REPUBLIC OF TURKEY

HEALTH SYSTEM STRENGTHENING AND SUPPORT PROJECT (HSSSP)

 (LN: 8531-TR)

4th SUBJECT-ORIENTED HEALTH TECHNOLOGY ASSESSMENT (HTA) STUDY – (HTA Study on Rheumatoid Arthritis)

TERMS OF REFERENCE

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| **Project Component/Part:** | Part III: Improving the Effectiveness of Overall Health Sector Administration |
| **Project Sub-component/part:** | C |
| **Procurement Plan No:** | SAGEM/2016/CS/E.6.1.2.2.a.4/CQS/1 |
| **Job/Assignment Title:** | 4th Subject-Oriented Health Technology Assessment Study – (HTA Study on Rheumatoid Arthritis) |
| **Job/Assignment Objectives:** | To analyze and assess all aspects of the subject of "Rheumatoid Arthritis" using the Health Technology Assessment method and to produce Health Technology Assessment full reports |
| **Job/Assignment Duration:** | 18 months |
| **Procurement/Consultancy Type:** | Consulting Services - Consulting Firm |
| **Procurement/Selection Method:** | Selection Based on the Consultants' Qualifications (CQS) |
| **Prior Review:** Yes/No | Yes  |
| **Reporting to (Implementing Agency):** | General Directorate of Health Research (GDHR) |

# BACKGROUND

The Republic of Turkey has applied for financing in the amount of US$ 134.3 million equivalent (EUR 120.00 million) from the World Bank toward the cost of the Health System Strengthening and Support Project (HSSSP). Part of the proceeds will be applied to payments for goods, works, related services and consulting services to be procured under this project.

 The Project consists of the following parts:

 Ø Part I: Primary and Secondary Prevention

Ø Part II: Increasing Efficiency of Public Hospital Management

Ø Part III: Improving the Effectiveness of Overall Health Sector Administration

Part I: Primary and Secondary Prevention

 Raising awareness (both of the population in general and among health care providers) on risk factors related to Non-Communicable Diseases (NCDs) and promoting healthy life styles and behavior changes, through the following activities:

(A) (i) Developing public outreach materials, methodologies and targeting to raise population awareness about NCDs and the importance of healthy living; (ii) promoting physical activity in Healthy Living Centers, including rehabilitating community health centers to reconfigure for physical activity; and (iii) implementing a nationwide campaign on substance addiction and strengthening the infrastructure of the treatment and research centers for adults and children suffering from alcoholism and substance addiction.

(B) (i) Improving the capacity of post-screening diagnosis centers; (ii) introducing and maintaining national cancer registry software and provision of training to health workers on said software; and (iii) developing guidelines, standards and training modules for palliative care.

(C) (i) Strengthening the Family Physician Training Program, including through expanding the infrastructure and hardware of the distance learning system to nationwide coverage; (ii) improving service delivery and quality of care by family physicians through the analysis of current workload practices and procedures.

Part II: Increasing Efficiency of Public Hospital Management

(A) Strengthening public hospital management and clinical operations in: (i) clinical engineering; (ii) drug and medical supply management; (iii) clinical care processes; and (iv) administrative and financial information systems, by (a) providing training to public hospital staff; (b) developing national guidelines and classifications; (c) supporting public hospital teams to implement guidelines and standards; and (d) strengthening information systems.

(B) Developing and implementing architectural and technical standards for health facilities; and

(C) Strengthening the capacity of the General Directorate of Health Investments in managing public-private partnership ("PPP") contracts and administering PPP investments in engagement with the relevant stakeholders, including the Undersecretariat of Treasury and the Ministry of Development, and in developing in-house capacity in legal, financial, operational, and structural aspects of contract management.

Part III: Improving the Effectiveness of Overall Health Sector Administration

(A) (i) Institutionalizing health sector performance assessments and harmonizing health sector data; (ii) developing and adopting national e-health standards and reviewing applicable legislation to improve quality of health data; (iii) developing and implementing a health management information system; and (iv) enhancing the technical audit capacity of the Ministry of Health and widening the use of evidence-based medical practice to improve the quality of health services.

(B) (i) Developing a model for raising awareness about the Borrower's health sector; and (ii) developing pre-hospital trauma care systems for disasters.

(C) Strengthening capacity for the health technology assessment.

(D) Supporting the Project Management and Support Unit in project implementation, including in the areas of financial management, procurement, disbursement, and monitoring and evaluation.

Under the HSSSP, a "Project for Strengthening, Roll-out and Sustainability of Health Technology Assessment (HTA) Capacity" is prepared by the GDHR within the framework of sub-component C of Part III titled “Improving the Effectiveness of Overall Health Sector Administration”, which consists of the works and operations for “Strengthening capacity for the health technology assessment".

The aim of the project is to prepare an HTA strategy document for the development and sustainability of evidence-based health policies and health practices and to roll out HTA-based activities within this scope. The Project consists of development, roll-out and sustainability work packages.

Health Technology Assessment (HTA) is a commonly used method which assesses, rationally, the safety, clinical effectiveness and social aspects as well as cost-effectiveness of such health technologies as drugs, medical devices and surgical interventions in developed countries. Health technology refers to all sorts of practices -notably drugs, medical devices, surgical methods and health systems- that are used for health protection and promotion, and disease prevention, diagnosis and treatment. Health Technology Assessment (HTA) refers to systematic review and interpretation of health technology in terms of its general characteristics, reliability, effectiveness and efficiency, economic aspects and cost, and social and ethical aspects. The primary aim of HTA is to inform the policy-makers after the health technology assessment is completed. The policy-makers reach a decision, in line with national and international standards, by assessing the report submitted by the research group from different perspectives such as patients, health specialist, academic circles and technology producers. HTA covers not only direct and intentional results but also indirect and unintended results of the technologies.

During the restructuring of the Ministry of Health, Article 12 of the Statutory Law No. 663 included HTA works and operations in the duties of the General Directorate of Health Researches (GDHR). In this context, a Department of Health Technology Assessment was established so as to perform HTA works and operations within the organizational structure of the GDHR. And, HTA works were initiated after HTA Regulation and Policy Declaration was published and it was decided how the HTA process would be managed and what the main principles would be. HTA works were carried out about 6 (six) subjects until 2016. In this scope, an HTA project/study will be implemented to analyze and assess all aspects of the subject of "Rheumatoid Arthritis" using the HTA method and to produce a full-report.

Rheumatoid arthritis (RA) is the most common type of inflammatory joint diseases. It begins with the inflammation of a tissue named "synovium" which lines the inner surface of joints and it may cause damages in cartilage, bones, tendons and ligaments. In addition to the joints, the disease which deteriorates gradually may also have an influence on the internal organs. It generally involves multiple joints; and it is a long-lasting (chronic) disease but one may also observe long-lasting silent periods between the attacks. This disease with an unknown origin differs greatly from one person to another. It is mostly seen in young/middle-aged adults, and it is 3 times more common in females than males. Research shows that an annual amount of 8 to 10 billion Turkish Liras is spent on rheumatic diseases in Turkey. It is of importance to carry out a Health Technology Assessment study on RA in order to determine the most effective treatment option(s) and to make a contribution to the sustainability of resources allocated to healthcare services by reducing the financial loss to the minimum level possible.

# DEFINITIONS

1. Administration: Department of Health Technology Assessment within the General Directorate of Health Research
2. PICO: An approach employed in a health-related survey to formulate questions that can be answered in 4 parts as follows:

1.‘P’ Patient/Problem: How would you describe a patient group with a similar problem?

2. ‘I’ Intervention: What examination, intervention or treatment would you plan?

3. ‘C’ Comparison: What is the most significant alternative of the intervention you plan?

4. ‘O’ Outcome: What do you seek as an outcome?

1. HTA Full-Reporting: Reporting of the questions in the Assessment Element Tables for HTA Core Model for Medical and Surgical Interventions in 9 topics (below) by applying HTA method:

1. Health Problem and Current Use of Technology

2. Description and Technical Characteristics of Technology

3. Safety

4. Clinical Effectiveness

5. Costs and Economic Evaluation

6. Ethical Analysis

7. Organizational Aspects

8. Social Aspects

9. Legal Aspects

1. Contractor/Consultant: The firm determined as a result of the consultancy service procurement tender.

# OBJECTIVE

The objective is to analyze and assess all aspects of the subject of "Rheumatoid Arthritis" using the HTA method and to produce a full-report. This study aims to develop evidence-based health policies and health practices and ensure their sustainability, and to create a scientific and objective information source for decision-makers.

# SCOPE OF WORK

The contractor/consultant is expected to perform the following roles and duties within the scope of the work subject to tender: The contractor/consultant will submit a work plan and a work schedule to the Administration no later than 5 days following the contract signing. The contractor/consultant will execute the project according to the work plan and the work schedule both of which are approved by the Administration and will remain in force unless they are revised by a mutual written agreement of the parties:

1. The HTA full-report which will be produced by studying the subject of Rheumatoid Arthritis using the HTA method and its annexes (reports for the executive and the patients' relatives) will be prepared in Turkish and English.
2. If considered appropriate as a result of necessary research, this study may also be carried out as an "Adaptation" study. In this case, the study will stick to the scope above and, again, the reports will be prepared in Turkish and English.
3. The contractor/consultant will create a study group, which consists of 3 editors and 9 authors, in agreement with the Administration, including those who have expertise and competency in their fields from all disciplines required for report sections based on 9 topics (Health Problem and Current Use of Technology, Description and Technical Characteristics of Technology, Safety, Clinical Effectiveness, Costs and Economic Evaluation, Ethical Analysis, Organizational Aspects, Social Aspects, Legal Aspects) specified in the Project for HTA full report study. If a member of key personnel leaves for any reason during the execution of the work, the contractor/consultant will employ someone with the same or better qualifications on condition that it is approved by the Administration in advance.

**3. Preparation**

The contractor will review the literature to formulate policy question and PICO at the preparation stage. The contractor together with the Administration will arrange a meeting which will be held to determine the policy question and PICO no later than 2 months following the contract effectiveness.

## 4. Literature Review and Article Evaluation

It includes subject-based literature review, systematic evaluation, meta-analysis and article evaluation in line with international criteria, all of which are carried out by a study group of at least 3 people who may consist of authors and editors and will work individually with the same key words on the subject of "Rheumatoid Arthritis". The databases specified in the HTA Directive at http://www.hta.gov.tr/pdf/STD\_HTA\_Yonerge.pdf will also be taken into account during the selection of databases for literature review. The articles that will be used in the study will be submitted to the Administration in digital environment after the literature review is completed.

**5.** The whole methodology used in the project will be described in detail in the relevant sections of the report. All data collected within the scope of the study will be delivered to the Administration after the study is completed.

## 6. Preparation of Draft Section Texts by Study Groups

Following the literature review, the authors who are responsible for 9 topics included in HTA full report will share the questions in the Assessment Element Tables for HTA Core Model Application for Medical and Surgical Interventions (3.0) and then, draft texts will be prepared based on the answers to those questions.

## 6. Joining Section Texts and Submitting Draft HTA Report

The draft texts for each topic will be submitted to the editors by the authors.The editors will review and edit the texts so that the topics can be consistent with each other, and after necessary corrections are made in terms of spelling, grammar and terminology, the Draft HTA Report will be submitted to the Administration.

## 7. Submitting Final Reports

The Final HTA Report and its annexes will be delivered after prepared as in Section F hereof.

# RESPONSIBILITIES AND QUALIFICATIONS OF KEY PERSONNEL

The Consultant will work in close cooperation with a Project Coordinator who will be assigned by the Administration, fulfill the roles and responsibilities stated in Section F hereof to produce an HTA full report by studying the subject of "Rheumatoid Arthritis" using the HTA full-reporting method and supply the below-stated key personnel. The Contractor will submit Non-Disclosure Agreements and Conflict-of-Interest Statements to the Administration as attachment to the Initial Report after signed by all personnel employed within the scope of work. The same documents will be delivered to the Administration for each new personnel no later than 1 (one) week before the relevant personnel begin to work.

1. **Project Executer (1 person):** She/he will design the duties of all study group members who will work in the Project in agreement with the Administration and ensure coordination among the study group members.
2. Minimum Qualifications:
	1. Holding a Master's Degree at a minimum,
	2. Minimum 5 (five) years of professional experience in public or private sector,
	3. Having participated in at least one study as a project officer or executer in the field of Health Technology Assessment, health economy, pharmacoeconomy, health-related economic analyses or cost-effectiveness analyses.
3. Responsibilities:
4. She/he will be accountable to the Administration for the execution of the work.
5. She/he will ensure coordination between the study group members and the Administration and among the study group members.

**2. Author (5 people):** She/he will be responsible for writing texts for the sections of HTA reports, which will be delivered to the Administration at the end of the study, in a period and in a way projected, planned and requested in the Terms of Reference and other relevant documents.

1. The project will include five (5) authors in total;
	1. 1 (one) for the first (Health Problem and Current Use of Technology) and the second (Description and Technical Characteristics of Technology) topics,
	2. 1 (one) for the third (Safety) and the fourth (Clinical Effectiveness) topics,
	3. 1 (one) for the fifth topic (Costs and Economic Evaluation),
	4. 1 (one) for the sixth (Ethical Analysis) and the ninth (Legal Aspects) topics,
	5. And, 1 (one) for the seventh (Organizational Aspects) and the eighth (Social Aspects) topics.
2. Minimum Qualifications: The authors shall hold a doctoral degree -the medical doctors shall be a specialist doctor- in one of the disciplines (medicine, nursing, sociology, psychology, health administration, social services, economics, health economy, law, engineering, biomedical engineering, etc.) related to the topic for which they are responsible.
3. Responsibilities: She/he will be responsible for preparing draft and final HTA full-report texts related to the topic that they are in charge of, in line with HTA study principles.

**3. Editor (3 people):** She/he will be responsible for editing the HTA report texts which are written in a period and in a way projected, planned and requested in the Terms of Reference and other relevant documents and for ensuring that these texts constitute a meaningful whole at the end of the study.

* 1. Of the 3 editors;
* 1 (one) will be responsible for health problem, current use of technology, description and technical characteristics of technology, clinical effectiveness, and safety,
* 1 (one) for economic analysis and costs, and
* 1 (one) for ethics, legal aspects, organizational aspects and social aspects.
	1. Minimum Qualifications
1. Holding, at a minimum, an associate professorship title in one of the disciplines (medicine, nursing, sociology, psychology, health administration, social services, economics, health economy, ethics law, engineering, biomedical engineering, etc.) for which she/he is an editor under the project.
	1. Responsibilities
2. To ensure that the draft section texts are consistent with each other and to join these texts during the reporting process,
3. To ensure the integrity of the report at the draft report and final report stage,
4. To ensure that the report texts in Turkish and English are written in plain, clear and scientific language by exercising due diligence in spelling rules and to make necessary editing changes.
5. **Project Coordinator:** She/he will be the personnel of the HTA Department of the GDHR who works on behalf of the Administration in this study. She/he will ensure communication and coordination with the representatives of the contractor firm, other key personnel and other relevant people, institutions and organization within the framework of the relevant legislation and documents.

# REPORTING LIABILITIES OF THE CONSULTANT

During the term of the contract, the Contractor will prepare and submit the following reports to the Administration:

### The reports that the Contractor will submit to the Administration are: (i) initial report, (ii) progress report, (iii) Draft HTA Full Report and Final HTA Full Report.

### *Initial report:* It will be submitted to the Administration in two months after the contract is signed. This report shall include policy questions, information on PICO, key words to be used while reviewing the literature, confidentiality agreements and conflict-of-interest statement. If there is any critical problem that might affect the work progress, it shall be presented to the attention of the Administration. This report will be submitted to the Administration electronically and in 2 (two) printed copies.

### *1.2. Progress Reports*: They will be submitted in the 5th, 10th and 15th months of the project. The progress reports aim at informing the Administration on the progress of the work.

### (i) The first progress report: the report that will be submitted in the 5th month will include detailed information on the strategies of literature review and article evaluations. If literature review and article evaluations are completed in less than 5 months, they can be submitted earlier.

### (ii) The second progress report will include the activities conducted in the period covered.

### (iii) The third progress report will include section texts prepared in order to submit to the editors. These reports will be submitted to the Administration electronically and in 2 (two) printed copies.

*1.3. Draft HTA Full Report*: In the 17th month after the contract is signed, Draft HTA Full Report will be prepared to be disseminated for revisions, and, following the dissemination of this report, it will be submitted to the Administration. The Administration will publish the Draft HTA Full Report on the HTA website (www.hta.gov.tr) and wait for **20 (twenty) working days** for revision requests, and, if any, the Administration will request that the Contractor/Consultant makes necessary revisions depending on the feedback provided.

* 1. *Final HTA Full Report*: It is the report that will be submitted to the Administration when the study is completed. The revised Final HTA Full Report will be submitted to the Administration in **15 (fifteen) days** at the latest after the Administration conveys the feedback to the Contractor/Consultant. The Annex of Final HTA Full Report will include the summary of patients and their relatives as well as the executive summary of the HTA Full Report. HTA Full Report and its enclosed summaries will be prepared in Turkish and English languages and they will be submitted in digital format and in two printed copies

## 2. The Contractor/Consultant will come to an agreement with the Administration on the format, content and quality of the report. The Contractor will come to an agreement with the Administration on the analyses to be used in reports and the reporting formats before the reports are prepared.

3. The reports will be written plainly and clearly and they will be edited in a way not to include any incomprehensibility, spelling or grammar mistake.

4. Since the Contractor conducts the study on behalf of the Administration, all rights related to the publications and studies under the Project such as articles, etc. pertain to the Administration.

# G. SERVICES AND FACILITIES TO BE PROVIDED BY ADMINISTRATION

### **1.** The Administration will follow-up the project together with a coordinator responsible for the whole study.

**2.** HTA Full Report will be prepared in nine topics together with the questions included in the Assessment Element Tables for HTA Core Model Application for Medical and Surgical Interventions (3.0). For the tables in English, please see <http://meka.thl.fi/htacore/BrowseModel.aspx> or [www.hta.gov.tr](http://www.hta.gov.tr).

**3.** The Consultant will work in close cooperation with a Project Coordinator to be assigned by the Administration. The Project Coordinator will be the key personnel acting on behalf of the Administration in this study, and s/he will communicate and ensure coordination with the representatives of the contractor firm, key personnel and other relevant persons, institutions and organizations during the term of the project.

**4.** When necessary and applicable, the Administration will allow that the contractor firm and key personnel use meeting halls and databases, which s/he is a member of, provided that it will be limited to the scope of the work.

**5.** The Administration will be responsible for providing all logistic services of the below-stated meetings to be conducted in and out of Ankara province. The Contractor will cover the contractor personnel's transportation expenses to the meetings, excluding the meetings to be conducted out of Ankara province.

**6.** With an intent to prepare policy question and PICO; a one-day meeting will be conducted in Ankara with the participation of minimum 20 persons including the clinicians and other health professionals working on HTA; the representatives of minimum two associations for RA; the associations for patients diagnosed with RA and their relatives; the representatives of firms producing medicines and medical devices in this field.

**7.** Opening Meeting: It is a one-day meeting to be conducted in Ankara province which aims at introducing the project and which covers all study groups of "Rheumatoid Arthritis" that will be studied in nine topics in two months at the latest after the contract is signed, all stakeholders (Social Security Institution; Public Hospitals Institution of Turkey; General Directorate of Health Services; Universities and Training and Research Hospitals; firms, specialty associations and associations for patients and their relatives that conduct studies on Rheumatoid Arthritis) and the relevant institutions and organizations.

## 8. Evaluation Meetings: During the term of the contract, minimum 2 (two) meetings will be held with the members of the study group at the General Directorate of Health Researches so as to evaluate the study process.

## 9. Closing Meeting: After the final reports are submitted and the project is completed, a one-day meeting, which includes all stakeholders of the project and comprises minimum 30 persons, will be conducted in Ankara province so as to determine the introduction and roll-out strategy related to the project.

**10.** Minimum 3 (three) meetings/workshops -opening meeting of the project, project evaluation meetings to be organized in accordance with the work program and project closing meeting- will be organized in Ankara and the Contractor/Consultant will provide support to the Administration in planning these meetings and determining the participants.

# H. SUPERVISION OF WORK BY THE ADMINISTRATION

The Administration will supervise whether or not the project/study is carried out in line with the specifications. The Administration will perform necessary controls at every stage of the study. The Administration has right to request that the service is reprovided or corrected if the service provided does not comply with the specifications or the content of the report is not in line with the HTA study principles.

# TIME, DURATION AND WORKPLACE

Duration of the work is 18 (eighteen) months as of the signature date of the contract excluding the times elapsed during the inception and acceptance procedures. The work is centered in *Ankara* province. The work will start when the contract is signed.

**İ. PROFICIENCY CRITERIA REQUIRED FROM THE FIRM**

1. The contractor firm shall have experience in conducting national or international studies (reports, reviews, analyses, scientific publications) on Health Technology Assessment, health economics, pharmacoeconomics and cost-effectiveness analyses or economic analyses regarding health over the last five years.

 **2.** The Contractor is supposed to have personnel and administrative capacity qualified enough to conduct similar projects.