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Hellenic Association of Pharmaceutical Companies 280 Kifissias Avenue & 3 Agriniou Str, TK 152 32, Chalandri

<u>Cc.</u> Office of the President of EOPYY

Subject: "Regarding the determination of the transgression of the budget for the pharmaceutical expenditure (claw back) and the calculation of the market share of pharmaceutical companies for the allocation of the clawback".

Exhibits: Document of SFEE sent by e-mail on 28-3-2014.

In reply to the above relevant document of the Hellenic Association of Pharmaceutical Companies we inform you of the following:

As it is already known, based on the contents of the relevant letters sent to the companies for the allocation of the clawback, the determination of the pharmaceutical expenditure is made by the sum of the expenditures of the Organisation for the off-Hospital pharmaceutical healthcare of its persons insured. The calculation of the expenditure is based on the actual data of payments/obligations of EOPYY based on the following:

- ✓ For the pharmacies of EOPYY, it is concluded by the sum of the invoices issued by the pharmaceutical companies dealing with the pharmacies of EOPYY. From the final figure of the expenditure the enacted 5% rebate on the hospital price is deducted as well as any discount granted to EOPYY which derives from an agreement with the pharmaceutical companies.
- ✓ For private pharmacies, it is concluded from the amount requested to be paid by the pharmacists again based on their invoices for the accounts of the prescriptions prepared in the reference months and accounts which, due to delays in the filing and due to special processing on the grounds of assignments/ confiscations and debts to Tax Offices etc. are processed and paid in the reference months.

The expenditure for private pharmacies is concluded from the sum of the payments effected through the KMES and the payments effected through the Regional Directorates of EOPYY.

From the said amounts, the following amounts are subtracted:

- ✓ the expenditure for medicinal products administered for severe diseases, which are administered only for hospital use. The said expenditure is subtracted by resolution of the BoD of EOPYY and the decision of the Ministry of Health, following the consent of the Troika, whereas it was deemed wise that the provision of medicinal products for hospital use by EOPYY to the State Hospitals and Private Clinics which "present deficiencies" due to financial problems of the Hospital Pharmacies, not to encumber the off-Hospital expenditure. The said expenditure is subtracted by the sales that shape the market share of the companies selling them,
- ✓ the rebates of article 22, of Law 4052/12 (9% on the ex-factory price and the additional escalated rebate on the ex-factory price) and
- \checkmark the rebates of articles 24 & 26 of Law 4052/12 that concrn the private pharmacies.

Taking into account the above, the final transgression from the target is calculated on a monthly basis, as these are analytically presented in the Table attached, in the third page of the letters.

As regards the determination of the market shares of the pharmaceutical companies, we inform you that:

A. By virtue of the provisions of Law 4052/2012, as substituted by Law 4093/2012 the automatic clawback mechanism for the amount of transgression of the off-hospital pharmaceutical expenditure was established and it is provided among other things that:

"By virtue of the decision of the Minister of Health, every detail for the application of this article is defined, and mainly the exact manner of calculation that each MAH is obligated to pay, based on: i) the percentile participation proportion of <u>each medicinal product in the expenditure (not including VAT</u>), which is calculated based on the quantity that was provenly offered to insured persons, as concluded by the System of Electronic Prescription or by another electronic system for the scanning of prescriptions,

ii) the market share of each medicinal product in the therapeutic category of the positive list".

B. For the calculation of the market shares for the first six-months period of 2013, given that the system for electronic prescriptions and scanning of prescriptions had been further developed, EOPYY was <u>able for the first time to accurately determine the quantity per medicinal product that was offered</u> to the insured persons thereof (as defined by laws 4093/2012 and 4052/2012).

Consequently, for the first six months of 2013 the determination of the market shares of the pharmaceutical companies is more objective, given that the actual data for the quantities offered to the persons insured of EOPYY were used, and not an approximate depiction of the market shares, as was the case in 2012. For the determination of the market shares of the companies, data for each medicinal product at the retail price were obtained, after the subtraction of the VAT for sales through private pharmacies and of the end sale price to the pharmacies of EOPYY, after the subtraction of the VAT, exactly as it is performed from the date the measure entered into force.

Suggestively the following table for the calculation of the market share and the clawback of each company is quoted (numbers are random):

МАН	PRIVATE PHARMACIES EXPENDITUR E IN RETAIL PRICES - VAT	EOPYY EXPENDITURE (NT-5%) - VAT	SUBTRACTION DUE TO HOSPITAL	FINAL EXPENDITURE	TOTAL EXPENDITURE OF SIX MONTHS (SUM OF THE TOTAL EXPENDITURE OF ALL COMPANIES)	SHARE (FINAL EXPENDITURE/ TOTAL SUM OF EXPEND. OF COMPANIES	TRANSGRESSION	FINAL AMOUNT FOR 2 nd SIX- MONTHS PERIOD
PHARMA S.A.	€2,018,027.65	€5,005,678.94	€810,258.76	€6,213,447.83	€1,525,511,348.19	0.4073%	€49,956,457	€203,473.96

Given that before the issue of the decisions for the allocation of the rebate for the 2nd six-months period of 2013, some pharmaceutical companies raised objections as to the manner of calculation of their market shares, claiming that based on the provisions of the Ministerial Decision 110034/15-11-2012 (Exhibit 5) par. 4, the market shares must be calculated at the expenditure of EOPYY, after the subtraction of the participation of the persons insured, the amounts with which the persons insured are encumbered, the rebates of the pharmaceutical companies and the rebates of the pharmaceus.

We inform you that:

a) The Organisation believes that the reference to the said Ministerial Decision to the "participation of the pharmaceutical companies in the shaping of the pharmaceutical expenditure" is a reference to the actual data for the quantities of medicinal products for each pharmaceutical company that are included in prescriptions granted to EOPYY's insured persons and to the actual procurement of medicinal products by the pharmacies of EOPYY.

b) The legislation in force (Law 4052/2012 and Law 4093/93) makes clear reference to the market share in the expenditure before VAT and there is no authorisation for deviations.

THE PRESIDENT OF EOPYY

DEMETRIOS KONTOS