



REQUEST FOR QUOTATION (RFQ)
(Goods)

All Interested	DATE: December 26, 2016
	REFERENCE: UKR-HP-2016-02

Dear Sir / Madam:

We kindly request you to submit your Quotation for **Supply of medicines for treatment of patients with Epidermolysis Bullosa for the National Public Health Programme to the Ministry of Health (MoH) in Ukraine** (2 lots) as detailed in Annex 1 of this RFQ. When preparing your Quotation, please be guided by the form attached hereto as Annexes 3-6.

Quotations may be submitted on or before **10:00 AM (Kyiv time), Tuesday, January 10, 2017** and via ☒ *e-mail* to the address below:

United Nations Development Programme
tenders.ua@undp.org
Procurement Unit

Quotations submitted by email must be limited to a maximum **of 5 MB**, virus-free and no more than 5 email transmissions. *Files larger than 5 MB will not be delivered and therefore the Quotation will not be considered.* 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. *Please ensure that you received an autoreply from above-mentioned E-mail address indicating that the message was received.* 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 goods.

DATA SHEET

Delivery Terms [INCOTERMS 2010]	<input checked="" type="checkbox"/> DAP Kyiv, Ukraine – to the Central warehouse of the MoH designated by UNDP. The products shall be supplied to the Central Warehouse of MoH or designated by them entity appointed by UNDP. Exact location of the warehouse will be notified at the time of contracting. Partial delivery is acceptable: maximum 3 consignments under delivery of one Lot/Item.	
Customs clearance, if needed, shall be done by:	<input checked="" type="checkbox"/> Central warehouse of the MoH designated by UNDP.	
Exact Address/es of Delivery Location/s (identify all, if multiple)	Exact location of the warehouse will be informed to the selected Offeror/s	
UNDP Preferred Freight Forwarder, if any	N/A	
Shipping documents	<ul style="list-style-type: none"> • Commercial invoice – 2 originals. • Packing list – 1 copy. • Manufacturer's Certificate of Analysis for each batch – copies certified with the stamp of the Supplier. • Certificate of Origin, if goods are being imported • Air Way Bill (air shipments)/Bill of Lading (sea shipments), if goods are being imported 	
Latest Expected Delivery Date and Time <i>(if delivery time exceeds this, quote may be rejected by UNDP)</i>	<input checked="" type="checkbox"/> As per technical specification	
Delivery Schedule	<input checked="" type="checkbox"/> Required <input type="checkbox"/> Not Required	
Packing Requirements	As per technical specification	
Mode of Transport	<input checked="" type="checkbox"/> AIR	<input checked="" type="checkbox"/> LAND
	<input type="checkbox"/> SEA	<input type="checkbox"/> OTHER <i>[pls. specify]</i>

Preferred Currency of Quotation	<p><input checked="" type="checkbox"/> United States Dollars (USD) - strongly advised to use as a risk mitigation measure against the impact of the local currency devaluation.</p> <p><i>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).</i></p> <p><input checked="" type="checkbox"/> Local Currency (UAH)</p> <p><i>Prices submitted by Offerors will be evaluated versus each other based on UN Operational exchange rate effective at the closure day of the Quotation submission (please refer to treasury.un.org)</i></p>
Value Added Tax on Price Quotation	<p>Operations on supply (transfer) of pharmaceuticals and medical products shall be temporarily, until March 31, 2019, exempt from VAT, if importation and/or supply is done under contracts with specialized procurement organizations listed in the Law of Ukraine 'On Public Procurement', concluded with the objective of implementing agreements between the central executive body of Ukraine in charge of developing and implementing the national health policy and a relevant specialized procurement organization within the framework of budget programmes for implementation of public health action plans and/or comprehensive programme activities in the health sector.</p> <p>Provided VAT exemption condition may not be applied under the Ukrainian legislation. VAT amount should be clearly indicated in a separate line (if applicable).</p> <p>For more information on VAT exemption, please refer to the following legislation documents:</p> <p>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</p> <p>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</p> <p>Prices specified shall remain firm and not be increased. In case Offeror increase price after awarding contract, UNDP will consider this as a ground for contract termination and awarding the next qualified or initiating a new tender process.</p>

Ex factory / Pre-shipment inspection	A pre-shipment inspection may be carried out by UNDP or its representative for verification of quality, quantity, packing, labeling, 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 of invoices will then be subject to testing satisfactory results.
Deadline for the Submission of Quotation	10:00 a.m., <i>Tuesday, January 10, 2017 Kyiv time</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/Russian
Documents to be submitted	<input checked="" type="checkbox"/> Duly filled-in, signed and stamped Annexes 3-6. <input checked="" type="checkbox"/> Copies of required documents to establish conformity of Offeror to the qualifications requirements and products quoted to product standards and requirements as per Annex 3 "Criteria for award and checklist of documents required"
Period of Validity of Quotes starting the Submission Date	<input checked="" type="checkbox"/> 120 days In exceptional circumstances, UNDP may request the Offeror to extend the validity of the Quotation beyond what has been initially indicated in this RFQ. The Offeror shall then confirm the extension in writing, without any modification whatsoever in the Quotation.
Partial Quotes	<input checked="" type="checkbox"/> Not permitted <input type="checkbox"/> Permitted
Payment Terms	<input checked="" type="checkbox"/> 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. <input type="checkbox"/> Others

Evaluation Criteria	<p><input checked="" type="checkbox"/> Technical responsiveness/Full compliance to requirements and lowest price¹</p> <p><i>Submitted offers will be reviewed on “Pass” or “Fail” basis to determine compliance with the below criteria/requirement/s:</i></p> <ul style="list-style-type: none"> ✓ Offers must be submitted within the stipulated deadline ✓ Offers must meet required Offer Validity ✓ Offers have been signed by the proper authority ✓ Offers include requested company/organization documentation as mentioned above in <i>Documents to be submitted</i> ✓ Offers must comply with general requirements as per requirements listed in Annex 3 “Criteria for award and checklist of documents required” <p><input checked="" type="checkbox"/> Full acceptance of the Contract General Terms and Conditions http://www.undp.org/content/dam/undp/documents/procurement/documents/genconditionpurchaseorders.pdf (<i>Purchase Order</i>)</p>
UNDP will award to:	<p><input checked="" type="checkbox"/> One or more Offeror/s, depending on the following factors: Lowest-priced technically responsive offer <u>per Lot</u></p>
Type of Contract to be Signed	<p><input checked="" type="checkbox"/> Purchase Order</p> <p><input type="checkbox"/> Long-Term Agreement</p> <p><input type="checkbox"/> Other Type/s of Contract: Contract for Professional Services</p>
Special conditions of Contract	<p><input checked="" type="checkbox"/> Cancellation of PO/Contract if the delivery/completion is delayed by 30 days</p> <p><input checked="" type="checkbox"/> Liquidated damages: Up to 0.5% of total contract amount per day of delay may be applied on discretion of UNDP. If the Supplier fails to supply the specified Goods within the time period(s) stipulated in the individual contract (Purchase Orders), the UNDP may without prejudice to its other remedies under the contract, deduct 0.5% of the complete consignment for each day of delay until actual delivery, up to maximum deduction of 10% of the value of the Purchase Order. Once the maximum is reached, UNDP may consider termination of the PO.</p>
Conditions for Release of Payment	<p><input checked="" type="checkbox"/> Written Acceptance of Goods by UNDP/MOH based on full compliance with requirements.</p>

¹ 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.

Annexes to this RFQ	<input checked="" type="checkbox"/> Technical Specification (Annex 1) <input checked="" type="checkbox"/> Brief Summary on simplified procedure of registration (Annex 2) <input checked="" type="checkbox"/> Criteria for award and checklist of documents required (Annex 3) <input checked="" type="checkbox"/> Form for Submitting Quotation (Annex 4) <input checked="" type="checkbox"/> Price Schedule Form (Annex 5) <input checked="" type="checkbox"/> Commitment letter (Annex 6) <input checked="" type="checkbox"/> General Terms and Conditions / Special Conditions (Annex 7) Non-acceptance of the General Terms and Conditions (GTC) shall be grounds for disqualification from this procurement process.
Contact Person for Inquiries (Written inquiries only)	<i>Procurement Unit</i> <i>UNDP Ukraine</i> <i>Health.procurement.ua@undp.org, +38 044 2539363</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 and 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.

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 awarding the 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/Contract 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 herein attached as Annex 7.

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.

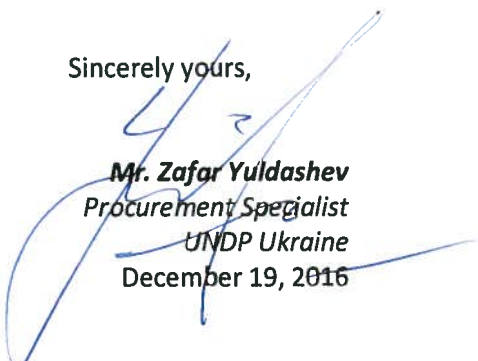
Please be advised that UNDP's vendor protest procedure is intended to afford an opportunity to appeal for persons or firms not awarded a purchase order or contract in a competitive procurement process. In the event that you believe you have not been fairly treated, you can find detailed information about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

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

Thank you and we look forward to receiving your Quotation.

Sincerely yours,



Mr. Zafar Yuldashev
Procurement Specialist
UNDP Ukraine
December 19, 2016

SCHEDULE OF REQUIREMENTS AND TECHNICAL SPECIFICATIONS

1. EXECUTIVE SUMMARY

A new policy and legislation on conducting procurement in the public health sector through international organizations was adopted in Ukraine in April 2015, with the main goal to prevent corruption, and to protect the rights of patients in Ukraine to have access to affordable and quality medicines.

In 2015 the Government of Ukraine was in urgent need to secure the availability of the state programme medicines and essential health commodities at affordable prices and in sufficient quantities. In 2015, the Ministry of Health of Ukraine requested the UN System in Ukraine to support the procurement and distribution of a number of state programme medicines and other medical products as an emergency measure.

Acknowledging the challenges of the State procurement and supply management system and following recently adopted legislation allowing selected international organizations to provide procurement support services, the Ministry of Health of Ukraine has requested UNDP to support the procurement and distribution of a number of 2015 State Programme medicines and other medical products as an emergency measure.

For the 2015 budget, UNDP procured medicines and medical products under eight state health programs. In 2016-2017 UNDP Ukraine will continue to support the Ministry of Health of Ukraine with procurement of essential and vital medicines.

UNDP in Ukraine is fully committed to play this role in resolving the immediate crisis and to support the Ministry of Health of Ukraine in its mid- and long-term efforts to reform its procurement and supply management system. UNDP will bring its extensive expertise in establishing the procurement system that corresponds to the highest standards of transparency, accountability, cost-efficiency, equity and sustainability.

The main objective of this RFQ is to source high quality medical supplies from reliable suppliers and in accordance with the value-for-money principle needed to meet the current health crisis. This RFQ targets to source medicines for patients with Epidermolysis Bullosa.

2. PRODUCT STANDARDS

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

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

OPTION 1 [A+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

participating in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (www.ich.org). Current participants are set out below for general reference only: (a) in case of the European Union both European Medical Agency (EMA) and (b) national competent authorities are included) which is a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ICH (European Union member States, Japan, United States) ; or (c) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO); or (d) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein*

***) In case product is registered by SRA authorities for “export only”, 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.**

OPTION 1 [B+C]:

B) Registered in Ukraine and the supplier has successfully completed at least one supply contract for this product in Ukraine within the past three years (since December 2013)

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.**

3. REGISTRATION / AUTHORIZATION FOR USE IN UKRAINE

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

Successful Offerors whose products are registered with MOH at time of award will be granted with a contract.

Successful Offerors whose products comply with quality standards but are not registered with MOH at time of award, will sign a conditional contract and will be required to register their products before supply.

UNDP will evaluate Offers for both registered and non-registered medicines. Non-registered products must meet **quality standards as per OPTION 1 [A+C]**. Offerors quoting non-registered products that are compliant with quality standards, must start the registration process with MOH preferably before, but not later than 5 days after signing a conditional contract for the supply of product(s). Failure to obtain registration and submit the required documents to UNDP will serve, at no claim to UNDP, as a ground for contract termination, liquidating Performance Security amount and either awarding the next qualified

Offeror or initiating a new tender process. The decision to transfer the award or initiate a new RFQ will be at the discretion of UNDP.

Summary on the simplified procedure of state registration of medicines procured with involvement of the international organizations provided for reference in the Annex 2.

4. PRODUCTS SPECIFICATION:

Lot/Item	INN	Pharmaceutical Presentation	Dosage	Quantity
1	Dexpanthenol	ointment	5% ointment in 30 g tube	12 452
2	Comb drug Zinc Oxide + Benzyl Alcohol + Benzyl Benzoate + Benzyl Cinnamate	cream	250 g in a jar	4 579

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.

5. DELIVERY TIMEFRAMES

Early delivery of medicines to Ukraine is critical therefore we encourage **shortest delivery periods**. 100% quantities must be delivered within 2 months at the latest after signing the contract. The Quotations with later delivery dates will be disqualified.

6. SHELF LIFE

Products must have a minimum of 75% of the total product shelf life or should have 15 months' shelf life remaining at the time of delivery and must bear the dates of manufacture and expiry. Shelf life shall be indicated for all products quoted in the offer submitted. Products must not have been subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect fully comply in all aspects with the Technical Specifications and with the conditions laid down in the Contract.

7. PACKAGING, LABELLING, DELIVERY

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

2) Pharmaceuticals shall be transported and stored in accordance with the temperature mode specified in the product instruction. All temperature restricted commodities must be shipped with clear marking the corresponding temperature conditions. It is the responsibility of the Offeror to provide complete packing as required for transportation. Offerors shall explain their capabilities and experience to handle temperature control items where applicable.

3) The individual packages shall be packed in carton boxes. Each carton shall contain only one product and one batch. Packing must be sufficiently strong to withstand rough handling and exposure to extreme temperatures and air moisture.

4) Labelling of primary package at the moment of supply must correspond to the one in the product's state registration record (State Register of Medicines in Ukraine). In case of any deviations found, the supplier must provide additional documentation to enable receipt of goods.

5). Primary packaging must preserve quality, safety and stability of the product it contains. The entire package must be duly sealed and protected from spoiling. Each package shall contain instructions for the use of the medicinal product in Ukrainian (preferably) or the original language.

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

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

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

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

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

7) Pre-shipment inspection

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

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

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

In case of the detection of a defective product either in the quality of a product or other defects such as packaging, the Supplier will be requested to replace the complete batch at its own cost within one (1) month. In the event of a dispute by the Supplier, a counter analysis will be carried out by an independent

neutral laboratory agreed by both UNDP and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective batch. In the event of the independent analysis confirming the quality of the product, UNDP will meet all costs for such analysis.

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

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

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

10) Quality Assurance

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

BRIEF SUMMARY
on the simplified procedure of state registration of medicines
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>

Criteria for award and checklist of documents required

Following documents should be attached to the filled-in sections #3-6

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

Award Criteria	Corresponding document	Yes	No	Reference
Compliance of Offeror with Qualifications Requirements				
Minimum 3 years of experience in similar nature and minimum 2 similar contracts fulfilled over the past 3 years	1. Certificate of Registration of the business, including Articles of Incorporation, or equivalent document if Offeror is not a corporation			
	2. Statement of Satisfactory Performance (Reference letters) from the Top 3 Clients in terms of Contract Value the past 3 years. Please provide reference letters to prove experience in similar nature of contracts			
Minimum annual turnover over the past 2 years shall equal to no less than 75% of the total amount to be contracted	3. Latest Audited Financial Statement (Income Statement and Balance Sheet) or Auditor's Report for the past 2 years			
Compliance of product/quoted with product standards and requirements (please complete checklist for each product quoted)				
<p>The product(s) will be procured on the following options (please refer for details to Annex 1 para #2 Product Standards Requirements of RFQ):</p> <p>OPTION 1: A+C A) Approved/registered by a Stringent National Medicines Regulatory Authority (SRA) as defined by WHO AND C) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities</p> <p>OR</p> <p>OPTION 2: B+C B) Registered in Ukraine and the supplier has successfully completed at least one supply</p>	A) A copy of valid Registration/Approval of Stringent National Medicines Regulatory Authority (SRA) as defined by WHO			
	B.1) A copy of valid Registration Certificate issued by the Ministry of Health of Ukraine			
	B.2) List of previous contracts for similar supply for the last 3 years. At least one contract for the supply of quoted medicine to/in Ukraine within the past three years, in case medicine does not have approval/registration of Stringent National Medicines Regulatory Authority (see Annex 1, Product Standards Requirements for details)			

Award Criteria	Corresponding document	Yes	No	Reference
<p>contract for this product in Ukraine within the past three years (since December 2013) AND C) The product is being manufactured at sites with valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities</p>	<p>C) A copy of valid WHO Public Inspection Report (WHOPIR) or GMP Certificate issued by PIC/S authorities for the manufacturing site(s) of the proposed product(s)</p> <p>Please provide information manufacturing site, including concrete manufacturing unit/block in the Annex 4.</p>			
<p>Availability of valid registration in Ukraine at the time of supply as defined in Annex 1, para #3, Registration/Authorization for use in Ukraine (if, at the moment of the bid submission, the quoted medicinal products are not registered in Ukraine but comply with the quality requirements of this RFQ, a Commitment letter shall be provided as per Annex 6)</p>	<p>Option A: A copy of a valid registration certificate for every medicinal product quoted issued by the Ministry of Health of Ukraine. If a bid is submitted less than 90 days prior to the product's registration expiration date, a letter issued by MoH confirming the application and documents package for renewal by the owner must be provided at the time of the submission as part of the documents package</p>			
	<p>Option B: If, at the moment of the bid submission, the quoted medicinal products are not registered in Ukraine but comply with the quality requirements of this RFQ, a Commitment letter (Annex 6) from the Offeror acknowledging acceptance of the terms and conditions for undertaking a simplified registration procedure (see Annex 1, para #3 Registration/Authorization for use in Ukraine for details) and confirming the ability to comply with submitting the package of documents for state registration will be required. By submitting the Bid, the Offeror automatically agrees to maintain and renew registration of these products until their shelf life expiration.</p>			
<p>Compliance with shelf life, packing and labelling requirements (please refer for details to Annex 1 of RFQ). Products must have a minimum of 75% of the total product shelf life or should have 15</p>	<p>Please provide Information on shelf life in the Annex 4</p>			

Award Criteria	Corresponding document	Yes	No	Reference
months' shelf life remaining at the time of delivery and must bear the dates of manufacture and expiry.				
Acceptability of the Transportation/Delivery Schedule (please refer for details to Annex 1 of RFQ)	Please provide Information on delivery schedule in the Annex 4			

List of other documents required for evaluation of Offeror	Yes	No	Reference
Company profile (maximum 5 pages) or link to company's web-site			
List of Shareholders and Other Entities Financially Interested in the Firm owning 5% or more of the stocks and other interests, or its equivalent if Offeror is not a corporation			
Valid Certificate of Authorization to act on behalf of the Manufacturer in case the Offeror is not a Manufacturer.			
All information regarding any past and current litigation during the last five (5) years, in which the Offeror is involved, indicating the parties concerned, the subject of the litigation, the amounts involved, and the final resolution if already concluded.			
Quality Certificate (e.g., ISO, etc.) and/or other similar certificates, accreditations, awards and citations received by the Offeror, if any			
Environmental Compliance Certificates, Accreditations, Markings/Labels, and other evidences of the Offeror's practices which contributes to the ecological sustainability and reduction of adverse environmental impact (e.g., use of non-toxic substances, recycled raw materials, energy-efficient equipment, reduced carbon emission, etc.), either in its business practices or in the goods it manufactures, if any available			

List of other documents required for evaluation of product quoted (please complete checklist for each product quoted)	Yes	No	Reference
Instruction for the medical use in accordance with the legislation of Ukraine. In case quoted medicines are not registered, instructions for the use in the original language shall be provided (which is compliant with one accompanied to SRA approval/registration).			
A copy of the Certificate of Pharmaceutical Product (COPP) from the national regulatory body in the country of manufacture for each product shall be provided. If available WHO type COPPs for products being imported into the countries within WHO certification Scheme are requested to be provided.			
Patent Registration Certificate/s, in case any product quoted has been patented by the Offeror			

FORM FOR SUBMITTING SUPPLIER'S QUOTATION²
(This Form must be submitted only using the Supplier's Official Letterhead/Stationery³)

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 UKR/HP/2016/002**:

TABLE 1: BRIEF COMPANY PROFILE

BRIEF COMPANY PROFILE	
The Service Provider must describe and explain how and why they are the best entity that can deliver the requirements of UNDP by indicating the following:	
Full registration name	
Year of foundation	
Legal status	
Legal address	
Actual address	
Bank information	
VAT payer status	
Contact person name	
Contact person email	
Contact person phone	
Company's core activities	
Profile – describing the nature of business, field of expertise, licenses, certifications, accreditations (If any);	
Business Licenses – Registration Papers, Tax Payment Certification	
Certificates and Accreditation	Please indicate here applicable including Quality Certificates, Patent Registrations, Environmental Sustainability Certificates.

² This serves as a guide to the Supplier in preparing the Quotation and price schedule.

³ Official Letterhead/Stationery must indicate contact details – addresses, email, phone and fax numbers – for verification purposes

Please provide contact details of at least 3 previous partners for reference	Please attach the 3 signed reference letters <i>to prove experience in similar nature of contracts.</i>
Company is not in the UN Security Council 1267/1989 List, UN Procurement Division List or Other UN Ineligibility List.	Please confirm (Answers: Yes, we are in the list/No, we are not in the list)

TABLE 2: Conformity to the specification

Lot/ Item	INN	Pharmaceutical Presentation	Dosage	Quantity	Product Trade Name	Manufacturer name and country of origin	Manufacturing site (address, block, unit)	Number of units per primary pack	Number of primary packs per secondary pack	SRA Approval (please indicate issuing authority)	Registration in Ukraine (please indicate registration reference)	Registration in Ukraine (please indicate registration validity)	GMP Certificate (please indicate issuing authority)	GMP Certificate (please indicate certificate validity)	Total shelf life (please indicate total shelf life in number of months)	Remaining shelf life (please indicate product's expiration date)	Patent Certificate/s (please indicate patent/s reference/s if, applicable)	3koduct's lead time (production time)	Expected delivery date/s
1	Dexpanthenol	ointment	5% ointment in 30 g tube	12 452															
2	Comb drug Zinc Oxide + Benzyl Alcohol + Benzyl Benzoate + Benzyl Cinnamate	cream	250 g in a jar	4 579															

TABLE 3: Offer to Comply with Other Conditions and Related Requirements

Other Information pertaining to our Quotation are as follows :	Your Responses		
	<i>Yes, we will comply</i>	<i>No, we cannot comply</i>	<i>If you cannot comply, pls. indicate counter proposal</i>
Delivery time (2 months from PO signature)			
Validity of Quotation (min. 120 days)			
All Provisions of the UNDP General Terms and Conditions. http://www.undp.org/content/undp/en/home/operations/procurement/how we buy/contract terms/			

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]

PRICE SCHEDULE FORM

Please refer to the attached Excel form

COMMITMENT LETTER

(This should be written in the Letterhead of the Offeror. 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 RFQ)* in accordance with your Request for Quotation dated .

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

Products:

1. _____
2. _____
3.

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

We remain,
Yours sincerely,

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

Name and Title of Signatory: _____

Name of Firm: _____

Contact Details: _____

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

GENERAL TERMS AND CONDITIONS FOR GOODS

1. ACCEPTANCE OF THE PURCHASE ORDER

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

2. PAYMENT

- 2.1.1 UNDP shall, on fulfillment of the Delivery Terms, unless otherwise provided in this Purchase Order, make payment within 30 days of receipt of the Supplier's invoice for the goods and copies of the shipping documents specified in this Purchase Order.
- 2.1.2 Payment against the invoice referred to above will reflect any discount shown under the payment terms of this Purchase Order, provided payment is made within the period required by such payment terms.
- 2.1.3 Unless authorized by UNDP, the Supplier shall submit one invoice in respect of this Purchase Order, and such invoice must indicate the Purchase Order's identification number.
- 2.1.4 The prices shown in this Purchase Order may not be increased except by express written agreement of UNDP.

3. TAX EXEMPTION

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

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

4. RISK OF LOSS

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

5. EXPORT LICENCES

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

6. FITNESS OF GOODS/PACKAGING

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

7. INSPECTION

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

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

8. INTELLECTUAL PROPERTY INFRINGEMENT

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

9. RIGHTS OF UNDP

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

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

10. LATE DELIVERY

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

11. ASSIGNMENT AND INSOLVENCY

- 11.1. The Supplier shall not, except after obtaining the written consent of UNDP, assign, transfer, pledge or make other disposition of this Purchase Order, or any part thereof, or any of the Supplier's rights or obligations under this Purchase Order.
- 11.2. Should the Supplier become insolvent or should control of the Supplier change by virtue of insolvency, UNDP may, without prejudice to any other rights or remedies, immediately terminate this Purchase Order by giving the Supplier written notice of termination.

12. USE OF UNDP OR UNITED NATIONS NAME OR EMBLEM

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

13. PROHIBITION ON ADVERTISING

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

14. CHILD LABOUR

The Supplier represents and warrants that neither it nor any of its affiliates is engaged in any practice inconsistent with the rights set forth in the Convention on the Rights of the Child, including Article 32 thereof, which, inter alia, requires that a child shall be protected from performing any work that is likely to be hazardous or to interfere with the child's education, or to be harmful to the child's health or physical, mental, spiritual, moral or social development.

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

15. MINES

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

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

16. SETTLEMENT OF DISPUTES

16.1 Amicable Settlement

The Parties shall use their best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to this Purchase Order or the breach, termination or invalidity thereof. Where the Parties wish to seek such an amicable settlement through conciliation, the conciliation shall take place in accordance with the UNCITRAL Conciliation Rules then obtaining, or according to such other procedure as may be agreed between the Parties.

16.2 Arbitration

Unless, any such dispute, controversy or claim between the Parties arising out of or relating to this Purchase Order or the breach, termination or invalidity thereof is settled amicably under the preceding paragraph of this Section within sixty (60) days after receipt by one Party of the other Party's request for such amicable settlement, such dispute, controversy or claim shall be referred by either Party to arbitration in accordance with the UNCITRAL Arbitration Rules then obtaining, including its provisions on applicable law. The arbitral tribunal shall have no authority to award punitive damages. The Parties shall be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such controversy, claim or dispute.

17. PRIVILEGES AND IMMUNITIES

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

18. SEXUAL EXPLOITATION:

18.1 The Contractor shall take all appropriate measures to prevent sexual exploitation or abuse of anyone by it or by any of its employees or any other persons who may be engaged by the Contractor to perform any services under the Contract. For these purposes, sexual activity with any person less than eighteen years of age, regardless of any laws relating to consent, shall constitute the sexual exploitation and abuse of such person. In addition, the Contractor shall refrain from, and shall take all appropriate measures to prohibit its employees or other persons engaged by it from, exchanging any money, goods, services, offers of employment or other things of value, for sexual favors or activities, or from engaging in any sexual activities that are exploitive or degrading to any person. The Contractor acknowledges and agrees that the provisions hereof constitute an essential term of the Contract and that any breach of this representation and warranty shall entitle UNDP to terminate the Contract immediately upon notice to the Contractor, without any liability for termination charges or any other liability of any kind.

18.2 UNDP shall not apply the foregoing standard relating to age in any case in which the Contractor's personnel or any other person who may be engaged by the Contractor to perform any services under the Contract is married to the person less than the age of eighteen years with whom sexual activity has occurred and in which such marriage is recognized as valid under the laws of the country of citizenship of

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

19.0 OFFICIALS NOT TO BENEFIT:

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

20. AUTHORITY TO MODIFY:

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