REQUEST FOR PROPOSALS (RFP)
#UKRSAFEMED176A

Name of the RFP	**Development of the IT-infrastructure strategy for the state enterprise**

"Management Sciences for Health, Inc." (MSH), implementing the USAID Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) Project, invites you to submit a proposal following the requirements of this request.

Proposals must be received no later than the date and time listed in the table below:

Date of request for proposal:	November 4, 2024
Final date for submitting questions:	November 8, 2024, by 6:00 pm Kyiv time
Final date and time of submission of the proposal:	November 15, 2024, by 6:00 pm Kyiv time
Contact Information:	ua-safemed-procure@safemedua.org

Full description of needs / Terms of reference / Specifications

I. Background

Management Sciences for Health (MSH), an implementing partner of USAID-funded project SAFEMed, calls for the submission of quotes for the development of IT-infrastructure strategy for the State Service of Ukraine on Medicines and Drugs Control (SMDC).

Following recent amendments to the Law of Ukraine "On Medicinal Products," a significant restructuring is mandated for the State Service of Ukraine on Medicines and Drugs Control (SMDC) and the State Expert Center of the Ministry of Health of Ukraine (SEC). This legislative change necessitates the merger of these two bodies to form a single executive authority with specialized status. This new entity will be responsible for the comprehensive management of the lifecycle of medicinal products, including their development, market approval, and ongoing regulation. Additionally, it will oversee the technical regulation and market surveillance of a broad range of health-related products.

The restructured authority will have an expanded scope of responsibilities, encompassing not only traditional pharmaceuticals but also medical devices, in vitro diagnostic devices, implantable medical devices, biologic implants, and cosmetic products. Furthermore, the authority will manage the regulation of blood and blood components, ensuring the safety and efficacy of blood transfusions and related practices. The oversight will extend to narcotics, psychotropic substances, and their precursors, with a strong emphasis on combating their illicit circulation.

To support these extensive and varied regulatory functions, a robust IT infrastructure is essential. The recent IT audit conducted by the USAID-funded SAFEMed project highlighted multiple areas for improvement in the existing systems of SMDC. These include enhancements in data protection, process automation, resource management, and the capabilities for big data analysis. The findings from this audit provide a

foundational understanding of the IT enhancements needed to support the expanded roles and responsibilities of the new regulatory authority.

A thorough legislative review following the IT audit identified the need for automation across various segments: 210 business processes within medicinal products legislation; 26 processes related to narcotics and psychotropic substances; 26 processes in the realm of non-food product market surveillance; and 7 processes within blood safety legislation. These figures illustrate the vast and varied landscape of regulatory tasks that will be streamlined through automation. This automation will support the newly consolidated regulatory framework, enhancing its efficiency and responsiveness to sector needs.

Given the scope and complexity of the tasks ahead, the development of an integrated IT strategy is crucial. This strategy will not only address the immediate needs identified through the IT audit but also lay a robust groundwork for future expansions and adaptations. The strategy will encompass the automation of identified processes and consider the development of new systems and directives that have not yet been implemented. Full access to the detailed IT audit report will be provided to the winning bidder after the signing of a Non-Disclosure Agreement, ensuring the confidentiality and security of the information. This comprehensive approach will ensure that the regulatory authority is well-equipped to manage its responsibilities effectively, keeping pace with international standards and the dynamic nature of healthcare regulation.

II. Scope of work

1. Develop recommendations for the potential integration of existing electronic solutions into a single electronic system or multiple systems by consolidating individual components based on the audit results of the SMDC and the SEC. This will address the existing open questions regarding the country's plans for the future reorganization of these entities.
2. Provide recommendations on the operational effectiveness of existing electronic systems and propose options for their reduction to streamline operations and improve efficiency within the newly structured regulatory framework.
3. Conduct a comparative analysis of the existing IT infrastructures of regulatory bodies in various EU countries to identify best practices and propose potential models that could be adapted for Ukraine. This analysis will help in aligning Ukraine’s regulatory IT infrastructure with European standards.
4. Offer recommendations on the development and implementation of additional electronic systems, modules, or registers needed to effectively fulfil the functions and tasks assigned to the respective state structures. This includes enhancing capabilities for tracking and monitoring regulated products and activities.

Period of provision of services: expected 3 months (13 weeks) from the date of contract signing.

Contract type: it will be a fixed-price contract in UAH without VAT.

Payment: payment on delivery after completion of every implementation stage in UAH excluding VAT.

#	Deliverables	Timeline (number of weeks from the date of contract signing)
STAGE 1		
1	Analytical report including a review of the IT infrastructure of European regulatory agencies and a comparative analysis with the current state in Ukraine to identify key differences and opportunities for improvement.	4 weeks
2	Report on the primary needs of the target audience for digital services and IT solutions, considering the specific needs of the SMDC	6 weeks
3	Report with developed strategic goals and product concept outlining a roadmap for transitioning from the "as-is" to the "to-be" state.	8 weeks
STAGE 2		
4	Roadmap detailing tasks, timelines, and budget estimates, including a plan for implementing the concept over the coming years.	11 weeks
5	Presentation and accompanying text document for discussion with stakeholders and to gain support for the IT infrastructure development concept	13 weeks

III. Qualification requirements

To participate in this tender process, the bidder must comply with the following requirements:

- Legal registration in Ukraine.
- Minimum of 3 years' experience in developing and integrating complex IT systems, particularly in healthcare or regulatory environments.
- Experience in conducting comparative analyses of IT infrastructures, preferably within the regulatory sector.
- Extensive knowledge and experience in adapting IT systems to comply with national and international regulatory standards.
- Proposal validity for 30 calendar days.
- Acceptable payment terms (payment upon delivery in UAH excluding VAT within 10 bank days following the completion of each stage of the project implementation).

IV. Terms of payment and requirements for VAT exemption

The SAFEMed project is entitled to tax benefits and is exempt from VAT on goods (works, services) purchased in the customs territory of Ukraine, so payment for services is made without VAT. Applicants who are VAT payers must be ready, in case of acceptance of the tender offer, to go through the procedure of exemption from value-added tax (see "Requirements for exemption from VAT").

SAFEMed project address	5/24 Irynynska street, office 89, Kyiv 01030, Ukraine
Payment terms	**Bank transfer without VAT. Payment within 10 business days following the completion of each stage of the IT audit.**
Requirements for exemption from VAT	The Safe, Affordable and Effective Medicines for Ukrainians (Safe and Affordable Medicines) - SAFEMed project is an international technical assistance project implemented in Ukraine with the financial support of the United States Agency for International Development (USAID), Agreement No. AID-121-C-17-00004, following the Agreement between the Government of Ukraine and the Government of the United States of America on humanitarian and technical and economic cooperation of May 7, 1992 (hereinafter - the "Agreement"). The project purchases goods, works and services from the Tender Winner following the above Agreement and the Procedure for Attracting, Using and Monitoring International Technical Assistance, approved by the Resolution of the Cabinet of Ministers of Ukraine of February 15, 2002, N 153 (153-2002-п) "On creation of a unified system for attracting, using and monitoring international technical assistance". The cost of such goods, work, and services is exempt from value-added tax. Procurement of goods, work, and services is carried out at the expense of the international technical assistance project and corresponds to the category (type) of goods, works and services specified in the procurement plan. The winner will be provided with a package of documents for exemption from VAT, namely: 1. Copy of the registration card of the Project, within which the purchase of goods, work, services are provided, certified by the seal of the Project. 2. Copy of the procurement plan, certified by the seal of the Project. 3. Copy of the contract for the provision of services, certified by the signature and seal of the Project. The SAFEMed Project Accountant upon request can provide additional clarifications on the VAT exemption procedure.

V. Submission of proposals

To participate in the tender, kindly submit your proposal electronically to the following address: ua-safemed-procure@safemedua.org **by 6:00 pm on November 15, 2024.** The participant is responsible for the accuracy of the information provided in their tender proposal.

VI. Content of the proposal

Proposals submitted must be valid for consideration for at least 30 calendar days.

Proposals should be submitted by two separate PDF files in with the following information:

1. Technical Proposal.
2. Cost Proposal.

Proposals should be submitted both in English and Ukrainian.
Registration documentation does not require translation and should be submitted in the origin language.

Technical Proposal

Required copies of documents under the qualification requirements:

- Registration documents of a legal entity.
- Confirmation of compliance with qualification requirements (Appendix #1).

Full contact information of the offeror:

- Legal name, physical and legal addresses.
- VAT payer registration number, EDRPOU identification code.
- Contact details for explanations and clarifications.

Company's capacity and experience:

- Information on the successful implementation of similar IT projects (examples of Transfer and Acceptance Certificates, case studies, client testimonials).
- A concise executive summary outlining the proposed approach and how it addresses the scope of work.
- A detailed plan describing the methods and strategies to be employed, including a timeline of activities and a project schedule.
- Examples of comparative analyses previously conducted, particularly in regulatory or healthcare sectors.
- Documentation of project management credentials, such as PMP or PRINCE2 certifications.
- A proposed team structure for the project, including resumes of key team members and their roles.

Recommendations:

- If you have not provided services for MSH in the last 3 years, please provide contact information of 3 current/former customers for recommendations or reference letters;
- Information on cooperation with international technical assistance projects (USAID-funded or other donors' projects) and governmental institutions *(if available).*

Cost Proposal

Information on the total cost of services following the scope of work:

- Overall summary budget.
- Budget with detailed breakdown into stages of the project implementation.

Prices must be offered in Ukrainian Hryvnia (UAH) and should exclude Value Added Tax (VAT).

VII. Evaluation criteria

Technical and cost proposals will be evaluated according to the following criteria:

Evaluation criteria	Maximum possible points
Compliance with qualification requirements	
- Legal registration in Ukraine. - Minimum of 3 years' experience in developing and integrating complex IT systems, particularly in healthcare or regulatory environments. - Experience in conducting comparative analyses of IT infrastructures, preferably within the regulatory sector. - Extensive knowledge and experience in adapting IT systems to comply with national and international regulatory standards. - Proposal validity for 30 calendar days. - Acceptable payment terms (payment upon delivery in UAH excluding VAT within 10 bank days following the completion of each stage of the project implementation).	YES / NO If there is at least one "NO" answer, the tender offer will be rejected
A. Ability to Meet the Scope of Work	
Evaluate how well the proposed plan addresses all requirements in the scope of work, considering the clarity and effectiveness of the methodologies and strategies	**15**
B. Technical Expertise and Experience	
Bidder's relevant past performance and technical knowledge in similar projects, especially those involving IT systems in healthcare or regulatory environments	**30**
C. Project Management and Team Expertise	
Qualifications and experience of the proposed project team, examining the appropriateness of team structure and individual roles	**15**
D. Recommendations	
- Contact information of 3 current/former customers for recommendations or reference letters; - Information on cooperation with international technical assistance projects (USAID-funded or other donors' projects) and governmental institutions (if available).	**10**
E. Cost of services	
Costing realism and best value principle	**30**
Maximum Total Score	**100**

When conducting tenders/competitions, the SAFEMed Project, implemented in Ukraine by MSH, works on the principle of "value for money", so none of the criteria is preferable. All price proposals will be considered and evaluated according to a set of criteria.

A request for a commercial offer does not in any way oblige SAFEMed to enter into any contract. SAFEMed reserves the right to purchase any or all ordered services, change their number if necessary, or cancel them altogether. The intention to purchase a service/product is official only upon receipt of a written order from SAFEMed. SAFEMed will not reimburse the company for the preparation of the commercial offer.

SAFEMed Procurement staff are prohibited from making any requests or accepting commission offers related to the order placed; SAFEMed has a procedure for tracking such payments. Please do not offer or pay such commissions, as this may result in the rejection of your commercial offer. If any SAFEMed representative requests such payments, please notify auditcommittee@msh.org