Number DYG3A/G.P.95872 (2)

Procedure of implementation of reference price system for setting up, revising and supplementing the reimbursement list

THE MINISTERS
OF HEALTH AND SOCIAL SOLIDARITY - EMPLOYMENT AND SOCIAL INSURANCE

Taking into account:

1. The provisions of case b. of paragraph 1 of Article 12 of Law 3816/2010 (A' 6), as replaced by paragraph 3 of Article 68 of Law. 3984/2011 (Government Gazette 150/A΄/27−6−2011).
2. The provisions of article 35 of Law 3918/2011 (A' 31).
3. Presidential Decree 95/2000 "Organization of the Ministry of Health and Welfare" as amended and in force.
4. Presidential Decree 89/2010 "Appointment of Ministers, Substitute Ministers and Deputy Ministers" (Government Gazette 154/A΄/7−9−2010).
5. Presidential Decree 63/2011 "Appointment of Vice President of the Government, Ministers, Substitute Ministers and Deputy Ministers" (Government Gazette 145/A΄/17−6−2011).
6. The provisions of article 90 of Presidential Decree 63/2005 (A' 98) "Codification of legislation on government and government bodies".
7. Joint ministerial decision number DYG3a/ oik.2466/31−12−2010 (B΄ 58) "Determination of implementation of objective criteria for setting up, revising and supplementing the list of prescription medicines based on the provisions of article 12(1)(b) of Law 3816/2010 (A΄ 6)".
8. The fact that this decision does not incur any expense burdening the state budget and the budget of the insurance organisations, we hereby decide:

Article 1
Procedure for setting up the list – therapeutic categories

The setting up, revising and supplementing of the Positive Reimbursement List introduced by article 12(1) of Law 3816/2010 (A΄6) uses a system of classification of the medicines and a system for calculating the reference prices per therapeutic category of active ingredients.

Active ingredients are classified into therapeutic categories based on the Anatomical Therapeutic Chemical classification− ATC system of the World Health Organization (WHO), in which a reference price system is integrated. Specifically, the grouping of the medicinal products into therapeutic categories takes place at the 4^{th} level of the ATC system per group of pharmaceutical forms, also taking into account the grouping of the active ingredients as referred to in the standard terms of the European Directorate for the Quality of Medicines −E.D.Q.M., operating under the auspices of the Council of Europe. For the cases where the same pharmaco-therapeutic category of the 4^{th} ATC level includes medicinies that have a marketing authorization for more than one indications, there can be a sub-classification of the active ingredients at the same ATC level. The approved strength and packaging for all marketed products are included for each medicinal product (reference and essentially similar products). More specifically, with regard to packaging case g) of paragraph 2 of this decision is taken into account.

Article 2
Introduction of Reference Price System

a) The reference price of each therapeutic category according to the above classification of paragraph 1 of this decision is the maximum reimbursement price paid by the social insurance funds for the medicinal product of the whole therapeutic category and is calculated according to the following formula:

$$\text{Reference price} = \frac{CDT_1 + CDT_2 + \ldots CDTv}{v}$$

Where,

a-1) CDT: Cost of Daily Treatment of each product of each different group of active ingredients, which results from the quotient of the ex factory price (EF) to the Number of Daily Doses (NDD) on the package:

$$CTD = EF/NDD$$

• Number of Daily Doses (NDD): is the quotient of the Total Strength of Active Ingredient on the packaging (SAP) to the Daily Defined Dose (DDD) according to the World Health Organization or the Daily Average Dose (DAD) according to the Summary of the Product's Characteristics.

NDD = SPA / DDD or DAD.

• The Daily Average Dose is selected as the denominator of the previous formula in any case where the Daily Defined Dose (DDD) cannot be used.
a-2) v: All strengths and packages, taking into account case g) of the same paragraph of this decision, of all marketed products, of each therapeutic category per group of pharmaceutical form.
b) Medicinal products with a CDT lower or equal to the reference price are included in the positive reimbursement list and are reimbursed by social insurance funds. The provisions of article 35(1) of Law 3918/2011 (A' 31) apply for these medicinal products with regard to the rebate owed by pharmaceutical companies to the social insurance funds (4% on the producer's price).
c) Medicinal products with a CDT exceeding the reference price of the therapeutic category in which they belong are included in the positive reimbursement list and are reimbursed by social insurance funds, if the following apply:
i. Marketing Authorization Holders (hereinafter MAHs) return to social insurance funds the amount calculated by extrapolating the difference of the CDT of each product from the reference price of the therapeutic category to which each product belongs and on the packaging of each product multiplied by 1.5.
ii. MAHs submit the application for the acceptance of the above reimbursement system.
iii. Independently of prior cases i. and ii. the provisions of article 35(1) of Law 3918/2011 (A' 31) apply for these medicinal products with regard to the rebate owed by the MAHs to the social insurance funds (4% on the producer's price).
d) Medicinal products of the following therapeutic categories:
1) All non therapeutic products (V07);
2) All contrast media (V08);
3) General anaesthesia medications (M03AB, M03AC, N01A);
4) Injectable local anaesthetics (N01BA, N01BB);
5) Immune sera and immunoglobulins (J06) ;
6) Blood substitutes and infusion solutions (B05);
7) Coagulation factors (B02BD);
8) Vaccines (J07);
9) Insulin and derivatives (A01A), for which the Cost of Daily Treatment (CDT) is objectively difficult to calculate, are included in the positive reimbursement list and are reimbursed by the social insurance funds, if the following apply:
i. The MAHs submit the application for the acceptance of the above reimbursement system.
ii. The provisions of article 35(1) of Law 3918/2011 (A' 31) apply for these medicinal products with regard to the rebate owed by the MAHs to the social insurance funds (4% on the producer's price).
e) Medicinal products with a CDT lower or equal to 0.3 euro, as well as products of small strength for children, even if their price is higher than the Reference Price are included in the positive reimbursement list and are reimbursed by social insurance funds, only if they have been positively evaluated by the Special Committee with regard to the therapeutic benefit and provided that the following apply:
i. The MAHs submit the application for the acceptance of the above rebate system.
ii. The provisions of article 35(1) of Law 3918/2011 (A 31) apply for these medicinal products with regard to the rebate owed by the MAHs to the social insurance funds (4% on the producer's price).
g) As regards inclusion in the positive list, the following are examined:
i. Medicinal products, whose packaging has a number of doses covering exclusively monthly treatment or an aliquot of monthly treatment. Medicinal products whose marketing authorization is for 'hospital use' are excluded from this rule.
ii. Medicinal products with regard to which the Special Committee can choose from the product's marketing authorization only some of the indications or specific categories of patients for which it will include them in the positive list, as well as the optimum strength and packaging that serves the needs of the pharmaceutical treatment related to treatment cost and alternative treatments.
h) The inclusion of the medicines in therapeutic categories and the formulation of the CDTs are posted on the website of the National Organization for Medicines (EOF).

All medicinal products included in the positive reimbursement list and reimbursed by social insurance funds, are published with JMD of article 12(1)(c) of Law 3816/2010 and are posted on the EOF website.

Article 3
Categories of pharmaceutical products not included in the list

The list does not include pharmaceutical products of the following categories:
i. Medicinal products whose marketing authorization specifies that no medical prescription is needed and are published with decision DYG3a/GP52241/12−5−2011/(B΄840) as updated from time to time.
ii. The medicinal products included in the list that are administered with medical prescription and are not reimbursed by the social Insurance fund and are published with decision DYG3a/oik.32294/2011 (B΄559), as updated from time to time.
iii. The medicinal products of the MAHs who do not accept the terms of this joint ministerial decision.

Article 4
Supplementing, Revising of the List - Objections

a) Supplements to the list are issued within 90 days after the issuance of a Price Bulletin including new pharmaceutical products. In any case the medicinal products are included in the list only having proven that they are marketed, under the responsibility of the MAHs.
b) The list is revised after the issuance of a Price Bulletin that includes a general re-pricing of medicinal products.
Revision means the amendment of the reference prices due to a change in the classification of the therapeutic categories because of additions or removals of medicinal products in them or change of the prices of each therapeutic category. During the first implementation of this decision, a revision may be carried out once regardless of the general re-pricing.
c) Objections may be submitted by the MAHs to the Special Committee within 15 days after the date of publication of the list of medicines of section h) of par. 2 of this decision. Objections are examined within 30 days after their submission. A potential acceptance of the objections and therefore potential amendments that arise from the above procedure, are published in the following supplements or revisions of the list according to the previous cases of this paragraph. Rejected objections must be fully justified.

Article 5
Reference prices - Rebates

a) The reference prices per therapeutic category are announced by the Special Committee exclusively to the social insurance funds, the MAHs, the Medicinal Products' Pricing Department of the Ministry of Health and Social Solidarity and the Directorate of Insurance, Illness and Motherhood of the Secretariat-General of Social Insurance, under the responsibility of EOF.
b) The calculation of the rebate owed for each pharmaceutical product, which is described with the procedure of case i., section c), paragraph 2 of this decision and which the MAHs are obliged to return to the social insurance funds, is determined by the Minister for Health and is calculated by EOF or its subsidiaries and is announced exclusively to the Directorate of Insurance, Illness and Motherhood of the Secretariat-General for Social Insurance, the Social Insurance Funds and the MAHs. The list with the rebate amounts for each pharmaceutical product is not published. This list is revised with the same procedure as in the cases of paragraph 4 of this decision.
c) The MAHs are invited by EOF to declare in writing within 5 working days after the announcement of the amount of rebate they have to return for their products, that they accept the terms of this joint ministerial decision so they can be included in the reimbursement list.
d) From the publication of this decision and henceforth, at the end of every 2 months, until the electronic prescription system (hereinafter EPS) is implemented across all Social Insurance Funds or a different electronic prescription scanning system that allows the accurate calculation of the quantities of medications is available, EOF is obliged to calculate the amount of rebate corresponding to each medicinal product included in the list and for which the pharmaceutical company has submitted the corresponding letter of acceptance. The calculation of the amount takes into account the ratio of public to private pharmaceutical expenditure, i.e 65% - 35%, after deducting direct exports, sales

to hospitals and parallel exports. The deposit of the relevant amount is made to the account determined by the Secretariat-General of Social Insurance, until the end of the month following the 2 month period of the sale. If upon lapse of the above period, the relevant amounts have not been deposited in the account, then the medicinal products of these companies are removed from the list and are re-included in a subsequent revision, provided that in the interim the pharmaceutical companies pay all their debts.
The obligation to pay rebates enters into force the first month of the first implementation of the positive reimbursement list.
e) After the Social Insurance Funds are included in the EPS or have a different electronic prescription scanning system that allows the accurate calculation of the quantities of the medicines, then the quantity calculation and rebate system of the previous paragraphs ceases to be implemented. In these cases the amounts of rebate per product and company are calculated by the social insurance funds through the EPS or a different system and are paid directly in an account suggested by each Social Insurance Fund. The amounts will be collected within one month after the companies have been notified of the required amounts. If, after the lapse of the month, the relevant amounts have not been deposited in the account determined by each Social Insurance Fund, then the latter shall be entitled to request removal from the list of medicinal products whose corresponding amounts have not been paid. A medicinal product is included in the list again following the procedures and the terms of the previous paragraphs.
Joint ministerial decision number DYG3a/ oik.2466/31−12−2010 (Government Gazette 58, B 26−01−2011), “Amendment of joint ministerial decision no. Φ80000/οικ.8755/892/9−04−2010 “Determination of implementation of objective criteria for setting up, revising and supplementing the Reimbursement List based on the provisions of article 12(1) (b) of Law 3816/2010 (A΄6)” is repealed.
The effect of this decision begins as of its publication in the Government Gazette. This decision shall be published in the Government Gazette.

Athens 08.09.11

THE MINISTERS

EMPLOYMENT AND SOCIAL INSURANCE — HEALTH AND SOCIAL SOLIDARITY

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