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NOTIFICATION

From the Ministry of Health:

NOTIFICATION AMENDING THE NOTIFICATION REGARDING THE PRICING OF PHARMACEUTICALS FOR HUMAN USE

ARTICLE 1 – Clauses (cc) and (hh) in Article 2 of the Notification Regarding the Pricing of Pharmaceuticals for Human Use published on the Official Gazette dated 22/09/2007, with No. 26651 have been amended as follows:

"cc) Reference product: The original product taken as reference in pricing the product (except for co-marketed products, co-promoted products and licensed products),"

"hh) Directive: The document published upon the consent of the institutes sending their representatives to the Commission for the designation of the Working Procedures and Principles of the Price Evaluation Commission,"

ARTICLE 2 – The third paragraph in Article 4 of the said Notification has been amended as follows.

"(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 priced 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 sale price to wholesalers of other package types of the product sold to the public. A unit price which is at least 10% less than this price shall be determined. The product's sale price to wholesalers shall be determined upon multiplying the designated unit price with the package amount. The relevant company may request a price which is lower than this price."

ARTICLE 3 – The first sentence in the first paragraph in Article 5 as well as clauses (b) and (d) in the said Notification have been amended as follows:

"(1) The pricing of the below-mentioned products shall be subjected to special conditions. The current prices of this group of products may be re-evaluated within the framework of designated special conditions, in case relevant application is made."

"b) For twenty-year old products, transactions shall be conducted with the current prices in Turkey. The current fixed Euro values on the announcement date of the decision shall be preserved. The reference pricing system shall not be applied when these products. Products with New/Advanced technology such as MR, SR and effervescents shall be subjected to the reference pricing system and will be excluded from the category of twenty-year old products. Official or generally accepted databases shall be used for information indicating that these products have surpassed 20 years as of the date specified in the definition of "twenty-year old products" in this Notification. However, this quality alone cannot be used as a justification for raising the price. When determining the sale price to wholesalers of twenty-year old original products to be priced for the first time, the reference price, if available, and in case of its absence, the cost data shall be taken into account and the reference country will not be tracked for these products. The sale price to wholesalers of twenty-year old generic products to be priced for the first time (excluding modified effect forms such as MR, SR and effervescents with a new/expensive technology, blood products, vaccines, serums, enteral nutritional products) shall not be higher than the Euro value

fixed on 15/06/2004 of the original drug in Turkey. The sale price to wholesalers of 20-year old generic drugs with no original in Turkey shall not surpass the reference price. The prices of these products shall be revised each year."

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

ARTICLE 4 – Clauses (f) and (g) in Article 6 of the said Notification have been amended as follows and clause (j) has been added:

"f) 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 whose manufacture is discontinued, but which 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 compiled from databases constituted for different purposes shall not be taken as basis for this subject matter. In case the reference price taken as basis in designating the reference price increases, the reference country and/or reference price information shall be updated, provided that the current sale price to wholesalers is preserved."

"g) The sale price to wholesale approved for a product shall be the linear proportionalized price for larger forms of this product to be registered consequently (except for the price amendments envisaged for all products) until a lower price is requested."

"j) The prices of products to be issued a different price upon making a distinction of products with or without a set, upon being a assigned a barcode, shall be evaluated as equal on the basis of products without a set and a set price which is 50 New Kuruş higher shall be assigned for products in a set."

ARTICLE 5 – Clause (c) in Article 7 of the said Notification has been amended as follows:

"c)) In case the original product is registered in Turkey for the first time and this product has 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, primarily products with a package of up to 50% larger than the product package amount for which a reference designation is made shall be taken into account for each reference country. In case of presence of products only with packages which are more than 50% larger in any reference country, including the country of manufacture and/or import, the product with the closest package shall be taken into account among these and a proportionalization will be performed. Hospital packaged products shall not be taken into account in the proportionalization."

ARTICLE 6 – The statement in clause (b) in Article 8 of the said Notification, which reads, "...and if available, the sale price to wholesaler of the other generic with the highest sale price to wholesalers available in the market..." and the whole of clause (ç) have been removed.

ARTICLE 7 – Paragraphs two and four in Article 10 of the said Notification have been amended as follows and the following paragraph has been added to the said article as paragraph nine:

"(2) The Commission will hold ordinary meetings once every three months. In its 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 pharmaceutical products. It shall designate the 'Periodic Euro Value' to be used in the determination of pharmaceutical prices."

"(4) When a decision to reduce prices is adopted in relation with the foreign exchange rate,

the products' sale price to wholesalers may be reduced down to 3 YTL. This decision shall not apply on products with a sale price to wholesalers which is lower than 3 YTL.; in case of original products whose price remains below the declared reference country price and generic products that have been granted a price which is less than 80% of the reference price, it shall be applied until it offsets the difference between the reference values and the current values. As the reference value may be 80% less than the reference price of the original product for imported and manufactured products, the reference price for importing or manufacture designated for the product shall be taken as basis in the offsetting transaction. 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."

"(9) The Directive Regarding the Working Procedures and Principles of the Price Evaluation Commission shall be enforced upon being posted on the official web site of the General Directorate within 4 months pursuant to the enforcement date of this Notification."

ARTICLE 8 – Paragraph two in Article 12 of the said Notification has been amended as follows:

"(2) Wholesalers' and pharmacies' profit rates to be applied in the designation of public sale prices of products shall be applied as follows. The Price Evaluation Commission shall be authorized to re-establish these rates upon 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 pharmaceuticals for human use in the last 3 years."

ARTICLE 9 – Clause (a) in Article 14 of the said Notification has been amended as follows and the term 'web' in clause (e) has been replaced with 'official web'".

"a) If the approved price is below the reference country price, the principles set forth in paragraph four of Article 10 in this Notification shall apply."

ARTICLE 10 – The date '31/12/2007' in Temporary Article 2 of the said Notification has been amended as '01/02/2008'.

ARTICLE 11 – The following sentence has been added to the end of Article 4 of the said Notification:

"However, this article shall not apply for original and generic products which remain below the declared reference country price."

ARTICLE 12 – The term 'web page' indicated in Temporary Article 5 of the Notification has been amended as 'official web site'.

ARTICLE 13 – The following article has been added as 'Temporary Article 6' of the said Notification:

"**TEMPORARY ARTICLE 6** – (1) For products encompassed by the definition of "twenty-year old drugs" in accordance with this Notification, the price implementation in twenty-year old drugs shall be made upon the application of paragraph four in Article 10."

ARTICLE 14 – This Notification shall become effective on the date of its publication.

ARTICLE 15 – The provisions of this Notification shall be executed by the Minister of Health.