INSTRUCTION ON HEALTH TECHNOLOGY ASSESSMENT

PART ONE
Objective, Scope, Basis and Definitions

Objective and scope

ARTICLE 1 – (1) The objective of this Instruction is to define the health technology assessment process and its steps.

(2) This Instruction includes the works and procedures of health technology assessment carried out at the Ministry of Health of Turkey.

Legal Basis

ARTICLE 2 – (1) This Instruction has been drawn up on the basis of the articles 2, 12 and 40 of the Decree Having the Force of Law on Organization and Duties of the Ministry of Health and its Affiliates No. 663.

Definitions

ARTICLE 3 – (1) For the purposes of this Instruction;

a) Minister denotes to Minister of Health,

b) Ministry denotes Ministry of Health,

c) Head of Department denotes Head of Department of Health Technology Assessment of the General Directorate of Health Researches,

ç) Department denotes to Department of Health Technology Assessment of the General Directorate of Health Researches,

d) Efficacy means the usefulness of health technology in the solution of a particular problem under ideal conditions such as a laboratory environment or clinical research protocol,

e) Clinical Effectiveness means the usefulness of health technology in the solution of a particular problem under general and common conditions,

f) General Director denotes to General Director of Health Researches,

g) General Directorate denotes to General Directorate of Health Researches,

ğ) Rapid reporting indicates to the report planned to be completed between 1 and 3 months, which includes the assessment of health technology in terms of clinical safety, efficacy and effectiveness, and its burden on the budget,

h) Short reporting indicates to the report planned to be completed between 3 and 9 months, which includes the assessment of health technology in terms of clinical safety, efficacy, effectiveness, and economic and institutional aspects,

ı) Commission denotes to the Topic Selection Commission,

i) Health technology refers to any practice used to maintain and improve health, and prevent, diagnose and treat diseases including primarily drugs, medical devices, surgical methods and healthcare service systems,

j) Health technology assessment (HTA) means the systematic evaluation and interpretation of health technology in terms of its general characteristics, safety, efficacy and effectiveness, economic aspects and cost, institutional functioning aspects and social and ethical aspects,

k) Full reporting indicates to the report planned to be completed between 18 and 36 months, which includes all elements in the definition of HTA,

l) Adaptation study refers to translation into Turkish and adaptation of health technology assessment reports published by international or other national HTA organizations.

PART TWO
Topic Suggestion, Commission and Topic Selection

Topic suggestion

ARTICLE 4 – (1) Natural and legal persons can make suggestions to the General Directorate of Health Researches for topics to be included in health technology assessment program.

(2) Suggestions shall be made by completing the form provided in Appendix 1 and sending it to the General Directorate. Applications that are not duly made shall be disregarded.

Topic selection commission

ARTICLE 5 – (1) Topic Selection Commission shall be determined upon proposal of the General Director and approval of the Minister. The selection of topics with which health technology assessment will be initiated shall be made upon decision of the Commission.

(2) The Commission shall consist of 13 members indicated below:

a) One representative from the General Directorate of Health Services,

b) One representative from the Public Health Agency of Turkey,

c) Two representatives from the General Directorate of Pharmaceuticals and Pharmacy,

ç) One representative from the Public Hospitals Agency of Turkey,

d) One representative from the Social Security Institution,

e) Two representatives from the Ministry of Science, Industry and Technology,

f) One representative from non-governmental organizations related to patients or patient rights,

g) One representative from non-governmental organizations engaged in drug production at the national level or from public professional organizations operating in this field.

ğ) One representative from non-governmental organizations engaged in medical device production at the national level or from public professional organizations operating in this field.

h) General Director and Head of Department shall be regular members of the Commission and shall not attend the voting for topic selection, except for the case set forth in paragraph 7.

ı) For the representatives set forth in sub-paragraphs (a), (b), (c), (ç), (d) and (e), relevant agencies shall present in writing the names of permanent members and substitute members which shall be equal to the number of permanent members.

i) For the representatives set forth in sub-paragraphs (f), (g) and (ğ), the Ministry shall publish an announcement on its website and invite them. Among the candidates submitted in writing by the relevant organizations, permanent and substitute members shall be determined by the approval of the Minister.

(3) The Commission shall be presided over by the General Director. In the absence of the General Director, it shall be presided over by the Head of Department.

(4) Terms of office of the members shall be two years. A member, whose term of office has ended, may be re-elected for two additional periods. Membership of those who fail to attend three consecutive meetings in a period or resign from organizations they represent shall cease. The relevant organization shall submit a new member in place of the member, whose term of office has ceased, among the representatives set forth in sub-paragraphs (a), (b), (c), (ç), (d) and (e) no later than 15 (fifteen) work days. Where permanent representatives fail to be determined due to any reason, the working period shall be completed upon participation of the substitute member.

(5) The Commission shall convene based on a pre-determined meeting agenda, provided that it shall convene no less than once a year upon invitation by the General Director. All topic proposals submitted duly shall be received for consideration by the Commission. The agenda shall be sent to the commission members prior to the meeting.

(6) Invitation to meeting shall be notified to the members in writing or in the electronic environment no later than 15 days prior to the date of meeting.

(7) Commission shall convene with no less than 7 members excluding the regular members. Decisions shall be taken by absolute majority of the full number of members. In the event of an equality of votes, the head of the Commission shall exercise his right to vote, and majority shall be obtained by his vote.

(8) Negotiations in the commission shall be carried out in the order of the agenda items. By absolute majority of those who attend the meeting, the order of the agenda items may be changed, or it may be proposed to negotiate an item not included in the agenda. Such proposals shall be received for consideration based on absolute majority of those who attend the meeting.

(9) The decisions taken shall be signed at the end of the meeting, whereas the reasons, annotations and other remarks shall be recorded into minutes and signed within five work days from the end of the meeting.

(10) Functions of the Commission's secretariat shall be executed by the Department of Health Technology Assessment.

Topic selection

ARTICLE 6 – (1) The following points shall be taken into consideration in the selection of the topics on which the studies shall be conducted and in the determination of the type of HTA on which such topics shall be assessed:

a) Importance of the burden of disease relating to the health technology,

b) Budget effect of the health technology in the provision of the health service,

c) Public attention, including the social and ethical aspects relating to the health technology,

ç) Presence of sufficient data resources about health technology and of qualified human resources that shall be able to conduct assessment.

(2) Priority shall be given to topics on which burden of disease and budget effect relating to health technology are high, the attention of the public is focused, and qualified human resources and data resources are available so that the study can be completed.

(3) All topic proposals duly made shall be received for consideration by the commission, and the decisions of the commission shall be published along with the reasons thereof on the website of the General Directorate.

PART THREE
Health Technology Assessment Process

Pre-assessment

Article 7 – (1) In relation to the HTA topic determined by the commission, the following steps shall be followed:

a) National and international HTA reports published related to the topic shall be screened and examined.

b) Literature review shall be conducted to provide sufficient data for the pre-assessment related to the topic.

c) Based on the HTA reports and/or literature information examined, a pre-assessment report shall be written. It shall be decided whether the health technology topic on which the study will be conducted shall be designed as an original or adaptation study, and the team that shall execute the project shall be formed.

Types of health technology assessment

Article 8 – (1) The type of health technology assessment shall be determined based on the level of scope and reporting method of the study.

(2) Levels of scope shall be the levels for which the health technology assessment report is aimed and which are recommended to be applied, and shall be as follows:

a) National level (studies to be conducted throughout the country),

b) Regional level (studies to be conducted for the region where the health technology shall be implemented or used),

c) Institutional level (studies to be conducted for health institutions or research centers).

(3) Reporting methods shall be determined with respect to the urgency of the required information about the topic of the study, existing fund of knowledge regarding the topic and scope of the social aspects of the topic, and shall be as follows:

a) Full Reporting,

b) Short Reporting,

c) Rapid Reporting.

(4) A brief and clear version of all reports shall be separately published for patients.

(5) All reports shall be published in Turkish and English. Full or short versions in other required languages may be published as well.

Formation and functioning of the project team, and reporting

Article 9 – (1) Project team shall consist of no less than 5 persons, at least one of which shall be from among the employees of the Department to lead the team and the others from universities, education and research hospitals, relevant public agencies and among specialists studying on the topic. Team members shall be determined by the approval of the General Director.

(2) A list of questions that shall be requested at the beginning of the study to be answered shall be prepared with respect to the qualities of the health technology on which the assessment shall be conducted and to the level of scope and reporting method of the assessment.

(3) Health technology assessment studies shall refer to common terminology and glossaries used by the European Union and other international unions.

Literature review

Article 10 – (1) The following points shall be taken into consideration in the literature review:

a) Literature review shall include ULAKBİM national databases as well as MEDLINE®, EMBASE® and other similar databases.

b) In the literature review, the keywords selected shall have such quality and quantity that they shall allow access to the broadest data regarding the topic.

c) Quality of evidences following the review shall be assessed based on internationally accepted criteria.

ç) In the literature review, no language restriction shall be made for keywords, and publications in languages other than Turkish and English shall also be considered depending on the content of the topic and importance of the evidences.

(2) Literature reviews for the assessments of efficacy and clinical effectiveness, and the report of efficacy and clinical effectiveness to be prepared subsequently shall be prepared by specialists in the relevant field.

(3) Economic assessments and assessments in social and ethical fields shall be conducted by the members of the team, who work in such fields.

(4) Following institutional and legal assessments, the report relating to the HTA on which the study is being conducted shall be finalized and published on the website of the General Directorate in draft form, so that it can be examined by all relevant parties and necessary objections, if any, can be raised.

(5) The time period for feedbacks shall be 20 (twenty) work days from the publication of reports for full reporting, and 15 (fifteen) work days for short and rapid reporting. At the end of this period, the draft report shall be removed, and upon the assessment of feedbacks, if any, the necessary corrections shall be made within no later than 15 (fifteen) work days. The final HTA report shall be published by the approval of the General Director.

Monitoring and updating

Article 11 – (1) The HTA reports published shall be advisory, but it shall be monitored whether they are implemented by relevant organizations and institutions.

(2) Necessary assessments shall be conducted in cooperation with relevant agencies regarding the reasons for which the published HTA reports have not been implemented.

(3) The HTA reports published shall be assessed periodically once in three (3) years to check for their currency. If any, feedbacks given to the General Directorate shall be used to determine whether any HTA report requires update. When an update is required, the process of publishing a new HTA report shall be initiated.

CHAPTER FOUR
Miscellaneous and Final Provisions

Other issues

Article 12 – (1) The General Directorate may issue an additional regulation or publish guidelines regarding the level of scope and reporting method of HTA as well as how the studies shall be carried out.

(2) The forms attached to the Instruction, which shall be used in HTA studies, shall be published on the website of the General Directorate, and shall be periodically reviewed to keep them updated.

Enforcement

Article 13 – (1) This Instruction shall enter into force on the date of approval by the Minister**.**

Execution

Article 14 – (1) Provisions of this Instruction shall be executed by the Minister of Health.

Sağlık Bakanlığı Sağlık Araştırmaları Genel Müdürlüğü	**DEPARTMENT OF HEALTH TECHNOLOGY ASSESSMENT** **Topic Suggestion Form for Health Technology Assessment**	**Document Name:** STD-F.01-R.00 **Publication Date:** 01.01.2013 **Page No:** 1/3 **Approved by:** DB

NOTE !

The information you present by means of this form will be used for topic selection purposes by the staff and consultants of the Ministry of Health, General Directorate of Health Research (SAGEM). Please do not indicate any unrelated names or persons in your comments. The Ministry shall contact you by e-mail or postal service, if necessary.

By presenting your data through this website, you state that you have read and accepted all above-mentioned conditions and that the personal and private information provided by yourself can be kept and used in our organization.

1. Proposer
Full name *(for natural persons)* and/or **Name of organization** *(for corporations)***:**
E-mail address:
Address *(if e-mail is unavailable)***:**
Date:

2. For natural persons *(please select only one option that best describes)*
☐ Patient
☐ Patient's relative
☐ Health employee
☐ Voluntary or member of an association
☐ Other *(please explain)*

3. For corporations *(please select only one option that best describes, and explain it)*
☐ Public sector
☐ Public health sector
☐ Private sector
☐ Private health sector
☐ Non-governmental organization
☐ Other *(please explain)*

4. What is the health technology that you ask to be assessed?
☐ Drug
☐ Medical device
☐ Surgical treatment method

☐ Non-surgical treatment method
☐ Other *(please explain)*

5. Proposal *(please explain your proposal briefly) (maximum 50 words)*

6. Which disease, condition or public health issue is related to the health technology that you propose to be assessed? *(e.g., diabetes, obesity, smoking cessation, physical activity, vaccination, cancer, etc.) (maximum 40 words)*

7. Is there any community or group of patients on which your proposal can be implemented? *(e.g., a particular age group such as children, a particular gender (female/male) group, patients who have recently had a heart attack, people facing the risk of a particular disease, etc.) (maximum 40 words)*

8. How do you define the primary intended use of the health technology that you would like to be assessed?
☐ Protective / preventive
☐ Diagnostic
☐ Therapeutic
☐ Rehabilitative
☐ Different treatments
☐ No idea

☐ Other *(please explain)*

9. Is there any health inequality issue relating to the health technology that you would like to be assessed arising in terms of geographical, socioeconomic, cultural, and religious, etc. factors that you would like to highlight? *(e.g., challenges faced by disabled people in accessing or using health technologies, etc.) (please explain)*

Please send this form and other information to sagem@saglik.gov.tr or to the following address by mail:

Sağlık Araştırmaları Genel Müdürlüğü
Bayındır 1 Sokak No:13 06430 Kızılay / ANKARA