The Decision was consolidated with the below amendments;
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- Decision Regarding the Pricing of Medicinal Products for Human Use - 17.01.2009 -27113(*)(red colored)
- Decision Regarding the Pricing of Medicinal Products for Human Use - 18.09.2009 -27113(**)(blue colored)
- Decision Regarding the Pricing of Medicinal Products for Human Use – 03.12.2009 – 27421 (green)

SATURDAY, June 30 2007 **Official Gazette** No. : 26568

DECISION OF THE COUNCIL OF MINISTERS

Decision No : 2007/12325

The Council of Ministers has decided on 12/6/2007 to enforce the annexed "Decision Regarding the Pricing of Medicinal Products for Human Use", pursuant to the letter of the Ministry of Health, dated 1/6/2007, with No. 31014.

Ahmet Necdet SEZER
PRESIDENT

Recep Tayyip ERDOĞAN
Prime Minister

A. GÜL — Minister of Foreign Affairs & Depty Prm. Min.
A. ŞENER — Minister of State & Depty Prm. Min.
M. A. ŞAHİN — Minister of State & Depty Prm. Min.
B. ATALAY — Minister of State
A. BABACAN — Minister of State
M.AYDIN — Minister of State
N. ÇUBUKÇU — Minister of State
K. TÜZMEN — Minister of State
F. KASIRGA — Minister of Justice
M. V.GÖNÜL — Minister of National Defense
O. GÜNEŞ — Minister of Interior Affairs
K. UNAKITAN — Minister of Finance
H. ÇELİK — Minister of National Education
F. N. ÖZAK — Minister of Public Works & Settlement
R.AKDAĞ — Minister of Health
İ. YILMAZ — Minister of Transportation
M. M. EKER — Minister of Agriculture & Rural Affairs
F. N.ÖZAK — Deputy Minister of Labor & Social Security
A. COŞKUN — Minister of Industry & Trade
M. M.EKER — Deputy Minister of Energy & Natural Resources.
A. KOÇ — Minister of Culture & Tourism
O. PEPE — Minister of Agriculture & Forestry

DECISION REGARDING THE PRICING OF MEDICINAL PRODUCTS FOR HUMAN USE

Purpose and legal basis

ARTICLE l – (1) In line with Law No. 1262 Regarding Pharmaceuticals and Medicinal Preparations and Law No. 3359 Regarding the Fundamental Law on Healthcare Services, the Ministry of Health shall adopt the relevant measures and designate the maximum prices so as to ensure that medicinal products for human use are accessed by the consumers in adequate conditions. The prices requested by registration holders or applicants in compliance with this Decision shall be approved by the Ministry of Health and announced along with the effective date.

Designation of prices

ARTICLE 2- (1) No more than 10 and no less than 5 member states of the European Union (EU) shall be selected annually as "reference countries" by the Ministry of Health and announced as such by means of a communiqué. The "reference countries" so selected may be changed provided by a no less than two-month advance notice. The reference price is defined as the "selling price to the warehouser", which is the lowest discount-exclusive price at which a registered and currently marketed original product can be sold to a warehouser in the named countries. However, the countries of manufacture or exportation shall not be regarded as reference countries and where a lower selling price to warehouser is applied in such countries, the price applicable in the country where a lower selling price to warehouser is applied shall be taken as the reference price. Reference currency shall be Euro. It shall be the companies' responsibility to monitor reference prices of their respective products and to declare them accordingly to the Ministry of Health. National or international databases may be used for monitoring reference prices. Where relevant, the Ministry of Health may verify the declared reference prices using national or international databases and/or formal channels.

(2) For products which are currently on the market and assigned a Ministry of Health-approved price, or for which a pricing application has been submitted for the first-time; the "ex-factory price" of an original product may not exceed the reference price until a generic of it is launched; the "ex-factory price" of an original product with a marketed generic shall be no more than 66% of the reference price as registered in the Ministry of Health's database; the ex-factory price of a product whose original is unavailable in the country shall be equal to 66% of the reference price as registered in the Ministry of Health's database; also, all generic products, the first one included, may be assigned an "ex-factory price" up to 66% of the reference price that applies to the original product. Reference price reductions occurring after the setting of a price by the Ministry of Health upon launch of a first generic shall not be applied to the "ex-factory price" until they fall below the 66% threshold. Where the reference price falls below the 66% threshold, an "ex-factory price" up to 100% of the new reference

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price may be assigned; this procedure shall be equally applied to generic products also. Ex-factory price of a generic product may not be higher than the ex-factory price of the original designated as reference. As of 01.01.2010, 20 year-old products with ex-factory price above 6.79 TL may be priced up to 100% of the reference price; generics of these products may not be priced higher than the ex-factory price of the original designated as reference. In the case of "products packaged for hospital use", the retail selling price shall be set at no less than 10% below the unit price of the lowest priced one among the packaging forms available of the product at retail.

(3) This Decree shall not apply to products that have been granted 20 year-old status by the Board of Ministers Decree #2004/6781 of 06.02.2004 and have an ex-factory price of less than 6.79 TL, and to all drugs which have an ex-factory price less than 3.56 TL, as well as non-prescription drugs, blood products, medical baby food products, radiopharmaceuticals, enteral nutrition products and products which are not on the reimbursement list of the state. The principles and procedures governing pricing of the foregoing products shall be announced by the Ministry of Health via a notification.

(4) Where new reference countries are selected according to the first paragraph, a new declaration must be submitted for all products which are on the market or which have an approved price. The Price Assessment Committee shall be authorized to re-set the ex-factory price of products whose reference price is affected from these countries, taking into account no more than 66% of the reference price. The same procedure shall be applied to generic products whose price is set based on the reference price of the original product or, where the original product is unavailable in the country, according to the reference-based pricing system.

~~(2) For currently marketed original products whose price has been approved by the Ministry of Health or for which a first application shall be made for a pricing approval, the "selling price to warehouser" may not exceed the reference price until the market launch of a generic of it takes place, while the "selling price to the warehouser" of an original product whose generic has been granted marketing authorization shall be no more than 60% of the reference price as registered in the Ministry of Health's database. The selling price to the warehouser of a product whose original is not available in Turkey shall be 60% of the reference price as registered in the Ministry of Health's database, while, beginning with the [*launch of a*] first generic, a "selling price to the warehouses" up to 60% of the original product's reference price may be applied to all generics products. No drops in the reference prices occurring after the setting by the Ministry of Health of a price following the [*launch of a*] first generic shall be applied to the "selling price to warehouser" until such drop in reference price falls below the 60% threshold, while a "selling price to warehouser" up to 100% of the new reference price may be applied when the reference price falls below the 60% threshold. The same procedure shall be equally applied to generic products also. The selling price to warehouser of generic products may not be higher than the selling price to warehouser of [*their respective*] original products. In the case of "products packaged for hospital use", a retail selling price shall be determined no less than 10% below the unit price of the lowest-priced one of the product's other packaging forms which are sold at retail.~~

~~(3) This Decree shall not apply to any product which, by the Decree #2004/6781 dated 06.02.2004 of the Board of Ministers, has been granted the status of 20+ year old drug and whose selling price to warehouser is below 6.79 TL, or to any drug with a selling price to warehouser of less than 3.56 TL, any non-prescription drugs, blood products, medical baby-food products, radiopharmaceutical products and enteral nutrition products. Specific pricing procedures and principles of the foregoing products shall be announced by a communiqué by the Ministry of Health.~~

~~(4) Where new reference countries are designated on basis of the first paragraph hereof, a new declaration must be submitted for all currently marketed products or products which have an approved price. The pricing assessment committee shall be competent to reset, taking into consideration no more than 60% of the respective reference prices, the selling prices to warehouser of products whose reference prices are affected by these countries. The same procedure shall be applied to generic products whose prices are set according to the reference price of their respective originals or where their respective originals are unavailable in Turkey, by applying the reference system.~~

~~**ARTICLE 2** – (1) Each year, the Ministry of Health shall select minimum 5 and maximum 10 countries as "reference countries" among the countries of the European Union (EU) and announce these with a notification. The "reference countries" selected may be modified provided that this is announced four months in advance. The reference price is the "sale price to wholesalers". This price is the lowest sale price, except for the discount to wholesalers, of the original product which is registered and sold in the market in selected countries. However, the countries of manufacture or import of the relevant product shall be other than the reference countries and in case of a sale price to wholesalers which is below the reference country prices, the price of the country with a lower sale price to wholesalers shall be accepted as the reference price. The currency of the reference price shall be Euro. The Ministry of Health may use national and international databases in designating and following up the reference price and may also receive service in this area. It may adopt decisions for the verification and correction of the data used during the inspection and surveillance of the process.~~

~~(2) Original products may obtain a "sale price to wholesalers" provided that this price does not surpass the reference price. Whereas generic prices may obtain a "sale price to wholesalers" amounting to up to 80% of the reference price. For "hospital-packaged products", the retail sale price shall be designated in a manner so as to be 10% below that of the cheapest unit price of other packages of the product in retail sales.~~

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~~(3) The provisions of this Decree may not apply for products whose absence in the market might have a negative impact over public finance or may constitute a threat for public health, orphan drugs, drugs older than 20 years upon the Decision dated 6/2/2004, with No. 2004/6781 of the Council of Ministers, non-prescription drugs, blood products, formulae for medicinal purposes, radiopharmaceutical products and enteral nutritional products that are not included into the pricing system of EU member countries and the reference prices of which cannot be designated. The procedures and principles relating to the pricing of these products shall be announced by the Ministry of Health through a notification.~~

Price Evaluation Commission

ARTICLE 3 - (1) A "Pricing Assessment Committee" shall be established under coordination of the Ministry of Health with the participation of representatives from the Ministry of Finance, Undersecretariat of State Planning Agency, Undersecretariat of Treasury and the Social Security Institution to assess the prices of medicinal products. The Committee shall quarterly convene in ordinary sessions, or where necessary in extraordinary sessions upon the call of a representative of any entity represented on the Committee to adopt decisions on the procedures concerning implementation of the present Decree or on matters of raising, lowering or maintaining the present level of drug prices and to determine the "period Euro value" and the "period Euro value band" both used during setting of drug prices. The lower limit of the period Euro value band shall be the period Euro value while the upper limit of the band shall be 10% more than the lower limit value. No fluctuation in the currency exchange rates within the range of 5% lower than the lower limit of period Euro value band or 5% higher than the upper limit shall be admissible as grounds for a price change.

(2) Where the 90-day simple moving average value calculated daily on basis of the daily Euro currency selling rates applied by the Central Bank of Turkey which are announced as indicators in the Official Journal varies upward or downward more than 5% in excess of the upper or lower limit, respectively, of the "period Euro value band", the Pricing Assessment Committee shall upon the call of the Ministry of Health convene in an extraordinary session to reassess prices.

(3) Drug prices may be raised only up to the rates which shall be set by the Pricing Assessment Committee. Any revision of the price list shall be effective 5 working days ~~45 days~~ after its publication date. However, such holding period shall not apply to new products which are listed anew. In the case of voluntary price reductions by the companies, however, this holding period may be waived provided that the company concerned gives assurance that any losses incurred on pharmacy stocks shall be compensated. The secretarial services of the Committee shall be undertaken by the Ministry of Health.

~~**ARTICLE 3** - (1) A "Price Evaluation Commission" shall be constituted with the participation of the representatives of the Ministry of Finance, Undersecretariat of the State Planning Organization, Undersecretariat of Turkish Treasury and the Chairmanship of the Social Security Institute, under the coordination of the Ministry of Health, for the purpose of evaluating the prices of drugs. The commission will convene once every three months on an ordinary basis and on an extraordinary basis, where necessary, upon the invitation of the Ministry of Health, to adopt decisions relating to the procedures for the enforcement of the Decree and the increases, decreases or freezing of pharmaceutical prices and designate the "periodic Euro value" to be used in determining pharmaceutical prices. The secretarial services of the Commission shall be conducted by the Ministry of Health.~~

~~(2) In case of a modification of more than 5% for a period of 30 consecutive days on the "periodic Euro value" in the Euro Exchange Currency of the Central Bank of the Republic of Turkey, announced on the Official Gazette and acting as an indicator, the Price Evaluation Commission shall convene, on an extraordinary basis, upon the request of the Ministry.~~

~~(3) The prices of pharmaceuticals may only be increased at the rates to be designated by the Price Evaluation Commission. The amendments to be conducted on the price list shall become effective 45 days pursuant to the issue date. However, it will not be necessary to wait for the completion of this period for new products added on the price list. In price decreases applied by the companies upon their own will, it will not be necessary for the completion of the period provided that the relevant company commits to compensate for the losses to occur in pharmacy stocks.~~

~~**Reimbursement Commission**~~

~~**ARTICLE 4** - (1) A **"**Reimbursement Commission" shall be 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, for the purpose of designating the procedures and principles pertaining to reimbursement, upon receiving the views of the pharmaceutical industry and relevant non-governmental organizations as well. The directive stipulating the working procedures and principles of the Reimbursement Commission shall be published by the Chairmanship of Social Security Institute upon receiving the positive views of the Ministries of Finance and Health. The Commission shall convene once every 2 months on a regular basis and on an extraordinary basis, where necessary, upon the invitation of the Chairmanship of the Social Security Institute. The secretarial services of the Commission shall be conducted by the Chairmanship of the Social Security Institute.~~

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Price applications

ARTICLE 5 – (1) In their requests to obtain an initial price or a reference modification, registration holders or applicants shall apply to the Ministry of Health along with the Price Declaration Form. Applications for receiving an initial price shall be concluded within 60 days. This period may be extended by 30 days according to the work load. The responsibility for the accuracy of the submitted documents rests with the applicants. Registration holders who cause public loss upon their declarations shall be obliged by the Ministry of Finance and the Chairmanship of the Social Security Institute, to provide compensation, keeping reserved the provisions of the Turkish Penal Code no. 5237, dated 26/09/2004.

Reference price modifications

ARTICLE 6 – (1) In case the rate of the reductions to be applied on reference prices surpasses 3%, it shall be obligatory to notify this within 3 months and reflect it on the prices. In case the reduction rate exceeds 3%, this reduction has to be reflected onto the prices. Registration holders who do not announce price reductions exceeding 3% in total and do not apply for a price modification, shall be obliged by the Ministry of Finance and the Chairmanship of Social Security Institute, to compensate for the public losses to arise, keeping reserved the provisions of the Turkish Penal Code with No. 5237.

Profit rates

ARTICLE 7 - (1) The profits rates for wholesalers and pharmacies to be applied when designating the retail sale price of products shall be as indicated below. The Price Evaluation Commission holds the power to re-establish these rates upon taking into consideration the data in the Turkish Statistical Institute's manufacturer's prices of chemical substances, chemical products and man-made fibers of the previous year and the data on the distribution of the cumulative sales of medicinal products in the last three years.

Regarding the sale price to wholesalers;	**Wholesalers' Profit (%)**	**Pharmacists' Profit (%)**
The part up to 10 YTL (including 10 YTL.)	9	25
The part between 10- 50 YTL. (including 50 YTL.)	8	25
The part between 50-100 YTL. (including l00 YTL.)	7	25
The part between 100-200 YTL. (including 200 YTL.)	4	16
The part above 200 YTL.	2	12

Price modifications

ARTICLE 8 – ~~(1) In case the wholesalers' sale price of the original products already on the market or with an approved price on the date this Decision has been enforced remains below the lowest reference country price, the approved effective sales price to the wholesalers shall be fixed, except for the reductions and raises to occur due to updates in foreign currency, the reductions in the official sales prices to wholesalers in the reference countries or the price reductions applied upon the companies themselves and they will not be raised to the level of the reference price or any price in the range between the fixed price and the reference price.~~

~~(2) However, in accordance with the second paragraph in clause (d) of Article 13 in the Notification Regarding the Prices of Medicinal Products for Human Use, enforced upon being published on the Official Gazette dated 3/3/2004, with No. 25391, the right of companies that decrease prices upon their own will to raise their prices up to the fixed Euro value shall be kept reserved.~~

(3) The prices of products that should be available in the market on the ground of public health and products that provide cost saving in terms of public finance through market availability may be raised upon the decision of the Price Evaluation Commission.

Provisional Articles

PROVISIONAL ARTICLE 1- (1) 20 year-old drugs, other than those which, by the Decree #2004/6781 dated 06.02.2004 of the Board of Ministers, have been granted the status of 20+ year old drug and whose selling price to warehouser is below 6.79 TL, shall be priced according to the reference price until 01.01.2010 ~~April 30, 2010~~

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Power to issue notifications

ARTICLE 9 – (1) The Ministry of Health shall be authorized to issue notifications relating to this Decision.

Revoked legislation

ARTICLE 10 – (1) The Decision of the Council of Ministers, dated 6/2/2004, with No. 2004/6781 has been revoked.

Enforcement

ARTICLE 11 – (1) This Decision shall become effective as of 1/8/2007.

Execution

ARTICLE 12 – (1) This Decision shall be executed by the Council of Ministers.

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