Strasbourg, 31 October 2019 T-CPM (2019) 01

COMMITTEE OF THE PARTIES TO CONVENTION ON THE COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

(T-MEDICRIME)

INFORMATION DOCUMENT CONCERNING THE T-MEDICRIME

Secretariat Memorandum prepared by
the Directorate General Human Rights and Rule of Law (DGI)

1. Following the decision of the Heads of State and Government of the Council of Europe at the 3rd Summit in Warsaw in May 2005 which stressed their commitment to ensuring security for European citizens in the full respect of human rights and fundamental freedoms by taking specific action and, if appropriate, by promoting measures to counter challenges attendant on scientific and technical progress, the Committee of Ministers entrusted the European Committee on Crime Problems (CDPC) with the preparation of a comprehensive international instrument focusing on the preventive, protective and criminal law aspects of the fight against the counterfeiting of medical products and setting up a specific monitoring mechanism. This initiative resulted in the drafting of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health [CETS N°211] (hereinafter the MEDICRIME Convention).

2. The Convention was prepared by all member States of the Council of Europe as well as by its oberser countries. It was adopted on 8 December 2010 and opened for signature on 28 October 2011 in Moscow, the Russian Federation. To date, 16 States have signed the Convention and 16 (Albania, Armenia, Belgium, Benin*, Burkina Faso*, Croatia, France, Guinea*, Hungary, Portugal, Republic of Moldova, the Russian Federation, Spain, Switzerland, Turkey and Ukraine) have ratified it. The Convention entered into force on 1 January 2016 following its fifth ratification.

3. The Convention is the first international treaty which criminalises the counterfeiting of medical products in such a broad manner as to ensure that certain intentional offences related to medical products and public health are specifically criminalised, including the manufacturing of counterfeit medicines for human and veterinary use, medical devices and other related products, the supplying, offering to supply and trafficking in counterfeits, importing and exporting of counterfeit medical products, the falsification of documents and similar crimes involving threats to public health. In this regard, it ensures that States in Europe and beyond establish specific legislation and pragmatic measures with an emphasis on keeping the protection of public health at the forefront to prevent the counterfeiting of medical products but also to protect victims, prosecute perpetrators, and to promote national and international co-operation. The protection of intellectual property rights does not fall within the scope of the Convention

4. The Convention provides for the establishment of a Committee of the Parties to monitor its implementation (see Chapter VIII which is appended to this memorandum). The systematic monitoring of the Convention is one of its major strengths.

5. In accordance with the Convention[1], the Committee shall be composed of representatives of the Parties to the Convention and shall meet for the first time within a period of one year following the entry into force of this Convention for the

* Non Council of Europe member States.

[1] Article 23, Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, [CETS N°211].

tenth signatory having ratified it. The first meeting of the Committee of the Parties took place on 17 December 2018.

6. The Convention provides for the traditional follow-up competencies of the Committee of the Parties (see the explanatory report of the Convention concerning Article 25 and Appendix 2) which should:

   a) play 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;

   b) play a general advisory role in respect of the Convention by expressing an opinion on any question concerning the application of the Convention;

   c) serve 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.

7. According to Articles 23 and 25 of the Convention, it is left to the Committee of the Parties, through its rules of procedure, to determine the actual method of procedure for evaluating whether or not, or to what extent, the Convention is being implemented by the parties. Therefore, the second meeting of the Committee will aim primarily at discussing and adopting the rules of procedure of the Committee.

8. The idea is for the Committee of the Parties to serve as a centre for the collection, analysis and sharing of information, experiences and good practices between States to improve their policies to prevent and combat the counterfeiting of medical products and similar crimes, as mentioned in paragraph 148 of the explanatory memorandum. Thanks to the flexibility of the provisions of Articles 23 and 25, and in particular through the use of the rules of procedure, a variety of possibilities exist for the structure and functions of the Committee of the Parties. Several models exist within other Council of Europe bodies/committees which could also serve as a basis for the draft of the rules of procedure and ensure an effective and feasible monitoring procedure.

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Appendix I

CHAPTER VIII OF THE COUNCIL OF EUROPE CONVENTION ON THE COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

Chapter VIII – Follow-up mechanism

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.

Appendix II

EXTRACT OF THE EXPLANATORY REPORT CONCERNING CHAPTER VIII

Chapter VIII – Follow-up mechanism

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 inter-governmental 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 inter-governmental, 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 41 – 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 Minimizing 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.

Appendix III

Chart of signatures and ratifications

Opening for signature	Entry into force
Place: Moscow Date : 28/10/2011	Conditions: 5 Ratifications including at least 3 member States of the Council of Europe Date : 01/01/2016

Status as of: 25/10/2019

Member States of the Council of Europe

States	Signature	Ratification	Entry into force	Notes	R.	D.	A.	T.	C.	O.
Albania	17/12/2015	06/06/2016	01/10/2016							
Andorra										
Armenia	20/09/2012	05/02/2016	01/06/2016							
Austria	28/10/2011									
Azerbaijan										
Belgium	24/07/2012	01/08/2016	01/11/2016							
Bosnia and Herzegovina	04/12/2015									
Bulgaria										
Croatia	03/09/2015	20/09/2019	01/01/2020		R.					
Cyprus	28/10/2011									O.
Czech Republic										
Denmark	12/01/2012									
Estonia										
Finland	28/10/2011									
France	28/10/2011	21/09/2016	01/01/2017		R.			T.		
Georgia										
Germany	28/10/2011									
Greece										
Hungary	26/09/2013	09/01/2014	01/01/2016		R.					
Iceland	28/10/2011									
Ireland										
Italy	28/10/2011									
Latvia										
Liechtenstein	04/11/2011									
Lithuania										
Luxembourg	22/12/2011									
Malta										
Monaco										
Montenegro										
Netherlands										
Norway										
Poland										
Portugal										
Republic of Moldova	28/10/2011	18/12/2018	01/04/2019							
Romania	20/09/2012	14/08/2014	01/01/2016							

Russian Federation										
San Marino	28/10/2011	20/03/2018	01/07/2018		R.	D.	A.			
Serbia										
Slovakia	02/10/2019									
Slovenia										
Spain	06/03/2019									
Sweden	08/10/2012	05/08/2013	01/01/2016			D.				
Switzerland										
The former Yugoslav Republic of Macedonia	28/10/2011	25/10/2018	01/02/2019			D.	A.			
Turkey	29/06/2012	21/09/2017	01/01/2018			D.				
Ukraine	28/10/2011	20/08/2012	01/01/2016							
United Kingdom										

Non-member States of the Council of Europe

States	Signature	Ratification	Entry into force	Notes	R.	D.	A.	T.	C.	O.
Belarus	24/06/2019									
Benin	29/05/2018	29/05/2018	01/09/2018							
Burkina Faso	16/02/2017	27/07/2017	01/11/2017							
Canada										
Congo				63						
Guinea	03/07/2019									
Holy See	10/10/2012	24/09/2015	01/01/2016							
Israel										
Ivory Coast	28/10/2011									
Japan										
Mexico										
Morocco	13/12/2012									
Tunisia				63						
United States of America										

International Organisations

Organisations	Signature	Ratification	Entry into force	Notes	R.	D.	A.	T.	C.	O.
European Union										

Total number of signatures not followed by ratifications:	16
Total number of ratifications/accessions:	16

Notes:

- (63) Since 2013 the decision to invite a non-member State to sign the treaty is valid five years as from its adoption. See the following **Chart.**

a: Accession - s: Signature without reservation as to ratification - su: Succession - r: Signature "ad referendum".
R.: Reservations - D.: Declarations - A.: Authorities - T.: Territorial Application - C.: Communication - O.: Objection.

Source : Treaty Office on **http://conventions.coe.int**