Ministerial Decision No. oik.101933

Amendment of the Ministerial Decision No DYG3(a)/oik.97018/12 (OJ 2719/B/8-10-2012), as amended and in force

THE DEPUTY MINISTER OF HEALTH

Having regard to:

(...)

WE DECIDE AS FOLLOWS:

Article 6

Pricing of reference medicinal products after the expiry of the protection period under Article 10 para 1 subparagraph b of Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012)

1. After the verification by any appropriate method of the expiry of the 10-year or 11-year, as appropriate, protection period under Article 10 para 1 subparagraph b of the Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012), and respectively of the 6-year period for products authorised prior to the entry into force of Joint Ministerial Decision DYG3a/83657/2005 (Government Gazette B 59), the wholesale prices of reference medicinal products shall be reduced by 50%, without an application by the marketing authorisation holder.

2. Pharmaceutical companies must indicate in the Price Verification Sheet data on the medicinal product concerned, including full EOF-assigned code, start and expiry date of the first national or European patent protecting the active substance of the medicine, as well as the requested price. Otherwise, a fine shall be imposed by decision of the Minister of Health in accordance with the provisions of Law 3557/2007 and Article 69 of Law 3984/2011. Following the opinion of the Pricing Committee, any products that fail to comply with the aforementioned information requirement may be excluded from pricing.

3. At the first implementation of this Decision, the prices of products fallen out of protection (as defined in paragraph 1 of this article) shall be determined at 50% of the latest price assigned to the product while under protection, if such price is lower than

the latest published price in the Price Bulletin. Until EOF, in collaboration with recognised international and national agencies develops a full database with all necessary information, the price reduction of 50% for medicines whose patent protection expired from 2001 until 2005, applies on the highest price that has been assigned to them by a price bulletin until the expiry of the protection period. For the medicines of the present article, which have received at the price bulletin in force a retail price between €5 and €10, a price reduction of 5% on the retail price in force is applied, while respectively for the medicines which have received a retail price lower than €5 a 3% reduction is applied. The provisions of article 4 hereof apply to the categories of medicines that EOF will propose with the concurrent opinion of the Pricing Committee, i.e. to the medicines whose patent protection has expired but there are no generics marketed.

4. Ceilings on price reductions may be imposed, following a recommendation of EOF and with the concurrent opinion of the Pricing Committee, for low-cost or other special cases of medicinal products, with a view to protecting and keeping them in the market.

5. By an application submitted at the competent service, the marketing authorisation holder may request a lower price, without any restriction; such lower price shall be approved immediately through a supplementary/corrective Price Bulletin.

6. The final wholesale price shall be determined as the lower of the prices resulting under paragraph 1, paragraph 2 (adjusted to the wholesale price level), paragraph 3 and paragraph 5 of this article.

Article 7

Generic medicinal products

1. The wholesale prices of generic medicinal products shall be reduced to 40% of the latest price of the reference product under protection of the patent. At the first implementation of this Decision, the prices of existing generic medicinal products shall be determined at 40% of the latest price assigned to the reference patented product, if such price is lower than the price published in the latest Price Bulletin. Generics, for which the reference product has a retail price up to €10 in the Price

Bulletin in force, receive a retail price up to 80% of the retail price of the reference product after the expiry of the protection foreseen by article 10 par. 1 subparagraph b of the Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government's Gazette 2347/B/24.8.2012).

2. Generic products cannot have a price higher than 80% of the price of the reference products after the expiry of their protection period.

3. If the reference medicinal product has a different pack size or strength, a correlation shall be carried out in accordance with the provisions of Article 12 hereof. A similar correlation shall also take place when the price of the original product is priced in a different form or strength. In this case, the other cost parameters shall also be considered. When a generic medicinal product corresponds to a reference product not marketed in Greece, its price shall be determined in accordance with the provisions of Articles 5, 6 and 7 hereof, following a recommendation from the competent department of EOF and the opinion of the Pricing Committee.

4. For parenteral preparations, uniform prices shall be determined on the basis of the active substance, strength, pack size and other cost parameters.

5. By an application submitted at the competent service, the marketing authorisation holder may request a lower price, without any restriction; such lower price shall be approved immediately through a supplementary/corrective Price Bulletin.

We order that this Decision be published in the Government Gazette.

Athens, October 19, 2012

THE ALTERNATE MINISTER OF HEALTH

MARIOS SALMAS