

Counterfeit Medicinal Products

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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?**

   According to information from the State Agency of Medicine (SAM) recently updated in year 2009, no falsified medicinal products have been detected in the premises of the participants of the "official" medicinal products marketing chain, i.e. holders of activity licenses for wholesale trade in medicinal products or for provision of pharmacy services. However, the customs authorities are known to sometimes cease parcels containing falsified medicinal products sent to individuals in Estonia, most likely as a result of such individual ordering falsified medicinal products via the Internet. In addition, as there have been such cases in the past, marketplaces and kiosks remain suspect as likely distribution centers for falsified medicinal products which mainly originate from Russia.

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

   According to our knowledge and publicly accessible information, no notable cases have occurred recently. Although not very recent, it can be noted that in year 2008, the Tax and Customs Board ceased a parcel sent to Estonia from India, which contained 12000 tablets of counterfeit Viagra – named Vectra and being substantially similar to Viagra as to the shape, size and color of the tablets.

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.

Pursuant to Article 194 of the Estonian Penal Code, illegal manufacture of medicinal products, or provision or mediation of illegally manufactured medicinal products, or possession of illegally manufactured medicinal products with the intention of provision, if the act does not constitute a criminal offence related to narcotic drugs or psychotropic substances (as referred to below), is punishable as a criminal offence by a pecuniary punishment or up to one year of imprisonment. Insofar as a falsified medicinal product can be classified as a narcotic drug or psychotropic substance, the unlawful handling thereof is punishable as a criminal offence under Articles 183-184 of the Estonian Penal Code.

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

No, not in the legislation currently in effect; however, adding the definition to the Medicinal Products Act is envisaged in the draft act implementing 2011/62/EU.

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 basic measures to ensure the safety of medicinal products and to prevent falsification of medicinal products arising from the Estonian Medicinal Products Act are the following. According to Article 13 (1) of the Medicinal Products Act, only (1) medicinal products in respect of which a marketing authorization has been issued by the State Agency of Medicines or the Commission (hereinafter authorized medicinal products) which are released for dispensing within the European Economic Area, (2) medicinal products concerning which the State Agency of Medicines has issued a single authorization for import and use, and (3) medicinal products prepared in pharmacies in adherence to the requirements provided by the Medicinal Products Act or legislation established on the basis thereof may be sold and used in Estonia. The manufacturing and wholesale of medicinal products as well as provision of pharmacy services require respective activity licenses. Where not covered by activity licenses, the import and export or intra-EEA delivery of medicinal products require special authorization obtained from or an according notification given to the State Agency of Medicines. According to Article 25 (3), mail order sale of medicinal products as well as delivery by post or express service of medicinal products ordered through the Internet is prohibited. Pursuant to Article 44 (1)-8 and Article 45-7 of the Medicinal Products Act, the holder of an activity license for manufacture of medicinal products or wholesale trade in medicinal products or for provision of pharmacy services is required to notify the State Agency of Medicines of detection of defective or counterfeit medicinal products, or ensure that State Agency of Medicines is notified thereof. The bodies conducting state supervision over the fulfillment of the requirements arising from the Medicinal Products Act are the State Agency of Medicines and, according to their competence, the Health Board, the Veterinary and Food Board, the Competition Board and the Tax and Customs Board.

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.

Pursuant to Article 100 (6) of the Medicinal Products Act, the Tax and Customs Board shall check, for goods requiring special import or export authorization of the State Agency of Medicines, the existence and conformity of the import or export authorization or written permit pursuant to the procedure prescribed by the Medicinal Products Act and the Customs Act. With regard to customs regulations, due to Estonia being a Member State of the EU, the Community Customs Code is applicable in Estonia. According to Article 9 (1) of the Estonian Customs Act, the customs authorities shall perform all of the controls provided for in Article 13 of the Community Customs Code. Further, as per Article 10 of the Customs Act, if a prohibition or restriction established by legislation is in force concerning trade between the Member States of the European Union, postal consignments moving between such states or goods carried by persons travelling from one Member State to another, and the customs authorities exercise supervision of compliance therewith, a customs official is authorized to exercise, upon performance of his or her duties, every right granted to him or her by Community legislation and the Estonian Customs Act for the implementation of the customs rules if he or she has reason to believe, after assessing the risks involved, that such prohibition or restriction may be disregarded. As the Tax and Customs Board has confiscated parcels containing counterfeit drugs sent to individuals in Estonia, it can be concluded that the customs authorities are monitoring this sphere and will react when counterfeit products are detected. Otherwise, assessment of the efficiency of the regulation in a broader sense is difficult due to little publicly available information on this matter.

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?

Pursuant to Article 44 (1)-8 and Article 45 -7 of the Estonian Medicinal Products Act currently in force, the holder of an activity license for manufacture of medicinal products or wholesale trade in medicinal products or for provision of pharmacy services is required to notify the State Agency of Medicines of detection of defective or counterfeit medicinal products, or ensure that State Agency of Medicines is notified thereof.

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

Yes. The State Agency of Medicine has issued warnings regarding falsified drugs. Also, the NGO Association of Consumer Protection has informed consumers of the dangers related to falsified drugs.

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. A draft act implementing 2011/62/EU has been prepared but is currently still subject to review and coordination between relevant Ministries before it can be presented to the parliament.

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?

Information on this matter is currently not to be found from public sources.