ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ
ΣfEE
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

To:
Mr. Antonis Dimopoulos,
Secretary-General of Public Health

Cc.: Mr. M. Timosidis, Deputy Minister of Health and Social Solidarity
Mr. D. Balasopoulos, Legal Advisor to the Minister of Health and Social Solidarity
Ms. Z. Dede, Chairman of the Pricing Committee
Ms. A. Kyrlesi, Director-General of Health
Mr. N. Karapanos, Director for Medicinal Products and Pharmacies

Halandri, June 21, 2011

OBSERVATIONS OF SFEE ON THE DRAFT MINISTERIAL DECISION ON PRICING OF MEDICINAL PRODUCTS

Dear Mr. Secretary-General,

We set out below the observations of SFEE on the Draft Ministerial Decision on Pricing of Medicinal Products. These observations have been prepared by the competent committee of our Association for pricing issues, in collaboration with the Association's legal department, and have been unanimously approved by the Association's BoD.

Pricing of products after expiry of the patent (article 5 §3 and article 6)

If the price of the medicinal product, after expiry of the patent, is lower than the average of the three lowest prices in the 22 EU countries, **the provisions of article 14 of the authorizing legislation, i.e. Law 3840/2010, (Gov. Gaz. 53/A/2010) must apply, in other words the price given must be the average of the three lowest prices in the 22 EU countries. Otherwise, there would be a breach of the above authorizing legislation.**
The price must be reduced when the market sufficiency with products of the same active ingredient is guaranteed, on the basis of the EOF (National Organization for Medicines) data (e.g. after essentially similar products have been on the market for at least one year).

Patent (article 1§7, article 4§3 and article 6)

- The term 'first' patent is not felicitous. A medicinal product may contain many active ingredients, each one having a patent with a different expiry date. In such cases the product in question is protected until the expiry date of the last patent for any of these active ingredients. In all cases account **must** be taken of the supplementary national or European patent in force, or six-month protection for paediatric medicines, since the protection is total (Law 1733/1987, Min. Decision 11475 EFA 2388, Gov. Gaz. 1165/B/25.6.2008).

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It is also recommended that the principle of marketing data exclusivity (or dpe = data protection exclusivity) should be taken into account on the basis of Article 11 of the Ministerial Decision ΔΥΓ 3ª/83657/2006 (Gov. Gaz. 59/Β/2006) pursuant to the provisions of which a product is protected for a decade (10 years). The decade begins with the issuing of the product marketing authorization. An essentially similar product, for which a marketing authorization has been issued, will not be available on the market before 10 years have passed from the date of the original marketing authorization of the reference product in a member state or in the Community. In any case, a price should not be allotted to essentially similar products if a patent still in force can be cited.

Increases in prices of medicinal products, justified on the basis of law

Within the framework of re-pricing of medicinal products on the basis of Article 14 of the authorizing legislation (Law 3840/2010), apart from any reductions that result, the corresponding increases must also be granted to those medicinal products for which an increase is justified under the current legislation.

Partial removal of plafond (article 7§2)

It should be made clear that the partial removal of the plafond concerns **all** medicinal products (within and outside patents, and essentially similar products). Also, the criteria used to decide the partial removal of the plafond are not transparent and create conditions in which there may be unequal treatment of original and essentially similar products.
Although the intention is to protect inexpensive products, the text of the Decision allows the removal of the plafond only for products with a retail price of over 15€. It should be noted that even if the reduction results to a price lower than 15 Euro, a minimum price level should be ensured, i.e. 15 Euro.
There is no reference to the old and well-established products for which there is still a ceiling on increases, e.g. aspirin, resulting to the increase of parallel exports, shortages in the Greek market and selective treatment, and therefore a lack of transparency.

Hospital price (article 1§4)

The hospital price should be determined on the basis of the ex-factory price, not the wholesale price. Changes in the wholesaler's profit, affecting the wholesale price, should not affect the hospital price (the relevant table is attached). Given that the published prices in Greece affect prices in the European countries, we propose that the hospital price should not be published, which is also the case for the ex-factory price.

Pricing of orphan medicines, blood derivatives and vaccines (article 5§§2,6)
We must point out the contradiction between paragraphs 2 and 6 of article 5. A precise definition is required of the method of pricing orphan medicines. To ensure adequate supplies and smooth circulation of these products, we propose that the hospital price should be equal to the ex-factory price – a proposal which had, in

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fact, been accepted by the previous Pricing Committee. We remind you that because of the special nature of orphan medicines, vaccines and blood derivatives it is necessary that they are priced on the basis of the average of the prices in the reference countries, to ensure adequate supply and availability in the Greek market.

Price notification (article 12 §6)

- The pharmaceutical companies need to be informed at least one week before the issuance of the Price Bulletin about the prices for their products, so that they have reasonable time to make any corrections/observations and, in case of disagreement, present their views timely to the Pricing Committee.
- It is proposed that a Corrective Price Bulletin should be issued within a short time, e.g. twenty days, allowing the possibility of resolving all pending matters and/or objections. This proposal had already been accepted and introduced during the term of the previous Pricing Committee.
- **At the same time, for reasons of transparency, the companies must be notified of the three lowest prices and the countries taken into consideration by the Pricing Committee in determining the price of a medicinal product. This notification will speed up procedures for examining the appeals filed by the pharmaceutical companies**.

Verification Sheets (article 4§3)

- It is proposed that the re-pricing coincides with the first Price Bulletin of each year, and takes place once per year. We suggest that products which were priced during the previous year should not be included.
- The Price Bulletins with new medicinal products should be issued quarterly, the precise dates should be set in advance, **as in fact it is envisaged in the legislation** (ΔΥΓ 3ª οικ/83657/2006, Gov. Gaz. 59/B/2006).
- The Verification Sheet should not cover products which are proven to be withdrawn from the Greek market for more than a year, as evidenced in the data kept by EOF.

We note that products not marketed continue to remain under the flat reduction level of May 2010, and are dragging down prices across Europe.

- The pharmaceutical companies must be given a reasonable period of at least 10 working days to complete the Verification Sheets, given the volume of data asked and the reliability requirements.
- It is completely unnecessary to fill details about forms, strengths and packaging not available in Greece. We propose independent pricing of strengths/forms and in case of lack of a packaging compatible with that used in Greece, the closest form of packaging should be taken into account.
- Finally, only the ex-factory price should be given in the verification sheets.

Reference countries/notification of sources of data (article 4§4 and article 5§1)

We propose that countries which do not have published data should not be taken into account, as it has been the case in the recent past, as well as countries with variable depreciation rates – Great Britain, Holland and Finland. In respect of the other countries which will be used as reference countries, we propose that the sources to be used for each country should be announced, as well as the clear methodologies in calculating the ex-factory price.

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In cases where there is disagreement with the price issued by the Ministry (e.g. depreciation rates) there should be in advance notification of the documents (certificates) which will be accepted by the Ministry (indicative invoices).
Finally, only the ex-factory price should be given in the verification sheets.

Penalties (article 4§5)
The great number of countries and products, and the tight deadlines, make it more likely that there will be errors in the declaration of data, and therefore we propose that the submission of prices with reservation is accepted.

Change in or addition to packaging or strength or form (article 12 §2)
The word "similar" in the phrase "of similar form" should be deleted, given that there is no such term in the pharmaceutical terminology. Moreover, EOF has classified and named all the pharmaceutical forms, as they appear in the Verification Sheet. If the form being studied has been the object of research and development, the average of the three lowest prices in the EU countries should be taken into account, and not the correlation with any other existing form.

Definition of essentially similar products (article 1§8)
The definition should include the statement that an essentially similar product is one which has the same active ingredient, **strength and form,** in accordance with the definition given in Ministerial Decision ΔΥΓ3α/83657/2006 (Gov. Gaz. 59/B/2006).

Discounts (article 3)
The ban of granting discounts should be extended to private clinics, since no discount rate provides a direct or indirect benefit to the insurance funds or to the patient.

Panhellenic Pharmaceutical Association withholding (article 11§7)
A withholding in favour of the PPA should be made in the case of domestic use of medicinal products. In the case of exports, the levy should be returned.

General observations
- There should be no infringement of the principle of the average of the three lowest prices in the 22 countries of the EU, even in cases where the patent has expired, in implementation of the provisions of Article 14 of the authorizing legislation – i.e. Law 3840/2010 (Gov. Gaz. 53/B/2010).
- A provision should be adopted concerning the increases in prices of medicinal products, when this is justified, as envisaged in Community Directive 89/105 relating to the transparency of measures regulating the pricing of medicinal products, and the relevant national legislation.
- The prices of OTCs should be deregulated, since they are not reimbursed by the national insurance system.
- A Price Bulletin should be issued immediately with the new products for which applications were submitted from 1.1.2011 until 30.4.2011.
- Provision should be made for the marketing of products belonging to the category "innovative treatments", even if they are available in fewer than three countries, in accordance with the provisions of the Ministerial Decision under

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publication.

- It should be legislated that medicinal products for serious diseases as referred to in Law 3816/2010 (Gov. Gaz. 6/A/2010) are not subject to the provisions of Article 35(2) of Law 3918/2011 (hospital rebate, Gov. Gaz. 31/A/2011). Otherwise there will be unequal treatment between pharmaceutical companies and pharmacists, who are exempted in this specific case.

We ask you to set a meeting as soon as possible between SFEE's Pricing Committee and the corresponding committee of the Ministry of Health, to allow the Ministry to issue without delay a Ministerial Decision that can be implemented immediately and be acceptable to all.

Yours respectfully,

Fotis Mangalousis
General Director

Pascal Apostolidis
Vice President

Dionysios Filiotis
President

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