

To
the Honorable
Mr. Andreas Lykourantzou
Minister of Health

Cc.: Mr. Yannis Stournaras, Minister of Finance
Mr. Marios Salmas, Deputy Minister of Health

Halandri, July 30, 2012

Honorable Minister,

With great surprise we were informed by the media that the Government intends within the next few days to send to the pharmaceutical companies the notes imposing the Automatic Return Mechanism (Clawback). At the same time we were informed that the Ministry intends to receive from the implementation of this measure the amount of €152,6 mio.

Herewith, we would like to clarify that we are completely opposed to this action, which lacks any sense of logic that your Government has been called to serve.

More specifically, while the greatest challenge is transparency and credibility the calculation of outpatient expenditure is still full of mistakes and inaccuracies (as there is no common denominator for the calculation, no final agreement excluding, as it should, the VAT and the products for exclusively hospital use).

Moreover, the State insists on the implementation of flat measures, while at the same time during the entire first half of 2012 it delays intentionally or not the implementation of the already legislated measures and reforms concerning the medicine. Accordingly, these measures should have equal impact to all stakeholders of the supply chain.

In conclusion, the clawback measure encourages and motivates the State -which is what actually happened- not to implement measures against the rationalization of the pharmaceutical budget, because the pharmaceutical companies will be called to pay this deficiency at the end of the day. And for this simple reason we are completely opposed to this measure.

Pharmaceutical companies are not in any way willing to pay the clawback, the calculation of which is completely non transparent, while other legislated measures have been either not implemented or partly implemented i.e.:

1. Reduction of the prices of off patent / generics at the correct level
2. Payment of pharmacists rebate
3. Reduction of profit margins of the supply chain to 15%
4. Co-payment rates
5. Full implementation of e-prescribing
6. Fight against fraud through combating the phenomenon of fake prescriptions, through the completion of the IT infrastructure of the health system etc.

We remind you that SFEE has already filed an application for the annulment of the relevant Ministerial Decision before the Council of State for the following supplementary reasons:

- 1) This measure violates the principle of equal treatment, because, in an arbitrary way, it imposes this measure only to the pharmaceutical companies and not to the other stakeholders of the supply chain.
- 2) The criteria according to which the measure is imposed are vague since they do not clearly identify the amount that the pharmaceutical companies need to return and the methodology followed for the accurate allocation of the amount exceeding the expenditure to the liable company.
- 3) The liable companies do not contribute to the exceeding of the pharmaceutical expenditure since the physicians are those who prescribe.
- 4) This measure is supplementary and it should be implemented only under the condition that the full implementation of the measures foreseen by the Memorandum is insufficient and the pharmaceutical expenditure exceeds budget limits.

Only if the following requirements are met, can the calculation of EOPYY's pharmaceutical expenditure be transparent, fair and objective:

- 1) The distinction between pharmaceutical and hospital expenditure is absolutely necessary in order to stop the systematic and rapid rollover of the expenditure from hospitals to EOPYY in 2012.
Hospitals should start, at last, supplying hospital medicines immediately. In any case, the other "hospital" medicines that will continue to be included in the outpatient expenditure should be sold from now on at ex-factory price, without any hospital discount.
- 2) VAT must not be included in the calculation of pharmaceutical expenditure as it constitutes a tax and thus an income for public finances, as everywhere else in the EU.
- 3) The cost of hospital products distributed by EOPYY pharmacies is deducted from the pharmaceutical expenditure according to the OECD definition. EOPYY has its own distribution chain allowing the distribution of hospital medicines unlike other European countries. All the medicinal products of the list 3816 (OJ 1003/B/2012 appendix 1a) are included in the hospital expenditure as well as the following categories: a) growth hormones and erythropoietin factors, b) interferons, c) revlimid, d) remicade and e) IFET medicines for short hospitalization.
- 4) Delays in pharmacists' payments result to the non collection of the rebate which amounts to around €5 mio per month. Since this delay is a fault of the State, the latter cannot ask from the pharmaceutical industry to pay the relevant losses as a clawback.

Finally, all the above happen while the State needs to reason the devastating for our companies delays in the settlement of the accumulated debts of EOPYY and hospitals, literally leaving their debts to reach uncontrollable amounts, without suggesting any timeframe for their settlement.

At this point, we have to stress out that the pharmaceutical companies have contributed to the reduction of health expenditure more than anyone else.

During the period 2009-2012 the public pharmaceutical expenditure will have been reduced by € 3 bill., i.e. -40%. It is obvious that we cannot continue to operate and supply the pharmaceutical market, without having at least secured the settlement of the debts you own to us.

Honorable Minister,

For all the above reasons we urge you to reexamine the clawback issue and of course for transparency reasons to inform us in detail on the methodology followed for its calculation.

Faithfully yours,

Fotis Mangalousis
Director General

Konstantinos Frouzis
President