Ministerial Decision no 82961 (GG 2219/B/9.9.2013)

Amendment of the Ministerial Decisions No ΔΥΓ 3(α) 104744/2012 as amended with the Ministerial Decision ΔΥΓ3(α)/οικ.19389, Gov. Gazette 17.12.2012 "Procedure of application of the Reference Prices System for the preparation, revision and supplementation of the list of prescribed medicines", issues concerning the reimbursement of new medicines

THE DEPUTY MINISTER OF HEALTH

Having considered:

1. The provisions of par. 2 of article 12 of Law 3816/2010 (Α΄ 6), as amended and in force.
2. The provisions of article 35 of Law 3918/2011(Α΄ 31)
3. The provisions of articles 10, 16, 18 and 19, 21, 22, 23 of Law 4052/2012 (ΦΕΚ Α΄ 41)
4. The provisions of article 30 of Law 4058/2012 (Α΄ 63).
5. The Decision No ΔΥΓ3(α)/οικ.104744, Gov. Gazette 2912, 30/10/2012
6. The Decision No ΔΥΓ3(α)/οικ.19389, Gov. Gazette 3356, 17/12/2012
7. The Decision No ΔΥΓ3 (Α) οικ.29311 Gov. Gazette 692 ,/26/3/2013
8. The Decision No ΔΥΓ3/57066/11-6-2013
9. The provisions of article 90 of the P.D. 63/2005 "Codification of legislation for the Government and Government bodies" (Α΄ 98).
10. The provisions of the P.D. 95/2000 "Organisation of the Ministry of Health and Welfare" (Α΄ 76), as amended and in force.
11. Article 9 of the P.D. 142/1989 (Gov. Gazette Α΄ 68).

    The P.D. 83/2012 "Appointment of Mrs Antonios Samaras, son of Constantine, Leader of the Political Party of "Nea Democratia" as Prime Minister (Gov. Gazette Α΄ 140).

    The P.D. 119/2013 "Appointment of Vice President of the Government, of Ministers, Alternate Ministers and Deputy Ministers" (Gov. Gazette Α΄ 153).

    The Joint Decision of the Prime Minister and of the Minister of Health No οικ. 3402/3.7.2013, Gov. Gazette 1642 Β΄/3.7.2013.

12. The fact that no expenditure is incurred against the State Budget by this Decision:

Decides

At the end of paragraph 7 of article 2 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744, Gov. Gazette 2912, 30/10/2012, the following clause is added:

More specifically, all reference medicines that are priced for the first time, upon the approval of their authorisation, are listed for the needs of this Ministerial Decision by the Special Committee

for the preparation of the positive list set out in par. 1 of article 12 of Law N.3816/10, in two categories: a) medicines which according the relevant suggestion of EOF, fall into the scope of par. 2a of article 12 of law 3816/10 which are intended for in-hospital use and treatment of serious diseases and b) other medicines. For all reference medicines that are priced for the first time, the provisions of paragraphs 1 to 6 of this article apply in relation with the criteria and procedures for the inclusion thereof in the positive list and the classification into the respective therapeutic categories. As provided for by par. 7 of article 21 of Law 4052/12, medicines whose marketing has been approved after 01.01.2012 are included in the positive list provided that their cost is provenly compensated by Social Insurance Agencies in the 2/3 of member-states of the European Union which are marketed or in at least 12 member-states of the European Union following the relevant evaluation by valid Health Technology Evaluation Organisations, provided that the Directive (EC) 89/105/EO is fully observed. More specifically, as regards the inclusion and classification of new reference medicines in specific cases, the special provisions of paragraphs 5 and 6 hereof may justifiably apply, together with the exceptions provided for by article 21 par. 7 of Law 4052/2013. In addition, after the evaluation from the competent committee, medicines whose retail price is lower than the reference price of the category in which they are included, are included in the positive list by priority, thus securing resources saving for the Social Insurance Agencies.

In addition, the competent Committee by taking into account the clinical and financial efficiency data and the procedures set out in par. 3 to 6 hereof, is able, in writing and with proper justification in its final decision, to set the conditions and rules that define the strict observance of the medicines indications, as set out in the marketing authorisation thereof and/or the incorporation of restrictions regarding the indications, the application of clinical protocols for the administration of specific pharmaceutical products, the obligatory inclusion of the beneficiaries in patients' registries and the monitoring of the proper use of medicines, specifically for rare diseases and the contingent exclusive administration thereof by specific and specialised centres.

Article 2 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744, ΦΕΚ2912, 30/10/2012, is supplemented with paragraphs 8 and 9.

8. In addition, EOPYY, in co-operation with the Special Innovation Committee of ΔΥΓ3/57066/11-6-2013, reserves the right to impose further conditions and restrictions for the compensation of the cost of pharmaceutical products set out in this decision, as well as the ability to enact fixed budgets per therapeutic category of medicines or per specific medicine and to determine the claw back or pay back by the marketing authorisation holders per medicine or per therapeutic category or the conclusion of price-volume agreements or risk-sharing agreements. The provisions of this paragraph as well as of the preceding one may apply for medicines that have already been included in the positive list when this decision was published.

9. More specifically for the pharmaceutical products set out in article 12 par.2a of Law 3816/10, Hospital Institutions of the NHS (Hospitals, Health Centres and other NHS Units), as well as private Clinics, may include the beneficiaries-patients in registries and thereapeutic protocols which are collected per Health Region under the care of the Management of the *ΥΠΕ*. By virtue of the circular issued by the competent General Secretary within at least 15 days from the issue hereof, the above procedure is particularised.

In article 1 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744, Gov. Gazette 2912, 30/10/2012, paragraph 3 is substituted as follows:

3. The positive list of prescribed medicines is posted at EOF's website and is published with a Ministerial Decision in the Gov. Gazette. The list is revised within 30 days from the occasional issue of the prices bulletin and the respective corrective bulletin thereof or respectively from the issue of a prices bulletin for new medicines. The respective negative list is in parallel revised, if necessary.

In Article 1 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744, Gov. Gazette 2912, 30/10/2012, paragraph 7 s substituted as follows:

The restrictions referred to in the respective paragraphs of article 2 do not apply for medicines imported upon emergency procedures by IFET and EOF, until the final evaluation thereof by the competent committee or the end of the suggestive treatment period.

Paragraph 3 of article 3 of the Ministerial Decision ΔΥΓ3(α)/οικ.19389 Gov. Gazette 3356, 17.12.2012, is substituted as follows:

3. The above provisions concern all contents and packages of any medicine whose cost is reimbursed. For the calculation of the compensation price for each medicine, the following mathematical formula is applied: Medicine Compensation Price = Reference Price x Number of Daily Dosage (*ΑΗΔ*). In case a medicine selected has a retail price higher than the compensation price, the patient covers, apart from his/her participation provided for by the law, the whole difference between the compensation price and the retail price of the medicine. For the exceptional cases where a medicine with no generic is selected or a therapeutic category in whole includes only one active substance without generics, where the medicine selected has a retail price higher than the compensation price, the patients covers, apart from his/her participation provided for by the law, half of the difference between the compensation price and the retail price of the medicine. In the cases were the retail price of the medicine is lower than the compensation price, the difference between the retail price and the compensation price is subtracted from the participation of the patient provided for by the law, up to ½ thereof.

Paragraph 7 of article 3 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744, Gov. Gazette 2912, 30.10.2012, as amended with the Ministerial Decision ΔΥΓ3(α)/οικ.19389 Gov. Gazette 3356, 17.12.2012, is substituted as follows:

7. New generics are automatically included in the positive list upon the approval of their prices. New generics whose reference medicine is included in the negative list are automatically included in the negative upon the approval of their price. In case the new generic corresponds to a reference medicine which had no generic medicine until the approval of the price of the generic, the reference price is redefined, based on the price of the new generic, provided that the sales are recorded in the HDIKA.

Paragraph 5 of article 3 of the Ministerial Decision ΔΥΓ3(α)/οικ.104744, Gov. Gazette 2912, 30.10.2012, as amended with the Ministerial Decision ΔΥΓ3(α)/οικ.19389 Gov. Gazette 3356, 17.12.2012 is abolished.

This Decision must be published in the Government Gazette.

Athens, September 5 2013

THE DEPUTY MINISTER OF HEALTH

ANTONIOS BEZAS