

THE ADDED VALUE OF THE MEDICRIME CONVENTION FROM THE CRIMINAL LAW PERSPECTIVE

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I. GENERAL CONSIDERATIONS

- MEDICRIME Convention is the first binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health.
- The Council of Europe has long been concerned about the absence of harmonised international legislation in this field.
- Incidences of counterfeit medical products and similar crimes undermine public trust in healthcare systems and authorities' surveillance thereof.

I. GENERAL CONSIDERATIONS

- The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving a threat to public health –Moscow 2011– (hereinafter: MEDICRIME Convention) is essentially a Convention of criminal nature, which implies to the Parties the adoption of domestic legislation consistent with the definition of the crimes relating to counterfeiting of medical products established in the MEDICRIME Convention.

I. GENERAL CONSIDERATIONS

- Characterization of several offences:
 - Manufacturing of counterfeits (art. 5).
 - Supplying, offering to supply, and trafficking in counterfeits (art. 6).
 - Falsification of documents (art. 7).
 - Similar crimes involving threats to public health (art. 8).

II. The principle of legality in the Convention

- MEDICRIME Convention: obliges Parties to introduce in their domestic law the offences provided for in the Convention (principle of legality). The Criminal Law doctrine considers that the national legislation of each State shall introduce these offences in their legal systems by mean of a formal law passed by Parliament.
- In connection with this type of crime it is usual to define the offences by reference to technical concepts which oblige to connect criminal law with other spheres (pharmaceutical legislation, etc.).

II. The principle of legality in the Convention

- The Convention generally refers with sufficient precision to the core of the conduct prohibited in each offence (respect of the principle of taxativity).

III. Public health as legally protected interest of collective character

- The offences included in the Convention constitute threats to public health, which is the legally protected interest. From this perspective, public health must be understood as the health of the community, that is, the physical and mental health of citizens considered not from an individual point of view (what goes beyond the individual perspective).

IV. The structure of crimes involving threats to public health

- Crimes involving threats to public health:
 - Hypothetical danger: Explanatory Report notes that the offences described therein are considered to be so inherently dangerous to public health that Articles 5 to 8 will be applicable also in cases where only a potential threat to public health has been detected, and no actual physical or psychological damages to victims have materialised. In practice, this means that the competent authorities of a Party will not have to prove that a certain conduct on the part of the perpetrator has led to actual damages to public or individual health, as long as the conduct in question falls under one or more of the categories of offences set out in Articles 5 to 8.

V. Mens rea and negligence

- No punishment shall be imposed in the absence of mens rea (negligence is not punishable under MEDICRIME Convention).

VI. Substantive Criminal Law

- Criminal offences:
- Article 5: Manufacturing of counterfeits
 - intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.
 - As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.

VI. SUBSTANTIVE CRIMINAL

LAW

- Criminal offences:
- Article 6: Supplying, offering to supply, and Trafficking in counterfeits
 - supplying or offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.
- Article 7: Falsification of documents
 - the term “document” shall mean any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof;

VI. SUBSTANTIVE CRIMINAL LAW

- Criminal Law offences:
- Article 8: Similar crimes involving threats to public health
 - the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of medicinal products without authorisation (where such authorisation is required under the domestic law of the Party) or medical devices without being in compliance with the conformity requirements (where such conformity is required under the domestic law of the Party).
 - the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

VI. SUBSTANTIVE CRIMINAL LAW

- Article 9: Aiding or abetting and attempt.
- Article 11: Corporate liability.
- Article 12: Sanctions and measures
- Article 13: aggravating circumstances.
 - the offence caused the death of, or damage to the physical or mental health of, the victim.
 - the offence was committed by persons abusing the confidence placed in them (professionals/manufacturers/suppliers).
 - the offences of supplying and offering to supply were committed having resort to means of large scale distribution (Internet).

II. SUBSTANTIVE CRIMINAL LAW

➤ Article 13: aggravating circumstances.

- the offence was committed in the framework of a criminal organisation.
- the perpetrator has previously been convicted of offences of the same nature.

➤ Article 14: previous convictions.

- Each Party shall take the necessary legislative and other measures to provide for the possibility to take into account final sentences passed by another Party in relation to the offences of the same nature when determining the sanctions.

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