MEDICRIME COMMITTEE

Committee of the Parties to
the Council of Europe Convention
on the counterfeiting of medical products
and similar crimes involving threats
to public health

Rules of Procedure

adopted by the Committee
at its 2nd meeting
(Strasbourg, 12-13 December 2019)

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

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The Committee of the Parties (hereinafter "MEDICRIME Committee"),

Determined to contribute effectively to the attainment of the common goal of combating crime involving counterfeiting of medical products and similar crimes involving threats to public health;

Having regard to Chapter VIII of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211, hereinafter referred to as "the Convention");

Considering that the purpose of the Convention is to prevent and combat threats to public health through criminal law measures, protection of the rights of victims and promotion of national and international co-operation;

Pursuant to paragraph 3 of Article 23 of the Convention,

Adopts the present rules of procedure.

Rules of procedure of the MEDICRIME Committee

Part I – The MEDICRIME Committee

Rule 1 – Functions

1.1. Monitoring of the implementation of the Convention

Pursuant to paragraphs 1 and 3 of Article 25 of the Convention and in accordance with Part II of these rules, the MEDICRIME Committee shall monitor the implementation of the Convention by the Parties and, where appropriate:

a. make proposals to facilitate or improve 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;

b. express an opinion on any question concerning the application of the Convention;

c. make specific recommendations to Parties concerning the implementation of the Convention.

1.2. Exchange of information, experiences and good practices

Pursuant to paragraphs 2 and 3 of Article 25 of the Convention and in accordance with Part III of these rules, the MEDICRIME Committee shall 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. Where appropriate, the MEDICRIME Committee shall:

a. facilitate the exchange of information on significant legal, policy or technological developments;

b. express an opinion on any question concerning the application of the Convention.

1.3. Amendments to the Convention

1. Pursuant to paragraph 2 of Article 27 of the Convention, any amendment proposed by a Party shall be communicated to the European Committee on Crime Problems (CDPC) and other relevant Council of Europe intergovernmental or scientific committees, which shall submit to the MEDICRIME Committee their opinions on the proposed amendment.

2. The MEDICRIME Committee shall examine all the opinions received by the CDPC and other relevant Council of Europe intergovernmental or scientific committees on the proposed amendment; it shall adopt an opinion and submit it to the Committee of Ministers.

3. Pursuant to paragraph 3 of Article 27 of the Convention, the Committee of Ministers, having considered the proposed amendment and the opinion submitted by the MEDICRIME Committee, may adopt the amendment.

Rule 2 – Composition

2.1. Members

1. Pursuant to Article 23 of the Convention, members of the MEDICRIME Committee shall be representatives of the Parties to the Convention.[1]

2. Parties to the Convention shall nominate as their representatives experts having the highest possible rank and level of expertise in the fields relevant to the Convention, considering that the purpose of the Convention is to prevent and combat threats to public health and that the Parties should carry out the provisions of the Convention concerning substantive criminal law taking into account its purpose and the principle of proportionality.

3. Each member of the MEDICRIME Committee may be accompanied by other national representatives. Where a Party designates more than one representative, only one of them shall have the right to vote. The Party holding the chairmanship of the MEDICRIME Committee may appoint an additional expert who

1. Pursuant to Article 28 of the Convention, the member states of the Council of Europe, the European Union, the non-member States which have participated in the elaboration of the Convention or enjoy observer status with the Council of Europe may become Parties to the Convention. Pursuant to the same Article any other non-member State of the Council of Europe upon invitation by the Committee of Ministers and the European Union may become Party to the Convention. According to Article 2.*g* of the Vienna Convention on the Law of Treaties (1969), a State party should be understood as a "State which has consented to be bound by the treaty and for which the treaty is in force".

will be reimbursed for travel and subsistence expenses. Only one representative of that Party shall have the right to vote.

4. The travel and subsistence expenses of one member per Party shall be borne by the Council of Europe in accordance with the rules adopted by the Committee of Ministers and within the limits of budgetary appropriations.

2.2. Participants

1. Each of the following shall appoint representatives to participate, without the right to vote, in the meetings of the MEDICRIME Committee:

- ***a.*** the Parliamentary Assembly of the Council of Europe;
- ***b.*** the CDPC;
- ***c.*** relevant Council of Europe intergovernmental or scientific committees and bodies.

Where applicable, the defrayal of expenses of these participants shall be governed by the rules or terms of reference of the institutions and bodies listed above.

2. The following may appoint representatives to participate, without the right to vote, in the meetings of the MEDICRIME Committee:

- ***a.*** the Congress of Local and Regional Authorities of the Council of Europe;
- ***b.*** the Conference of International Non-Governmental Organisations (INGOs) of the Council of Europe;
- ***c.*** any other Council of Europe body invited to do so by the Committee of Ministers after consulting the Committee of the Parties.

Where applicable, the defrayal of expenses of these participants shall be governed by the rules or terms of reference of the institutions and bodies listed above.

3. The following may appoint representatives to participate in the meetings of the MEDICRIME Committee without the right to vote or to defrayal of expenses:

a. member States of the Council of Europe that are not yet Parties to the Convention;

b. States which have observer status with the Council of Europe;

c. States invited to accede to the Convention.

2.3. Observers

1. The following may appoint representatives to participate in the meetings of the MEDICRIME Committee without the right to vote or to defrayal of expenses:

a. the European Union and its agencies, including Europol and Eurojust;

b. the United Nations and its specialised agencies, including the World Health Organization;

c. Interpol;

d. the World Customs Organization;

e. the International Organisation of the Francophonie;

f. other intergovernmental organisations and any other entity authorised to participate in meetings of steering and ad hoc committees by virtue of a resolution or decision of the Committee of Ministers.

2. Pursuant to paragraphs 4 and 5 of Article 24 of the Convention, representatives of relevant official bodies of the Parties and representatives of civil society, in particular of non-governmental organisations, may be admitted as observers to the MEDICRIME Committee following the procedure set out in Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.[2] A balanced representation of the different sectors and disciplines shall be ensured.

3. The MEDICRIME Committee may also authorise, on an ad hoc basis, the participation as observers of representatives of additional bodies, in particular:

- ***a.*** private sector organisations involved in information and communication technologies;
- ***b.*** financial institutions;
- ***c.*** commercial and industrial sectors;
- ***d.*** other relevant civil society actors.

4. In accordance with Resolution CM/Res(2011)24, observers shall have neither the right to vote nor to defrayal of expenses.

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2. See Part III.C.8.*a* of Resolution CM/Res(2011)24: "as a general rule, upon their request to the Secretary General, observers are admitted, to steering and ad hoc committees or any subordinate body answerable to them, on the basis of a unanimous decision by that steering or ad hoc committee; in the event where unanimity is not reached, the matter may be referred to the Committee of Ministers at the request of two-thirds of the members of the committee concerned. The Committee of Ministers shall decide on the matter by a two-thirds majority of all the representatives entitled to sit on it."

Rule 3 – Chairperson and vice-chairperson

1. The MEDICRIME Committee shall elect a chairperson and a vice-chairperson from among its members.

2. The term of office of the chairperson and vice-chairperson shall be two years, renewable once.

3. The chairperson and the vice-chairperson shall be elected by a simple majority of the members with a right to vote. The elections shall be held by secret ballot, unless the MEDICRIME Committee, by a unanimous decision, decides otherwise .

4. The chairperson shall conduct proceedings and sum up conclusions whenever he or she thinks necessary. He or she may call to order a speaker who departs from the subject under discussion or from the MEDICRIME Committee's functions set out in Rule 1 above. The chairperson shall retain the right to speak and to vote in his or her capacity as a member of the MEDICRIME Committee, except in cases where an additional expert from the same Party has been appointed to sit on the MEDICRIME Committee.

5. The vice-chairperson shall replace the chairperson if the latter is absent or otherwise unable to preside over the meeting. If the vice-chairperson is absent, the chairperson shall be replaced by another member of the bureau, appointed by the latter, or where there is no bureau, by a member of the MEDICRIME Committee appointed by the latter.

6. The MEDICRIME Committee shall strive to achieve gender balance, as well as geographical balance while electing its chairperson and vice-chairperson.

Rule 4 – Bureau

1. The MEDICRIME Committee shall appoint a bureau consisting of the chairperson, the vice-chairperson and up to three other members of the MEDICRIME Committee.

2. The main functions of the bureau are to:

a. assist the chairperson in conducting the MEDICRIME Committee's activities;

b. supervise the preparation of meetings at the MEDICRIME Committee's request;

c. prepare the draft workplan of the MEDICRIME Committee and propose priorities for future work for consideration by the plenary;

d. review the agenda of plenary meetings and propose the ways in which the MEDICRIME Committee's functions should be accomplished;

e. ensure continuity between meetings as necessary;

f. select/propose experts to carry out specific activities;

g. appoint members to participate in other Council of Europe bodies;

h. report back to the MEDICRIME Committee on its activities between the plenary meetings;

i. promote common positions of the Parties in relevant international fora;

j. execute other additional specific tasks delegated by the MEDICRIME Committee.

3. Except where otherwise decided by the bureau, it shall meet in closed session.

4. The other members of the bureau shall be elected in the same manner as the chairperson and vice-chairperson, taking into account geographical distribution and gender balance. Their term of office shall be two years, renewable once.

Rule 5 – Secretariat

The Secretary General of the Council of Europe shall provide the MEDICRIME Committee with the necessary staff, including an executive secretary, as well as with the administrative and other services it may require.

Rule 6 – Languages

1. The official languages of the MEDICRIME Committee shall be those of the Council of Europe, namely English and French.

2. Any document written in a language other than the official languages shall be translated into one of the official languages; the member, participant or observer submitting it being responsible for making the necessary arrangements and covering the costs.

3. The bureau may decide, by a unanimous vote, to hold a particular meeting in only one of the two languages.

Rule 7 – Venue of meetings

1. The MEDICRIME Committee shall normally be convened at the premises of the Council of Europe in Strasbourg.

2. Exceptionally, the Secretary General may authorise the convening of the MEDICRIME Committee elsewhere, in particular

in other Council of Europe premises, if there is no objection from the government of the State on whose territory it is intended to hold the meeting and if suitable technical facilities are available, in accordance with the principles of sound management and within the resources available.

Rule 8 – Convening of meetings

1. Pursuant to paragraph 2 of Article 23 of the Convention, the MEDICRIME Committee shall meet whenever at least one third of the Parties or the Secretary General so requests. It shall hold such meetings as are required for the exercise of its functions as set out in Rule 1.

2. The meetings shall be convened by the Secretary General of the Council of Europe in accordance with the single procedure set out in Resolution CM/Res(2011)24. The place, date and time of the meeting, its probable duration and the subjects to be dealt with shall be communicated to all members, participants and observers. Convocations shall be circulated at least six weeks in advance of the proposed date of the meeting, except in cases of urgency which shall be duly explained.

3. Members, participants and observers who are unable to attend a meeting or a part thereof shall notify, in due time, the secretariat who shall inform the chairperson.

Rule 9 – Agenda

1. The secretariat, in close consultation with the chairperson, shall draw up the draft agenda which shall be concrete, operational and result oriented.

2. The agenda shall be adopted by the MEDICRIME Committee at the beginning of the meeting.

Rule 10 – Documents, list of decisions and meeting reports

1. The secretariat shall submit the working documents in advance to the chairperson for his/her information and possible consideration.

2. The secretariat shall be responsible for distributing all the working documents for the meetings of the MEDICRIME Committee.

3. Documents requiring a decision shall be sent, in the official languages, to members at least three weeks before the opening of the meeting at which the decision is to be taken. However, in exceptional cases, if no member objects, the MEDICRIME Committee may deliberate on a document submitted at a later stage.

4. Documents shall be made public after the meeting of the MEDICRIME Committee for which they were prepared, unless the MEDICRIME Committee decides otherwise.

5. At the end of each meeting, the executive secretary shall submit to the MEDICRIME Committee a list of the decisions taken during the meeting for its approval. Unless the MEDICRIME Committee decides otherwise, the approved list of decisions shall be made public.

6. Information and communication technologies should be used whenever possible.

Rule 11 – Privacy of meetings

Meetings shall not be held in public, unless the MEDICRIME Committee decides otherwise.

Rule 12 – Quorum

There shall be a quorum if a majority of the members of the MEDICRIME Committee are present.

Rule 13 – Proposals

1. Any proposal must be submitted in writing in an official language if a member of the MEDICRIME Committee so requests. In that case it shall not be discussed until the proposal has been circulated.

2. Proposals made by participants and observers may be put to a vote if they are submitted at least two weeks before the opening of the meeting at which the proposal is to be discussed.

3. Proposals made by participants and observers during a meeting may be put to a vote if sponsored by a member of the MEDICRIME Committee.

Rule 14 – Order of voting on proposals or amendments

1. Where a number of proposals relate to the same subject, they shall be put to a vote in the order in which they were submitted. In case of doubt as to the order of priority, the chairperson shall decide.

2. Where a proposal is the subject of an amendment, the amendment shall be put to a vote first. Where two or more amendments to the same proposal are presented, the MEDICRIME Committee shall vote first on whichever departs furthest in substance from the original proposal. It shall then vote on the next furthest removed from the original proposal, and so on until all the amendments have been put to a vote. However, where

the acceptance of one amendment necessarily entails rejection of another, the latter shall not be put to a vote. The final vote shall then be taken on the proposal as amended or not. Where there is a doubt as to the order of priority, the chairperson shall decide.

3. Parts of a proposal or amendment may be voted on separately.

4. In the case of proposals with financial implications, the most costly shall be put to a vote first.

Rule 15 – Points of order

During the discussion of any matter, a member of the MEDICRIME Committee may at any time raise a point of order which shall immediately be decided upon by the chairperson in accordance with these rules. Any appeal against the decision of the chairperson shall immediately be put to a vote. A member may not, in raising a point of order, speak on the substance of the matter under discussion.

Rule 16 – Order of procedural motions

Procedural motions shall take precedence over all other motions except points of order. They shall be put to a vote in the following order:

a. suspension of the sitting;

b. adjournment of the debate on the topic being discussed;

c. postponement of a decision on the substance of a proposal until a specified date;

d. closure of the discussion on the topic.

Rule 17 – Reconsideration of a question

When a decision has been taken, re-examination may only occur if a member of the MEDICRIME Committee so requests, and if this request receives a two-thirds majority of the votes cast.

Rule 18 – Voting

1. Each member of the MEDICRIME Committee shall have one vote. Where the delegation of a Party is composed of more than one representative, only one is entitled to take part in voting. Voting requires a quorum.

2. The participants and the observers shall not have the right to vote.

3. The decisions of the MEDICRIME Committee are taken by simple majority of the votes cast, subject to any provision in these rules requiring a two-thirds majority or unanimity.

4. For the purposes of these rules "votes cast" shall mean the votes of members cast in favour or against. Members abstaining shall be regarded as not having cast a vote.

Rule 19 – Working groups

1. The MEDICRIME Committee may, within the framework of its general functions, whenever necessary and within the limits of resources available, set up ad hoc working groups to deal with specific matters.

2. The terms of reference of such working groups shall be defined by the MEDICRIME Committee.

Rule 20 – Hearings

The chairperson, the bureau or the MEDICRIME Committee may decide to organise hearings with any qualified persons in a position to contribute to the work of the MEDICRIME Committee within the limits of resources available.

Rule 21 – Periodic reports

The MEDICRIME Committee shall periodically – at least once a year – inform the CDPC, the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and the Committee of Ministers on the state of its work.

Rule 22 – Financial contribution

1. A contracting Party which is not a member of the Council of Europe shall contribute to the financing of the MEDICRIME Committee in a manner to be decided by the Committee of Ministers upon consultation of that Party.

2. Any contracting Party which is not a member of the Council of Europe and which has failed to pay all or a substantial part of its financial contribution to the budget of the MEDICRIME Committee for a period of one year, shall no longer take part in the decision-making process.

Part II – Monitoring of the implementation of the Convention

Rule 23 – General principles

1. Noting that the counterfeiting of medical products and similar crimes by their very nature seriously endanger public

health and bearing in mind that the purpose of the Convention is to prevent and combat threats to public health through criminal law measures, the protection of the rights of victims and promotion of national and international co-operation, while carrying out its functions, the MEDICRIME Committee shall use a multisectoral and multidisciplinary approach.

2. The MEDICRIME Committee shall also bear in mind the international instruments on the protection of public health referred to in the preamble to the Convention.

Rule 24 – Country profile

1. Following ratification and within six months from the entry into force of the MEDICRIME Convention in respect of the Party concerned, every Party to the Convention shall be required to reply to a questionnaire aimed at providing the MEDICRIME Committee with a general overview of its legislative practice, institutional framework and policies for the implementation of the Convention at the national, regional and local levels. Thereafter, the Parties should regularly inform the MEDICRIME Committee of any substantial changes to the situation described in their replies to the general overview questionnaire.

2. States which have signed the Convention shall be invited to reply to the questionnaire referred to in paragraph 1 of this rule.

3. The secretariat shall compile the replies received and make them public on the Committee's website.

Rule 25 – Thematic monitoring

1. The monitoring of the implementation of the Convention by the Parties shall be based on a procedure divided into rounds, each round dealing with a theme chosen by the MEDICRIME

Committee, or any other approach deemed appropriate by the MEDICRIME Committee within the scope of the Convention.

2. The MEDICRIME Committee shall determine the length of each monitoring round in the light of the themes selected and the provisions of the Convention to be monitored.

3. The monitoring round shall be initiated by addressing a questionnaire on the implementation of the relevant provisions of the Convention with respect to the selected theme. The Parties shall respond to the questionnaire within the time limit set by the MEDICRIME Committee.

Rule 26 – Questionnaires

1. The MEDICRIME Committee shall adopt the questionnaires referred to in Rule 24, paragraph 1, and in Rule 25, paragraph 3, which shall be prepared by the bureau with the support of the secretariat.

2. The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".

3. Parties shall co-ordinate with their respective domestic authorities to collect replies, which shall be submitted to the secretariat in one of the official languages of the Council of Europe within the time limit set by the MEDICRIME Committee. The replies to the questionnaires shall be detailed, as comprehensive as possible, answer all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

4. The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.

5. The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits.

Rule 27 – Implementation reports

1. The MEDICRIME Committee shall adopt reports on the implementation of the Convention by the Parties. These shall be based on the information collected through the questionnaires (replies submitted by the Parties and comments thereon), and, if need be, by any other means deemed necessary by the MEDICRIME Committee.

2. The implementation reports shall be prepared by the secretariat with the assistance, if necessary, of independent experts.

3. The MEDICRIME Committee shall decide during the early stages of the monitoring round whether it wishes to prepare implementation reports for each Party or a thematic report for all Parties.

a. When the implementation reports are prepared for each Party, each Party shall receive a draft copy of its implementation report before it is sent to the MEDICRIME Committee. This allows the Party to comment on the draft and clarify any misunderstandings before the draft report is sent to the MEDICRIME Committee for examination and adoption.

b. When the implementations reports cover all Parties, each Party has the opportunity to comment on the draft and clarify any misunderstandings throughout the drafting phase of the implementation report.

4. The implementation reports shall contain at least the following elements:

a. a general description of the relevant legislation, case law or other documentation, including relevant statistics, and a summary of good practices in implementing the Convention;

b. an overview of any problems in implementing the Convention and of the negative effects of any declaration or reservation made under the Convention;

c. where appropriate, recommendations as to the steps to be taken to improve the effective implementation of the Convention.

5. The implementation reports, together with any comment from the Party concerned, shall be transmitted to the CDPC, the CD-P-PH and to the Committee of Ministers of the Council of Europe for information. They shall be made public on the day of their adoption by the MEDICRIME Committee.

6. The MEDICRIME Committee shall review progress made in the implementation of recommendations within 24 months of the adoption of the report.

Rule 28 – Independent experts

The MEDICRIME Committee may ask its executive secretary to commission the services of independent experts, within the limits of budgetary appropriations, to assist it in carrying out its tasks.

Rule 29 – Special reports and urgent situations

1. If the MEDICRIME bureau receives reliable information indicating a situation where problems require immediate attention to prevent or limit the scale or number of serious violations of the Convention, it may designate one or more of its members and/or independent experts as referred to in Rule 28 to assess the specific situation. The bureau shall immediately inform the MEDICRIME Committee about the aforesaid designations. Where warranted and with the consent of the Party or Parties concerned, the assessment may include an on-site visit within its/their jurisdiction(s). This visit takes place in co-operation with the national authorities of the Party or Parties concerned, the member of the MEDICRIME Committee nominated by the latter and the relevant Council of Europe bodies.

2. After examining and adopting the findings of the assessment referred to in paragraph 1 of this rule, the MEDICRIME Committee shall transmit these findings and its recommendations to the Party or Parties concerned. The findings and recommendations, together with any comments received from the Party or Parties concerned, shall be transmitted to the CDPC, the CD-P-PH and to the Committee of Ministers of the Council of Europe for

information. The findings and recommendations, as well as any comments received from the Party or Parties concerned, shall be made public.

Part III – Exchange of information, experiences and good practices

Rule 30 – General principles

Members, participants, observers and the secretariat shall systematically bring to the MEDICRIME Committee's attention any relevant information, experience and good practice falling within the Convention's remit with a view to improving the Parties' capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health, and to enhancing international co-operation.

Rule 31 – General comments and opinions

1. Having regard to the conclusions of the implementation reports adopted to fulfil its monitoring functions or as a result of any discussion during its work, the MEDICRIME Committee may decide to:

a. issue general comments or opinions on its interpretation of the Convention;

b. make and discuss any appropriate proposal for the amendment of the Convention in the light of significant legal, policy or technological developments, in accordance with Article 27 thereof;

c. consider adopting an opinion on any question concerning the application of the Convention, pursuant to Article 25, paragraph 3.b, of the Convention.

2. Proposals for amendments to the Convention agreed upon by the MEDICRIME Committee as a result of the discussions referred to in paragraph 1.*b* of this rule, may be communicated to the Secretary General by the Party or Parties that support(s) them with a view to their possible adoption in accordance with the procedure laid down in Article 27 of the Convention.

3. Opinions on the interpretation or the application of the Convention may take the form of guidance notes representing the common understanding of the Parties as to the use of the Convention.

Rule 32 – Expertise

The MEDICRIME Committee may provide expertise within its field of competence to Council of Europe bodies and to other bodies if considered appropriate.

Part IV – Amendments to the rules of procedure and entry into force

Rule 33 – Amendments to the rules of procedure

The rules of procedure may be amended through a proposal by a Party or the secretariat. Such proposals for amendments shall be decided by a two-thirds majority.

Rule 34 – Entry into force of the rules of procedure

The present rules, as well as any amendment, shall enter into force on the day following their adoption.

Rule 35 – Rendez-vous clause

These rules of procedure will be reviewed by decision of the MEDICRIME Committee, but not later than after two rounds of monitoring.

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