

## **Turkey Amends its Legislation on Pricing of Human Medicinal Products**

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### **I - Introduction**

Early this year, on February 6<sup>th</sup>, 2017, the Ministerial Cabinet has published its decision on Pricing of Human Medicinal Products (“Decision”) and announced that the requirements of the Communiqué on Pricing of Human Medicinal Products (published in 2015) that do not conflict with the Decision, shall remain applicable.

This transition process has come to an end at the end of last week when, on September 29<sup>th</sup>, 2017, the Ministry of Health (“Ministry”) has published the new Communiqué on Pricing of Human Medicinal Products (“Communiqué”) on the Official Gazette.

Upon publication of the Communiqué, the predecessor Communiqué on Pricing of Human Medicinal Products (published in 2015 - “Abolished Communiqué”) has been abrogated.

### **II – What’s New?**

The Communiqué adopts a simpler and reader-friendly language regarding the technicalities of pricing principles, while governing Turkish drug pricing system and encouragement of domestic drug manufacturing. The most striking amendment introduced with the Communiqué is that the prices will be amended once a year, rather than the “twice a year” arrangement that was governed with the Abolished Communiqué.

Some of the other major amendments introduced with the Communiqué can be outlined as the following:

- The Communiqué, while preserving the reference countries as is<sup>1</sup>, has abandoned the “reference price” wording and introduced the “real source price” term. Although the mechanism behind the reference price calculation is preserved, its definition is now changed. Article 3 of the Abolished Communiqué defined the reference price as “*The lowest price of the source product in the reference markets and the market in the countries where the batch is released / imported, respectively, or the lowest price of the product on the market in EU countries, or the ex-factory price of the product on the market in any country in the world*”. Whereas, under Article 3 of the Communiqué real source price is described as “*Wholesale sales price of the product (announced in Euros in the price list) which is licensed and put on the market in the country of origin*”. Real source price will be calculated in line with the principles set forth under Article 5 of the Communiqué.

- As per Article 3 of the Communiqué “*Price (specified in Euros on the price list) which is the basis of the wholesale sales price in Turkey and is determined in line with the procedures in*

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<sup>1</sup> As per Article 4 of the Communiqué, reference EU countries are France, Spain, Italy, Portugal and Greece.

*this Communiqué*” will be accepted as the source price and its calculation will be made in accordance with Article 6.

- Pricing principles are regulated under Article 7 of the Communiqué. In this sense, compared to the Abolished Communiqué, it is clearly seen that the Ministry has developed and detailed the pricing principles.

- As to price increase requests, as per the Abolished Communiqué, price increase requests due to reference price increases up to 100% of the current ex-factory price, were assessed by the Turkish Medicine and Medical Devices Institution (“Institution”) and price increase requests of more than 100% were assessed by the Commission<sup>2</sup>. The Communiqué has amended this rule and regulated that,

(i) In the event of a change in the source country, an increase request of up to 20% of the current selling price to wholesalers, shall assessed by the Institution.

(ii) If there is no source country change, increase requests up to 50% of the current sales price to the wholesalers, shall be assessed by the Institution.

(iii) The increase requests more than the rates specified in subparagraphs (i) and (ii) shall be assessed by the Commission, if the application is made during the Commission evaluation period.

In this respect, the upper limit for an increase in the sales prices to wholesalers has been amended to 20 % where there is a change in the source country; and to 50 % in cases where this request does not result from a change in the source country prices. This will enable to control the effect of a change/increase in the source country prices on the prices in Turkey.

### **III - Transition Period**

The Ministry has announced its transition schedule under Provisional Article 1. In this respect, the sales prices to the wholesalers for the products falling within the scope of the provision of *“The changes in the selling price to the wholesalers approved in Turkey due to the reference price or reference country change shall not be reflected in the price unless it exceeds 3%. Only reference and reference country information shall be updated.”* abolished by the Decision will be updated during real source price amendment period of 2017, in line with their source prices. Changes which lead to an increase in the prices will be made upon the request of the license-holders, while changes which lead to a decrease will be made by the Institution *ex officio*. These updated prices will be effective as of the effective date of the final interim list issued at the end of the actual source price amendment period.

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<sup>2</sup> The Price Evaluation Commission established, under the coordination of the Ministry, with participation of the representatives of the Ministry of Finance, the Ministry of Development, the Undersecretariat of Treasury and the Social Security Institution.

Finally, amendments introduced with the Communiqué on real source price amendment period shall not be applied to real source price amendment period of 2017, except for paragraphs 1, 4, 5 and 7 of Article 10<sup>3</sup>. Provisions under the Abolished Communiqué will be taken into account for real source price amendment period of 2017.

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<sup>3</sup> Please see a detailed announcement of the Ministry on 2017 real source amendment period at this link: <http://www.titck.gov.tr/Duyurular/DuyuruGetir?id=3124>