HELLENIC REPUBLIC
MINISTRY OF LABOUR & SOCIAL INSURANCE
GENERAL SECRETARIAT OF SOCIAL INSURANCE
DIRECTORATE OF HEALTH & MATERNITY INSURANCE
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RE: Determination of the application of objective criteria for the preparation, revision and supplementation of the Reimbursement list of prescription medicinal products, based on the provisions of article 12, par. 1 case b of law 3616/2010 <A, 6l>

THE MINISTERS OF
ECONOMY, COMPETITIVENESS AND SHIPPING
LABOUR & SOCIAL INSURANCE
AND
HEALTH & SOCIAL SOLIDARITY

Having considered:

1. The provisions of article 12 par. 1 case b of law 3616/2010 (A, 6).
2. The provisions of article 96 of the Code of legislation on “Government and Governmental Bodies” that was ratified by article one of the P.D. 63/2005 (A, 93).
3. The fact that this Decision does not cause any expense at the charge of the State Budget and of the budgets of the insurance organizations.

WE DECIDE

For the preparation of the Reimbursement list of prescription medicinal products, the medicinal products are classified according to the system of Anatomical Therapeutic Chemical Classification - ATC) of the World Health Organization (WHO).

The pharmaceutical companies must refund (rebate) to an account in favour of the Social Insurance Entities an amount equal to 3% of the total sales of each medicinal product included in the Reimbursement list of prescription medicinal products. This amount concerns a period of three months during which the medicinal products are included in the List and is reimbursed within a period of fifteen (15) days from the completion of each quarter into an account maintained with the Bank of Greece for the General Secretariat of Social Insurance. The medicinal products are automatically removed from the Reimbursement list of prescription medicinal products in case of non-timely payment of the amount by the company.

The objective criteria that must be taken into consideration by the Special Committee provided for in article 12 par. 1 case c of law 3616/2010 (A,6) in order to issue the Reimbursement List of Prescription Medicinal products are defined as follows:

1. Reference Prices System - Economic evaluation

A. A Reference Prices System is incorporated in the classification system of medicinal products. The Reference Price shall be a function of the retail prices per dosage unit of all the medicinal products, original and generic, of the same pharmacotherapeutic category ATC per pharmaceutical form. In order to ensure comparability, as unit of measurement is used the daily dose as related to the duration of treatment. The function from which the reference price will be derived is described by the following equation:

Reference price = the ratio of the sum of the retail prices per dosage unit of the original medicinal products and the average price of the retail price per dosage unit of the generics of the same original to the sum of the number of originals and the number of originals with generics.

$$\text{Reference Price} = \frac{(\text{L.T.M.D. of original } P_1 + \ldots + \text{L.T.M.D. of original } P_N) + \text{Average price of original } PG_1 + \ldots. + \text{Average of the L.T.M.D. of the generics of the same original } PG_N)}{\text{Number of originals (P) + number of originals with generics (PG)}}$$

(wherein L.T. is the Retail Price of a medicinal product, P is the number of original medicinal products, PG the number of original medicinal products with generics and M.D. the Dosage Unit).

B. Included in the List are the medicinal products whose price is lower or equal to the reference price of the pharmacotherapeutic category to which they belong.

For medicinal products whose price exceeds the reference price of the pharmacotherapeutic category to which they belong, the company marketing them may submit pharmaco-economic studies and/or clinical trials in order to document the different price.

The Special Committee evaluates the data submitted and the reports of special rapporteurs and alternatively:

1) Proposes a reduction in the price of the medicinal products whose price exceeds the reference price to the level of the latter.

2) Accepts the price and includes it in the List with a maximum price per dosage unit by 20% higher than the reference price under the following conditions:

the medicinal product should:

- belong to the first and second category of the classification system for medicinal products “Amélioration du Service Médical Rendu” of the Committee for the Evaluation of Medicinal Products following the agreement of the Transparency Committee of the French Ministry,
- demonstrate a higher therapeutic value in comparison with the medicinal products that belong to the same ATC category,
- not exceed the former price of the medicinal product.

In any other case the Special Committee rejects the medicinal product giving its reasons.

C. Especially for essentially similar medicinal products, the Special Committee applies a “dynamic invoicing” system. In particular:

- for every increase strictly equal to or higher than 5% of the annual sales in value, a price decrease by 2.5% shall be required
- the calculation shall be effected at the end of each 12-month period after inclusion of the medicinal product in the list.

D. For cases B1) B2) and C mentioned immediately above, the difference of the new price derived from the reference price [(L.T.M.D. - T.A.) x M.D.] is reimbursed every six (6) months as rebate to the social insurance entities and is calculated based on the total sales of the medicinal product during the immediately preceding period of six (6) months. The pharmaceutical companies must pay the amount corresponding to them within fifteen (15) days from the relevant decision of the Special Committee. The medicinal product in question is automatically removed from the Reimbursement list of prescription medicinal products in case of non-timely payment of the amount by the company.

E. The low content medicinal products that refer to children are included in the List even if their price is higher than the reference price, only if they have been positively evaluated by the Special Committee as to their therapeutic benefit.

2. The proven therapeutic effectiveness that is evaluated based on:

a. The gravity of the disease

b. The relation of effectiveness - safety, tolerability

c. The high therapeutic value as compared with respective medicinal products.

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

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

The above takes into account the cost in relation to the clinical effect of the treatment under consideration, in relation to the cost per clinical effect of other

treatments in case there are no differentiations in therapeutic effectiveness. The above-mentioned economic parameter must be documented with economic results of clinical trials and, if necessary, with pharmaco-economic studies based on clinical trials.

3. The parallel reimbursement of the medicinal products under consideration by social insurance entities of other countries of the European Union.

The medicinal products under consideration must be reimbursed by the social insurance entities of France and Spain. For medicinal products that are not reimbursed by the social insurances of those countries, those supported by the international bibliography as regards the adequate documentation of their effectiveness and safety are selected.

Included in the List are:

A) Medicinal products, whose package contains a number of doses covering the monthly treatment or an integer submultiple of the monthly treatment (package of 3, 5, 6, 10, 15 or 30 tablets). Companies that market medicinal products that do not meet the above-mentioned requirement are given the possibility to adapt within a period of three months from the issue of the list by the Special Committee.

B) Medicinal products for which the Special Committee may select from the marketing authorisation of the medicinal product only certain of the indications with which it will include the product in the List as well as the optimum content and packaging that serves the needs of pharmaceutical treatment in relation with the cost of treatment and the alternative treatments.

C) Medicinal products that have obtained a marketing authorisation from EOF (National Drug Organisation) with method of distribution “for hospital use only”. Those products are also administered to patients who continue treatment at home under the conditions specified by the existing legislation.

The list shall include a detailed description of all the data concerning each medicinal product included therein, a reference to the cost of treatment, recommendations and restrictions on indications, on side effects, on matters of prescription and distribution of the medicinal products, according to the judgement of the Committee and to the provisions of the relevant ministerial decisions and circulars or to the content of the instruction leaflet of the medicinal product issued by the EOF and the EMEA.

The above shall be codified so as to constitute an important guide for the Greek physician for the most appropriate therapeutic approach and in order to facilitate the work of pharmacists, nursing personnel and insurance entities.

The List does not include:

A) Categories of medicinal products specified by the Special Committee of clause c and d of par. 1 of article 12 of L. 3816/2010.

More specifically, categories of medicinal products:

1. whose marketing authorisation specifies that they are administered without medical prescription
2. for which it is considered that it is not advisable for their indications to be covered by social insurance (e.g. medicinal products belonging to the "contemporary lifestyle".

Any rejection of a medicinal product must be fully justified.

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

This decision should be published in the Official Gazette.

THE MINISTERS

OF ECONOMY, COMPETITIVENESS & SHIPPING

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