



UNDP Procurement Support Services to the Ministry of Health of the Republic of Moldova

Frequently Asked Questions

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General Questions

1. Why has the Ministry of Health asked development partners for support to procure vital medicines for the Republic of Moldova?

In 2014-2015, the Moldovan public health system faced a severe crisis in ensuring adequate supply of medicines and pharmaceutical products to public medical institutions. Thus, a need emerged to identify safe and reliable supply mechanism, including the procurement of quality assured medicines and health products at affordable prices.

The United Nations has significant global experience in supporting governments with large-scale procurement. That is why the Ministry of Health (MoH) approached various UN agencies to explore the possibility to provide procurement support services to the Ministry of Health of the Republic of Moldova.

2. Why did the Ministry of Health choose UNDP specifically to provide support in medicine procurement?

UNDP is one of the largest procurers in the UN system. Apart from capacities at country office level to undertake both international and national procurement, the organization also has a specialized procurement support office and an office working exclusively on the implementation of large projects financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria, which have significant procurement components. Building on the work of the UNDP-Global Fund partnership, an increasing number of governments and partners are requesting UNDP to help strengthen national capacities and systems specifically in area of the procurement and supply chain management of essential medicines and other health commodities.

UNDP has a well-functioning, state-of-the-art managerial and operational system, which delivers cost-effective procurement and supply chain management in several countries – including in Central and Eastern Europe such as Ukraine, Montenegro, Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan - and with a wide variety of partners.

UNDP manages the United Nation's largest procurement capacity, procuring over USD 3 billion worth of goods and services each year including drugs and medical products, guaranteeing countries access to life-saving medicines, emergency relief supplies and a breadth of other needed items.

In November 2015, UNDP became the first UN agency to procure the most common HIV treatment for less than US\$ 100 per patient per year for a number of countries. This was a historic breakthrough, compared to the US\$ 10,000 per year it cost only 10 years ago.

Several governments, including the Government of the Republic of Moldova, have requested UNDP to provide health procurement and supply chain services, including development of capacity of national systems and procurement reform, mainly using governments' own budgets, and going well beyond HIV, TB products. In Ukraine, UNDP procures medicines and medical products since 2015.

UNDP's Procurement Support Services to the Ministry of Health of the Republic of Moldova therefore builds on the organization's long-term experience in procurement and supply chain management for health and non-health related projects and programmes.

3. What is the legal framework of this public medicine procurement by UNDP?

The Government of the Republic of Moldova has requested the UNDP to provide support to ongoing reform processes and to the establishment of a transparent, accountable, cost-efficient, equitable and sustainable national health procurement and quality assurance system in the next few years. An Agreement for the provision of procurement support services was signed between UNDP and the Ministry of Health in 2017 for a combined total of USD 4,350,000. The Ministry of Health has provided 4,250,000 USD to procure medicines and health products included in the list of the national and special health programs medicines. In addition to procurement support services, the UNDP will allocate 100,000 USD for modernization of drug storage facility.

Based on this Agreement, during 2017 the UNDP will procure medicine and other health products for treatment and diagnosis of diseases included in the national and special health programs, in accordance with its corporate standards, using modern tools and transparent procurement procedures.

4. What are the objectives of the UNDP medicine procurement programme in Moldova?

On the short term, UNDP provides support to the Ministry of Health for the cost-effective and timely procurement of life saving medicines in the Republic of Moldova, such as those intended for diagnosis and treatment of patients with HIV / AIDS and STIs, oncological diseases, hematological, tuberculosis, rare diseases, diabetes and other medicines and health products included in the list of the national and special health programs.

On the long term, UNDP plans to strengthen the capacity of the Ministry of Health to ensure transparency, accountability and effectiveness of the public procurement of medicines and to create a coherent pharmaceutical policy. It will also contribute to the modernization of storage of medicines, in line with international standards of good distribution practices (GDP).

This initiative aims to avoid the fraud related to public procurement, the risk of discontinuity in the drugs supply and to reduce the time and cost of delivery and improve quality of procured medicines. As result of the UNDP assistance, the most vulnerable people from Republic of Moldova will have ongoing access to quality medicines at reasonable price and in required quantities. More details about the medicine procurement programme in Moldova see here: www.undp.md/medicamento

5. What is UNDP performance record in international procurement?

UNDP procures goods and services for each of its 166 Country Offices, as well as UNDP Headquarters in New York. However, the responsibility for procurement is decentralized, which means that the entire procurement cycle – from sourcing to contract management – is done locally, clearance and approval of high value procurements are always subject to approval by

UNDP's HQ in Istanbul or New York, adding a further level of check and balance to guarantee procedural integrity and fairness.

Today, an increasing number of partners, including governments and international donors worldwide, approach UNDP with requests to provide procurement and supply chain support.

Indeed, the best value-for-money of products and services delivered by UNDP and its direct procurement handling costs being lower than those of most other international procurement arrangements, make it a partner of choice for all stakeholders willing to benefit from world-class procurement and supply chain service.

In April 2016, the Aid Transparency Index has recognized UNDP as the leading aid organization among 46 international agencies, representing 98% of Official Development Flows. This index is produced by 'Publish What You Fund', a non-profit organization that advocates for and measures transparency. <http://ati.publishwhatyoufund.org/index-2016/results/>

6. Which standards and principles does UNDP procurement apply?

UNDP procurement procedures comply with both UN and international standards and abide by the following principles:

- **Best Value for Money**, which consists of the selection of the offer that best meets the end-users' needs and that presents the best return on investment. Best Value for Money is the result of several factors, including quality, experience, the vendor's reputation, life-cycle costs and benefits, and parameters that measure how well the good or service allows the organization to meet its social, environmental or other strategic objectives.
- **Fairness, Integrity and Transparency**, which ensures that competitive processes are fair, open, and rules-based. All potential vendors should be treated equally, and the process should feature clear evaluation criteria, unambiguous solicitation instructions, realistic requirements, and rules and procedures that are easy to understand.
- **Effective International Competition**, understood as giving all potential vendors timely and adequate information on UNDP requirements, as well as equal opportunity to participate in procurement actions, and restricting them only when it is absolutely necessary to achieve UNDP development goals.
- **In the best interest of UNDP**, which means that any business transactions must conform to the mandates and principles of UNDP and the United Nations.

7. What medicines does UNDP procure?

UNDP procures and supplies quality medicines based on a list of products given by the Ministry of Health, which stipulates the required quantities and the available budget. Under the procurement budget allocated by the Ministry of Health in 2017, UNDP handles centralized procurement of the medicines and medical products for the following national and special health programs:

1. Diabetes treatment

2. Immunoprophylaxis and anti-epidemic measures
3. Mental Health
4. Rare Diseases
5. Combating cancer
6. Transplantation Service
7. Transfusion Security and Self-Insurance of the Country with Blood Products
8. HIV/TB/STD control and prophylaxis
9. Prophylaxis and tuberculosis control

The detailed information on the tender requirements may be found by following the below web links:

- UNDP Moldova - <http://www.undp.md/tenders/index.shtml>
- UNDP corporate – <http://procurement-notice.undp.org/index.cfm>
- UNGM – <https://www.ungm.org/Public/Notice>

This has also been reflected on the transparency page for health products and medicines procurement:

http://www.md.undp.org/content/moldova/en/home/operations/projects/effective_governance/servicii-de-sus_inere-a-achiziilor-pentru-ministerul-sntii-/transparency-of-procurement/

List of medicines, medical products and other products included in the national and special programs, to be procured by the UNDP in 2017 is available here:

<http://www.md.undp.org/content/dam/moldova/docs/anexa%20nr.%202%20Lista%20medicamentelor%20dispozitive%20medicale%20-%202003.0317.pdf>

This list is subject of continuous updates. The list of the competitions for the rest of the medicines will be updated and new announcements and contract awards will be published during the year.

8. For how long will UNDP procure medicines and medical products for the Republic of Moldova?

Starting in 2017 UNDP will procure medicines and other health products for treatment and diagnosis of diseases included in the national and special programmes, in line with the detailed list provided by the MoH. The list of health programs and/or relevant medicines and health products may be revisited beyond this initial phase and subsequent years.

Being temporary in its nature, a smooth exit strategy will be developed in the first 6 months of the project, ensuring that by the end of the project, relevant systems are in place to conduct procurement of medicines in a transparent, efficient and accountable manner.

Bidding Questions

9. Who can participate in the bidding process?

All Moldovan pharmaceuticals companies, as well as international manufacturers, meeting the eligibility requirements and quality standards detailed in the tenders announced by UNDP are encouraged to participate and submit bids. The selected Suppliers are requested to manufacture products only at manufacturing sites/units/blocks, which are certified by WHO (WHOPIR) or PIC/S GMP.

UNDP will evaluate offers for both registered and non-registered medicines in the Republic of Moldova. Bidders offering nonregistered products that are compliant with quality standards, must require One-time Importation Permission from the MoH prior to importing medicines to Moldova. The procedure is guided and released by the MoH within one week and does not imply any additional costs.

10. What are the eligibility criteria for bidders?

While further specific qualification criteria may be required for a particular purchase, in general terms all vendors must meet the following commercial criteria to qualify for UNDP procurement:

- Provide audited financial statements for completed fiscal years upon request;
- Comply fully and effectively with UNDP General Terms and Conditions of Contract;
- Demonstrate the adequate organizational structure, facilities, experience, accounting and operational controls to perform the contract;
- Present adequate insurance levels and technical skills (such as quality controls, property and production control systems, standards and safety programmes applicable to goods produced or services performed);
- Have a record of satisfactory performance with UNDP, when applicable; and
- Have sufficient material and financial resources to meet all commercial commitments specified in the contract.

Eligible vendors are qualified vendors that have not been temporarily suspended or debarred by UNDP or any other UN agency, fund or programme. More details in the Schedule of Requirements and Technical Specifications:

<http://www.md.undp.org/content/dam/moldova/docs/Annex%201-2%20eng%20medicine.pdf>

11. What are the specific requirements and process peculiarities?

- Medical products registered and non-registered medicines in the Republic of Moldova that meet the quality criteria as listed in the tender requirements solicitation.
- Detailed administrative and technical requirements are elaborated for each product/programme separately and listed in tender requirements.

- Bidders can submit their proposal in English, Romanian or Russian. The financial proposal(s) can be made in US dollars.
- Bidders can submit proposals for one or several lots within the same tender.
- Bids are submitted electronically or by courier/hand delivery. Late submissions are not accepted.

As part of risk mitigation measures, UNDP may require “performance security” instruments, such as bank guarantees, to bind a bidder to fulfill the commitment made in the framework of its offer to UNDP. Performance security is an amount sufficient to protect UNDP in case of a breach of contract by the supplier.

In case a Performance Security is required, its submission and the confirmation of its acceptance by UNDP is a condition for the contract between the successful bidder and UNDP to effectively enter into force. When deemed necessary by UNDP, Quality Control or testing may also be arranged for some medical products.

12. How does UNDP select the company/companies which will supply the medicines?

The selection process follows 4 steps:

1. Announcement of the tender:

Tenders are announced on UNDP Moldova website (<http://www.undp.md/tenders/index.shtml>), UNDP’s corporate website (<http://www.undp.md/tenders/index.shtml>), and on the United Nation’s Global Market place (<https://www.ungm.org/>), for a minimum of two weeks.

In order to maximize circulation and ensure a satisfactory number of bidders for fair competition, UNDP supplements the tender publication on corporate websites with direct notifications to the potential bidders as identified by UNDP’s sound market research. The UNDP may also post advertisement in other print (newspaper, publications, etc.) and electronic means, such as the MoH website, UNDP’s social media platforms and online news portals.

2. Pre-bidding conferences:

When appropriate, a pre-bidding conference is conducted at the date, time and location, specified in the solicitation document. All interested bidders are encouraged to attend to ask questions, and conference.

However, non-attendance does not disqualify potential bidders. Minutes are published on the UNDP website and sent to the individual companies who have registered or expressed interest with the solicitation, regardless of their attendance to the pre-bidding conference. Minutes are also added as amendment in the form of a Supplemental Information to the Invitation to Bid.

3. Public bid opening:

Upon the tender deadline and in case of a high value competition of USD 150 000+, UNDP publicly opens received bids. Only bidders, who submitted their proposals, can participate.

4. Tender evaluation, which consists of three stages:

a. Preliminary examinations of the bids received (administrative evaluation)

UNDP shall examine the bids to determine whether they are complete with respect to minimum documentary requirements, whether the documents have been properly signed, whether or not the bidder is in the UN Security Council 1267/1989 Committee's list of terrorists and terrorist financiers, and in UNDP's list of suspended and removed vendors, and whether the bids are generally in order, among other indicators that may be used at this stage. UNDP may reject any bid at this stage.

b. Technical evaluation

UNDP then reviews the bids that have made it through the preliminary examinations stage to confirm that all terms and conditions under the UNDP General Terms and Conditions and Special Conditions of the tender have been fully accepted by the bidder.

Bids are evaluated on the basis of their responsiveness to the Schedule of Requirements and Technical Specifications, as well as other documentation provided. Selection criteria cannot be changed once bids have been received.

However, UNDP may undertake a post-qualification exercise prior to awarding a contract, aimed at determining the validity of the information provided by the bidder. Such post-qualification is always fully documented and may include the following, among others:

- Verification of the legal, technical and financial accuracy and authenticity of the information provided;
- Confirmation of bids compliance with the requirements and evaluation criteria listed in the solicitation document;
- Cross-referencing with Government entities whose jurisdiction the bidder is subject to, or with any other entity that may have engaged in business activities with the bidder;
- Inquire for reference and credentials by checking with previous clients the quality of performance and delivery for on-going or past contracts;
- Physical inspection of the bidder's production plant, factory, branches or any other business touch points, with or without notice to the bidder;
- Testing and sampling of completed goods presenting similar requirements than those of UNDP, where available; and

- Other means that UNDP may deem appropriate, at any stage within the selection process, prior to awarding the contract.

c. Financial evaluation

Bidders presenting the lowest rates are selected, provided they have successfully passed the two previous selection stages.

13. To what extent will be the Ministry of Health involved in selection process? Who is going to have the last word?

Ministry of Health of the Republic of Moldova participates as an observer in the procurement process, without the right to vote.

14. What are the main contractual terms and conditions?

As result of the evaluation process, UNDP issues a Purchase Order to the winning bidder(s), listing the following:

- Requisites of both sides: supplier (bid winner) and purchaser (UNDP).
- Specification and quantity of goods to be supplied, including shelf life and delivery terms.
- Shipping terms and addresses, including the list of shipping documents required from the supplier, transport and storage (i.e., temperature, etc.).
- Terms and conditions for the reimbursement of defective or damaged goods and their disposal.
- Terms and conditions for payment (30 calendar days after the effective delivery, upon a written acceptance of goods duly signed and stamped by UNDP/MoH and the provision of the original invoice).
- Terms of performance security issuance, if applicable.
- UNDP's General Terms and Conditions for Goods.

Progress payments can be made if deliveries are divided into several shipments. All suppliers are expected to deliver the goods at the quality and quantity levels specified in their bid and in compliance with the contract terms and tender requirements.

Quality Assurance

15. What are the quality requirements for the medicines and medical products to be procured?

The medical products to be procured must meet the following set of criteria, to ensure the highest quality of health products delivered under each programme:

- Prequalified by World Health Organization (WHO), or

- Approved by a Stringent National Medicines Regulatory Authority (SRA) of countries with a Pharmaceutical Inspection Convention Scheme (PIC/S)
- Recommended by the Expert Review Panel for The Global Fund, or
- Registered in Moldova and at least one successfully completed supply of this product in the similar volume in/to Moldova within the past two years (since February 2015)
- All products must be manufactured at sites with a Good Manufacturing Practice (GMP) certificate provided by the WHO or PIC/S authorities.
- The remaining shelf life of products procured must be at least 80% of the total product shelf life or should have 18 months' shelf life remaining at the time of delivery.

Additionally to the criteria listed above, other requirements cover packaging, labelling and delivery. 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.

16. How does UNDP evaluate/check the quality of health products procured?

Upon analysis of potential risks, UNDP reserves the right to perform, at any time, inspections and tests for quality assurance and to reject the items if found as not complying with the required specifications, and this up until three months after the goods delivery to the final destination indicated in the Purchase Order.

Prior to shipment or upon arrival at the final destination, some batches of the product may be tested randomly to ensure that the products meet the Quality Assurance requirements and contractual standard. Such tests can involve an independent laboratory and in-house quality checks, or both. Any consignment or batch(es) of goods not meeting the agreed standards and requirement is rejected.

Upon receipt of a written notice from UNDP, the supplier must, as swiftly as possible, replace the defective Goods at its own expense and at the final delivery location. The supplier is also required to remove, at his own risk and expense, the defective goods upon replacement with valid ones. If the defective goods are not removed within 30 days, UNDP will dispose of them at the supplier's expense.

Labelling and delivered quantities under each Purchase Order are the supplier's responsibility until goods are inspected by UNDP or its representative. A Clean Report of Findings may also be issued by UNDP or its representative upon delivery, if needed.

In case discrepancies are found in labelling and/or quantities between the Purchase Order requirements and the actual delivery, these must be rectified promptly by the supplier at its own expense.

17. In what language, should be the text on the packaging/stickers on the procured medicines will be written?

Each package shall contain instructions for the use of the medicine in Romanian (preferably) or English/Russian language.

Delivery

18. How much time does it take to deliver the procured medicines to Moldova?

The medicines are delivered in accordance with Contract terms and conditions. In light of latest procurement, the delivery process takes on average 1 to 3 months. Liquidated damages may be applied in case of violation of delivery terms by the supplier.

19. Does UNDP carry-out pre-shipment inspection?

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. 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.

When all the goods from a specific purchase order are ready for shipment with their final packing and marking, a pre-shipment inspection may be carried out by UNDP or its representative for verification of quality, quantity, packing, labelling, marking and sampling. In cases when pre-shipment inspection is required, the corresponding Purchase Order will indicate this.

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

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

replacement and disposal of the defective batch. In the event of the independent analysis confirming the quality of the product, UNDP will meet all costs for such analysis.

20. Who is responsible for customs clearance?

Suppliers must arrange customs clearance themselves and these expenses should be included in the financial proposals.

21. How is the medicine stored?

UNDP will procure and supply quality items according to the list of medicines and health products, quantities, quality requirements and budget agreed with the MoH in line with national and international regulations and to the designated delivery place indicated in the solicitation documents.

22. How will UNDP contribute to the modernization of the infrastructure for medicines' storage in Moldova?

One of the key objectives of the project refers to infrastructure upgrade, also seen as a sustainability measure. UNDP will contribute to the modernization of the infrastructure for medicines' storage in Moldova, in line with WHO and EU recommended good distribution practices (GDP).

23. Will UNDP charge any fees for the services and assistance provided to the Ministry of Health?

UNDP applies a 5% General Management Service fee on the budget allocated to the procurement. This fee is used to cover the administrative and operational expenses incurred by running the procurement programme.

24. What happens after delivery? Who takes care of the distribution?

UNDP is responsible for the procurement process of the medical products and until they are delivered to a designated destination in Chisinau. The distribution chain from Chisinau will be assured by the Ministry of Health through its subordinate institutions. UNDP will provide support and cover the costs from the project budget, if needed, to service providers for customs clearing, in-country storage and distribution as agreed with the MoH, while the MoH will be a consignee and owner of the products.