

REQUEST FOR PROPOSALS (RFP)

DRAFTING OF CMU DECREE FOR ESTABLISHMENT OF REIMBURSEMENT MODEL IN UKRAINE

The goal of this solicitation is to obtain proposals in the framework of activities related to the development of draft mechanism (model) of reimbursement of essential medicines, as well as draft regulatory and legislative framework to create a holistic system of reimbursement of medicines in Ukraine.

In 2014-2015, fulfilling USAID mandate, *Systems for Improved Access to Pharmaceuticals and Services (SIAPS)* Program in Ukraine, implemented by Management Sciences for Health (MSH), developed a draft regulatory and legislative framework to establish an updated National Essential Medicines List (NEML), in line with modern requirements of European legislation. It is expected that the updated National Essential Medicines List will become the sole basis for public procurement in 2017 and the list will also serve as the basis for reimbursement for pharmaceuticals.

Some initial steps were taken to develop a medicines reimbursement system, at the end of 90s, when Cabinet of Ministers approved Decree N 1303 (On the Regulation of Free and Subsidized Sale of Drugs).

Subsequently, first attempts were made to establish the reimbursement mechanisms, through the introduction of two pilot projects involving anti-hypertensives (2012) and insulin (2015). However, the experiments were not perceived as a success by all stakeholders.

The implementation of the mechanism for reimbursement of medicines included in EML will constitute the basis for transparent processes of ensuring access to medicines, mitigate the scope for corruption, improve quality of care, and support cost-effective use of limited resources in Ukraine.

MSH invites you to submit an offer in accordance with the requirements of the following Solicitation. Proposals must be received by MSH no later than the Date and Time indicated in the table below.

Issue Date:	September 01, 2016
Due Date and Time for Written Questions:	September 12, 2016
Proposal Due Date and Time:	September 16, 2016
Written questions and Proposals should be submitted via email to:	uasiaps@msh.org

MSH, a global health nonprofit organization, uses proven approaches developed over 40 years to help leaders, health managers, and communities in developing nations build stronger health systems for greater health impact. Through strengthening capacity, investing in health systems innovation, building the evidence base, and advocating for sound public health policy, MSH is committed to making a lasting difference in global health. For more information visit: <http://www.msh.org/>

If any company or individual submitting an offer in response to this RFP is found to have offered anything of value to any member of MSH staff, they will be disqualified from participation in this procurement and may be disqualified for any future procurements with MSH. MSH staff are instructed not to request or accept anything of value from companies or individuals receiving RFQ's. If an MSH representative asks you for any kind of incentive payment or other gift please report it to the following email address: auditcommittee@msh.org

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I. SCOPE OF WORK

A. Scope

The purpose of the assignment is:

- I. Analysis of the existing legislation in the area of hypertension and diabetes drug reimbursement pilots;
- II. Analysis of international practices of drug reimbursement system implementation;
- III. Development of regulatory documents in the area of pharmaceutical market regulation and attending documents, consultations on the support and coordination of such documents in the central executive power authorities;
- IV. Participation in the sessions of Working Group on Drug Reimbursement Mechanism Implementation, meetings;
- V. Legal support of the EML Expert Committee and Ministry of Health of Ukraine (MoH) for official approval of the NEML.

Specific tasks to be performed:

#	Tasks	Timeline
I	Analysis of the existing legislation in the area of hypertension and diabetes drug reimbursement pilots	September
II	Analysis of international practices of drug reimbursement system implementation.	October 30
III	Development of drafts regulatory documents in the area of pharmaceutical market regulation and attending documents, consultations on the support and coordination of such documents in the central executive power authorities	March 19 -20
IV.	Legal support of Working Group on Drug Reimbursement Mechanism Implementation, meetings.	September November
V.	Legal support of the NEML EC and MoH during official approval of the NEML.	September 2016 – November 2016
VI	Legal support of the EML EC and MoH during the development of the NEML.	September 2016 June 2017

B. Deliverables to be developed:

Deliverables	Deadline
List of all current regulations on reimbursement which needed to be changed and updated agreed by all partners	September
Legal justification for using international reimbursement practices with taken into account current situation in Ukr. Legal framework. Roadmap of implementation suitable international practices on reimbursement in Ukraine	October 30
Drafts of next documents	November 30
1) Order of the Ministry of Health of Ukraine "On the Establishment of	September

Working Group on the Issue of Drug Reimbursement Implementation”; 2) Decree of the Cabinet of Ministers of Ukraine “On the Implementation of Drug Reimbursement Mechanism”, which would: <ul style="list-style-type: none"> • Set out the basic principles of mechanism implementation; • Approve the Procedure of Drug Reimbursement; • Approve the list of INNs and/or their combinations based on which drugs will be reimbursed; • Determine levels of drug reimbursement; • Amend Decree of the Cabinet of Ministers of Ukraine of August 17, 1998, N1303 “On the Regulation of Free of Charge and Reduced Price Dispensing of Drugs Based on Prescriptions for Ambulatory Treatment of Certain Groups of Patients with Selected Categories of Diseases”; • Amend Decree of the Cabinet of Ministers of Ukraine of October 17, 2008, N955 “On the Measures for Stabilization of Prices for Drugs and Medical Devices”; 	November
Draft decree with NEML is submitted for approval to the CMU	November 2016
Reports of EML EC submitted to MoH, officially published at the website of EML EC	September 2016 –June 2017

C. Contract Term/Period of Performance

The term of the contract issued as a result of this solicitation shall be September 18, 2016 – June 30, 2017.

D. Payment Terms

Payment terms for the contract issued as a result of this solicitation shall be 10 days payment on service delivery and signing of Acceptance Certificate. Payment to the selected offeror for services rendered shall be made via EFT to the bank account provided by the offeror. MSH is willing to consider any offerors proposed method of billing for services, including frequency of payments, provided that the proposed method does not include pre-payment for services not yet completed.

II. REQUIRED QUALIFICATIONS

In order to be selected for award the offeror must have the following qualifications:

The local legal firm with

1. More than 5 years of experience of working in health care and pharmacy legislation;
2. Experience in drafting Ukrainian legislation based on international best practices;
3. Evidence of previously drafted regulatory documentation currently in use in the health care sector;
4. Experience in the development of regulatory and legislative documents to reform healthcare system especially to Essential medicines selections;
5. High level of English language proficiency.

III. SUBMISSION INSTRUCTIONS

Due Date and Time for Written Questions:	September 12, 2016
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Proposal Due Date and Time:	September 16, 2016
Written questions and Proposals should be submitted via email to:	uasiaps@msh.org

A. Contents of Proposals

Offerors shall submit their proposals as two separate files. One shall be titled *Technical Proposal* and the other shall be titled *Cost Proposal*.

1. Technical Proposal

Offerors Technical Proposal shall include all of the following:

- a) Completed & signed Attachment A – Proposal Cover Sheet
- b) Statement indicating any objections to MSH's Standard Terms and Conditions of Supply viewable at www.msh.org/about-us/doing-business-with-us that would need to be settled in order for the offer to accept a contract from MSH.
- c) Name & contact information for at least 3 current or previous clients that can serve as references for the offeror.

Note: Failure to provide any of the information requested above will result in rejection of the proposal.

IV. EVALUATION OF OFFERS

A. General Information

MSH anticipates receiving at least one round of questions from potential vendors; however MSH reserves the right to award a contract without discussions.

Each offer submitted will be reviewed by an evaluation committee consisting of MSH employees in accordance with the criteria below and award will be made to the responsible vendor whose offer represents the best overall value to MSH.

B. Evaluation Criteria

Award will be made to the offeror whose proposal, conforming to the solicitation, is determined to offer the best value to MSH. Offers will be evaluated as follows:

1. Ability to meet the Scope of Work
2. Possession of all "Required Qualifications" listed above
3. Price
4. Past performance/references

Factors are listed in order of importance.

C. Determination of the Competitive Range and Contract Award

If MSH determines that discussions are necessary, a Competitive Range will be established which is composed of only the most highly rated offers. MSH may exclude an offer if it is so deficient as to essentially require a new proposal. Should a competitive range be established, MSH may invite those in

the competitive range to present their offers to the evaluation team. Should oral presentations occur, they will be evaluated as part of the offer.

D. Non-Profit Pricing

MSH is a registered 501(c)(3) non-profit corporation. Offerors should provide any and all discounts available to MSH based on its status as a U.S. Government contractor and as a non-profit.

E. Acceptance of Offer and Award

This RFP is non-binding and in no way obligates MSH to award any contract. MSH reserves the right to make an award in whole or in part, or not to make an award, in accordance with the best interests of MSH. Firm commitment to purchase is not established until a written order/contract is issued by MSH.

F. Cost of Proposal Preparation

The cost of the proposal preparation in response to this solicitation shall be solely the responsibility of the Offeror.

G. Validity of Offers

Offers submitted in response to this solicitation shall be valid for at least 90 days from date of submission. Prices quoted by the offeror and subsequently incorporated in contract resulting from this solicitation shall be valid for the full period of performance.

V. ATTACHMENT A - PROPOSAL COVER SHEET

Vendor's full legal name			
Headquarters address			
Location(s) of any additional offices			
Website address			
Vendor's Ownership			
Length of time in business			
Contact information for individual who will serve as MSH's single point of contact for the duration of the RFP Process	Name:		
	Phone:		
	Email:		
<p><u>By signing below, I certify that:</u></p> <p>A. I am authorized to respond to this solicitation on behalf of the Company named above.</p> <p>B. I have reviewed MSH's Standard Terms and Conditions of Supply viewable at www.msh.org/about-us/doing-business-with-us and understand that these terms shall govern any contract, unless otherwise negotiated with MSH and agreed to in writing.</p> <p>C. I understand that MSH retains the right to reject, in whole or in part, any and all bids for any reason, or no reason.</p> <p>D. I have not, and will not, offered anything of value to any member of MSH staff & understand that if my company is found to have offered anything of value to any member of MSH staff, they will be disqualified from participation in this procurement and may be disqualified for any future procurements with MSH.</p>			
PRINTED NAME:			
SIGNATURE:		DATE:	