

Counterfeit Medicinal Products

GREECE
Zepos & Yannopoulos

CONTACT INFORMATION
Julia Pournara
Zepos & Yannopoulos
75, Katehaki & Kifissias Ave.
115 25 Athens, Greece
30.210.6967.000
j.pournara@zeya.com
www.zeya.com

1. **Is the problem of counterfeit medicinal products identified in your jurisdiction? What is the amount of falsified medicinal products on the market?**

   The circulation of counterfeit medicinal products has been identified by Greek authorities as a serious issue affecting patients.

   Cases related to the sale of counterfeit medicines on the Greek market through legal distribution channels are extremely rare; practically non-existent. This is mainly due to the existence of a special safety feature on the packaging of medicinal products, namely the Authenticity Band (see below, under question No 5) as well as due to the fact that medicinal products for human use (especially prescription products) are lawfully sold solely by pharmacies in Greece.

   Nonetheless, the National Drug Organization for Medicines ("EOF") has found that a significant number of consumers purchase medicines on the internet. Even though Greek law forbids the distribution of medicinal products on the internet, many patients resort to buying such products from foreign websites, where products are usually advertised and promoted as being low-cost and of supposedly "guaranteed" quality and effectiveness.

   Such formulations that are purchased through webpages are mostly slimming pills, drugs for erectile dysfunction and nutritional supplements with various properties.

EOF regularly issues announcements on its website warnings against the purchase and use of specific products that can be ordered online, by translating into Greek and releasing the relevant information provided to it from other EU member-states as well as from the U.S., Canada, Australia etc.

There is currently no publically available information on the estimated amount of counterfeit products circulating in Greece though illegal distribution channels (i.e. products entering the Greek territory that have been ordered online/ that have been smuggled).

2. Have there recently been any cases related to counterfeit medicinal products?

In recent years, the EOF has handled only two notable cases concerning counterfeit medical products. The above cases involved the distribution of counterfeit anabolic steroid products, which are illegally used for the enhancement of the performance of athletes. In the above cases, following inspections from EOF in unauthorized places of sale of medicines (the respective authentic product may be legally sold in Greece only through pharmacies under a prescription that must be retained for two years), several packages of a counterfeit product were found. The counterfeit product did not contain the substance *nandrolone*, which is contained in the authentic product. The above products had presumably been ordered online from an undisclosed source to be used for athletic performance enhancement, according to the relevant press release of EOF, which was issued in 22/6/2012 (on the most recent case).

3. Is activity related to counterfeiting a medicinal product a crime? Please state which criminal law provisions may be potentially used against entities engaged in such activity.

In Greek law, there is a specialized provision penalizing the counterfeiting of medicinal products.

According to par.9 of article 19 of Legislative Decree 96/1973, "*pharmaceutical products […], that are found upon inspection to be adulterated or the composition of which is not in compliance with their approved composition […] or where such products have been improperly manufactured or where such products are considered to threaten public health*" are seized by the authorities and destroyed. The persons manufacturing or distributing or holding such products with the intention of selling them are punished with administrative fines and penalties. In case of repeated perpetration of such offense, criminal prosecution is initiated and the offense is punishable and with a monetary penalty and/or imprisonment of up to one year. Such provision is stipulated to be without prejudice to more severe penalties that may apply, depending on a case by case basis.

In addition, article 31 of law 5607/1932 "*on the codification and complementation of the pharmaceutical legislation*" provides that "*persons manufacturing pharmaceutical products that are adulterated or that are (found to be) of a reduced quantity of active elements shall be punished by a fine of one hundred thousand drachmas (approx. € 300) and imprisonment of up to six months. In case of recidivism (repeat of the offense) the offense shall be punishable by temporary or*

permanent withdrawal of the manufacturing license of the respective laboratory or plant". Though, to the best of our knowledge, the above provision is rarely if ever enforced, it still remains in force and may be potentially used, specifically against entities engaged in the adulteration of medicinal products.

The applicability in parallel with the above of other criminal offences may not be excluded e.g. fraud (article 386 of the Greek Criminal Code - "G.C.C."). In case the use of the above products leads to injury or death of a patient, other criminal offences possibly relevant to the distribution of counterfeit medicinal products are manslaughter due to negligence (article 302 of Greek Criminal Code), bodily injury due to negligence (article 314 of G.C.C.) etc.

Other offences perpetrated in connection with the above, such as acts of smuggling, unauthorized import and circulation of regulated/controlled substances may also be punishable in parallel with the above, depending on the factual background of each case.

4. Is there a definition of a falsified medicinal product in your jurisdiction?

There is no comprehensive statutory definition of a falsified medicinal product in Greece.

However, a few closely related definitions can be traced in Greek Law, such as the definition of "*adulterated agricultural medicine*", which has been included in law 721/1977 "*on the approval of the circulation and control of agricultural medicine, where such product is defined as "medicine, i) the content of which as to its active and secondary ingredients differs from its guaranteed composition or ii) the inscription on its label differs from the one approved*".

Most sources usually refer to the definition developed by the World Health Organization:

"*A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging*".

A relevant announcement issued by EOF aiming to encourage public awareness on the issue of counterefeit and falsified product available on the internet sets out some of the main characteristics of such products:

- such products are not approved by the competent authorities;
- they may be contaminated with pollutants;
- they are made by unknown or suspicious manufacturers;
- they may potentially have very serious effects on the health of the consumer;
- Often such products contain substances not listed on the packaging, which may cause the user to manifest allergic reactions or other adverse effects that may even lead to death.

A specific statutory definition of falsified medicines is expected to be introduced into Greek law, upon implementation of the Falsified Medicines Directive (2011/62/EU, amending Directive 2001/83/EC). For more details about implementation of this directive into Greek law, please see the answer to question 9.

The Falsified Medicines Directive defines a falsified medicinal product as:

"*Any medicinal product with a false representation of:*

(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
(c) its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights".

5. Please advise on regulations in place to ensure safety of medicinal products and to prevent falsification of medicinal products. Who is authorized to enforce relevant laws?

EOF issues to pharmaceutical companies the Authenticity Band, which is a safety feature placed on the packaging of medicinal products. The Authenticity Band is pasted on each medicinal product package, which ensures the product's authenticity and provides a means of reimbursement by insurance funds and companies. As of 1-1-2005, the authenticity brand bares a bar-code. Today, a second bar-code has been incorporated to the authenticity brand offering direct access to a number of important details regarding each package of any medicinal product marketed in Greece.

6. Please advise regarding existing boarder measures (and related legal provisions) allowing regulatory authorities and right holders to fight against counterfeited medicinal products and about the efficiency of such measures.

According to Greek law (article 3 par. 2 of national Customs Code (law 2960/2001)), Greek customs authorities are competent to proceed (through their officers at the points of entry and exit from the territory of the country, the customs offices' yards and, in general the customs territory of the country) with the inspection of persons, luggage, goods and means of transport for the detection of, among others, counterfeit goods (including medicinal products).

In this respect, it is noted that, in the event certain medicinal products are suspected to infringe intellectual property rights, the competent Greek customs authorities shall proceed with the following action (in the context of Council Regulation 1383/2003/EC and Council Regulation No. 1891/2004/EC implementing the said regulation), as the case may be:

i. In the event of filing of a relevant application for action by the right-holder (on the basis of the aforementioned regulations) and to the extent such application is approved, the competent authorities shall specify the period during which they shall take action, which does not exceed one year (however an extension of such period may be granted, under conditions). In this respect, it is noted that the competent authority for the filing of the aforementioned application in Greece is the Customs Directorate of Attica (in Greek "Διεύθυνση Τελωνείων Αττικής" – "Diefthinsi Telonion Attikis"). The approval of the aforementioned application by the said Directorate shall be sent immediately to the customs offices that are likely to deal with the medicinal products in question and such customs offices shall suspend the release of such products or detain them. In the event the applicant is the right-holder of a Community intellectual property right, in addition to requesting action by the Greek customs authorities, he may also request action by the customs authorities of other EU Member States.

ii. In the event the customs authorities (i.e. the competent customs offices), before an application for action has been lodged by the right-holder, have sufficient grounds for suspecting that the medicinal products in question infringe an intellectual property right, they may suspend the release of such products or detain them and notify the right-holder and the declarant, if the latter are known, in order to enable the right-holder to submit an application for action as explained above (i.e. to the Customs Directorate of Attica). However, in the event no application for action is filed within three working days from the receipt of the notification, the products in question shall be released.

Finally, it is noted that, in the event an infringement of intellectual property rights (on the basis of Council Regulation 1383/2003/EC) is found to exist, then the competent customs office shall impose a relevant penalty, which may range from Euro 2,000 to Euro 20,000, depending on the seriousness of the relevant infringement (i.e. the type, the quantity, the value of the counterfeit products as compared to the original ones, the frequency of relevant imports and the recurrence of the relevant offence).

7. Are there any regulations allowing manufacturers, distributors or marketing authorization holders to eliminate falsified products from the market? Are there any other legal measures competitors, manufacturers, distributors or marketing authorization holders could take?

Legitimate participants in the pharmaceuticals market may take various actions against counterfeit products.

1) *Based on intellectual property law.* As falsified products by their marking or labelling often infringe intellectual property rights, entities whose rights are threatened may demand:

   a) injunction measures which may include also the provisional seizure of the defendants property assets;
   b) cessation and desistance in the future of actions violating intellectual property rights;
   c) penalty threat for any violation of cease and desist court order;

d) removal of the effects of prohibited practices (including destruction of infringing products);
e) publication of final judicial awards;
f) redress of injury under general rules (including moral damages);
g) disgorgement of unjustified benefits under general rules;
h) criminal prosecution of the persons involved in the prohibited actions (see also below)

2) *Based on unfair competition law.* Some actions related to falsified medicinal products also constitute acts of unfair competition which may be challenged in civil proceedings. For example, a designation of products or services, or lack thereof, which may mislead customers with respect to the origin, quantity, quality, components, manufacturing process or other significant features of the product is prohibited, as is imitating a finished product by technical means of reproduction. The injured party may demand:

a) injunction measures;
b) cessation and desistance in the future of actions of unfair competition;
c) penalty threat for any violation of cease and desist court order;
d) removal of the effects of prohibited practices (including destruction of infringing products);
e) publication of final judicial awards;
f) redress of injury under general rules (including moral damages);
g) disgorgement of unjustified benefits under general rules;
h) criminal prosecution of the persons involved in the prohibited actions (see also below)

3) *Notification of competent authorities.* Any person may notify the relevant authorities, particularly the Police, the Customs Service or the Greek National Drug Organization, of suspicions regarding specific medicinal products. Upon receipt of such information, the competent authority is required to undertake an investigation or inspection and proceed to criminal prosecution or intervention accordingly.

Some acts of unfair competition or infringements of intellectual property rights also constitute a crime, for example copying the external image of a product or release of such product for free circulation creating the possibility to mislead customers as to the identity of the producer or product, or marking (or not marking when required to do so) goods or services which misleads the customer as to their origin, quantity, quality, content, method of production, or other significant features, or releasing onto the market goods marked with a counterfeit trade mark. If the relevant authorities do not take any steps against the violators, it is also possible to file a private indictment.

8. Do public authorities or non - governmental organizations inform of dangers related to falsified drugs?

EOF as well as the Hellenic Association of Pharmaceutical Companies (“SFEE”), which is a non-profit professional association and a member of the European Federation of Pharmaceutical Industries and Associations have in the past -including

recently- issued public announcements aiming to increase social awareness of the risks associated with buying and using medical products that originate from unlawful sources and are very likely to be counterfeit.

Such awareness campaigns typically stress that the Greek regulatory framework for distribution of medicines ensures that no counterfeit medicines are placed on the Greek market, while they warn against the purchase of medicines through the internet. For example, in a press release issued by SFEE in 2009 it is stated: "*Greek citizens must have confidence in the legal chain for the distribution of medicines. On the contrary they should not trust 'electronic drugstores', which, in their vast majority distribute falsified (counterfeit) medicines, [which are] dangerous for public health*". An English version of the above press release can be found on SFEE's website (http://www.sfee.gr/files/story/Falsified_(Counterfeit)_Medicines.pdf)

9. Have draft acts implementing 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use been already prepared?

A draft ministerial decision on the implementation of Directive 2011/62/EU is currently being prepared by the officials of EOF. No form of the relevant draft has been made publically accessible up to today.

10. Does your jurisdiction consider signature and ratification of the Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health?

The Hellenic Ministry of Health is considering the possibility of Greece becoming a party to the Medicrime Convention. EOF is expected to formally submit its opinion on this issue to the Ministry but so far no final decision has been made by the Government.