

Counterfeit Medicinal Products

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

   Yes, there have been cases of counterfeited medicinal products in Romania. According to an unofficial estimation, the counterfeited medicinal products would represent between 5% - 7% from the pharmaceutical market in Romania.

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

   We are not aware of any recent cases related to counterfeit medicinal products.

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.**

   Yes. According to the provisions of Article 834 from the Law no. 95/2006 regarding the reform in the healthcare field, as further modified and completed (hereinafter "Law no. 95/2006"), as currently in force, "*counterfeiting or the placing on the market of a medicinal market without the observance of the legal provisions represent a criminal offense sanctioned with imprisonment from 3 months to 3 years*". If the counterfeited medicinal products are harmful to health, such act is punished with imprisonment from one to eight years. In case any of these acts had as a consequence the illness or the aggravation of an illness of a person, the punishment is imprisonment from two to eight years, and if the consequence was the death of a person, the punishment is imprisonment from five to fifteen years.

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

Currently no.

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?

The distribution of medicinal products in Romania is strictly regulated. For example, the holder of a wholesale distribution authorization has to acquire medicinal products only from persons or entities that have a manufacturing authorization or a wholesale distribution authorization, as the case. Also, the holders of a wholesale distribution authorization has to supply medicinal products only to persons that are holders of a wholesale distribution authorization or are authorized to supply medicinal products to the population. Moreover, the wholesale distributors are compelled to have an efficient system in place in case of any suspicion of counterfeited medicinal products and have to notify immediately the National Agency for Medicines and Medical Devices ("ANMDM") in case of any such suspicions. Any counterfeited medicinal product or suspected one has to be immediately separated from the other and labeled in order to impede their further distribution and sale. Finally, if the products are officially confirmed as counterfeited such have to be destroyed. Also, at the level of the distribution chains there have to be in place proceedings regarding emergency recalls of counterfeited products.

Also, at the level of ANMDM an emergency alert situation can be put in place in case of counterfeited medicinal products.

Also, any person that uses medicinal products may inform ANMDM in case of quality deficiencies of such.

The general legal provisions regarding consumers' protection are also applicable.

ANMDM, the National Authority for Consumers Protection, the police, prosecution public offices, customs authorities are the main authorities to enforce the relevant laws regarding counterfeiting of medicinal products.

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 the provisions of the Law no. 344/2005 regarding certain measures for insuring the observance of intellectual property rights during customs actions ("Law no. 344/2005") together with its implementing regulation, in case of any goods infringing intellectual property rights, the customs authorities may either suspend the customs operation for a limited period of time, detain the goods suspected of infringing an intellectual property right for a limited period or suspend the release of goods suspected of infringing an intellectual property right either through an ex-officio action or based on an approved customs intervention action application. The

rightholders have to have or to apply for a customs intervention action application and to take further actions as provided by the law. In general, the customs authorities from Romania are pro-active in case of counterfeiting.

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?**

   Yes. Please refer to answer to question 5 herein above. In any case, the competitors, manufacturers, distributors or marketing authorization holders have to notify ANMDM in case of any counterfeited or suspected counterfeited products.

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

   Yes. ANMDM has launched an Internet platform (www.crimemedicine.ro) that has as purpose to inform the public, offer documentation and fight against counterfeiting of medicinal products.

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?**

   To the best of our knowledge, no such draft acts implementing Directive 2011/62/EU into Romanian legislation are currently publicly available. As a note, the Romanian version of this directive may be accessed on ANMDM website - http://www.anm.ro/anmdm/_/DIRECTIVE%20REGULAMENTE/dir_2011_62_ro.pdf.

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?**

    Until the date of this survey Romania has not signed this Convention. Information with respect to this aspect can be found at: http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=211&CM=8&DF=&CL=ENG.

    We are not aware of any public expressed point of view from the Romanian authorities as to the signing of this convention.