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### DECISIONS

#### **Decision No οικ.38733**

Amendment of Article 14, par. 2 of the Ministerial Decision No 3457 (Gov. Gazette 64/B/16-01-2014) “Regulation of issues concerning the pricing of medicinal products”

### THE MINISTER OF HEALTH

Having considered:

1. The provisions of article 14, par. 3 of Law 3840/2010 (Gov. Gazette A’ 53).
2. The provisions of article 90 of the P.D. 63/2005 “Codification of legislation for the Government and Government bodies” (A’ 98).
3. The P.D. 119/2013 “appointment of the Vice-President of the Government, Ministers, Alternate Ministers and Deputy Ministers” (Gov. Gazette A 153).
4. The provisions of the L.D. 96/1973 and mainly article 17 as amended and in force (Gov. Gazette A 172).
5. The provisions of the L.D. 136/1946 “for the Market Police Code” (Gov. Gazette A’ 298), as amended and in force.
6. The provisions of article 13 of Law 3408/2005, as amended and in force (Gov. Gazette A 272).

7. The provisions of Law 3842/2010 (Gov. Gazette A 58) as amended and in force.
8. The provisions of article 4 par. 2 of Law 3899/2010 (Gov. Gazette A 212), for the amendment of VAT Code.
9. The provisions of article 32 of Law 1316/1983 “Establishment, Organisation and competencies of EOF” (Gov. Gazette A 3), as already amended and in force.
10. The provisions of the P.D. 95/2000 “Organisation of the Ministry of Health and Welfare” (A’ 76), as amended and in force.
11. The provisions of articles 38, 39, 40 and 51 of Law 3918/2011 (Gov. Gazette A 31) as amended and in force.
12. The provisions of articles 11, 16, 17 19, 20, 21 and 23 of Law 4052/2012 (Gov. Gazette A 41).
13. The Joint Ministerial Decision (KYA) No ΔΥΓ3α/Γ.Π.32221/2013 (Gov. Gazette 1049/B/29.4.2013), “approximation of Greek legislation to the respective European one in the area of production and marketing of medicinal products for human use, in compliance with the directive 2001/83/EC “on the Community code relating to medicinal products for human use (Law 311/28.11.2001) as in force and as amended by the Directive 2010/84/EU, regarding pharmacovigilance (Law 348/21.12.2010) regarding pharmacovigilance.
14. The Ministerial Decision No ΔΥΓ3(α)/οικ.86767/10.9.2012 “Revocation of the decision for the application of competencies to EOF regarding the pricing of medicinal products” (Gov. Gazette B 2462).
15. The Ministerial Decision No ΔΥΓ3(α)/οικ.94274/28.9.2012 “Application of article 15 in Law 4052/2012” (Gov. Gazette B 2675).
16. The Ministerial Decision No 3457 (Gov. Gazette 64/B/16-01-2014 “Regulation of issues concerning the pricing of medicinal products.
17. The Ministerial Decision No 325/5851/Γ.Π. (Gov. Gazette 88/B/21-01-2014) on “Provisions for Pricing of Medicinal Products”.
18. The provisions of the Ministerial Decision No 22405 (Gov. Gazette 740B/26-03-2014) “Approval of the positive list set out in article 12 par. 1 clause a of Law 3816/2010, as amended and currently in force”.
19. The provisions of article 12 of law 3816/2010 (Gov. Gazette A/26-01-2010), as supplemented by par. 5 of article 63 of Law 3918/2011 (A’31) and the provisions of article 51 of law 3918/2011 (A’31).
20. The Ministerial Decision No Γ.Υ./ΟΙΚ 6161 (Gov. Gazette 2761/B/30-10-2013).

21. The Ministerial Decision No ΔΥΓ3(α)/οιλ.104744, as amended by the Ministerial Decision No ΔΥΓ3(α)/οικ.19389 (Gov. Gazette 3356/B/17-12-2012) according to the Ministerial Decision No 82961 9Gov. Gazette 2219/B/09-09-2013).

22. The provisions of article 22 of Law 4213/2013 (Gov. Gazette 261/A7/9-12-2013).

23. Article 34 of Law 4025 (Gov. Gazette 228/A/2-11-2011).

24. Article 24 of article 127, par. 6 of Law 4249/2014 (Gov. Gazette 73A/24-03-2014).

25. Order No ΓΥ/ΟΙΚ.2567/29-04-2014 of the Minister of Health.

The fact that no expenditure is incurred against the State Budget from this decision, we decide:

Paragraph 2 of article 14 of the Ministerial Decision 3457 (Gov. Gazette 64/B/16-01-2014) is substituted by the following paragraph: The classification of medicinal products in clusters with the same active substance and pharmacotechnical form is made in accordance with the provisions of articles 1 and 2 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744 (Gov. Gazette 2912/B/30-10-2012) as amended by the Ministerial Decision 82961 (Gov. Gazette 2219/B/09-09-2013). The reference price in each cluster with medicinal products with the same active substance and pharmacotechnical form is determined for every available alternative content (strength). In order to calculate the Reference Price, the provisions of article 3 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744 (Gov. Gazette 2912/B/30-10-2012) as amended by the by the Ministerial Decision No ΔΥΓ3(α)/οικ.19389 (Gov. Gazette 3356/B/17-12-2012) and Ministerial Decision 82961 (Gov. Gazette 2219/B/09-09-2013). In order to calculate the Reference Price, the provisions of par. 2 of article 3 of the Ministerial Decision No ΔΥΓ3(α)/οικ.19389 (Gov. Gazette 3356/B/17-12-2012) apply on generics with a lower daily treatment cost (DTC), that account for 20% of the total sales in terms of volume of generics of the specific cluster, per strength. More specifically, the generics are classified based on the DTC in increased order, starting from the medicinal products with the lower DTC and continuing to the immediate next, until the medicinal product with the highest DTC. The Reference Price results next, as the weighted average of the generics with the lower DTC that account for 20% in sales during the last six months before the calculation of the prices, among the generics of the occasional cluster and per strength. Sales derive based on the expenditure for EOPYY. In case the patient selects a medicinal product

with a retail price that coincides with the insurance price, the patients may the enacted participation percentage. In case a medicinal product with a retail price higher than the one reimbursed is selected, the patient covers, apart from his/her enacted participation, the total difference between the reimbursement price and the retail price of the medicinal product. In the cases where the retail price of the medicinal product is lower than the reimbursement price, the difference between the retail price and the reimbursement price is deducted from the enacted participation of the patient provided for, up to the half thereof.

This Decision must be published in the Government Gazette.

Athens, April 29, 2014

The Minister

SPYRIDON-ADONIS GEORGIADIS

**Decision No οικ. 38714**

Provisions for the sale and pricing of OTC medicinal products

**THE MINISTER OF HEALTH**

Having considered:

1. The provisions of article 2 par. 5 of Law 1316/1983, as substituted by article 1 of Law 1965/1991 and the provisions of article 9, par. 7 of Law 1965/1991.
2. The Ministerial Decision No οικ.101754 (Gov. Gazette 2840/B/07-11-2013) “Updated List of OTC Medicinal Products”.
3. The Ministerial Decision No ΔΥΓ3α/127858 (Gov. Gazette 284/B/05-02-2004) “Terms and conditions for the marketing of medicinal patent medicines, for whose sale “no medical prescription is required” (OTC).
4. The P.D. 187/2009 (A 214).
5. The P.D. 189/2009 (A221).
6. The Ministerial Decision No 3457 (Gov. Gazette 64/B/16-01-2014 “Regulation of issues concerning the pricing of medicinal products.
7. The Ministerial Decision No 325/5851/Γ.Π. (Gov. Gazette 88/B/21-01-2014) on “Provisions for Pricing of Medicinal Products”.

8. The provisions of article 12 of law 3816/2010 (Gov. Gazette A/26-01-2010), as supplemented by par. 5 of article 63 of Law 3918/2011 (A'31) and the provisions of article 51 of law 3918/2011 (A'31).
9. The provisions of articles 19, 20, 21 and 23 of Law 4052/2012 (Gov. Gazette A 41/01-03-2012).
10. The provisions of par. 8 and 10 of par. F of subparagraph F.1 of article 1 of Law 4254 (Gov. Gazette 85/02-04-2014).
11. The email dated 25-04-2014 of the office of the Minister of Health to the directorate of Medicinal Products and Pharmacies.
12. The P.D. 95/2000 of the Organisation of the Ministry of Health and Welfare.
13. The P.D. 63/2005 (A 98) "Codification of Legislation for the Government and Governmental Organs".
14. The P.D. 119/2013 "appointment of the Vice-President of the Government, Ministers, Alternate Ministers and Deputy Ministers" (Gov. Gazette A 153).
15. The Ministerial Decision No Γ.Υ./ΟΙΚ 6161 (Gov. Gazette 2761/B/30-10-2013).
16. The fact that no expenditure is incurred against the State Budget from this decision, we decide:

1. The prices of the OTC medicinal products as concluded by the occasional issue of the prices bulletin, according to the existing provisions, are the maximum prices.
2. Manufacturers, packers and importers may grant unlimited discount on the ex-factory price to the wholesalers, pharmacists and partnerships and public or private hospitals, for OTC medicinal products.
3. The wholesalers may grant unlimited discounts on the wholesale price to the pharmacists and hospitals, for the OTC medicinal products, provided that such discount will be recorded on the sales invoices.
4. Pharmacists may sell the OTC medicinal products at prices unlimitedly lower than the maximum prices, as the latter are fixed in the occasional medicinal products prices bulletin, provided that such discount will be recorded on the sales invoice.
4. Transactions between manufacturers, packers, importers, wholesalers, pharmacists, partnerships and public or private hospitals that concern OTC medicinal products, are conducted at arm's length and are not subjected to any restriction or mandatory credit. More specifically, in the Ministerial Decision 3457/16-1-2014 (Gov. Gazette 64) in article 4, the two-months credit set out in par. 3 and 4 does not apply to the OTC

medicinal products, as well as the provisions of article 9. In addition, in the Ministerial Decision 325/5851/22-1-2014 (Gov. Gazette 88) and in article 4 thereof, the two-months credit set out in par. 3 and 4 does not apply for the OTC medicinal Products as well as the provisions of article 9.

This Decision enters into force from the date following its publication in the Government gazette.

This Decision must be published in the Government Gazette.

Athens, April 28, 2014

The Minister

SPYRIDON-ADONIS GEORGIADIS