

Counterfeit Medicinal Products

BULGARIA
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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, it is. The issue of counterfeit medical products is legally identified in the Medicinal Products in Human Medicine Act (MPHMA) and Ordinance No 9, dated 23.04.2008 on the terms and conditions for blocking and withdrawal of medical products, deviating from quality, safety and efficiency requirements (the "Ordinance"). Although counterfeit medicinal products exist as legal notion and are usually combated with heavy penal-administrative measures, however their manufacturing and distribution are slightly discussed both in legal theory and court practice. According to unofficial (unrepresentative) statistical data, the amount of falsified medical products in the country is comparatively insignificant, which is explained with the small size of the local drug market. Howvere, exact data about for their quantity is missing.

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

   We are not aware about such cases; there is quite insufficient court practice on this issue in general. According to some statistical researches, only two cases/events concerning falsification of drugs have been registered for 2012.

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.

Activity related to counterfeiting a medicinal product is not a crime under local laws. The Bulgarian Penal Code lacks provisions, incriminating such activities. More specifically, activities such as manufacturing, distribution or storage of counterfeit medical products have not been criminalized yet, whereas only property sanctions (fines) have been established in civil/administrative laws. For instance, the provisions of MPHMA incorporate some penal-administrative measures for overcoming possible risks of medical falsification, such as fines for selling, storing or providing counterfeit medical products, as well as medicinal products of undetermined origin, shall be imposed a fine of BGN 25,000 to BGN 50,000 (circa Euro 12,500 to Euro 25,000). Sanctions are envisgaed also for manufacturing, import, selling, storing or allowing the use of counterfeit medical products within the country.

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

Yes, “Counterfeit medical product” is a medicinal product with false data, concerning its identity, indicated on the product, on the primary or other packaging (e.g. misleading statement about the name, composition, quantity of the active substance per dose unit or other elements), history or origin (e.g. misleading statement about the manufacturer, the state in which the product is manufactured, state of origin or market authorisation holder). The counterfeit medical product may contain the correct components or other components, it may not contain an active substance or it may contain such substance in a quantity, different from the correct one or it may be with a forged packaging. Distinguished from counterfeit medical products shall be the legitimately authorized medicinal products with deviations in the quality or products, which do not comply with the requirements of the Good Manufacturing Practice or the Good Distribution Practice.

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?

There are number of regulations and legal requirements in place to ensure the safety of medicinal products - the production, wholesale (distribution) and retail of medicinal products in Bulgaria is subject to very strict and strong rules. Thus, for instance the Bulgarian MPHMA, fully synchronized with the EU framework, provides for the observance of a number of very strict regulations for obtaining of license for manufacture, import, sale (wholesale and retail) of medicinal products, marketing authorisations, etc. A counterfeit medicinal product obviously may not comply with such requirements. Sale of drugs, as a rule, may take place only in pharmacies with the exception of some light, common spread drugs, which may be sold also in drugstores. Sale of drugs via internet is prohibited in general, safe for some non-prescription drugs, but in all cases the sale via the net shall be done by pharmacies, registered with the Regulator that perform sales on the net. Advertisement of medicinal products is subject to very strict regulatation - no advertisement to public of prescription drugs is admitted, etc. These measures in their

entirety contribute for the safety on the medicinal products markets, minding that the biggest amount of counterfeit products is distributed via internet. Medicinal policy is part of the State health policy in the country and is implemented by the Minister of Health. The regulator in the field - Bulgarian Drug Agency ("BDA") is a specialised authority, subordinated to the Minister of Health, which supervises the quality, safety and efficacy of drugs. BDA conducts quality, efficacy and safety evaluations of medicinal products in relation to their marketing authorisation, as well as exercises control on the manufacturing, import, storage, wholesale and retailing, clinical trials, safety and advertising of these products. BDA also acts as coordinator and consultative body on the issues of quality, efficacy and safety of drugs. In addition to the above - Ministry of Health and the Executive Director of BDA - authorised to enforce the relevant laws are also the Chief State Health Inspector and Directors of Regional Health Inspectorates. The customs authorities have powers in relation to imports of counterfeit products, the officials from the Protection of Consumers Commission have authority in respect to falsified products on the market, the Commission for Protection of the Competition in respect to imitation and other anti-competitive actions, etc.

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.

The Bulgarian Marks and Geographical Indications Act allows proprietors of trademarks/right holders to request the customs authorities detain goods carried across the international border of the Republic of Bulgaria which can be reasonably suspected to infringe intellectual property rights. The Regulator - BDA is, of course, competent to issue orders for blocking, withdrawal and destruction of counterfeit medicinal products, as per MPHMA. Apart from these measures, the Executive Director of the Agency is entitled to prohibit the supply of medicinal products and order their prohibition and withdrawal from the market when the quantitative and qualitative composition of the product does not correspond to those declared during licensing for use. Powers of withdrawal are also vested in the ChiefHealth Inspector, who shall be informed by the director of BDA for the blocking and withdrawal of the counterfeit medical product. The order for blocking and withdrawal, issued by the executive director, shall later be sent to the regional inspectorates for preservation and control of public health, which organize the withdrawal of counterfeit products. The border control measures are in principle efficient. With respect to imports of counterfeit medicinal products, these measures usually end with confiscation and destruction, since the products (as being false) do not have import license by BDA and thus along with the medicinal products regulations, violate also the customs laws.

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?

The currently effective legislation has not introduced any specific provisions, permitting manufacturers, distributors or marketing authorization holders to eliminate directly falsified products from the market. The authority, competent to influence the

drug market by imposing protective measures, such as prohibition or withdrawal of counterfeit medicinal products under MPHMA, is BDA. The Protection of Consumers Commission is also competent in general, as it is in all cases of false products. However, the manufacturers, distributors and marketing authorization holders dispose with several possibilites for legal protection - any of them, as well as any medical establishments or individual may notify the Agency upon suspicion of medical products not compatible with the requirements of quality, efficiency and safety regulations. Notified may be also the protection of consumers authorities, police authorities and revenue authorities (who in case of non-legally compliant sales of the falsified products will impose some penalties or even confiscate goods). The interested persons may also notify the Commission for Protection of Competition, which upon establishment of violation of competition rules (imitation inclusive) may also impose severe penalties.

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

Yes, they do. Information for dangerous and/or falsified drugs is published on the website of BDA and often released in public media by the Ministry of Health and the Chief Health Inspector. Non-governmental organizations (associations) also inform through their websites or other media.

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?

Yes, they were. On 12th of July 2012 the Council of Ministers proposed and submitted in the National Assembly draft bill for amending and supplementing Medicinal Products in Human Medicine Act, with respect to the implementation of Directive 2011/62/EU. The parliament healthcare commission discussed the draft changes and made proposition for adoption of respective amendments and supplements on first vote on its regular session, held on 12.07.2012. Under Bulgarian law the procedure for transformation of a draft bill into legal act requires adoption on two consecutive votes by the Assembly and promulgation in the State Gazette. Considering the normal practice in such cases, the adoption of the final act (which still has to be implemented in the internal legislation before 2nd of January 2013) is expected to take few months.

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?

Till present Bulgaria has neither signed, nor ratified the Medcrime Convention. We do not dispose with specific information whether Bulgarian authorities consider ratification of the Convention.