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SUBSTANTIVE CRIMINAL LAW OF THE MEDICRIME CONVENTION AND THE CRIMINAL LEGISLATURE OF BOSNIA AND HERZEGOVINA
The Ratio of Harmony and Disharmony[**]

ABSTRACT: The trade in counterfeit medical products is a growing global crime industry (especially in the domain of organized crime), which represents a big threat to natural persons, i.e., patients, but also to healthcare systems. The circulation and sale of counterfeit medical products takes place through unregulated channels (on the side of the road, in a marketplace, online, or even in bars, nightclubs or bakeries). The Convention of the Council of Europe on counterfeit medical products and other illegal acts that include threats to public health represents the first international agreement of that kind, that is, an international instrument that establishes a legal framework for the fight against this criminal black market. It criminalizes certain actions, prescribes certain provisions related to the criminal justice procedure, protects the rights of victims and improves national and international cooperation in criminal justice matters.

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INTRODUCTION

Contemporary threats to public health, based on counterfeit medical products and similar illegal acts have become global. The production and trade in counterfeit medical products is a billion dollar criminal industry. At the same time it creates a large threat for the undisturbed functioning of the healthcare systems of a large number of countries. The phenomenon is especially connected to the activities of organized crime due to the fact that the penal policies are very lenient, while at the same time these activities generate large profits compared to other types of crime.

The Convention of the Council of Europe on counterfeit medical products and other criminal acts involving threats to public health[1] (hereinafter: MEDICRIME Convention or Convention) was adopted on December 8, 2010, and it established a legal framework for the global fight against counterfeit or forged medical products and other similar crimes by focusing on the following: ensuring the criminalization of certain actions, the protection of the rights of victims of crimes established in the Convention and on the promotion of national and international cooperation. Bosnia and Herzegovina signed the Convention at the end of 2015 (November 4) and ratified it on September 18, 2020, while it has been in full application since January 1, 2021.

The goal of this article is to provide answers to the following questions: (1) has Bosnia and Herzegovina carried out the obligations accepted in this convention, (2) has it incriminated particular actions as felonies and (3) do specific institutes of the general part of the criminal justice legislation of Bosnia and Herzegovina match the contents of the Convention.

[1] It is important to note here that the translations of the Convention into the languages of Bosnia use the term "pharmaceutical" instead of "medical" products. What the reason behind this, we dare say, completely inaccurate translation (given the fact that full title of the Convention in the English language, which is, alongside French, the official language of the Convention, reads: Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health) is open to interpretation.

WHAT IS THE MEDICRIME CONVENTION AND WHY HAS IT BEEN ADOPTED?

Given their lucrative character, the counterfeiting of medical products and similar crimes are a new global threat that the international community faces. The low degree of control over criminal production networks facilitates the infiltration of those counterfeit medical products into the legal supply chain and their marketing as authentic products. The lack of transparency of these networks makes it more difficult to fight against these new forms of socially dangerous behaviors.[2]

The Convention seeks to protect the lives of the citizens of the countries that are the members of the Council of Europe, public health, the integrity of the legal system, as well as bolster international cooperation and the provision of international legal assistance. The authors of the Convention decided not to tackle the question of the legal protection of intellectual property (which is the subject of other international instruments) and to focus only on establishing the legal framework for the adoption of national material and procedural law when it comes to the provision of an adequate response to the growing threat of counterfeit medical products (as well as the question of strengthening international legal assistance in criminal justice matters). In that regard, the Convention can be divided into several parts: (1) the introduction (contains the goal, subject matter, fundamental principles and definitions of terms), (2) material criminal law, (3) criminal procedural law, (4) national and international legal assistance in criminal matters, (5) the protection of the victims of criminal actions and (6) monitoring the implementation, the relation with other international agreements, amendments and cancellations. We will focus only on the parts that relate to the matters of substantial criminal law.

In this way, member states of the Council of Europe concluded that it is necessary to approach a criminal justice response to this global threat, which is why they started to develop an international instrument that will represent a suitable basis for further fights against counterfeiting medicines and medical products as well as other related socially dangerous actions. The purpose and goal of the Convention is:

(a) incrimination of certain actions,

(b) the protection of the rights of victims and

(c) the promotion of national and international assistance in criminal justice matters.

[2] Alarcón-Jiménez, O. (2015). The MEDICRIME Convention: Fighting Against Counterfeit Medicine. *Eurohealth International*, 21(4), 24.

For the purposes of monitoring the implementation of the aims and goals of the Convention, the formation of a special mechanism or body was prescribed (in this regard, today, there is a Committee of Parties that will not be addressed in this article).[3] The authors of the Convention did not tackle the protection of intellectual property rights because they believed that those rights were already adequately protected in national and international regulations, thus they do not question the prosecution of individuals who violate those rights. The guiding idea for the authors of the Convention was to protect human life and health by incriminating certain actions.

The application of the Convention was restricted to medicines and other medical products which are used in human and veterinary medicine.

Following a special discussion owing to a specific regulatory approach when it comes to defining medical products and in contrast to the situation with pharmaceuticals, a special *ad hoc* committee decided to include medical devices in the scope of the application of the Convention given the obvious dangers for public health that such devices can cause. In accordance with that, parts, materials and equipment needed to produce or use medical devices were also included. The *ad hoc* committee decided not to include the related but different categories such as food, cosmetics, and biocides into the scope of the Convention but did not exclude the possibility that those categories might become the subject of special protocols in the future.[4]

Until the present moment, the Convention has been ratified (and implemented) in 15 member states of the Council of Europe and 4 countries that are not members of this regional international organization - Guinea, Burkina Faso, Benin and Belarus, while countries such as Chile, Congo, Canada, Japan and others have been invited to join (which makes this Convention especially interesting). The question why the remaining member states of the Council of Europe have not joined the Convention opens many other questions about the mutual relations among these countries and the existence of various interests, which will not be addressed in this article.

[3] See: Article 1 and Articles 23–25 of the Convention.

[4] See: Terzić, S., Šandor, K., Andrišić, M., Žarković, I., Vujnović, A., Perak Junaković, E., Vretenar Spigelski, K., Sinković, S., Pehnec, M., Fajdić, D. (2020). Konvencija Vijeća Europe o krivotvorenju farmaceutskih proizvoda i sličnim kažnjivim djelima koja uključuju prijetnje javnom zdravlju. *Veterinary Station*, 51(1), 3; Keitel, S. (2012). The MEDICRIME Convention: criminalizing the falsification of medicines and similar crimes. *Generics and Biosimilars Initiative Journal*, 1(3–4), 139.

SUBSTANTIVE CRIMINAL LAW – THE SOLUTIONS FROM THE CONVENTION AND THE SOLUTIONS IN THE LEGISLATURE OF BOSNIA AND HERZEGOVINA

Felonies

Chapter 2 of the Convention contains the provisions on the substantive criminal law (felonies and some institutions of the general part of criminal law). The acts described in this chapter are considered so dangerous for public health that the articles of the Convention will be applied even in cases when only a potential threat to public health was discovered without causing real physical or psychological damage to the victims. In practice, this means that the authorized bodies responsible for implementing the law will not be tasked with proving that a particular behavior on the part of the offender resulted in real damage to the public health or the health of an individual as long as the behavior in question falls into one or more categories of criminal acts listed in articles 5 to 8 of the Convention. The Convention prescribes the following felonies: (1) the production of counterfeit goods, (2) distribution, marketing or trade in counterfeit goods, (3) forging documents and (4) similar crimes that include threats to public health.

Bosnia and Herzegovina is a complex country which received its special administrative structure in 1995 following the adoption of the *General Framework Agreement for Peace in Bosnia and Herzegovina* whose Annex IIb is the current Constitution of Bosnia and Herzegovina. This complex government and legal structure results in a specific division of (legislative) authority between the state, two entities and one district. Initially, substantive criminal law was exclusively under the jurisdiction of the entities (Republic of Srpska and the Federation of Bosnia and Herzegovina) and the Brčko District until the adoption of the state criminal law which regulates a certain set of socially unacceptable behaviors. The protection of public health and the incrimination of socially dangerous actions that damage public health and the health of individuals was entrusted to all four legislative bodies in Bosnia and Herzegovina. The consequences of this were four criminal laws (i.e., three laws and one code) which regulate the matters of substantive criminal law.

The production of counterfeit goods represents intentional production of counterfeit medical and pharmaceutical products, their active substances, auxiliary substances, parts, materials and equipment used for medical purposes as well as the deliberate reduction of the quality of legitimate medical (pharmaceutical) goods. Therefore, this is an example of *delicta communis omnium* or a crime that can be committed by anyone (special characteristics of offenders are not prescribed). The crime can be committed only in a premeditated

manner while the criminal action has alternative definitions. The Convention does not prescribe criminal sanctions, and this aspect was left to the discretion of individual signatory countries. The Criminal Law of Bosnia and Herzegovina[5] (hereinafter: CLB&H) does not contain a group of crimes defined by the common feature of damaging or threatening public health. However, there are certain actions that can be at least indirectly subsumed under the incriminations from Article 5 of the Convention. One example is the crime of smuggling dangerous substances into Bosnia and Herzegovina.[6] The description of this crime states that the person who, contrary to the laws and regulations of Bosnia and Herzegovina smuggled into Bosnia and Herzegovina harmful radioactive or other substances and waste products that can damage human life or health will be punished with a fine or with up to three years of imprisonment. Next, we observe a crime from Article 214 of CLB&H (illegal production) whose first paragraph states that the person who produces or processes goods whose production or processing are prohibited in the laws and regulations of Bosnia and Herzegovina or international law, if such an act does not constitute another crime that include a stricter penalty, will be punished with a fine or with up to one year of imprisonment. Certain elements can be observed in the crime from Article 214 (smuggling) whose paragraph 3 states that a penalty of between one and ten years of imprisonment will be issued to the person who "crosses the state border while carrying objects, goods or substances which pose a threat to the life and *health of human beings* or public safety…". The Criminal Code of the Republic of Srpska[7] (hereinafter: CCRS), in its specific part, contains a group of crimes against human health.[8] The felony described in Article 5 of the Convention is most similar to the crime described in Article 202 Paragraph 1 of the CCRS (production and trafficking in products that are harmful for a treatment process). Namely, in Article 202, Paragraph 1, it is stated that a penalty of two years of imprisonment and a fine will be issued to the person who produces, sells or in some other way trafficks in medicines or other means of treatment which are harmful to human health. We can say that there are similarities between these descriptions of criminal acts, but it cannot be argued that the norm is identical to the Convention. We are of the view that this incrimination cannot comprise anything other than counterfeit medicines, substances or other materials that are used to produce pharmaceuti-

[5] *Official Gazette of Bosnia and Herzegovina*, no. 3/2003, 32/2003 – amd., 37/2003, 54/2004, 61/2004, 30/2005, 53/2006, 55/2006, 8/2010, 47/2014, 22/2015, 40/2015, 35/2018 and 46/2021.

[6] Article 166 of the CCB&H.

[7] *Official Gazette of the Republic of Srpska*, no. 64/2017, 104/2018 – decision of the Constitutional Court, 15/2021 and 89/2021.

[8] See: Chapter 17 CCRS.

cals. In addition to this crime, we are also interested in the felony from Article 377 of the CCRS (the production of harmful substances for treating animals). Namely, according to this incrimination, the person who produces, sells or trafficks in means of treatment or preventing contagion in animals that are dangerous for animal life or health will receive a penalty of between six months and three years or imprisonment. Here too we can observe certain similarities. Finally, it is worth pointing out that the CCRS recognizes the crime of smuggling dangerous substances into the Republic of Srpska,[9] whose essence is identical to the essence of the abovementioned crime from Article 166 of the CLB&H. All of this suggests that there is no complete match between these pieces of legislation, and consequently, they should be amended to the degree that is necessary to harmonize them with the Convention in relation to Article 5. The CLB&H,[10] like the CCRS, contains a special group of crimes against human health,[11] but it does not contain incriminations similar to Article 5 of the Convention (apart from Article 160, i.e., the crime of smuggling dangerous substances into the Federation of Bosnia and Herzegovina), which is why we believe that the CLB&H should be amended or supplemented in the sense of the provisions of Article 5 of the Convention. The Criminal Law of the Brčko District of Bosnia and Herzegovina[12] (hereinafter: the CCBDB&H), like the laws of the two entities, contains a special group of crimes against human health (Chapter XXI), but, like the CLB&H, it does not contain crimes that can be identified with the incrimination from Article 5 of the Convention (apart from, again, the crime of smuggling dangerous substances into the Brčko District of Bosnia and Herzegovina from Article 159).

Supplying, offering to supply and trafficking in counterfeits is a crime defined in Article 6 of the MEDICRIME Convention, which refers to intentional supply, offers of supply, including mediation, trade, warehousing, import and export of counterfeit medical and pharmaceutical products, active substances, auxiliary substances, component parts, materials and equipment. This is a crime that does not necessitate some special characteristics of the offender and it can be committed only in a premeditated manner, but the action that constitutes the crime has alternative definitions. The expressions "supplying" and "offering to supply" are not specifically defined in the Convention, but it is understood that they cover, in their broadest sense, actions

[9] Article 387 CCRS

[10] *Official Papers of the Federation of Bosnia and Herzegovina*, no. 36/2003, 21/2004 – amd., 69/2004, 18/2005, 42/2010, 42/2011, 59/2014, 76/2014, 46/2016. and 75/2017.

[11] See: Chapter 21 CCFB&H.

[12] *Official Gazette of the Brčko District of Bosnia and Herzegovina*, no. 19/2020 – proofread.

of mediation, procurement, sales, gifting or offering without remuneration as well as promoting (including the advertising of these products). "Offering to supply" represents a special form of a criminal act which should be distinguished from "an attempt to supply" (which will be addressed at a later point). Finally, the term "trafficking in counterfeits" should be understood in the sense of selling, stockpiling for the purpose of selling, as well as import and export. The laws that regulate the material of substantive criminal law in Bosnia and Herzegovina contain criminal acts which can be partially identified with the abovementioned incrimination (this applies only to the CLB&H in relation to the crime of smuggling from Article 214 and in that sense the lawmakers of B&H owe a certain debt to this international instrument).

Falsification of documents is a crime in which the perpetrator purposefully (i.e., in a premeditated fashion) creates false documents or alters and changes real documents.[13] This is a crime that can in principle be committed by any person while the form of guilt is always premediation (direct or eventual), while the criminal action consists of the creation of false documents or alternation of real ones. Therefore, this crime can be committed either by forging a completely new false document or by altering a document in relation to its content and/or appearance. In both cases the purpose is to mislead the person who reads or looks at the document into believing that the medical product, active substance, auxiliary substance, part, material or equipment that the document accompanies is authentic and not counterfeit. The term "document" is very broad and underdetermined. It does not encompass only certificates and other documents that are used in trading but also packaging and labels on medical products as well as texts on web pages which are specifically designed to accompany the product in question.[14] Criminal laws in Bosnia and Herzegovina (apart from the CLB&H) contain crimes that are related to forging documents and in this regard they are fully harmonized with Article 7 of the Convention. The CCRS defines the crime of falsification of documents.[15] Namely, this crime is committed by a person who creates a false document or alters a real one with the intention of using this document instead of a real one as well as by the person who uses such a document as a real one or obtains it for the purpose of using it. Also, Article 350 of the CCRS states that those individuals who create, obtain, possess, sell or procure means for falsifying documents are also punishable under this law.[16] The CLB&H con-

[13] Article 7 of the Convention.

[14] For more details, see: Stojanović, Z. (2020). Falsifikovanje isprave u crnogorskom krivičnom pravu. *STUDIA IURIDICA MONTENEGRINA*, 2(II)/2020, 7–37.

[15] See: Article 347 CCRS.

[16] Babić, M., Marković, I. (2018). *Krivično pravo, Posebni dio*. Banja Luka: Faculty of Law, University of Banja Luka, 304–315.

tains a crime of falsifying documents[17] whose description is identical to the description of the crime from Article 347 of the CCRS. The same applies to the CLBDB&H.[18]

Similar crimes involving threats to public health covers all other socially dangerous behaviors that represent threats to public health. Under this title, the Convention lists: 1) the production, stockpiling for the purpose of supplying, import, export, offering to supply or trafficking (medicines without permission when such a permission is required according to the national legislature of a signatory party or medical products which do not meet the requirements stated in the regulations in cases in which such requirements exist under the national legislature of the signatory party) and 2) commercial use of authentic documents outside the scope for which they were intended in a legal supply chain of medical and pharmaceutical products as defined in the national legislature of the signatory party (Article 8 of the Convention). This provision covers certain crimes that can be considered akin to counterfeiting medical products for the reason that they represent a serious threat for public and individual health.

Crimes described in Articles 5–8 of the Convention are punishable only if they are committed intentionally, i.e., in a premeditated fashion (either directly or eventually), while the possibility of committing these crimes out of negligence is not completely excluded. The component of premeditation is interpreted in the context that it has in the national legislature of the signatory party. Almost all crimes from Articles 5–8 of the Convention are transnational in nature, i.e., these are crimes that can be associated with at least two criminal legislatures.[19]

Criminal penalties

The provisions of Article 12 of the Convention are closely linked with the provisions from Article 5–8. Namely, Article 12 is concerned with criminal sanctions for the perpetrators of the listed crimes. Of course, this should not be understood as the statement of a concrete sanction for each crime. This article obliges the signatory parties to adjust their national legislatures to the seriousness of these crimes and the degree of social harm or danger that they can create and to define sanctions which are "effective, proportionate and

[17] See: Article 373 CCFB&H.

[18] Article 367 CLBDB&H defines the crime of Counterfeiting documents.

[19] See: Simović, M. N., Blagojević M., Simović V. M. (2013). *Međunarodno krivično pravo*. East Sarajevo: Faculty of Law in East Sarajevo, 19, and Softić, S. (2013). Transnacionalno krivično pravo. *Legal thought*, 1–2/2013, 7–24.

dissuasive".[20] What the convention defines is the type of sanction or penalty. The signatory countries are obliged to implement penalties of at least one year of imprisonment for the crimes from Articles 5 to 8. Also, Article 12 prescribes that a sanction must be such that it makes the crime conducive to extradition (in accordance with the European Convention on Extradition). The alternative to the penalty of imprisonment that countries can implement is a fine, but a fine that is of a sufficient size as to fulfill the purpose of punishment in accordance with the domestic law. Apart from penalties, countries can prescribe other measures such as: a) temporary or permanent prohibitions on exercising certain business activities, b) placement under court ordered surveillance and c) a court order for the dissolution of a company.[21] It is apparent that these measures represent the penalties that apply to legal persons. The existing criminal laws of Bosnia and Herzegovina prescribe virtually identical penalties for legal persons (apart from placement under court ordered surveillance, see Articles 131 and 137 of the CLB&H, Articles 111 and 116 of the CCRS, Articles 135 and 141 of the CLFB&H and Articles 135 and 141 of the CLBDB&H). Finally, every country should undertake all the necessary legislative and other measures in order to: 1) enable the seizure and confiscation of medical and pharmaceutical products, active substances, auxiliary substances, component parts, materials and equipment, as well as documents and other instruments used to commit illicit activities established in accordance with the Convention or to assist another person in committing such acts or financial gain realized by committing illicit activities or assets whose value matches that financial gain, 2) enable the destruction of seized medical and pharmaceutical products, active substances, auxiliary substances, component parts, materials and equipment which serve as the object of a criminal act established in accordance with the Convention and 3) undertake the appropriate measures in response to the punishable act with the aim of preventing future punishable acts.[22] The question of the seizure of assets used for committing a crime or assets that were obtained by committing a crime is appropriately regulated in the current legislature of Bosnia and Herzegovina in accordance with this Convention.[23]

[20] Article 12/1 of the Convention.

[21] Article 12/a/i-ii of the Convention.

[22] Article 12/b-c of the Convention.

[23] See: Articles 110-112 CCB&G, Articles 83-85 CCRS, Article 114-116 CCFB&H and Articles 114-116. CC BDB&H, and Jovašević D., Ikanović V. (2016). *Krivično procesno pravo Republike Srpske*. Banja Luka: Paneuropean University "Apeiron", 317–318, and Marković, I. (2010). Oduzimanje imovinske koristi. *Serbian Legal Thought*, 16 (42–43), 73–82.

Stages in felony commission and the status of an accomplice

The question of the status of an accomplice and attempt at a crime are specifically addressed in Article 9 of the Convention. Namely, the authors of the Convention wanted to establish special and separate crimes that are related to incitement or assistance as well as attempt. The Convention requires the parties to establish special crimes related to assistance and incitement to commit the crimes described in Articles 5-8. The majority (in fact almost all) signatory parties regulate the question of the status of an accomplice in the general parts of their substantive criminal laws, which raises the question of the justification of this demand. The justification could perhaps be found in the motivation to place emphasis on the need to penalize incitement and/or complicity as part of the norms that concern the criminalization of the actions described in the Convention in the process of the harmonization of national criminal laws. An abetter or an accomplice will be responsible when the presence of a subjective component or intention to commit a crime is established on their part.[24] In this sense, the concept of an accomplice matches the one in the criminal legislature of Bosnia and Herzegovina.[25] When it comes to the attempt to commit a crime from Articles 5 to 8 of the Convention, its authors prescribed special punishment for attempt (actually, it was stated that an attempt at these crimes should be criminalized as well but this requirement clashes with the purpose of certain institutes of the general part of criminal law). The interpretation of the attempt at committing a crime was left within the purview of domestic law, and the Convention does not deal with it in detail. The only thing that the Convention contains is the demand from the states to be able to attach significance to the difference between an attempt at committing a crime and, as stated in the Preamble to the Convention, "mere preparatory actions that do not justify punishment".

Precisely because of this significant incursion into the criminal justice sovereignty of signatory countries, the Convention left open the possibility for the signatory countries to place reservations against the provisions that are related to the attempt at committing a crime, a felony defined in Article 7 (counterfeiting documents) and Article 8 (similar crimes that involve threats

[24] Article 9/1 of the Convention.

[25] See: Babić, M., Marković I. (2019). *Krivično pravo, Opšti dio*. Banja Luka: Faculty of Law, University of Banja Luka, 286–290. For more details, see: Jovašević, D. (2019). Podstrekavanje u krivičnom pravu. *Legal word: A Journal of Legal Theory and Practice*, 60/2019, 33–59; Vasiljević, D. (2016). Saizvršilaštvo i teorija vlasti nad djelom – (mit)tatherschaftslehre. *Serbian Legal Thought*, 22 (49), 227–244; Jovašević, D. (2019). Saizvršilaštvo u krivičnom pravu. *Legal word: A Journal of Legal Theory and Practice*, 64/2021, 527–558.

to public health), due to potential differences in the legal systems of the signatory countries.

Ius puniendi

It is interesting that the Convention touched upon the question of the jurisdiction of the states in view of the application of their rights to punishment. Thereby, it is emphasized that the countries are obliged to secure the application of their substantive criminal law made compatible with the Convention to: a) their state territory, b) ships that sail under the flag of the country in question, c) aircrafts registered under the regulations of the signatory country, and d) the legal citizens of the signatory country or persons who have registered temporary or permanent residence on the territory of the signatory country.[26] Therefore, this is simply a matter of territorial jurisdiction of a country in relation to the application of its right to punishment (*ius puniendi*). Also, each party is obliged to ensure the establishment of its jurisdiction in cases when the victim of one of the crimes defined in this Convention is its legal citizen or a person with a registered permanent or temporary residence on the territory of the signatory country. The justification for the introduction of this provision can be found in the fact that one of the primary functions of criminal law is precisely the protective one. By means of criminal law mechanisms, the state protects its citizens (but also persons who find themselves on the territory of the country) from socially harmful behavior of other persons. In addition, the state is obliged to process the perpetrators of criminal actions defined in the Convention, i.e., to establish its jurisdiction even when there is no possibility of extradition to the country in which the crime was committed or whose citizen was the victim of the crime.[27]

The responsibility of legal persons

The Convention follows the contemporary trend of the recognition of, as it is stated "corporate responsibility", i.e., the responsibility of legal persons for criminal actions. The authors of the Convention were of the view that due to the seriousness of the crimes in the realm of medical crime, one should include the responsibility of legal persons. The intention of the creators of the Convention was that all legal persons (meaning primarily corporations but

[26] Article 10/1 of the Convention.

[27] Article 10/3 of the Convention.

also other legal persons such as foundations, alliances, societies, associations, etc.) should be held responsible for crimes that are committed by the authorized persons inside those organizations, and if they commit crimes through the misuse of the legal person in question or in order to acquire certain material benefits for that legal person. Natural persons in a legal person can commit a crime as lone actors or as parts of governing bodies inside a legal person on the basis of: (1) an authorization to represent the legal person, (2) an authorization to make decisions on behalf of the legal person, (3) an authorization to carry out supervision (monitoring) within a legal person.[28]

The Convention, therefore, prescribes the conditions, whose fulfillment makes the legal person responsible for a crime. These are the following four conditions: (1) one of the crimes defined in the Convention must be committed, (2) the crime in question must be committed for the benefit of the legal person, (3) a person in a decision-making position must be the perpetrator of a crime (regardless of whether they actually carried out the crime or they incited or aided another person in committing the crime) and (4) a person in a decision-making position must act in the domain of their authorities (whether they represented the legal person, were responsible for decision-making or carried out monitoring and supervision) and in addition, it must be proven that the person acted within their authority. All four conditions must be fulfilled cumulatively in order to make the legal person responsible for the crime. What is more, a legal person can be held responsible even if a person in a decision-making position did not commit a crime but another person who works for the legal person did. Namely, this case concerns the employees or legal representatives of the legal person who are acting within the domain of their authorization. Of course, in this case the following conditions have to obtain cumulatively: (a) the crime must be committed by an employee or a legal representative of the legal person, (b) the crime must be committed for the benefit of the legal person, (c) the criminal activity must have occurred due to a mistake on the part of a person in a leadership position or on the part of a person responsible for the supervision or monitoring of employees or legal representatives (in this context, the provision should be interpreted as the failure of due diligence that would prevent the employee or representative from committing the crime on behalf of the legal person and these responsibilities and steps are evaluated on a case-by-case basis).[29]

[28] Article 11/1/a-c of the Convention.

[29] Article 11/2 of the Convention. For more details, see: Stojanović, Z. (2010). Odgovornost pravnih lica za krivična djela. Presentations of the participants of the *Seminar o odgovornosti pravnih lica za krivična djela i praćenju, oduzimanje i povraćaju dobara*, Kolašin: Office of the Anti-Corruption Initiative, October 21–24, 2009, and Šuput, J. (2009). Odgovornost pravnih lica za krivična dela. *Foreign Legal Life*, 1/2009, 169–189.

The criminal law of Bosnia and Herzegovina has been expanded to include the responsibility of legal persons during the reforms from 2003 in the form of the laws that regulate substantive criminal legislation (CCB&H, CCRS, CCFB&H and CCBDB&H). The concept that a legal person can be responsible only when the crime was committed on behalf or for the benefit of the legal person. We see the following elements as the basis of criminal responsibility of legal persons in the legislation of Bosnia and Herzegovina: (1) when the essence of a committed crime stems from a conclusion, decision, order or permission of the leadership or supervisory bodies in a legal person, (2) or when the leadership or supervisory bodies of a legal person impacted a person or enabled them to commit the crime, (3) or when the legal person makes use of illegally acquired assets or utilizes instruments that were created in a criminal manner and (4) when the leadership or supervisory bodies in a legal person failed to apply due diligence over the legality of their employees' work.[30]

Aggravating circumstances

The Convention obliges the signatory parties to adjust their substantive criminal law with Article 13 of the Convention which concerns the aggravating circumstances. Upon deciding on the punishment for the perpetrator of a crime from Articles 5–8 of the Convention, the following aggravating circumstances can be taken into account: 1) the illicit act resulted in death or damage to the victim's physical or mental health, 2) the illicit act was committed by persons who abused the victim's trust given to them as experts (e.g. physicians, pharmacists), 3) the illicit act was committed by persons who abused the victim's trust given to them as producers of medical or pharmaceutical products, 4) a criminal act of supplying or offering to supply was committed by reporting to means of wider distribution such as information systems, including the internet, 5) the crime was committed through a criminal organization and 6) the perpetrator was already sentenced for crimes of the same nature.[31] It is important to state that circumstances that are included in the definition of the crime will not be taken as aggravating circumstances. National courts are allowed to decide whether they will include a particular element as an aggravating circumstance on a case-by-case basis but the court is not obliged to

[30] See Article 124 CCB&H, Article 105 CCRS, Article 128 CCFB&H and Article 128 CCBDB&H and Simović, M. N., Jovašević, D., Simović, V. M. (2016). *Privredno kazneno pravo*. East Sarajevo: Faculty of Law, University of East Sarajevo, 37-38 and Ikanović, V. (2012). *Odgovornost pravnih lica za krivična djela*. Banja Luka: International Association of Academic Workers – AIS, 248–255.

[31] Article 13 of the Convention.

apply them (consequently, across Europe, there are several difference concepts related to the aggravating circumstances and there are significant differences in legal systems and their basic principles).

The provisions from Article 13 of the Convention regulate the question of aggravating circumstances. The signatory countries are expected to adjust their national legislations in accordance with these provisions of the Convention, i.e. to introduce specifically defined aggravating circumstances that should (but do not have to) be taken into account upon determining a punishment for the perpetrator of a crime on the part of national courts (the Convention uses the phrase "can take into account"). A court from a signatory country is allowed to punish a perpetrator of a crime more severely if a) the committed crime resulted in death or serious damage to physical and mental health of a physical person, b) the crime was committed by professionals or experts who have abused the trust given to them based on their status, c) a crime was committed through the abuse of trust by a producer or supplier, d) crimes of supplying and offering to supply were committed through the use of the means of wide distribution, such as information systems, including the internet, e) the crime was committed by a criminal organization and f) the perpetrator of the crime has previously been sentenced for the crimes of the same kind (Article 13 of the Convention). The aggravating circumstances can be taken into account only when they are not especially prescribed as aggravated circumstances for crimes defined in the legislatures of the signatory members. The first aggravating circumstance relates to the violation of the most significant value protected by law, namely, human life. If an illegal act committed by a person (by committing a crime from Articles 5-8 of the Convention) resulted in death of a natural person or the consequence of the use of counterfeit medical and pharmaceutical products was a serious damage to the physical but also psychological health of a natural person, the perpetrator can be punished more severely. Of course, national courts are obliged to determine the existence of a causal relationship between the consequence that occurred and the use of counterfeit medical products. The second aggravating circumstance refers to the abuse of trust given to the perpetrator by the victims or the trust that a passive subject had in their professional capacities and expertise. This is primarily concerned with the crimes committed by physicians, pharmacists and other medical staff (even though other professions are not excluded). The third aggravating circumstance is that the crime was committed through the abuse of trust given to the perpetrators as producers and suppliers (we are of the view that this circumstance does not need to be clarified further). The fourth aggravating circumstance is when the crime of supplying and offering to supply was committed through the use of large scale distribution, including information technology systems (this primarily refers to

the distribution/sale of mostly cheap, counterfeit medicine and other medical products via the internet which contributes to the easier spread of counterfeit goods in all parts of the world and the perpetrators of these crimes who use web pages to advertise and sell their products can easily be traced and identified). The fifth aggravating circumstance is the commission of a crime on the part of a criminal organization, i.e. an organized criminal group formed specifically to carry out serious crimes for profit, i.e. for material gain, power and influence. The authors of the Convention emphasized that a criminal organization should be interpreted in the sense of the provisions of organized crime which define an organized criminal group as a "structured group consisting of three or more people which has existed for a longer period of time in order to engage in repeated criminal activities described in the Convention with the goal of obtaining, directly or indirectly, financial or other form of gain".[32] The sixth and final aggravating circumstance is linked to recidivism, or repeated criminal activity. It is emphasized that persons who return to the same crimes or crimes of the same kind should be punished more severely (which represents the basis for a national policy of suppressing crime existing in any state, or this at least should be the case).

Counterfeiting medical and other products and their sale is a growing criminal market (industry) populated by transnational organized criminal groups. It happens quite frequently that members of a criminal organization (or individuals – perpetrators of crimes) are sentenced for criminal activities in two or more countries. National legislatures prescribe more severe sanctions for repeated felons, which has already been discussed. However, the question is whether a person will be considered a repeated felony if they have been officially sentenced for a crime in one country while being tried for the same crime described in the Medicrime Convention. Traditional legal theory stands at the position that the previous sentences of foreign courts should not be taken into account upon weighing a sentence because criminal law is primarily national law (because there are significant differences in criminal laws of different countries) and criminal sentences are, as a rule, tied to the country in which the person was tried. Traditional considerations should be avoided to a smaller or lesser degree because of the internationalization of crime which can receive a proper response only through an international effort. Over time, the international community has adopted an array of instruments which internationalize criminal law (e.g. the UN Convention on Transnational Organized Crime, the Convention on Cybercrime from 2001, the New York Convention on Narcotic Drugs from 1961 and others). Some of those instruments contain

[32] Mijalković, S., Bajagić, M. (2012). *Organizovani kriminal i terorizam*. Belgrade: University of Criminal Investigation and Police Studies, 26.

principles on international extradition. Namely, in Article 36 of the New York Convention on Narcotic Drugs, it is prescribed that national courts must take into account foreign sentences when it comes to repeated felons (of course, in accordance with their constitutional and legal systems and national laws). In relation to this, the MEDICRIME Convention prescribes that national courts should take into account all enforceable decisions of foreign courts upon weighing a sentence if according to domestic laws doing so would result in a more severe punishment. This would further entail that the court will take into account convictions or acquittals of foreign courts as well as other decisions which the courts made during criminal procedures.[33] In the explanations of this position on the part of the authors of the Convention, it is stated that this does not produce a positive obligation for the courts and prosecutors of the signatory countries to undertake steps of any kind in order to establish whether a person has been sentenced or if there is a criminal investigation against them in some other country in relation to the crimes described in the Convention because this is not explicitly prescribed.[34] However, courts and prosecutors of the signatory countries which are simultaneously signatories of the European Convention on Mutual Assistance in Criminal Matters are entitled to request data from foreign legal bodies which are relevant for the investigation that they are carrying out, i.e. for the criminal procedure itself. In that case, if there is a probability that a person has engaged in transnational crimes, courts and prosecutors have the obligation to investigate that.

CONCLUSION

The Convention of the Council of Europe on the Counterfeiting of Medical (Pharmaceutical) Products and Similar Crimes represents a valuable instrument from the legal standpoint because it provides a solid legal framework for the protection of the most vulnerable social groups or patients and users of medical equipment (which was especially obvious during the COVID-19 pandemic). This international instrument prescribes adequate international cooperation among the signatory members as well as between countries and international organizations (Council of Europe, WHO). A framework for coordinating national and international bodies which are concerned with legal, security and healthcare matters was established. Counterfeit medical products (drugs, active substances, auxiliary substances, medical equipment, supplies, etc.) can lead to serious consequences for human life and health. Their

[33] Article 14 of the Convention.

[34] *Explanatory Report CoE* 2011.

consequences can range from the filling up of hospital capacities of a particular country due to damages done to the health of its citizens up to the loss of life. The Convention that has been presented in this article is a unified response to this threat that has reached global proportions.

The Convention is open to all parties: members of the Council of Europe, observers in the Council of Europe, the European Union, as well as non-members. Up to the present moment, the Convention has been ratified and implemented in 19 countries (which is, we dare say, a disappointing number given the fact that the Council of Europe has 47 members), which breaks down into 15 members of the European Council and 4 non-members. Bosnia and Herzegovina adopted the Convention in 2015 and ratified it in 2020, while it officially came into power towards the beginning of 2021. By adopting this important international agreement, Bosnia and Herzegovina has undertaken certain obligations. These obligations are related to the incrimination of certain actions (if such incriminations do not exist in the national legal tradition), the adjustment of the criminal procedural law to the provisions of the Convention, the improvement of international legal assistance and the protection of the victims of crimes defined in the Convention. We are now in 2022 and the COVID-19 pandemic is approaching its end, but Bosnia and Herzegovina has not yet fulfilled (completely) its obligations under international law. The pandemic that had encompassed the world a little over two years ago has shown us that the mechanisms prescribed in the MEDICRIME Convention are absolutely necessary. Regardless of its particular state structure, an oversized administrative system and a conflict about the distribution of authority, the changes that the Convention requires of Bosnia and Herzegovina are relatively small, which is why the above mentioned circumstances cannot be the excuse for avoiding to protect the most vulnerable groups in the society - patients and those who have to use some type of medical product. This represents only the criminal legal aspect of the solution to this problem. Other aspects are related to allowing citizens access to legitimate medical products and equipment and this can be the subject of a debate. Finally, the Convention represents the foundation for a broader development of one relatively new but increasingly differentiated area - medical criminal and penal law.

The criminal law (or laws) of Bosnia and Herzegovina has, to a large extent, been made compatible with the Convention. Nonetheles, there are certain shortcomings that can be overcome with relatively small legislative interventions. The CCB&H satisfies the standards prescribed in the Convention in its general and specific parts, while, on the other hand, the laws of the two entities and Brčko District do not contain certain incriminations in their specific parts even though the general parts of the law are compatible with the standards of the Convention (and are perhaps even better). We believe that

the response of the criminal justice system of Bosnia and Herzegovina would be much better if the entities and Brčko District included the incrimination of smuggling into their laws in order to cover Article 6 of the Convention. On the other hand, the legislators of the entities and Brčko District should consult Article 5 in order to make the substances of certain crimes closer to the incrimination contained in Article of the Convention. When it comes to the crime of counterfeiting documents from Article 7 of the Convention, the conclusion that we can reach suggests that the laws of the entities and the law of Brčko District meet all the standards of the Convention, while the CCB&H does not contain such an incrimination. We are of the view that as long as this incrimination exists in the laws of the two entities and Brčko District in the context of the Convention, there is no need to prescribe it in the federal law even though such an option could be considered in the future (if court practice before the authorized bodies of the two entities and Brčko District does not produce adequate results).

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