

**SECTION E'**  
**PROVISIONS FOR THE COMPETENCY OF THE MINISTRY OF HEALTH**  
**SANCTIONS FOR VIOLATIONS FROM HEALTHCARE PROVIDERS**  
**DURING THE TRADE AND DISTRIBUTION OF MEDICINES AND OTHER**  
**PROVISIONS**

**Article 95**

**Sanctions imposed on pharmacists and marketing authorisation holders for medicinal products**

1. In article 12 of the l.d. 96/1973 (A' 172) a paragraph numbered 4 is added, which reads as follows:

“4. The license holders for the wholesale of medicines are obliged, when distributing the medicines, to record on the necessary vouchers the multi-digit code assigned to the specific medicine by EOF (Medicine's Barcode). If violation of the above obligation is verified, then a monetary fine ranging from Euro five thousand (€5,000) to Euro one hundred thousand (€100,000) is levied, with regard to the frequency and severity of the violation”.

2. At the end of par. 1 of article 12A of the l.d. 96/1973 (A' 172), as supplemented by article 15 of law 3580/2007 (A' 134), the following sentence is added:

“If shortage of a medicine is noticed and this shortage is the result of the violation of the obligations undertaken by the license holder for the wholesale of medicines or the marketing authorisation holder (MAH), then, by decision of the Minister of Health, accumulatively with all other sanctions provided for by the law, a monetary fine is levied to the liable person, ranging from Euro thirty thousand (€30,000) to Euro one million (€1,000,000) with regard to severity of the violation”.

3. The second clause of par. 2 of article 12A of the l.d. 96/1973 (A' 172), as supplemented by article 15 of law 3580/2007 (A' 134), is substituted as follows:

“The data on the authenticity sticker of exported medicines are entered in real time, under the responsibility of the license holders for the wholesale of medicines, electronically in the Database of EOF. If violation of the above obligation is verified, then a monetary fine ranging from Euro one hundred thousand (€100,000) to Euro one million (€1,000,000) is levied, with regard to the frequency and severity of the violation. The release of medicine batch is prohibited, if the authenticity data have not been previously entered in the aforementioned electronic Entry System of EOF”.

4. At the end of par. 2 of article 12A of the l.d. 96/1973 (A' 172), as supplemented by article 15 of law 3580/2007 (A' 134), the following sentences are added:

“The license holders for the wholesale of medicines, following the prohibition due to shortage, of exports of specific medicines, are obliged to declare at the website of EOF the stock they hold for these medicines and immediately dispose them in the market at first demand. Whoever, despite the prohibition of the preceding sentence, exports or collects medicines for the purposes of exporting them, is levied with a fine ranging from Euro one hundred thousand (€100,000) to Euro one million (€1,000,000) with regard to the severity of the violation, accumulatively with any other sanction provided for”.

5. Par. 12 of article 19 of the l.d. 96/1973 (A' 172), is substituted as follows:

“12. The administrative fines are levied by decision of the Minister of Health, upon the suggestion of the BoD of EOF and are collected in accordance with the provisions of the Internal Revenue Code. Revocation of marketing authorizations is imposed by resolution of the BoD of EOF. Suspension of profession licenses is imposed, if no other relevant provision applies, by decision of the Minister of Health, following the

granting of opinion of the relevant Disciplinary Board. The revocation of the license of operation of a pharmacy and a wholesale drugstore is effected by decision of the Minister of Health, following the suggestion of the BoD of EOF. Publications and announcements of the sanctions are effected by resolution of the BoD of EOF”.

6. At the end of paragraph 4 of article 27 of law 1316/1983 (A’ 3) the following sentence is added as follows:

“The Marketing Authorisation Holders (MAH) for pharmaceutical products, are obliged to declare the data of the inventory sheets of the authenticity sticker in the Electronic Submission System of EOF in real time. Violation of this obligation incurs for the MAH a monetary fine ranging from Euro thirty thousand (€30,000) to Euro three hundred thousand (€300,000) with regard to the frequency and severity of the violation”.

7. The violators of the provision of par. 1 of article 116 of the Joint Ministerial Decision No Δ.ΥΓ 3α/Γ.Π.32221/2013 are levied in the aggregate with: a) the sanctions of article 458 of the Penal Code and b) a monetary fine ranging from Euro twenty thousand (€20,000) to Euro one hundred thousand (€100,000), by resolution of the BoD of EOF.

Whoever without being properly qualified in accordance with the law or without having the necessary license from the competent authorities, sells medicines or medicinal products acting as a pharmacist, is levied with a monetary fine ranging from Euro thirty thousand (€30,000) to Euro fifty thousand (€50,000) and in case of repetition of the violation, with a fine ranging from Euro fifty thousand (€50,000) to Euro two hundred thousand (€200,000), by resolution of the BoD of EOF.

The above sanctions are accumulatively levied with any other sanction provided for. Pharmacies operate under the constant presence and supervision of a licensed pharmacist. If, following the inspection by the competent inspection bodies, it is discovered that a pharmacy does not operate under the constant presence and supervision of a licensed pharmacist, then the holder of the operation license (the pharmacist) is levied with a monetary fine ranging from Euro five thousand (€5,000) to Euro thirty thousand (€30,000), by resolution of the BoD of EOF, with regard to the frequency and severity of the violation.

8. The last sentence of par. 2 of article 4 of the P.D. 121/2008 (A’ 183) is substituted as follows:

“The prescription is necessarily accompanied by the health book of the insured person, where the pharmacist inspects the recording of the medicines and marks the execution of the prescription by signing and sealing it”.

9. Case (b) of par. 15 of article 4 of the P.D. 121/2008 (A’ 183) is substituted as follows:

“b. A temporary prohibition to the pharmacy for the execution of EOPYY’s prescriptions for a period ranging from three (3) months to two (2) years”.

10. After the first sentence of case (c) of par. 15 of Article 4 of the P.D. 121/2008 (A’ 183) a sentence is added as follows:

“The above sanctions are obligatorily levied by the General Inspector of Department of Control of Health Expenditures of Social Security Agencies (YP.E.D.Y.F.K.A.), following the suggestion of the competent Directorate, in case that, following the conduct of an inspection, sale of the medicinal products by a pharmacy or wholesale drugstore is verified, subject to the specific cases exclusively set out by the law, where under certain conditions, the return of medicines from a pharmacist or a wholesale drugstore is permitted”.

11. After case (c) of par. 15 of article 4 of the P.D. 121/2008 (A' 183), a case (d) is added as follows:

“d. If during the inspection, there are strong indications for financial damage of EOPYY, the Board of Directors thereof is entitled, upon the suggestion of the General Inspector of YP.E.D.Y.F.K.A., to resolve the suspension of the agreement that was executed between the pharmacists and EOPYY for as long as the inspection is in progress”.

12. The second sentence of case (ee) of par. 15 of article 4 of the P.D. 121/2008 (A' 183) is substituted as follows:

“After the lapse of the above deadline, the General Inspector of YP.E.D.Y.F.K.A., imposes, regardless of any other sanction, provisional prohibition to the pharmacy from executing prescriptions of EOPYY for a period ranging from five (5) days to twelve (12) months”.