ΣΥΝΔΕΣΜΟΣ ΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΠΙΧΕΙΡΗΣΕΩΝ ΕΛΛΑΔΟΣ — ΣfEE — HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

To
the Honourable Minister
of Health and Social Solidarity
Mr Andreas Loverdos

Cc: Mr Georgios Koutroumanis, Minister of Labour and Social Security
Mr Michael Timosidis, Deputy Minister of Health and Social Solidarity
Mr. Demetrios Vartzopoulos, Deputy Minister of Health and Social Solidarity
Mr Antonios Demopoulos, Secretary-General for Public Health
Ms Athena Dretta, Secretary-General for Social Security
Mr Nikolaos Polyzos, Secretary-General of the Ministry of Health
Mr. Ioannis Tountas, President of the National Organisation for Medicines
Mr G. Voudouris, President of EOPYY
Ms M. Skouroliakou, Vice-President of EOF

Halandri, 17 February 2012

Dear Minister,

As a follow-up to the various discussions we had with you as well as with the Secretary-General for Public Health, Mr. A. Demopoulos, the Secretary-General of Social Security Ms Athena Dretta and the President of EOF, Mr I. Tountas, in the context of the efforts to rationalise public pharmaceutical spending, we would like to set out SFEE's positions on the draft law, re: "*Regulation of matters relating to the National Health System, medicines, pharmacies and other provisions*" implementing the recent Memorandum of Understanding.

The draft law contains some measures with which we agree, but also some measures that dramatically worsen the quality of pharmaceutical treatment available to Greek citizens. Moreover, they have the potential of causing serious supply shortages and letting into the market products of dubious quality or even dangerous to the lives of patients.

For instance, the draft law punishes Greek patients and excludes them from early access to new innovative medicines by stating that they have to wait until such medicines are reimbursed in 18 European Union countries (2/3 of Member States).
<u>This is tantamount to a prohibition of innovative medications and will encourage a black market for such products at an exorbitant cost to patients.</u>

The priorities and focus of the envisaged measures are clearly misplaced: rather than seeking to rationalise pharmaceutical expenditure through full computerisation and incentives against waste and corruption, the thrust is exclusively on cost matters and on physicians' prescription behaviour, without any mention as to who will ultimately determine the appropriate pharmaceutical treatment and who will control quality.

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Also, the pharmaceutical industry, a very healthy sector that has been making a huge contribution to therapeutics worldwide and in our country, is condemned to ruin and decay through measures that are unrealistic: e.g. the penalty rebate payable at the end of each quarter effectively penalises companies for just doing their job as required by law, which is to supply the market with adequate quantities of their products and make them available to Greek patients.

The draft law envisages a barrage of dire measures against our industry, as well as against patients; neither pharmaceutical companies nor patients can possibly sustain such measures.

We would like to recall that our industry has already contributed a lion's share to the reduction in pharmaceutical spending by around €2 billion in the years 2010-2011 and has faced repeated and across-the-board price cuts and too onerous rebates, plus a ticket in an aggregate amount of about €175 million,

Honourable Ministers and Secretaries-General,

Faced with the lowest prices in the European Union and with administrative intervention measures that stifle competition, the pharmaceutical industry cannot afford and is *de facto* unable to pay the amounts suggested by the Memorandum. Even more so, considering that the outstanding debts of the public sector to pharmaceutical companies are still huge and the Greek government bonds we were forced to accept in settlement of arrears are now at risk of a haircut, threatening to put us out of business.

Against this background, we would like to submit our proposal, outlining the areas and points that should be given priority and suggesting ways to control pharmaceutical spending. Here is our proposal:

- **Reimbursement list**

The stipulation of the draft law under which a medicine can be reimbursed only if it is marketed and reimbursed in 18 EU countries (2/3 of member countries) punishes and condemns Greek patients to not having immediate access to new and innovative medicines, depriving them of the opportunity to get an early treatment and benefit from scientific progress. This will result in social inequality, as access to new innovative treatments will be a privilege of well-off citizens. Moreover, this measure is incompatible with Article 26 of the Lisbon Treaty on the Functioning of the European Union on the free movement of goods.

A fair and simple system should instead be introduced, involving the automatic inclusion of all pharmaceutical products in the list, in return of a flat low-rate rebate on the turnover of each product. Such automatic inclusion in the list will help avoid time-consuming procedures, including approval by the relevant committee, etc.

The State must reward innovation and scientific advances. In this context, all the originator patented pharmaceuticals should be classified in an ATC5 list.

It is also a well-known fact that pharmaceutical companies have paid the reimbursement list ticket by 31 December 2011.

- **Rebates**

SFEE is downright against multiple rebates. The already legislated measures to rationalise the system can alone bring about the sought-for savings on public pharmaceutical expenditure, provided they are effectively implemented across the entire spectrum of stakeholders. It is not fair that whenever the government fails to enforce already legislated measures it resorts to the pharmaceutical industry and imposes impracticable agendas such as across-the-board price cuts and multiple rebates. Pharmaceutical companies are truly unable to withstand these measures, which condemn them to ruin and decay.

Concerning the automatic claw-back mechanism, threatening the industry with a quarterly rebate if pharmaceutical expenditure exceeds budget limits, we would like to stress that this measure will undermine the effort to rationalise the system, for two reasons:

- first, the other stakeholders in the system will have weaker incentives to promote the other structural measures aimed at rationalisation, knowing that any expenditure overruns will in any case be allocated to the pharmaceutical industry; and
- second, it will trigger uncontrollable competition for sales, given that the rebate will be imposed without the system being able to ascribe responsibility for the overrun.

- **Expiry of patent**

Although the new Memorandum of Understanding recently passed by Parliament rightly states that the prices of originator medicines and generics will be reduced after the expiry of the patent, the draft implementing law states that this will occur upon the expiry of the first national or European patent. The term “first” patent is legally and scientifically inappropriate, since the patent is single. Therefore, any reference in the implementing law to the “expiry of the first national or European patent” should be rephrased to read as “expiry of the patent”.

- **Protecting free competition**

Marketing authorisation holders (MAHs) should reserve the right to further cut the prices of off-patent originator medicines or generics, subject to an application and approval process. This would foster competition between off-patent and generic medicines, as also stated in the Memorandum of Understanding passed by Parliament.

- **Prescribing by active substance – Substitution by pharmacist**

If prescribing by active substance is implemented, as provided for in the draft law, it will cause huge problems to the market and by extension to public health, not to mention that it will prove counterproductive and, rather than reduce it will increase pharmaceutical spending, in the absence of a system for controlling prescriptions.

- **Electronic prescribing – Therapeutic protocols**

For several years now, SFEE has argued that prescription volumes can be controlled by fully implementing electronic prescribing alongside the introduction of therapeutic protocols, a patient card and patient history. This is the only way to ensure sound and fraud-proof prescribing practices.

- **Authenticity tag**

Social security funds are burdened with reimbursement costs for medications not actually administered to their insured, in the context of an illegal trafficking of authenticity tags of re-exported pharmaceuticals. This phenomenon can only be eradicated by rigorous controls and by legislation making it mandatory that the deleted authenticity tags of re-exported products be retuned to EOF.

- **VAT**

Public health insurers and public social security should be exempted from VAT. This can help reduce red tape and make public pharmaceutical expenditure more clear-cut. At the same time, VAT on all medicines should be reinstated at the 1st-class rate, whatever this will be, e.g. 12%, applicable to all pharmaceuticals sold to private-sector clients, including foreigner visitors of Greece. This could yield additional government revenue of over €100 million, coming mostly from presumably well-off consumers, Greeks or foreigners.

- **Patient co-payments**

Patient co-payments should be streamlined and become fairer and more cost-efficient, thereby also helping to control the system and stem reimbursement costs. In this direction, we propose a new scheme of co-payment per package, with lower co-payment rates for the economically weak, poor, unemployed, etc. and higher rates for well-off consumers.

According to income categories, EOF should further refine therapeutic categories, taking into account similar classifications in many EU countries.

This co-payment scheme would ensure better management, highly effective control and huge savings for the system. Of course the pharmaceutical industry **has proposed and agrees to print the co-payment rate on the authenticity tag of each package.**

Dear Ministers and Secretaries-General,

Great caution and moderation is warranted. Excessive and forced price squeezes will not only kill the healthy industry of pharmaceuticals, with adverse implications in terms of unemployment, loss of tax and contribution revenue, etc., but will also trigger a chain of adverse reactions, i.e. supply shortages followed by a withdrawal of generics and, ultimately, substitution with newer and much more expensive medicines.

We always remain at your disposal and ready to help in the directions outlined above.

Sincerely,

Fotis Mangalousis
Director-General

Ioannis Chrysospathis
Legal Advisor

Dionysios Filiotis
President

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