

DIRECTIVE REGARDING THE OPERATING PRODURES AND PRINCIPLES OF THE PRICE EVALUATION COMMISSION OF THE MINISTRY OF HEALTH

SECTION ONE Purpose and Scope

Purpose ARTICLE 1 – (1) The purpose of this Directive is to set forth the operating procedures and principles of the Price Evaluation Commission.

Scope ARTICLE – (1) This Directive encompasses the principles relating to the establishment, duties, power, responsibilities and the operation of the Price Evaluation Commission.

Legal Basis ARTICLE 3 – (1) This Directive has been prepared on the basis of the Notification Regarding the Council of Ministers' Decision and the Pricing of Medicinal Products for Human Use, with No. 2015/7752, dated 15/06/2015, enforced upon being published on the Official Gazette No. 29559, dated 11/12/2015.

Definitions ARTICLE 4 – (1) The following terms shall apply for the purposes of this Directive;
a) Euro value: The Euro value designated by calculating the annual average Euro value, to be calculated upon taking into account the daily indicative Euro foreign exchange sale rate realizations of the Central Bank of the Republic of Turkey, declared on the Official Gazette of the previous year, with 70% of the designated adaptation coefficient,

b) Ministry: The Ministry of Health,

c) Medicinal Product for Human Use: Any natural and/or synthetic-derived active substance or combination of substances, enteral nutrition products and/or medical infant food, administered to humans for the purpose of treating and/or preventing a disease, making a diagnosis or correcting, restoring or modifying a physiological function,

ç) Decision: The Decision Regarding the Pricing of Medicinal Products for Human Use Annexed to the Council of Ministers' Decision, with No. 2015/7752, dated 15/06/2015,

d) Commission: The Price Evaluation Commission established for the purpose of evaluating the prices of medicinal products for human use with the participation of the representatives of the Ministry of Finance, Ministry of Development, Undersecretariat of Treasury and the Presidency of the Social Security Institution, under the coordination of the Ministry,

e) Agency: The Medicines and Medical Devices Agency of Turkey,

f) Secretariat: The relevant Head of Department conducting the secretarial services in topics falling into the area of responsibility of the Commission,

g) Notification: The Notification Regarding the Pricing of Medicinal Products for Human Use, published on the Official Gazette with No. 29559, dated 11/12/2015, based on the Decision No. 2015/7752 of the Council of Ministers.

SECTION TWO Establishment and Duties

Representatives to Participate in the Commission ARTICLE 5 – (1) The Price Evaluation Commission shall be composed of 5 (five) full members, with the participation of one representative each, holding a signing authority, from the Ministry of Finance, Ministry of Development, Undersecretariat of Treasury and the Social Security Institution, under the coordination of the Ministry of Health. Full members may bring the technical personnel from the same agency with the full member.

(2) Reserve members, holding a signing authority and corresponding to twice as much of the number of full members, shall be designated. Those appointed to replace the Commission members who leave their post due to any reason shall be reported to the secretariat. Reserve members shall attend the meetings in cases where the full members of the Commission cannot attend the meeting. Persons other than members and technical personnel may attend the meetings only upon being invited.

Operating Procedures and Principles of the Commission ARTICLE 6 – (1) It is mandatory for all members to attend the meetings. The relevant agency shall be responsible for ensuring the participation in meetings.

(2) The Commission shall convene on an ordinary basis in the first five days of January, April, July and October each year upon the invitation of the President of the Agency and on an extraordinary basis, where necessary, upon the invitation of any one of the agencies represented in the Commission.

(3) The correspondence relating to the work and operation of the Commission shall be conducted by the secretariat.

(4) The Commission shall convene with the simple majority of the full number of members and will adopt decisions with the simple majority of the full number of members. No abstention vote shall be used in the meetings. In case of tie, the vote used by the President of the Commission shall be regarded as majority of votes.

(5) The secretariat of the Commission shall communicate the meeting agenda of ordinary meetings at least 10 (ten) working days in advance. In case the Commission is called to an extraordinary meeting, the agenda, meeting day and time shall be forthwith communicated to members prior to the meeting date.

(6) The Commission may invite registration/permit holders in order to meetings in order to receive their views or may ask for their written opinion. The Commission may procure or request from the relevant parties the information and documents it regards as necessary during its activities.

The Commission and Its Duties ARTICLE 7 – (1) The duties of the Price Evaluation Commission shall be as follows: a) To evaluate the requests for products priced below the reference price to be raised to the reference price,

b) To evaluate the applications made for receiving a price 50% lower than the average price of products with the same active substance at the same amount or with different package sizes currently available on the market, including itself, for any product available on the market or to be newly introduced into the market, in order to ensure their market availability for maintaining market balances,

c) To designate vaccines to be subjected to special conditions and products of critical importance in terms of public health,

ç) To decide on the designation of the price of plasma-sourced blood products, which are regarded necessary, manufactured via a recombinant method, in terms of ensuring their market availability,

d) To evaluate the requests, in case the products subjected to a special condition request a price according to the cost card, if the price requested is higher than the reference price at a rate higher than the rates specified in article 7 of the Notification,

e) To designate the vaccines subjected to the pricing implementations defined in clause one of article 7 of the Notification and products holding a critical importance in terms of public health and to evaluate the possibility to grant a price above the designated price for these products upon taking into account the general principles of the Notification,

f) To evaluate the price increase requests of more than 100% of the current ex-factory price and arising from the increase in the reference price,

g) To evaluate the price increases requested by companies which have received a price below the ex- factory price indicated below the cost card, up to the ex-factory price indicated afterwards in the cost card,

ğ) To designate the products whose pricing procedures are indicated in clause fourteen of article 8 of the Notification and whose non-availability in the market may threat public health or public cost, and the identify their prices,

h) To decide on the procedures regarding the enforcement of the decision or on the increase, decrease or preservation of the prices of medicinal products for human use,

ı) To convene within the first five days of January of each year and designate 1 (one) Euro value to be used in pricing medicinal products for human use,

i) To designate upon differentiating the prices and/or profit rates of medicinal products for human use without being bound to the provisions of the Decision and Notification, for medicinal products for human use subjected to the procurements to be made upon using the alternative reimbursement models according to Article 73 of Law No. 5510 Regarding Social Insurances and Universal Health Insurance,

j) To evaluate the increase in the prices of products whose market availability is mandatory due to public health and products which provide savings in terms of public finance upon ensuring their market availability.

SECTION THREE Final Provisions Revoked legislation ARTICLE 8 – (1) The Directive Regarding the Operating Procedures and Principles of the Price Evaluation Commission, dated 22/02/2008, has been revoked.

Entry into Effect ARTICLE 9 – (1) This Directive shall become effective upon the approval of the Minister of Health.

Execution ARTICLE 10 – (1) The provisions of this Directive shall be executed by the Minister of Health.