

## **IB. REGULATIONS ON ISSUES OF THE MINISTRY OF HEALTH**

### **IB.1 REGULATIONS OF ISSUES CONCERNING THE National Organization for Health Care (EOPYY)**

1. a. At the end of case (c) of paragraph 17 of article 13 of Law 4052/2012 (A' 41) a case (d) is added that reads as follows:  
“(d) on 1.12.2012 of the Unified Fund for the Insurance of the Employees of Means of Massive Transportation (ETAP – MME)”.
- b. Paragraph 14 of article 44 of Law 4075/2012 (A' 89) and any administrative act that was issued, authorized by the said provision, are abolished from the date of publication hereof.
2. The contribution of the persons insured under the Agricultural Insurance Organization (OGA) for healthcare, will amount from 1.1.2013 to a percentage of 2.50% on the amount of the insurance category set out in article 4 of Law 2458/1997 (A' 15), as today in force, in which the insured person has been included and cannot be less than the one corresponding to the amount of the 5<sup>th</sup> Insurance Category, as today in force.

### **IB.2 REGULATIONS ON ISSUES CONCERNING PHARMACEUTICAL EXPENDITURES, OFF-SETTING OF CLAIMS AND CLEARED DEBTS OF HOSPITALS**

1. Article 11 of Law 4052/2012, is substituted as follows:
  - a. The monthly pharmaceutical expenditure of the Social Insurance Agencies (*FKA*) cannot exceed 1/12 of the sum recorded on the annual Social Budget and corresponds to the pharmaceutical expenditure. The excessive monthly amount is sought by the FKAs from the Marketing Authorization Holders for the pharmaceutical products in question. The above amount is calculated on a six-month basis and is paid by the liable Marketing Authorization Holders within a month from its certification, in a bank account that each Agency will notify. By decision of the Minister of Health, every detail for the application of this article is set out, and mainly the exact manner of calculation of the amounts each Marketing Authorization Holder is obliged to pay, based on:
    - i) the percentile proportion of participation of each medicinal product in the expenditure (without VAT), which is calculated based on the quantity that was proved to have been offered to insured persons, as concluded by the System of Electronic Prescriptions or through another electronic system that scans the prescriptions
    - ii) The market share that each medicinal product holds in the therapeutic category of the Positive List
    - iii) the ability to finally set off and remaining amounts, based on the total turnover of each company

iv) the comparative consumption of each medicinal product, with the market share it held in the respective period of the preceding year

v) every detail that concerns the manner and time of payment of the amounts due, as well as the procedure of any offsetting of subsequent amounts. In case the amounts set out in this paragraph are not timely reimbursed, these are collected following the procedure of K.E.D.E.

b. For the calculation of the above parameters, the sales data for medicinal products kept by the National Organization for Medicines (EOF) and the relevant FKA is utilized, after the removal of parallel exports and sales to hospitals. In addition, the growth rate (product added value) can also be co-estimated either disjunctively or cumulatively of each Marketing Authorization Holder. Any calculations effected until the publication hereof are approved.

c. The provisions of paragraphs (a) and (b) of this article are applied regardless of par. 1 of article 35 of Law 3918/2011 (A' 31) as in force from time to time.

d. EOPYY can set off the above amounts with equal debts thereof to the Marketing Authorization Holders, concerning pharmaceutical products, from the supply of pharmaceutical preparations for the needs of its pharmacies. The said off set is made only between the amounts of pharmaceutical products returned by the Marketing Authorization Holders and the cleared debts of EOPYY to the said Marketing Authorization Holders, which were generated within the same year.

e. This article is valid from 1.1.2012 to 31.12.2015”.

2. Paragraph 1 of article 12 of Law 4052/2012 (A' 41) is substituted as follows:  
“1. If, after the offsetting referred to in paragraph 3 of article 11 of Law 3052/2012 (A' 41), there is an outstanding balance of claims or in case the pharmaceutical companies or the Marketing Authorization Holders for pharmaceutical products have no claims against EOPYY but only against hospitals, then the above claims may be assigned to the hospitals against the payment of the hospitalization fees of their insured persons, and the hospitals obligatorily set off the amount of the claims assigned as above, with the debts to the pharmaceutical companies and the Marketing Authorization Holders for pharmaceutical products. The offsetting is only made between the claims assigned to Hospitals, as set out in the preceding clause, and the cleared debts of Hospitals to pharmaceutical companies or Marketing Authorization Holders for pharmaceutical products, which were generated within the same year. Claims of insurance agencies who have not been included in the EOPYY against pharmaceutical companies or Marketing Authorization Holders for pharmaceutical products, which exist by virtue of article 12 of Law 3816/2010

(A' 6), as supplemented with paragraph 1 of article 36 of Law 4025/2011 (A' 228) of par. 1 of article 35 of Law 3918/2011 (A' 31) as substituted by article 22 of Law 4052/2012 (A' 41) and of article 11 of Law 43052/2012 (A' 41) are obligatorily assigned to Hospitals against the payment of the hospitalization fees of their insured persons. Hospitals obligatorily set off the amount of the above assigned claims with their debt against the pharmaceutical companies. The said offsetting is only effected between the claims assigned to hospitals, as set out in the preceding clause, and the cleared debts of Hospitals to pharmaceutical companies or to Marketing Authorization Holders for pharmaceutical products, which were created within the same year. The joint decision of the Minister of Finance and the Minister of Health, defines the amounts each time assigned and set off in accordance with the provisions of this paragraph, the relevant procedure as well as any detail necessary for the application of the preceding clauses”.

3. The second clause of paragraph 2 of article 24 of Law 3965/2011 (A' 113) is substituted as follows:

“As regards the payment of contracted suppliers and pharmacists, which can be effected via a distribution account or through the pharmaceutical association, where possible, EOPYY and the other Social Insurance Agencies pay the amount claimed as advance payment, after the withholdings provided for by the law, within sixty (60) days from the date the account is submitted”.

4. Case (d) of paragraph 1 of article 34 of Law 3918/2011 (A' 31) is abolished and cases (e) and (f) are re-numbered as (d) and (e) respectively.
5. In the first clause of paragraph 2 of article 34 of Law 3918/2011 (A' 31), the phrase (subject to the timely payment of these debts” is deleted.
6. In case (a) of paragraph 3 of article 34 of Law 3918/2011 (A' 31) the word “timely” is deleted.
7. Case (b) of paragraph 3 of article 34 of Law 3918/2011 (A' 31) is substituted as follows:

“b) The expenditure requested for the pharmaceutical products set out in par. 2 of article 12 of Law 3816/2010 is subject to independent obligation of return (rebate) of a percentage of five percent (5%) of the expenditure claimed for these pharmaceutical products”.
8. In the first clause of paragraph 2 of Article 35 of Law 3918/2011 (A' 31) after the words “pharmaceutical products to” the phrase “the pharmacies of EOPYY” is added.

9. The fourth clause of case (b) of paragraph 1 of article 12 of Law 3815/2010 (A' 6) is substituted as follows:  
“By decision of the Minister of Health, which is posted at EOF’s official website, the manner of drawing up the therapeutic categories and determination of the reference prices for each therapeutic category are specified, together with the procedures for the revision and supplementation of the list, as well as the compensated indications, conciseness and packages per pharmaceutical product and any other relevant issue”.
10. The provision of case 8 of this subparagraph IB.2 applies retrospectively from January 1, 2012.
11. At the end of case (b) of paragraph (5) of article 21 of Law 4052/2012 (A' 41) the following clauses are added “By decision of the Minister of Health, the mechanism of implementation and information of physicians are defined, as well as any further exceptions in the manner of prescribing based on the active substance, which should cover very limited groups of products given the known sensitivities in the treatment of patients, according to the international standards and the best therapeutic practice. The percentage of the prescriptions with the brand name cannot exceed 15% of the total value of prescriptions each physician issues”.
12. From 01.01.2014 it is defined that patients will pay in favor of the EOPYY the amount of one (1) Euro per prescription prepared by any pharmacist, as well as the amount of Euro twenty-five (25) for each hospitalization in NHS Hospitals.  
The joint Decision of the Minister of Finance, the Minister of Social Insurance and Welfare and Health, defines the criteria, the details, the procedures as well as the scope of application of this provision and the amounts paid by the patients can be revised.