

No 49135

HELLENIC REPUBLIC

MINISTRY OF ECONOMY, COMPETITIVENESS AND SHIPPING

Athens, 29/04/2010

Reference no: A3-1162

General Secretariat of Trade

General Secretariat of Internal Trade

Directorate of Prices for Industrial and Medicinal Products

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Price Control Order 07/2009

PRICE CONTROL ORDER no. 3

SUBJECT: "Amendment of articles 331 and 333 of Chapter 27 on "Medicinal Products" of the Price Control Order 7/200, as currently in force and replacement of article 2 of the Price Control Order 2/2010"

Having regard to:

1. Article 90 of the Legislation Code for the Government and Governmental Bodies, ratified by the first article of the Presidential Decree 63/2005 (Government Gazette 98/A/2005);
2. Legislative decree 96/73, as amended by the Law 784/78, Law 1316/83 (G.G. 3/A/11.1.1983) and Law 1965/91 (G.G. 146/A/29.9.1991), Law

Μεταφραστική Υπηρεσία Υπουργείου Εξωτερικών, Αθήνα

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Service de Traductions du Ministère des Affaires Etrangères de la République Hellenique,
Athènes

1969/91 (G.G. 167/A/30.10.1991), Law 2992/02 (G.G. 54/A/20.03.02), Law 3408/05 (G.G. 272/A/4.11.05), Law 3730/08 (G.G. 262/A/23.12.2008), Law 3790/09 (G.G. 143/A/7.08.2009), Law 3816/2010 (G.G. 6/A/26.1.2010) and Law 3840/2010 (G.G. 53A/31.03.2010);

3. Legislative Decree 136/1946 (G.G. A298) on "Price Control Code";

4. Presidential Decree 397/88 on the "Bylaws of the Ministry of Trade", as later amended;

5. Presidential Decree 185/09 "Reestablishment of the Ministry of Finance, consolidation of the Ministry of Economy and Finance with the Ministry of Development, the Ministry of Mercantile Marine and the Ministry of the Aegean and Island Policy and its renaming into Ministry of Economy, Competitiveness and Shipping, conversion of the Ministry of Macedonia – Thrace into General Secretariat of Macedonia – Thrace and subjection of the General Secretariat of Macedonia – Thrace and the General Secretariat of the Aegean and Island Policy into the Ministry of Interior";

6. Presidential Decree 187/2009 "Appointment of Ministers and Deputy Ministers";

7. Law 2026/92, article 4, paragraph 1 (G.G. 43/A/23.3.1992) on organization and staff issues in Public Administration;

8. Law 3408/05, article 13 (G.G. 272/A/4.11.2005);

9. Law 3260/2004 (G.G. 151/A/06.08.04) "Issues of Public Administration";

10. Price Control Order 07/2009 on "Codification of Price Control Orders issued up to 14/05/2009", as currently in force as well as Price Control Orders 08/2009 and 2/2010;

11. The necessity to amend some articles of the Price Control Order 7/09 related to medicinal products, within the framework of unhindered trade-distribution-marketing of the product;

12. The necessity to replace article 2 of the Price Control Order 2/2010, due to emergent and imperative public interest which calls for a transitional

regulation with the temporary amendment of wholesale prices for medicinal products, provided that:

a. According to document no. A3/1087/27-4-2010 issued by the Directorate of Prices for Industrial and Medicinal Products, on the survey of medicinal products prices in all EU countries during the last four years and based on the average of the three (3) lowest prices for medical products in the EU Member-States, it has emerged that a remarkable part of the medicinal products released in Greece have extremely higher prices than those prevailing in other EU countries.

b. There is a necessity to temporarily regulate the prices of medicinal products because of the financial difficulties that the country faces, caused by its public deficit and debt, which pose the risk of viability of Insurance Funds, against both insured persons and public health and interests of pharmaceutical companies which are suppliers of Insurance Funds as well as against National Economy.

c. According to document no. 774/16-03-2010 issued by the Pan-Hellenic Association of Pharmaceutical Industries, it emerges that the aforementioned association recommends and accepts discounts on medicinal products prices by fifteen per cent (15%).

13. The assent no. ΔΥΓ3(α)/οικ. 50622 rendered by the Minister of Health and Social Solidarity, dated 29/04/10

The fact that no expenses are incurred by the regulation hereof against the State Budget

We Decide

ARTICLE 1

Amendment of Price Control Order 07/2009

1. Paragraph 4, point a, article 331 of the Price Control Order 07/2009, as replaced by article 1 of Price Control Order 2/2010 (Government Gazette 380/B/01-04-2010) is hereby replaced as follows:

The maximum hospital price of medicinal products is the sale price applied to the State, Public Hospital Institutions supervised by the Ministry of Health and Social Solidarity and the Ministry of Labor and Social Insurance and dispensaries of Private Clinics. Such price is the wholesale price reduced by 13%. Such price shall also apply for the sale by manufacturer or packager or importer to private pharmacies of the medicinal products, specified in paragraph 2, article 12, Law 3816/2010 (G.G. 6/A/26-01-2010)."

2. Article 331 of Price Control Order 07/2009, as replaced by article 1 of Price Control Order 2/2010 (G.G. 380/B/01-04-2010), is supplemented by paragraph 9, as follows:

"9. In particular for the medicinal products of paragraph 2, article 12, Law 3816/2010 (G.G. 6/A/26-01-2010), their retail price from private pharmacies to beneficiaries is their hospital price, increased by the pharmacist's legal profit and VAT.

Such medicinal products are charged by public hospital dispensaries to Social Insurance Institutions and the Civil Service Insurance Organization (OPAD) in their wholesale price, superadded by 3% plus all legal charges".

3. In article 333 of Price Control Order 07/2009, as replaced by paragraph 3, article 1 of Price Control Order 2/2010 (G.G. 380/B/01-04-2010), paragraph 2 is replaced as follows:

"Manufacturers, packagers and importers may provide: a) additional discount on hospital prices to the State, Public Hospital Institutions, Institutions supervised by the Ministry of Health and Social Solidarity and the Ministry of Labor and Social Insurance and dispensaries of Private Clinics, b) additional discount up to 5% to medicinal product traders, pharmacies and their associations on wholesale prices, provided that such discount is mentioned on their sale invoice."

ARTICLE 2**Replacement of article 2 of Price Control Order 02/2010**

a) From the following day that this Order is published in the daily press up to the issuance of the next Price List for Medicinal Products, which shall be issued according to this order and any amending Price List for Medicinal Products that shall be issued based on the provision of case c' hereof, wholesale prices of medicinal products are specified as follows:

Wholesale Price of a Medicinal Product, as being in force up to the effective date hereof	Percentage of change in Medicinal Products Prices in comparison to their Price which was in force up to the effective date hereof
From 100.01 € and above	-27 %
From 50.01 € up to 100 €	-25 %
From 20.01 € to 50 €	-23 %
From 5.01 € to 20 €	- 20 %
From 1.01 € to 5 €	-3 %
From 0 € to 1 €	0 %

b) The aforementioned regulation of point a' shall not apply to orphan medicinal products and blood derivative products. For such medicinal products, price definition method as well as their price shall be specified under an opinion of the Committee of Medicinal Products Prices.

c) Within ten days from the effective date of the Price List for Medicinal Products, pharmaceutical companies shall be entitled to submit to the competent authority an application for remedy, accompanied by the supporting pricing information.

d) Sale prices of medicinal products that are in force at the effective date of this price control order shall remain in force for fourteen (14) days for

medicinal products stores and twenty (20) days for pharmacies, from the effective date of this price control order.

ARTICLE 3

This Price Control Order shall be published in the daily press and the Government Gazette. This order shall enter into effect on the date following its publication in the daily press.

THE MINISTER OF ECONOMY, COMPETITIVENESS AND SHIPPING

Louka T. KATSELI

True photocopy of the original, certified by Giannis CHRYSOSPATHS,
Solicitor, Athens, 06/05/2010

(Signature – Seal)

Exact translation from the certified photocopy in Greek

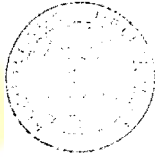
Athens, 11/05/2010

The translator, Elena ASIMAKI



REPUBLIQUE HELLENIQUE
MINISTRE DES AFFAIRES ETRANGERES
Vu pour l'original de la signature ci-dessus
du Traducteur du Ministère des Affaires
Etrangères ayant traduit le texte ci-annexé.

Athènes le, 12 MAY 2010



PAR DELEGATION DU MINISTRE
Le Directeur adm.

ARGYROU ELENI
Fonctionnaire Admin.

