts	syrup	50 mg/1 mL	2,167	60 days from the issuance of the Purchase Order (PO) Date
8	Atomoxetine	capsules	80 mg	309	60 days from the issuance of the Purchase Order (PO) Date
9	Atomoxetine	capsules	10 mg	31,284	60 days from the issuance of the Purchase Order (PO) Date

**\*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.

**\*\*Bidder** may propose their own schedule for delivery. Early delivery will be an advantage.

## 1. PRODUCT STANDARDS

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

### OPTION 1 [A+C]:

- A) **Approved/registered by a Stringent National Medicines Regulatory Authority (SRA) as defined by WHO.** Stringent Drug Regulatory Authority (SRA) means a regulatory authority:
- (a) a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission (in case of the European Union both European Medical Agency (EMA) and European Union member States) and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
  - (b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or
  - (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway
- \*) In case product is registered by SRA authorities for “export only” (i.e. registered but not marketed on the country of SRA authority), UNDP will conduct additional verification of product’s compliance to the products standards.

AND

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

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

NB: GMP certificates should be provided for all manufacturing sites where product is being produced (incl. manufacturing, packaging, batch release and quality control activities).

### OPTION 2 [B+C]:

- B) **Registered in Ukraine OR at least one successfully completed supply of the product in the similar volume in/to Ukraine within the past five years (since January 2015).**

AND

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

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

NB: GMP certificates should be provided for all manufacturing sites where product is being produced (incl. manufacturing, packaging, batch release and quality control activities).

### OPTION 3 [D+C]:



**D) Prequalified by World Health Organization**

AND

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

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

GMP certificates should be provided for all manufacturing sites where product is being produced (incl. manufacturing, packaging, batch release and quality control activities).

**SPECIAL CONDITIONS:**

An instruction on the use of a medicinal product in Ukrainian is required.

The approved instruction in the original language shall be accompanied by the original version of the instructions in Ukrainian.

**2. IN-COUNTRY REGISTRATION REQUIREMENTS**

UNDP will evaluate offers for both registered and non-registered medicines. Non-registered medicines must meet quality standards.

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

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

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

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

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

### 3. DELIVERY TIMEFRAMES

Delivery timeframes: 60 days from the issuance of the Purchase Order (PO) Date. Selected Bidder is obliged to sign purchase order/s within 2 weeks after receipt of Purchase Order/s electronically authorized by UNDP.

### 4. SHELF LIFE REQUIREMENTS

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

### 5. PACKAGING AND TRANSPORT REQUIREMENTS

5.1. 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.

5.2. 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.

#### 5.3. 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 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

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.

5.4. 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.

5.5. 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 medicine in the language of country of destination or the original language.

5.6. In case medical products 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.

5.7. The information mentioned on the secondary packaging should be coherent with the information printed on the primary packaging and shall at least provide the following information:

- The International Non-Proprietary Name (INN) of the product;
- The statement of the net content (number of units, weight or volume);
- The batch number;
- The expiry date in an encoded form;
- Any special storage conditions or handling precautions that may be necessary;
- Directions for use, warning and precautions that may be necessary;
- The name and address of the manufacturer or the company responsible for placing the product on the market;
- The marketing license number.

5.8. The Product Leaflet should at least contain the following information:

- Product name in INN format;
- Instructions for use;
- Precautions;
- Storage conditions.

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

## 6. QUALITY ASSURANCE

6.1. Upon receipt of an incoming batch/s, UNDP follow a thorough quality verification procedure, which may include review of Certificates of Analysis (CoA) for each batch of finished product to be supplied, control against specifications, sample testing in accordance with UNDP and/or national QC protocols, labelling and packaging, etc.

6.2. 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.

6.3. Upon request, the contractor shall provide detailed Finished Pharmaceutical Product release specifications and methods of analysis. Those FPP specifications might be shared with the QC laboratory in charge of the testing of samples.

6.4. In the event of a dispute by the Contractor, a counter QC testing will be carried out by an independent neutral laboratory agreed by both UNDP and the Contractor. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Contractor 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.

6.5. Information about relevant medicines stability studies must be available upon request.

**Sergei Mostovoy**

*Sergei Mostovoy*

**Operations Manager a.i.**

**United Nations Development Program**

*[Signature]* 12

## **Annex 2. FORM FOR SUBMITTING SUPPLIER'S QUOTATION**

### **FORM FOR SUBMITTING SUPPLIER'S QUOTATION<sup>9</sup>**

***(This Form must be submitted only using the Supplier's Official Letterhead<sup>10</sup>)***

---

We, the undersigned, hereby accept in full the UNDP General Terms and Conditions, and hereby offer to supply the items listed below in conformity with the specification and requirements of UNDP as per RFQ Reference No. **RFQ No. 010-2020-UNDP-UKR**.

Offer to Supply Goods Compliant with Technical Specifications and Requirements:

#### **TABLE 1: Technical Information on product/s**

#### **TABLE 2: Price Schedule Form**

#### **Forms: A-D**

#### **Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List**

All other information that we have not provided automatically implies our full compliance with the requirements, terms and conditions of the RFQ.

*[Name and Signature of the Supplier's Authorized Person]*  
*[Designation]*  
*[Date]*

---

<sup>9</sup> This serves as a guide to the Supplier in preparing the quotation and price schedule.

<sup>10</sup> Official Letterhead/Stationery must indicate contact details – addresses, email, phone and fax numbers – for verification purposes

### Annex 3. Certificate of Authorization

#### 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 required as per RFQ] 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:\_\_\_\_\_

## **Annex 4. BRIEF SUMMARY ON VAT EXEMPTION 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 March 31, 2020, 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:

6.5.1.1. 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>

6.5.1.2. 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>

## Annex 5. 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.

Before submitting your Bid, please ensure compliance with the Bid Submission instructions.

### General Bid information:

<b>Have you duly completed all the Returnable Bidding Forms?</b>	
▪ Form A: Bid Submission Form	<input type="checkbox"/>
▪ Form B: Bidder Information Form	<input type="checkbox"/>
▪ Form C: Certificate of Authorization (if applicable)	<input type="checkbox"/>
▪ Form D: Supportive documents to Table 1: Technical Form (valid GMP certificates, Registration Certificates, ISO, IFU etc.)	<input type="checkbox"/>
<b>Have you provided the required documents to establish compliance with quality criteria in Annex 1 of the Bidding instructions?</b>	<input type="checkbox"/>

### Technical Information and Price Schedule:

▪ Table 1: Technical Form <b>in excel and PDF format (signed version)</b>	<input type="checkbox"/>
▪ Table 2: Price Schedule Form <b>in excel and PDF format (signed version)</b>	<input type="checkbox"/>

### Other:

▪ Latest Business Registration Certificate	<input type="checkbox"/>
▪ Written Self-Declaration of not being included in the UN Security Council 1267/1989 list, UN Procurement Division List or other UN Ineligibility List	<input type="checkbox"/>