

Strasbourg, 10 February 2025

T-MED (2024) LD1

# Committee of the Parties MEDICRIME Convention

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## 8th Plenary meeting List of Decisions Strasbourg, 21-22 November 2024

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The Committee of the Parties (hereinafter referred to as “the MEDICRIME Committee” or “the CoP”) to the MEDICRIME Convention (hereinafter, the Convention), under the Chairmanship of Mr Christian Tournié (France), decided:

### 1. Opening of the meeting

- **to take note** of the information provided by Mr Rafael Benítez, Director of the Directorate of social rights, Health and Environment, who welcomed to all the Parties and signatory countries to the convention that were present and informed them that in 2025 the activities relating to Bioethics and Bio-Medicine will also be integrated within the department of Health.



- **to take note** of the welcoming remarks by the Chair to all Parties, participants, observers and independent experts to this CoP meeting; Mr Christian Tournié, informed all participants of the passing of Professor Carlos María Romeo Casabona in August. He emphasised Prof. Romeo Casabona's expertise, which was crucial to the development of the Committee's work, along with his valuable contributions. In honour of his legacy, the Chair requested a moment of silence.

## 2. Adoption of the draft agenda

- **to take note** of the decisions of the last Plenary Meeting (28-29 November 2023);
- **to adopt** the agenda and the order of business of the meeting without amendment (the list of participants and the agenda appear in Appendices I and II respectively);

## 3. Information by the Chair and the Secretariat

- **to take note** of the information provided by its Chair, Mr Christian Tournié, and the Secretariat on activities undertaken since the last Plenary meeting as well as on the recent developments of relevance to the work of the CoP and within the Council of Europe, in particular, regarding the bureau meetings that took place during the year of 2024, where the bureau has gathered three times online and twice in person. The Chair also informed about the work that has been done during this year regarding the 24/7 Network and the meeting that took place in Portugal which resulted in a report that will help with the implementation of the 24/7 Network.
- **to take note** of the information provided by the Secretariat that all state Parties to the Convention were present apart from three (Moldova, the Russian Federation and Belarus). The Secretariat informed it was the first time with so many participants present including four signatory countries, which showed the interest for the topic.
- **to take note** the signature of Chile that will take place on 27/11/2024.
- **to remind** that the main goal of the meeting was the adoption of the first monitoring report.

## 4 Exchange of Information / Tour de table

- **to take note** on the information provided by all members of the CoP on the most recent (criminal law) developments in their national frameworks and also to the suggestions for possible new initiatives by the MEDICRIME Committee and any issue raised relating to the CoP scope of activities;
- **to take note** the exchange of views between the Minister of Health and Public Hygiene of Guinea, Dr Oumar Diouhé BAH, and the members of the CoP on the most recent and significant issues related to the Convention in his country. The Minister informed that since the 5th of September 2021, the Guinean authorities started to undertake a battle to combat fake medical products, which gave rise to burn almost 400 containers of falsified medical products. He informed that national authorities are currently working in the drafting of Guinean pharmaceutical law, where all forms of trafficking of medical products will be criminalised.

## 5. Monitoring of the MEDICRIME Convention and future work

### 5.1 Country profile Questionnaire and its replies

- a) Status of play and answers received
  - **to take note** of both the state of play of the Country Profile Questionnaire (CPQ) and the answers received from the different state Parties;
- b) Call for request to the following state Parties:
  - **to take note** that the answer to the Country Profile Questionnaire is still missing for certain state Parties (Albania, Armenia, Belarus and Benin) and recalled them to provide it at their earliest convenience;
  - **to remind** all Parties Article 24 of the MEDICRIME Rules of procedure, whose paragraph 1 recalls that *“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 the legislation 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”*
- c) Call for request to other signatory countries
  - **to take note** that the Bureau considered the Country Profile Questionnaire to be answered on a voluntary basis by both signatory countries and all Council of Europe member states non-Parties to the MEDICRIME Convention;
  - **to discuss** in detail the above consideration, **agree** to such proposal and **instruct** the Secretariat to draft a letter to be signed by the Chair of the CoP informing both the signatory countries and CoE member States non-Parties to the MEDICRIME Convention about this decision;

### 5.2 1st Thematic Monitoring round: *The protection of public health through the MEDICRIME Convention in times of pandemics*

- a) Status of play and answers received
  - **to take note** of the latest Status of Play (on date of 17 October 2024) of the answers received to the 1<sup>st</sup> thematic monitoring questionnaire.
- b) Discussion and adoption of the Final draft Report
  - **to recall** that at the 6th Plenary Meeting (10-12 May 2023), Parties were requested to provide (by 27 November 2023) comments to the draft 1st Monitoring round report for the bilateral discussions with the Secretariat. In the same plenary meeting, and due to an explicit official request by Switzerland, the Secretariat was tasked with the translation into French of the draft 1st Monitoring round report. The draft report was translated into French by September 2023.

- to **take note** that given the latest additional answers provided by some Parties, a new report was drafted and sent to Parties on 27 July 2024 for possible comments (before 26 September 2024);
- following bilateral discussions with some Parties in mid-October, to **take note** that a revised new version of the report (Final draft 1st Monitoring round report-rev) was prepared and shared with the Parties for its discussion and adoption at the forthcoming 8th Plenary meeting. Against this background, state Parties were also informed that the answers to the “optional questions” provided by all state Parties were reviewed and updated in the new version of the report to accommodate the new position resulting from the bilateral discussions held with one of the Parties. Thus, the changes related to these optional questions’ answers were introduced during the meeting and the Parties agreed to them;
- to **take note** that some Parties submitted additional comments to the draft 1<sup>st</sup> monitoring report shortly before the plenary meeting and agree, in principle, the draft report pending the final submission of the revised draft for its adoption by written procedure early next year. The CoP also agreed that these additional comments would only reflect the views of the Parties submitting comments and would not apply to the entire report. Consequently, the CoP instructed the Secretariat to continue bilateral discussions with those state Parties that provided comments and to prepare a final version for written adoption;
- in relation to those countries that did not submit their answers to the monitoring report, to **take note** of the information provided by the Secretariat: while the ideal scenario would be to monitor all countries simultaneously, delays often occur, particularly in monitoring cycles due to a lack of familiarity with the procedure or the accession of new countries (non-CoE member States). To address this situation, the CoP agreed to divide the monitoring in groups (Group A, Group B, etc.) where countries would be monitored;

c) Situation with non-answering Parties (Discussion)

- to **recall** Article 25 of the MEDICRIME Convention<sup>1</sup> and Rule 25.3 of the MEDICRIME Rules of Procedure<sup>2</sup> and **invite** those Parties that did not do so (**Albania, Belarus, Benin, Burkina Faso, Guinea, Moldova, Niger and Ukraine**) to fulfil their conventional obligation and submit their answers to the 1st monitoring round questionnaire so that their replies could be assessed at a later stage;
- to instruct the Bureau to discuss this issue and take a decision to be discussed at the Plenary meeting;

### 5.3 2nd Thematic Monitoring round: *Deposit and destruction measure of seized counterfeit<sup>3</sup> medical products, active substances, excipients, parts, materials, and accessories*

a) Draft Questionnaire- discussion and adoption

<sup>1</sup> Article 25 MEDICRIME Convention: “*The Committee of the Parties shall monitor the implementation of this Convention*” and that “*the rules of procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention*”.

<sup>2</sup> Article 25.3 Rules of Procedure of the MEDICRIME Committee: “*The monitoring round shall be initiated by addressing a questionnaire (...)*” and that “*the Parties shall respond to the questionnaire within the time-limit set by the MEDICRIME Committee*”.

<sup>3</sup> Guidance Note to meaning of counterfeit being the same as falsified.

b) Explanatory Note to the 2<sup>nd</sup> Thematic Monitoring Round Questionnaire

- to **examine** the draft questionnaire of the 2nd monitoring round, the Explanatory Note and the Chronology and to **have** an exchange of views about them;
- to **amend** the above-mentioned documents and **adopt** them;
- to **instruct** the Secretariat to send the Questionnaire adopted and the explanatory Note to all Parties;

5.4 **MEDICRIME Strategy 2024-2025**

- to **take note** of the Strategy Interim Report and have an exchange of views with the Secretariat on its status of implementation.

5.5 **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**

- to **take note** of the preparation work carried out by this Working Group and the responses received regarding its establishment, as it is set to begin its activities in 2025.

5.6 **Requests received by the MEDICRIME Committee for comments:**a) Recommendation CM/Rec(2024)3 of the Committee of Ministers to member States on *reporting of disappearances of medicinal products for human and veterinary use from the legal supply chain*

- to **welcome** the Recommendation (2024) *on reporting disappearances of medicinal products for human and veterinarian use form the legal supply chain* adopted by the Committee of Ministers on 10 April 2024;

## b) Draft Council of Europe Recommendation on best practices for the remote and online provision of medicines

- to **note** the MEDICRIME Committee's answer provided to the EDQM Secretariat and have an exchange of views with the EDQM Secretariat on the drafting process of this new CoE recommendation;

6 **Exchange of information, experiences and good practices**6.1 **Exchange of views with the Chair of the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED)**

- to **have an exchange of views** with Mr Chris McGuire, Chair of the CD-P-PH/CMED, who informed about the feedback of the latest meetings held by the committee (in spring and autumn 2024) as well as on the latest activities implemented by the committee of experts, namely: the Guidance for CM/Rec(2024)3 on reporting of disappearances of medicinal products for human and veterinary use from the legal supply chain and the Guidance on Falsified medicines.

6.2 **Exchange of views with the Network of Official Medicines Control Laboratories (OMCLs)**

- to **take note** that this issue will be dealt in a future CoP meeting;

### 6.3 Presentation of relevant initiatives of the Parliamentary Assembly of the Council of Europe (PACE)

- to **take note** that this item will be dealt in a future meeting;

### 6.4 Presentation of relevant activities by national authorities, international governmental organisations, observers as well as other services of the Council of Europe

- Following the Bureau's request, **to hold** an exchange of views with the representatives of:
  - a) AIDF, Brazzaville Foundation and ASOP Europe.
    - Representing **AIDF**, Mr Sylvian Daya Abazene and Ms Epse Mamoudou Aissatou Kote Oumarou informed that on 19 September 2024, a training session on the MEDICRIME Convention was held in Strasbourg, attended by over 150 participants. These included representatives from approximately fifteen countries, such as Benin, Burundi, Cameroon, the Central African Republic, the Union of the Comoros, Congo-Brazzaville, Ivory Coast, Gabon, Mali, and the Democratic Republic of Congo. The training aimed to enhance and expand the technical expertise of customs officers in combating the falsification of medical products. Additionally, a roundtable discussion was organised to share insights on various seizures conducted in their respective countries.
    - From **Brazzaville Foundation**, Mr Foulo Basse, informed of the work that has been ongoing, with the support of the World Health Organization, the Gates Foundation as well as other foundations and the West African Health Organization, to help Togo to modernize its national plan to combat falsified medical products through a collaborative approach involving multiple ministries and organizations. He also informed that they are establishing a lectureship at the Sorbonne to advance research on this issue and create an African database of genuine pharmaceuticals. This database will help differentiate between real and fake products and improve public communication in multiple languages.
    - From **ASOP Europe**, Mr Mike Isles, informed about the Rogue RX activity report, on how to make the internet a safer place to buy medicines (through Global Signal exchange, the gTLD DotPharmacy and the longitudinal market research).
  - b) the **Pompidou Group**: Mr Denis HUBER, Executive Secretary of the Pompidou Group, highlighted the shared areas of collaboration between this partial agreement and the CoP, while expressing the Group's commitment to strengthening synergies between both entities;

### 6.5 Gender issues

- to **take note** that, due to the absence of the Gender Equality Rapporteur in this meeting, she will be asked to present her report and actions on this topic (survey) at the next meeting;

## 7. Technical Co-operation activities

### 7.1 CRIMFAMED Global Programme: latest developments

- to **take note** of the developments of the multiple activities implemented in 2024 within the CRIMFAMED Project, which is a French voluntary contribution;
- to **take note**, particularly on the outcomes of the third Working Group meeting on 24/7 Network organised in Lisbon, at the Headquarters of the Polícia Judiciária, which highlighted the importance of implementing the criminal law provisions of the MEDICRIME Convention (Article 5-14; Chapter II Substantive criminal law). Moreover, in this WG, the majority of participants: a) supported a 24/7 Network integrated into an existing cooperation and information exchange network operating with the same staff and recognising medical product-related crimes as a specific crime type; b) recommended the CoP the establishment of a 24/7 Network dedicated to cooperation and information exchange, specifically addressing falsified medical product crimes and similar crimes;
- to **have an exchange** of views on whether a 24/7 Network is to be set up and agreed and based on the recommendation adopted by the WG members, the Parties decided to set-up a 24/7 Network;
- to **take note** of the outcomes of the different drafting legislative process within the CRIMFAMED Project, in particular the working meetings organised in 2023 and in 2024 (12 February, 21 February, 13 March and 18 September) within the Project to help the Ivorian authorities to draft its national law implementing the MEDICRIME Convention.
- to **take note** that the MEDICRIME Committee also provided comments to the draft revised African Union Model Law on Medical Products Regulation.

## 7.2 HELP Training

- to **take note** of both the face-to-face training provided to legal professionals and law-enforcement authorities in Spain and the different translations to the HELP online training on MEDICRIME Convention  
(<https://help.elearning.ext.coe.int/course/view.php?id=4292>)

## 7.3 Call for voluntary contributions

- to **take note** that the Council of Europe welcomes voluntary contributions from member States and other entities (observer states, non-member states, the European Union, international organizations, foundations, etc.) that share the Organization's goals and values, to support the implementation of the CoP's activities. Both financial and in-kind contributions are highly appreciated and play a crucial role in advancing the CoP's efforts;
- to **remind** all those interested in providing any voluntary contribution to contact the Secretariat for further details;

## 8. Request for Observer status

- to **take note** of the presentation made by the Director of FEDEFARMA, a trade association entity that groups 18 pharmaceutical companies of research and development in the region of Central America and the Caribbean, and which supports authorities and governments through technical cooperation activities;

- to **have an exchange** of views with the Director on the basis of the documentation received and after voting, in camera, grant the observer status to FEDEFARMA.

## 9. Financing of the Committee of the Parties

- to **take note** of the Parties' financial obligations and in particular of Article 23.5 of the MEDICRIME Convention:

*“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”.*

- to **instruct** the Secretariat to contact the Parties not fulfilling this conventional obligation so that they could regularise their situation at their earliest convenience;
- to **inform** the communication of the Russian Federation of 27 September 2024, regarding the suspension of practical cooperation in the context of the MEDICRIME Convention;

## 10. Elections

- to **express** its warmest thanks to Ms Judith Voney (Switzerland) and Mr Mkrtich Shakaryan (Armenia), Bureau members, that are leaving the BUREAU-Medicrime due to the limitation of their term of office in accordance with Art. 4.4 RoP, for their excellent way in which they contributed to the CoP's work since 2019 and the work implemented so far in the fight against counterfeiting of medical products and similar crimes;
- to **proceed** with the election of 2 new Bureau members. In this regard:
  - the rules for proceeding with the voting and Rule 3 of the RoP were explained to all Parties;
  - the voting process was implemented in the room, ballot papers were distributed to all Parties. However, given that there was only one candidate, all Parties agreed, by acclamation, to elect Mr Iván A. Bujdos (Hungary) as a new Bureau member;
- to **take note** that the election of the Chair and Vice-Chair will take place at the forthcoming Bureau members following the end of their mandate;
- to instruct the Secretariat to contact all Parties asking for applications;

## 11. Information points

### 11.1 New accessions to the MEDICRIME Convention

- to **welcome** Cyprus for having ratified the convention, and Chad, Chile and Tunisia that having signed the convention

### 11.2 Participation of the MEDICRIME Committee in outside events

- to **take note** of the different events where the CoP was represented, mainly the WGEO in November, where the CoP was represented by its Chair;

**11.3 Website**

- **to take note** that the MEDICRIME Committee's website is being amended;
- **to instruct** the Secretariat to contact national delegations to provide and update their information;

**12. Any other business**

- to **invite** Parties to provide in writing any suggestions for possible new initiatives, topics or any other relevant issue to be considered by the CoP;

**11. Dates of the next Plenary meeting**

- to **take note** that the next Plenary meeting will last 2 days and that the tentative dates of the forthcoming CoP meeting will be in March 2025 (week of 24<sup>th</sup> March);
- to **instruct** the Secretariat to inform all Parties, participants and observers once the dates are finally agreed upon.

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