



HUNGARY

This country profile has been prepared in view of sharing information and assessing the current state of implementation of the MEDICRIME Convention under domestic legislation. It does not necessarily reflect official positions of the country covered¹ or of the Council of Europe.

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1. Background

The intention of signature and ratification of MEDICRIME Convention was due to the following circumstances: as in 2012 Hungary was preparing the new Criminal Code, it was an excellent occasion also to examine the provisions of the MEDICRIME Convention at the same time. The previous Hungarian Criminal Code had not contained either a separate, complex and comprehensive criminal offence related to counterfeiting of medical products or the majority of criminal conducts as they are specified by the Convention were not criminalised.

During the examination of MEDICRIME Convention it was obvious, that in general the Hungarian national legal system mostly complied with the Convention. However, one crucial provision was missing, the substantive criminal law provision about the counterfeiting of medical products. Moreover, during the review of existing Hungarian criminal procedural rules it also has been identified that the <u>Act XIX of 1998 on Criminal Proceedings</u> (hereinafter: CP) and the <u>Act</u>

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XXXIV of 1994 on Police had to be modified as well. The main purpose of these amendments was to establish the possibility to carry out covert operations in connection with this criminal offence.

2. Hungarian implementation

The new Hungarian Criminal Code is the Act C of 2012 on Criminal Code (hereinafter: CC). When it entered into force on 1st July 2013, the CC introduced a new provision of counterfeiting of health care products (Section 186) in Chapter XVII, in which the common feature of the criminal offences is that they endanger the public health. The main purpose of punishing these conducts is to protect the human life and health and the public health. Furthermore this Chapter also includes criminal offences related to drugs (Sections 176-183), to new psychoactive substances (Sections 184-184/D), to performance-enhancing drugs (Section 185), to quackery (Section 187), to toxic substances (Section 188) and to harmful consumer goods (Section 189).

The CC determines the object of the criminal offence. The CC explains the definition of health care product in an explanatory provision, bearing in mind the specialities of national health law. The definition extends to the medicinal products, veterinary medicinal products, medical devices, in vitro diagnostic medical devices, and investigational medicinal products, but the concrete meanings of the elements of this list are determined by the Hungarian health law. The MEDICRIME Convention contains the terms of active substance, excipient, accessory, parts and materials. The definition of health care product in the CC, however, does not specify these terms as if they are falsified for the purpose of manufacturing health care product, the falsification of these elements of health care product results a false health care product. Thus the commission of the criminal offence could be completed also by falsifying any of the abovementioned elements.

The CC also determines the definition of health care product not authorized in Hungary, which definition comes from the health law as well. According to the explanatory provision, health care product not authorized in Hungary inter alia covers medical device which is traded on the market without a conformity assessment test and any products in which active ingredients are used in violation of the mandatory provisions on the composition of a given products.

In virtue of the explanatory provision, it is unambiguous that authorized health care product is that medical device which is traded on the market following a conformity assessment test. The medicine is deemed to be authorized as well if it does not have an authorization to trade on the market, but it has an official licence or it is notified by the competent authority.

The CC punishes the following criminal conducts implementing the Article 5, 6 and 8 of the Convention within one separate provision:

- to make false health care products or to alter health care products;
- to supply, to offer to supply, to trade on the market or to traffic with false or altered health care products, or health care products which have not been authorized in Hungary;
- to import or to export, or to transport in, transit through the territory of Hungary false or altered health care products; or to acquire, to possess such products in undue quantities;
- to import or to export, or to transport in, transit through the territory of Hungary health care products which have not been authorized in Hungary, to acquire, to possess such products in undue quantities;
- to use an original document related to health care products for commercial purposes for other reasons than such document was intended.

The sanction of the abovementioned conducts is imprisonment up to three years.

According to MEDICRIME Convention and Hungarian practice of criminal law, the CC punishes – among others – the making of false health care product or the altering of health care product. This distinction exists in the practice as follows:

- false product gives the appearance of genuine product. In this case a new copy, which is similar to the original product, comes off. The method of the making products or the quality of the result is indifferent. It is not required that the false product seems to be perfect. It has to only be similar to the original product as much as possibility of the deception can be occurred with the using of it;
- altering of product means the modification of an existing genuine product. A new copy
 does not come off in this case. The perpetrator makes a product, which differs from the
 genuine product.

It is important to note related to the other criminal conducts, that the "brokering" mentioned in the Convention does not emphasize in the CC as the Curia of Hungary determined in its <u>Uniformity Decision no. 1/2007 BJE</u> that the term of trafficking covers the term of brokering due to the jurisprudence. Therefore it is not necessary to specify "brokering" in Section 186.

The CC uses the condition of undue quantity concerning with certain conducts, mainly in connection with acquiring and possessing, because it is assumed that the purpose of the Convention is not to punish the consumers. Therefore an explanatory provision determines that the undue quantity shall mean any quantity that goes beyond what is considered to serve the personal needs of a specific person.

The punishment is imprisonment between one to five years in the following qualified cases:

- if the perpetrator commits the criminal conducts:
 - a) as a healthcare employee;
 - b) as an employee of an authorized manufacturer, wholesaler or public supplier; or
 - c) in criminal association.

The main reason of the enhancement of these circumstances as qualified cases is that the consumers, in particular the most vulnerable persons, the patients, deem with confidence to professionals working in healthcare system. The same confidence is placed to the manufacturer, wholesaler or public supplier because they carry out their work in possession with authority licence and their job is regularly controlled by a competent authority. The definition of healthcare employee is included in the Hungarian health law. According to the point b) and c) of Article 13, the Hungarian legislator were convinced that all healthcare employees and employees of an authorized manufacturer, wholesaler and public supplier who committed the criminal offences contained in Section 186 of CC shall be punishable with more serious sanctions, due to the fact, that the patients have well-founded reasons to trust in them because of their professions. Thus the level of penalty is increased in these qualified cases.

It is also a qualified case in the CC, if the criminal offence was committed in criminal association. The CC contains the definition of criminal association in an explanatory provision (Point 2 of Section 459), according to which it shall mean when two or more persons commit criminal offences in an organized way, or they conspire to do so, and they attempt to commit at least one criminal offence, without, however, creating a criminal organization.

The point e) of Article 13 of the Convention contains the commission of criminal offences in the framework of a criminal organization as aggravating circumstance. Due to the fact, that the CC includes a general provision about criminal organization, it does not regulate the commission in criminal organization in Section 186. According to Point 1 of Section 459, criminal organization shall mean a long-term organized group including three or more persons, which is operated in a co-ordinated way and the purpose of which is to commit intentional criminal offences punished by imprisonment five or more years. If the perpetrator commits a criminal offence in the framework of a criminal organization, the maximum level of penalty prescribed for the criminal offence shall be doubled, however, it shall not exceed twenty-five years (Paragraph 1 of Section 91).

The punishment is also imprisonment between one to five years:

• if false or altered health care products, or health care products which have not been authorized in Hungary are widely distributed to consumers by the perpetrator.

This conduct covers those cases where the dealing or supplying happens through information systems. The criminal offences committed via the Internet concerning the counterfeiting of medical products are huge threat in global proportions. Several advertisements are available for consumers and patients through the various websites or their e-mails. Most consumers are usually uninformed about the risks and danger of buying cheaper counterfeited or unauthorized medicines or other medical products via the Internet. According to the point d) of Article 13, the CC punishes the large scale distribution as a qualified criminal offence.

In those cases where the perpetrator a kind of manufacturer or supplier, and:

- the criminal offense results in permanent disability or serious health impairment, the punishment is imprisonment between one to five years,
- the criminal offense results death, the punishment is imprisonment between two to eight years.

With regard to point a) of Article 13, the CC enhances those reasons, which lead to the most horrible and serious outcomes. The Hungarian legislator limited the scope of perpetrators to these two abovementioned cases. The criminal offence is only punishable, if the perpetrator is a manufacturer or a supplier because the death or the impairment of health as results of the criminal offences do not basically connect to the criminal conducts related to transport or possess but these results are primarily concerned the responsibility of the manufacturer or

supplier. Where the qualified cases contain the results, the negligence of the perpetrator has to exist in respect of qualified result. If the intention of the perpetrator extends to the result, the criminal offence can be qualified as criminal offences against life, limb and health, for example manslaughter or battery.

Point f) of Article 13 specifies the previous conviction on account of the commission of the same nature criminal offence as an aggravating circumstance as well. Sections 89-90 of the CC provide the detailed rules about the specific recidivist, the repeating recidivist and the violent recidivist.

As regards Article 7 of the Convention, Hungary punishes the use of falsified private documents in a separate provision (Section 345). This criminal offence is punishable by imprisonment up to one year. The Explanatory Report of the MEDICRIME Convention underlines that the aim of the provision is to deceive the person reading or looking at the document into believing that the medical product, active substance, excipient, part, material or accessory, which the document accompanies, is legitimate and not a counterfeit or the subject of a criminal conduct. This statement supposes that the purpose of the Convention is not to punish the simple making of false document or the act of tampering with documents. The dangerous of this criminal conduct arises only in those cases when the false or tampered documents are used by the perpetrator for the purpose of misleading of other persons.

It also has to be underlined that according to the Hungarian criminal law practice, there is an opinion of Criminal Department of Curia about the evaluable circumstances during the sentencing: <u>56. BK opinion</u>. The Curia shows guidelines in this opinion how and which circumstances can be evaluated during the sentencing as aggravating or mitigating circumstances.

According to Article 9, it has to be mentioned that Hungary punishes the attempt of all criminal offences regulated in the CC (Section 10). The penalties applicable to a completed criminal act shall also apply to attempt. The aider or abettor is punished in general as well and the penalties applicable to offenders of a criminal offence shall also apply to the aider or abettor (Sections 12 and 14).

As regards Article 10, it is important to be noted that the CC contains jurisdiction rules (Section 2 and 3) which comply with the nationality and territory principles of the Convention. Taking into account that Hungary does not know the principle of habitual residence it used the possibility to take reservation not to apply the provision in this regard, which is ensured by the Convention. In connection with Paragraph 3, it has to be underlined that the rules of jurisdiction in the Hungarian criminal law are quite extensive. Due to this fact, there are only few cases, in which Hungary does not fulfil the extradition. In these rare cases, the provisions of the Act XXXVIII of 1996 on International Mutual Assistance in Criminal Matters (hereinafter: Act XXXVIII of 1996) shall be applied. According to these rules, the decision whether the criminal proceedings can be initiated or not if the extradition was refused, falls within the discretion of the Chief Public Prosecutor (Section 28). Besides, there is also an opportunity to take the criminal proceedings over from the foreign state (Section 43).

The Convention covers the rules of corporate liability in Article 11. The criminal liability of legal persons in Hungary is ruled by the Act CIV of 2001 on Measures Applicable to Legal Entities under Criminal Law. The criminal liability of legal persons is connected to the criminal liability of natural person in Hungary. According to the basic principle, to be able to punish a legal person, a link must exist between the criminal offence and the legal person. This link is the benefit and from the 1st July 2013 the commission with the use of the legal person (Section 2). The conditions provided by the Convention relating to ascertaining of the liability of legal persons are the same like in Hungarian law. The measures against the legal persons – as a general rule – can only be applied, if the court has determined the criminal liability of a natural person. However, from 1st July 2013, the legislator widens significantly the scope of those cases when a measure can be applied against a legal person, even if the natural person committing the crime cannot be held criminally liable, though the fact that a crime occurred is obvious (Section 3).

The measures against the legal person can be the

- a) winding up the legal person;
- b) limiting the activity of the legal person;
- c) imposing a fine.

As regards paragraph 4 of Article 11 of the Convention, it is necessary to mention that there are not any rules in Hungary that would require to terminate the proceedings against a natural person or to acquit a natural person perpetrator on the basis that a criminal measure was imposed against a legal person.

It has to be highlighted in connection with Article 14, that the Act XXXVIII of 1996 shall be applied in this regard, which contains the rules of recognition of the validity of foreign judgements (Section 47-48). If the validity of the foreign judgement has been recognized by the Hungarian court, the offence shall be regarded as having been finally adjudicated by a Hungarian court.

Furthermore, it has to be noted as well, that there is a Council Framework Decision 2008/675/JHA of 24 July 2008 on taking account of convictions in the Member States of the European Union in the course of new criminal proceedings (hereinafter: FD). According to the FD, Hungary amended in 2010 the CP and the Act XLVII of 2009 on Criminal Records (hereinafter: Act XLVII of 2009) to establish a separate register, namely the register of judgements adjudicated by the courts of Member States of the European Union against Hungarian nationals (Chapter III of Act XLVII of 2009). The purpose of this register is to contribute the mutual exchange of the data contained in the final judgement and to take into account the data contained in the final judgement in the criminal proceedings conducted due to another criminal offence against the convicted person. The data of this register shall be obtained by the Hungarian authorities during the criminal proceedings. If any data arise in connection with a foreign judgement against the Hungarian suspected person and the validity of foreign judgement has not been recognized yet by the Hungarian court, the prosecutor will have to initiate the recognising of judgement at the Minister of Justice (Section 178/B of CP). In this case, the court will have to suspend the proceedings if the recognition is not occurred until the finishing of presentation of evidence.

Not-mentioned provisions herein from the substantive criminal law part of the Convention have been in force for a long time in the Hungarian criminal law. For example, provisions contained in Paragraph 5 and 6 of Article 10 are undertaken in accordance with general rules and obligations of international and European Union cooperation. Moreover, Hungary implemented the Council Framework Decision 2009/948/JHA of 30 November 2009 on prevention and settlement of conflicts of exercise of jurisdiction in criminal proceedings. Due to this fact, if a jurisdiction conflict emerges among Member States of the European Union, there is an opportunity for exchanging information or direct consultations.

On the other hand, the rules of seizure and confiscation in CC comply with international requirements, thus they meet with Paragraph 3 of Article 12 as well.

The requirements of the Convention concerning criminal procedural law in Article 15 and 16 are fulfilled by the CP (Paragraph 1 of Section 170, Paragraph 1 of Section 201) and the Act on Police (Section 69). The other provisions in relation to national co-operation of authorities (Article 17) and preventive measures (Article 18) are granted by the national sector acts. The rules of Chapter VI (Article 19 and 20) concerning the protection of victims and the victims' rights in criminal proceedings are fully ensured by the CP and the Act CXXXV of 2005 on Crime Victim Support and State Compensation. Obligations prescribed in Chapter VII of the Convention pertaining to international co-operation (Article 21 and 22) are completely guaranteed by the Act XXXVIII of 1996 and the Act CLXXX of 2012 on Judicial Cooperation in Criminal Matters with Member States of the European Union.

Finally, it has to be mentioned that Hungary took two reservations to the Convention in 2013. The first reservation concerns with Article 7 as regards the falsification of documents because the definition of document determined by the Convention is much wider than the Hungarian rules. The other reservation connects to Article 10 because Hungary does not know the principle of jurisdiction based on habitual residence concerning either the perpetrator or the victim.

Furthermore, it has to be noted that the Act II of 2012 on Infractions, Infraction proceedings and the Registration System of Infractions contains a provision, called Pharmaceutical offence (Section 153/A) regarding the conducts which are concerned as administrative offence. This rule does not connect directly to the MEDICRIME Convention but it is important in order to ensure that all conducts, which linked to the manufacturing and distribution of medicines without any licence, or the possession of undue quantity of any substance or product, classified as a medicine, available on prescription in Hungary, are considered as administrative offences. The administrative proceedings initiated for Pharmaceutical offence falls within the competence of the customs organisation of the National Tax and Customs Administration. Community service, payment of a fine, or warning can be imposed as a sanction for this administrative offence.