



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?**

To date, Swissmedic (Swiss Agency for Therapeutic Products, the Swiss regulatory authority responsible for market authorizations and market survey of medicinal products) reported relatively few cases of counterfeited medicinal devices. In most press releases concerning counterfeit medicinal devices, Swissmedic stated that no such devices have been found in Switzerland so far, but that it is possible for such devices to also show up in Switzerland. That only a few cases of counterfeit medicinal devices in Switzerland is primarily due to the fact that Switzerland's size allows the distribution channels to be relatively neat and transparent. The distribution channels are monitored by the pharmaceutical companies themselves as well as through federal inspection. However, when orders are placed abroad (especially over the internet) this can present a danger for patients in Switzerland because the orders' origin cannot be traced and such distribution channels escape official monitoring. Numerous unapproved, counterfeited, expired or ineffective medicinal products and devices of dubious quality can be ordered over the internet. Often misleading claims about the positive effect are made without any mention of possible risks.

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

As to our knowledge there have been no recently reported cases relating to medicinal products counterfeited in Switzerland. However, Swissmedic reported several

foreign cases of counterfeit medicinal products and indicated that such products may become available on the Swiss market. These press releases are meant more as a regulatory warning for these products. In such cases Swissmedic informs on how to recognize the falsified from the original product and asks patients and citizens to report any suspicious device to Swissmedic. As for the most recent warnings of counterfeit medicinal devices, Swissmedic warned that „Ligacclip® Extra Ligaturclip Magazine“ and „Ligacclip® Extra Ligating Clip Cartridges“ from the company „Ethicon Endo-Surgery“ have been found to be sold by a non authorized dealer in the US.

Swissmedic has provided a checklist for counterfeited medicines (on <http://www.stop-piracy.ch/en/services/documents/s3001e.pdf>) for market surveillance purposes.

There have been no certified cases where falsified products were found in official distribution channels (either in hospitals or drug stores) in Switzerland so far.

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 Switzerland the Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (TPA) states in Art. 86 et seq. that several activities related to counterfeiting a medicinal device are to be punished as a crime. These provisions serve both health and fraud protection.

If the person concerned acts in his professional capacity, he or she shall be liable to a term of imprisonment not exceeding five years and to a fine not exceeding 500,000 Swiss francs.

Article 86 para. 1 lit. e TPA states, that, whoever places medical devices on the market which do not satisfy “the requirements of this Act“ along with several other misdemeanors shall be liable to a term of imprisonment or to a fine not exceeding 200,000 Swiss francs.

Also, in the Swiss Criminal Code (SR 311.0) counterfeiting of goods shall be liable to a custodial sentence not exceeding three years or to a monetary penalty provided the act is not subject to a more severe penalty under another provision hereof. If the offender acts for commercial gain, he shall be liable to a custodial sentence not exceeding five years or to a monetary penalty provided the act is not subject to a more severe penalty under another provision hereof.

The counterfeiting of goods might also be subject to other criminal provisions (such as fraud, endangering of life or even attempted homicide, to name a few) depending on how serious the offence is.

Also, if the medicinal device is protected by Swiss patent protection (SR 232.14), further provisions might apply. As such a patent owner can proceed against an infringer at a civil and penal level. Before taking legal action, the owner of the patent

should notify the infringer of his infringement ("warning"). Depending on the situation, a warning can be enough to solve the problem without legal action. The next level is the actual action against infringement, taken before the competent court. Since the costs for plaintiff and defendant alike quickly reaches 50,000 Swiss francs or more because of the complexity of the materials, it is not uncommon for patent infringement cases to be settled out of court at some point during the procedures. One possible solution for such cases is licensing. In all cases it is recommendable to retain a patent attorney for the purpose of clarifying the situation and deciding on the approach to take.

In certain situations counterfeiting of medicinal devices may also be punishable under the Federal Act on Trademarks and Appellations of Origin (SR 232.11). On complaint, any person shall be punished to a custodial sentence up to one year, or to a monetary penalty who (i) unlawfully marks goods with the trademark of another person in order to mislead and thereby give the impression that the goods are original goods or offers, (ii) brings into circulation or supplies as original goods or services unlawfully marked with the trademark of another.

In case of illegal import, the goods are seized by customs. The Swiss Customs Service and Swissmedic collaborate regarding illegal imports. Once the goods are blocked by customs, Swissmedic initiates an administrative procedure that results in the loss (usually destruction) of the medicinal device. Although only the costs for the work carried out are charged, these costs amount to at least around 300 Swiss francs and must be borne by the person who placed the order in Switzerland. In case of repeated offences or the importation of medicines that represent a threat to health, criminal proceedings against the person placing the order are also possible. The importation of medicines with the intention of reselling them is in particular vigorously pursued by Swissmedic, since trading with medicines is subject to stringent requirements (notably the need for a license).

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

In Swiss law there is no universally recognized definition of counterfeiting itself or of what a falsified medicinal device is.

However the Medicrime Convention, which has recently been signed but has not yet been ratified and therefore has no legally binding value yet, defines counterfeiting as follows: "The term "counterfeit" shall mean a false representation as regards identity and/or source."

The Swiss Federal Institute of Intellectual Property defines counterfeiting as follows: "Counterfeiting is used to refer to the infringement of protected trademark, designs, indicating source or patent rights through imitating the original."

Pursuant to Swiss Law there is a distinction between medical devices and medicinal product. Medical devices are products, including instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have or are presented as having a medical use and whose principal effect is not obtained with a

medicinal product. Medicinal products are products of chemical or biological origin that are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products.

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?

Swissmedic (Swiss Agency for Therapeutic Products) is the central office for medicinal product safety. It collaborates closely with the cantonal health authorities to uphold the Swiss drug law. Swissmedic is responsible for drug and medicinal products' safety and for enforcing "drug law" (TPA SR 812.21) in Switzerland. Swissmedic is active in the European Council and at other European and international levels in various committees. The national network with authorities such as the customs agents, the police, and the Institute of Intellectual property is important for this as well. Communication with the pharmaceutical industry and consistent prosecution in cases of infringement are central to the fight against counterfeiting. The industry supports measures by the approval authorities, which draw the public's attention to the risks involved in medicines ordered over the internet. Every pharmaceutical company has its own strategy for products, which are particularly vulnerable to counterfeiting: Technological instruments, such as bar codes, can be used to exactly trace the path of a product. To some extent, visually recognizable elements such as holograms or hidden identification marks can also be used.

The customs authorities are entitled, to hold back shipments of therapeutic products at the border or in a customs warehouse and to call upon the enforcement authorities, if they suspect an infringement of the provisions of the TPA. Swissmedic then has to make any further enquiries and take the necessary measures.

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.

International collaboration in the fight against counterfeited medicinal devices has been intensified by the following:

In Moscow on 28 October 2011 the Swiss Federal Council signed the Medicrime Convention. The Council of Europe Medicrime Convention ("convention") is the first international convention that aims at preventing threats to the health of the public from counterfeit medicinal products. By signing the convention, parties are obliged to criminalize the manufacturing of and the supplying, offering to supply and trafficking in counterfeit medicines. Moreover, it lays down a framework for national and international cooperation between the relevant authorities. As mentioned before, the

convention still needs to be ratified by Switzerland.

Experts from Swissmedic were closely involved in the Council of Europe working groups during the drafting of the Medicrime Convention. Switzerland's Therapeutic Products Act and associated ordinances already provide a very good legal basis for prosecuting counterfeiters of medical products. Certain elements of the convention have already been incorporated into the Therapeutic Products Act as part of the ordinary revision of the act.

However, various additional amendments to the Therapeutic Products Act and other Swiss laws are required before the Medicrime Convention can be ratified. The necessary legal amendments are currently being drawn up and are expected to be submitted to interested parties for their views in winter 2012. Parliament is then expected to debate the proposal in autumn 2013.

Where a patent, trademark or copyright infringement is involved, the provisional border measures as set of in the legal provisions for the protection of these intellectual property rights directly apply. Accordingly, rights owners can fight against the import, export and carrying in transit of counterfeited and pirated products by petitioning the customs administration for assistance. In such cases, customs officials can check the shipment for suspicious products and, if appropriate, withhold them so that the rights owners can initiate the legal help of their choice. An official form that shows the requirements for an application for assistance, the supporting documents to be submitted to the customs administration, the process etc. has been created (<http://www.stop-piracy.ch/en/candp/cap50.shtm>).

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?

On a private or administrative law basis, a company can ask the court to order an interim measure, provided the applicant shows credibly that a right to which he or she is entitled has been violated or a violation is anticipated, and the violation threatens to cause not easily reparable harm to the applicant.

Certain federal laws, such as the Federal Act of Protection of Design or the Federal Act of Protection of Patent require the harmed party to report relevant infringements, so that penal and administrative procedures can be started that are to be taken by Swissmedic or any other competent federal or cantonal institution.

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

Swissmedic is obliged to inform the public (article 67 TPA).

Article 67 TPA states, that Swissmedic shall ensure that the public is informed of

occurrences specifically relating to therapeutic products, which endanger health, and shall issue appropriate recommendations. It shall publish information of general interest about the therapeutic products sector, in particular regarding authorization and revocation decisions as well as about amendments to professional and patient information concerning medicinal products.

Also, the competent Federal offices may inform the public on the correct use of therapeutic products for the purpose of protecting health and combating the abuse of such products.

Swissmedic has also published a guideline informing the public about potential dangers in acquiring medicinal devices over the internet.

Also “STOP-Piracy” is an association that aims to fight against counterfeiting and piracy through active awareness-building and enhanced coordination and cooperation between, as well as within, the private and the public sectors. Due to its membership structure, “STOP-PIRACY” is politically neutral and cannot take sides in individual cases where law enforcement is concerned. “STOP-PIRACY” adopts a public position by supplying facts and actively educating the public about counterfeiting and piracy. It names itself the “Swiss Anti-Counterfeiting and Piracy Platform”.

This association is a public-private initiative between the Swiss Federal Institute of Intellectual Property and the Swiss National Committee of the International Chamber of Commerce. A variety of activities, such as promoting cooperation between business and federal agencies and educating the public, should serve to fight the problem in a sustainable way. According to their website, STOP-Piracy is fighting the continuing growth of counterfeiting and piracy (<http://www.stop-piracy.ch/en/home/h1.shtm>).

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?

Articles 76-84 of the directive 2001/83/EC have been implemented on an ordinance basis (AMBV SR 812.212.1) as applicable in Switzerland. These terms apply to the “Good Distribution Practice”. So far, no implementations of the directive 2011/62/EU have been drafted. Also, the link made to the 2001/83/EC directive is not dynamic, which means, even after the amending directive 2011/62/EU, the Swiss ordinance still refers to the 2001/83/EC directive.

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 Medicrime Convention has already been signed by Switzerland on October 28 2011. However, various additional amendments to the Therapeutic Products Act and

other Swiss laws are required before the Medicrime Convention can be ratified. The necessary legal amendments are currently being drawn up and are expected to be submitted to interested parties for their views in winter 2012. Parliament is then expected to debate the proposal in autumn 2013.