Terms of Reference

Working Group for the preparation of a report and a Guidance Note [and a Recommendation] on unauthorised removal, including theft, from the supply chain of medical products.

1. Duration

Terms of reference are valid from 1 January 2024 until 31 December 2025.

2. Main tasks

Having regard to:

- Article 25.2, 25.3 MEDICRIME Convention;
- Article 19 Rules of Procedure of the MEDICRIME Committee;
- agreement by the MEDICRIME Committee at its 6th Plenary meeting (Mai 2023)[1];
- agreement by the MEDICRIME Bureau (in September 2023);
- [the decision adopted by the MEDICRIME Committee at its 7th Plenary meeting (November 2023];

The MEDICRIME Committee will prepare a report -including conclusions- for its adoption by the Committee of the Parties as well as a Guidance note based on such conclusions.

The MEDICRIME Committee will explore the possibility of preparing – seeking the opinion of the European Committee of Crime Problems – a recommendation for its submission to the Committee of Ministers in view of its adoption.

3. Expected results

A report – including conclusions– is prepared and finalised by the MEDICRIME Committee by December 2025. It is aimed to determine how best the MEDICRIME Convention could support the enablement of the prevention, detection, investigation and prosecution of such crimes. On the basis of the above conclusions, a Guidance Note will also be drafted.

A Committee of Ministers Recommendation including an Explanatory Report will be considered during this exercise.

The objectives of the report are *inter alia*:

a. to identify the circumstances, including availability and choice of product types, in which medical products are lost to the supply chain through unauthorised removal from the authorised regulated market, including by theft;

[1] List of decisions:
"on the need to move forward with this work and mandate its Bureau to decide the procedure to be followed for the drafting of a report and its recommendation"

b. To ascertain the consequences for the public health system regarding the undermining of the system's ability to ensure the security of supply to the authorised market, the security at the point of loss from the system, and the infiltration in a falsified and unauthorised manner to a market in a different jurisdiction;

c. to highlight the consequences to the criminal justice system (undermining the system's ability to adequately address such crimes);

d. to illustrate the need for national and international cooperation to address this truly transnational crime with an impact on public health;

e. to identify the added value of the MEDICRIME Convention in the areas of investigation and judicial cooperation to prosecute the intentional behaviours involved that lead to the counterfeiting of medical products and similar crimes.

The report will examine:

- the consequence of poor governance and security in the procurement and supply of medical products, when combined with an inadequate criminal justice system and a low risk of detection and prosecution, results in a favourable environment for criminal groups to exploit;

- reports of the removal from the authorised supply system, including by diversion, where not permitted by law and theft from the different markets of the Parties, signatories and Council of Europe member States with a view to determining whether these trends are common in all situations.

- whether there were resources available to States for use by their investigation and prosecution authorities and those tools that have been developed but may not yet be implemented, such as the MEDICRIME Convention and the Palermo Convention.

- the role played by international cooperation to assist law enforcement and judicial cooperation to rapidly exchange vital investigative information facilitating evidence collection in other States on these crimes

- whether a dedicated MEDICRIME 24/7 network could better facilitate cooperation in these circumstances.

- the impact on victims to see what lessons can be learned concerning their protection.

It is understood that these elements – as proposed at the concept paper agreed by the Committee of the Parties[1] – are elements for reflection. Their feasibility would need to be determined during the drafting of the report. Other elements may also be considered in the course of the process.

4. Working methods

The draft report, to include the drafting of the guidance note, and possibly the CM Recommendation on this issue will be prepared by a Working Group and adopted by the MEDICRIME Committee.

[1] T-MEDICRIME(2021)10.

The Working Group meetings will be held in closed sessions (Article 11 Rules of Procedure).

Whenever appropriate, the Working Group may make use of working methods that are environmentally sound and protective of the health of participants, such as virtual meetings facilitated by information technology and written procedures. The MEDICRIME Rules of Procedure will apply *mutatis mutandis* to decision-making and meetings by electronic means and written procedures within that Working Group.

The Working Group will report and meet back-to-back with the MEDICRIME Bureau.

5. Composition of the Working Group

The Working Group will consist of representatives of State Parties as appointed by MEDICRIME Heads of Delegation without defrayal of expenses.

The MEDICRIME shall elect seven representatives of State Parties (appointed by the MEDICRIME Heads of Delegation) taking into account expertise, geographical distribution, gender balance and legal systems. Their cost for travel and per diem will be borne by the Council of Europe within the limits of budgetary appropriations should any physical meeting is to be considered.

The Working Group will be chaired by a Chair who will be the rapporteur of the report and in his/her absence by a Vice-Chair.

Participants and observers included in the Rules of Procedure of the MEDICRIME Committee may appoint a representative without the right to vote and without defrayal of expenses.

Individual experts may be invited to participate in meetings of the Working Group.

6. Meetings

The Working Group will determine the number of meetings to be considered for attaining its results. However, a meeting every quarter during 2024 is needed to make sure that the initial work is implemented accordingly.