

To
Mrs. Louka Katseli
Minister
Ministry of Economy, Competitiveness and Shipping
119 Mesogeion St.
101 92 Athens

Cc: Mr. Stefanos Komninos, Secretary General of Trade
Mrs. Athina Linou, President of the Committee for the Prices of Medicines
Mr. Michael Kakazianis, Director General, Directorate of Prices of
Industrial Products and Medicines

Halandri, April 6, 2010

Dear Mrs. Katseli,

The Hellenic Association of Pharmaceutical Companies after having been informed on the new Market Decree would like to notify the following:

The new Market Decree represents a heavy blow to the pharmaceutical Companies and has substantial and processing problems and errors, and it is against the National and European Union legislation. Especially as we have repeatedly up until today underlined, our country cannot be compared with countries having significantly lower GDP or PPP, namely Greece cannot be compared with Bulgaria, Poland, Latvia and Romania. Besides the countries you have already excluded (Denmark, Sweden, Estonia and Malta), there are other countries, such as: United Kingdom, the Netherlands, Cyprus, which should also be excluded or you should thoroughly identify the official certificates needed for the determination of the ex factory price. Consequently you must immediately notify the prices per company and most importantly give enough time to the companies to submit the necessary supporting documents, which will guarantee the reliability of the entire procedure.

In detail:

Regarding the Article 1 of the Ministerial Decision (Amendment of the Market Decree):

1. Article 331 §3: In view of the forthcoming opening of the closed professions, the institution of obligatory discounts among individuals is in disagreement with the Government's intention to open the professions and is totally incompatible (e.g. obligatory discount from companies to wholesalers, obligatory discount from companies to Private Clinics, obligatory discount from companies to pharmacies etc.)
2. Article 331 §4: The application of this provision according to which the companies should market their medicinal products to the pharmacies of private clinics in a state hospital price, creates a legally untenable

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expansion of the application field of the Hospital price, which is exclusively designated for the State. At the same time it does not serve any interest to the State, on the contrary it can create serious implications to the market (e.g. shortages of medicines etc.)

The same applies to the high cost medicinal products (par.2, article 21 of the L.3816/2010), where besides everything else mentioned so far, creates also an issue of adequacy of medicines in the market, as the companies cannot afford to provide (excluding the wholesalers sector) these medicinal products directly to 11.500 pharmacies throughout the country.

3. Article 331 §5: This particular paragraph should be excluded, since it is beyond legislative authorization.
4. Article 333: The reference to the Private clinics should be excluded from the second paragraph for the same reason mentioned in the second bullet.
5. Article 336: SfEE is against the provision of §1, and insists upon its initial suggestion to have a free competitive price and a special insurance price for the Insurance Funds.

Furthermore the reference within the provision according to which in order to determine the price of a medicinal product, this product must have been granted a price in the same form and content in at least three (3) countries of the European Union, must be omitted since it restricts free circulation of products and is opposed to the European Union Law.

6. Article 336 §3: The prices of pharmaceutical products based on exchange rates equivalencies, when these prices remain unaltered in the local currency, should not be taken into consideration.
7. Article 337 §1: The term “First Patent” should be omitted because it is legally false (it doesn’t exist). In parallel at the time of expiry of the Patent it should also be included the time of Supplementary Patent (for the cases hold valid). See European Union Law

After the reduction of price by 20% (due to the expiration of Patent), the price that results should not in any case be lower that the one that results based on Article 336 (3 lowest prices in the E.U.).

Therefore upon the submission of documents from the pharmaceutical companies, proving that the Patent of a pharmaceutical product has not yet expired, nor has the time of the Marketing Data Exclusivity, the Authority will bare responsibility in case it grants a price to such a product.

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Moreover no reduction of price because of the expiry of a patent can be accepted, unless branded essentially similar pharmaceutical products of the same pharmaceutical form have not legally been marketed in adequate quantities.

8. Article 338 §1: The phrasing of section 1 of §1 is wrong, since no relative legislative authorization has been provided. Consecutively the referred to 72% provision should be omitted.

Regarding the Article 2 of the Ministerial Decision (Amendment of the Market Decree):

9. The suggested null increases for medicinal products more than 5,01 € are illegal, since they are against the Article 336 of the Market Decree and the European Union Directive 89/105. In any case the suggested price readjustments should be gradual (e.g. according to the income tax scale).

At this point we ought to point out our serious reservation for the included table.

Summarizing we would like once again to point out that the only viable and commonly accepted solution for the price determination is the institution of a free competitive price and a lower insurance price for the Insurance Funds. Only in this way will the adequacy of medicines in the Market be ensured and the replacement of old, well-established medicines by newer and more expensive ones be avoided (unless it is obligatory).

We must underline that the implementation of the Market Decree (as it is) will cause serious problems to the smooth operation of pharmaceutical companies and consequently will have a major impact on the flawless operation of the Pharmaceutical Market in Greece.

What is most important though, is that in case this Market Decree is implemented (as it is), the rationalization of the Public Pharmaceutical Expenditure, which we all look so forward to and desire, will not be achieved.

With Respect,

Dionysios Filiotis
President of SFEE

Pascal Apostolides
Vice-President of SFEE