COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

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Committee of the Parties to the MEDICRIME Convention (MEDICRIME CoP)

Preliminary draft Guidelines for monitoring the implementation of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention)

Thematic monitoring

MEDICRIME Secretariat

Contents

Guidelines on the procedure for monitoring the implementation of the Council of Europe MEDICRIME Convention in the context of selected thematic areas

These guidelines were prepared by the Secretariat of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211), hereinafter the MEDICRIME Convention, having regard to its Rules of Procedure. It aims at providing additional guidance to the Committee of Parties of the Convention (the MEDICRIME Committee) on the procedure for monitoring the implementation of the MEDICRIME Convention on selected themes.

PART I: MONITORING PROCEDURE

Section 1 – Monitoring round

1.1. Monitoring by rounds

The MEDICRIME Committee shall monitor the implementation by Parties of the MEDICRIME Convention to prevent and combat threats to public health. To this end, the MEDICRIME Committee shall follow a procedure divided into thematic rounds.

1.2. Adoption of monitoring themes

The MEDICRIME Committee shall discuss and adopt the theme or any other approach deemed appropriate within the scope of the Convention for each monitoring round. The theme shall be suggested by the Chair, the Bureau, any of the Parties or the Secretariat.

1.3. Duration of rounds

In principle, the monitoring round shall last around (…) years. The duration may be shortened or extended by decision of the MEDICRIME Committee, in the light of the themes selected and the provisions of the Convention to be monitored.

1.4. Initiation of rounds

All Parties shall undergo all monitoring rounds unless otherwise decided by the MEDICRIME Committee by two thirds majority of the votes cast. The monitoring round shall be initiated by addressing a questionnaire (see section 2) to each Party at the earliest (…) year and at the latest (…) years following the entry into force of the Convention for each Party concerned.

PART II: MEANS OF MONITORING

Section 2 – Questionnaires and replies

2.1. Questionnaires

The questionnaires shall be prepared by the Bureau with the support of the Secretariat. For each round, the MEDICRIME Committee shall adopt a questionnaire on the implementation by the Parties of the relevant provisions of the Convention with respect to the selected theme.

The questionnaire shall be public once adopted by the MEDICRIME Committee.

The questionnaire shall be addressed to the Parties, through the "contact person" appointed by the latter to liaise with the MEDICRIME Committee.

2.2. Delay for replies

The Parties shall reply to the questionnaire within (…) months from the day it was sent or any time limit set by the MEDICRIME Committee. The replies to the questionnaire shall be returned to the Secretariat.

2.3. Content of replies and requests for additional information

Parties shall co-ordinate with their respective domestic authorities to collect replies.

Replies to the questionnaire shall be detailed, as comprehensive as possible, answer all questions, and contain all relevant reference texts. References may be made to the information contained in the Parties' 'General Overview' questionnaire, so-called 'Country Profile Questionnaire' (CPQ), where appropriate, so as to avoid unnecessary repetition.

The Secretariat may request additional information if it appears that the replies are not exhaustive or are unclear.

2.4. Language of replies

Replies should be submitted in one of the official languages of the Council of Europe (English or French).

2.5. Publication of replies and requests for additional information

The replies to the questionnaire and any other additional information shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

2.6. Information from civil society

Any non-governmental organisation and member of civil society admitted as an observer to the MEDICRIME Committee and involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health may also submit information relating to

questionnaires to the MEDICRIME Committee. This may be done on a voluntary basis or at the request of the MEDICRIME Committee. The replies to the questionnaire or requests for information shall be returned to the Secretariat.

The information shall be provided in one of the official languages of the Council of Europe and within the time limit set by the MEDICRIME Committee. The Secretariat shall transmit these comments to the Party or Parties concerned. The information shall be made public.

PART III: REPORTS AND CONCLUSIONS

Section 3 - Preparation of the draft reports

3.1. Content of draft thematic reports

The Secretariat shall prepare a draft thematic report in coordination with independent experts. The report shall consist of three parts: a descriptive part, an analytical part and conclusions.

The **descriptive part** shall be based on the replies to the questionnaire and any other findings collected by the MEDICRIME Committee related to the implementation by the Parties of the provisions of the Convention in the context of the selected theme being monitored. It shall include at least 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.

The **analytical part** shall consist of reasoned observations on the Parties' implementation. It shall contain at least an overview of any problems in implementing the Convention and of the negative effects of any declaration or reservation made under the Convention. The replies to the questionnaire may be assessed against the related background information provided by the Parties when answering the "General Overview" questionnaire on the implementation of the MEDICRIME Convention (hereinafter "Country Profile Questionnaire") and any other relevant information from reliable sources.

The **conclusions** shall set out suggestions and proposals concerning the way in which the Parties may deal, on an individual or joint basis, with any problems which have been identified. It shall include, where appropriate, recommendations as to the steps to be taken to improve the effective implementation of the Convention.

3.2 Drafting procedure

The Secretariat shall compile the replies to the questionnaire and send the compilation to the independent experts for review within (…) weeks from the deadline for receipt of replies to the questionnaire.

The Secretariat shall prepare the descriptive part of the report, with the assistance of independent experts. The descriptive part of the report shall be finalised within (…) months from the receipt of the compilation of replies to the questionnaire. The Secretariat shall submit it to the Parties for consideration.

The MEDICRIME Committee may decide to extend the duration of the monitoring round on the basis of requests for additional information.

The descriptive part of the report shall be considered final once the additional findings and relevant comments by Parties are incorporated into the draft report, and the MEDICRIME Committee considers it to be ready to be analysed by the independent experts.

The independent experts shall have at least (…) months to submit their individual written analysis and conclusions to the Secretariat.

The preliminary draft thematic report shall be fine-tuned within an additional period of (…) months. It shall be made available to the Bureau.

On the basis of the comments made by the Bureau, the Secretariat and the independent experts shall revise the preliminary draft report. It will then be sent to each Party for written comments. Parties shall have at least (…) month to submit any observations to the Secretariat.

The comments provided by the Party shall be reviewed by the Secretariat and the independent experts with a view to determining which of them are acceptable. If the views of the experts differ on this question, a compromise solution shall be negotiated.

The revised version of the draft thematic report shall be sent to the Bureau before its submission to the MEDICRIME Committee for adoption. The report shall be submitted to the Party representatives at least 3 weeks before the Plenary meeting.

Section 4 – Examination, discussion, and adoption of the thematic reports

4.1. Examination and discussion in plenary

The debate on the thematic report during the Plenary meeting shall start with an oral presentation of the independent experts. In response, the representatives of each Party may provide a general statement on the state of play of implementation of relevant provisions of the Convention in the context of the selected theme of the monitoring round.

Any further recommendations or points addressed during the plenary meeting by any of the Parties may be included in the thematic report.

4.2. Adoption by the MEDICRIME Committee

The thematic report and conclusions shall be adopted by the MEDICRIME Committee at the close of the discussion by simple majority of the votes cast.

The thematic report shall be made public on the day of its adoption by the MEDICRIME Committee.

The thematic report shall be transmitted to the CDPC, the CD-P-PH and to the Committee of Ministers of the Council of Europe for information.

Section 5 – Compliance with the recommendations

5.1. Country-specific reports on implementation

Each Party shall address the MEDICRIME Committee a report on the measures taken to implement the recommendations in the (…) months following its adoption.

The Secretariat shall publish the country-specific reports on the implementation of these recommendations.

5.2. Progress review

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