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NOTIFICATION

From the Ministry of Health:

NOTIFICATION REGARDING THE PRICING OF MEDICINAL PRODUCTS FOR HUMAN USE

Purpose and legal basis

ARTICLE 1 – (1) The purpose of this Notification is to set forth the implementation principles of the Decision of the Council of Ministers Regarding the Pricing of Pharmaceuticals for Human Use with No. 2007/12325, enforced upon being published on the Official Gazette dated 30/06/2007, with No. 25568.

(2) This Notification has been prepared on the basis of Articles 11 and 43 of the Decree Law No. 181 Regarding the Organization and Duties of the Ministry of Health and Article 9 of the abovementioned Decisions of the Council of Ministers.

Definitions

ARTICLE 2 – (1) For the purposes of this Notification, the following definitions shall apply;

a) Allergen products: Products used to modify or define a specific immune response against an allergic agent,

b) Euro: The joint currency of the European Union,

c) Maximum price: The sale price of the relevant product, which is not to exceed the sale price to wholesalers in Turkey and is the cheapest price, excluding discounts, among the reference countries designated by the Ministry and the countries of origin or import of the relevant product,

d) Ministry: The Ministry of Health,

e) Similar product: Different pharmaceutical forms and/or unit amount of raw material and/or unit package amount of the same active substance/substances,

f) Pharmaceutical drug (product): Any natural and/or synthetic sourced active substance or combination of substances administered to humans for the purposes of curing and/or preventing a disease, performing a diagnosis, or improving, correcting or modifying a physiological function,

g) Wholesalers' sale price: The sale price of the product from wholesalers to pharmacies, excluding VAT,

h) Sale price to wholesalers: The official sale price to wholesalers, excluding VAT and discounts, of the reference product in the country/countries where it placed on the market and in case of non-availability of such a price, the sale price to wholesalers calculated upon deducting the VAT, pharmacy and wholesaler profit rates from the public sale price,

i) Periodic Euro value: The Euro value determined by the Price Evaluation Commission and to apply in the calculation of all pharmaceutical prices until the next period,

j) Pharmacies' sale price: The pharmacies' sale price of the product, excluding VAT;

k) Enteral nutrition products: Products used to compensate for insufficient nutritional intake and/or fulfill all nutritional value requirement in cases where the individual fails to take a sufficient amount of nutrition orally due to various reasons such as lack of appetite, various diseases and surgeries,

l) Equivalent product: Products which have the same active substance/substances, pharmaceutical form and unit amount of raw material (similar pharmaceutical forms like new technology products such as MR, SR, XR, CR, effervescents, ready-to-use syringes, pre-filled pens, ready-to-use cartridges; solid forms such as tablets, coated tablets, dragées; injectable forms such as vials and flasks, or liquid forms such as suspension and syrup shall be evaluated as the same pharmaceutical form provided that their grouping is performed by the Ministry),

m) Price declaration form: The form to be used by companies in their price applications, the format of which shall be drafted by the Ministry and to be completed by companies in accordance with the properties of their products

n) Price Evaluation Commission: The commission convening under the coordination of the Ministry of Health and constituted by one representative each from the Ministry of Health, Ministry of Finance, Undersecretariat of State Planning Organization, Undersecretariat of Treasury and Chairmanship of Social Security Institute;

o) General Directorate: The Pharmaceutical General Directorate,

p) Official web site of the General Directorate: The official web site (www.iegm.gov.tr) of the Pharmaceutical General Directorate,

q) Hospital packaged products: Large packed products to be used only in hospitals and priced accordingly,

r) Manufacture site: The country where the product is released (batch release) so as to be introduced into the market,

s) Discount: Any type of reduction applied by companies other than their official sale prices (discounts applied to reimbursement institutions, tender discounts and other commercial discounts, discounts applied so as to achieve

budgetary balance, special applications regarding product classification and discounts occurring as a result of special taxation applications);

t) Import location: The country where the product's final loading is conducted as defined in the control document,

u) Generic product: The product that has been registered/permitted by healthcare authorities on the basis of the original product, which contains the same active substance/substances with the original product and provides the same efficiency and safety;

v) Blood products: Products procured by public or private entities from human blood or plasma via industrial methods and based on blood components containing products especially such as albumen, immunoglobulin and coagulation factors,

w) Decision: The Decision of the Council of Ministers, with No. 2007/12325, Regarding the Pricing of Pharmaceuticals for Human Use,

x) The sale price to wholesalers obtained upon being proportionalized: The sale price to wholesalers proportionalized to Euro in products taken as reference and the price of which is in a foreign currency other than Euro, or the sale price to wholesalers in Euro to be calculated upon proportionalizing the package unit amount in the closest similar product according to the unit amount in the package of the product with no exact equivalent in the reference countries;

y) Original product: The product which has been registered/permitted so as to be introduced into the world market for the first time upon proving that it avails of scientifically acceptable efficiency, quality and safety in terms of active substance/substances;

z) Public sale price: The product's sale price from the pharmacy to the public, including VAT,

aa) Radiopharmaceutical products: Products prepared for medical use whose content, when ready for use, consists of one or more radionuclides,

bb) Non-prescription drugs: Drugs categorized by the Ministry as the class of drugs which may be sold without prescription,

cc) Reference price: The lowest official sale price to wholesalers, excluding discounts, declared on the price declaration form, of the relevant product relating to its original product registered and sold in the market in reference countries and countries of manufacture or import,

dd) Reference price change: The reductions to occur in the prices of pharmaceuticals for human use in reference countries (except for temporary price changes to occur as a result of the discount applications implemented so as to achieve budgetary balance, the prices to be achieved in tenders, special applications relating to product classification and special taxation applications);

ee) Reference countries: Minimum five, maximum ten countries to be designated each year by the Ministry among EU member countries on the basis of the Decision of the Council of Ministers with No. 2007/12325,

ff) Reference product: The original product taken as reference in the pricing of the product,

gg) Fixed Euro value: The Euro value designated upon calculating the sale price to wholesalers according to the periodic Euro value and to be used in all changes that may occur in the prices of products,

hh) Notification: The notification published on the basis of the Decision of the Council of Ministers, with No. 2007/12325,

ii) Infant formulae for medical use: Infant formulae and similar products specially manufactured in due compliance with the food codex and to be used under medical surveillance,

jj) Sale price to wholesalers in Turkey: The official sale price, excluding VAT and discounts, of the product introduced into the Turkish market by manufacturers or imports;

kk) Orphan drugs: Drugs used in diseases which have been specifically defined and exhibit a prevalence that may affect less than 100,000 persons in one country

ll)Twenty-year old drugs: Products any pharmaceutical form of which has been introduced into the world market for the first time before 1/8/1987,

mm) Directive: The document published upon being undersigned jointly by the representatives of the Reimbursement Commission so as to designate the working procedures and principles of the said Commission.

Reference countries and reference price

ARTICLE 3 – (1) EU candidate countries that are still within the membership process with the EU countries and whose membership has become certain within the present year may be selected as reference countries within the scope of this Decision. The reference countries for the following year will be announced by the Ministry via a notification no later than August 31 of the present year. In case no notification is published by August 31 of the present year, the reference countries of the present year shall apply also in the following year.

(2) Reference country selection will be made by the determination of various criteria such as product spectrum, common diseases, population, age distribution of the population, etc. Prices of reference countries shall be used as the

basis for the products to be priced in our country.

(3) The reference price shall be the lowest official “sale price to wholesalers”, excluding discounts, of the original product registered and marketed within the reference countries. However, if countries where the product is manufactured or from where it is imported are other than the reference countries and there is a designated sale price to wholesalers in these countries which is below the price in the reference countries, the price in the country where the sale price to wholesalers, excluding discounts, is lower shall be accepted as the reference price. In countries where there is no official sale price to wholesalers despite the fact that that the product is sold in the market, the sale price to wholesalers shall be obtained upon making a regressive calculation by deducting the VAT and official profit rates from the public sale price.

(4) Euro shall be used as the currency of the reference price. In case of a country where a different currency is used, conversion shall be made by using the Periodic Euro exchange rate designated by the Ministry upon utilizing the foreign exchange sale rate of the Central Bank of Turkey of the date when the periodic exchange rate is taken as basis. In countries for which the official foreign exchange sale rate of the Central Bank of the Republic of Turkey is not declared, in case of presence of the official representation of our country, the Euro conversion rate of the of the periodic Euro value on the application date of the currency pertaining to the relevant country shall be obtained from the concerned representation and adapted to the periodic foreign exchange rate. The official document to be obtained via this method shall apply for a period of 30 days.

(5) Official or generally accepted databases may be tracked by the General Directorate in tracking the changes in the prices of reference products in selected countries and to be utilized in the first issuance of the price or service may be procured from intermediary entities for conducting the referred tracking process. Explanatory information and documents shall be requested from the relevant company regarding all matters designated by monitoring the databases. A relevant transaction shall be conducted in the light of all information and documents submitted by the relevant company to the General Directorate.

Maximum prices in products

ARTICLE 4 – (1) Companies may request maximum 100% of the reference price of for original products.

(2) For generic products including those with no original in Turkey, companies may request maximum 80% of the reference price of the original product announced by the General Directorate.

(3) Hospital packaged products shall obtain a reference price according to the hospital packaged products in reference countries, including the country of manufacture and/or import, if available. In case of absence of an officially prices hospital packaged product in any of the reference countries including the country of manufacture and/or import, the cheapest unit price shall be designated among the other package types of the product sold to the public. A unit price which is at least 10% less than the referred price shall be determined. The public sale price will be determined upon multiplying the designated unit price with the package amount. The relevant company may request a price lower than this price.

(4) The General Directorate shall designate as maximum price the lowest price among the reference country prices. Any price request submitted by companies shall be evaluated in terms of conformity with the Decree the quality and content of the documents. Requests regarded as adequate will be approved by the General Directorate. Approved prices pertaining to products which have received a sales permit will be posted on the official web site of the General Directorate along with their date of validity.

Products which shall be priced upon being subjected to special conditions

ARTICLE 5 – (1) The pricing of the below-mentioned products shall be subjected to special conditions:

a) For products which avail of a price designated by the General Directorate but have not been brought into our country due to various economic reasons, and thus pose a threat for public finance and public health, a price designation may be conducted again via the documented decision of Price Evaluation Commission and by remaining below the prices calculated according to this Notification. In case of presence of other products used in the same indication, the closest current option shall be used as the basis. The price of the relevant product to be determined upon evaluating various aspects such as the price costs documents of the product for the request is made, the annual sale amounts and the prevalence of the disease, shall not be higher than the price of the product used as therapeutic equivalent for the relevant disease. Even if there is a very significant difference between the price of the product requested to be re-evaluated and the other product which is used in the same indication and is the cheapest, the new sale price to wholesalers to be determined upon taking as basis the price cost data shall not twice higher than the previous sale price to wholesalers. The prices of these products shall be revised each year upon making calculations over the sale amounts.

b) For twenty-year-old products, transactions shall be conducted with the current prices in Turkey. The fact that the product age has surpassed 20 years through time cannot be used as a justification for raising the price solely on the basis of this characteristic. The current fixed Euro values on the announcement date of the decision shall be

preserved. The reference pricing system will not apply on these products. The prices of products to be priced for the first time shall be determined within the framework of principles to be designated by the Price Evaluation Commission upon taking into account the prices of equivalent products used in the same indication. The prices of these products shall be revised each year.

c) The cheapest reference pricing system of the Decision shall not be implemented for non-prescription drugs. Transactions shall be conducted for these products regardless of whether they are original or generic. The price to be requested shall not be higher than the current highest sale price to wholesalers of the product in the reference countries. The prices of these products shall be revised each year.

d) The cheapest reference pricing system of the Decision shall not apply on plasma-derived blood products. For original and generic products, the reference price may be maximum 10% more than the reference country price where these products are cheapest so as to ensure competitiveness and product availability, without prejudice to the principles of the Decision. The prices of these products shall be revised each year.

e) The cheapest reference pricing system of the Decision shall not apply on infant formulae for medical purposes and enteral nutritional products. For original and generic products, the reference price may be maximum 5% more than the reference country price where these products are cheapest, with the decision of the Price Evaluation Commission, so as to ensure competitiveness and product availability, without prejudice to the principles of the Decision. The prices of these products shall be revised each year.

f) The prices of radiopharmaceutical products manufactured in Turkey and/or imported shall be designated by reaching a consensus between the relevant company and the Ministry upon taking into account pharmacoeconomic data. The prices of these products shall be revised each year.

g) The cheapest reference pricing system of the Decision shall not apply on allergy products. These products shall be priced upon adding maximum 5% more than the reference price indicated by official documents that have been procured from the source from which the products are brought. The prices of these products shall be revised each year.

h) These products shall be priced upon adding maximum 5% more than the price indicated by the cost documents in case they are manufactured and by the official documents procured from the source from which the products are brought. The prices of these products shall be revised each year upon making calculations over the annual sale amounts.

(2) Annual evaluations shall be made in November and December each year.

General rules to be abided in the pricing of original and generic drugs

ARTICLE 6 – (1) The following general aspects shall be complied with in the pricing of original and generic prices:

a) The rebates to be requested by companies for any form of a product shall not be applied on other forms of the relevant product without their own application.

b) In case the product is imported from a country other than the reference countries, and is registered and sold in the market of its import country and its sale price to wholesalers is lower than the reference price indicated on the declaration, the sale price to wholesalers in its country of import shall be taken as reference upon being calculated in line with the proportionalization methods indicated in this Notification.

c) In case the countries of import and manufacture of the product are different, the product is registered and sold in the country of manufacture and its sale price to wholesalers is lower than the reference price indicated on the declaration, the sale price to wholesalers in its country of manufacture shall be taken as reference upon being calculated in line with the proportionalization methods indicated in this notification.

d) In case the product is not available in the market of reference countries including the countries of manufacture and/or import, the cheapest sale price to wholesalers in the country among the EU countries where it is registered and marketed shall be taken as reference. If it is consequently registered in any reference country, including the countries of manufacture and/or import, and marketed with a sale price to wholesalers which is lower than the designated reference price, this shall be declared by the relevant company and the reference price will be re-designated.

e) For a product co-marketed with the original product, the same price applied on the original product may be issued. If the price of these products is lower than that of the original, it shall not constitute the reference price for generic products.

f) In case the proportional product price to be used in proportionalizing the different unit amounts of the same active substance is below the lowest reference price, no proportionalization shall be conducted among the forms of the product according to the current sale price to wholesalers in Turkey. The current prices shall be preserved. The prices of the products to be newly registered shall be designated according to the principles of this Notification.

g) In order for a product’s price in the reference countries to be accepted as reference, it shall be necessary for that product to be marketed in that country during the price application of the companies. The price of products

withdrawn from the market or the manufacture is which is discontinued that remain in the market until their stocks are consumed shall not be accepted as reference price. The presence or absence of the product in the market shall be declared by the relevant company during the price application. Information complied from databases constituted for different purposes shall not be taken as basis for this subject matter. In case the product in the reference country which designates the reference price is repealed from the market, the reference country and the reference price information shall be preserved until the reference country is amended.

h) The sale price to wholesalers approved for a product shall be the linearly proportionalized price until a lower price is requested for larger forms of this product to be registered consequently (except for price modifications to be envisaged for all products).

i) If the similar product is proportionalized, the reference price shall be designated upon making a linear proportion with the similar product containing the smallest amount of raw material among the reference countries including the countries of manufacture and import.

h) If the equivalent product is proportionalized, the reference price shall be designated by making a linear proportion firstly with the equivalent product containing the closest smallest package amount among reference countries and in case of absence of the small package, the closest large package amount.

i) Combined preparations shall be priced according to the reference pricing system. In case of absence of a reference product for combined preparations, the price to be obtained upon proportionalizing the combinations with the same active substance rates of sale price to wholesalers shall be accepted as the reference price. This price shall not be higher than the total of the unit prices of active substances. In case the combination is not available in the market in any one of the reference countries, the total of the reference prices of the active substances included into the combination shall constitute the reference price. If any substance does not avail of an individual reference price anywhere, the price for this combination shall be designated by the Price Evaluation Commission.

j) Applications submitted so as to obtain a price 60% lower than the average of the similar products available in the market including itself, for any product available in the market or to be newly introduced into the market, shall be evaluated by the Price Evaluation Commission for the purpose of preserving competition and market balances, and ensure the availability of the products.

Designation of the price of original products

ARTICLE 7 – (1) The prices of original products shall be designated as follows:

a) If the original product is registered in Turkey for the first time in the world, the price shall be determined upon reaching a consensus between the Ministry and the relevant company, by taking into account the pharmacoeconomic data. In parallel registration applications, in case of a pricing application to the other registration center, this application may be presented as an official document. If no application has been made to the other registration center in parallel application, the pharmacoeconomic data shall be presented.

Example: If the product is registered for the first time in the world, the current cost of treatment methods in the diseases where it is indicated and the specialist's report calculating the current therapeutic methods in the diseases where it is indicated as well as the therapeutic cost over the price requested shall be submitted together.

b) If the original product is registered in Turkey for the first time and in case of absence of an essentially similar package amount among the equivalent products available in the market of reference countries including the countries of manufacture and import and in case of absence of any comparable package amount, the lowest declared reference country price shall be accepted as the price of the product. For countries where the product is not available in the market, the statement "the equivalent of this product is not available in this country" shall be written in the remarks section of the price declaration form.

Example: For a product which is 5 mg, 5 tablets, 5 Euros, if the reference country is France and the reference price is 5 mg, 5 tablets, 5 Euros, and this product in the other reference countries, the requested price shall be accepted.

c) In case the original product is registered in Turkey for the first time and this product has the various package amounts of the same unit of raw material in the same pharmaceutical form in reference countries including the countries of manufacture and import, if available the product with the same package, if not available the closest smallest package and where that is not available up to 50% of the amount of product package for which a reference designation is made shall be taken into account for each reference country; the prices of products with a package amount 50% more shall not be taken into account. The statement "Only the product with a 50% larger package is available" shall be written in the remarks section of the price declaration form for the country in which the price information is not provided.

Example: For a 5 mg, 5 tablet product; if the reference country 1- France is 5 mg, 5 tablets, 5 Euros; the price of the reference country 2- Italy is 5 mg, 5 tablets, 6 Euros and 5 mg, 7 tablets and 7 Euros; the price of the reference country 3- Portugal is 5 mg, 15 tablets, 12 Euros, the French price shall be the reference price. As there is an essentially similar, 5 mg, 5-tablet package in Italy, the 7 tablet product shall be taken as reference and as there is a

package amount difference of more than 50% in Portugal, the 15 tablet product shall not taken as reference.

d) If the product is imported from a country other than the reference countries and it is registered and marketed in its country of import and the sale price to wholesalers is lower than the reference country prices indicated in the declaration, the sale price to wholesalers in the country of import shall be taken as reference.

e) If the countries of import and manufacture of the product are different, the product is registered and sold in the market of its country of import and its ex-factory sale price is lower than the reference price indicated on the declaration, the sale price to wholesalers in the country of manufacture shall be taken as reference.

f) In case the product has no equivalent in any reference country including the country of manufacture and import but avails of the same active substance and pharmaceutical form with the similar original product and has a different unit amount of raw materials, the price shall be designated upon being proportionalized according to the unit price. Products with large raw material amounts shall not be taken into account.

Example: For a 10 mg, 10 tablet product; if the price in the reference country 1- France is 5 mg, 5 tablets, 5 Euros; the price in the reference country 2- Italy is 5 mg, 5 tablets, 6 Euros and 20 mg, 10 capsules, 30 Euros and the price in the reference country 3- Portugal is 20 mg, 10 tablets, 25 Euros, the French price shall be the reference price. As the 20 mg. forms in Italy and Portugal contain a higher amount of raw materials compared to the 10 mg. form, they shall not be taken into account due to their large raw material amount.

g) If there is no similar product in the market of any reference country including the countries of manufacture and import of the product, the reference price shall be designated in line with the abovementioned principles among the countries where it is available in the market in the EU. In case it registered consequently in any reference country including the countries of manufacture and import and introduced into the market with an ex-factory sale price lower than the designated reference price, this shall be declared by the relevant company and the reference price shall be re-designated.

h)If the original product is registered for the first time in Turkey and this product has multiple, different package amounts containing the same unit of raw material in the same pharmaceutical form; first of all, both two or more package amounts should be proportional in terms of the unit amount and for the smallest package among these packages, its equivalent in the reference countries or the cheapest product's price among the smallest package amounts shall be taken as basis and proportionalized and the price will be determined upon proportionalizing the large packages with the small package form.

Example: For 5 mg, 5 tablets, 5 mg, 10 tablets, 5 mg 15 tablets, 5 mg, 5 tablets shall be priced first and the other 2 forms will be proportionalized to this form. For 5 mg, 5 tablets, if the reference price in reference country 1-France is 5 mg, 5 Euros and the reference price in reference country 2-Italy is 5 mg, 5 tablets, 6 Euros, the French price shall be the reference price. For 5 mg, 10 tablets, the price shall not surpass 10 Euros, whereas for 5 mg 15 tablets, the price shall not surpass 15 Euros.

j) Upon preserving the exception indicated in Article 6 (f) of this Notification, the linear proportion rates shall not be surpassed when pricing the product with the larger amount of raw material compared to the product with the smaller amount of raw material among different unit amounts of the same raw material. However, even if the product with a larger amount of raw material requests for a lower price, the price of the product with the smaller amount of raw material shall not be reduced.

Example: If the small form of the product is 5 mg, 5 tablets, 5 Euros, the price of 10 mg, 5 tablets shall not surpass 10 Euros. If 8 Euros are requested for 10 mg, 5 tablets, this price shall be granted, but the price of 5 mg, 5 tablets, 5 Euros shall not be changed.

Designation of the price of generic products

ARTICLE 8 – (1) The prices of generic products shall be designated as follows.

a) For generic products whose origins are defined, maximum 80% of the reference price of the original product which has been approved by the Ministry and announced, shall be designated as the reference price. Companies may request for a sale price to wholesalers which is below the said limit.

If the lowest price among the official sale price to wholesalers, excluding discounts, in the countries where the import generic product is manufactured, imported from or takes its pharmaceutical shape is 80% below the original reference price in Turkey, this generic product shall not receive a price which is higher than the lowest official sale price to wholesalers, excluding discounts, among the prices in the countries where it is manufactured, imported from or takes its pharmaceutical form.

The sale price to wholesalers of generic products shall not surpass the Euro value of their originals in Turkey, fixed on 15/06/2004, or the latest fixed Euro value constituted through the reductions in reference price after 15/06/2004, and, if available, the sale price to wholesalers of the other generic with the highest sale price to wholesalers in the market.

b) In case the generic product has no original in the Turkish market, its reference price in Turkey shall be determined by reference designation, within the framework of the procedures set forth in Article 6 of this Notification, as in original products. For these generic products, 80% of the official sale price to wholesalers, excluding discounts, in the reference countries shall be taken into account. The price of these generic products shall not surpass the sale

price to wholesalers in the country where they are manufactured, imported from or take their pharmaceutical form and, if available, the sale price to wholesalers of the other generic with the highest sale price to wholesalers in the Turkish market.

c) If the product has no reference in any country and the generic product will be launched only in the Turkish market, the price shall be designated by reaching a consensus between the Ministry and the relevant company, upon taking into account pharmacoeconomic data.

d) If any pharmaceutical form of the product (except for modified effect forms such as MR, SR and effervescents, blood products, vaccines and serums, enteral nutritional products and similar products) has been launched in the world 20 years ago, no reference price shall be sought for this product. The current official sale price to wholesalers in Turkey shall be preserved. However, if the original of the product launched in the world 20 years ago is available in Turkey, the price of the generic product shall not be higher than the Euro value of the original product fixed on 15/06/2004. In case of presence of other generic products in the market, the price of the highest priced generic product shall not be surpassed.

Price changes

ARTICLE 9 – (1) If the rate of reductions in reference prices exceeds 3% in total (including 3%), this shall be announced within 3 months. The changes to occur in the approved sale price to wholesalers in Turkey due to the change of reference price or reference country shall not be reflected on the price until they exceed 3%. The Ministry shall announce the change in the reference price on the official web site of the General Directorate within 7 days as of the notification date of the company. In the announcement, the new reference price, the date of modification and the relevant reference country shall be specified in the announcement. Companies manufacturing or importing generic products are obliged to apply to the Ministry within 7 days of the announcement date, so as to obtain a new price. In case of delay, the price shall be reduced ex-officio. In order to prevent any disruption due to official holidays, validity date shall be announced in advance.

Price evaluation commission

ARTICLE 10 – (1) The Price Evaluation Commission shall consist of representatives of the Ministry, the Ministry of Finance, Chairmanship of the Social Security Institute, Undersecretariat of the State Planning Organization and the Undersecretariat of Treasury.

(2) The commission will hold ordinary meetings every three months. In the ordinary meetings, the commission shall evaluate the prices of pharmaceuticals for human use in accordance with changes in economic indicators and make proposals to the Ministry of Health for the increase, reduction or preservation of the price of medicinal products. It shall designate the “Periodic Euro Value” to be used in the establishment of pharmaceutical prices.

(3) In case of a change exceeding 5% compared to the “Periodic Euro Value” for an uninterrupted period of 30 days in the Euro sale rate of the Central Bank of the Republic of Turkey, the Price Evaluation Commission shall hold an extraordinary meeting latest within one five work days, upon the invitation of the Ministry, and re-evaluate the prices of products.

(4) When a decision to reduce prices is adopted in relation with the foreign exchange rate, this decision shall be applied upon offsetting the difference between the reference values and the current values, on products whose sale price to wholesalers is lower than 3 YTL., original products whose price remains below the declared reference country price and generic products that have obtained a price which is 80% lower than the reference price. When a decision is adopted for increasing prices, the increase rates shall apply on all products that have been granted a price by the General Directorate. In this implementation, the requests of companies for applying reductions or not applying any price increases shall be taken into account.

(5) Implementation of changes in the price list shall start 45 days after being published. However, this period shall not be observed for products that are newly added to the price list. Furthermore, price reductions that are made due to reference changes or by the companies themselves upon their own will shall be enforced without waiting for the completing of this period so as to compensate for the losses to be incurred in pharmacy stocks.

(6) Other members of the commission as well as sectorial NGOs or companies may file a request with the Ministry for an extraordinary meeting of the commission.

(7) The secretarial services of the commission shall be carried out by the Ministry.

(8) The Ministry shall announce on the official web site of the General Directorate the changes in the reference price, price modifications, periodic Euro value, the prices of new products and products not available in the market.

Mode of application and the evaluation period

ARTICLE 11 – (1) For original and generic products, application shall be submitted along with the price

declaration form whose outline is drafted by the General Directorate and whose completion guideline is prepared.

(2) For original products, the price declaration form as well as the documenting indicating the product's price in reference countries shall be submitted to the Ministry. Price documentation prepared by the price authorities of relevant countries or the declaration letters to be signed by the authority in the country where the headquarters of the company is located shall be approved by the representation of the Turkish Ministry of Foreign Affairs. In placses where there is no such representation, the apostilled document approved by the notary-public of the relevant country shall be accepted.

(3) If the periodic Euro value indicated by the company at application and the periodic Euro value on the approval date are different, the reference price shall be designated according to the periodic Euro value on the approval date. For different foreign currency types, request shall be made to the Ministry according to the Periodic Euro Value upon making conversion according to paragraph 4 of Article 3.

(4) The Ministry shall designate the sale prices to wholesalers as defined in Article 7 of this Notification for original products and Article 8 for generic products.

(5) There is no obligation to submit Declarations in periodic modifications to be implemented through the decision of the Price Evaluation Commission. However, Declaration shall be submitted for modification requests for modifications other than the periodic modification rate. For original products, during the initial pricing request for the product, registration or application holders are obliged to prove that their products are original and document the sale prices to wholesalers in reference countries, along with the Price Declaration Form.

(6) Documents of the company applying for a price shall be reviewed and the 60-day pricing period shall start as of the application date for those applications where price declaration form information and enclosed documents are complete. Erroneous or incomplete application documents shall be returned upon indicating the relevant justifications, within 30 work days. Price related applications other than the initial pricing shall be finalized within 10 days.

(7) In case the changes occurring in the approved sale price to wholesalers in Turkey exceeds 3% due to the modification of the reference price or the reference country, this shall be reported to the Ministry and reflected on the prices latest within 3 months. It shall not be obligatory to reflect on the prices the reductions which do not exceed 3%.

(8) However, temporary price changes that may occur in reference countries in consequence to discounts applied for the purpose of achieving budgetary balance and which should not be interpreted as reduction in reference, the prices to be achieved in tenders, special applications concerning product categorization and special taxation procedures shall not be evaluated within the context of the reference price reductions mentioned in the Decision.

(9) The price correction requests of companies relating to the previously submitted price application made due to erroneous notifications made inadvertently and financial errors shall be finalized within 10 days, provided that they are documented and the previously announced price will be corrected and posted on the official web site of the Ministry. Such type of correction requests shall not be evaluated as a price increase within the scope of this Decision and Notification.

Tiered pricing

ARTICLE 12 – (1) According to the product's sale price to wholesalers, wholesaler and pharmacy profits shall be added separately to the figures corresponding to each tier established in the Decision so as to designate the wholesaler and pharmacy sale prices. The public sale price including VAT shall be designated by adding the VAT to the pharmacy price.

(2) Wholesaler and pharmacy profit rates to be used in the calculation of public prices of products shall be applied as follows. The Price Evaluation Commission shall be authorized to re-establish these rates considering the data on the chemical products wholesale price index of the previous year compiled by the Turkish Statistical Institute and the data on the distribution of total sales of medicinal products in the last 3 years.

In the sale price to wholesalers;	**Wholesalers' profit (%)**	**Pharmacists' profit (%)**
For the part up to 10 YTL. (including 10 YTL.)	9	25
For the part up to 10-50 YTL. (including 50 YTL.)	8	24
For the part between 50-100 YTL. (including l00 YTL.)	7	23
For the part between 100-200 YTL. (including 200 YTL.)	4	16
For the part above 200 YTL.	2	12

Liability

ARTICLE 13 – (1) Registration or application holders shall be liable to submit price declarations in line with

the principles established by the Decision and Notification, confirm accuracy of the information/document submitted to the Ministry and accept all responsibility arising from the consequences. In case a false statement is detected in the declarations, procedures shall be carried out in accordance with the Turkish Penal Code dated 26/09/2004, with No. 5237. Public losses incurred in case of information submitted in the Price Declaration Forms being false, or in case of reference reductions not being reflected on prices shall be compensated by the companies. The compensation procedure shall be established by the Ministry of Finance and the Chairmanship of the Social Security Institute. Public losses will be collected by the referred two institutes in line with the method established.

Exceptions

ARTICLE 14 – (1) The sale prices to wholesalers approved as of the enforcement date of the Decision have been fixed to the Euro value dated 15/06/2004 and will comprise the following exceptions:

a) If the approved price is below that of the reference country price, then it cannot be increased up to the reference price.

b) Prices may increase or decrease because of differences in exchange rates.

c) Reference reductions in reference countries shall be reflected on the prices.

d) Any price reduction offered by companies on their products upon their own will before the enforcement date of the Decision shall be deemed as an acquired right and they may increase prices up to level of the fixed Euro value. This right is earned in accordance with the second paragraph of clause (d) amended by the Notification published in the Official Gazette dated 04/03/2005, with No. 25745 of Article 13 of the Notification Regarding the Pricing of Medicinal Products for Human Use enforced upon being published on the Official Gazette dated 03/03/2004, with No. 25391.

e) The prices of products which shall be available in the market on the grounds of public health and products which provide savings for public finance through their availability in the market may be increased upon the decision of the Price Evaluation Commission.

f) The 45-day period for the commencement of the effectiveness of pharmaceutical prices shall be announced on the web site of the General Directorate. In case the 45th day coincides with a public holiday, the following first day of work shall be announced as the date of effectiveness.

f) A declaration may be submitted for a re-increasing the price for products subjected to the pricing procedure defined in items (c), (d), (f), (g) and (h) of Article 5 of this Notification.

Temporary Articles

TEMPORARY ARTICLE 1 – (1) The Periodic Euro Value to apply as of the enforcement date of the Notification shall be designated by the extraordinary meeting of the Price Evaluation Commission.

TEMPORARY ARTICLE 2 – (1) Before the enforcement date of the Decision and Notification, companies may submit a price application latest by 31/12/2007 along with a new price declaration for original drugs whose approved sale price to wholesalers in Turkey has decreased more than 3% compared to the reference countries as per the provisions of the Decision and for generic drugs with no original in Turkey. They may submit a price application for generic products within 10 days along with the price declaration form, in consequence to the announcement of the price of the original product on the official web site of the General Directorate. In these applications, the pharmacy profit for products with a sale price to wholesalers of more than 200 YTL. shall be reflected on the public sale price over the new rates.

TEMPORARY ARTICLE 3 – (1) For the years 2007 and 2008, France, Italy, Spain, Portugal and Greece shall be the reference countries.

TEMPORARY ARTICLE 4 – (1) The sale price to wholesalers of products whose profit rates to wholesalers and pharmacies have been reduced in accordance with the revoked Decision No. 2004/6781 of the Council of Ministers, but whose sale price to wholesalers has increased despite that fact that the public sale price remained the same as per the provision “It shall not surpass the prices of March 1, 2004” of the said Decision, shall be reduced to the current periodic Euro value of the sale price to wholesalers of 01/03/2004.

TEMPORARY ARTICLE 5 – (1) As the pharmacies’ profit rate of 10% in products over 200 YTL. in the revoked Decision No. 2004/6781has been re-arranged in Article 7 of the Decision No. 2007/12325 and increased to 12%, the new public sale prices shall be re-designated by submitting a declaration, upon by keeping fixed the sale prices to wholesalers and sale prices to pharmacies in this group of drugs and adding 2 points according to the tiered pricing rule on the previous sale prices to pharmacies. The new prices shall become effective 45 days pursuant to their announcement on the web page of the General Directorate.

Revoked legislation

ARTICLE 15 – (1) Notification Regarding the Prices of Medicinal Products for Human Use, enforced upon being published on the Official Gazette dated 03/03/2004, with No. 25391, has been revoked

Enforcement

ARTICLE 16 – (1) This Notification shall become effective on the date of its publication, as of August 1, 2007.

Execution

ARTICLE 17 – (1) The provisions of this Notification shall be executed by the Ministry of Health.