**ROMANIA**

**HEALTH SECTOR REFORM - IMPROVING HEALTH SYSTEM QUALITY AND EFFICIENCY PROJECT**

**IBRD LOAN NO. 8362RO**

**TERMS OF REFERENCE**

**Technical Assistance to Support the Health Technology Assessment Development and Implementation in Romania**

## A. BACKGROUND

**International Experience**. All health systems face the challenge of managing and allocating finite resources to address an unlimited demand for healthcare services. Therefore, resource allocation decision-making is a complex process that takes place along a continuum that moves from evidence generation to deliberation and communication of the decision made. Health Technology Assessment (HTA) examines the consequences of the application of health technologies and is closely related to evidence-based medicine (EBM). However, HTA is only a part of a broader ecosystem to set explicit priorities in a more systematic fashion. Both HTA and EBM are aimed at better informing decision makers.

Over the past decades, different taxation-based and social health insurance systems have established their own HTA organizations aimed at better informing healthcare policies and clinical practice. According to the International Network of Agencies for Health Technology Assessment (INAHTA), there are more than 55 HTA agencies in over 35 countries serving this purpose. Yet in Central and Eastern European countries, few have institutionalized it or have a clear roadmap for HTA implementation despite the need for rational priority setting.

There is no "one size fit all" approach to HTA implementation, as institutional arrangements can take the form of committees, collegiate bodies, technical units or independent bodies (agencies), their role can also vary considerably according to the context and need. For instance, some HTA agencies draw upon principles of comparative safety and efficacy/effectiveness while others use economic analyses of drugs, medical devices, and procedures to inform coverage, reimbursement, procurement, quality, and more recently, pricing decisions. Therefore, there is a need to consider key procedural principles for their robust operation while bearing in mind the local context in which they will operate.

**Romanian experience with HTA.** Romania has already made steps towards institutionalization of HTA in recent years by issuing regulations and establishing an HTA unit within the National Agency for Medicines & Medical Devices (NAMMD). Also, an HTA methodology applicable to drugs only has been developed and implemented since 2014, with amendments in the subsequent years. As a result of the methodology's application, around 200 new International Nonproprietary Names (INNs) or new indications have been included on the positive list of drugs covered by public funds ("reimbursement formulary") throughout 2014-2020, of which 56 were subject to Managed Entry Agreements (MEAs).

In 2017-2018, a comprehensive analysis of the HTA practices and infrastructure was carried out as part of a technical assistance project for "Institution building of Health Technology Assessment structure, including training for the National Agency for Medicines & Medical Devices", funded through Health Sector Reform - Improving Health System Quality and Efficiency Project (IBRD 8362 RO).

The existing HTA methodology does not take into account the local environment. Instead, it consists of a simplified approach based on a scorecard that records the clinical/economic evaluation results of the

submitted health technology in other EU countries, notably France, Germany and the United Kingdom. The scorecard is completed with a minimum budget impact analysis. Selected therapeutic areas and drug categories are subject to favorable criteria, e. g. all orphan drugs, drugs for rare disease without a currently reimbursed therapeutic alternative and HIV/ TB drugs, which results in a high rate of intake of these drugs to the positive list of drugs covered by public funds.

Key findings of the situational analysis were the following:

- The current application of HTA within the NAMMD, using a simplified scorecard approach, is not facilitating skill development or promoting the application of rigorous methods. Moreover, appraisals are developed without consideration for the decision problem and opportunity costs.
- Institutional experience has been limited to scoring HTA dossiers submitted for reimbursement by Market Authorization Holders (MAHs). No rigorous clinical and/ or economic evaluation has been conducted by the Agency or any other governmental stakeholder, even as a pilot project or a test. In addition, the institutional arrangement for HTA is fragmented: the medicine prices are set prior to HTA by the Ministry of Health, the assessment is carried out by the NAMMD with limited involvement from MoH and other health practitioners, the drafting of prescription guidelines is split between NAMMD and MoH specialty committees. The National Health Insurance House (NHIH), which is the single payer in the social health insurance system, is not involved at any stage in the reimbursement decision-making.
- Above all, Romania has limited availability of local expertise and data to inform HTA processes both in the governmental and non-governmental sectors. There are few educational programs on HTA, which have been delivered to a limited number of beneficiaries, while data on resource utilization, epidemiology, and treatment patterns is either fragmented, inadequate or unavailable.

In addition, a set of plans and templates were developed with the objective of establishing a full-HTA system in Romania over 5 years, which was informed by international best practice. The deliverables covered *inter alia*: (i) new HTA methods, including for non-drug technologies, (ii) capacity building plans; (iii) detailed institutional arrangements; (iv) an action plan for 2019-23; and (v) a draft reference case for medicines and vaccines.

## B. SCOPE OF WORK

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.

## C. MAIN TASKS AND RESPONSIBILITIES

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 cost-effectiveness 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.

## D. EXPECTED DELIVERABLES

The following results are expected:

1. an assessment of the current HTA methodology and its output, together with an evaluation of the applicability in the short and medium term of the recommendations provided in the deliverables of the project *"Technical Assistance for institution building of Health Technology Assessment structure"*;
2. detailed proposals for updating the HTA methodology that consider cost-effectiveness in the local context, as well as the local institutional capacity, expertise and data availability;
3. draft regulation on the HTA methodology;
4. summary of feedback and proposals received during internal technical meetings and public consultations with regards to the deliverables from tasks 1 to 3;
5. final draft of an MoH order regarding the update of the HTA methodology;
6. HTA reports on 40 to 50 INNs based upon the updated HTA methodology.

## E. REPORTING REQUIREMENTS AND DELIVERIES

The Consultant shall submit reports to the Minister of Health/State Secretary, the head of the Project Management Unit (PMU) for the Health Sector Reform Project, the head of Pharmaceutical Policy Department within the Ministry of Health and the Chairman of the National Agency for Medicines & Medical Devices.

The consultant shall deliver inception, progress and final reports to be approved by the Ministry of Health and the National Agency for Medicines & Medical Devices in order to ensure achievement of the objectives set forth, as follows:

- inception report will be submitted within 6 weeks from the date of commencement of the services and will be related to task no. 1 mentioned in the section "Main Tasks & Responsibilities";
- progress report no. 2 will be submitted within 20 weeks from the date of commencement of the services and will be related to task no. 2;
- progress report no. 3 will be submitted within 30 weeks from the date of commencement of the services and will be related to tasks no. 3, 4 and 5;
- progress report no. 5 will be submitted within 70 weeks from the date of commencement of the services and will be related to task no. 6;
- Final report will be submitted in the last week before contract completion and will include a description of tasks performed and the overview of the project results.

All the progress reports will include (among others) a section on the progress made so far, will update the working plan and the methodology for fulfilment of tasks, will identify any aspects and solutions for obtaining a successful result for this consultancy.

The Consultant will submit for review and comments the reports in a draft form. MoH, National Agency for Medicines & Medical Devices and PMU will provide feedback and comments within five (5) working days and the Consultant must submit back the final versions of the reports in a maximum 3 working days. The standard form of the final report and the chapters to be included will be agreed with MoH, NAMMD and PMU representatives.

All deliverables must be submitted in English and in electronic format, using the Microsoft Office products (Word, Excel, Power Point and Access). The data files and the data analysis procedures should be presented in an electronic format agreed by the Ministry of Health, the National Agency for Medicines and Medical Devices and the Consultant.

All deliverables shall be the exclusive property of the Client and may not be used by the Consultants without the Client's exclusive written consent.

## F. ESTIMATED EFFORT LEVEL

The estimated duration of the assignment is 70 weeks, to commence within one week from the date of contract signing.

| Crt. No | Task | Indicative duration |
|---|---|---|
| 1 | Task 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"* | 6 weeks |
| 2 | Task 2 - Develop an updated HTA methodology ready for implementation, that considers cost-effectiveness in the local context | 14 weeks |
| 3 | Task 3 - Assist MoH, NAMMD and NHIH in developing the draft regulation on the updated HTA methodology | 6 weeks |
| 4 | Task 4 - Attend technical internal meetings and public consultations with the stakeholders on the situational analysis and the draft regulation on the updated HTA methodology | |

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| 5 | Task 5 - Assist MoH, NAMMD and NHIH in the finalization of draft regulation on the updated HTA methodology based on consultations with stakeholders | 4 weeks |
| 6 | Task 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 newly updated HTA methodology | 40 weeks |

**G. CONSULTANT'S QUALIFICATION REQUIREMENTS**

The assignment should be carried out by a qualified firm with in-depth experience in health technology assessment (HTA) of pharmaceuticals defined as developing, regulating and implementing HTA at European level. The Consultant will provide a Consulting Team (Consultant), formed out of a Team – Leader and at least 2 key - experts.

The estimated cumulated number of working days of the Consultant is 170 working days, out of which at least 50 working days will be worked at the headquarters of NAMMD. This requirement is subject to variations in the epidemiological situation and travel restrictions.

The Consultant's team members shall meet the following requirements:

Team Leader

- graduate degree in health economics or another discipline that is relevant to HTA. A PhD is an advantage;
- at least 7 years' experience in health technology assessment of pharmaceuticals;
- proven experience in coordination of experts' teams in research/projects etc;
- proven track record of developing/regulating/implementing health technology assessment systems at European level;
- experience in Central and Eastern European Countries is an advantage;
- knowledge/experience on European Commission work on strengthening EU cooperation on HTA (financed projects, studies, regulations) is an advantage;
- excellent written and oral communication skills in English language.

Key-experts

- graduate degree in health economics, biostatistics or another discipline that is relevant to HTA. A PhD is an advantage;
- at least 3 years' experience in health technology assessment of pharmaceuticals;
- proven track record of developing/regulating/implementing health technology assessment[1] systems at European level;
- experience in Central and Eastern European Countries is an advantage;
- particularly knowledge in the Romanian health technology assessment system is a plus;
- excellent written and oral communication skills in English language.

[1] *The Consultant must propose a team of experts whose proven cumulated experience covers these requirements (developing, regulating and implementing HTA at European level)*

## H. INSTITUTIONAL ARRANGEMENTS, DATA, LOCAL SERVICES AND FACILITIES TO BE PROVIDED BY THE CLIENT

The Consultant shall have a participatory approach, constantly working in close collaboration with the Ministry of Health, National Agency for Medicines and Medical Devices.

The Consultant will liaise with MoH and NAMMD, which in turn will communicate with other stakeholder.

The Client shall provide the Consultant will all the relevant documents (laws, regulations, reports), shall ensure access to the data required and shall contribute to the coordination of all the factors involved.

Meetings with institutions, organizations and relevant natural persons will be established.

The consultant will work remotely and at the headquarters of the National Agency for Medicines and Medical Devices, as agreed with the NAMMD.

The Consultant shall have the responsibility to organize translation/ transport/ accommodation activities. The PMU shall provide, to the extent possible, suggestions and references for organizing logistic assistance. The Consultant shall bring his/her own computer and the necessary equipment for the accomplishment of the work.

**Special requirement: confidentiality and absence of conflict of interests under the consultancy contract.**