

Str. Cristian Popişteanu 1-3,etaj 2, cam. 235-236 Tel: 021.3072589/590/686; Fax: 021.3072587

Reg. no. 2043/13.05.2022

REQUEST FOR EXPRESSIONS OF INTEREST CONSULTANCY SERVICES

ROMÂNIA MINISTRY OF HEALTH Health Sector Reform Improving Health System Quality and Efficiency Project Loan no. 8362 – RO

Reference no.: CS/B/51-2

Assignment title: Technical Assistance to Support the Health Technology Assessment Development and Implementation in Romania

Romania has received a loan from the International Bank for Reconstruction and Development (IBRD) to support the implementation of the Health Sector Reform. The Ministry of Health (MoH) through the Project Management Unit (PMU) is implementing the Health Sector Reform - Improving Health System Quality and Efficiency Project ("Project"), Project no. 8362 – RO. The Romania Health Sector Reform Project (the Project) was approved on March 28th, 2014, ratified by Law no. 179 on December 16, 2014, with subsequent amendments. The project amount is EUR 250.00 million and the closing date is December 31st, 2024.

The objective of the Project is to contribute to improving access to and quality of selected public health services.

The Project support the comprehensive reforms in the Health Sector on medium and long term, focusing on four main areas/components:

Part A: Strengthening Health Service Delivery;

Part B: Public Health Sector Governance and Stewardship Improvement;

Part C: Project Management, Monitoring and Evaluation

Part D: Strengthening of Public Health Emergency Response to COVID -19.

Part B of the Project aims to support the improvement of the sector governance and stewardship of the MoH and other relevant governmental institutions to bridge the gap between policy and practice and to strengthen the capacity of improving the quality of medical care services.

Ministry of Health, through Project Management Unit intends to apply a part of the proceeds for consulting services in order to provide *Technical Assistance to Support the Health Technology Assessment Development and Implementation in Romania*



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within Part B of the Project – "Public Health Sector Governance and Stewardship Improvement".

The purpose of this consultancy services is to support Romanian relevant authorities – MoH, NAMMD, NHIH and the MoH-established HTA Taskforce – to revise the existing HTA methodology for medicines, taking into consideration the existing institutional setup, capacity and data availability, as well as to the recommendations from the "Technical Assistance for institution building of Health Technology Assessment structure". The revised HTA methodology should: (i) be an improvement compared to the current regulations and practice, by considering cost-effectiveness in the local context, and (ii) be in keeping with the long-term objective of a fully institutionalized HTA process resembling European Union and international best practices. Also, the Consultant will assist NAMMD in assessing 40 to 50 INNs based upon the updated improved HTA methodology and using the current institutional capacity, expertise and data availability.

The consultant will undertake the following tasks: 1). analyze the current HTA methodology and its output, as well as the deliverables within the "Technical Assistance for institution building of Health Technology Assessment structure"; 2). develop an updated HTA methodology ready for implementation that considers costeffectiveness in the local context; 3), assist MoH, NAMMD and NHIH in developing the draft regulation on the updated HTA methodology; 4), attend technical internal meetings and public consultations with the stakeholders on the situational analysis and the draft regulation on the updated HTA methodology; 5), assist MoH, NAMMD and NHIH in the finalization of draft regulation on the updated HTA methodology based on consultations with stakeholders; 6), provide hands-on technical support to National Agency for Medicines and Medical Devices in assessing a number of between 40 and 50 INNs by using the updated HTA methodology. The 40 to 50 INNs refer to INNs or indications newly submitted for reimbursement as well as to the most expensive INNs currently reimbursed unconditionally from the National Health Insurance Fund, based on the criteria set out in the updated improved HTA methodology. By most expensive, it is understood INNs with the highest total value reimbursed by the National Health Insurance Fund in the last calendar year.

Ministry of Health, through Project Management Unit, now invites eligible companies to indicate their interest in providing the Services. Interested Consultants should provide information demonstrating that they have the required qualifications and relevant experience to perform the Services. A Consultant will be selected in accordance with the provisions of *CQS – Selection Based on Consultants Qualification* method set out in the Consultant Guidelines.

The attention of interested Consultants is drawn to paragraph 1.11, 1.12 şi 1.13 regarding the Eligibility from Guidelines Selection and Employment of Consultants under IBRD Loans and IDA Credits & Grants by World Bank Borrowers, January 2011.



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According to para 1.13 (b) The Consultants which are Government-owned enterprises or institutions of the Borrower's country may participate in the Borrower's country only if they can establish that they (i) are legally and financially autonomous, (ii) operate under commercial law, and (iii) are not dependent agencies of the Borrower or Sub-Borrower2. Exceptions from the provisions 1.13 (b) are the cases detailed in para 1.13 (c).

The attention of interested Consultants is drawn to paragraph 1.9. of the World Bank's Guidelines: Selection and Employment of Consultants under IBRD Loans and IDA Credits & Grants by World Bank Borrowers, January 2011 ("Consultant Guidelines") setting forth the World Bank's policy on Conflict of Interest.

The Expression of Interest must contain detailed information regarding the address, contact person, number and country of registration and information regarding the Consultant's Profile as it is described within the Terms of References for Consulting services *Technical Assistance to Support the Health Technology Assessment Development and Implementation in Romania*, as follows:

General qualifications - 30 points

Consultants shall provide information on: core business and years in business, presentation of services provided which are relevant for this assignment, references;

- Specific experience - 40 points

Consultants shall provide relevant information and a presentation of the similar projects/assignments implemented by the Consultant, that are similar to this assignment, considering the specificity of the present assignment: at least 5 years of general experience in research/studies in the areas of health technology assessment (HTA) of pharmaceuticals defined as developing, regulating and implementing HTA.

Availability of appropriate skills among staff - 30 points

Consultants shall provide relevant information regarding the availability of appropriate skills among their staff, as requested in the ToRs. Consultants shall provide relevant information regarding their Human Resources capacity, in terms of number of employed experts and/or freelance collaboration experts and their relevant skills, as necessary for implementing the requested services. Consultants may associate to enhance their qualifications.

The "association" may take the form of a Joint Venture and/or a sub-consultancy. In case of a Joint-Venture (JV), all members of the JV will be evaluated jointly for the purpose of short listing and shall be jointly and severally liable for the assignment and shall sign the contract in case of award is made to that JV group. Interested consultants should clearly indicate the structure of their "association" and the duties of the members and sub consultants in their application. Please note that a firm shall submit



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only one Expression of Interest in the same selection process either individually as a consultant or as a member in a joint venture.

A short-list will be prepared in accordance with the provisions of paragraphs 2.6, 2.7 and 2.8 of the World Bank's Guidelines: Selection and Employment of Consultants under IBRD Loans and IDA Credits & Grants] by World Bank Borrowers, January 2011 ("Consultant Guidelines"). Only the selected firm shall be asked to submit a combined technical and financial proposal and, if such proposal is responsive and acceptable, be invited to negotiate a contract in accordance with the provisions of paragraphs 3.7 of the World Bank's Guidelines: Selection and Employment of Consultants [under IBRD Loans and IDA Credits & Grants] by World Bank Borrowers, January 2011 ("Consultant Guidelines").

Expressions of Interest must be submitted in English to the address below by **31.05.2022,15:30**, **Bucharest local time**. Also, the Expressions of Interest may be submitted by e-mail.

Further information can be obtained at the address below during office hours Monday – Thursday from 8:30 to 17:00 hours and Friday from 08:30 – 14:30 hours.

Ministry of Health

Project Management Unit

Attn: Mr. Mihai Monoranu, Head of PMU, Anna – Maria Mareş, procurement consultant Str. Intrarea Cristian Popișteanu, nr. 1-3, etaj 2, camera 236, sector 1,010024, Bucuresti

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