To:

Ms Zoe Dede,
Chair of the Pharmaceutical Pricing Committee;

the Members of the Pharmaceutical Pricing Committee

Cc: Mr Andreas Lykourentzos, Minister of Health
Mr M. Salmas, Alternate Mimister of Health
Ms Ch. Papanikolaou, Secretary-General for Public Health
Mr N. Karapanos, Director of the Directorate of Medicines and Pharmacies
Prof. Dr I. Tountas, President of EOF
Ms M. Skouroliakou, 1st Vice-President of EOF

Subject: SFEE's positions regarding the pricing of medicinal products

Halandri,7 October 2012

Dear Ms. Dede,

Dear Members of the Pharmaceutical Pricing Committee,

SFEE's key positions with respect to the medicine pricing system are set out below:

• Development of a transparent, objective and predictable pricing system.

• Facilitating patient access to existing and new innovative treatments and protecting domestic production of medicines.

• Avoiding a negative impact on other European countries that use Greece as a reference country, in order to ensure adequate supply of pharmaceutical products in the domestic market and safeguard public health.

• Additional cost savings in the health system, to be achieved mainly from the pricing of off-patent and generic products.

For these objectives to be attained, a crucial condition is that an originator (on- or off-patent) product, irrespective of its price level, cannot be is in no way lower than the average of the three lowest prices of the EU reference pricing basket, in order to avoid shortages of products in the Greek market and to ensure the access of Greek patients their proper treatments.

For **on-patent** products, the above condition is already provided for in the existing legal framework of medicine pricing (Law 4052/2012) and the proposed draft Ministerial Decision in question.

Regarding **off-patent** products, it is absolutely necessary that a similar clause, setting as a floor the average of the three lowest prices of the basket of the EU reference pricing basket, be introduced by the Ministerial Decision that is currently under elaboration. Otherwise, we are bound to see serious shortages and withdrawals from the market, due to higher parallel exports, and complications in the pricing of pharmaceuticals in other EU countries that use Greece as a reference country. At the same time, low-cost older drugs will be withdrawn and be substituted with more expensive ones.

Besides, in designating a product as off-patent, implying a significant reduction in its price (e.g. 50% under Law 4052/2012), the following should be considered:
a) whether all the patents of the product (e.g. for its active substance, pharmaceutical form, method of administration, method of preparation, indications, etc.) have expired;
b) whether, at the time of re-pricing, the copy/generic is legally on the market without any type of unsettled legal issues in this respect.

It is not legally sound to use only data protection as a criterion for the designation of a medicinal product as off-patent, therefore its pricing according to the relevant methodology; in fact, data protection legislation explicitly makes itself subject to the rules on industrial property rights and trade marks (in respect of approved patents). All patents have the same legal status and cannot be violated. This is also explicitly mentioned in Article 10 para 1 of the recent Ministerial Decision DYG3a/82161/2012 implementing EU Directive 2010/84: “without prejudice to the provisions governing the protection of industrial and commercial property rights...”

Instead, using only data protection as a criterion for designating a medicinal product as off-patent, and therefore significantly reducing its price, will cause serious problems in the pharmaceutical market and major supply shortages, as a result of

withdrawals and increasing parallel exports. This would be tantamount to circumventing the very meaning of patent protection for medicinal products.

Please find attached a note with SFEE's detailed remarks on the draft Ministerial Decision.

Sincerely,

Nikos Kefalas
Vice-President

Comments on the draft Ministerial Decision on medicine pricing

In response to the proposed draft Ministerial Decision forwarded to SFEE on Friday, 5 October 2012, we would like to submit the following comments, along with corresponding proposals:

Article 1 paragraph 4

The Maximum Hospital Price should not be published in the Price Bulletin, in order to avoid problems from the use of hospital prices as reference prices in other EU countries.

Article 2 paragraph 2(c)

We propose a reduction in the profit margin (currently at 32.4%) of pharmacists on the wholesale price of prescription medicines priced under €200, in order to meet the MoU 2 target for a total pharmacy margin of 15%, provided that the target of €2.88 billion for outpatient pharmaceutical expenditure is also maintained for the year 2012.

Article 3

Paragraphs 3 and 4 require pharmaceutical companies to supply their products to pharmacies, wholesalers and cooperatives on credit for at least two months. This provision is unconstitutional and in breach of Article 4 on freedom to conduct business, while blatantly violating free competition rules. The duration of any credit should be optional and at the discretion of each company, as in the case of credit from wholesalers to pharmacies under paragraph 4 of the same article.

Article 4 paragraph 1

The official sources used for pricing purposes should be announced at least one month ahead of the issuance of a Price Bulletin. Any countries that do not publish reliable reference prices or face major exchange rate variations could be excluded from the basket of reference countries. Reference countries shall be publicly announced once a year.

Article 4 paragraph 2

Paragraph 2 lists among the data necessary for determining the price of medicines the date of expiry of the 10-year or, where appropriate, 11-year protection under in Article 10, paragraph 1, subparagraph b of Joint Ministerial Decision DYG3a/oik.82161/24.8.2012, or 6-year protection for medicines authorised prior to the entry into force of Joint Ministerial Decision DYG3a83657/2005 in accordance with Article 150 thereof.

The above wording is contrary to national and EU legislation on patent protection and the Convention signed between our country and the European Patent Office.

Consequently, the phrase "the expiry date of the 10-year patent protection or, where appropriate, the 11-year patent protection under Article 10 para 1 subparagraph (b) of Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012), or the 6-year patent protection for medicinal products authorised prior to the entry into force of Joint Ministerial Decision DYG3a/83567/2005" should be replaced as follows: ***"the expiry date of all the patents that protect the medicinal product (e.g. for the active substance, pharmaceutical form, method of production, method of administration, indications, etc.), in line with national and EU legislation on industrial property rights".***

Article 4 paragraph 4

The sentence "Any sale invoices shall not be considered as eligible input in this respect" should be deleted, as there are several countries which do not officially publish net producer or import prices, in which case the invoice is perhaps the only evidence of the price.

Moreover, the phrase "the start and expiry date of the first national or European patent for the active substance of the medicinal product" should be replaced as follows: "***the expiry date of all the patents that protect the medicinal product (e.g. for the active substance, pharmaceutical form, method of production, method of administration, indications, etc.), in line with national and EU legislation on industrial property rights".***

Article 5 paragraph 3

No specific provision has been made for the pricing of orphan medicinal products which are recognised as necessary to address life-threatening conditions, have been

approved by international organisations and are essential for public health (antiretroviral, non-prescription, etc). It should be clarified that this paragraph should act only in a positive direction (e.g. protection of orphan medicines, accelerated pricing procedure for specific categories, etc.) rather than having a negative effect (e.g. across-the-board price reductions).

Article 6 paragraph 1

The phrase "the expiry date of the 10-year patent protection or, where appropriate, the 11-year patent protection under Article 10 para 1 subparagraph (b) of Joint Ministerial Decision DYG3a/oik.82161/24.8.2012 (Government Gazette 2374/B/24.8.2012), or the 6-year patent protection for medicinal products authorised prior to the entry into force of Joint Ministerial Decision DYG3a/83567/2005" should be replaced as follows: ***"the expiry date of all the patents that protect the medicinal product (e.g. for the active substance, pharmaceutical form, method of production, method of administration, indications, etc.), in line with national and EU legislation on industrial property rights. This reduction shall not lead to a price lower than the average of the three lowest prices in the EU reference pricing basket, as laid down in Article 4 paragraph 3 of the Ministerial Decision".***

Any further reductions, beyond 50%, in the prices of off-patent products without establishing a floor equal to the average of the three lowest prices in the EU would result in the withdrawal of low-cost medicines from the market and their substitution with new expensive ones, or an increase in parallel exports and supply shortages in the Greek market. It would also give rise to complications in medicine pricing in several European and other countries that use Greece is a reference country.

Also, an exemption from the 50% reduction in prices should be introduced for OTC and non-reimbursed medicinal products. For these categories, in particular OTC products, prices should be determined freely, subject only to regulatory monitoring for excess profit or excess price increases.

Article 6 paragraph 2

With reference to the data to be included in the Price Verification Sheet, the phrase "expiry date of the first national or European patent of the active substance" should be

replaced as follows: "***the expiry date of all the patents that protect the medicinal product (e.g. for the active substance, pharmaceutical form, method of production, method of administration, indications, etc.), in line with national and EU legislation on industrial property rights."*** Off-patent designation, and the associated price reduction of 50%, should not be applied to a reference medicinal product before the expiry of all such patents.

Article 6 paragraph 3

The first sentence should be replaced as follows:

"At the first application of this Decision, the prices of off-patent medicinal products (as defined above) shall be set at 50% of the latest price assigned to the medicine while on patent (or at the time of the pricing of the first corresponding generic). This reduction cannot lead to a price lower than the average of the three lowest prices of the EU reference pricing basket as defined in Article 4, paragraph 3 of the Ministerial Decision".

Article 6 paragraph 4

This paragraph should be replaced as follows: "Marketing Authorisation Holders may apply for a lower price, but not less than the price of the respective generic product, as defined in Article 7, paragraph 1 or paragraph 5 of the Ministerial Decision".

Article 7 paragraph 1

The first sentence should be replaced as follows: "The wholesale prices of generic medicinal products shall be 20% lower than the current price of the reference originator product for the same active substance, form and strength, as such price has been reduced following the expiration of relevant patents."

Article 7 paragraph 5

This paragraph should be replaced as follows: "Marketing Authorisation Holders may apply for a lower price, up to 20% lower than the official price of the respective generic product, as defined in Article 7, paragraph 1 of the Ministerial Decision".

Article 8 paragraph 4

The provision of Article 8, paragraph 4 introduces a discrimination against domestically produced originator medicines: their prices, unlike what is the case with the corresponding imported products, will be determined in almost all cases on the basis of the average price in their respective ATC4 class, notwithstanding the provisions of paragraphs 1 to 3 of the same article, since in practice the average (mainly driven by the prices of generics) will almost always be lower! This discriminatory treatment, apart from being open to appeal, acts as a clear disincentive for the development of original proprietary medicines domestically, contrary to the alleged intention! A paragraph to this effect was accepted for inclusion in the existing Ministerial Decision, which provides for a safety ceiling equal to three times the average of prices for the ATC4 class, and should remain so.

Article 10 paragraph 4

A sentence has been added, reading as follows: "In the event of an exceptional number of applications or in exceptional circumstances, the period may be extended for a number of days." This is contrary to EU Directive 89/105, stating that medicinal products shall be priced within 90 days of the submission of a pricing application.

Article 12 paragraph 3

The price reduction of 25% for the conversion from a smaller to a larger pack, when the corresponding increase for the conversion from a larger to a smaller pack is 12%, is totally incoherent.

Article 12 paragraph 5

We propose that a draft Price Bulletin be made public, allowing time for companies to provide feedback within two days and for the Pricing Committee to review any objections ahead of the official publication of the final Price Bulletin.

Article 12 paragraph 7

In the article containing the conversion tables, a paragraph has been added with a reference to the positive list, enabling the respective committees to exempt products from the positive list at their discretion and not on the basis of transparent criteria.