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Global Practice Guide

Counterfeit Medicinal Products

A Global Practice Guide prepared by the
Lex Mundi Life Sciences Group

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About This Guide

The counterfeiting of medicinal products is a serious and complex problem. First, it threatens the health and life of individuals. Falsified medicines can result in treatment failure or even death. Further confidence in public health care systems may be undermined as a consequence of counterfeit drugs on the market. Additionally, trade in such products causes significant losses to manufacturers and distributors of genuine medicinal products and, moreover, profits from the sale of such products contribute to the development of a "black economy".

The scale of the problem is difficult to assess. According to the WHO, trade in falsified products in countries with most effective regulatory systems is less than one percent of market value. However, the global average is 10 percent and some countries may even be 30 percent.

Several international organizations fight these practices. In 2006, the WHO launched an International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Recently, the European Union and the Council of Europe have taken legislative action: the EU by adopting Directive 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, as regards the prevention of the entry into the legal supply chain of falsified medicinal products as well as the Council of Europe with its Convention on the counterfeiting of medical products and similar crimes involving threats to public health, which is already signed by 12 countries.

As these measures are not yet enforced, it is important to analyze why previous laws and supervisory systems did not succeed and why there are increasingly more counterfeit drugs available on the market. Will the new regulations be satisfactory or is it more of a question of education and public awareness rather than new strict laws.

This Global Practice Guide is designed to give readers a better understanding of the issues relating to counterfeit medicine in the jurisdictions listed. Each Lex Mundi member firm was asked to respond to a series of questions, regarding counterfeit medicine in their jurisdiction.

The descriptions set forth below are intended only as a general overview of the law as of October 2012. No summary can be complete, and the following is not intended to constitute legal advice as to any specific case or factual circumstance. Readers requiring legal advice on any of the specific case or circumstance should consult with counsel admitted in the relevant jurisdiction.

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Austria

Prepared by Lex Mundi member firm CHSH Cerha Hempel Spiegelfeld Hlawati

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

   Counterfeit medicinal products are an increasing problem in Austria. Counterfeit medicinal products are mainly sold via internet and are sent in very small packages. For more details see question 2.

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

   In 2011 the Austrian customs authorities seized 41.589 counterfeit medicinal products, which was the double amount compared to 2010. In the past years the vast majority of counterfeit medicinal products (up to 95 percent) came from India. In 2011 a change has been notified. Nearly 38 percent of seized counterfeit medicinal products entered the European Union through Singapore. However, it is assumed that the products are produced in other countries and just sent from Singapore.

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.**

   There is no special prohibition against counterfeit medicinal products in Austrian law.
   However, several laws provide for (administrative) sanctions that might apply to sellers of counterfeit medicinal products:

   - Distance-selling of medical products is forbidden in Austria (Section 59 Austrian Medicines Act - Arzneimittelgesetz).
   - Sections 83 et seq,. of the Austrian Medicines Act regulate sanctions for selling products which do not comply with the Austrian legislation.
   - Furthermore it is forbidden under the Austrian Medicinal Products Import Act – Arzneiwareneinfuhrgesetz – to order medicinal products online without having a special permission (section 17 of the Austrian Medicinal Products Import Act) or under certain circumstances from a registered pharmacist in an EEA country.
   - Section 21 of Austrian Medicinal Products Import Act states sanctions for – imports of medicinal products which do not comply with the law.

   Furthermore, in case of deaths or injuries caused by counterfeits, criminal provisions on manslaughter (§ 80 Austrian Criminal Code) and bodily injury caused by negligence (§ 88 Austrian Criminal Code) might be applicable.

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

   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?**

   Each medicinal product must receive a marketing authorization before it can be marketed in Austria. Authorized products are approved by the Federal Office on the Safety of Health Care (BASG).

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The most important law in this context is the Austrian Medicines Act. It regulates the production and the marketing of medicinal products.

Furthermore there are strict rules for pharmacists under the Pharmacists' Act (Apothekengesetz), which aim to ensure an efficient supply with medicinal products. Selling of many medicinal products can only be done by licensed pharmacies.

The Federal Ministry of Health is in charge of enforcing the Austrian Medicines Act (as long as there are no special competencies bestowed on special agencies such as the Federal Office on the Safety of Health Care).

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 Austrian Medicinal Products Import Act regulates the requirements for importing medicinal products to Austria. It gives the Austrian Toll Customs Authorities the power to confiscate products, to sent them back or to destroy them (Section 19 Austrian Medicinal Products Import Act) The arising costs have to be paid by the person who ordered the products. Furthermore an administrative penalty up to € 7.260,-- may be imposed.

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?

Participants in the market of medicinal products may take various actions to fight against counterfeit medicinal products.

1) *Based on intellectual property law*: Counterfeit medicinal products often infringe intellectual property rights. Entities concerned may demand for consequence to protect their intellectual property rights.
2) *Based on unfair competition law*: Counterfeit medicinal products are often misleading in several ways (e.g. origin, quality, components…) and therefore constitute acts of unfair competition.
3) *Notification of competent authorities*: Everyone can inform authorities, if the impression of a counterfeit medical product arises. The competent authority in Austria is Federal Office in the Safety of Health Care (http://www.basg.gv.at/).

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

Yes, the Austrian Federal Office for Safety in Health Care announces warnings of counterfeit medicinal products on its Webpage (http://www.basg.gv.at/omcl/arzneimittel-faelschungen/warnungen/).

Furthermore a campaign from the Federal Ministry of Finance and the Austrian Pharmacists Chamber in with the title „Auf der sicheren Seite", which means „ On the save side" started in September 2010. The public was informed about the danger of counterfeit medicinal products through various information channels (webpage, online games, radio and cinema spots and directly in pharmacies)

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?

There has been a draft amendment of the Austrian Medicines Act which implements the 2011/62/EU directive. However, this draft act has not yet been approved by Parliament and is still subject to

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modifications. Therefore, at the moment a full implementation of the directive is still missing under Austrian law.

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?**

    Austria signed the convention on 28th of October 2011.

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Bulgaria

Prepared by Lex Mundi member firm Penkov, Markov & Partners

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. However, 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 envisaged 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 authorization 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.

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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 authorizations, 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 regulation - 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 specialized 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 authorization, 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 - authorized 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 Chief Health 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

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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 possibilities 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 Medicrime Convention. We do not dispose with specific information whether Bulgarian authorities consider ratification of the Convention.

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Cyprus

Prepared by Lex Mundi member firm Dr. K. Chrysostomides & Co LLC

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

   Yes, the problem is identified by the competent authorities, though the actual market problem is rather small.

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

   Only a very limited number of seizures at points of entry (mainly relating to internet purchases).

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.**

   There is no specific criminal offence for counterfeiting a medicinal product.

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

   Not yet.

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 general provisions of the Law and Regulations are relating to pharmaceutical products for human use. The competent Authority responsible for the enforcement of the Law is the Pharmaceutical Services Department of the Ministry of Health of the Republic. With regard to counterfeit medicinal products, Cyprus Customs are responsible for preventing their importing into Cyprus.

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.**

   Cyprus Customs Authorities actively enforce the provisions of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights. Right holders can benefit from the applicable procedures which can prove particularly effective, especially in cases where Customs receive full support from right holders (e.g. specific product identification guides, training etc).

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?**

   No specific regulations. Protection can be obtained through general legal and administrative procedures for protecting IP rights and the general legislation concerning pharmaceutical products for human use.

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

   Yes, mainly through printed matter such as informative brochures, leaflets etc.

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 Law implementing Directive 2011/62 is currently under preparation.

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?**

    Cyprus has signed the Medicrime Convention but has not yet ratified the same.

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Estonia

Prepared by Lex Mundi member firm LAWIN

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

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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 requires 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.

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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.

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Finland

Prepared by Lex Mundi member firm Roschier, Attorneys Ltd.

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

   The number of counterfeit medicinal products are has increased dramatically in Finland in recent years, and consequently they are recognized as a significant problem. There is reason for concern, as there is no way for the consumer to verify that the counterfeit medicinal products indeed contain the relevant active substance, or the correct amount of it. In addition, the counterfeit medicinal products may contain substances which are harmful or even dangerous to the consumer. As a starting point, counterfeit medicinal products also infringe third party intellectual property rights.

   Nearly all pharmaceutical imports to Finland are intended for private domestic use, i.e. small amounts are imported by private persons for their own use. Consequently, there have not been any cases in Finland involving counterfeit pharmaceuticals transiting to other countries for several years. Most counterfeit pharmaceuticals are imported from India and China.

   The majority of the counterfeit medicinal products entering Finland are erection medicines, but also pain-killers, allergy medicines and slimming pills have been identified. Counterfeit medicinal products have so far not been found within the legal distribution chain such as in pharmacies. Consequently, it is virtually impossible to determine the amount of counterfeit medicinal products on the Finnish market, as all trade takes place illegally.

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

   In Finland, counterfeit medicinal products are usually ceased by the customs authorities in connection with boarder control measures. In 2011, the customs seized a record of 264 000 tablets ordered by Finnish citizens from abroad, the majority of which were counterfeits. Nevertheless, it has also been estimated that the customs are currently able to cease only 5-10 percent of all counterfeit medicines which enter Finland.

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.**

   There is no specific provision in the Finnish Criminal Code (39/1889) which would explicitly relate to counterfeiting or related activity of medicinal products.

   However, in the event that counterfeiting activities would be discovered in Finland, it is likely that Chapter 44 Section 5 of the Criminal Code regarding a medicines offence would be applicable. According to said provision, a person who intentionally or through gross negligence in violation of the Medicine Act or a regulation issued on the basis of article 100a or 235 of the EEC Treaty pertaining to the supervision of medicine, or a provision or an order given in general or in an individual case on their basis

   1) produces, imports, stores, keeps for sale or gives medicines referred to in the Medicine Act,
   2) neglects to give a notice, neglects a duty to provide information or neglects a duty to maintain a register related to medicines referred to in the Medicine Act, or
   3) violates a prohibition on medicine issued by a Finnish supervisory authority

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or the Commission of the European Communities or the Council of the European Union and referred to in the Medicine Act, shall be sentenced, unless a more severe penalty for the act has been provided elsewhere in the law, for a medicine offence to a fine or to imprisonment for at most one year.

In addition to a medicine offence, it is possible that the provisions in Chapter 21 of the Criminal Code regarding homicide and bodily injury may be applicable to counterfeiting of medicinal products, if the activities result in bodily harm or death of a person.

Lastly, a counterfeiter of medicinal products may also be guilty of patent, copyright or trademark infringement, as specified more in detail in our answer to question 7.

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

There is no statutory definition of a falsified medicinal product in Finland. Consequently, the definition by the World Health Organization ("WHO") is relevant also in Finland and used for example by the Finnish Medicines Agency on its webpage. According to the WHO definition:

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled 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."

The current situation will change once the Falsified Medicines Directive (2011/62/EU, amending Directive 2001/83/EC) is implemented into Finnish law. For more details about implementation of this directive, please see our 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 labeling, 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 authorization 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?

The Medicines Act (395/1987) is the most crucial regulation concerning the safety of medicinal products.

According to the Act, medicinal products may only be manufactured industrially by medicinal product manufacturers that have acceptable production facilities and equipment and a license from the Finnish Medicines Agency. Furthermore, medicinal product manufacturers must comply with good manufacturing practice for medicinal products corresponding to the principles and guidelines relating to provisions issued by the European Union and the Convention on mutual recognition of inspections of manufacture of pharmaceutical products (Finnish Treaty Series 20/1971). Only such active substances as have been manufactured in accordance with the European Union guidelines on good manufacturing practice may be used in the manufacture of medicinal products.

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Furthermore, a medicinal product may be sold to the general public or otherwise released for consumption only if the Finnish Medicines Agency has granted an authorization for the product or registered it or if it has a marketing authorization granted by an institution of the European Union. Holders of marketing authorizations, parallel import marketing authorizations and registrations must notify the Finnish Medicines Agency about placing a medicinal product on the market, discontinuation of keeping a medicinal product on the market and temporary interruptions to keeping a medicinal product on the market.

Medicinal product manufacturers may sell or otherwise supply medicinal substances only to another medicinal product manufacturer or medicinal product wholesaler or pharmacies. Medicinal products not restricted under law or other provisions to being sold solely by pharmacies may however be sold or otherwise supplied to retailers of such products.

The Finnish Medicines Agency is the national competent authority for regulating pharmaceuticals. As a central administrative agency operating under the Ministry of Social Affairs and Health it promotes the health and safety of the population by regulating medicinal, blood and tissue products, and by developing the pharmaceuticals sector. The Finnish Medicines Agency is also authorized to enforce the provisions in the Medicines Act.

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.

Community-wide regulation on anti-counterfeiting measures at the borders exists as supranational legislation in Finland. The relevant Regulation currently in force is Council Regulation No 1383/2003/EC. According to the Regulation the Finnish Customs may, based on the right-holders' application, seize a shipment of counterfeit products entering the territory of Finland. The application for border control may either be national or EU wide, but basically the same set of rules is applied in both cases.

In addition the Regulation, the Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code and the Commission Regulation (EC) No 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 are relevant also in Finland.

The relevant pieces of national legislation applied in connection with Customs seizures of counterfeit goods are the Customs Act (1466/1994), which includes some additional procedural and administrative provisions relating to the seizures, and certain IP specific legislation. The most important pieces of IP legislation in connection with counterfeit pharmaceuticals are the Trademarks Act (7/1964), the Patents Act (550/1967) and the Design Act (221/1971) (e.g. if the tablet or package in question is protected with a registered design). The question of infringement and remedies available for the right-holder are defined in the national IP legislation and the Penal Code.
When a Finnish Customs office encounters pharmaceuticals that are suspected of infringing an intellectual property right referred to in Article 2(1) of the Regulation, it suspends the release of those goods or detains them.

Finnish Customs usually notifies the right-holder or its representatives of the nature of the counterfeits suspended by telephone, facsimile and/or e-mail. At this point, Finnish Customs also usually sends digital pictures by email of a selection of the suspected goods to the right-holder or its representatives to enable preliminary assessment of the infringement. They are usually also given the opportunity to inspect the goods.

If the right-holder has not yet filed an application for Customs action (so-called ex officio seizure), the right-holder has a period of three (3) working days calculated from the notification to the right-holder to do this and request for an official seizure of the allegedly counterfeit goods. When the Customs applications is in place (either national or EU wide) the right-holders shall within a period of ten

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working days (extendible once for further 10 working days) calculated from the notification to the right-holder conduct their investigations and to commence relevant legal proceedings, if found necessary.

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?

There are several ways for manufacturers, distributors and marketing authorization holders to act against counterfeit products on the market.

First, the right holders can make a request based on the Trademarks Act, the Patent Act or the Design Act, that any counterfeit goods which infringe their intellectual property rights must be destroyed, and any further commercial use of the infringing products prohibited.

Second, the Unfair Business Practices Act (1061/1978) provides that good business practice may not be violated, and nor may practices that are otherwise unfair to other entrepreneurs be used in business. Furthermore, a false or misleading expression concerning one's own business or the business of another may not be used in business if the said expression is likely to affect the demand for or supply of a product or harm the business of another. An entrepreneur may be prohibited from continuing or repeating practices that violate good business practice and the prohibition may be reinforced through a conditional fine.

Third, the Consumer Protection Act (38/1978) provides that false or misleading information shall not be conveyed in marketing. In particular, it is prohibited to mislead the consumers as to the origin, manufacturing and use of a consumer product. The consumer protection authorities supervise that the provisions in the Consumer Protection Act are followed, meaning that right holders may inform the authorities of e.g. any suspect counterfeit medicinal products if official action is required. However, the authorities in Finland are fairly active and would most likely react also at their own initiative if the health of the consumers is at risk.

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

Both public authorities and non-governmental organizations in Finland are fairly active in informing the public of the dangers of counterfeit medicinal products.

For example the Finnish Medicines Agency arranged a campaign in 2008, which was featured in printed media and which focused on the problems involved with separating a counterfeit pharmaceutical from a genuine one. For this purpose, a special webpage was established, to which consumers were directed through internet advertising.

In 2012, the Finnish Anti-Counterfeiting Group (FACG) together with the Finnish customs authorities and a number of celebrities from the music world arranged a public campaign called "Fake no more". The organizers gathered in shopping malls with the aim of discussing the problems involved with both counterfeit pharmaceuticals and other fake products directly with in particular young consumers. The campaign included a webpage with the possibility to win genuine goods by answering a number of questions, where the answers could be found in the information provided on the webpage.

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 government bill on the subject is currently being prepared by the Ministry of Social Affairs and Health, which most likely will be presented to the Parliament for discussion and approval in October 2012. However, the draft government bill is currently not publicly available.

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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?

Yes. A working group has been established, which is currently assessing whether Finland could sign and ratify the Convention, but so far no definite decisions have been taken.

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Counterfeit Medicinal Products

Greece

Prepared by Lex Mundi member firm Zepos & Yannopoulos

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 special safety features 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, and 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).

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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 mislabeled 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 counterfeit 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;

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- 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 labeling, 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 authorization 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

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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 labeling 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 false 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;

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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.

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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.

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Counterfeit Medicinal Products

Ireland

Prepared by Lex Mundi member firm Arthur Cox

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

   In recent years an increase in the trafficking of medicinal products (including the trafficking of counterfeit products) into Ireland has been identified.

   According to the most recent figures provided by the Irish Medicines Board ("IMB"), a total of 822,484 dosage units of medicinal products were detained by it during 2010. This figure includes the detention of 290,240 units of weight loss products containing the active substance sibutramine, an almost fivefold increase on the 2009 figure. In addition 131,805 units related to erectile dysfunction products were detained. Other products detained included the active substances, diazepam, zopiclone, flurazepam and testosterone. Medicinal products destroyed during 2010, in compliance with the Waste Management Acts 1966-2001, amounted to 1,400 kg. Please note that this figure relates to medicinal products which were illegally on sale in Ireland – while this figure would include counterfeit medicines it does not solely relate to counterfeits.

   In addition, we note that from 20-27 September 2011 the IMB, the Revenue Customs Services and the Garda Síochána (the Irish police force) took part in an INTERPOL coordinated operation named Panegea IV. This operation has been described as the largest internet-based action of its kind in support of the International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT).
   A total of 492 packages containing 51,621 tables, capsules and creams with an estimated value in excess of €150,000 were intercepted by Revenue Customs Officers during the week of operation Pangea IV. The substances detained included products for weight loss, erectile dysfunction and mood stabilizers. Over the course of the week, 470 websites were closed or curtailed from illegally providing medicinal products into Ireland.

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

   The most recent annual figures provided by the IMB relates to 2010, in which a total of 3,936 investigations were ordered by the IMB, the Garda Siochána and Revenue Customs. The majority related to the mail order/internet importations of prescription only medicines. Please note that this figure relates to medicinal products which were illegally on sale in Ireland – while this figure would include counterfeit medicines it does not solely relate to counterfeits.

   During 2010, the IMB was involved in five prosecutions, however these related to the unauthorized supply of medicinal products rather than the counterfeiting of 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.**

   The counterfeiting of medicinal products is criminalized under two separate legislative regimes - the Irish trademark and customs legislative regime and medicinal products legislative regime. The majority of Irish legislation in these areas has been enacted pursuant to EU Directives.

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a. General Irish Trademark and Customs Legislation

The Trademarks Act 1996, as amended, provides criminal and civil remedies where a trademark is infringed. A "trademark" for the purposes of this act includes Irish trademarks, Community trademarks and international trademarks under the Madrid protocol designating Ireland. It is a criminal offence for any person who is not the trademark owner (or who is not authorized by the trademark owner) to:

(i) apply a mark identical or nearly resembling a registered trademark to goods or to material used or intended to be used for labeling, packaging or advertising goods;

(ii) sell, let for hire, offer or expose for sale or hire, or distribute goods bearing such a mark or material bearing such a mark which is used or intended to be used for labeling, packaging or advertising goods;

(iii) use material bearing such a mark in the course of a business for labeling, packaging or advertising goods; and

(iv) possess in the course of a business goods or material bearing such a mark with a view to doing any of the above.

Penalties for a breach of the above include a term of imprisonment not exceeding five years and/or a fine of up to €130,000. In addition, a court may order that the infringing goods be delivered up to the trademark owner, destroyed or forfeited.

The EU Customs Regulation (EC No. 1383/2003) concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, its Implementing Regulation (EC No. 1891/2004) and the Customs Act, 1876, as amended, enable trademark owners to notify the Revenue Customs Service to detain any goods that are suspected of infringing relevant IP rights (such as counterfeit goods bearing an trademark which is identical to or substantially indistinguishable from a registered trademark). In addition, the Revenue Customs Service is permitted to detain goods and notify rights holders of their detention to permit the rights holder to submit an application for customs action (such as having the goods seized or destroyed)

b. Regime Governing Medicinal Products

The Irish legislative regime governing medicinal products has largely been enacted pursuant to EU legislation. It contains a number of wide-ranging prohibitions, which include prohibitions on:

(a) the importing, the placing on the market of or otherwise selling any medicinal product or the procuring of the manufacture for sale of any medicinal product without a license granted by the IMB, or where appropriate the European Medicines Agency, (the Medicinal Products (Control of Placing on the Market) Regulations S.I. 540/2007 (as amended) which implement Directive 2001/83/EC on the Community Code relating to medicinal products for human use (as amended) and the Manufacture (Medicinal Products (Control of Manufacture) Regulations 2007 S.I. No. 537/2007 (as amended));
(b) keeping, offering for sale, or selling by wholesale any medicinal product without a wholesale license granted by the IMB, or where appropriate the European Medicines Agency, (Medicinal Products (Control of Wholesale Distribution) Regulations 2007, S.I. No. 538/2007, as amended));
(c) supplying prescription-only products without a prescription (Medicinal Products (Prescription and Control of Supply) Regulations 2003, S.I. No. 540/2003 (as amended)); and

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(d) supplying prescription products by mail order (Medicinal Products (Prescription and Control of Supply) Regulations 2003, S.I. No. 540/2003 (as amended)).

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

We note that Directive 2011/62/EU amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products has introduced a definition of a falsified medicinal product as follows:

"Any medicinal product with a false representation of:

(a) its identity, including its packaging and labeling, 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 authorization 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.

Ireland is required to bring into force a regulation transposing this Directive by 2 January 2013 and to apply this definition from this date. We note that Ireland has not yet published a bill to transpose this directive.

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?

Please refer to paragraph 3.2 above. The IMB is the authorizing body which approves medicinal products for sale in Ireland by awarding marketing authorizations to suitable products. In addition to its regulatory activities the IMB also carries out enforcement of many of the regulations for which it has responsibility. Enforcement activities include investigation of potential breaches of regulations and a range of measures, including prosecution, may be applied. IMB personnel are permitted, under the Irish Medicines Board Act, 1995, as amended, to examine and detain any medicinal product for the purposes of enforcement.

The Revenue Customs Service has responsibility for the implementation of import and export control. Revenue Customs Officers may detain, sample and seize prohibited or restricted medical products imported into Ireland under the Customs Act 1876, as amended. In addition, a Revenue Customs Officer is deemed to be an authorized officer under the Irish Medicines Board Act, 1995, as amended, and is permitted to examine and detain any medicinal product for the purposes of enforcement.

A Memorandum of Understanding has been signed by the Revenue Customs Service and the IMB with the aim of ensuring effective enforcement, co-ordination and co-operation in deterring international trafficking in medicinal products, pursuant to which the bodies have implemented information exchange practices and procedures and have established a Joint Task Force.

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.

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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?**

   Manufacturers, distributors or marketing authorization holders may report falsified products entering the country to the Revenue Customs Service. The EU Customs Regulation (EC No. 1383/2003) concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, its Implementing Regulation (EC No. 1891/2004) and the Customs Act, 1876, as amended, enable trademark owners to notify the Revenue Customs Service to detain any goods that are suspected of infringing relevant IP rights (such as counterfeit goods bearing an trademark which is identical to or substantially indistinguishable from a registered trademark).

   In addition, manufacturers, distributors or marketing authorization holders may report falsified products to the Irish Medicines Board who may prosecute the importing, the placing on the market of or otherwise selling any medicinal product or the procuring of the manufacture for sale of any medicinal product without a license granted by the IMB, or where appropriate the European Medicines Agency, (the Medicinal Products (Control of Placing on the Market) Regulations SI 540/2007 (as amended) which implement Directive 2001/83/EC on the Community Code relating to medicinal products for human use (as amended) and the Manufacture (Medicinal Products (Control of Manufacture) Regulations 2007 (as amended)).

   Alternatively, a manufacturer, distributor or marketing authorization holder may wish to initiate a civil claim for the tort of passing off.

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

   The IMB informs the Irish public of dangers related to falsified drugs. It issues warnings or advisory notices where a specific issue has been identified.

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?**

   Ireland is required to bring into force a regulation to comply with Directive 2011/62/EU by 2 January 2013. Ireland has not yet published a bill to transpose this 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?**

    Ireland has not yet signed the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (the MediCrime Convention).

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Counterfeit Medicinal Products

Lithuania

Prepared by Lex Mundi member firm LAWIN

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

   The scale of counterfeit medicinal products in Lithuania is rather limited as most of the reported accidents are associated with online orders of the counterfeit medicinal products intended for the private use. The medium scale accidents, i.e. when over 1000 tablets / capsules are being seized occur few times in a year. According to the official information of Customs Department under the Ministry of Finance in 2010, 52 events of falsified medicines have been confirmed and 9,393 tablets have been inspected. In 2011, 20 falsified medicine reports have been investigated and 954 tablets were inspected. The majority of the seized drugs were “Viagra” and “Cialis”. It must be noted that while falsified medicines remain minor issue in Lithuania, the scale of medicinal products being smuggled from Russian Federation, Belarus retains high volumes and there are hundreds of such events reported annually, but they include the smuggling of the medicinal products that are registered in the Russian Federation, but not in the EU and therefore such occurrences do not amount to the cases of falsified medicines.

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

   To the best of our knowledge no cases have been brought to Administrative, Civil or Criminal court regarding the counterfeit medicinal products in the recent years.

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.**

   Lithuanian Criminal Code contains Article 275 on unlawful pharmaceutical activities where a natural and / or legal entity who has unlawfully (i) manufactured medicinal products, inter alia counterfeit medicinal products with an intention to distribute them; (ii) manufactured any active ingredients for such products with an intention to distribute them; (iii) distributed such medicinal products, may be sanctioned with a fine, arrest, or imprisonment up to two years. If any of the aforementioned actions resulted in a persons’ serious injury or death it shall be sanctioned with imprisonment up to eight years. Lithuanian Administrative code contains (i) Article 44(1) on unlawful pursuit of drug related activities, inter alia counterfeit medicinal products, that have not caused any severe consequences or were not pursued on a major scale – the natural person may be sanctioned with the fine from 145 to 290 EUR with or without the confiscation of counterfeit medicinal products; head of the legal entity may be sanctioned with a fine from 869 to 1,738 EUR with or without the confiscation of counterfeit medicinal products; (ii) Article 44(3) on the breach of pharmacy practice and activities related to drugs, inter alia counterfeit medicinal products is applicable in the case of any non-compliance with regulatory requirements for pharmacy practice – the natural person may be sanctioned with the fine from 29 to 579 EUR; head of the pharmaceutical activity may be sanctioned with a fine from 869 to 2,896 EUR with or without the confiscation of counterfeit medicinal products, plus the prohibition to undertake professional activities for a time period decided by the Court; (iii) Article 44(6) on the violation of requirements relating to the medicinal product marketing authorization is applicable in the case where marketing authorization holder has breached its obligations – head of the entity may be sanctioned with a fine from 290 to 1,448 EUR.

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

The Law on Pharmacy is the main legal act containing the definitions for the majority of pharmacy-related terms. However, the Law on Pharmacy is silent on a definition of falsified medicinal products. From the systemic reading of the Law on Pharmacy it may be derived that the equivalent to counterfeit medicinal product would be considered a medicinal product which satisfies any of the following conditions: (i) is harmful while used in normal conditions; (ii) is ineffective; (iii) has unfavorable risk-benefit ratio for the use of the medicinal product in the approved conditions; (iv) does not comply with the declared qualitative and / or quantitative composition of medicinal product; (v) has not undergone control of the intermediate stages of production of medicinal product and / or it's composite materials; (vi) does not comply with the requirements for issuance of the marketing authorization.

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 main legal act detailing the regulations of safety and prevention of falsified medicinal products is the Law on Pharmacy, which regulates pharmaceutical and other activity related to medicinal investigational products, veterinary medicinal products, active and other medicinal substances as well as medicinal purpose products, veterinary pharmaceutical activity as well as state management and control of the activity. The Law on Pharmacy does not regulate activities related to precursors of narcotic and psychotropic substances. State Medicines Control Agency (SMCA), link: http://www.vvkt.lt/index.php?3327723903 is the competent authority to enforce the Law on Pharmacy regarding the safety of medicinal products intended for the human use, while State Food and Veterinary Service (SFVS), link: http://vmvt.lt/en/ is a competent institution to enforce the Law on Pharmacy regarding the safety of veterinary 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.

The manufacturers of medicinal products are invited to organize trainings to State Border Guard Service under the Ministry of the Interior (SBGS) and educate the Border Guards about any noticeable differences while evaluating the investigated medicinal products. The manufacturers are sometimes disclosing semi-corporate secrets related to medicinal product evaluation guidelines and sharing know-how regarding the dissociation between genuine and falsified medicinal products. Border Guards are also performing in-depth check-ups to all the shipments containing medicinal products from the higher risk countries, e.g. India, China, Russian Federation, Belarus, etc. Current measures aim to prevent falsified medicines from appearing in Lithuanian market from the non-EU countries. Such measures shall be considered as rather efficient as the events of falsified medicines are not reported on a nation-wide scale and are restricted to individual cases, as well as there are nearly no falsified-medicine-related adverse effects reported by general pediatricians, specialist doctors and they are not logged by the public authorities, which are constantly collecting the information from the healthcare professionals, pharmaceutical companies and other competent authorities in other EEA Member States.

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 State Medicines Control Agency (SMCA), may, without a prior notice, on its own initiative or at the request of another EEA state, the European Commission or the European Medicines Agency, perform an inspection of active substances used as starting materials within the premises of manufacturers or the medicinal product marketing authorization holder if it is reasonable to assume that Good Manufacturing Practice is not complied with. Manufacturers of starting materials may be inspected at their own request. In practice the interested parties, e.g. manufacturers, distributors,

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marketing authorization holders are invited to inform the SMCA (both in official writing and anonymously) about any suspicious medicinal products, based on which the inspection of such medicinal product may be carried out. Upon confirming that the inspected medicinal product intended for the human use amounts to falsified medicinal product, the SMCA shall withdraw it from the market and prohibit the prospective supply of similar product to the market. This measure would be enforced by all relevant competent authorities, including State Border Guard Service and Customs Department in every EEA Member State. Also the SMCA may (i) prohibit supplying to the market only those batches of the medicinal product which give rise to doubts that this is a counterfeit medicinal product; (ii) apply their full or partial removal; (iii) suspend the manufacturing or imports of counterfeit medicinal products coming from the third countries. Alternatively, if the counterfeit medicinal product qualifies as the veterinary medicinal product it shall be inspected and similar sanction shall be imposed by the State Food and Veterinary Service (SFVS).

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

State Medicines Control Agency (SMCA), which is the competent authority to ensure the safety of medicinal products, intended for the human use, is occasionally informing the general public about the dangers related to counterfeit medicinal products, yet no social campaigns have taken place in the recent years. State Food and Veterinary Service (SFVS) is a competent institution to monitor the safety of veterinary medicinal products. Due to the low number of reported accidents of falsified veterinary medicinal products, the SFVS has no active policy towards educating the society about the associated risks. Yet SFVS is capable of successfully informing about the confirmed cases of falsified medicinal products as they have established good communication networks throughout national press. There are no non-governmental organizations with a policy or activities related to information about medicinal products. Several patient advocacy groups are capable to carry such initiatives, but they have not yet publicly engaged the society regarding the issue of falsified medicines.

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?

The aforementioned Directive will be implemented by amending Administrative Code, Law on Pharmacy, Order of the Minister of Health and by enacting a new order of the Minister of Health. The amendments to Administrative Code and the Law on Pharmacy are currently waiting for the reading in Lithuanian Parliament, while the remaining amendment and the new Order of the Minister of Health will be registered for the reading until the end of 2012.

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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?

Lithuanian Ministry of Justice, which is preparing the positions regarding joining the Conventions of Council of Europe, has no action plan regarding MEDICRIME convention. It is likely that Lithuania will reconsider joining the MEDICRIME Convention after it enters into force and if the number of Member States of the Council of Europe that have ratified the Convention will be steadily increasing.

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Counterfeit Medicinal Products

Peru

Prepared by Lex Mundi member firm Estudio Olaechea

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

   Yes, counterfeit of medicinal products is a serious problem. In our jurisdiction the problem of counterfeit of medicinal products is regulated by the Health Ministry in coordination with the General Directorate of Medicines, Supplies and Drugs (DIGEMID).

   According to information given to the World Health Organization by the Minister of Health of Peru, it is estimated that the illegal sale of these drugs are between 15 percent and 20 percent of the local market.

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

   Government agencies are continuously conducting raids in both, legal and illegal markets around the country. There is a very tight coordination between the Health Ministry, the DIGEMID, The Public Ministry, the Police among other entities and associations to fight the problem of counterfeited medicines.

   These raids are also getting considerable media coverage as part of the intent of the government of informing the population of the dangers of consuming counterfeited medicines.

   Several raids conducted in the Commercial Center “El Hueco” in down town Lima have been recently conducted by the authorities. Also small raids in formal drugstores that also sell counterfeited medicines have been conducted after some intelligence investigations.

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, counterfeiting of medicinal products is considered a crime in Peru.

   In April 2011, the section related to crimes against public health of the Peruvian Criminal Code was modified including three new crimes and raising the high end of the penalties predetermined.

   These modifications were conducted in order to have a more specific regulation against medicinal counterfeiting. Previously, some of the actions described below were also considered a crime in Peru under section 288º of the Criminal Code that sanctioned the commercialization and traffic of noxious products. This section established jail sentences between two and eight years.

   Together with the modification of the criminal code, the Health Ministry and other institutions are continuously carrying out media campaigns informing the public of the dangers of using counterfeited medicinal products. Also the Public Ministry and the police are often conducting raids into both informal and formal markets that commercialize these illegal products and prosecuting the infringers.

   Regarding the criminal regulations, sections 294-A, 294-B and 294-C of the Criminal Code establish penalties of jail starting at 4 and up to 15 years depending on the action conducted by the infringer and the results of the action.

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Section 294-A sanctions with imprisonment of 4 to 10 years to who falsifies, contaminates or adulteress pharmaceutical products, medical devices or sanitary products or alters their expiration date.

The same sentence will be faced by who knowingly imports, commercializes, transports or distributes pharmaceutical products, medical devices or sanitary products in the abovementioned conditions.

Section 294-B establishes jail sentences from 4 to 8 years for who sells, import or commercializes pharmaceutical products, medical devices or sanitary products after the expiration date has passed and for who stores, transports or distributes with the purpose of commercializing them.

Finally Section 294-C establishes aggravating situations that will determinate that the infringer of sections 294-A and 294-B will have to face a jail sentence between 8 to 15 years.

If as a consequence of the actions described on sections 294-A or 294-B, serious injuries or death occurs and the agent could have foreseen that as a consequence of his acts, he/she will be facing a jail sentence form 8 to 15 years.
The same sentence will be faced by an agent that has the condition of technical director of a pharmaceutical establishment or health establishment and incurs on the actions abovementioned described.

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

Law Nº 29459 defines pharmaceutical products as *"Preparation of known composition, labeling and packaging evenly, intended for use in the prevention, diagnosis, treatment and cure of disease, preservation, maintenance, restoration and rehabilitation of health*[1]*"*. In addition this law as well classifies pharmaceutical products as: a) Medicinal products b) Medicinal herbals, c) Dietetic product and sweetener d) Biological products e) Galeanic products. However there is not a specific definition on our legislation on what is understood by falsified medicinal products.

According to OMC definition a falsified medicinal product is a product deliberately and fraudently labeled improperly regarding it identity and/or its origin. Both, brand named products and generic medicinal products are suitable to be falsified. Falsified products may include products with the correct or incorrect ingredients, with or without the active principles or with falsified packaging.

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?**

Law Nº 29459 known as the law of pharmaceuticals, medical devices and health products defines and establishes the principles, norms and basic criteria's regarding pharmaceutical products devices and health products for human use, aimed to prevent, diagnose, or for treatment among others. According to this regulation, it even extents to the control of active substances, recipients, and materials used for their manufacture. This law also regulates the actions of the individuals or companies involved in the manufacture, import, export, storage, distribution, marketing, promotion, advertising, prescription, pharmaceutical care, sale, use and final destination of the aforementioned products, as well as the responsibilities and powers of the National Health Authority.

All products under the classification of Article 6 of the abovementioned law require authorization. This authorization is the sanitary registration which entitles the holder to manufacture, import, storage, distribution, marketing, promotion, supply, the sale or use of these products. In this sense, any future amendment must also be indicated in such records. The health record is temporary and renewable

[1] Law Nº 29459 , art. Nº 4 inc. 1)

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every five years. The Decree Supreme Nº 016-2011-SA also known as the Regulation for Registration, Health Surveillance and Control of Pharmaceuticals, Medical Devices and Health Products, rules the procedure in order to apply for the sanitary registration according to each medical products classification.

The authority authorized to enforce the abovementioned laws is the General Directorate of Medicines, Supplies and Drugs (DIGEMID). This authority is in charge of sanitary registry as well as in charge of the Control and surveillance of sanitary authorizations of places which commercialize and manufacture medical products, Control and surveillance of sanitary authorizations for medical products, Control of illegal commerce of medical products and Control of advertisement of medical 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.

Peruvian legislation on Intellectual Property protects the rights of Copyright and their related rights and trademarks; by Legislative Decree Nº 1092, border measures were approved and aimed to provide greater protection regarding Intellectual Property rights.

The abovementioned legislation of border measures gives the holder of Intellectual Property rights additional mechanisms to defend their rights against third parties. The main objectives of said rule are the following:

(i) Enhance and improve control over the import, export and transit of counterfeited goods (any copy that was made without the consent of the copyright holder) or falsified (any merchandise bearing without authorization a trademark identical or validly registered for such goods);
(ii) directly Protecting Copyrights and trademark rights, which it indirectly enable the protection of consumer rights;
(iii) Identify, through physical and documentary research conducted by the Customs Authority and INDECOPI possible networks dedicated to counterfeiting of goods.
(iv) Remove the large revenue losses related to taxation.

The Registry of Intellectual Property rights by the holder must be executed at the National Intendance of Customs Technique (INTA) by filing an application containing the following information:

- Information identifying the owner of the right: names and last name or trade name; identification document; legal or fiscal domicile, phone number, email address, as it corresponds;
- Information identifying the applicant as legal representative or proxy: names and last name or trade name, identification document, legal or fiscal domicile, phone number, email address; simple copy of the power or document certifying the representation;
- Information identifying the right to be registered: specification of the type of right (copyright, related right or trademark right), registration number, certificate, class, as it corresponds;
- Precise and detailed technical description of the right to be protected attaching documentation, informatics supports and images identifying its features; and
- To the extend reasonably available, any other information facilitating Customs the provision of control actions such as, information or data about the type or tendencies of fraud, countries of production; countries of origin, transport paths used, technical differentiation of the authentic and fake products, if applicable. Additional relevant information obtained later by the owner of the right, its proxy or legal representative.

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Customs will coordinate with the Distinctive Sign Direction or the Copyrights Direction, as it corresponds, to grant the registration or reject it if it does not get a favorable opinion from INDECOPI. Let we mention that this registration is annual and must be renewed each year.

Finally as positive contributions of this boarder measures can be found as follows:

a. Distinguishes pirate counterfeit goods;
b. It applies to goods in transit
c. Do not stop goods that have no commercial purposes, provided clear evidence to the products entering through customs;
d. Create a registry of holders of intellectual property rights in Customs;
   Granting of a recognizance bond or equivalent security;
e. Implementation of a system of information exchange between the INDECOPI and Tax Office (SUNAT)

To conclude, it is effective in order to advise or alert the possible entrance of counterfeiting products, in order to initiate the corresponding actions.

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?

Other legal measures that can be initiated by manufacturers, distributors or marketing authorization holders in order to act against falsified products is by filling a claim for trademark infringements or patents infringements against any infringer before the Peruvian Intellectual Property and Trademark Office (INDECOPI).

Under this administrative proceeding it is possible to obtain the seizure of the counterfeited products and also, the prohibition of further imports to an entity or subject and depending on the case the destruction of the falsified products.

In pharmaceutical market, patents lead to further investigation in order to find cure to diseases as well as in order to found new medical treatments. In Peru the regulation of patents and intellectual property are basically ruled by Decision 486 of the Andean Community, the Legislative Decree Nº 1075. In the case of trademarks and patents protection is given by the registration at the Intellectual Property Office.

Also, as part of a criminal prosecution, when a guilty sentence is issued, the products that were seized during the initial stages of the investigation must be destroyed.

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

The General Directorate of Medicines, Supplies and Drugs (DIGEMID) through his area of Illegal Commerce, promote different campaigns in order to inform consumers, and any individual regarding the dangers of falsified drugs as well as how to prevent the acquisition of falsified products. For example: Advising consumers, to buy medical products only on authorized pharmacies, hospitals, and to avoid buying medical products in markets, tradeshows or street sellers.

Also DIGEMID and the Ministry of Health conduct several press campaigns and publish advices on medical centers and drugstores informing of the risks of consuming counterfeited medicines.

Also, there is a group called CONTRAFALME leaded by the Health Ministry (through the DIGEMID) and formed by several public (such as The National Police, The Customs Office, Trademarks Office, Judicial Power, and Public Ministry) and private institutions that works under the parameters of the National Medicinal Politic. The CONTRAFALME was formed to prevent and fight the smuggling, illegal commerce and counterfeit of pharmaceutical products. As part of their activities, the

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CONTRAFALME also conducts education campaigns related to the dangers of the use of counterfeited drugs.

For instance, at the moment, the Consumers Protection Office (INDECOPI) is advising in its website, to be aware of product REUMOFAN that has no sanitary registration, this is that the mentioned product has no authorization approved by the General Directorate of Medicines, Supplies and Drugs (DIGEMID). It is possible to get this product by internet (for further reference, please check website http://www.indecopi.gob.pe/0/modulos/NOT/NOT_DetallarNoticia.aspx?PFL=0&NOT=488) and it can cause severe injuries as unknown secondary effects.

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?**

   Not applicable.

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?**

    Not applicable.

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Counterfeit Medicinal Products

Poland

Prepared by Lex Mundi member firm Wardyński & Partners

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

   Counterfeiting of medicinal products is recognised as a serious problem in Poland. Such products do not meet the quality requirements established for medicinal products and thus endanger the life and health of consumers. In particular, they may not contain the appropriate amount or type of active substance or may contain substances whose safety is unknown. Counterfeit medicinal products also infringe intellectual property rights.

   Counterfeit medicinal products find their way onto the Polish market mainly from non-EU countries, above all from Asia. They are brought into the country by tourists or sent by postal and courier services. Observation and analysis of cases reveal that Poland is a destination rather than a transit country for the distribution of counterfeit medicinal products. The main distribution channels are border markets, sex shops, gyms, fitness clubs, and above all the internet. So far no cases have been reported of counterfeit medicinal products being sold through legal distribution channels supervised by Poland's Main Pharmaceutical Inspectorate.

   According to the Polish Customs Service, the quantity of counterfeit medicinal products in Poland is increasing constantly. At the same time, police data show changes in the range of medicines that are being falsified. Now they include not only medicines for erectile dysfunction, but also steroids, pharmacological slimming pills, and even cancer, antipsychotic and cardiac medicines.

   Trading in counterfeit medicines takes place on the black market. Therefore it is extremely difficult to assess the scale of the problem in Poland. However, within Europe, Poland is classified as a high-risk country, mainly due to its geographical location and the proximity of former Soviet republics. The quantity of falsified medicinal products on the Polish market may be estimated based on the statistical data of relevant institutions.

   For example, the Police dealing with economic crime every year seize thousands of items of falsified medicines. In 2011 the Police commenced over 300 proceedings in the battle with illegal trade in medicinal products. In 2011, the law enforcement division of the Customs Service inspected and seized 170,526 items (16,926 grams) of anabolic steroids and medicinal products worth PLN 1,227,776 (about EUR 293,000).

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

   The main institutions responsible for combating activities concerning counterfeit medicinal products are the Customs Service and the Police. Both publish statistics from time to time and information about the most spectacular cases concerning falsified medicines.

   Based on the most recent information available on the website of the Customs Service, during the last 12 months the Customs Service on several occasions intercepted significant amounts of counterfeit medicinal products, ranging in value from EUR 6,000 to EUR 50,000. In the vast majority of cases, the seized products included counterfeit versions of medicines for erectile dysfunction, such

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as Viagra or Cialis, and anabolic steroids. The counterfeit medicines originated mainly from Asian countries (e.g. Thailand and Pakistan) and former Soviet republics (e.g. Belarus and Ukraine).

Similar figures can be found in information published by the Police. The value of counterfeit medicinal products seized during individual operations ranged from EUR 7,500 to EUR 25,000. Among the intercepted products were, again, counterfeit versions of medicines for erectile dysfunction and steroids, as well as antipsychotic medications. The most surprising case concerned 50,000 pills labelled as Viagra but found upon examination to contain plaster.

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 Polish criminal law, there is a specific provision related to counterfeit medicinal products. Art. 165(1)(2) of the Penal Code provides that any person who endangers the life or health of many people or property of a significant value by producing or marketing substances, foodstuffs or other commonly used goods that are detrimental to health, or pharmaceutical preparations that do not conform to binding quality standards, is subject to imprisonment for six months to eight years. If these acts result in the death of a person, or grievous bodily harm to many people, the offender is subject to imprisonment for two to 12 years. However, if the act was done unintentionally, the offender is subject to imprisonment for up to three years, or in case of the death of a person or grievous bodily harm to many people, the offender is subject to imprisonment for six months to eight years.

Additionally, Article 306 of the Penal Code provides that any person who removes, alters or falsifies identification marks, a date of manufacture, or expiration date, is subject to imprisonment for up to three years.

Some acts of unfair competition or infringement of intellectual property rights also constitute crimes. Please see the answer to question 7.

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

There is no statutory definition of a falsified medicinal product in Poland. Currently most sources, including publications on the subject, usually refer to the definition created by the World Health Organization:

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled 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."

Additionally, there are various definitions created and used by different institutions for their own purposes. For instance, according to the definition published on the website of the Main Pharmaceutical Inspectorate, a counterfeit medicinal product is a medicine of inappropriate quality, which has been manufactured illegally, without the knowledge of the responsible person and without the permission of the authorities of the State Pharmaceutical Inspectorate.

Posters prepared for a public awareness campaign by the Main Pharmaceutical Inspectorate set out some of the main characteristics of such products:

- They pretend to be medicines, are manufactured illegally and are not tested.
- They contain large amounts of highly toxic pollutants that are very dangerous to the human organism.
- They often have weak or inappropriate effects or no effect at all due to the inappropriate amount or lack of active substance, or an active substance other than stated on the packaging.

The current situation will change once the Falsified Medicines Directive (2011/62/EU, amending Directive 2001/83/EC) is implemented into Polish law. For more details about implementation of this directive, please see the answer to question 9.

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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 labeling, 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 authorization 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?**

The main regulation to ensure safety of medicinal products is the Pharmaceutical Law of 6 September 2000, which provides that manufacturing, distribution and trade of medicinal products are strictly regulated and subject to the control of state authorities. However, state authorities have control only over products which are in the legal chain of distribution, and shall eliminate products non-compliant with safety and quality regulations. The Police and the Customs Service are appointed to combat crimes related to trading in falsified products.

The safety of medicinal products is ensured by the following rules and procedures:

1) Each medicinal product, before launch on the market, must be granted marketing authorization in one of the registration procedures (state, centralized, decentralized or mutual recognition procedure). In the course of the marketing authorization procedure, the authorities analyze first of all whether the risk of use of the drug is balanced by the expected therapeutic effect, whether it has the declared therapeutic efficacy, and whether the therapeutic efficacy is sufficient. Generally, with some exceptions, the documentation submitted in the registration procedure is accompanied by results of clinical trials, which helps to assess the safety of the drug. Marketing authorization may be revoked in the event of an unexpected serious adverse reaction to the medicinal product, constituting a hazard to human life or health, or if the medicinal product does not have the declared therapeutic efficacy or the risk of its use is not balanced by its therapeutic effect.

2) It is prohibited to trade in or use medicinal products non-compliant with the established quality requirements, or expired medicinal products. Such products are to be destroyed.

3) Manufacturing and import (from outside of the European Economic Area) is subject to a permit. Additionally, manufacturers of active substances must be registered by a state authority. Entities conducting manufacturing or import are required to comply with strict regulations regarding premises, equipment and technical requirements, including Good Manufacturing Practice rules. If they violate these rules, the relevant permit may be revoked. Manufacturers and importers are inspected by the Main Pharmaceutical Inspectorate at least once every three years, and ad hoc if there are suspected irregularities.

4) Each series of a medicinal product must be inspected by a competent person at the manufacturer's premises. Additionally, some products, e.g. some immunological medicinal products for human use or blood-derived drugs, may be traded only if they have undergone an initial batch inspection.

5) Trading in medicinal products, wholesale or retail, may be conducted only upon permit (with the exception of some OTC drugs), and businesses conducting such activity must meet specific requirements with regard to premises, equipment and conditions of storage and distribution.

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The Main Pharmaceutical Inspectorate supervises conditions of manufacturing and import of medicinal products, quality, and trade in medicinal products. The Main Pharmaceutical Inspector may issue decisions ordering:

1) Suspension of trade, or recall from the market, or withdrawal from use in healthcare establishments of medicinal products if it is suspected or established that the product is not authorized for marketing in Poland or does not meet the quality requirements established for it.

2) Suspension of trade or withdrawal from generally accessible pharmacies of goods which are subject to a prohibition of trade.

In Poland, there are a number of bodies responsible for verification and quality of medicinal products, such as the National Medicines Institute (the equivalent of the Official Medicines Control Laboratory (OMCL)), the Institute of Hematology, and the State Veterinary Institute, operating under supervision of the Ministry of Health.

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.

It is the task of the Customs Service to prevent import or release of falsified products. The Customs Service is required to inspect and review imported goods, and detect, prevent and combat crimes related to release of certain goods in Poland or infringement of copyright and other intellectual property rights.

In the area of protection of intellectual property rights, the Customs Service operates pursuant to the following laws:

- Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code
- Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994
- Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights
- Commission Regulation (EC) No 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights as amended by the Commission Regulation (EC) No 1172/2007 of 5 October 2007
- Polish Act on Copyright and Related Rights of 4 February 1994
- Polish Intellectual Property Law of 30 June 2000.

If the Customs Service suspects infringement of intellectual property rights, it may take the following actions:

- *Upon application of injured party*

The holder or authorized user of an intellectual property right may file an application with the Customs Service to take measures to protect intellectual property rights, based on Commission Regulation 1891/2004. Upon request, the action of the Customs Service may also be extended to other EU member states in the case of Community-registered rights. Protection is granted by the Customs Service for one year.

If during the protection period the Customs Service has justified suspicions that specific goods infringe the intellectual property rights of the entity to whom protection has been granted, it will seize

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the goods and notify the entity, which then has 10 business days to seek institution of a criminal investigation or an interim injunction from the civil court.

- *At the Customs Service's own initiative*

If the Custom Service has sufficient evidence to suspect that goods infringe an intellectual property right, it may suspend admission of the goods or seize them for three business days following receipt of notification from the right holder, in order to allow the holder to apply to the director of the Warsaw Customs Chamber to take action against the goods. If such application is not filed, the Customs Service will release the goods.

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 labeling often infringe intellectual property rights, entities whose rights are threatened may demand cessation of actions violating intellectual property rights.

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) cessation of prohibited practices
   b) removal of the effects of prohibited practices
   c) publication of one or more statements of appropriate content and form
   d) redress of injury under general rules
   e) disgorgement of unjustified benefits under general rules
   f) in the case of an intentional act of unfair competition, judgment for an appropriate amount of money to be used for a specific social purpose connected with support for Polish culture or protection of the national heritage.

3) *Notification of competent authorities*. Any person may notify the relevant authorities, particularly the Police, the Customs Service or the Pharmaceutical Inspectorate, of suspicions regarding specific medicinal products. Upon receipt of such information, the competent authority is required to undertake an investigation or inspection.

   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.

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

Both public authorities and non-governmental organizations in Poland take actions 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.

The most spectacular campaign, launched in 2009, used the WHO's "Snake" poster, "Counterfeit Drugs Kill." The purpose was to warn patients against counterfeit medicinal products and instruct them how to buy safe medicines. Information on the poster explained what counterfeit medicines are and why they may be dangerous. The information was published on the websites of the Main Pharmaceutical Inspectorate, the Ministry of Health, the Police, the National Institute of Health, the Ministry of Finance, and the Customs Service, as well as pharmaceutical companies. About 1,000 printed copies of the poster "Counterfeit Drugs Kill" were also placed in healthcare institutions. There is a section on the website of the Main Pharmaceutical Inspectorate on counterfeit medicinal products, providing FAQs for consumers.

At the end of 2010, another campaign, "STOP Counterfeit Medicines: Don't Look for Excuses, Talk to Your Doctor," was launched, under the auspices of the Polish Urological Association and Polish Sexual Medicine Association.

The most recent conference on counterfeit medicinal products took place on 2 April 2012, organized by Young Pharmacy (the student section of the Warsaw Branch of the Polish Pharmaceutical Association).

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?

The Falsified Medicines Directive (2011/62/EU) will be implemented into Polish law essentially through amendment of the Polish Pharmaceutical Law. A draft amendment has already been prepared by the Main Pharmaceutical Inspector and published on the website of the Ministry of Health. The draft was opened for public comment on 2 August 2012. The deadline for submission of comments is 17 August 2012.

The new regulations will affect various participants of the pharmaceutical industry, e.g. manufacturers, importers and distributors of medicinal products, active substances and excipients, as well as persons brokering medicinal products (a new category) and businesses selling medicinal products by mail order.

Most significantly, the draft would introduce into Polish law a statutory definition of a counterfeit medicinal product and the criminal offence of counterfeiting a medicinal product or active substance and marketing a counterfeit medicinal product or counterfeit active substance. The proposed definition, drawn straight from the directive (see the answer to question 4 above), would enable a distinction between medicinal products that are counterfeit and those that are illegal and thus should not be in trade for other reasons.

According to the draft amendment, any person who counterfeits a medicinal product or an active substance, or who markets or conceals for purpose of marketing a counterfeit medicinal product or a counterfeit active substance is subject to a fine, probation, or imprisonment for up to five years.

In order to protect the market against counterfeit medicinal products, new obligations would also be imposed on wholesale distributors. A Certificate of Good Distribution Practice would be introduced for businesses that prove that they comply with distribution principles and guidelines.

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Businesses selling medicinal products by mail order would also be subject to stricter control. They would have to notify their pharmacy or point of sale to the regional pharmaceutical inspector 14 days before beginning such sales. This information would be publicly available.
Finally, the draft amendment provides that patients will be entitled to return a purchased medicinal product not only if there are quality defects or the product was dispensed improperly, but also if they suspect that the product is counterfeit.

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 Polish Ministry of Health is considering the possibility of Poland becoming a party to the Medicrime Convention. The Main Pharmaceutical Inspectorate is supporting this initiative, but so far no final decision has been made.

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Counterfeit Medicinal Products

Romania

Prepared by Lex Mundi member firm Nestor Nestor Diculescu Kingston Petersen

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 five percent – 7 percent 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 have 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 counterfeit, 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.

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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 right holders 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.

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

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Counterfeit Medicinal Products

Spain

Prepared by Lex Mundi member firm Uría Menéndez

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

   The problem of counterfeit medicinal products is clearly identified in Spain as an important, and increasing, public health problem.

   In 2008, the Spanish Medicines and Medical Devices Agency (*Agencia Española de Medicamentos y Productos Sanitarios* – "AEMPS") issued a Strategy Paper on Counterfeit Medicinal Products for the period 2008-2011 (*Estrategia frente a Medicamentos Falsificados* 2008-2011). The strategy was based on five pillars: (i) cooperation among all stakeholders, both public institutions and private entities, in the healthcare sector and in other areas (tax, border control, security forces, etc.); (ii) implementing quick, efficient information mechanisms among these stakeholders, as well as with the health authorities of other countries and other international organisms; (iii) reinforcing education and raising awareness of the authorities, civil servants, private entities, and citizens.

   In 2012, a new Strategy Paper on Counterfeit Medicinal Products was issued for the period 2012-2015 (*Estrategia frente a Medicamentos Falsificados 2012-2015*). It maintains the general principles of the prior strategy, and adapts them in following the experience gained and the approval of Directive 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, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. There are no reliable figures on the amount of counterfeit products on the market, but it is estimated that roughly one percent to three percent of the medicines purchased in Spain could be counterfeit, and Spain ranks as the fourth country in Europe in terms of volume of falsified medicines on the market. So far, however, no cases have been detected in the legal supply chain, where surveillance and control measures are reportedly proving effective. Falsified medicinal products reach patients through illegal means, mainly, via the Internet and, less frequently, through illegal establishments such as gyms or herbalists.

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

   No cases of counterfeit medicinal products have been reported in the legal supply chain, in spite of the fact that during the period 2008-2011 over a hundred inspections of wholesale distributors of medicines were performed, which included a review of the areas of risk concerning counterfeit products. However, in view of cases that took place in neighboring countries, this issue remains a priority with the health authorities. On the other hand, the presence of counterfeit medicines has increased in illegal supply chains. The Spanish security forces have carried out several operations against manufacturers and importers of falsified medicines, both individually and in cooperation with Interpol, Europol and national agencies in other countries. Also, in the past few years, over 300 websites have been investigated, and measures taken to close or ban access to those which illegally sell medicines (including counterfeit medicines) over the internet.

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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. Counterfeiting medicines is recognized as a crime under the Spanish Criminal Code, provided, however, that the activity poses a risk to the life of health of individuals. In particular, article 362 of the Spanish Criminal Code recognizes the following as criminal offences: (i) the alteration of quantities, doses of composition of medicines, thereby depriving them totally or partially of therapeutic efficacy; (ii) the imitation or simulation of medicines with the aim to place them on the market or use them in any way; and (iii) the deposit, advertising, offer, exhibition, sale, provision for use of medicines by those who know of their alteration or falsehood; provided, in all cases, that this poses a risk to the life of health of individuals.

These crimes may be penalized with a sentence from six months up to a maximum of three years imprisonment, and with fines ranging from six to eighteen months; and one to three years special disqualification from practicing the profession related to the offence committed (or three to six years if the crime is committed by pharmacists or technical directors of authorized laboratories).

Please note the day-fine system consists of a financial penalty from a minimum of two EUR to a maximum of 400 EUR, established according to the nature of the infringement and the financial situation of the convicted party.

These penalties may be increased by one degree (i.e. by taking the maximum duration of the penalty as its minimum duration, and increasing the maximum duration by 50 percent) if aggravated circumstances concur. It is of note that the legal entity itself could not be pursued criminally for this type of offence, but rather the individuals personally responsible for the offence, including, where applicable, the (legal or de facto) managers of the entity.

On the other hand, the counterfeiting of medicines (even if no risk to health is caused) constitutes a very severe administrative infringement under article 100.2.c).2 of Spanish Law 29/2006, on the Guarantees and Rational Use of Medicines and Medical Devices (the "Spanish Medicines Act"), which may be punished with fines ranging from 90,000 EUR to 1,000,000 EUR. The fines which may be imposed under administrative regulations, if the infringement is qualified as an administrative (i.e. not criminal) offence, are paradoxically, potentially much higher than those that may be imposed under the Criminal Code if the action qualifies as a crime.

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

As of this date, falsified medicinal products are not defined by any piece of Spanish legislation. The AEMPS position papers recognize the definition provided by Directive 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, as regards the prevention of the entry into the legal supply chain of falsified 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?

Generally, under the Spanish Medicines Act and complementary regulations, medicinal products may only be sold or purchased, or physically handled, by duly authorized entities:

- Manufacturers of medicines must be in possession of an authorization as a pharmaceutical laboratory ("laboratorio farmacéutico") granted under Royal Decree 824/2010, of 25 June, governing pharmaceutical laboratories, manufactures of active principles for pharmaceutical use, and the external trade of medicines and investigational medicines. This obligation also applies to importers of medicines, who are generally responsible for the compliance of the imported products and for guaranteeing that each imported batch is subject, in Spain, to the pertinent qualitative and quantitative controls to guarantee that they fulfill the terms of the marketing authorization.

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- Distribution of medicines may only be performed by pharmaceutical wholesalers holding the pertinent distribution authorization granted under Royal Decree 2259/1994, of 25 November, governing pharmaceutical wholesalers and wholesale distribution of human medicines and pharmaceutical products.
- According to article 2.6. of the Spanish Medicines Act, the custody, conservation and dispensation of human medicines corresponds exclusively to legally authorized pharmacies open to the public, and to the pharmacy departments of hospitals and healthcare institutions.

Wholesalers, pharmacies and hospitals are bound to purchase medicines only from authorized pharmaceutical laboratories (manufacturers or importers) or from wholesalers, and all entities in the supply chain are bound to supply the medicines to entities duly authorized to purchase and handle them. For these purposes, the AEMPS makes available, through its website, the lists of authorized pharmaceutical laboratories (*Registro de Laboratorios Farmacéuticos* - https://labofar.aemps.es/labofar/registroFarmaceutico/consulta.do?metodo=detalleBusqueda) and of authorized wholesalers (*Catálogo de Almacenes Mayoristas* - https://sinaem.agemed.es/AlmacenesMayoristas).

Wholesalers are also bound to keep counterfeit medicines which are detected in the distribution channel separate from the remaining medicines, label them as not fit for sale, and immediately inform the competent authorities as well as the marketing authorization holder of the product.

Both pharmaceutical companies and wholesalers are subject to periodical inspections by the health authorities. Among the aspects covered by such inspections are precisely the areas of risk concerning counterfeit, following a specific questionnaire. The procedure has already been applied in over 100 inspections carried out by the health authorities on pharmaceutical distributors.

Purchasing medicines from, or making them available to, entities who are not in possession of the relevant authorization constitutes a severe infringement under Article 100.2.b).17 of the Spanish Medicines Act, which may be punished with fines ranging from EUR 30,000 to EUR 90,000. Also, as previously stated (see question 3), falsification of medicinal products may be recognized as an administrative infringement under article 100.2.c).2 of the Spanish Medicines Law. In all cases, the authorities may also decree the seizure of the illicit benefit obtained. They may also close establishments operating without the pertinent authorizations and seize the counterfeit medicines.

The health authorities are responsible for the enforcement of the above regulations. Citizens and undertakings are not generally entitled to demand the opening of sanctioning proceedings or inspections. However, they are entitled (and encouraged) to report any information on counterfeit medicines to the health authorities. In this regard, the AEMPS has put in place an electronic communication system for the reporting of cases of counterfeit products detected in the legal distribution chain.

As stated, counterfeit medicines have not yet been detected in the legal supply chain, and falsified medicinal products reach patients through illegal means, primarily via the internet. Spanish pharmacies may not sell medicines online, but medicines (most of them being counterfeit) are offered to patients by “online pharmacies”, which are usually established abroad. The AEMPS has performed almost 300 investigations in the last few years, and closed or banned access to many of these sites. The Strategy Paper on Counterfeit Medicinal Products for the period 2012-2015 mentions that package shipments and parcel delivery firms must be paid special attention for border inspections.

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.

Regulations on border controls of medicines have been recently updated. Currently, the procedure is regulated by Order 2136/2011 of the Ministry of Health, of 19 June 2011, which establishes the form of the border health controls carried out by the pharmaceutical inspection service and regulates the

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Computerized System of Pharmaceutical Inspection for External Health (*Orden SPI/2136/2011, de 19 de julio, por la que se fijan las modalidades de control sanitario en frontera por la inspección farmacéutica y se regula el Sistema Informático de Inspección Farmacéutica de Sanidad Exterior* – the "Order").

The Order is applicable to medicines, including bulk drugs, raw materials destined for the manufacture of medicines, medical devices, cosmetics, biocides, etc. It is established that these products shall be subject to systematic border controls. There are three different levels of controls:

(i) documentary controls: analysis of certificates and other relevant documentation accompanying the products
(ii) identity controls: visual inspection of the correspondence between the products and the certificates, and the presence of the signs and marks that must accompany the products in accordance with EU and national regulations, including the inspection of the labeling
(iii) physical controls: controls of the product itself, its labeling, packaging, instructions for use, storage conditions, etc. This control may include the analysis of samples.

All products subject to the Order shall be systematically subject to the first level of controls (documentary controls). The frequency of identity and physical controls shall be determined based on the potential risk in relation to the products, and in coordination with the AEMPS. The main criteria for establishing the level of necessary controls are based in the country of origin of the deliveries and the experience gained in recent years. The AEMPS has, in recent years, organized several training sessions addressed for the border inspections, and has granted them online access to all relevant information (authorized medicines, authorized pharmaceutical laboratories and wholesalers) and also put in place a rapid information exchange system with the border control authorities.

The main tools to fight against counterfeited medicinal products, both for the regulatory authorities and for the rights holders, are those set out in Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, and its implementing regulations.

In Spain, this Regulation has been implemented by Order 2343/2006 of the Ministry of Economy and Treasury, of 3 July 2006, regarding the intervention of border authorities in the event of reported goods suspected of infringing intellectual property rights (*Orden EHA/2343/2006, de 3 de julio, relativa a la intervención de las autoridades aduaneras en los casos de declaración de mercancías sospechosas de vulnerar derechos de propiedad intelectual*). This Order essentially reproduces the contents of Regulation 1383/2003, but it also implements Article 11 which provides for a simplified procedure to enable customs authorities to have the goods placed for destruction under customs control, without there being any need to determine whether an intellectual property right has been infringed, when the rights holder so requests and the declarant or holder of the goods, duly informed, does not object to the destruction thereof.

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?

Any participant in the supply chain who detects the presence of falsified medicines in his possession must immobilize them, keep the separate from legal medicines, label them as not fit for sale, and immediately report the issue to the health authorities and to the marketing authorization holder so that they may take the appropriate measures. The holder of the goods may only submit the products for destruction (which should be performed by a duly authorized entity) with the prior authorization of the health authorities.

The health authorities are entitled to take interim measures (medidas provisionales) in cases involving imminent risk to health, including the recall of the products from the market and their

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seizure. If lacking the consent of the holder of the goods, the destruction of the products may only be decreed by the authorities following the relevant sanctioning proceedings.

Rights holders may enforce their intellectual property rights before the civil courts (and, in some cases, before the criminal courts). The civil courts, following the applicable procedure, are competent to declare an infringement of intellectual property rights and order the destruction or take other appropriate measures in connection with the falsified goods. In these cases, what will become of the goods generally depends on which measures the rights holder requests within the judicial proceedings. Intellectual property regulations enable the rights holder to request the destruction of the goods, but in some cases they also allow for alternative measures such as the donation of the goods for humanitarian purposes (under trademark laws), or their transformation (under patent laws). It is unlikely, however, that these measures would ever be considered appropriate in the case of falsified medicines.

When criminal actions are pursued, the courts may, as interim measures, order the destructions of the goods apprehended, whilst conserving a sufficient number of samples, (to serve as evidence in the proceedings) if this is found to be appropriate due to the nature of such goods or to the danger associated with their conservation. In any case, the final judicial decision should also order the destruction of the goods, as they would not be fit for sale.

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

Yes. In the last few years, several consumer awareness campaigns have been carried out, both by the health authorities and by private entities, including some pharmaceutical companies, pharmacist's associations, and patient associations.

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 Royal Decree governing distribution of medicines for human use (*Proyecto de Real Decreto sobre Distribución de Medicamentos de Uso Humano*) was issued by the Ministry of Health in July 2012 and submitted to the interested parties for their observations. This Draft incorporates certain provisions to implement Directive 2011/62/EU, such as the regulation of medicines brokerage, or the detail of the controls that all suppliers of medicines must perform on their respective suppliers (an obligation which already stems from Spanish law). It does not refer to those measures whose implementation is pending the adoption of delegated acts by the European Commission (namely, the safety features to be included in the outer packaging of medicinal products according to Articles 54. (o) and Article 54a of Directive 2001/83/EC, as amended by Directive 2011/62/EU).

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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?

Yes. On 13 July, 2012, the Council of Ministers took the formal decision to authorize signature of the Convention.

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Counterfeit Medicinal Products

Switzerland

Prepared by Lex Mundi member firm Pestalozzi

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 have been found 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 „Ligaclip® Extra Ligaturclip Magazine“ and „Ligaclip® 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

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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

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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).

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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

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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.

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Counterfeit Medicinal Products

Taiwan

Prepared by Lex Mundi member firm Tsar & Tsai Law Firm

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

   Yes, the problem of counterfeit medicinal products has been identified in Taiwan. According to a Correction Report released by the Control Yuan in 2010, the problem of "illegal medicine", including counterfeit, misbranded and prohibited drugs, was described as outrageous. The amount of illegal medicine is estimated to be between six percent and 42 percent of the medicinal products on the market. It was further reported that a total of 155 cases of smuggled counterfeit and prohibited medicinal products were discovered by the Customs Authority and reported to the prosecutor's office for investigation in 2010.

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

   There are cases of counterfeit medicinal products reported from time to time.

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, activity related to counterfeiting a medicinal product is a crime under Pharmaceutical Affairs Act.

   According to Article 82 of Pharmaceutical Affairs Act, any person who manufactures or imports counterfeit or prohibited drugs shall be subject to punishment of imprisonment for a period up to 10 years and may in addition thereto, be imposed with a fine up to NT$10 million. The imprisonment sentence may be extended to life imprisonment or more than 10 years in case the offence results in personal death; or at least seven years of imprisonment in case the offence results in serious personal injury. Any person who commits the offence by negligence shall be punished with imprisonment up to three years, detention or a fine up to NT$500,000. An attempter of such offence shall be punished as well.

   According to Article 83 of Pharmaceutical Affairs Act, any person who knowingly sells, supplies, dispenses, transports, stores, brokers, transfers or displays with intent to sell counterfeit drugs or prohibited drugs shall be punished with imprisonment up to seven years and may, in addition thereto, be imposed with a fine up to NT$5 million. The imprisonment sentence may be extended to exceed seven years in case the offence results in personal death; or between three and 12 years of imprisonment in case the offence results in serious personal injury. Any person who commits the offence by negligence shall be punished with imprisonment up to two years, detention or a fine up to NT$300,000. An attempter of such offence shall be punished as well.

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

   According to Article 20 of Pharmaceutical Affairs Act, the term "counterfeit drugs" as used in the Act refers to drugs which are found to fall within any of the following circumstances after inspection or testing:
   1) The drugs are manufactured without prior approval;
   2) The active ingredients of the drugs are inconsistent with the ingredients thereof previously approved;

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3) The drugs are packed or alternated with the products of others; or
4) The duration of validity marking or label of the drugs has been altered or replaced.

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 Pharmaceutical Affairs Act is the major law in relation to the safety of medicinal products and the prevention of falsification of medicinal products.

For instance, Article 79 of the Act requires that counterfeit or prohibited drugs being discovered shall be confiscated and destroyed. Whenever a counterfeit or prohibited medicine is discovered, the relevant manufacturers or importers are required to report the incident to the medical care institutions, pharmacies and pharmaceutical dealers immediately and shall, within a given time limit, recall the medicaments in question which shall be dispose of in accordance with the Pharmaceutical Affairs Act.

The Department of Health, Executive Yuan is the central government agency authorized to enforce the Pharmaceutical Affairs Act and the relevant laws and regulations.

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.

Fighting against counterfeited medicinal products is among the duties of the Department of Health. Articles 71, 72, 73, 77, 78, 79 and 80 of Pharmaceutical Affairs Act empower the health authorities to inspect the premises, business, facilities and products of pharmaceutical manufacturers, medical institutes and pharmacists on annual and ad-hoc basis and to confiscate and destroy counterfeited medicinal products. The efficiency however had been seriously challenged by the Control Yuan according its Correction Report issued in 2010.

To address the concerns of insufficient actions due to lack of coordination among various government agencies, a task force led by the Executive Yuan was formed in 2010 aiming to crack down counterfeit and misbranded medicinal products with coordinated efforts within the administration. The efficiency of such task force has yet to be verified.

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?

In general, the law encourages everyone to report cases of counterfeit and misbranded medicinal products on the market. If a reported case leads to actual seize of counterfeit or misbranded medicinal products by the competent authorities, the reporter will be given certain cash rewards.

There are no special regulations for manufacturers, distributors or marketing authorization holders to eliminate falsified products from the market proactively.

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

The task force formed by the Executive Yuan in 2010 is also given the duty to alert the public to the danger of counterfeit and misbranded 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?

Not applicable.

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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?

Not applicable.

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Counterfeit Medicinal Products

USA, Florida

Prepared by Lex Mundi member firm Akerman Senterfitt

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

   Florida had that problem about 10 years ago. The state instituted a drug pedigree program to trace each step the drug travels in the channel of trade and instituted more laws on counterfeit drugs. Florida also increased restrictions on secondary wholesalers where some of these drugs were making it into the drug distribution system. Florida has a very broad definition of adulterated and counterfeit drugs. It is still a problem for some foreign manufactured drugs.

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

   Not in Florida that I am aware of.

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. 499.0051, Florida Statutes, make several activities involving "contraband drugs" which includes counterfeit drugs a crime.

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

   Yes.499.003, FS (12) “Contraband prescription drug” means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter. (14) “Counterfeit drug,” “counterfeit device,” or “counterfeit cosmetic” means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor. 499.0051 499.0051 Criminal acts.—(1) FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.— (a) A person, other than a manufacturer, engaged in the wholesale distribution of prescription drugs who fails to deliver to another person complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (b) A person engaged in the wholesale distribution of prescription drugs who fails to acquire complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (c) Any person who knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree papers concerning any prescription drug or contraband prescription drug in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006: (a) A person engaged

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in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (b) A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who

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?**

   Department of Business and Professional Regulation and Law Enforcement Agencies.

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.**

   Florida has a very detailed drug pedigree program which is strictly enforced.

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?**

   If there is no drug pedigree, the drug cannot be distributed. Bar coding and RF Tags on drugs for tracking the movement in commerce.

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

   Yes.

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?**

   I do not know.

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?**

    I do not believe so but do not know about European measures. I am in Florida in the US.

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