

Halandri, July 20, 2012

SFEE's Memo

1. EOPYY financing

EOPYY is the largest social security fund in Greece covering practically more than 9 million insured citizens. The state needs to focus immediately its attention to resolve the problem of EOPYY financing, since the situation which has been formed due to the outstanding debts to pharmaceutical companies exercises great pressure to the latter and causes huge problems to their liquidity and their ability to supply the market. As a result, the Greek citizen and patient bear the entire burden of poor coordination of the state.

Within this framework it should be noted that the EOPYY's budget has been compressed to €2,88 bn per year and there are pressures for further reductions. SFEE underlines that EOPYY's budget should not be lower than 2,6 bn on a yearly basis because otherwise great problems will be caused to the operation of the market and the viability of the pharmaceutical companies and the other partners of the pharmaceutical supply chain.

Therefore, a permanent and sustainable solution to EOPYY's financing should be immediately given in order to ensure the smooth operation of the pharmaceutical market and consequently the unhindered patients' access to medicines and new therapies.

2. Outstanding debts of the State to pharmaceutical companies

Pharmaceutical companies are facing acute problems and serious difficulties in supplying their products to the market because of the continuous accumulation of debts of EOPYY and public hospitals. By the end of July 2012 these debts will have reached the exorbitant amount of **€1.65 bn**. More specifically:

- Debts of IKA-EOPYY amount to **€640 million** and concern unpaid invoices for at least 19 months.

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- Debts of NHS hospitals amount to **€820 million** and concern unpaid invoices since end 2010.
- Debts of military hospitals amount to **€140 million**, 1/3 out of which concern unpaid invoices issued during the period 2007-2010.
- Other debts (IFET etc.): **€50 million**.

The lack of liquidity impacts severely the healthcare sector and consequently damages social solidarity and cohesion. Therefore, it is absolutely necessary to ensure that the outstanding debts for the years 2010 and 2011 will be settled as soon as the new tranche of €6.5bn will be allocated to the Greek Government by Troika in September. The normal flow of payments is an absolutely necessary prerequisite for a sustainable healthcare system.

3. “Haircut” of the bonds of pharmaceutical companies

The inclusion of pharmaceutical companies’ bonds in the PSI 2 is not only an unfair and disastrous development for a dynamic sector of the economy that supports the development of the country, but it also has broad implications in the pharmaceutical market.

Pharmaceutical companies’ bonds are “special type” bonds and not investment bonds. They were issued in 2010 to cover suppliers’ verified claims against public Hospitals dating back to 2007, 2008 and 2009, and repayable over a horizon of more than four years, i.e. in 2011, 2012 and 2013 respectively. That is, the bonds represent claims which, although overdue, were repayable free of interest within about four years of their due date, implying a financial cost for suppliers. Therefore, the inclusion of these bonds in PSI 2 causes automatically even higher losses to their holders, who have already lost a substantial part of their original claims.

Furthermore, the acquisition of these Bonds was not an investment choice made by suppliers, but a virtually forced solution that would ensure the full satisfaction of their claims on public hospitals. Therefore, their inclusion in PSI 2 caused their holders to suffer the consequences of an investment that they did not choose but which was instead forced upon them.

The chronic failure of public hospitals to fulfill their obligations vis-à-vis suppliers in combination with the inclusion of the pharmaceutical companies' bonds in PSI 2, jeopardize directly their survival and therefore the smooth supply of public hospitals. It should be noticed that the damage incurred to pharmaceutical companies amounts to around €1billion. For all the above reasons the issue of the haircut of pharmaceutical companies' bonds through PSI2 must be immediately revisited.

4. Patients' access to new innovative therapies

Greek patients in violation of the national and EU legislation - according to which Price Bulletins with new medicines must be issued every 90 days- are waiting for more than 2 years for new innovative treatments and medicines to be marketed. No price bulletin with new medicines has been issued since December 2010 and it should be noted that some of the medicines in question concern serious diseases which up to now remain uncured. More specifically, some of the medicines which are delaying for more than 19 months concern the following diseases:

- Metastatic prostate cancer
- Chronic myeloid leukemia
- Advanced (unresectable or metastatic) melanoma in adults
- Transplant
- Hepatitis C
- Pulmonary hypertension
- Tuberous sclerosis
- Cystic fibrosis
- Rare diseases

The Government must immediately proceed with the issuance of the Price Bulletin with new medicines in order to meet the therapeutic needs of Greek patients and improve their quality of life.

5. Transparency: Structural Healthcare Reforms & Industry's stricter self regulation

❖ The Greek Government has to move quickly with the complete implementation of all the **structural healthcare reforms** foreseen by the MoU. The

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complete implementation of e-prescribing and the complete computerization of social insurance funds and public hospitals is the only effective and reliable choice for the containment of public expenditure. The implementation of an IT system in combination with the e-prescribing and the introduction of electronic patient record should belong to the top priorities of the Government for the monitoring of health expenditure. Furthermore, the complete computerization of the healthcare sector will effectively cover the need to tackle fraud and mismanagement and it will restore transparency in the system.

❖ SFEE's emphasis on the implementation of the **Code of Ethics** is characterized by a strong moral dimension of responsibility to the scientific community and to society as a whole. SFEE will submit to the Greek Government within September a comprehensive package of measures aiming to the more austere self-regulation of the pharmaceutical sector and the stricter implementation of the Code of Ethics. The pharmaceutical companies reinvent themselves in response to the extraordinary financial difficulties our country is facing and are determined to set stricter rules re congresses, scientific events, donations, payments to healthcare professionals, market research, reduction of promotional expenses etc. This is an integrated initiative for **stricter self-regulation** which will be implemented with consistency, determination and constant vigilance that the value of ethics is imperative.

6. Return to development & growth: Enhance innovation, clinical trials & investments in Greece

Innovation is vital to any successful long-term economic strategy. Pharmaceutical innovation contributes significantly to economic growth because it constitutes a huge investment. The pharmaceutical industry creates important added value and belongs to one of the most dynamic and evolving sectors of the economy. It should be mentioned that the pharmaceutical industry spends €27.5 billion per annum on research and development in Europe. Especially in Greece clinical trials (investment) reached €85 million in 2010. It is estimated that this amount could quadruple if there was a stable environment rewarding innovation in our country and if a series of measures were taken which would remove the disincentives and the market distortions, i.e:

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- Elimination of bureaucracy (under the current regime central approvals, regional approvals and hospital approvals are required)
- Acceleration of the approval procedures in EOF
- Transfer of responsibilities for the approval of clinical trials from the Health Districts (Y.PE.) to the hospitals
- Single procedure and documents required for the approval of clinical trials
- Simplification and efficiency of the legal framework
- Harmonization of the current framework with the European standards
- Transparent method for the pricing of medical operations by the hospitals
- Transparent method of payment of HCPs
- R&D costs should be treated in a privileged way from a fiscal point of view

The recognition of the developmental dimension of clinical research and its contribution as an engine for economic growth and investment can reveal Greece as one of the European centers for clinical research. Greece should become competitive compared to other EU countries and attract more clinical trials.

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