GOVERNMENT GAZETTE

OF THE HELLENIC REPUBLIC

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DECISIONS

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(7)

Provisions for the sale and offer of the medicinal products included in par. 2 of article 12 of Law 3816/2010, as amended and in force.

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 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 2462/B).

15. The Ministerial Decision No ΔΥΓ3(α)/οικ.94274/28.9.2012 "Application of article 15 in Law 4052/2012" (Gov. Gazette 2675/B).

16. The Ministerial Decision No ΔΥΓ3(α) 7789/22.01.2013 (Gov. Gazette B 94) of the Deputy Minister of Health.

17. The Ministerial Decision No 57408/14.06.2013 (Gov. Gazette B 1446) of the Deputy Minister of Health "Provisions for Pricing of Medicinal Products".

18. The Ministerial Decision No 69010/25.07.2013 (Gov. Gazette B 1814) "Provisions for Pricing of Medicinal Products".

19. The provisions of the Ministerial Decision No ΓΠ/οικ/90281/02/10/13 (Gov. Gazette B 2467) "Approval of the positive list set out in article 12(a) of Law 3816/2010", as amended and in force

20. The provisions of article 12 of law 3816/2010 (Gov. Gazette A 6), 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).

21. The Ministerial Decision No Γ.Υ./οικ.6161/30.10.2013 (Gov. B 2761).

22. The Ministerial Decision No 3457 (Gov. Gazette 64/B/16-01-2014 "Regulation of issues concerning the pricing of medicinal products".

23. The order of the Minister of Health No ΓΥ/oik.3037/21-05-2014.

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

1. The cost of the medicinal products set out in par. 2 of article 12 of Law 3816/2010,

regardless of their sales network, is fully reimbursed by the insurance organisations and were offered to the patients without copayment. EOPYY and the hospitals are supplied the specific products in accordance with the applicable legal provisions at a hospital price minus 6.5%. Especially for the medicinal products with new active substances, an additional discount of 5% applies for one year, in accordance with the applicable legislation.

2. From the next pricing, the above medicinal products can also be offered by private pharmacies. In this case the Marketing Authorisation Holders (MAHs) are subject to the same volume and inclusion rebates for the Reimbursement List, to which all other medicinal products offered by the private pharmacies are subject. Especially for the medicinal products with new active substances, an additional discount of 5% applies for one year, in accordance with the applicable legislation. For these medicinal products the applicable provisions for rebates and discounts of the pharmacies do not apply.

3. The specific medicinal products are sold by the MAHs at the ex-factory price to the wholesalers. For the wholesale drugstores, the gross profit mark-up is set up to 1.5% on the ex-factory price of the medicinal products. The gross profit mark-up of the pharmacies is defined in accordance with the table attached, on the wholesale price of the said medicinal products.

Wholesaler's price	Gross Profit Mark-up of Pharmacy
0-100	32.40%
100-150	28.00%
150-200	23.00%
200.01-300	16.00%
300.01-400	12.00%
400.01-500	9.00%
500.01-600	8.00%
600.01-700	7.00%
700.01-800	6.50%
800.01-900	6.00%
900.01-1000	5.50%
1000.01-1250	5.00%
1250.01-1500	4.25%
1500.01-1750	3.75%
1750.01-2000	3.25%
2000.01-2250	3.00%
2250.01-2500	2.75%
2500.01-2750	2.50%
2750.01-3000	2.25%
3000.01-3500	2.00%
3500.01-4000	1.75%

4. In these cases, the MAHs reserve the right, if they so decide, to offer the said medicinal products from private pharmacies, only in the case of patients who have been included in registries. In these registries, patients must be characterised by a unique code and a verification mechanism must be available, in order to verify that the patient has indeed received the treatment. The MAHs will declare in the said cases

by means of an official letter to EOF, the distribution channel for the products set out in par. 2 of article 12 of Law 3816/2010 they select, so as to ensure the adequacy of the domestic market and the unobstructed access of patients with serious diseases.

5. When the patent protection expires for medicinal products of the specific list and generics are available, they may be classified in clusters by the competent Reimbursement List Committee, with the exception of biological products and products with narrow treatment range. Alternatively and additionally, the competent Committee for the Prescription Protocols may establish special criteria for the use thereof, such as the compulsory subjection of new patients to the generic or the cheaper medicinal product.

6. EOPYY may approve beforehand the use of the specific medicinal products with a high acquisition value or high annual treatment cost, via its committees and offer them via its pharmacies. If the Committees of EOPYY approve beforehand the use of a specific medicinal product, this must apply to all medicinal products of the same cluster. For the unobstructed service of the insured persons, EOPYY is obliged to develop an electronic system for the approval of the use of these medicinal products within a reasonable period from the date the relevant request is filed by the attending physician and in accordance with the applicable therapeutic protocols or the prescription guidelines.

7. EOPYY may decide the preliminary approval of the use or the purchase and offer by its pharmacies, of medicinal products with high treatment cost which are not necessarily included in par. 2 of article 12 of Law 3816/2010. Medicinal products with a price of over Euro 3,000 may not be offered by private pharmacies but only by the pharmacies of EOPYY and of State Hospitals. In addition, EOPYY may decide the exclusive offer of medicinal products with very high treatment cost or those administered in rare diseases (orphans) by its pharmacies.

8. The maximum limit for the preparation of prescriptions of the above medicinal products by the private pharmacies is the amount of Euro 20,000 for each one pharmacy operation license per month.

This decision must be published in the Government Gazette.

Athens, May 22, 2014

The Minister

SPYRIDON – ADONIS GEROGIADIS