DECISIONS

Ministerial Decision No. DYG3 (a)/oik.104744

Implementation of a reference pricing system for drawing up, revising and supplementing the list of reimbursed medicinal products

THE ALTERNATE MINISTER OF HEALTH

Having regard to:

1. the provisions of Article 90 of the Code of legislation on government and government bodies as ratified by the first article of Presidential Decree 63/2005 (Government Gazette A 98);

2. Presidential Decree 86/2012 (GG A 141/21.06.2012) re: "Appointment of Ministers, Alternate Ministers and Deputy Ministers";

3. Decision No. Y47/3.7.2012 (GG B 2105) delegating tasks to the Alternate Health Minister Marios Salmas, as amended by Decision No. DY1a/oik.78084/25.07.2012 (GG B 2339/2012);

4. Presidential Decree 95/2000 re: "Organisation Rules of the Ministry of Health and Welfare", as amended and currently in force;

5. Point (d) of paragraph 1(b) of Law 3816/2010 (GG A 6/26.01.2010) re: "Restructuring of business and professional debts owed to credit institutions, provisions on credit bureau data processing, and other provisions", as amended and supplemented;

6. the provisions of Article 35 of Law 3918/2011 (GG A 31);

7. the provisions of Law 1316/1983 (GG A 3) re: "Establishment, organisation and responsibilities of EOF", as amended and supplemented;

8. the provisions of Articles 10, 16, 18 and 19 of Law 4052/2012 (GG A 41);

9. Presidential Decree 95/2000 (GG A 75);

10. Article 9 of Presidential Decree 142/1989 (GG A 68);

11. Ministerial Decision No. DYG3d/oik. 57364/06.06.2012 (GG B 1907) re: "Implementation of EOF's medicine pricing tasks";

12. the fact that this Decision does not give rise to expenditure out of the State Budget;

WE DECIDE AS FOLLOWS

Article 1

System for drawing up a positive reimbursement list with reference prices

1. Only the medicinal products included in the positive reimbursement list, introduced by paragraph 1 of Article 12 of Law 3816/2010 (GG A 6), shall be reimbursed by social security funds. The positive reimbursement list shall be drawn up, revised and supplemented using a system for the classification of medicinal products and a system for the computation of reference prices by therapeutic category of active substances. In particular, the assignment of active substances to therapeutic classes shall be based on the fourth level of the Anatomical Therapeutic Chemical Classification System of the World Health Organization (ATC4), to which an internal reference pricing system shall be integrated, whereby the reference price of each therapeutic class shall be the price of reimbursement by social security funds.

2. The positive list shall refer to medicinal products which according to their marketing authorisation are only dispensed with a prescription; it shall not include non-prescription products or products in the negative list. The positive list shall be drawn by the Ad Hoc Committee referred to in paragraph 1 of Article 12 of Law 3816/2010, based on scientific data and criteria. Any objections shall be considered by a relevant Review Committee in accordance with the provisions hereof and applicable legislation.

3. The positive list of reimbursed medicinal products shall be posted on the website of EIF and published in the Government Gazette by Ministerial Decision. The list shall be revised periodically following the issuance of a Price Bulletin that includes a general re-pricing of medicinal products and within 60 days of the issuance of a corrective Price Bulletin for newly authorised products. At the same time, if deemed necessary, the corresponding negative list shall also be revised.

4. In the first application of this Decision, the list shall be drawn up within 10 days of the adoption hereof and shall refer to products already approved and placed on the market, which shall not be subject to an obligation to pay the aforementioned entry fee, provided that the relevant entry fee has been paid. Any medicinal products for which, through the fault of the marketing authorisation holder, the 2011 entry fee and/or the relevant rebate have not been paid, shall be excluded from the list, and EOPYY shall demand the amounts corresponding to the respective sales. For each new medicinal product included in the positive list and reimbursable by social security funds, the marketing authorisation holder shall pay to EOPYY a one-off contribution of EUR 2,000 per pharmaceutical form, strength and dosage.

5. All medicinal products included in the positive list shall be subject to the provisions on statutory rebates payable by marketing authorisation holders (MAHs) to social security funds. If MAHs fail to duly pay the rebate amounts as provided for by applicable legislation, the respective products shall automatically be excluded from the positive list. Also excluded shall be any products the MAHs of which have stated in writing that they do not agree with the terms hereof. Finally, the list shall not include any products for which there have been no sales in the three years preceding the establishment of the list.

6. The e-prescribing system shall be adapted accordingly and incorporate the reference price, the retail price and the total participation of the patient in the cost of each medicinal product in the positive list, for the information of physicians, pharmacists and the insured. At the same time, it shall also be adapted with a view to enabling control for any restrictions on the use of medicines.

7. Any medicinal products imported by EOF and the Institute of Medical Research and Technology (IFET) under emergency procedures shall be reimbursed by social security funds irrespective of whether they are included in the positive list or not.

Article 2

Drawing up the list and establishing therapeutic classes

1. All medicinal products shall be grouped in therapeutic classes at the fourth (4th) level of the ATC classification (ATC4), taking account of the route of administration, nomenclature and grouping of pharmaceutical forms, as communicated by the European Directorate for the Quality of Medicines (EDQM), which operates under the auspices of the Council of Europe, and according to the EDQM Standard Terms.

2. Where an ATC4 class includes medicines which have been authorised for more than one indication, a subclassification of active substances at the same ATC level may take place. New classes may be developed only where an active substance in an ATC4 class is not therapeutically interchangeable and automatically substitutable in the primary indication with the other medicines in its class.

3. Medicinal products shall be reimbursed solely for their approved indications. The Ad Hoc Committee responsible for preparing the positive list may, based on well-documented and comprehensive assessments, recommend that a medicinal product be included in the list and reimbursed by social security funds for only some of the approved indications, forms, strengths or patient groups. In addition, the Committee

may impose restrictions on prescribing on the basis of scientific documentation with a view to ensuring the rational use of medicines and protecting public health. Any rejection of a medicinal product from the list shall be fully justified. If social security funds wish to change any of the restrictions or introduce additional medicines to the list, they shall submit a request for an assessment by the relevant Ad Hoc Committee and, upon positive recommendation by the latter, may amend their reimbursement policies.

4. For the inclusion of pharmaceutical products in the positive list, account shall be taken of data on their efficacy, safety, quality, cost-effectiveness and wider socio-economic implications. The list shall refer to dosing schedules and packages covering a monthly treatment or submultiples thereof. The list shall not include medicinal products for which, in the light of their indications, reimbursement by social security is not deemed appropriate, e.g. lifestyle products. Furthermore, any products classified in negative lists or lists of non-prescription medicines in other European countries shall be excluded from the positive list and shall automatically be included in the negative list.

5. After the first application of this Decision, exclusively on the basis of the criteria referred to in paragraphs 1 to 4 of this article and upon request of the marketing authorisation holder to the relevant Ad Hoc Committee, in very limited and exceptional cases, certain already approved products may be classified in a category corresponding to the active substance (ATC5).

Specifically, subject to positive assessment by the Ad Hoc Committee, ATC5 classification may be assigned to medicinal products which after 01.01.2010 have been approved following an accelerated procedure by the FDA or the EMA and are classified at ATC5-level in the corresponding positive list of Germany or in an ASMR 1 or 2 class of France, thereby fulfilling the criterion that their additional therapeutic benefit must have been assessed and recognised by the competent bodies. In these cases, MAHs shall submit to the Ad Hoc Committee official translations of any documentation evidencing such recognition. The Ad Hoc Committee may, by reasoned decision, reject the request.

6. Additionally, following an assessment by the Ad Hoc Committee, the list may include medicinal products which after 01.01.2010 have received a positive assessment from other reputable European health technology assessment bodies such as the UK National Institute of Health and Clinical Excellence (NICE). In this case,

the marketing authorisation holder shall submit an application, accompanied by a translated copy of the decision of the foreign body and, if available, the dossier submitted to, or the prepared by, such body with evidence of clinical efficacy, cost-effectiveness or cost-utility/cost-benefit analysis, or the budget impact of the product underlying the foreign body's decision to include the product in the respective reimbursement list. Any such dossiers shall be in English or Greek. If considered useful, the dossiers may include more recent data and publications in important scientific journals published after the decision on reimbursement. They may also include further analyses and country-specific versions of the aforementioned international data, in line with local epidemiological and, most importantly, economic data, in order to better reflect the Greek reality. Moreover, they may include additional information on the overall impact of the medicinal product on the State Budget and the national economy as a whole. As mentioned herein and in accordance with international practice, the Ad Hoc Committee may request further data and propose the reimbursement of the medicinal product for specific patient subgroups or for a limited period of time or set specific conditions for the use of the products. In these cases, classification shall not be permanent.

Over the years, with the advances of pharmaceutical technology and scientific knowledge, medicinal products which have been classified by active substance (ATC5-level) may be moved to an ATC4 level, if the circumstances underlying the original decision change. Regardless of the above, EOPYY shall have the right to impose additional financial restrictions on the reimbursement of medicinal products or negotiate with marketing authorisation holders (MAHs) risk-sharing agreements, price volume agreements, closed budgets and rebates beyond the pre-set limits.

7. After their pricing and placing on the market, new products authorised in Greece as from 01.01.2012 shall be included in the positive reimbursement list in accordance with the provisions hereof, the legislation in force and Directive 89/105/EEC, provided that they are reimbursed in other EU countries following an assessment. The provisions of the preceding paragraphs of this article shall also apply to newly authorised medicines.

Article 3

Determination of reference prices and reimbursement

1. A reference price shall be defined for each therapeutic class in accordance with the provisions hereof and shall be the price at which all products in the class shall be

reimbursed by social security funds. According to the provisions of point b of paragraph 1 of Article 12 of Law 3816/2012, as amended, and the provisions of Article 35 of Law 3918/2011, the reference price shall be determined as the lowest cost of daily treatment (CDT) in each therapeutic class. The social security fund shall cover the reference price and, if a more expensive product is selected, the difference between the reference price and the retail price shall be paid by the patient. The reference price shall be determined for each individual therapeutic class as described below. No medicinal product shall be reimbursed at a higher price than its retail price.

2. The Ad Hoc Committee, after classifying the medicinal products as specified in Article 2 hereof, shall calculate the reference price per therapeutic class. According to the legislation in force, the reference price shall be determined on the basis of the lowest cost of daily treatment (CDT) in each class. The CDT shall be calculated on the basis of the Average Daily Dose (ADD) according to the Summary of Product Characteristics (SPC). In certain cases, if the Committee deems it necessary, account may also be taken of the average defined dose based on data from the e-prescribing system of the e-government centre for social security (IDIKA). The CDT shall be calculated using the following formula:

CDT = RP/NDD, where RP is the retail price and NDD is the number of daily doses, calculated as: NDD = QAS / ADD, where QAS: total quantity of active substance and ADD: average daily dose.

3. Included in each therapeutic category shall be all the products, strengths and packages which in accordance with the provisions of Article 2 hereof are eligible for reimbursement by social security funds. The Reference Price (RefP) of each therapeutic class shall be determined as the lowest CDT among all reference products (patented or otherwise) and the average of all generic products in the class.

I.e: RefP = Lowest CDT among: ($CDT_{1 \dots i}$ of products under patent protection, $CDT_{1 \dots n}$ products with patent protection, average $CDT_{1 \dots m}$ of generics).

4. New generic medicines shall be added to the positive list automatically upon their official pricing and shall be included in the calculation of the reference price when, according to IDIKA data, their sales exceed a level corresponding to 4% of the relevant active substance. New generic medicines the reference product of which is included in the negative list shall automatically be included in the negative list after their pricing. The provisions of this article shall apply also in the case of products

classified at active substance level (ATC5), as specified in the paragraphs of the preceding article.

5. For reference medicines which have fallen out of patent protection and for which generics have been placed on the market, the provisions of Article 21 of Law 4052/2012 and Ministerial Decision no. DYG3 (a) / oik GY/149 (GG 545, 01.03.2012) shall apply. Such products shall be subject to the reference price as calculated in accordance with this Decision.

6. For medicines subject to patient co-payment, where the retail price is lower than the reference price, the difference shall be deducted from the patient co-payment. If the difference between the retail price and the reference price equals or exceeds the patient co-payment, no co-payment shall be required on the patient. Products with a lower or zero co-payment rate shall feature in the e-prescribing system, so that the physician, the patient and the pharmacist can all be aware thereof at the time of prescribing or dispensing.

7. Any medicinal products which have been included in the positive list and have a CDT less than or equal to EUR 0.4, even if their retail price is higher than the reference price, shall be included in the positive list and reimbursed by social security funds at the retail price, provided that marketing authorisation holders duly pay the rebates required by the legislation in force.

Article 4

Revision of the list – Objections

1. After the first application hereof and after they have been priced and placed on the market, new products may be included in the positive reimbursement list following a written request of the marketing authorisation holder or the local representative to the Ad Hoc Committee, accompanied by a full dossier of supporting documents and clinical, pharmaceutical, financial and other data, subject to the stipulations hereof.

2. Where marketing authorisation holders or local representatives object to the classification, they shall have the right to submit written comments and objections within 15 days of the publication of the list in the Government Gazette. The Review Committee shall address the objections in writing by a reasoned decision within 30 working days of the date of submission.

3. If the objection is accepted, the medicinal product shall be included in the next update of the list or in a supplement to the list. Any rejections must be duly justified by the Committee.

Article 5

Exclusions and special cases

1. The list shall not include medicinal products of the following types: (i) products which according to their marketing authorisation are designated as non-prescription medicines and listed in Ministerial Decision DYG3a/GP52241/12.05.2011 (GG B 840), as updated from time to time; (ii) products which are prescription-only, not reimbursed by social security funds and listed in Ministerial Decision DYG3a/oik.32294/2011 (GG B 559), as updated from time to time.

2. The medicinal products of the following types: non-therapeutic products (V07); contrast media (V08); general anesthesia medications (M03AV, M03AC, NO 1A), injectable local anesthetics (N01VA, N01VV); immune sera and immunoglobulins (J06); blood substitutes and infusion solutions (V05); coagulation factors (B02BD); vaccines (J07); insulins and analogues thereof (A01 A), for which the cost of daily treatment (CDT) is difficult to calculate, shall be included in the positive list and reimbursed by social security funds, provided that MAHs comply with the provisions of applicable legislation and duly pay rebates to social security funds as required by the legislation in force.

We order that this Decision be published in the Government Gazette.

Athens, 25 October 2012

THE ALTERNATE MINISTER

MARIOS SALMAS