# TERMS OF REFERENCE

**Development of functional specifications to support the implementation of an electronic system to monitor pharmaceutical stocks in the Republic of Moldova, to identify/predict medicines stockouts.**

## 1. Background (Please briefly describe why the work is needed)

Universal health coverage (UHC) means that all individuals and communities receive the health services they need without suffering financial hardship. The Sustainable Development Goals call on all countries to use access to medicines and health products as a key indicator of universal health coverage. Access to Medicines and Health Products is one of the key components of UHC and one of the three core priorities of theth WHO-EPW is about moving towards universal health coverage.

Medicines and health products are needed to treat, diagnose, prevent diseases and should be available in the good quantity, at the right time for all patients in need. Therefore, is important to keep a good overview of the stocks available in country and to plan in advance future orders adequately. In the healthcare sector, having an efficient medical inventory system is important. Thus, a robust pharmaceutical stocks monitoring system ensures the seamless availability of vital supplies. It monitors drug availability at every point of the supply chain — from procurement to dispensing to restocking, and the cycle continues. This helps to enhance operational efficiency, and ultimately contributes to improved patient outcomes.

The Republic of Moldova was exposed to repeated shortages of essential medicines, caused also by supply chain disruptions due to the war in Ukraine, making challenging for the local and refugee population in the Republic of Moldova to get access to specific medicines on the local market, this being report across all areas of the country (see UNHCR 2023 Final Report of the 2024 Refugee Response Plan for Republic of Moldova). During a brief survey performed in May-June 2024, 14 essential medicines were identified in the Republic of Moldova as having availability issues due to shortages of various causes at different points in the supply system. Parallel exports are also a common occurrence in the Republic of Moldova.

The absence of an electronic system to monitor pharmaceuticals stocks was identified as a risk with major implications for patients' treatments by the National Health Strategy 2030, approved by the Republic of Moldova Government in 2023. Consequently, the development and implementation of an electronic system to track pharmaceuticals and medical devices was identified as one of the priority actions under Objective 3.1 of the National Health Strategy 2030. The Moldovan National Agency for Medicine and Medical Devices (NAMMD) requested the WHO Country Office (CO) technical assistance (request dated 23.10.2024) to support "the development of the concept, architecture and technical features for an electronic system to monitor pharmaceutical stocks, enabling proactive early identification of medicines shortages risks and activation of alternative methods to ensure supply of essential medicines to the people of the Republic of Moldova".

WHO Moldova country office is seeking the services of a company to support, in collaboration with the MoH, NAMMD and the eGov agency, the development of the functional specifications of an electronic system to monitor pharmaceuticals stocks in the Republic of Moldova.

**2. Deliverables of the work assignment, including technical report and financial statement**

I. **Objective of the work assignment**

The overall objective of the Assignment is to develop the required functional specifications aligned with global best practice standards to develop an interoperable electronic system for monitoring of pharmaceuticals stocks (medicines and health products) in the Republic of Moldova, to support an open, competitive procurement process led by the relevant national authority to identify a qualified vendor able to develop and implement such a system. The main purpose of this system shall be to inform national competent authorities of potential or actual shortages as early as possible, and provide detailed information to predict impacts better and implement preventive measures.

II. **Technical Activities**

1. Screening and mapping the current pharmaceuticals supply chain in the Republic of Moldova from the perspective of developing a track & trace system at national level. The Service Provider should describe the situation at all levels: customs level, wholesalers, central warehouses (receiving, inventory management, distribution), regional warehouses (replenishment), healthcare providers, pharmacies.

   The output of this activity shall be the Screening and mapping report, including a blueprint of current business processes, data, systems, and technologies in use in the Republic of Moldova in the field of medicines stocks, at all the levels of the supply chain: manufacturers, wholesalers, central and/or regional warehouses (public and private), health facilities, community health centers, pharmacies. A detailed stakeholders register of the parties involved in the pharmaceuticals supply chain will be developed. This document will describe, using an analytical method, the workflow of data and information for the whole pharmaceuticals supply chain from the entry point in the Republic of Moldova to the point of dispense or exit from the country. Users' roles and data owners, type of software used for stock management, as well as the coding standards in use should be described. A technical annex will be provided with the description of the legacy methods and technologies currently used along the supply chain.

2. Development of a draft Concept Note and product requirements scoping needed to develop a pharmaceutical stocks e-monitoring system (herein after SMeS) with the overall objective of mitigation of medicines shortages risks. The concept note must include at least the following elements, to help the national competent authorities being informed of potential or actual shortages as early as possible:
   A. Clear objectives of the SMeS, including description of key performance indicators relevant for the objectives, and product requirements scoping.
   B. Proposal of at least two traceability models adapted to the Republic of Moldova context, describing where and how the data are sourced from, stored and how verifications and analyses are performed, and presenting the advantages and disadvantages of each proposed model from the perspective of the national pharmaceutical supply chain.
   C. Recommendations for the feasibility of using the unit-level tracing vs. lot/batch-based tracing, including considerations related to the impact of transitioning to unit-level serialization in terms of costs for various stakeholders and timeline, specific for the Republic of Moldova's context.

D. Model interactions of the SMeS with other pre-existing information systems existing in the Republic of Moldova, including standards and/or identifiers (e.g. registration system, customs system, reimbursement system, pharmacovigilance, etc.).
E. Risk-benefit analysis to identify the benefits and impact of the SMeS implementation for supply chain stakeholders and on accessibility of medicines to Republic of Moldova's patients.
F. Alternative scenarios on governance type and funding of the Republic of Moldova's SMeS.
G. Proposal for a phased approach to develop and implement the SMeS, including timelines for implementation of various element of the e-system.

3. Organization of a stakeholders' consultation meeting to gather and integrate feedback on the SMeS Concept Note. The draft SMeS Concept Note will be presented and discussed during the stakeholders' consultation meeting and detailed minutes will be taken by the Service Provider. The stakeholders' feedback will be integrated and a final version of the SMeS Concept Note will be developed.

4. Development of a draft SMeS business processes documentation and provisions of technical coordination to the SMeS Working Group convened by NAMMD to reach a final version of the business processes documentation.
   The SMeS business processes documentation must describe the workflows, system's inputs/outputs, tasks and roles, SMeS process maps. The functions which will allow for forecasting using historic trends and patterns, as well as identification of the risk of medicines shortages, should be thoroughly described.

5. Development of the SMeS architecture, which will be presented to the SMeS Working Group convened by NAMMD. Architecture of the pharmaceutical stocks e-monitoring system shall describe the SMeS functional requirements for how the system must operate (software, hardware, machine/server requirements, etc.) and how its elements will be connected, automated and integrated.
   It will include the data model and specific functional requirements which must comply to the global standards widely in use, but mainly in the European Union. This document should include at least the components aligned with the national digital public infrastructure requirements :
   A. Requirements for standardization of the following elements: products, codes, stakeholders (manufacturers, suppliers, wholesalers, etc.), subsets of products based on manufacturing/production and locations.
   B. Requirements for identification of specific features: product name, active ingredient, strength, form, manufacturer, pre-determined market destination and the level of packaging for which identification is required, batch number, expiry date.
   C. Requirements for standardization of quantity of units uniquely identified, including for stock re-order management.
   D. Clear specifications of the levels of identification required and identification of the stakeholders in the supply chain which will need to verify and/or capture identification data, maintain specific stock levels and calculate re-order points based on product and category.

E. Clear requirements for the unique identifier of the pack, complying to the international standards in use.
F. Requirements needed for real-time/automatic identification, data capture coding and data exchange to allow for interoperability, complying with European Health Data Space standards.
G. Data privacy and cybersecurity requirements, complying with European Health Data Space standards.

6. Perform market research followed by a detailed cost estimation for SMeS development, implementation, and maintenance. This document shall include a detailed itemized cost estimation for the SMeS development, implementation, and maintenance (3-years' time horizon) based on the market research and on the previously prepared technical documents.

7. Provide technical and legal expert support to the NAMMD during the procurement process for development and implementation of SMeS, including technical support for the development of the detailed functional specifications in line with Republic of Moldova's procurement requirements. Draft proposal of the SMeS IT functional specifications needed to initiate the procurement procedures for the development of SMeS shall be developed in closed collaboration with the designated NAMMD technical staff. The Service Provider shall develop a specific roadmap and/or handover plan detailing the implementation steps and evaluation measures which will allow the NAMMD to take the procurement and implementation tasks forward.

**3. Realistic delivery dates and details as to how the work must be delivered (e.g., electronic submission, hard copy, what computer programme should be used, etc.)**

The duration of the services provision is from 06.01.2025 to 31.06.2025.

**Delivery dates**

| Activity | List of deliverables and technical outputs | Timeline |
|---|---|---|
| **Activity 1.** Screening and mapping the current pharmaceuticals supply chain in the Republic of Moldova | **Deliverable 1.** Screening and Mapping Report (in accordance with Activity 1 above) (*A detailed structure of the report together with a list of the stakeholders to be interviewed/screened shall be prepared and submitted to the WHO CO for prior validation).* | 2 weeks from the commencement date. |
| **Activity 2.** Development of a Concept Note for SMeS | **Deliverable 2.** Draft SMeS Concept note for the Republic of Moldova (in accordance with Activity 2 above) (*A detailed structure of the draft Concept Note shall be prepared and submitted to the WHO CO for prior validation).* | 5 weeks from the commencement date. |
| **Activity 3.** Organization of a stakeholders' consultation on the SMeS Concept Note | **Deliverable 3.** Final version of the SMeS Concept Note integrating stakeholders' feedback (in accordance with Activity 3 above) *(A detailed agenda and the list of participants to the stakeholders' consultation meeting shall be prepared and submitted to the WHO CO for prior validation.)* | 7 weeks from the commencement date. |
| **Activity 4.** Development of a draft SMeS business processes documentation | **Deliverable 4.** SMeS business process documentation (in accordance with Activity 4 above) *(The minutes of the SMeS working group convened by NAMMD shall be presented to the WHO CO).* | 10 weeks from the commencement date. |
| **Activity 5.** Development of the SMeS architecture | **Deliverable 5.** SMeS architecture (in accordance with Activity 5 above) *(A detailed structure of the SMeS architecture document shall be prepared and submitted to the WHO CO for prior validation. The minutes of the SMeS working group convened by NAMMD shall be presented to the WHO CO).* | 14 weeks from the commencement date. |
| **Activity 6.** Perform market research followed by a detailed cost estimation for SMeS development, implementation and maintenance. | **Deliverable 6.** SMeS detailed cost estimation (in accordance with Activity 6 above) *(The market research methodology shall be prepared and submitted to the WHO CO for prior validation).* | 14 weeks from the commencement date. |
| **Activity 7.** Provide technical support to the NAMMD during the procurement process. | **Deliverable 7.** Draft technical procurement package for SMeS and Specific Handover Plan (in accordance with Activity 7 above) *(The documents shall be prepared in close coordination with NAMMD technical staff and evidence of the coordination meetings shall be presented to the WHO CO).* | 20 weeks from the commencement date. |
| **Activity 8.** Administrative reporting | **Deliverable 8.** Assignment completion report *(The report shall contain a summary of the services performed during the Assignment with reference to the activities/deliverables set out in the ToR.* | 22 weeks from the commencement date. |

The technical deliverables will be made available in an editable electronic format, both in English and Romanian. They will have to be provided in Microsoft Office compatible format, in a single file or with a series of files following a structure that makes it easy to print and generate hard copies, with all support files also attached. All produced spreadsheets must be provided in Microsoft Excel compatible format, including all underlying formulas. Such formulas, graphs, visuals and similar shall be editable, unprotected, and available to the WHO CO. Deliverable 2 and Deliverable 7 will be submitted in 10 hard copies (only in Romanian) prior to the corresponding stakeholders' consultation meeting.

| **4. Budget breakdown** |
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| The payment will be made in several instalments (see below) upon satisfactory delivery of work with the submission of completed and signed financial statement. The level of effort (in days) allocated to each activity is just indicative; the Service Provider shall submit in its Financial Proposal its proposed level of effort allocated for each activity, the proposed fee rate per day and the proposed total amount of effort (in days and in USD). |

| *Budget line (according to activities under Section 3)* | *Level of effort, days (indicative)* | *Fee rate/day (USD)* | *Payment schedule following approval of corresponding deliverables (% of total contract amount)* |
|---|---|---|---|
| Activity 1 | 10 days | *(To be completed by the Service Provider in the Financial Proposal)* | 15% |
| Activity 2 and Activity 3 | 20 days | | |
| Activity 4 | 15 days | | 45% |
| Activity 5 | 25 days | | |
| Activity 6 | 20 days | | |
| Activity 7 | 20 days | | 40% |
| Activity 8 | 5 days | | |
| **TOTAL** | *(To be completed by the Service Provider in the Financial Proposal)* | | |

**5. Performance indicators for evaluation of results (e.g., timeliness, value of the services rendered in relation to their cost) and deliverables approval process**

**Performance indicators**

- Technical and professional level of performed work (will be judged by the quality of reports provided to the WHO as well as references of partners which might be involved).
- Timeliness of performed work.
- Volume of performed work (performance of tasks according to the above section 2 and section 3)
- The quality of work will also be assessed through evaluation of working relations, responsiveness, and communication skills of the contractual partner.

While performing the tasks, the Service Provider shall refer to the following existing documents:

- Existing technologies and "track and trace" models in use and to be developed by Member States (WHO) https://apps.who.int/gb/sf/pdf_files/MSM4/A_MSM4_3-en.pdf
- Policy paper on traceability of medical products (WHO) https://apps.who.int/iris/bitstream/handle/10665/340237/9789240021327-eng.pdf?sequence=1&isAllowed=y
- European Union UDI Requirements (HIBCC) https://www.hibcc.org/global-resources/european-udi-requirements/
- International Coalition of Medicines Regulatory Authorities (ICMRA) https://www.icmra.info/drupal/sites/default/files/2021-08/recommendations_on_common_technical_denominators_for_T&T_systems_to_allow_for_interoperability_final.pdf

**Approval of the Technical Deliverables**

The Service Provider shall submit the draft deliverables to the WHO CO in The Republic of Moldova and NAMMD focal point for their initial review and feedback through an e-mail correspondence. Within 2 working days after the submission of the draft deliverables, the Service Provider shall organize a review meeting (online format) with the WHO Moldova CO and NAMMD focal point participation. During the review meetings, the Service Provider shall present the contents of the deliverables and answer questions raised (if any). The WHO Moldova CO will also communicate to the Service Provider the full consolidated feedback in writing after the review meetings.

The Service Provider must revise the deliverables in line with the feedback received during the review meetings to the satisfaction of the WHO Moldova CO and re-submit the revised version of the deliverables within 3 working days after receiving the full consolidated feedback in writing. The iterations (submit – review meeting – feedback – resubmit) shall continue until the feedback is fully and correctly reflected to the deliverables to the satisfaction of the WHO Moldova CO. The deliverables will be considered approved only after the written confirmation (via email) of the WHO Moldova CO.