HELLENIC REPUBLIC
MINISTRY OF ECONOMY
COMPETITIVENESS
AND SHIPPING
SECRETARIAT GENERAL OF COMMERCE
DIRECTORATE GENERAL OF INTERNAL COMMERCE
DIRECTORATE OF PRICES FOR INDUSTRIAL & MEDICINAL PRODUCTS
DEPARTMENT C

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Market Decree 07/2009

MARKET DECREE No. 8

SUBJECT: "Amendment of articles 334,336, 340 and 342 of Chapter 27 "MEDICINES" of Market Decree 7/2009 as in force"

Taking into consideration:

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We decide

Article 1

Amendment of Market Decree 07/2009

1. Article 334 of Market Decree 7/2009, as in force, is replaced as follows:

"Article 334

Medicinal products produced in Greece

1. For medicinal products which are authorized and priced in the Greek market and not in the other EU member states, their price will be determined on the basis of list of prices which includes the expenses of production and packaging for every form and package, the expenses of Administration-Distribution and Diffusion determined by relevant tables, updated every two years and calculated on the basis of the equivalent average cost of the sector.

The following are not considered as cost elements:

a) Default interests

b) Personal taxes (for example income taxes etc.)

c) Expenses for infringement of provisions in force

d) Prices of active ingredients of any supplier (except for researcher of active ingredient) higher than the sale price of the research house

e) Commission of third parties and other expenses not related to the production and disposal of medicinal products.

2. For those medicinal products, for which research for active ingredient or Greek valid patented pharmaceutical form has been conducted and for which clinical pharmacokinetic studies and an EOF's opinion are available, concerning the improved therapeutic result, the value of new investments, the expenses of research and development of the active ingredient or the pharmaceutical form will be taken into account in the determination of the prices as well as the evaluation of the know-how. Cases of similar pharmaceutical forms are excluded.

3. The highest percentage of net profit is determined to 8,5% and is calculated on the total cost, while repayment, interests and profit of third parties for custom made are excluded".

2. Article 336 of Market Decree 07/2009, as in force, is **replaced** as follows:

"Article 336

Inquiry on sale prices- Price determination of medicinal products

1. The prices of medicinal products in the internal market are determined by the competent Department of the Secretariat General of Commerce, following the conduct of an investigation in the member states of the European Union (E.U.) where the medicinal product is marketed. The sale price to wholesalers shall be taken into account, resulting from the average of the three (3) lowest prices of the medicinal product in the member states of the European Union (E.U.) in which official data exist and which are officially announced by the competent authorities of these countries. The E.U. countries for which official data exist are announced in the 1st Price Bulletin each year. The medicinal product must have obtained a price in the same form and strength, in at least three (3) of the member states of the European Union. Especially for medicinal products designated as orphan in the marketing authorization as well as for blood derivatives, the Pricing Committee issues an opinion both on the price determination method as well as on their price.

2. The data for the price determination of each medicinal product are the following: a) active ingredient of the medicinal product, b) pharmaceutical form, c) strength of active

ingredient in the appropriate measurement unit for every medicinal product, d) the package of the medicinal product, e) the marketing authorization holder or the patent holder of the medicinal product, f) the name of the medicinal product, g) the classification of the medicinal products according to the Anatomic Therapeutic Chemical classification (ATC) of the World Health Organization, h) the wholesale price or/and the retail price or/and the sale price of the medicinal product to the wholesalers (ex-factory) according to the availability of the data in every EU member state.

3. The Department of Prices of Medicines of the Directorate of Prices for Industrial and Medicinal products of the Secretariat General of Commerce collects the above data for the pricing of medicinal products from the official sources of the EU member states, such as competent Ministries or other official authorities and bodies. The access to these sources for the collection of data is obtained through specialized websites of the official sources of every EU member state. In case the access through the websites of the competent Ministries or other official authorities and bodies is not possible or the collection of the above data from these sources is incomplete, then the entire or remaining data needed for the calculation of the price of medicinal products are detected in objectively reliable sources by the Department of Prices of Medicines of the Directorate of Prices for Industrial and Medicinal products of the Secretariat General of Commerce in collaboration with the National Organization for Medicines (EOF) or the Institute of Pharmaceutical Research and Technology (IFET). Before the issuance of the relevant Price Bulletin, the competent service of the Secretariat General of Commerce publishes the sources of the prices on its website.

4. Based on evidence of par.2 of the present article, the Department of Prices of Medicines of the Directorate of Prices for Industrial and Medicinal products of the Secretariat General of Commerce proceeds to a correlation of the medicinal products approved and marketed in the member states of the European Union (EU). For this correlation are taken into consideration additively the criteria b), c) and f) of par.2 of the present article. In case of non availability of the criterion f), are used additively the criteria a), b), c) and e). After the application of the procedures of the above paragraph, follows a localization of the medicinal products approved and marketed in the member states of the European Union (EU), which as to the criterion d) of par. 2 of the present article fully correspond to the medicinal products approved and marketed in the Greek market. In case such medicinal products cannot be localized in a country, then medicinal products with different packaging are localized and then compared and converted according to the provision of par. 3 and 4 of the present article 342. For the correlation and comparison

among medicinal products approved and marketed in the Greek market and medicinal products approved and marketed in the member states of the European Union (EU), the packages exceeding by four times the correspondent Greek package of the same medicinal product are taken into consideration, except the medicinal products of par. 2 of article 12 of L. 3816/2010 (OJ 6/A/26.01.2010). The above mentioned paragraph does not apply for the correlation and comparison of injectable medicinal products as well as in case the approved and priced in EU member states package of the medicinal product is unique and equal or four times superior to the equivalent Greek package of the same medicinal product.

5. For the conversion of prices of medicinal products from another currency to Euro (€), as far as the medicinal products approved and priced in EU member states not belonging to the Eurozone are concerned, the Department of Medicines' Prices of the Directorate of Prices for Industrial and Medicinal Products of the Secretariat General of Commerce refers to the official Euro exchange rates to other currencies, as reported in the official data announced by the National Bank of Greece the first working day of a two months period prior to the issuance of the relevant Price Bulletin.

6. In order to effect an investigation, the interested companies are requested to submit a price investigation form – solemn declaration to the competent Service of the Secretariat General of Commerce, that includes: a) the member states of the European Union (EU) in which the medicinal product whose price is to be determined , is marketed b) the name, the packaging, the active ingredient, the strength of active ingredient, the classification of the medicinal products according to the Anatomic Therapeutic Chemical classification (ATC) of the World Health Organization and the pharmaceutical form in which is marketed the apposite medicinal product. These data are submitted in printed form to the above mentioned service and in electronic form at: farmaka@gge.gr.

7. The price of the medicinal products is re-evaluated and re-priced by the Service three (3) times yearly, in accordance with par. 1, 2, 3, 4, and 5 of the present article. To this end the interested companies send price investigation forms of their medicinal products - solemn declarations as described in par.6 of the present article, without including the prices, in electronic from to the address farmaka@gge.gr of the competent Office of the Secretariat General of Commerce, the latest forty-five (45) calendar days after the announcement of the release date of each Price Bulletin at the website of the Secretariat General of Commerce.

8. Companies concealing or refusing to provide or supplying inaccurate or false data and information, are punished with a fine equal ten times the difference between the resulting price from the data submitted by the pharmaceutical company and the price

determined by the Service, multiplied by the quantity of the medicinal products sold for as long as the approved price was applied. The imposition of this fine, according to this paragraph, is independent from the claim of the Social Insurance Funds for damages incurred from the aforementioned difference in the price of the medicinal product.

3. Par. 1 of article 340 of the Market Decree 07/2009, as in force, is **replaced** as follows: "1. For the determination of the price of medicines, for which a market authorization has been issued by the National Organization for Medicines (EOF) or the European Medicines Agency (EMEA), or their price change, the submission of a relevant application is required. These applications are submitted to relevant Service of the Secretariat General of Commerce or send in electronic form to the address farmaka@gge.gr, the latest forty-five (45) calendar days from the date of issuance of each Price Bulletin at the website of the Secretariat General of Commerce".

4. Par. 6 of article 342 of the Market Decree 7/2009, as in force, is **replaced** as follows: "6. The approved prices are published in a Price Bulletin, following the opinion of the Pricing Committee of Medicines. The possibility of submitting their remarks on the resulting prices of the medicinal products, within two (2) working days counting from the next day of the meeting of the Pricing Committee, is provided to the interested parties after they take note of the suggested prices. This period of time is extended by two (2) working days for the Price Bulletins that reevaluate and re-price the medicinal products. The remarks of the interested parties will be examined and taken into consideration in case a corrective Price Bulletin is eventually issued within twenty (20) days."

Article 3

1. For the saving of resources of the Social Insurance Funds in view of the forthcoming implementation of a reimbursement list, as well as for the smooth adjustment of the market to the new pricing system of the medicinal products, after the time of entry into force hereof and until 31/03/2011, the maximum variations of the wholesale prices of the medicinal products resulting from the issuance of the 04/2010 Price Bulletin, may not exceed the percentages per price set in the following scale:

Wholesale Price of the Medicinal Product applied until the issuance of the 01/2010 Price Bulletin	Maximum Percentage limit of Reduction of the Price of Medicinal products in confront of the Price applied until the issuance of Price Bulletin 01/2010	Maximum Percentage limit of Increase of the Price of Medicinal products in confront of the Price applied until the issuance of Price Bulletin 01/2010
Up to 3 €	- 15 %	+ 10%
From € 3,01 up to € 5	- 20%	+ 10%
From € 5,01 up to € 10	- 25%	+ 5%
From € 10,01 up to € 15	- 30 %	+ 5%
From € 15,01 up to € 40	- 35 %	+ 5 %
From € 40,01 up to € 50	- 40 %	+ 5 %
From € 50,01 and above	According to the provisions of art. 336,337,338 and 342 of the Market Decree Code (a maximum limit in the percentage of Decrease does not apply)	+ 5%

Article 4

The present Market Decree will be announced in the Daily Press and published it in the Official Journal of the Government. The present will enter into force starting from the next day after its announcement in the Daily Press.

The Minister

of Economy, Competitiveness & Shipping

Louka T. Katseli