

No ΔΥΓ3(α)/οικ./19389

Amendment of the Ministerial Decision ΔΥΓ3(α)/οικ.104744/2012 “Procedure for the application of the system of reference prices for the preparation, revision and supplementation of the list of prescribed medicines” (Gov. Gazette B’ 2912).

THE ALTERNATE MINISTER OF HEALTH

Having considered,

1. Article 12, par. 1(b).4. of law 3816/2010 (Gov. Gazette 6/A/26.01.2010) “Settlement of business and professional debts to credit institutions, provisions for the processing of financial conduct data and other provisions” as amended and supplemented.
2. The provisions of article 90 of the Code of Legislation for the Government and the Government Bodies which was ratified with article 1 of the P.D. 63/2005 (Gov. Gazette A 98).
3. The P.D. 86/2012 (Gov. Gazette A 141/21.6.2012) “Appointment of Ministers, Alternate Ministers and Deputy Ministers”.
4. The Decision No Y47/3.7.2012 (Gov. Gazette B 2105) for the assignment of authorities to the Alternate Minister of Health, as amended by the Decision ΔΥ1α/οικ.78084/25.07.2012 (Gov. Gazette B/2338/2012).
5. The P.D. 95/2000 “Organisation of the Ministry of Health and Welfare” as amended and in force.
6. The provisions of article 35, of Law 3918/2011 (Gov. Gazette A 31).
7. The provisions of Law 1316/83 (Gov. Gazette A 3) “Incorporation, Organising and Authorities of EOF” as amended and supplemented.
8. The provisions of articles 16, 18 and 19 of Law 4052/2012 (Gov. Gazette A 41).
9. The P.D. 95/2000 (Gov. Gazette A 75).
10. Article 9 of the P.D. 142/1989 (Gov. Gazette A 68).
11. The Ministerial Decision No ΔΥΓ3δ/οι. 57364/6.6.2010 (Gov. Gazette B 1907) “Application of medicines pricing authorities to EOF”.
12. The Ministerial Decision No ΔΥΓ3(α)/οικ.104744/2012 “Procedure for the application of the system of reference prices for the preparation, revision and supplementation of the list of prescribed medicines” (Gov. Gazette B’ 2912).
13. The fact that no expenditure is hereby generated against the State’s Budget, we decide:

Article 3 of the Ministerial Decision No ΔΥΓ3(α)/οικ.104744/2012 “Procedure for the application of the system of reference prices for the preparation, revision and supplementation of the list of prescribed medicines” (Gov. Gazette B’ 2912) is amended and substituted as follows:

Article 3

Determination of Reference Prices and Compensation

1. In each therapeutic category a reference price (AT) is defined, in accordance with the provisions hereof, which is the compensation price paid by insurance funds and EOPYY for all products of any category. The special committee for the preparation of the positive list, after classifying the medicines as defined in article 2 of this Decision, calculates the reference, separately per therapeutic category. The said calculation includes all medicines, content and packages selected and compensated by the Social Insurance Agencies.

2. According to applicable law, the reference price is defined based on the lowest price for the cost of daily treatment (KHΘ) in each therapeutic category. For the calculation of the KHΘ for each medicine (content and package) the following formula is applied: $KH\Theta_k = AT_k / AH\Delta_k$, where AT_k is the retail price of the medicine (k) and $AH\Delta_k$ is the number of daily administered doses which is calculated as $AH\Delta_k = \Sigma\Pi\Delta_k / MH\Delta_k$, where $\Sigma\Pi\Delta_k$ is the total quantity of active substance and $MH\Delta_k$ is the average daily dosage. The reference price for each therapeutic category is set as the lowest KHΘ between the weighted average KHΘ of all reference prices (under protection or not) and the weighted average KHΘ of all generics of any category and are published in the list applied from time to time. Meaning, $TA_{reference\ category} = \text{Minimum} \{ \text{Weighted Average KH}\Theta_{of\ reference\ category\ medicines}, \text{Weighted Average KH}\Theta_{of\ reference\ category\ generics} \}$, where $\text{Weighted Average KH}\Theta_{of\ reference\ category\ medicines} = w_1 * KH\Theta_1 + \dots + w_m * KH\Theta_m$ and $\text{Weighted Average KH}\Theta_{of\ reference\ category\ generics} = y_1 * KH\Theta_1 + \dots + y_n * KH\Theta_n$, m and n is the total number of different forms of reference medicines and generics respectively in the category under examination. $KH\Theta_m$ and $KH\Theta_n$ are the Cost of Daily Treatment of the specific medicine (reference or generic respectively), with the form and content as defined in the occasionally published pricelist. w_m and y_n are the market share in values (based on the retail prices) of the reference medicines and generics respectively in the specific category. The above weight coefficients (w_m and y_n) are calculated with the use of the data provided by HDIKA, which concern the last six months before the preparation of the list and reflect the market share of each medicine in the total value of the respective medicines of the therapeutic category which are included and published in the occasionally circulated list. Meaning, $w_m = \text{Value of the Reference Medicine (per Package and Content) / Total Value of Reference Medicines of Therapeutic Category}$ and $y_n = \text{Value of Generic (per package and Content)}_n / \text{Total Value of Generics of Therapeutic Categories}$.

3. The above provisions concern all contents and packages of each medicine which are compensated. For the calculation of the compensation price of each medicine, the following formula is used: $\text{Compensation Price of the Medicine} = \text{Reference Price} \times AH\Delta$. If a medicine is selected with a retail price higher than the compensation price of the medicine, the patient covers half of the difference from the compensation price until the retail price of the medicine, and the insurance agency covers the remainder. For medicines for which the patient is requested to pay for participation and where the retail price of the medicine is equal or less than the compensation price, the patient will only pay the statutory participation percentage of the medicine on the Retail Price.

4. For reference medicines for which the protection period has expired and for which generics circulate in the market and the provisions of Law 4052/2012, Law 4093/2012 and of the ministerial decision EMII4, Gov. Gazette 3057/ 18.11.2012, the insurance price of the occasional therapeutic category is the price defined in accordance with the provisions of this decision. If a medicine with a higher retail price than the compensation price is selected, the provisions of the preceding paragraph apply.
5. The pharmaceutical products included in the Positive List which have a KHΘ less or equal to Euro 0.3, even if they have a price higher than the Reference Price, are included in the positive list of prescribed medicines and are compensated by the Social Insurance Agencies at their retail price, provided that the marketing authorisation holders regularly pay the rebates provided by applicant law.
6. The compensation prices and the participations of the patients will appear in the electronic prescribing system, so that the physician, the patient and the pharmacist are informed of it, upon the prescribing and preparation of the prescription.
7. New generics are automatically included in the Positive List upon approval of their price. New generics whose reference medicine is included in the negative list, are automatically included in the negative list upon approval of their price. The provisions of this article apply in the case of medicines classified at a level of active substance (ATC5), according to the provisions of the paragraphs of the preceding article.

This Decision must be published in the Government Gazette.

Athens, December 17, 2012

THE ALTERNATE MINISTER
MARIOS SALMAS