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Amendment of the Joint Ministerial Decision No. Φ80000/ΟΙΚ.8755/892/9.4.2010 (O.G. 417 A') ''Definition of the Implementation of objective criteria for the preparation, revision and supplementation of the Reimbursement List based on the provisions of article 12 §1 case b of Law 3816/2010 (O.G. 6 Α')"

THE MINISTERS

OF ECONOMY, COMPETITIVENESS & SHIPPING –

LABOUR AND SOCIAL SECURITY –

HEALTH AND SOCIAL SOLIDARITY

Taking into consideration:

1. The provisions of article 12 §1, case b of Law 3816/2010 (O.G. 6A').

2. The provisions of article 90 of the Code on the "Government and Governmental Bodies", P.D 63/2005 (A', 93).

3. The JMD No Φ80000/ΟΙΚ.8755/892/9.4.2010 (O.G. 417 A') «Definition of the Implementation of objective criteria for the preparation, revision and completion of the Reimbursement List according to the provisions of article 12 §1 case b of Law 3816/2010 (OG 6A')"

4. The joint decisions of the Prime Minister and the Minister of Health and Social Solidarity, under file No 128404 and 128405/14.10.2010 (O.G. 1647/issue Β'/15.10.2010) on the «Delegation of Duties to the Deputy Ministers of Health and Social Solidarity Chr. Aidonis and Mich. Timossidis respectively».

5. The fact that no expenditure to the detriment of the state Budget and the budgets of Insurance Funds is generated, we decide that:

For the preparation of the Reimbursement List the medicinal products are classified according to the system of Anatomical Therapeutic Chemical classification (ATC) of the World Health Organisation (WHO).

The objective criteria that the Special Committee, appointed according to Article 12 §1 case c of Law 3816/2010 (A, 6), should take into consideration, in order to issue the Reimbursement List, are defined as follows:

1. System of Reference Prices - Economic Evaluation

a. A System of Reference Prices is incorporated in the Classification system of medicinal products ATC. The reference prices of medicinal products are calculated according to level four (4) of the ATC system, per group of pharmaceutical form by taking into account the grouping of medicines as it is referred to the standard terms of the European Directorate for the Quality of Medicines –(E.D.Q.M.), which operates under the auspices of the European Council. When in the same therapeutic cluster of ATC level 4 medicinal products with different indications are included, the active ingredient is sub-classified at the same ATC level.

For each active ingredient, the approved strength and packaging will be included for all legally marketed medicinal products (reference products and essentially similar products). Precisely for packaging, point 4).a hereof is taken into consideration.

The Reference Price of groups of medicinal products, as these were previously described, is calculated according to the following equation:

$$\text{Reference Price} = \frac{C.D.T._1 + C.D.T._2 + \ldots\ldots C.D.T._n}{n}$$

Where:

i) C.D.T. : the Cost of Daily Treatment of each medicinal product in the group, derived as the quotient of the Retail Price (R.P.) divided by the Number of Daily Doses (N.D.D.) on the package

$$C.D.T. = R.P. / N.D.D.$$

The Number of Daily Doses (N.D.D.): is the quotient of the Total Active Substance Content on the package (A.S.C.) divided by the Daily Defined Dose (D.D.D.) according to the World Health Organisation or by the Average Daily Dose (A.D.D.) according to the Summary of Product Characteristics

$$N.D.D. = (A.S.C.) / D.D.D. \text{ or } A.D.D.$$

The selection of the Average Daily Dose (A.D.D.) as the denominator of the previous equation is used in every case where the implementation of the Daily Defined Dose (D.D.D.) is not possible.

ii) n: All strengths and packagings of all medicinal products, in every therapeutic cluster per group of pharmaceutical form.

b. In the reimbursement list are included:

1. Medicinal products, the prices of which are lower or equal to the reference price of the therapeutic cluster to which they belong.

2. Medicinal products with C.D.T. lower or equal to €0,6.

c. For medicines, whose price exceeds the reference price of the therapeutic cluster to which they belong, the company can submit either clinical trials or pharmaco-economic studies published in official scientific publications with impact factor >1 so as to document the price difference.

The Special Committee shall evaluate the information submitted, as well as the reports of special rapporteurs, and decide accordingly:

1) The Committee approves the additional information and suggests a price reduction for the medicinal products whose price exceeds the reference price at the defined level. If the price reduction is accepted the products in question are included in the Reimbursement List.

2) The Committee approves the additional information and suggests Inclusion in the Reimbursement List with C.D.T. up to 20% higher than the reference Price, provided that the medicinal product is proved to be of higher value compared to the medicinal products belonging to the same therapeutic ATC cluster. The Committee, in order to make this suggestion, takes into account the evaluation of each medicinal product by the European Evaluation Systems as per their therapeutic results and the criteria of § 2 hereof.

3) The Committee rejects with a justified decision the inclusion of a medicinal product in the Reimbursement List.

d. Low strength medicinal products for children are included in the Reimbursement List, even if their price is higher than the reference price, provided that they have been positively evaluated by the Special Committee as per their therapeutic benefits.

e. Medicinal products belonging to the following therapeutic clusters are included in the Reimbursement List without calculation of the reference price.

- All non-therapeutic medicinal products (V07),
- Contrast Media (V08),
- General Anaesthetics (M03AB, M03AC, N01A)
- Injectable medicinal products for local anaesthetics (N01BA, N01BB)
- Immune sera and immunoglobulins (J06),
- Blood substitutes and perfusion solutions (B05)
- Coagulation factors (B02BD),
- Vaccines (J07)
- Insulin and similar medication (A01A),

f. For all the medicinal products included in the Reimbursement List a system of ''dynamic pricing'' will be implemented. Precisely:

- for every increase of the annual sales strictly equal to or higher than 5% in value, a price reduction of 2,5% will be required
- the calculation will take place at the end of every twelve (12) months period following the inclusion of the medicinal product in the Reimbursement List.

2. The documented therapeutic efficacy is evaluated on the base of:

a. The gravity of the disease

b. The relation between efficacy- safety- tolerance

c. The high therapeutic value in relation to respective medicinal products

d. The possibility of implementing other treatments with or without medicines

e. The degree of contribution to the promotion of Public Health

The cost of the treatment under examination in relation to the clinical results, compared to the cost of other treatments per clinical result is also taken into account, when there is no differentiation in the therapeutic efficacy. The above-mentioned economic parameter should be documented with economic results of clinical trials and, when necessary, with pharmaco-economic studies based on clinical trials. The above studies must be published in official scientific publications with impact factor >1.

3. The parallel reimbursement of the medicinal products under consideration, by social insurance funds in other EU countries.

For the medicinal products under consideration, the coverage by social insurance funds in at least two other countries of the European Union will be taken into consideration. Among the medicinal products not reimbursed by social insurance in these countries, only the ones that are supported by international bibliography as regards the adequate documentation of their efficacy and safety, will be selected.

4) In the Reimbursement List are included:

a. Medicinal products, whose packaging includes number of doses, which exclusively cover a monthly treatment or sub-multiple of the monthly treatment. Medicinal products which according to their marketing authorization are for hospital use, are excluded.

b. Medicinal products for which the Special Committee can select only some of the indications to include in the Reimbursement List as well as the suitable strength and packaging which serve the needs of medical treatment in relation to the cost of treatment and other alternative treatments.

c. A detailed description of all the information relevant to each medicinal product included in the Reimbursement List, reference to the cost of treatment, recommendations and limitations concerning the indications and the side effects, according to the judgement of the Committee and what is specified by the relevant ministerial decisions and circulars or what is mentioned in the Summary of Product Characteristics issued by EOF (National Organisation for Medicines) and the EMA (European Medicine Association).

5) In the List are not included:

Categories of Medicines:

a. whose marketing authorisation indicates that they can be administered without prescription

b. whose indications are not considered necessary to be covered by social insurance (for example, life style medicinal products)

c. Any other category according to the Committee's judgement.

Any rejection of a medicinal product should be fully justified by the

Committee.

The publication of medicinal products in the cases a,b,c of §5) is announced by the Special Committee at the same time the present is published, irrespective of the time of publication of the Reimbursement List.

6) Regarding the supplements to the Reimbursement List, these are issued within 30 days following the publication of a Price Bulletin which includes new medicinal products.

7) Revision of the Reimbursement List means all the corrections of Reference Prices, as result of amendments in the classification groups of medicinal products, due to changes in prices following the issuance of Price Bulletins and/or additions or exclusions of medicinal products in already existing groups. Revisions of the List take place once a year following the publication of the Price Bulletin, which includes re-pricing of medicinal products.

8) The Marketing Authorization Holder can submit an objection for a medicinal product excluded from the List, in case the calculation of N.D.D. and C.D.T are contested. The objection is to be submitted before the Special Committee responsible for the establishment of the List, within 15 days from the date of publication of the List. The objection is examined within 60 days from its submission and it is either fully or partially accepted or rejected with justified decision. Any amendments of the List following the above procedure are to be published in annexes or Revisions of the Reimbursement List.

9) The pharmaceutical companies declare in writing that they accept the inclusion of their products in the Reimbursement List according to the provisions of the present JMD.

JMD No Φ80000/ΟΙΚ.8755/892/9.4.2010 (OJ 417 A') JMD "Definition of the Implementation of objective criteria for the preparation, revision and completion of the Reimbursement List according to the provisions of article 12 §1 case b of Law 3816/2010 (OG 6 A')" is repealed.

This decision enters into force on the date of its publication in the Official Gazette.

This decision shall be published in the Official Gazette.

Athens, December 31, 2010

THE MINISTERS

DEPUTY MINISTER FOR THE ECONOMY, COMPETITIVENESS AND SHIPPING

CONSTANTINOS ROVLIAS

MINISTER OF LABOUR AND SOCIAL SECURITY

GEORGIOS KOUTROUMANIS

MINISTER OF HEALTH AND SOCIAL SOLIDARITY

MICHAEL TIMOSSIDIS