DIRECTIVE ON THE WORKING PROCEDURES AND PRINCIPLES OF THE REIMBURSEMENT COMMISSION

Purpose and Basis

ARTICLE 1 – The purpose of this Directive is to set forth the working procedures and principles of the "Reimbursement Commission" established as per Article 4 of the Council of Minister's Decision dated 12.06.2007, with No. 2007/12325.

Definitions

ARTICLE 2- For the purposes of this Directive, the following definitions shall apply;
Reimbursement Commission: The Commission established under the coordination of the Chairmanship of the Social Security Institute, with the participation of the representatives of the Ministry of Finance and the Ministry of Health, regarding the payment procedures and principles of medicinal products for human use / pharmaceuticals for human use,

Commission for Medical and Economic Evaluation: The commission which adopts a preliminary decision upon evaluating the applications submitted by companies in relation with medicinal products for human use/pharmaceuticals for human use and prepares them so as to be presented to the Reimbursement Commission,

Technical Commission: The technical commission constituted by academicians and/or specialists from relevant branches, to be consulted for receiving their views and proposals,

Secretariat: The unit conducting secretarial services relating to the topics encompassed by the sphere of duties of the Commissions indicated in the Directive,

Medicinal product for human use: Any natural and/or synthetically derived active substance or combination of substances administered to human beings with a view to treating and/or preventing a disease, making a diagnosis or restoring, correcting or modifying a physiological function,

Notification: The Healthcare Implementation Notification and the Implementation Notification on Treatment Aids,

List: The lists relating to the drugs included into the annexes of notifications and the provisions regarding the principles for prescribing drugs,

Institute: The Social Security Institute, the Ministry of Finance and the Ministry of Health,

Reimbursement Institutes: The institutes responsible for providing healthcare services to persons indicated in the scope article of the notifications,

Chairmanship: The Chairmanship of the Social Security Institute.

Representatives to Take Part in the Commissions

ARTICLE 3- The Reimbursement Commission shall be constituted under the chairmanship of the General Director of the General Healthcare Insurance (GHI) Institute; by the Chairmen of the Departments of Monitoring and Evaluation, Healthcare Implementation and

Legislation, Policy Designation and Economic Management within the General Directorate of GHI, and at least two representatives each, serving at least as department heads, to be appointed by the Ministry of Finance and the Ministry of Health. A number of alternate members serving at least at the branch management level, corresponding to the number of full members serving in the Reimbursement Commission of each Institute, shall be designated. In cases where the full members of the Reimbursement Commission cannot fulfill their duties due to reasons such as leave, sickness, or temporary duty, they shall be replaced by their alternate members who will attend the meetings with the same powers.

The Commission for Medical and Economic Evaluation shall be chaired by a department chairman to be designated by the Chairman of the Social Security Institute, and constituted by the members selected from the professional groups of physicians, pharmacists, public health specialists, economists, statisticians, specialists, epidemiologists, pharmacologists and biostatisticians. Provided that they are from the abovementioned professional groups, four persons representing the Chairmanship of the Social Security Institute, two persons representing the Ministry of Health, two persons representing the Ministry of Finance, two persons among academicians to be designated from the abovementioned professional groups by the Ministry, and two persons in total from the original and generic pharmaceutical sectors representing IEIS (Pharmaceutical Manufacturers' Association), TISD (Turkish Pharmaceutical Industry Association) and AIFD (Association of Research-Based Pharmaceutical Companies) shall serve as full members. A number of alternate members corresponding to the number of full members shall be designated from the same professional groups.

Members appointed in place of the members of the Commission for Medical and Economic Evaluation who quit office due to any reason shall be reported to the Chairmanship. However, in cases where the said commission members cannot serve due to any reason such as temporary duty, leave, sickness, the alternate members shall attend the meetings.

Where necessary, the Commission for Medical and Economic Evaluation may convene to the meeting, or ask for a written opinion of, the representatives of pertinent non-governmental organizations operating in the fields of healthcare, pharmacy, medicinal products for human use and medical products so as to consult their views.

The secretarial services of the commissions shall be conducted by the unit established within the Chairmanship of the Department of Healthcare Implementation and Legislation in the General Healthcare Insurance Institute.

The list comprising the names of all full and alternate members to serve in the Reimbursement Commission and the Commission for Medical and Economic Evaluation shall be announced on the web site of the Social Security Institute and will be updated in case of amendment.

Duties of the Reimbursement Commission

ARTICLE 4- The duties of the Commission shall be as follows;

a) To evaluate the reports on applications prepared by the Commission for Medical and Economic Evaluation and adopt decisions on them,

b) In case of difficulties arising in the procurement of some drugs, to adopt decisions regarding the implementations that will facilitate the procurement of drugs upon the application of the Ministry of Health or the relevant institutes and institutions,

c) To indicate which drugs among those decided to be included into the list or which are reimbursed upon being imported from abroad in line with the relevant legislation, shall be exempt from patient co-payment share,

d) To prepare an annual report regarding the activities of the Commission and present it to the Chairmanship.

Duties of the Commission for Medical and Economic Evaluation

ARTICLE 5- The duties of the Commission for Medical and Economic Evaluation shall be as follows;

a) To control the literature and data presented with the application dossier,

b) To evaluate the registration modifications of the drugs included into the list, modified by the Minister of Health, modifications in the name of drugs, discount modifications occurring in relation with the modifications in the reference price, inclusion of the drugs with a unit price below the drug which the cheapest unit price among equivalent groups, and publish them upon the approval of the Chairman of the Reimbursement Commission,

c) To evaluate the original and generic products, for which an application is made so as to be included into the list, from a pharmacological perspective, taking into account the market shares of the products included into the list as well as their impact over the budget and for original products evaluating them also from an epidemological, pharmacological and public health perspective, formulate an opinion upon taking as basis the views of the Technical Commission where necessary and present it to the Reimbursement Commission,

d) Where necessary, to receive the views of the Technical Commission as well, and present to the Reimbursement Commission the evaluation report on the arrangements relating to the drugs reported to the Commission for Medical and Economic Evaluation so as to be delisted,

e) To conduct evaluations relating to the drug groups to be included into the scope of equivalent drug implementation, the market availability period of the drug to be designated as the cheapest drug setting the basis for the ceiling and the designation of the market shares and present the relevant arrangements in the form of a report to the Reimbursement Commission,

f) To formulate an opinion regarding the designation of the rules on the prescription and reimbursement of the drugs to be included into the List of Drugs to be Reimbursed for the first time and present it to the Reimbursement Commission,

g) In cases where the drugs included into the list on a conditional basis get additional indications, to present the evaluation report relating to the prescription and payment rules on the new indication to the Reimbursement Commission,

h) To examine the international procedures and principles of pharmaceutical reimbursement and present to the Reimbursement Commission the report prepared for formulating a view in the designation of the Social Security Institute’s policies,

i) To timely procure the information and documents relating to the lawsuits filed against the topics constituting the basis of the activities of the Commission for Medical and Economic Evaluation and present them to the relevant Department Chairmanship of the Social Security Institute,

j) To designate the standards of the information and documents to be requested during application and ensure the development and renewal of the relevant forms.

Working Principles of the Reimbursement Commission and the Commission for Medical and Economic Evaluation

ARTICLE 6- The Commission shall convene once every two months on an ordinary basis, and where necessary on an extraordinary basis, upon the invitation of the Chairman of the Reimbursement Commission. The Reimbursement Commission shall designate its annual workdays on the first meeting of each calendar year and post it on the web site of the Social Security Institute.

The topics and dossiers to be included into the agenda shall be reported to the members by the Chairman of the Reimbursement Commission at least one week prior to the meeting day. In case the Reimbursement Commission is convened to meet on an extraordinary basis, the agenda, meeting day and time shall be communicated to the relevant parties at least 3 days prior to the meeting date.

The Commission for Medical and Economic Evaluation shall meet once a week on an ordinary basis. If required, the Commission may also convene where deemed necessary by the Chairman of the Reimbursement Commission or the Chairman of the Commission for Medical and Economic Evaluation.

The work of the Reimbursement Commission and the Commission for Medical and Economic Evaluation shall continue without interruption until the topics to be discussed on the meeting agenda are finalized. The topics taken up in each meeting, the evaluations made, the decisions adopted as well as their justifications shall be recorded in detail by a rapporteur and signed by the members of the commissions.

In the applications or cases closely related with public health and necessitating the adoption of urgent measures, the relevant topic shall be discussed and evaluated with priority with the justified proposal of the Chairman of the Commission for Medical and Economic Evaluation.

Applications to be submitted by institutes and institutions, other than pharmaceutical companies, as well as individuals shall be evaluated by the General Directorate of the General Healthcare Insurance and sent to the relevant commissions so as to be discussed where necessary. Such applications sent to the Commission shall be subjected to the same procedure as company applications.

The Commission for Medical and Economic Evaluation shall primarily control the literature and data submitted with the application dossier. The applications of companies whose literature or data are designated to be incorrect or inapplicable shall be rejected and returned with the signature of the Chairman of the Commission for Medical and Economic Evaluation.

The participation of all representatives in the meetings is essential. Relevant institutes shall be responsible for fulfilling this requirement. The Commissions shall convene with the absolute majority of the full number of members and adopt decisions by majority of votes. In case of parity of votes, a majority shall be accepted to be established on the side that the Commission Chairman has voted. The reason for the disagreement of the members not agreeing with the decision adopted shall be indicated in written in the decision.

Within the scope of clause (b) of Article 5, the applications submitted between the 1st and 15th days of each month shall be finalized until the end of that month whereas the applications submitted between the 16th day and the end of the month shall be finalized until the 15th of the following month.

Among the applications submitted in relation with the other clauses of Article 5, those presented until five weeks before the meeting date of the Reimbursement Commission shall be assessed so as to be evaluated in the first coming meeting and submitted to the

Reimbursement Commission latest 15 days before the meeting date. The work which cannot be finalized shall be reported in written form within the same period to the Chairman of the Reimbursement Commission, along with the relevant justifications. The applications shall be finalized latest within two meeting terms of the Reimbursement Commission.

Where necessary, the commissions may invite the relevant company to present to the commission any type of information and documents relating to the drug for which the application has been made.

The decisions adopted as a result of the work of the Reimbursement Commission shall be sent to the Chairman of the Social Security Institute along with their justifications, within five work days as of the date of the decision. The Chairman shall accept them or return them for their re-evaluation within 15 days. Regarding decisions returned to the commission so as to be re-evaluated, a decision shall be adopted upon assessing them with priority in the first ordinary meeting of the commission. The decision adopted shall be sent for approval to the Chairman of the Social Security Institute within five work days as of the decision date, along with its justifications. The Chairman shall either accept or reject the decision within 15 days. Applications which have not been accepted shall be reported to the applicant authority within one week as of the approval date, along with the relevant justification.

Among the applications, the decisions accepted by the commissions and approved by the Chairman shall be simultaneously posted on the web page of the institutes within 10 days as of the approval of the Chairman upon indicating the enforcement date.

Regarding drugs for which decision has been adopted for being delisted by the Reimbursement Commission, other than company applications, the decision shall become effective three months as of the publication date.

Arrangement of the Demands for Barcode Modifications and Increase of Discount Rates

ARTICLE 7- The demands for modifying the barcodes and increasing the discount rates of the drugs included into the list shall be arranged by the personnel appointed by the General Director of General Healthcare Insurance and published on Friday each week by the General Director of General Healthcare Insurance or the department chairman appointed by the General Director of General Healthcare Insurance. The published list shall become effective on the first subsequent work day. If Friday coincides with an official holiday, it shall be published on the previous work day.

Establishment of Technical Commissions

ARTICLE 8 - The Reimbursement Commission shall constitute technical commissions, where necessary. The members of the Technical Commissions shall be composed by at least 3 physicians designated by the Chairman of the Reimbursement Commission from the list of consulting physicians determined by the Chairmanship of the Healthcare Implementation and Legislation Department. Where necessary, the participation of members from professional groups other than physicians shall be enabled or a technical commission constituted only by such members will be established.

In cases where the views of the Technical Commission are required also in the work of the Commission for Medical and Economic Evaluation, the members of the Technical Commission designated upon the written request of the Chairman of the Commission for Medical and Economic Evaluation and the positive view of the Chairman of the Reimbursement Commission shall take part in the work.

The Technical Commission shall present the results of its work in the form of a report.

Applications to be Submitted to the Reimbursement Commission and the Documents to be Requested

ARTICLE 9 - For all requests to be submitted regarding the provisions of the Notification relating to drugs, application shall be made to the Secretariat of the Reimbursement Commission.

In the applications;

a) Regarding medicinal products for human use for which request is made so as to be listed for the first time (in the form of a dossier in two copies along with an electronic format on CD);

The letter indicating the request of the company of the product in question, photocopy of the registration, photocopy of the sale permit, discount proposal, photocopy of the barcode approval document, print-out of the price list of the relevant product posted on the web page of the Ministry of Health, sample of the package insert (or the summary of product characteristics, patient information leaflet), studies pertaining to the pharmacoeconomic analysis and the evaluation reports encompassing the epidemiological information/data shall be presented with the application dossier.

In addition to the abovementioned documents in the applications of original products, information pertaining to their payment status in other countries, either one of the approval letters of FDA/NDA/EMEA and, where available, the copy of the certificate of authority for the product co-marketed with the original product shall be added to the application dossier.

In product applications pertaining to the molecules not included into the Reimbursement List, summarized literature information supporting the product, in case of availability of other therapeutic options in the same indication, the clinical studies comparing the products from the same class and a report summarizing the literature relating to these studies shall also be included into the dossier.

Along with the photocopy in the original language of the summarized literature information presented in the annex of the dossier, its Turkish translation, as well as the original photocopies of all other information, documents and reports, and, where necessary, their Turkish translations, shall also be submitted.

It is necessary to add to the application dossiers the proforma invoice, control document, import certificate, label sample and product information for nutritional formulae utilized for special purposes, enteral nutritional solutions and some low protein and non-gluteneous products.

b) In the application requests relating to the modifications requested to be performed on the list information of the relevant drug, even though it is included into the list;

The letter indicating the request of the company and, where available, the photocopies of the documents constituting the basis of the said request shall be submitted in the attachment.

c) In the applications for objecting to the decisions of the Commission for Medical and Economic Evaluation within its sphere of authority and to the decisions of the Reimbursement Commission;

The letter indicating the request of the relevant company and, where available, the photocopies of the documents constituting the basis of the said request shall be submitted.

The applications listed above shall be delivered by hand to the Secretariat. The Secretariat shall perform a preliminary assessment so as to detect any missing information and documents. The letter relating to the information and documents detected to be missing shall be sent to the relevant party latest within three work days as of the date when the application is received. The date when the missing information and documents are completed shall be regarded as the application date. Applications dossiers shall be processed according to the

dates of the application dossiers. In the applications of products for which request is made for their inclusion into the list for the first time, a copy shall be delivered to the Institutes/member companies included into the Commission for Medical and Economic Evaluation, by the relevant company, upon making up for the deficiencies.

The letter relating to the deficient or additional information and documents detected during the examinations of the Commission for Medical and Economic Evaluation, the Technical Commission or the Reimbursement Commission shall be sent to the relevant party within three work days as of the date of detection. The assessment process shall be stopped until the deficient /additional information and documents are remedied.

The letter pertaining to the deficient or additional information and documents detected by the Commission for Medical and Economic Evaluation and the Technical Commission required by this commission shall be sent with the signature of the Chairman of the Commission for Medical and Economic Evaluation, whereas the letter pertaining to the deficient or additional information and documents detected by the Reimbursement Commission and the Technical Commission required by this Commission shall be sent with the signature of the Chairman of the Reimbursement Commission.

The Commission for Medical and Economic Evaluation or the Reimbursement Commission shall be authorized to request in written form from the relevant parties the information and documents required in the work relating to their sphere of activities. The information and documents indicated in the written request shall be sent to the Secretariat of the Reimbursement Commission within the designated period as of the date of reception of the letter. However, in case the Commissions accept the request for additional time for the procurement of the requested information and documents by the relevant company, the end of this period shall be awaited. In case of failure to deliver the requested information and documents within the designated period, the Reimbursement Commission shall decide on the basis of the information and documents available to the Commission. The applications for objecting to this decision shall not be evaluated for one year.

Those submitting the information and documents to the Institute shall be responsible for the accuracy of any type of information and documents presented and ensure that the information is finalized. The damage to be incurred by the Public due to the decisions adopted on the basis of incorrect information and documents shall be collected from or compensated by those presenting the relevant information and documents to the Institute.

Objecting to the Decisions of the Commission for Medical and Economic Evaluation and the Reimbursement Commission and Re-Application

ARTICLE 10 - Pursuant to the publication of the decision or, in case of rejection of the application, within two months as of the notification of the referred decision to the relevant party, objection may be raised to the commissions along with the justifications and, if available, additional information and documents, against the decisions of the Commission for Medical and Economic Evaluation and the Reimbursement Commission. The Commission for Medical and Economic Evaluation or the Reimbursement Commission shall evaluate, for once only, the objection in accordance with the application and assessment calendar indicated in Article 6, upon requesting also the view of the Technical Commission, where deemed necessary.

In case a decision of rejection is adopted again pursuant to the objection raised, another application shall not be submitted regarding the same topic for a period of one year. However, in case of new data or indication modification pertaining to the product for which a decision of objection is adopted, this period shall not be taken into account.

Confidentiality of the Work of the Commissions

ARTICLE 11 - Those serving in all or in one part of the work shall not deliver any statement when the work of the commissions is ongoing or when it has been concluded, until the decisions adopted are published or announced.

Enforcement

ARTICLE 12 - This Directive shall become effective as of the date it is published on the web page of the Social Security Institute.

Temporary Article 1

The members to be included into the commissions shall be designated 15 days pursuant to the publication of this Directive. The Commissions shall hold their first meeting latest on the last work day of the week following the date when the units and assigned members indicated in name in Article three of this Directive and designate their work days until the end of the year. In the meeting, the Commission for Medical and Economic Evaluation shall designate the standards and formats of the documents to be requested at applications and post it on the web page of the Social Security Institute.

Temporary Article 2

Until the appointment of the relevant department chairmen of the General Directorate of General Healthcare Insurance to participate in the commissions in accordance with Article 3 of the Directive, department chairmen appointed by the Chairman of the Social Security Institute among the department chairmen serving at the department chairmanships under the General Directorate of General Healthcare Insurance of the Institutes transferred to the Social Security Institute shall serve as commission members.

Temporary Article 3

Applications submitted before the enforcement date of the Directive shall be evaluated according to the provisions of this Directive.

Temporary Article 4

Until the Commissions indicated by this Directive are established, within the scope of clause (b) of Article 5 and Article 7, arrangements pertaining to the discount modifications occurring due to the changes in the reference price in the applications submitted before the enforcement date of the Directive, shall be forthwith published, for once only, by the personnel within the Social Security Institute appointed on a temporary basis by the General Director of General Healthcare Insurance, pursuant to their signature by the General Director of General Healthcare Insurance.