

# THE SETTING UP OF A 24/7 NETWORK WITHIN THE MEDICRIME CONVENTION



Feasibility study

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Cover design and layout: Documents  
and Publications Production Department  
(SPDP), Council of Europe

Photo: Shutterstock

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Printed at the Council of Europe

*This report has been prepared within the framework of the Council of Europe project entitled Needs Assessment – Falsified Medical Products (NA-FAMED).*

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# 1. BACKGROUND AND CONTEXT

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## 1.1. Purpose of the study

This study has been prepared as part of the Council of Europe project entitled Needs Assessment – Falsified Medical Products (NA-FAMED) to examine the feasibility of creating a network of national focal points available on a twenty-four hour, seven-day-a-week (24/7) basis, to contribute to the achievement of the objectives of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211, MEDICRIME Convention).

The study will be used during consultations of the Committee of the Parties to the MEDICRIME Convention on the adoption of recommendations or guidelines relating to the organisation of a network of 24/7 focal points, with a view to improving the operational and judicial aspects of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, as well as the exchange of information in this field between the parties to the MEDICRIME Convention. The consultations should establish the organisational and logistical aspects of the envisaged system. This document seeks to determine the authorities that are able to host national 24/7 focal points and the capabilities, responsibilities and working procedures expected of those authorities, in accordance with the relevant provisions of the MEDICRIME Convention.<sup>1</sup>

## 1.2. Short presentation of the MEDICRIME Convention<sup>2</sup>

In the preamble to the convention and in Article 1, it is stated that the purpose of the convention is to prevent and combat threats to public health by providing for the criminalisation of certain acts, protecting the rights of victims of the offences established under the convention, and promoting national and international co-operation.

The focus of the convention is on the protection of public health. It does not cover issues related to the infringement of intellectual property rights in relation to the counterfeiting of medical products, active substances, excipients, parts and materials, which are generally adequately protected at both national and international levels. However, this approach is without prejudice to any possible criminal prosecution of infringements of intellectual property rights that may result from conduct criminalised under the convention, as stated in paragraph 20 of the explanatory report<sup>3</sup> to the convention.

Article 3 covers the scope of the convention, which concerns medical products, whether or not they are protected under intellectual property rights or are generic, including accessories intended for use together with medical devices, as well as active substances, excipients, parts and materials intended for use in the production of medical products. Article 4 contains the definitions that will be used when applying the provisions of the convention.

### 1.2.1. Substantive law and investigative (procedural) powers

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Chapter II on substantive criminal law, in particular Articles 5 to 7, calls on parties to take measures at the national level to criminalise the following unlawful acts, when committed intentionally: manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories and, as appropriate, any adulteration thereof; supplying, offering to supply, and trafficking in counterfeits; and making of false documents or the act of tampering with documents.

Each article also provides for the possibility of declaring a reservation with respect to the criminalisation of the specific acts foreseen, either in full or on certain conditions, or in cases regarding excipients, parts and materials or the documentation relating to them. Article 8 of the convention provides for the criminalisation of similar unlawful acts, when committed intentionally, insofar as such activities are not covered by Articles 5, 6 and 7.

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1. Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, CETS No. 211, Moscow, 28 October 2011.
  2. See: <https://rm.coe.int/168008482f>.
  3. See: <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016800d383b>.

Lastly, Article 9 calls for parties to take measures to establish as offences, when committed intentionally: aiding or abetting the commission of any of the offences established in accordance with the convention, or attempting to commit any of the said offences. Article 9, also provides for the possibility of declaring a reservation with respect to criminalisation of the attempt to commit any of the offences established in accordance with Articles 7 and 8.

As stated in paragraph 92 of the explanatory report, the aggravating circumstances set out in Article 13 may be taken into consideration in determining the sanctions for offences established under the convention, if they do not already form part of the constituent elements of the offences, as adopted in the implementation procedure under domestic law. To ensure that a previous conviction is to be taken into account in the sentencing phase of a trial before a national court, the convention provides for the obligation to take it into consideration, irrespective of which court, national or foreign, previously passed the final sentence (Article 13.f and Article 14).

Corporate liability and the applicable sanctions and measures are dealt with in Articles 11 and 12 of the convention.

Chapter III (Investigation, prosecution and procedural law), which provides for measures to be taken by the parties to ensure the effective investigation or prosecution of the offences established in Chapter II, is of great importance. In particular, Article 15 is designed to enable the *ex officio* investigation or prosecution of offences as a general rule; should a national system provide for a different option, criminal proceedings must be allowed to continue even if the complaint is withdrawn. As stated in paragraph 106 of the explanatory report, the purpose of this provision is to facilitate prosecutions, in particular by ensuring the continuation of criminal proceedings regardless of pressure or threats against victims by the perpetrators of offences.

Furthermore, to confirm the principle of effective investigation or prosecution, Article 16 provides for the adoption of measures at the national level that ensure, on the one hand, that persons, units or services in charge of criminal investigations are specialised in combating the counterfeiting of medical products and similar crimes involving threats to public health, or that persons are trained for this purpose, including financial investigations, and, on the other hand, the carrying out, where appropriate, of financial investigations, covert operations, controlled delivery and other special investigative techniques by the competent authorities. Such activities could encompass, as detailed in paragraphs 109-110 of the explanatory report, electronic and other forms of surveillance as well as infiltration operations. As indicated by the wording “where appropriate”, parties are not legally obliged to apply any or all of these investigative techniques, but if a party chooses to conduct investigations using these special techniques, the principle of proportionality, as referred to in the preamble to the convention, will also apply.

### **1.2.2. Co-operation mechanisms at national and international levels**

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Recognising the complexity of the threats and dangers to public safety posed by commission of the offences established by the convention, and recognising that preventing and combating such acts is not one’s task, Article 17 provides for co-operation and information exchange between the national competent authorities. As stated in paragraph 111 of the explanatory report, networking at national level based on a multidisciplinary and multisectoral approach is a key element in the fight against counterfeiting of medical products and similar crimes.

The convention leaves it to the parties to decide how this national co-operation is to be implemented while respecting the role and competences assigned to each authority, bearing in mind that the forms of assistance that could be provided are heterogenous but have the same objective: preventing and combating effectively the counterfeiting of medical products and similar crimes involving threats to public health.

Such national co-operation may rely on existing general procedures governing each authority that allow for the interinstitutional exchange of information or, in accordance with Article 17, on a more formalised, detailed or dedicated procedure that may be adopted in the implementation of the convention.

At the international level, the convention provides for two different mechanisms for international co-operation; on the one hand, international co-operation in criminal matters based on the provisions of the convention, in pursuance of relevant applicable international and regional instruments and arrangements agreed on the basis of uniform or reciprocal legislation and the parties’ domestic law, to the widest extent possible, for the purpose of investigations or proceedings concerning the offences established in accordance with the convention, including seizure and confiscation; and on the other hand, international co-operation with respect to prevention and other administrative measures.

The latter, foreseen in Article 22, provides firstly for international co-operation with respect to protecting and giving assistance to victims and, secondly, for the designation of a national contact point “which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health”.

Paragraph 134 of the explanatory report explains that Article 22, paragraph 1, covers only administrative measures related to the protection or assistance given to victims and does not concern international co-operation in criminal matters.

Related to designation of a national contact point, as in Article 22, for receiving requests for information and/or cooperation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health, As explained in paragraph 135 of the explanatory report, the role and purpose of the above-mentioned national contact point are to be defined outside the scope of international co-operation in criminal matters, and established without prejudice to the internal reporting systems of the parties.

The convention leaves it to the parties to determine the internal organisation of the point of contact, the type of information to be collected and the mechanism for transmission of such information.

### **1.2.3. Other relevant provisions**

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Chapter VI of the MEDICRIME Convention provides for legislative and other measures to be taken at the national level to protect the rights and interests of victims of an offence established in accordance with the convention. In particular, as detailed in Article 19, the measures should ensure: victims’ access to information relevant to their case and which is necessary for the protection of their health; the provision of assistance for victims in their physical, psychological and social recovery; and, last but not least, parties are asked to foresee in their domestic legislation the right of the victims to compensation from the perpetrators of offences.

Moreover, Article 20 requires the parties to take complementary measures at the national level related to the standing of victims in criminal investigations and proceedings, among them the right to be informed, to supply evidence and to choose the means of having their views, needs and concerns presented, to receive appropriate support services so that their rights and interests are duly presented and considered, and to be provided with effective measures for their safety, as well as that of their families and witnesses on their behalf, from intimidation and retaliation. Paragraphs 2 to 5 of Article 20 define more specific rights and measures for the victims of offences established in accordance to the convention, by requiring that parties grant victims the right to free legal aid when they can be parties to criminal proceedings; that victims may, with their consent, receive assistance or support from groups, foundations, associations or governmental or non-governmental organisations during criminal proceedings concerning the offences established in accordance with the convention; and that parties ensure that victims may lodge a complaint before the competent authorities of their state of residence even if the offence was committed in the territory of another party to the convention.

Chapter VIII of the MEDICRIME Convention is dedicated to the follow-up mechanism described in Article 23, and the composition of the Committee of the Parties or the appointment of other relevant representatives as laid down in Article 24. Relevant for the scope of this study are the provisions of Article 25 related to the functions of the Committee of the Parties with respect to:

- ▶ monitoring the implementation of the MEDICRIME Convention;
- ▶ facilitating the collection, analysis and exchange of information, experience and good practice between states to improve their capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health;
- ▶ facilitating the effective use and implementation of the convention, including the identification of any problems and the effects of any declaration or reservation made under the Convention;
- ▶ expressing opinions on any question concerning the application of the convention and facilitating the exchange of information on significant legal, policy or technological developments;
- ▶ making specific recommendations to parties concerning the implementation of the convention.

Based on these numerous functions, the Committee of the Parties may also give its interpretation of certain articles if relevant for the implementation of the MEDICRIME Convention.





## 2. EXPERIENCE OF THE 24/7 NETWORK ESTABLISHED UNDER ARTICLE 35 OF THE CONVENTION ON CYBERCRIME

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### 2.1. Framework

Article 35<sup>4</sup> of the Convention on Cybercrime (CETS No. 185, Budapest Convention)<sup>5</sup> provides that each party to the convention should designate a point of contact available on a 24/7 basis, in order to ensure the provision of immediate assistance for the purpose of investigations or proceedings concerning criminal offences related to computer systems and data, or for the collection of evidence in electronic form of a criminal offence.

According to the Article 35, such assistance shall include facilitating, or, if permitted by its domestic law and practice, directly carrying out the following measures:

- ▶ the provision of technical advice;
- ▶ the preservation of data pursuant to Articles 29 and 30;
- ▶ the collection of evidence, the provision of legal information, and location of suspects.

The above-mentioned article specifies the duties of the contact point stating that: “[i]f the point of contact designated by a Party is not part of that Party’s authority or authorities responsible for international mutual assistance or extradition, the point of contact shall ensure that it is able to co-ordinate with such authority or authorities on an expedited basis”.

The same article provides that each party shall ensure the availability of trained and equipped personnel to facilitate the operation of the network and the point of contact should have the capacity to carry out communications with the point of contact of another party on an expedited basis.

As stated in paragraph 300 of the explanatory report to the Budapest Convention,

[e]ach Party is at liberty to determine where to locate the point of contact within its law enforcement structure. Some Parties may wish to house the 24/7 contact point within its central authority for mutual assistance, some may believe that the best location is with a police unit specialised in fighting computer – or computer-related [–] crime, yet other choices may be appropriate for a particular Party, given its governmental structure and legal system. Since the 24/7 contact is to provide both technical advice for stopping or tracing an attack, as well as such international co-operation duties as locating of suspects, there is no one correct answer, and it is anticipated that the structure of the network will evolve over time. In designating the national point of contact, due consideration should be given to the need to communicate with points of contacts using other languages.

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4. Article 35 – 1. Each Party shall designate a point of contact available on a twenty-four hour, seven-day-a-week basis, in order to ensure the provision of immediate assistance for the purpose of investigations or proceedings concerning criminal offences related to computer systems and data, or for the collection of evidence in electronic form of a criminal offence. Such assistance shall include facilitating, or, if permitted by its domestic law and practice, directly carrying out the following measures:
    - a. the provision of technical advice;
    - b. the preservation of data pursuant to Articles 29 and 30;
    - c. the collection of evidence, the provision of legal information, and locating of suspects.
  2. a. A Party’s point of contact shall have the capacity to carry out communications with the point of contact of another Party on an expedited basis.
    - b. If the point of contact designated by a Party is not part of that Party’s authority or authorities responsible for international mutual assistance or extradition, the point of contact shall ensure that it is able to co-ordinate with such authority or authorities on an expedited basis.
    3. Each Party shall ensure that trained and equipped personnel are available, in order to facilitate the operation of the network.
  5. Convention on Cybercrime, CETS No. 185, Budapest, 23 November 2011. See : <https://rm.coe.int/1680081561>.

## 2.2. Competences of the 24/7 point of contact established under Article 35 of the Convention on Cybercrime

The enumeration of competences set forth in Article 35 of the Budapest Convention is broad and includes the most important requirements related to an investigation concerning a cyberoffence or related to electronic evidence. As a consequence, it is desirable to provide:

- ▶ immediate assistance:
  - for the purpose of investigations or proceedings concerning criminal offences related to computer systems and data; or
  - for the collection of evidence in electronic form of a criminal offence.

Such assistance shall include facilitating or, if permitted by its domestic law and practice, directly carrying out the following measures:

- ▶ the provision of technical advice;
- ▶ the preservation of data pursuant to Articles 29 and 30;
- ▶ the collection of evidence, the provision of legal information, and location of suspects.

If the competences related to international co-operation are not provided by national law and practice, it is highly desirable that the 24/7 point of contact is able to co-ordinate rapidly with an authority entitled to provide mutual legal assistance.

The tasks entrusted to the 24/7 point of contact under Article 35 represent a modern way of handling the needs of complex cybercrime investigations that require continuous availability, immediate action and specific skills when the assistance relates to electronic evidence.

Although there is no particular description of the skills expected of a 24/7 point of contact, these should include, but not be limited to, the ability to deal with:

- ▶ technical aspects of a computer-related crime;
- ▶ particularities of a crime that arise from the fact that a computer system was used to commit it;
- ▶ specific features of electronic evidence such as its volatility or its easily falsifiable character;
- ▶ the location of evidence, which is sometimes undetermined or hard to determine;
- ▶ the manner of obtaining electronic evidence, and the conditions and format that make it admissible under the law, etc.;
- ▶ legal aspects of and proceedings in criminal matters;
- ▶ legal aspects related to transferring evidence in the context of mutual legal assistance;
- ▶ different levels of understanding of foreign languages (reading, writing), though English is the language most used for correspondence;
- ▶ poor quality translations;
- ▶ different means of communication;
- ▶ different ways of summarising facts (sometimes the information received is too concise to fully understand what is needed and why it is needed, and what crime has been committed);
- ▶ differences in the interpretation of legal or technical terms;
- ▶ immediate action.

In practice, a 24/7 point of contact should be able to register and process on the same day requests for technical assistance, information on legal matters or preservation orders. If the answer requires more time, an immediate response may well be simply an acknowledgment of receipt. Ideally, this should summarise how the request will be handled, what results can be expected, how long it will take and, if the point of contact is not authorised to execute the request, the contact details of the person to which the request should be addressed, or any other useful information.

If the 24/7 point of contact is in a position to handle the request, but it does not contain the necessary information, it is advisable to request additional information promptly, as time is a critical factor in such investigations.

The use of the 24/7 point of contact to deal with urgent matters does not mean that requests with normal priority should be delayed. In all cases, it is important to remember that someone, such as an investigator, prosecutor or magistrate, is waiting for the response, a case needs to be solved, a victim needs redress or a life needs to be saved.

By following this approach, the formalistic view of assistance in criminal matters becomes dynamic.

The 24/7 point of contact as a communication channel is not meant to be used to bypass the customary means of communication with respect to mutual legal assistance in criminal matters. However, the possibility of executing or facilitating the execution of a request for mutual legal assistance is intended to complement efforts to provide rapid and extensive mutual legal assistance in criminal matters, particularly in cases of cybercrime and with respect to electronic evidence.

In the same way, this approach brings together professionals from different judicial and law-enforcement areas who, until recently, exercised their exclusive competences in an isolated manner.

### **2.3. State of play as reflected in the documents adopted by the Cybercrime Convention Committee (T-CY)<sup>6</sup>**

The study concluded in 2009<sup>7</sup> by the Council of Europe on the functioning of 24/7 points of contact for cybercrime revealed the diversity of structures and locations of these point of contacts, both in terms of their powers and with respect to their position in the national judicial organisational structure. In more than 85% of the countries that replied to the study, the 24/7 point of contact was located hierarchically under the Ministry of Interior, while it was located within the prosecution service in only a few countries.<sup>8</sup>

Without prejudice to the decision made by the national authorities regarding the location of the 24/7 point of contact, the two options of establishing it within a police body or a prosecution service each have advantages and disadvantages.

Strong points in favour of a police body were found to be in terms of organisation, staff, infrastructure, skills and training, which are more well established than those within prosecution services. On the other hand, prosecution services have powers given to them by law, such as the ability to handle mutual legal assistance requests or expedited preservation orders, although technical skills may be less developed. Subsequent assessments by the T-CY<sup>9</sup> have shown that mutual legal assistance and the useful role of the 24/7 points of contact are key factors in the investigation of cybercrime and with respect to electronic evidence in general.

One interesting point revealed by the 2009 study was the fact that when the 24/7 contact point's functions are entrusted to an existing body with the authority to investigate or prosecute cybercrime and to engage in international law enforcement co-operation, no separate legal basis is required. This seems to be the case in most countries. The national law on the ratification of the Budapest Convention and the declarations made with regard to Article 35 may also serve as a legal basis. From another perspective, the study also revealed that a specific legal basis may give the contact point more responsibility and make it more accountable for results achieved. It may also make it known at the national level thus facilitating co-operation with the national authorities, and may give it, if the legal system allows, powers for preservation and for dealing with mutual legal assistance requests.

In 2013, after a comprehensive effort to corroborate all the information gathered from the participating countries, the T-CY adopted the assessment report on the implementation of the preservation provisions of the Budapest Convention. The issue of the establishment and powers of the 24/7 point of contact were raised again in this context, and the results seemed to satisfy the requirements of the convention's provisions on mutual legal assistance, the object of the assessment, but once again revealed weaknesses with regard to competences

6. See Article 46 of the Budapest Convention.

7. See: <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016802fa3be>.

8. In the USA, the contact point is a prosecution service under the Department of Justice. Romania has two contact points, one prosecution service within the Prosecutor's office attached to the High Court of Cassation and Justice, which has been formally created by law, and a second one within the criminal police body. The contact point in Norway is a hybrid type in that it is a police body with judicial, prosecutorial functions.

9. See: <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016802e722c>; <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016802e726c>.

of the 24/7 point of contact in mutual legal assistance matters.<sup>10</sup> The T-CY assessment report on mutual legal assistance provisions of the Budapest Convention was adopted in December 2014 at the 12th Plenary meeting. The preliminary conclusion with respect to 24/7 points of contact was that unless they themselves have the authority to send, receive or execute Article 31-type mutual legal assistance requests, they should at least have the capability to facilitate swift execution of such requests.

Nevertheless, the findings pointed out the fact that the 24/7 points of contact of approximately half of the states questioned (36) replied they have competence to send or receive requests for mutual assistance. Some may also serve as channels for transmission only, such as Bosnia and Herzegovina, Estonia, Hungary and the Netherlands, while others can issue and execute rogatory letters, or supervise or participate in the execution of requests for mutual assistance (Costa Rica, Cyprus, Finland, Georgia, Lithuania, Norway, Romania, Serbia, North Macedonia and the United Kingdom). Finally, direct communication and regular liaison between 24/7 contact points and authorities responsible for executing mutual legal assistance requests were reported by Albania, Armenia, Australia, Austria, Bulgaria, Estonia, Japan, the Netherlands, Romania and Slovakia.

It was also highlighted that in a number of states there is a risk of a disconnection between the point of contact and the authorities responsible for mutual legal assistance. For example, the points of contact may not be informed as to whether or not preservation requests are followed up by mutual legal assistance requests, or practical arrangements for rapid co-ordination may not yet have been established between points of contact and the mutual legal assistance authorities.

## 2.4. Countries' practical experience

### 2.4.1. Romania

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#### 2.4.1.1. Primary 24/7 point of contact within the Prosecutor's Office

The Romanian 24/7 point of contact was established within the Prosecutor's Office attached to the High Court of Cassation and Justice by Article 62 of Law No. 161/2003. The Service for Combating Cybercrime was situated within the Organised Crime Fighting and Anti-Drug Section. In addition to the investigation of cybercrime cases, the service's competences encompass the duties foreseen in Article 35 of the Budapest Convention:

- ▶ provision of specialised assistance and information on Romanian legislation in the domain;
- ▶ ordering the expeditious preservation of data as well as the seizure of the objects containing computer data or the data regarding the data traffic required by a competent foreign authority;
- ▶ executing or facilitating the execution of letters rogatory in cases of cybercrime and in this respect co-operating with all the competent Romanian authorities.

In 2004, the Organised Crime Fighting and Anti-Drug Section was reorganised and the Service for Combating Cybercrime was incorporated into a new structure, the Directorate for Investigating Organized Crime and Terrorism. The competences of the service remained unchanged.

To summarise, the Service for Combating Cybercrime has nationwide investigative jurisdiction for cybercrime cases, orders for expedited preservation according to Articles 29-30 of the Budapest Convention, executing or facilitating the execution of mutual legal assistance requests and working directly with the International Judicial Assistance Service with the Directorate or with the specialised service within the Prosecutor's Office attached to the High Court of Cassation and Justice.

Specifically, the 24/7 point of contact plays the role of:

- ▶ intermediary to the investigative national authorities and similar foreign authorities for the purpose of securing evidence, especially e-evidence, such as subscriber information, traffic data or content data;
- ▶ advisor to the investigative national authorities in international co-operation matters and to similar foreign authorities on effective measures to be taken for obtaining e-evidence or the effectiveness of such measures;

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10. See: <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016802e726c>.

All parties questioned (33) have established such points of contact. Some of these seem to be active in sending, receiving and following up international preservation requests. Others are less active, even though they have the necessary powers. A number of points of contact are not able to send, receive or follow up on international requests as the domestic legal basis for preservation is weak or involves a formal mutual legal assistance procedure.

- ▶ requested authority in the execution of complex cybercrime mutual legal assistance requests;
- ▶ an investigative unit participating in joint or parallel investigations with other similar foreign authorities, if necessary.

With regard to the specific attributes of the 24/7 point of contact as provided in Article 35 of the Budapest Convention, the Romanian 24/7 point of contact:

- ▶ provides a single point of contact, irrespective of the substantive jurisdiction;
- ▶ has the authority of a service, not of a single person (there are more than 10 prosecutors);
- ▶ provides for a mandatory order of replacement for prosecutors (prosecutor-in-charge and substitutes);
- ▶ has a dedicated e-mail address and telephone number;
- ▶ uses a template for preservation requests (when Romania is a requesting authority);
- ▶ sends a standard feedback message to the requesting authority.

#### **2.4.1.2. Secondary 24/7 point of contact within the specialised police unit**

In acknowledgment of the benefits existing within the specialised cybercrime police unit in respect of technical skills and staff, Romania decided to establish a secondary point of contact within the Cybercrime Unit that is part of the Directorate for Combating Organized Crime of the General Inspectorate of the Romanian Police.

Due to the fact that in Romania the police have limited competences in matters of mutual legal assistance, preservation orders, or provisions related to the collection of evidence, the point of contact is mainly responsible for completing the communication and advisory work on technical problems arising from incoming requests received directly or through the 24/7 point of contact of the Prosecutor's Office.

### **2.4.2. Serbia**

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#### **2.4.2.1 General considerations**

The 24/7 point-of-contact system in Serbia regarding cybercrime is based on the provisions of Article 35 of the Budapest Convention and by regulations of the competent authorities for the suppression of the cybercrime. At the moment, there are no special laws or by-laws which specifically stipulate the existence of this particular system, but this is foreseen in the forthcoming changes to the criminal justice framework for combating cybercrime.

However, this does not mean that the 24/7 point-of-contact-system in accordance with Article 35 of the Budapest Convention does not exist. On the contrary, Serbia is currently one of the few countries in the world which is implementing the so-called "dual contact point system", which includes both police and prosecution services. Both authorities have organised their human and technical resources to be able to respond immediately to the communications and requests from the above-mentioned 24/7 system.

This is made possible to a certain extent by the existence of a specific Law on the Organization and Jurisdiction of the State Authorities for Combating High-Tech Crime, which was adopted in 2005 and enacted in 2006. This special law lays the foundations for the organisation of the specific and specialised state authorities responsible for the suppression of cybercrime and cyber-related crime and their substantive and territorial jurisdiction, which extends to the whole country.

The competences of the specialised cybercrime authorities and their organisation and structure are determined by law. Strictly speaking, it does not contain substantive, procedural or international provisions on legal assistance, but rather defines the specific organisational framework for the functioning of the specialised authorities, which are:

- ▶ the police department specialised in combating high-tech crime, at present the Department for Cybercrime within the Ministry of the Interior's Service for Combating Organized Crime;
- ▶ the Special Prosecutor's Office for High-Tech Crime;
- ▶ the court department specialising in high-tech crime cases, currently made up of judges specialising in these legal issues.

#### **2.4.2.2. Operation of the 24/7 point-of-contact system in Serbia**

To understand the functioning of 24/7 point-of-contact system in Serbia it is important to understand the underlying criminal justice system and its procedural organisation. The criminal justice system has its origins in

the classical civil law systems previously present in Austria and France. However, more recently, the significant influence of common law systems and changes to the criminal justice framework in the European Union countries has resulted in the adoption of some elements of common law procedures, thus effectively making it a hybrid system, which includes procedures from both legal traditions.

More precisely, Serbia abolished the inquisitorial system in criminal investigation and main trial proceedings, replacing it with an adversarial system, without the inclusion of a jury in the decision-making procedure.

However, possibly the most important change in procedural law is the introduction of the prosecution-led investigation, which stipulates that the public prosecutor is the state authority responsible for opening, leading and concluding criminal investigations. Within this system, the role of the police is to support the investigation by responding to requests and initiatives from the Prosecutor's Office, with no – or very little – autonomy in their actions.

These points are very important for a proper understanding of the 24/7 point-of-contact system and its organisation. Knowledge of the competences of the criminal justice and other related authorities which respond to mutual legal assistance inquiries or requests is of paramount importance for the proper functioning of the system and the meaningful communication of information and evidence.

#### **2.4.2.3. Police department specialised in high-tech crime**

The police department specialised in combating high-tech crime has the following 24/7 tasks:

- ▶ to organise the system of on-call duty officers according to a 24/7 shift-work schedule to ensure a rapid response by means of communication systems established for this purpose;
- ▶ to ensure the technical maintenance of dedicated e-mail, FTP and exchange servers, and the maintenance of dedicated 24/7 mobile and land telephone lines and other means of immediate communication;
- ▶ to be on permanent standby 24/7, with a primary officer present on the department premises to provide an initial response and a secondary officer on the on-call roster to provide support, if needed;
- ▶ to respond to 24/7 information requests related to co-operation between law-enforcement authorities;
- ▶ to be available 24/7 to communicate with the competent deputy public prosecutor on call, in order to report on 24/7 requests and receive further guidance or requests.

#### **2.4.2.4. Special Prosecutor's Office for High-Tech Crime**

The Special Prosecutor's Office for High-Tech Crime has the following 24/7 tasks:

- ▶ to organise the on-call system of deputy public prosecutors, who should be ready to react 24/7 and communicate with the 24/7 point of contact in the police department specialised in combating high-tech crime;
- ▶ to maintain technical equipment used for communication, primarily e-mail servers and dedicated telephone lines;
- ▶ to ensure that there is a means to communicate promptly with the pre-trial judge on call if an incoming request requires a court order;
- ▶ to communicate quickly and on a 24/7 basis with the Republic Public Prosecution Office of Serbia (General Prosecutor's Office), Department for Mutual Legal Assistance and Co-operation, if an incoming request requires such support;
- ▶ to facilitate further communication and co-ordination between all state or government authorities involved in the execution of an incoming request;
- ▶ to facilitate the initiation and maintenance of formal and administrative mutual legal assistance for the expedited acquisition and exchange of electronic evidence, where necessary and requested.

Clearly, the competences of the Special Prosecutor's Office for High-Tech Crime exceed those which are currently provided for by the Budapest Convention. However, due to its special position as the leading authority for conducting criminal investigations within the Serbian criminal justice system, and the possibility to exercise its competences on the basis of the Law on the Mutual Legal Assistance in the Criminal Matters of Serbia, which is based on the European Convention on Mutual Assistance in Criminal Matters (ETS No. 30, 1959) and its two Additional Protocols, this office represents the central authority responsible for responding to 24/7 requests in the field of cybercrime that go beyond the exchange of information between police authorities.



## 3. CONCLUSION

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### 3.1. Responsibilities of national 24/7 focal points in the context of establishing a 24/7 network of focal points under the MEDICRIME Convention

As highlighted in the introductory chapter, the MEDICRIME Convention is an international criminal justice instrument that provides for the criminalisation of specific illegal activities, the use of special investigative techniques, protection of victims and national and international co-operation.

Among the most important provisions for the purpose of this study are those in Chapter III, in particular Article 16, which requires the parties to the convention to take the necessary measures to ensure that the persons, units or services in charge of criminal investigations are specialised and have specific training in combating the counterfeiting of medical products and similar crimes involving threats to public health, including financial investigations. The text also requires that such units or services are provided with adequate resources.

The explanatory report gives no specific clarification of how to implement this article, the necessary measures being left to the discretion of the parties, as long as they ensure the specialisation and specific training of the persons, units or services in charge of criminal investigations in combating the counterfeiting of medical products and similar crimes involving threats to public health, including the carrying out of financial investigations.

As a consequence, the degree of flexibility available to the parties includes the establishment of specialised units, either within the law-enforcement agencies or within the prosecution service.

Depending on the national structure of the investigative bodies and the competences allocated to them regarding the crimes covered by the convention, the creation of new specialised units may require legal or administrative measures.

Thus, the most important precondition for the implementation of the provisions of the convention is the assessment by the parties of the status quo, the nature and impact of the threat posed by the crimes provided for in the convention and, accordingly, the need to create a specialised unit with the necessary competences and resources, whether it is a central authority with nationwide investigative jurisdiction, or an authority with supervisory powers limited to the collection of information or provision of assistance to other investigative units, depending on their substantive or territorial competence.

While deciding on the competences and powers to be given to such a central unit, with either investigative or limited powers, consideration should be given to assigning to it the role of a 24/7 focal point responsible for, for example:

- ▶ ensuring the provision of immediate assistance in the investigations or proceedings concerning the criminal offences provided for by the MEDICRIME Convention;
- ▶ providing technical and legal advice on specific national legislation;
- ▶ providing information about the system in place to assist the victims of the offences established in the MEDICRIME Convention;
- ▶ facilitating or executing requests for international co-operation related to the crimes provided for by the convention;<sup>11</sup>
- ▶ carrying out activities under Article 22 of the MEDICRIME Convention.

To summarise, Articles 16 and 22 of the MEDICRIME Convention provide the parties to the convention with a possible legal basis to establish, either by law or through internal regulations, one or more specialised units with the necessary competences in the framework of implementing the provisions of the convention, which is essential if they are to host the 24/7 focal point.

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11. If competences related to international co-operation cannot be afforded by the national law and practice, it is highly advisable that the 24/7 focal point should have the ability to co-ordinate with an authority entitled to provide mutual legal assistance on an expedited basis.



The internal mechanism for national interinstitutional co-operation based on Article 17 of the convention, whether formalised or not, may provide the necessary support network for the 24/7 national focal point, considering the fact that health authorities and the commercial and industrial sectors may provide the national 24/7 focal point with specific support and information.

### **3.2. Authorities that could host a national 24/7 focal point in the context of establishing a network of 24/7 focal points under the MEDICRIME Convention**

Bearing in mind the national practices outlined in this study regarding the establishment of a 24/7 national point of contact referred to in Article 35 of the Budapest Convention and the very specific competences of the 24/7 network, it appears that the decision to place the 24/7 focal point within a specialised unit in the prosecution service or a specialised police unit depended primarily on the specific judicial system existing in the parties to the convention.

The legal basis provided by Article 16 of the MEDICRIME Convention to ensure the specialisation of those involved in investigating the crimes established by the convention, allows each party to find the best solution among its national bodies which have powers of investigation in criminal matters and to designate it as the 24/7 national focal point.

While a specialised police unit, as host of the 24/7 focal point, may offer advantages in terms of availability, operability, manpower or skills, a specialised unit in the prosecution service may have advantages such as being able to offer legal advice or execute or facilitate the execution of international requests for co-operation, if such powers are to be given to the 24/7 focal point in addition to the requirements set forth in Article 22 of the convention.

Moreover, co-operation between law-enforcement authorities is easier to organise due to the fact that most police forces already have rapid response systems in place, which is consistent with the expected organisation of a 24/7 focal point. However, this kind of communication and co-operation may have one important shortcoming, namely the impossibility for the police authorities to acquire or exchange evidence themselves.

Of course, operational information from the police can be of crucial importance for rapid reaction in the field and for the setting up of a proper criminal investigation, and in some systems it will enable the police to initiate a criminal investigation itself, where this is within its competence. However, these systems are increasingly giving way to investigations led by the prosecution service.

It should also be noted that other Council of Europe conventions, such as the Budapest Convention, are laying the foundations for use of the 24/7 point of contact as a channel for expedited mutual legal assistance in cybercrime matters, as discussed within the framework of the drafting group on a second Additional Protocol to the Budapest Convention.

Additional considerations will also need to be addressed regarding the aim, activities and results expected of the authority which is going to be charged with hosting the 24/7 national focal point (see section 3.1 of this document). It is of paramount importance to understand what is expected from the authority and what kind of information – operational information or evidence – will be exchanged.

The same importance should be attached to the operationalisation of an internal mechanism for interinstitutional co-operation as defined in Article 17 of the convention. As stated previously in this study (section 3.1), such national co-operation may rely on the existing general procedures governing each authority that allow for the interinstitutional exchange of information or, alternatively, a more formalised, detailed or dedicated framework and procedure could be chosen that can be adopted in the process of implementing the convention. This more or less formalised mechanism could also serve as an internal/national support network for the 24/7 national focal point, regardless of a party's decision with respect to its position in the national judicial organisational structure .

The following steps are recommended for the establishment of the national network supporting the national 24/7 focal point:

- ▶ selection of the authorities which are going to participate in the network's operations at the national level based on their competences;
- ▶ organisation of a sufficient number of meetings for the selected authorities to analyse their role, capabilities, responsibilities and the procedures already in place for preventing and combating specific crimes in the context of the MEDICRIME Convention and the healthcare system;

- ▶ agreement on the format and content of the document to be adopted by the participating authorities on the modalities of their co-operation (a memorandum of understanding or similar document), and its signature;
- ▶ appointment of contacts persons for each authority;
- ▶ identification and provision of sufficient resources for performance of the allocated tasks;
- ▶ development of additional procedures for the operation of the network and measures to strengthen existing procedures.

The leading role in the national co-operation mechanism lies with investigative bodies, judicial bodies – such as the prosecution service or the investigating judge – or police bodies, since the purview of the MEDICRIME Convention falls within the scope of criminal justice and it is expected that its protective provisions will be applied by law enforcement, prosecution services and courts.

However, it should be noted that the organisation of government in some of the countries that have signed or ratified the MEDICRIME Convention is such that there are no centralised prosecution services or courts with nationwide jurisdiction for mutual legal assistance in criminal matters. Instead, these issues are dealt with by territorially distributed authorities within the limit of their competences.

In addition, in some countries there are centralised criminal investigation authorities made up of representatives of the various law-enforcement and prosecution services, with the open link towards the investigating judges.

In any case, it is also important for the functioning of the national support network to involve the healthcare system (ministry or department of health or similar general public authority), since law enforcement, prosecution services and courts lack sufficient knowledge of the medical and healthcare field. It will thus be necessary to create the conditions for effective support and co-operation between the competent healthcare authorities and the criminal justice system.

In addition, depending on local organisation and the competences assigned to each, other authorities, such as ministry of finance, customs authorities, money laundering prevention services and the national authority for intellectual property, should be involved and work in co-operation. As the aforementioned authorities already participate in the criminal justice systems of a number of countries in other areas of crime prevention that are similar or even identical to the prevention envisaged by the MEDICRIME Convention, their integration into the system will be a natural process and pose no major obstacles.

It is therefore important to be aware of the variety of organisational and jurisdictional issues which can have an impact on the operation of the 24/7 focal points and avoid establishing the 24/7 national focal point within an authority that is not able to provide an adequate response throughout the participating country.

### **3.3. Institutionalising the framework at national level**

As stated above, the MEDICRIME Convention provides a legal framework for the criminalisation of certain illegal acts, protection of the rights of victims of the offences established under the convention and the promotion of national and international co-operation. Although not directly stipulated in a specific article, the articles of the convention provide enough substantive space for the creation and institutionalisation of operational national 24/7 focal points for the purpose of establishing a 24/7 focal points network under the MEDICRIME Convention.

This is possible, as stated previously, due to the fact that authorities which could be designated as the national 24/7 focal point are at a sufficiently high level in the judicial system to be able to draft, adopt and implement regulations in this respect, without the need to have a higher level legal document, such as a law, in place. These authorities are also involved in the implementation of a variety of mandatory or repressive regulations, including those in the field of criminal justice, which can serve as a basis for the development and implementation of the system.

One particularly important aspect is that the authorities that could be designated as the national 24/7 focal point have emergency response services, divisions or departments which are capable of 24/7 activity. Such services will most probably already have procedures in place for on-call duty around the clock, which can be adapted to the new tasks.

Nevertheless, significant support will be needed for the establishment of the 24/7 national focal points forming a network of 24/7 focal points under the MEDICRIME Convention, as it is likely that additional funding will be required. During the initial phase of implementing these national 24/7 focal points activities can be organised using existing available resources, but it should be expected that, at an early stage, additional financial, technical and human resources will be needed.

### **3.4. Procedure for setting up a 24/7 focal points network under the MEDICRIME Convention**

As the capacity and responsibilities of the authorities that could host the national 24/7 focal point are defined by the criminal justice frameworks of the parties to the MEDICRIME Convention, it is unlikely that work on these issues will be necessary in the immediate future, unless the expected activities, their nature or content could be improved or expanded to meet eventual needs.

It is therefore strongly recommended that an analysis of the responsibilities be undertaken followed by, where appropriate, interventions in the areas in which problems or deficiencies have been identified.

In addition, it will be necessary to take note of the provisions of the convention relating to co-operation and those which have proven to be effective in practice in the implementation of existing networks, such as the 24/7 points of contact network under Article 35 of the Budapest Convention or other similar networks. The 1959 European Convention on Mutual Legal Assistance in Criminal Matters and its two Additional Protocols will also need to be taken into consideration.

To summarise, the procedures and competences of the 24/7 focal points network should be discussed and defined by a working group/drafting group of participating countries, with the approval of Committee of the Parties to the MEDICRIME Convention.

Bearing in mind the possible responsibilities mentioned in section 3.1 of this study, discussions and consultations should address the following issues.

- ▶ What information will be communicated and exchanged through the network, in particular between the 24/7 national focal points?
- ▶ How will communication and exchange take place in the network, in particular between the 24/7 national focal points?
- ▶ Will there be deadlines for launching the procedures?
- ▶ How and by whom will the efficiency of the 24/7 focal points network be evaluated?
- ▶ Will there be a system for reporting to the convention's Committee of the Parties?

The parties will undoubtedly play a crucial role in the discussions related to the foundation and operationalisation of the work of the 24/7 focal points network under the MEDICRIME Convention. Nonetheless, the discussions should include input from representatives of the ministries of the interior, justice and health, prosecution services and, where appropriate, the highest court instances and other relevant institutions.

Due to the importance of co-operation, it can be expected that the parties to the MEDICRIME Convention will take a keen interest in the setting up and operationalisation of this network.

That said, the Committee of the Parties to the MEDICRIME Convention should be prepared to make additional efforts to follow up this study in order to support the creation of the network and its promotion, to monitor its activities and to discuss and publish additional guidelines and/or recommendations for its operation.

# APPENDICES

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## I. Extract of the MEDICRIME Convention

### Chapter I – Object and purpose, principle of non-discrimination, scope, definitions

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#### Article 1 – Object and purpose

1. The purpose of this Convention is to prevent and combat threats to public health by:
  - a. providing for the criminalisation of certain acts;
  - b. protecting the rights of victims of the offences established under this Convention;
  - c. promoting national and international co-operation.
2. In order to ensure effective implementation of its provisions by the Parties, this Convention sets up a specific follow-up mechanism.

#### Article 3 – Scope

This Convention concerns medical products whether they are protected under intellectual property rights or not, or whether they are generic or not, including accessories designated to be used together with medical devices, as well as the active substances, excipients, parts and materials designated to be used in the production of medical products.

### Chapter III – Investigation, prosecution and procedural law

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#### Article 15 – Initiation and continuation of proceedings

Each Party shall take the necessary legislative and other measures to ensure that investigations or prosecution of offences established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn.

#### Article 16 – Criminal investigations

1. Each Party shall take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.
2. Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

### Chapter IV – Co-operation of authorities and information exchange

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#### Article 17 – National measures of co-operation and information exchange

1. Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.
2. Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

3. With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:
  - a. receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;
  - b. making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.
4. Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

## **Chapter VII – International co-operation**

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### **Article 21 – International co-operation in criminal matters**

1. The Parties shall co-operate with each other, in accordance with the provisions of this Convention and in pursuance of relevant applicable international and regional instruments and arrangements agreed on the basis of uniform or reciprocal legislation and their domestic law, to the widest extent possible, for the purpose of investigations or proceedings concerning the offences established in accordance with this Convention, including seizure and confiscation.
2. The Parties shall co-operate to the widest extent possible in pursuance of the relevant applicable international, regional and bilateral treaties on extradition and mutual legal assistance in criminal matters concerning the offences established in accordance with this Convention.
3. If a Party that makes extradition or mutual legal assistance in criminal matters conditional on the existence of a treaty receives a request for extradition or legal assistance in criminal matters from a Party with which it has no such treaty, it may, acting in full compliance with its obligations under international law and subject to the conditions provided for by the domestic law of the requested Party, consider this Convention as the legal basis for extradition or mutual legal assistance in criminal matters in respect of the offences established in accordance with this Convention.

### **Article 22 – International co-operation on prevention and other administrative measures**

1. The Parties shall co-operate on protecting and providing assistance to victims.
2. The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.
3. Each Party shall endeavour to integrate, where appropriate, prevention and combating of the counterfeiting of medical products and similar crimes involving threats to public health into assistance or development programmes provided for the benefit of third States.

## **Chapter VIII – Follow-up mechanism**

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### **Article 23 – Committee of the Parties**

1. The Committee of the Parties shall be composed of representatives of the Parties to the Convention.
2. The Committee of the Parties shall be convened by the Secretary General of the Council of Europe. Its first meeting shall be held within a period of one year following the entry into force of this Convention for the tenth signatory having ratified it. It shall subsequently meet whenever at least one third of the Parties or the Secretary General so requests.
3. The Committee of the Parties shall adopt its own rules of procedure.
4. The Committee of the Parties shall be assisted by the Secretariat of the Council of Europe in carrying out its functions.
5. A contracting Party which is not a member of the Council of Europe shall contribute to the financing of the Committee of the Parties in a manner to be decided by the Committee of Ministers upon consultation of that Party.

## **Article 24 – Other representatives**

1. The Parliamentary Assembly of the Council of Europe, the European Committee on Crime Problems (CDPC), as well as other relevant Council of Europe intergovernmental or scientific committees, shall each appoint a representative to the Committee of the Parties in order to contribute to a multisectoral and multidisciplinary approach.
2. The Committee of Ministers may invite other Council of Europe bodies to appoint a representative to the Committee of the Parties after consulting them.
3. Representatives of relevant international bodies may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
4. Representatives of relevant official bodies of the Parties may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
5. Representatives of civil society, and in particular non-governmental organisations, may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
6. In the appointment of representatives under paragraphs 2 to 5, a balanced representation of the different sectors and disciplines shall be ensured.
7. Representatives appointed under paragraphs 1 to 5 above shall participate in meetings of the Committee of the Parties without the right to vote.

## **Article 25 – Functions of the Committee of the Parties**

1. The Committee of the Parties shall monitor the implementation of this Convention. The rules of procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention, using a multisectoral and multidisciplinary approach.
2. The Committee of the Parties shall also facilitate the collection, analysis and exchange of information, experience and good practice between States to improve their capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health. The committee may avail itself of the expertise of other relevant Council of Europe committees and bodies.
3. Furthermore, the Committee of the Parties shall, where appropriate:
  - a. facilitate the effective use and implementation of this Convention, including the identification of any problems and the effects of any declaration or reservation made under this Convention;
  - b. express an opinion on any question concerning the application of this Convention and facilitate the exchange of information on significant legal, policy or technological developments;
  - c. make specific recommendations to Parties concerning the implementation of this Convention.
4. The European Committee on Crime Problems (CDPC) shall be kept periodically informed regarding the activities mentioned in paragraphs 1, 2 and 3 of this article.

## **II. Extract from the Explanatory Report to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health**

### **Chapter I – Object and Purpose, principle of non-discrimination, scope, definitions**

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#### **Article 1 – Object and purpose**

19. Paragraph 1 deals with the object and purposes of the Convention, which are to prevent and combat threats to public health by:
- a. providing for the criminalisation of certain acts, namely counterfeiting of medical products and similar crimes, including through the criminalisation of aiding or abetting and attempt;
  - b. protecting the rights of victims of offences related to the crimes mentioned under a);
  - c. promoting national and international co-operation against the crimes mentioned under a).



20. Thus the focus of the Convention is on the protection of public health; as it was felt that intellectual property rights are generally adequately protected at both national and international level, the Convention does not cover any issues related to the infringement of intellectual property rights in relation to the counterfeiting of medical products, active substances, excipients, parts and materials. However, the provisions on substantive criminal law of the Convention shall obviously be applied without prejudice to any possible criminal prosecution of infringements of intellectual property rights to which a conduct criminalised under the Convention may also give rise.

21. Paragraph 2 provides for the establishment of a specific follow-up mechanism (Articles 23-25) in order to ensure an effective implementation of the Convention.

### **Article 3 – Scope**

26. The scope of the Convention is expressly limited to medicines for human and veterinary use as well as medical devices, their active substances, excipients, parts or materials designated to be used in the production of medical products, including accessories designated to be used together with medical devices as defined in Article 4, irrespective of the status of these products, active substances, excipients, parts, materials and accessories under intellectual property law. Hence generic medical products are also included under the scope of the Convention.

27. After some discussion due to the particular regulatory approach as regards medical devices as opposed to the situation regarding medicinal products, the ad hoc committee decided to include “medical devices” under the scope of the Convention, because of the obvious dangers to public health posed by such devices when counterfeited or manufactured or supplied or placed on the market without being in compliance with the conformity requirements required by the domestic law of the Parties. Consequently, the parts, materials and accessories designated for use in the manufacturing of, or together with, medical devices have been included.

28. The ad hoc committee decided not to include the related, but distinct, categories of foodstuffs, cosmetics and biocides under the scope of the Convention, however not excluding that these categories of products could eventually become the subject of additional protocols in the future.

## **Chapter III – Investigations, prosecution and procedural law**

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### **Article 15 – Initiation and continuation of proceedings**

106. Article 15 is designed to enable the public authorities to prosecute offences established in accordance with the Convention *ex officio*, without a victim having to file a complaint. The purpose of this provision is to facilitate prosecution, in particular by ensuring that criminal proceedings may continue regardless of pressure or threats by the perpetrators of offences towards victims.

### **Article 16 – Criminal investigations**

107. The article provides for the specialised criminal investigation and combating of counterfeiting of medical products and similar crimes by persons, units or services of the competent national authorities of State Parties.

109. Paragraph 2 provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamental principles of their national law. The notion of “principles of national law” should be understood as also encompassing basic human rights, including those provided under Article 6 of the ECHR.

109. “Effective investigation” is further described as including financial investigations, covert operations, controlled delivery and other special investigative techniques. These could encompass electronic and other forms of surveillance as well as infiltration operations. As indicated by the wording “where appropriate”, Parties are not legally obliged to apply any or all of these investigative techniques, but if a Party chooses to conduct investigations using these special techniques, the principle of proportionality, as referred to in the Preamble of the Convention, will also apply.

110. The ad hoc committee underlined that “controlled delivery” is one of the most important investigative tools available to authorities in the area of counterfeiting of medical products and similar crimes. The measure of “controlled delivery” is already foreseen by a number of international legal instruments in the field of criminal law, in particular the United Nations Convention Against Transnational Organised Crime and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances and the Second Additional Protocol to the European Convention on Mutual Legal Assistance in Criminal Matters (ETS No. 182).

## **Chapter IV – Co-operation of authorities and information exchange**

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### **Article 17 – National measures of co-operation and information exchange**

111. Networking at national level based on a multidisciplinary and multisectoral approach is a key element in the fight against counterfeiting of medical products and similar crimes. Hence, Article 17 provides for the co-operation and information exchange between the competent authorities in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health. In this context, it should be noted that the involvement of health authorities in the prevention and combat of counterfeiting of medical products and similar crimes is a key tool for the efficient protection of public health. In addition, paragraph 2 provides for the facilitation of assistance to be provided by the relevant commercial and industrial sectors to the competent authorities as regards risk management, as these sectors have vast product expertise.

112. The ad hoc committee found that the wide range of authorities involved in the fight against counterfeiting of medical products and similar crimes, from law enforcement to health, usually requires a strengthening of the existing frameworks for co-operation. In particular, the Council of Europe model on a network of Single Points of Contact (SPOC) developed by the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Related Crimes (CD-P-PH/CMED) of the Council of Europe served as inspiration for the drafters of the Convention. This Council of Europe SPOC model is already in operation within the EU medicines enforcement sector and has been tabled as a working contact model for the International Medical Product Anti-Counterfeiting Task Force (IMPACT) under the World Health Organization (WHO), by the Permanent Forum on International Pharmaceutical Crime and the International Criminal Police Organization – INTERPOL. However, Article 17 does not in any way oblige Parties to introduce new bodies tasked with co-ordination and information exchange in the field of counterfeiting of medical products and similar crimes.

## **Chapter VII – International co-operation**

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### **Article 21 – International co-operation in criminal matters**

130. The article sets out the general principles that should govern international co-operation in criminal matters.

131. Paragraph 1 obliges Parties to co-operate, on the basis of relevant international and national law, to the widest extent possible for the purpose of investigations or proceedings of crimes established under the Convention, including for the purpose of carrying out seizure and confiscation measures. In this context, particular reference should be made to the European Convention on Extradition (ETS No. 24), the European Convention on Mutual Assistance in Criminal Matters (ETS No. 30), the European Convention on the Transfer of Sentenced Persons (ETS No. 112), the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (ETS No. 141) and the Council of Europe Convention [on] Laundering, Search, Seizure and Confiscation of the proceeds from Crime and on the Financing of Terrorism (CETS No. 198).

132. In the same way as for paragraph 1, paragraph 2 obliges Parties to co-operate, to the widest extent possible and on the basis of relevant international, regional and bilateral legal instruments, on extradition and mutual legal assistance in criminal matters concerning the offences established by the Convention.

133. Paragraph 3 authorises a Party that makes mutual assistance in criminal matters or extradition conditional on the existence of a treaty to consider the Convention as the legal basis for judicial co-operation with a Party with which it has not concluded such a treaty. This provision, which serves no purpose between Council of Europe member states because of the existence of the European Conventions on Extradition and Mutual Legal Assistance in Criminal Matters, dating from 1957 and 1959 respectively, and the Protocols to them, is of interest because of the possibility provided to third states to sign the Convention (cf. Article 28). The requested Party will act on such a request in accordance with the relevant provisions of its domestic law which may provide for conditions or grounds for refusal. Any action taken shall be in full compliance with its obligations under international law, including obligations under international human rights instruments.

### **Article 22 – International co-operation on prevention and other administrative measures**

134. As indicated by the title, Article 22 covers only administrative measures and is not concerned with international co-operation in criminal matters (see Article 21 above). This provision obliges Parties to co-operate on protecting and providing assistance to victims, cf. paragraph 1 of the article.



135. According to paragraph 2, the Parties shall designate a national contact point for receiving requests for information and/or co-operation outside the scope of international co-operation in criminal matters. The national contact point shall be established without prejudice to the internal reporting systems of the Parties. The ad hoc committee considered that it should be left to a Party to decide on how it would organise its national point of contact and the mechanism of information transmission with the relevant internal sectors in the fight against counterfeiting of medical products and similar crimes.

136. Paragraph 3 of the article obliges Parties to endeavour to include, where appropriate, preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health in development assistance programmes benefiting third states. Many Council of Europe member states carry out such programmes, which cover such varied areas as the restoration or consolidation of the rule of law, the development of judicial institutions, combating crime, and technical assistance with the implementation of international conventions. Some of these programmes may be implemented in countries faced with substantial problems caused by the activities criminalised under the Convention. In this context, it seems appropriate that such programmes should take account of and duly incorporate issues relating to the prevention and punishment of this form of crime.

## **Chapter VIII – Follow-up mechanism**

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137. Chapter VIII of the Convention contains provisions which aim at ensuring the effective implementation of the Convention by the Parties. The monitoring system foreseen by the Convention is based essentially on a body, the Committee of the Parties, composed of representatives of the Parties to the Convention.

### **Article 23 – Committee of the Parties**

138. Article 23 provides for the setting up of a committee under the Convention, the Committee of the Parties, which is a body with the composition described above, responsible for a number of Convention-based follow-up tasks.

139. The Committee of the Parties will be convened the first time by the Secretary General of the Council of Europe, within a year of the entry into force of the Convention by virtue of the 10th ratification. It will then meet at the request of a third of the Parties or of the Secretary General of the Council of Europe.

140. It should be stressed that the ad hoc committee intended to allow the Convention to come into force quickly while deferring the introduction of the follow-up mechanism until such time as the Convention was ratified by a sufficient number of states for it to operate under satisfactory conditions, with a sufficient number of representative Parties to ensure its credibility.

141. The setting up of this body will ensure equal participation of all the Parties in the decision-making process and in the Convention monitoring procedure and will also strengthen co-operation between the Parties to ensure proper and effective implementation of the Convention.

142. The Committee of the Parties must adopt rules of procedure establishing the way in which the monitoring system of the Convention operates, on the understanding that its rules of procedure must be drafted in such a way that the implementation of the Convention by the Parties, including the European Union, is effectively monitored.

143. The Committee of Ministers shall decide on the way in which those Parties which are not member states of the Council of Europe are to contribute to the financing of these activities. The Committee of Ministers shall seek the opinion of those Parties which are not member states of the Council of Europe before deciding on the budgetary appropriations to be allocated to the Committee of the Parties.

### **Article 24 – Other representatives**

144. Article 24 contains an important message concerning the participation of bodies other than the Parties themselves in the Convention monitoring mechanism in order to ensure a genuinely multisectoral and multidisciplinary approach. It refers, firstly, to the Parliamentary Assembly and the European Committee on Crime Problems (CDPC), and, secondly, more unspecified, to other relevant intergovernmental or scientific committees of the Council of Europe which, by virtue of their responsibilities would definitely make a worthwhile contribution by taking part in the monitoring of the work on the Convention. These committees are the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), and the Commission of the European Pharmacopoeia and its Advisory Group of the General Network of Official Medicines Control

Laboratories (GeON). In this context, it should be noted that the CD-P-PH is specifically mandated to co-operate with the CDPC to minimise public health risks posed by counterfeit medicines and other forms of pharmaceutical crimes.

145. The importance afforded to involving representatives of relevant international bodies and of relevant official bodies of the Parties, as well as representatives of civil society in the work of the Committee of the Parties is undoubtedly one of the main strengths of the monitoring system provided for by the negotiators. The wording “relevant international bodies” in paragraph 3, is to be understood as intergovernmental bodies active in the field covered by the Convention. The wording “relevant official bodies” in paragraph 4, refers to officially recognised national or international bodies of experts working in an advisory capacity for Parties to the Convention in the field covered by the Convention, in particular as regards medicinal products and medical devices.

146. The possibility of admitting representatives of intergovernmental, governmental and non-governmental organisations and other bodies actively involved in preventing and combating counterfeiting of medical products and similar crimes as observers was considered to be an important issue, if the monitoring of the application of the Convention was to be truly effective.

147. Paragraph 6 prescribes that when appointing representatives as observers under paragraphs 2 to 5 (Council of Europe bodies, international bodies, official bodies of the Parties and representatives of non-governmental organisations), a balanced representation of the different sectors and disciplines involved (the law-enforcement authorities, the judiciary, the pharmaceuticals and medical devices authorities, as well as civil society interest groups) shall be ensured.

#### **Article 25 – Functions of the Committee of the Parties**

148. When drafting this provision, the ad hoc committee wanted to base itself on the similar provision of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (CETS. No. 201), creating as simple and flexible a mechanism as possible, centred on a Committee of the Parties with a broader role in the Council of Europe’s legal work on combating the counterfeiting of medical products and similar crimes. The Committee of the Parties is thus destined to serve as a centre for the collection, analysis and sharing of information, experiences and good practice between Parties to improve their policies in this field using a multisectoral and multidisciplinary approach.

149. With respect to the Convention, the Committee of the Parties has the traditional follow-up competencies and:

- ▶ plays a role in the effective implementation of the Convention, by making proposals to facilitate or improve the effective use and implementation of the Convention, including the identification of any problems and the effects of any declarations made under the Convention;
- ▶ plays a general advisory role in respect of the Convention by expressing an opinion on any question concerning the application of the Convention, including by making specific recommendations to Parties in this respect;
- ▶ serves as a clearing house and facilitates the exchange of information on significant legal, policy or technological developments in relation to the application of the provisions of the Convention. In this context, the Committee of the Parties may avail itself of the expertise of other relevant Council of Europe committees and bodies. In addition to the committees mentioned above under the commentary to Article 24, paragraph 1, the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Related Crimes (CD-P-PH/CMED), which is, *inter alia*, tasked with the development and promotion of multisectoral risk prevention and management strategies for public health protection from counterfeit medical products and related crimes, and the General European Network of Official Medicines Control Laboratories (OMCL) could be mentioned as examples of such expert committees and bodies of the Council of Europe.

150. Paragraph 4 states that the European Committee on Crime Problems (CDPC) should be kept periodically informed of the activities mentioned in paragraphs 1, 2 and 3 of Article 25.

The multiregional Council of Europe project entitled “Needs assessment – Falsified medical products” (NA-FAMED) supports Council of Europe member states and other countries, Parties and non-Parties to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention) to fight the counterfeiting/falsification of medical products and similar crimes involving threats to public health. It is a preparatory project whose goal is to establish a baseline for future projects aimed at promoting and implementing the MEDICRIME Convention.

Within the NA-FAMED project, the study “The setting up of a 24/7 network within the MEDICRIME Convention” aims to support Council of Europe member states and other countries by examining the feasibility of creating a network of national focal points available on a 24-hour, 7-day-a-week (24/7) basis, to contribute to the achievement of the objectives of the convention.

This network of 24/7 focal points aims to improve the operational and judicial aspects of preventing and combating the counterfeiting/falsification of medical products and other similar crimes involving threats to public health, as well as the exchange of information in this field between the Parties to the MEDICRIME Convention and other countries. This document seeks to determine which authorities may be able to host a national 24/7 focal point and the responsibilities and working procedures expected of those authorities, in accordance with the relevant provisions of the convention.

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The Council of Europe is the continent’s leading human rights organisation. It comprises 47 member states, including all members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.