

Counterfeit Medicinal Products

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

   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 6% and 42% 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 7 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 3 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 7 years and may, in addition thereto, be imposed with a fine up to NT$5 million. The imprisonment sentence may be extended to exceed 7 years in case the offence results in personal death; or between 3 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 2 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;
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 encourage 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 is 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.

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.