**To**

**The member –companies of SFEE**

***Subject: Petition for cassation before the Council of the State, against the Greek State for the annulment of the* JudgementNo ΔΥΓ3/Γ.Π. οικ.70519 (Gov. Gazette 2243/18.8.2014) of the Ministry of Health titled: *Regulation of rebates****: Amendment of the Decision No Γ.Υ./οικ.3457 of the Minister of Health (Gov. Gazette 64/Β’/16-01-2014) "Regulation for of Issues related to the Pricing of Medicinal Products", as in force and of the Decision No Οικ. 38733/06.05.2014 of the Ministry of* Health (*Gov. Gazette 1144/Β’/06-05-2014) "Amendment of Article 14 par. 2 of the Ministerial Decision No 3457 (Gov. Gazette 64Β’/ 16-01-2014) "Regulation for of Issues related to the Pricing of Medicinal Products".*

**Chalandri, 5-11-2014**

**Following the relevant request of the companies, we quote an information note regarding the arguments raised by our association:**

The regulatory administrative act appealed against, enacts the amendment of par. 2 and 4 of article 13 and par. 2 of article 14 of the Decision No 3457/14.1.2014 of the Minister of Health (Gov. Gazette 64Β/16-1-2014), as amended by the Decision of the Minister of Health No 38733 /6.5.2014 (Gov. Gazette/Β/1144/6.5.2014).

By virtue of the above amendments, an attempt is made:

Α) for the retrospective enactment dated 01.7.2014 of the additional escalated returned percentage (rebate) which is enforced on the total three-months sales for all packages, contents and forms at a percentage of 1.5% for sales ranging from €0 to €2,500,000, 3% for sales ranging from €2,500,000 to €5,000,000 and 4.5% for sales exceeding €5,000,000.

Β) the retrospective enactment dated 01.7.2014 of the additional rebate, apart from the one referred in A, especially for the expensive medicines set out in par. 2 of article 12 of Law 3816/2010 such that the end price of EOPYY is respective with that achieved when it is supplied the said medicinal product from its pharmacies.

C) the enactment dated 15.9.2014 of the special encumbrance of the occasional pharmaceutical company, in case a medicinal product is selected with a retail price higher than the reimbursement price – where no generic can be selected – where the patient covers, apart from the provided for enacted participation thereof, half of the difference between the reimbursement price and the retail price of the medicinal product. The other half shall be borne by the pharmaceutical company or by the marketing authorisation holder (MAHs) in the form of a rebate.

The above amending acts, introduce **an unfavorable regulatory provision against the legal interests of our members** and for this reason, our Association, as a professional unincorporated union which represents almost all pharmaceutical companies in Greece, appealed against the said Ministerial Decision lawfully and on time, by virtue of the legal remedy of cassation, for the following legal, grounded and true reasons.

**C. Reasons for cassation**

***[It is noted in this case that our Association has already appealed against, by filing a petition for cassation before the Council of the State, the Ministerial Decision No 3457/16.1.2014 (Gov. Gazette Β64/16-1-2014) and awaits the scheduling of the hearing].***

**For the amending provisions of paragraphs Α &Β:**

1. **Violation of the Law** – direct violation of articles 5 par. 1 of the Greek Constitution, the provisions of articles 1 par. 1, 2 par. 2 and 3, 4 par. 1 and 6 par. 2 of the Directive 89/105 and of articles 34, 49, 56 and 4 of the Lisbon Treaty.

More specifically, the retrospective – since 01.7.2014 – enactment of additional rebate which is enforced on the total three-months sales for all packages, contents and forms at a percentage of 1.5% for sales ranging from €0 to €2,500,000, 3% for sales ranging from €2,500,000 to €5,000,000 and 4.5% for sales exceeding €5,000,000 is deemed that it is primarily enacted in violation of the constitutional principle of freedom of financial activity which includes the liberty to exercise commerce, since it unjustifiably enacts an additional limitation that reduces the price.

In addition, even if it could be assumed that this provision is constitutional, lies outside the regulatory framework of the Directive 89/105 and more specifically, outside the regulatory framework of articles 1 par. 1, 2, par. 2 and 3, 4 par. 1 and 6 par. 2 which enforces to the member-states, in order to enforce restrictions on the marketing price of a medicinal product, to do so with objective and verifiable criteria, taking into account the macroeconomic conditions in force from time to time in each member-state.

In this case, the enforcement of the rebate, as described above, was set **completely unjustifiably, thus the lack of proper justification is a direct violation of law.** Third, the enforcement of the above restrictions is in violation of articles 34, 49, 56 and 4 of the Lisbon Treaty for the prohibition of quantitative restrictions on exports and other measures with equivalent effect, for the prohibition of free establishment and provision of services in violation of the principle of subsidiarity.

**For the Third (C) amending provision:**

1. **Violation of the Law** – direct violation of articles 4 par. 1, 5 par. 1 and 78 par. 1 and 4 of the Constitution – violation of the principle of proportionality (article 25 of the Constitution).

C) the enactment dated 15.9.2014 of the special case for **encumbering the occasional pharmaceutical company** in case a medicinal product is selected with a retail price that is higher than the reimbursement price – where no generic may be selected - where the patient covers, apart from the provided for enacted participation thereof, half of the difference between the reimbursement price and the retail price of the medicinal product. **The other half shall be borne by the pharmaceutical company or by the marketing authorisation holder (MAHs) in the form of a rebate.**

The above amending provision (par. 3) is anti-constitutional because it violates the provisions of articles 4 par. 1 and 5 of the Constitution, article 5 par. 1 and article 78 par. 1 and 4 of the Constitution.

More specifically, all Greeks are equal before the law and participate without any distinction to the public weights, in proportion to their strengths. Everyone is entitled to freely develop his/her personality and freely participate in the financial life of the country. Finally, according to article 78S "no tax is levied or collected **without a typical law** that determines the subject of the taxation and the income, the nature of the property, the expenditures and the transactions or its categories, to which the tax refers. The object of taxation, the tax co-efficient, the releases or exemptions from taxation and the reimbursement of pensions cannot by the object of legislative authorisation".

In this case, the enforcement on pharmaceutical companies, of half of the difference between the reimbursement price of the medicinal product and the retail price thereof, is an indirect levy of tax, without a typical law and without a legislative authorisation by the Minister, which (tax) is levied on the companies without any distinction and illegally, since it does not take into account the objective criteria that the Constitution enacts and mainly article 78 par. 1 and 2 and is excessively onerous and disproportional in accordance with article 25S.

1. **Lack of Authority**

In this case, the provisions of paragraphs (a) and (b) are incompetently enacted by EOPYY since the latter acts without any special legislative authorisation.

1. **Violation of Substantial Form**

As regards paragraph (c), there is violation of the substantial form, in the sense that the enforcement of a tax must be effected with a standard Law and not with a Ministerial Decision.

For SFEE

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