Fight against counterfeit medical products: The Medicrime Convention and the Swiss experience

Andreas Balsiger Betts
Swissmedic, Swiss Agency for Therapeutic Products, Head Legal Sector

International Conference of Drug Regulatory Authorities (ICDRA), Singapore, 2 December 2010
What is the Medicrime Convention?

The Medicrime Convention, drawn up by the Council of Europe, is the first international instrument to criminalise:

- the manufacturing of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products;
- the falsification of documents concerning medical products;
- the unauthorised manufacturing or supplying of medicinal products and the marketing of medical devices that do not comply with conformity requirements.
The Medicrime Convention:
A comprehensive instrument against crime

Opportunity to put in place a complete system of:

• administrative proceedings
• preventive measures
• security, quality and efficiency standards
• criminal sanctions against counterfeiting and similar crimes
The Medicrime Convention and intellectual property

Absolute necessity to distinguish the health issues from the intellectual property issues:

→ The Medicrime Convention deals only with health issues
Swissmedic’s “Enforcement pyramid”

**Purpose:**
- **Penal proceedings**: to sanction infringements
- **Administrative proceedings**: to restore a state of legal compliance
- **Intervention**: to prevent health risks

**Evaluation**:
- **Targeted controls, surveillance**
- **Training, advice, recommendations**
- **Operative support, information**
Counterfeit and illegal products in Switzerland:

General remarks

• The controls of the authorised distribution channels are effective

• Low risk of counterfeit or otherwise illegal products being sold in authorised pharmacies

• Need to keep the high standards in place in the long term
Counterfeit and illegal products in Switzerland: Current challenges

• Internet orders
• Increasing number of seizures of imported products at the border
  • 2008: 687
  • 2009: 1154
  • 2010 (first 10 months): 1600
• Illegal domestic resale (retail trade) at an unknown scale
• Illegal activities by Swiss residents within international networks
Counterfeit and illegal products in Switzerland: Swiss Legislation

- **Act on Therapeutic Products (ATP)**
  - term “counterfeit” is unknown
  - mention of examples of illicit acts (illegal manufacturing, illegal trade, etc.)

- **Swiss penal code (PC)**
  - infringements of property (fraud; counterfeiting of goods)
  - infringements of “life and limb” (homicide; serious assault)

- **Infringements of intellectual property law**
- **Infringements of customs and tax law**
Counterfeit and illegal products in Switzerland: Swiss Legislation

Counterfeiting, falsification

- Louis Vuitton
- Lacoste
- Rolex

Infringements to the Act on Therapeutic Products

- Viagra
- Cialis
- Levitra
- Xenical
- Cancérostuff
- Cholestérostuff
- Rhumatop

+ Custom and tax infringements
+ (potentially) Penal Code
Act on Therapeutic Products: Penal provisions – applicable sentences

- **Crimes and misdemeanours (Art. 86 ATP, danger to health):**
  - Up to 3 years imprisonment or adequate cash penalty (plus possible fine)
  - Up to 5 years imprisonment or adequate cash penalty (plus possible fine) for aggravated infringements

- **Contraventions (Art. 87 ATP, no danger to health):**
  - Fine up to CHF 50,000.-
  - Cash penalty equivalent to 180 sentence days (plus possible fine) for aggravated infringements

- **Bodily harm or homicide → application of the Swiss penal code (maximum penalty: life sentence)**
Act on Therapeutic Products and Penal Law: Applicable measures

- Prevention from exercising a profession (Art. 67 PC)
- Note in criminal record (Art. 365 et. seq. PC)
- Publication of judgement (Art. 68 PC)
- Confiscation of dangerous objects used for or resulting from infringement → destruction (e.g.: dangerous medicines. Art. 69 PC)
- Confiscation of assets resulting from infringements or intended to reward the perpetrator (or compensatory claim on the part of the State, if assets are no longer accessible) (Art. 70/71 PC)
Benefits of Medicrime Convention for Switzerland

The Medicrime Convention highlights that:

- the infringements in question are serious:
  - they are lucrative
  - they are dangerous to people’s health
  - they cheat the consumer
- international collaboration has to be intensified
- national collaboration has to be optimized.

helps to:

- increase awareness at the political level (authorities/population)
- acquire procedural methods
- increase the penalties
- get more resources deployed
Thank you for your attention!