



Strasbourg, 1 March 2024

T-MEDICRIME (2023) LD2

# Committee of the Parties MEDICRIME Convention

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## 7th Plenary meeting

### List of Decisions

**Strasbourg, 28-29 November 2023**

Council of Europe  
Palais de l'Europe, Room 2

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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 Ms Hanne Juncher, Director, Information Society and Action against Crime, Directorate General Human Rights and Rule of Law, who both thanked all the Parties for their commitment to participate in the plenary meeting's work and welcomed observers and participants by stressing the importance of multisectoral and multidisciplinary approach. Ms Juncher also underlined the key role of the CoP in monitoring a criminal law convention and highlighted the CoP coordination work with observers and other intergovernmental and scientific committees;
- to take note of the welcoming remarks by the Chair to all Parties, participants, observers and independent experts to this CoP meeting;



## 2. Adoption of the draft agenda

- to adopt the agenda and the order of business of the meeting without amendments (the list of participants and the agenda appear in Appendices I and II respectively);
- to take note of the main items of the agenda presented by the Executive Secretary to the MEDICRIME Committee, Dr Oscar Alarcón-Jiménez;

## 3. Information by the Chair and the Secretariat

- to take note that the [CRIMFAMED project](#), funded by a voluntary contribution from France, is coming to an end by 31 December 2023 and that a project extension will be requested;
- to note the following activities implemented within the CRIMFAMED project: a) a conference was organised in Brescia, Italy, on 16-17 November 2023; b) a report on the 24/7 Network; c) the domestication of the Ivory Coast legislation;
- to encourage Parties and observers to both provide voluntary contributions to finance activities to promote the MEDICRIME Convention and invite other stakeholders to do so;

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

### 4.1 Country profile Questionnaire

- to take note of the [state of play](#) containing the answers received so far by Parties;
- to take note that the Country Profile Questionnaire is still missing for the following countries: Albania, Armenia, Belarus, Benin and Morocco;
- to note that Cyprus and Ivory Coast are also missing because they ratified the Convention in the second half of 2023;
- to remind all Parties of Article 24 of the MEDICRIME Rules of Procedure, in particular paragraph 1<sup>1</sup>;
- to consider the reasons why some Parties (Albania, Armenia, Belarus, Benin and Morocco) did not yet provide their answers to this questionnaire and remind these Parties of the date that the questionnaire was sent to them (Albania: 16 July 2020; Armenia: 28 September 2020; Belarus: 16 July 2020; Benin: 16 July 2020; Morocco: 19 April 2022);
- to encourage Parties to provide their replies to this questionnaire before the forthcoming Plenary meeting in 2024;
- to instruct the Secretariat to follow the submission by these Parties of the Country Profile Questionnaire and inform the Bureau accordingly so that further steps can be taken;

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<sup>1</sup> Art 24.1 Rules of Procedure of the MEDICRIME Committee: “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.”

#### 4.2 1st Monitoring round: *The protection of public health through the MEDICRIME Convention in times of pandemics*

- to recall Article 25 of the MEDICRIME Convention<sup>2</sup> and Rule 25.3 of the MEDICRIME Rules of Procedure<sup>3</sup>;
- against this background, to request the following Parties (**Albania, Armenia, Belarus<sup>4</sup>, Benin, Burkina Faso, Guinea, Moldova, Morocco, Niger, Portugal, Slovenia and Ukraine**) to provide information in a *tour de table* on the reasons for not having submitted their 1st monitoring round report yet. Against this background:
  - **Armenia** confirmed that the 1<sup>st</sup> Monitoring Round Questionnaire will be submitted in the first quarter 2024;
  - **Ivory Coast** confirmed that the Questionnaire will be replied to by March 2024;
  - **Cyprus** confirmed that they have just received the Questionnaire. A meeting with the different stakeholders will be organised and the Questionnaire may be submitted by April 2024;
  - **Republic of Moldova** confirmed that the Questionnaire will be ready by February 2024;
  - **Morocco** confirmed that the Questionnaire is about to be finalised;
  - **Niger** confirmed that the Secretariat is in contact with the Niger representative and that the Questionnaire is in process of being answered;
  - **Portugal** confirmed that a Working group with different bodies was set up and hoped to complete the Questionnaire by the first quarter of 2024;
  - **Slovenia** confirmed that the Questionnaire was submitted to the Secretariat a day before the plenary meeting of the CoP;
  - **Ukraine** confirmed that their Questionnaire was sent to the Secretariat. However, as the Secretariat did not receive it, the CoP invited the Ukrainian representative to resend it;
  - **Albania, Belarus, Benin, Burkina Faso and Guinea** were not present.
- to invite the above-mentioned Parties to submit their answers to the 1st monitoring round questionnaire before May 2024 so that these replies can be analysed together with the other Parties' answers so that the report can be adopted at the forthcoming Plenary meeting;
- to note that a letter, signed by the Chair, will be sent to Parties recalling the conventional obligation of monitoring the implementation of the Convention (Article 25);
- to instruct the Secretariat to follow the appointment of a focal point in the following countries: **Albania; Belarus; Benin; Burkina Faso; Guinea**, and discuss with this representative the submission of the Questionnaire and keep the Bureau informed;
- to instruct the Secretariat to liaise with the above-mentioned Parties (as well as the new Parties<sup>5</sup>) to follow with them the CoP's invitation, gather their answers to the 1st Monitoring Round Questionnaire and inform the Bureau accordingly; once the answers are compiled, to proceed in the same way as with the Parties that already replied to the Questionnaire (begin with the observation process);

<sup>2</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>3</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>4</sup> **Belarus** has not submitted yet the 1st monitoring round report. Following the Committee of the Parties' decision of 16 March 2023, Belarus physical attendance is restricted.

<sup>5</sup> **Ivory Coast** ratified the MEDICRIME Convention on 20 July 2023. **Cyprus** ratified the MEDICRIME Convention on 5 September 2023.

- to take note of the answers received to the 1<sup>st</sup> Monitoring Round Report by certain Parties (**Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Russian Federation, Slovenia, Spain, Switzerland and Türkiye**), warmly thank them and discuss the draft monitoring report;
- to instruct the Secretariat: a) to begin the observation process<sup>6</sup> (bilateral discussions) with those Parties that replied to the 1st monitoring round report; b) to gather these Parties' comments (if any) for examination; c) based on the comments received, to review the draft 1st monitoring round report ahead of its examination and approval at the next Plenary meeting in 2024;
- to agree on the Guidance document explaining the monitoring procedure, by including the comments made by Switzerland;
- to consider the theme(s) of its **2<sup>nd</sup> Monitoring round** submitted by Spain<sup>7</sup>, Hungary<sup>8</sup> and Switzerland<sup>9</sup>. Against this background, Hungary requested additional time to fine-tune its proposal. Some Parties supported the Swiss proposal, which was a "non-proposal". Against this background, the Secretariat both explained to the Parties the whole calendar of a Monitoring Round so that the Parties could understand and informed them that a theme for the 2<sup>nd</sup> Monitoring round needed to be chosen regardless of the timing of the 1<sup>st</sup> Monitoring round exercise. To overcome this situation, the Chair agreed to solve this issue by a public vote by informing the Parties that this exercise will not begin before 2025; then checked the quorum, orally asked the question and invited the Parties to vote<sup>10</sup>.
- as the result of the voting was positive for the launching of a 2<sup>nd</sup> Monitoring Round, the CoP instructed the Secretariat to send both proposals (Hungary and Spain) to all Parties for them to choose by written procedure;
- to allow Hungary some additional time to fine-tune its proposal;
- once the theme is chosen by written procedure, to instruct the Secretariat to begin with the drafting the 2<sup>nd</sup> Monitoring Round Questionnaire for discussion, review and amendment by the Bureau and then its adoption at the forthcoming Plenary meeting;

#### 4.3 Definition of the term "counterfeit" vs. the term "falsified and substandard"

- to take note of the new draft Guidance Note sent to the Parties, discuss it, and highlight page 12, the item 10.3 of the document, so that all Parties clearly understand the term to be used by the CoP from now onwards;
- as some Parties did not receive instructions about this issue, to instruct the Secretariat to request Parties to adopt by written procedure (two weeks' time) the draft Guidance Note on the meaning of the term "counterfeit" under the MEDICRIME Convention;

#### 4.4 Draft Strategy 2022-2024

- to take note of the explanations provided by the Chair on the need of having a MEDICRIME Strategy;

<sup>6</sup> Following the Guidance document explaining the monitoring procedure.

<sup>7</sup> Spain has provided the following theme: *Deposit and destruction measures of seized counterfeit medical products (possibly study the convenience of adding substances, excipients, parts, materials and accessoires)*.

<sup>8</sup> Hungary has provided the following theme: *the regulation of telemedicine and distance selling of medicines in relation to the MEDICRIME Convention*. A particular focus would be on the measures taken to protect public health against counterfeiting of medicinal products and similar criminal activities in the context of telemedicine and distance selling of medicinal products.

<sup>9</sup> Switzerland refrains from submitting a topic proposal for the 2nd Monitoring Round until the 1<sup>st</sup> Monitoring Round is finished.

<sup>10</sup> Question asked by the Chair: "Do you agree to begin with the 2<sup>nd</sup> Monitoring Round process?". Answers provided by countries: a) In favour: 11 countries; b) Against: 2 countries; c) Abstention: 1 country.

- to take note, consider, discuss and amend the Preliminary draft Strategy, in particular item 3.2 related to the “evaluation of the establishment of a 24/7 Network for the cooperation and exchange of information for the MEDICRIME Convention”;
- after agreeing to the amendments, to adopt the Strategy (Appendix IV);
- to instruct the Secretariat to publish it in the CoP’s website;

#### **4.5 Report on criminal activity resulting in leakages from the medical product supply chain**

- to consider the concept note of this report on criminal activity resulting in leakages from the medical supply chain and to take note the draft terms of reference (hereinafter, ToR) of a working group (hereinafter, WG), in particular that: a) the WG will meet every quarter in 2024 and for 2025 the WG will decide on the timings; b) WG meetings will be mainly online, with possible face-to-face meetings in 2024; c) the WG will be composed of up to 7 members; d) the Parties should send their nomination proposals to the Secretariat; e) the chair of the WG will be the rapporteur;
- to take note of the change of the title of the report as follows: “on unauthorised removal, including theft, from the supply chain of medical products”;
- to discuss, amend and adopt the ToR and instruct the Secretariat to send them to Parties, who will have two weeks for submitting their applications;

#### **4.6 Report on falsification of medical products for veterinary use**

- to thank Dr José María Fernández and Dr Sigitas Siriukaitis for their excellent report entitled “Survey on falsification of medical products for veterinary use”, which analyses all the answers received;
- to take note of the report, discuss it in detail, have an exchange of views on it and adopt it;
- to take note of the following information:
  - the information appeared in the Press (27 November 2023) “*One person found to be infected with H1N2 strain*” of a suspected case of swine flu in the United Kingdom;
  - the representative from Niger informed the meeting that in Niger there is a legal initiative to include under medicines also those for veterinary use;
  - the ASOP representative reminded the group how the Internet is being abused to provide consumers with illegally prescribed medicines and warned countries to be very alert on the existence of this problem;
  - the Belgium representative stressed that this is a real danger for human health coming from an issue related to animal health; she also informed the group that there is a pilot project organised by the World Organisation for Animal Health asking information on falsified medicines;
- to invite those Parties that did not yet do so to provide their answers to this survey and instruct the Secretariat to introduce their answers on the website;
- to instruct the Secretariat to contact the World Organisation for Animal Health with a view to sharing this report and network with them;
- to invite the Bureau to decide the best way to follow-up this report (further steps);

#### **4.7 Requests received by the MEDICRIME Committee for comments:**

- to have an exchange of views with the CD-P-PH/CMED representative and EDQM Secretariat;
- to notice that the CoP’s opinion on the draft *Council of Europe Recommendation on reporting of unaccounted disappearances of medicinal products for human and veterinary use from the legal supply chain* was sent to CD-P-PH/CMED;
- following the last request made in May by the CD-P-PH/CMED Secretariat, to reiterate the invitation to the Parties to provide their written comments to the Secretariat (no later than 15 December 2023)

on the draft *Council of Europe Recommendation on best practices for the remote and online provision of medicines*, to instruct the Secretariat to compile all the Parties' points of views and comments, to mandate its Bureau to draft, urgently before the end of the year, an opinion; to instruct the Secretariat to send that opinion to the CD-P-PH/CMED Secretariat before the end of the year;

## 5 Exchange of information, experiences and good practices

### 5.1 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 Ms Lynda Scammell, Chair of the CD-P-PH/CMED, on the work of this expert committee, in particular : a) the latest CMED meeting devoted to *inter alia* information exchange and discussion of: the impact of shortages of medicines, issues with food supplements in countries, theft, diversion of some medicines, abortion tablets sold online, vitamin infusion, etc); b) the training held in 2023 for inspectors of certain countries (Austria, Germany and Switzerland) and the training session to be held in 2024 in Bulgaria for inspectors from other countries (Armenia, Georgia, Moldova, Romania, Türkiye); c) communication publications; d) a report containing the results of a [survey on medical devices](#) (2023); e) on transversal activities such as a working group meeting and a network group of experts on Borderline products;
- to instruct the Secretariat to send the link of the above survey to the Parties;
- to thank Ms Scammell for all her excellent work as CD-P-PH/CMED Chair during the years;

### 5.2 Presentation of relevant initiatives of the Parliamentary Assembly of the Council of Europe

- to have an exchange of views with Ms Anita Gulami, PACE Secretariat from the Committee on Social Affairs, Health and Sustainable Development, on the work implemented by the PACE, in particular the PACE resolutions, recommendations and reports produced in the past years: the Recommendation 1673(2004) [on counterfeiting: problems and solutions](#), Recommendation 1794 (2007) [on the quality of medicines in Europe](#); a Report [on addiction to prescribe medicines](#) (2022) and a Report [on securing safe medical supply chains](#) (2022);
- to note that the PACE continuously encourages countries to sign and ratify MEDICRIME Convention; against this background, the PACE lead the drafting of the [Handbook for parliamentarians](#) on the MEDICRIME Convention to bring this issue in front of the national Parliaments;
- instruct the Secretariat to send to the Parties the link to the Handbook, which has been translated into English, French, Spanish and Russian;

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

- at the request of the Bureau, to hold an exchange of views with the observers to the CoP on the work implemented by them to fight against the counterfeiting of the medical products and other similar crimes in view of the promotion of the Convention;
- to take note on the information provided by Ms Caroline Allheily, from Les Entreprises du Medicament (LEEM), who introduced her organisation, stressed the explosion of falsified medicines and fake prescriptions, and explained the activities implemented by the LEEM, mainly the training activities addressed to police and customs authorities to fight against fake medicines; and to invite LEEM to provide a short presentation in writing to be delivered to the Bureau;
- to take note of the information provided by Mr Cedric Otse-Mawandza Cedric, representative from the Brazzaville Foundation, who introduced the Foundation aimed at *inter alia* promoting the fight against fake medicines, reinforcing the capacities of authorities and raising awareness; he also informed the group about two training sessions the Brazzaville Foundation has organised as a preparation for the conference to be organised at the end of 2024, and about the support given to help certain countries to join the Convention (Togo and Congo); to instruct Mr. Otse-Mawandza to provide a short presentation in writing to be delivered to the Bureau;
- to take note of the information provided by Mr Mike Isles, representative from the Alliance for Safe Online Pharmacy in Europe (ASOP-EU), who stressed the importance of working with Google to

identify companies who are working illegally (through the “key word” system and a legal screening); he highlighted the importance of a unified medical electronic record to prevent illegal networks and allow patients to know where to find more authentic medicines; he proposed Parties: a) to use top-level domain “DOT Pharmacy” (depending the language: “dotApotheke” or “dotPharmacie” or “dotFarmacia”) on a country-by-country basis, by creating certainty to patients that the domain is safe; b) to embark on a longitudinal multi-country market research project to ascertain and track trends (Appendix V). Against this background, the CoP informed the Parties that they could individually contact and discuss with Mr Isles on these proposals. The CoP welcomed Mr Isle’s proposal addressed to the observers consisting of including a reference to the MEDICRIME Convention in their respective websites;

- to instruct the Secretariat to invite those observers who could not participate in this plenary meeting to the forthcoming Plenary meeting in 2024 to hold an exchange of views;
- to instruct the Secretariat to draft a survey/questionnaire addressed to the observers and seek their input to help the CoP to promote and implement the Convention; the answers to the survey shall be provided to the Secretariat no later than the summer of 2024 for its examination and follow-up by the Bureau;
- at the invitation of the Chair, to have an exchange of views with the Parties on significant developments and take note on the statement of Mr Assane Coulibaly, Director general of the National Medicines agency from the Ivory Coast, who raised the issue of the falsification of the manufacturer’s identity; he advocated for the obligation to declare the identity of the manufacturer and distributor;

## 6. Technical Co-operation activities

### 6.1 CRIMFAMED Global Programme

- to take note of the development of the CRIMFAMED Project and its latest activities implemented since the last CoP meeting, notably:

#### a) A conference organised in Brescia, Italy, on 16-17 November 2023:

Despite the regular contacts between the Secretariat with three different governments since 2018, Italy has not yet signed the Convention. Given that Italy was recently considering changing its penal legislation, the Secretariat considered this to be a good moment to organise an event addressing criminal law issues. The University of Brescia hosted this event and speakers raised awareness on the need for Italy to ratify the Convention. At the end of the event a [Declaration](#) was adopted, which will be sent to the Italian authorities. The proceedings of the conference will be published in 2024.

#### b) Report on the 24/7 Network:

A report entitled “*24/7 Network on cooperation and information exchange capacity*” (Appendix III) was drafted within the CRIMFAMED Project. Although it was due to be delivered in February 2024, the experts involved (Ms Verica Trbić, Mr Hugo Bonar and Mr Catalin Zetu), managed to submit it early.

The CoP thanked the experts for their efforts in providing such excellent report before schedule and took note of it, in particular:

- its objective: to assess a) how best to support Parties to build preparedness for Cooperation and Information exchange in the context of the MEDICRIME Convention and b) current capacities of current 24/7 networks to address the MEDICRIME Convention.
- the key issues analysed:
  - the existence of **national measures** (legislative, policy, strategic plans or informal measures);
  - **State support** through training and resources for those responsible for co-operation and information exchange in relation with the fight against counterfeit medical products and related crime;

- the **functioning of national authorities** in a cohesive and co-operative spirit in domestic and international cooperation and information exchange;

The CoP took note of the recommendations of such report presented by Ms Trbić, Vice-Chair of the CoP, and had an exchange of views;

- on this b) issue, to instruct the Secretariat to convene the 2<sup>nd</sup> meeting of the 24/7 WG to be organised in February 2024 (tentative dates) in order to both present the above-mentioned report to the WG members and evaluate the need for a 24/ Network. Before the forthcoming plenary meeting in 2024, the WG shall advise the CoP on the necessity of setting-up such Network;

**c) Domestication of the Ivory Coast legislation:**

The Ivory Coast ratified the Convention in July 2023. The Ivorian authorities requested legislative support from the Secretariat to modify its national legislation in line with the Convention. Within the CRIMFAMED Project, the Secretariat, along with international experts and the collaboration of Ivorian national authorities, is providing legal support to accommodate (domesticate) the MEDICRIME Convention to its national legislation;

- on this c) issue, to take note of the legal support provided to the Ivory Coast by the CoP;

## 6.2 Exchange of Information / Tour de table

- to invite Parties to consider which technical co-operation activities may be implemented in the near future to implement the MEDICRIME Convention in different countries;
- to instruct the Bureau to consider how to accelerate the accession process of signatory countries to the Convention;
- to take note of the information provided by the Chair on his future visit to Tunisia;
- to take note of the meeting to be held on 30 November 2023 with the Ivory Coast to domesticate its legislation;
- to invite Parties, if need be, to contact the Secretariat for legal support in the accommodation process of the Convention into their national legislation;

## 7. Information points

### 7.1 New accessions to the MEDICRIME Convention

- to take note that 2023 was a positive year in terms of accession to the Convention, in particular as Cyprus and the Ivory Coast ratified the Convention and four other countries (Norway, Slovak Republic, Congo and Niger) signed the Convention;

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

- to remind Parties to keep the Secretariat informed of any possible event where the goals of the Convention may be introduced so that the CoP can be properly represented;

## 8. Gender issues

- to take note of the presentation made by Ms Lina GUDIMA, CoP's Gender Equality Rapporteur (hereinafter, GER) within the MEDICRIME Committee, on the main features in this topic;
- to consider that gender equality shall be considered in the CoP's work and to invite the GER to follow this topic closely and provide necessary inputs;

**9. Elections**

- to take note that elections for different positions within the Bureau (Chair, Vice-Chair and Bureau members) will be held in 2024 and to invite possible candidates to submit their applications to the Secretariat before July 2024;

**10. Any other business**

- to invite its Parties to provide in writing any suggestion for possible new initiatives to be followed/implemented by the CoP;
- with a view to organising bilateral meetings between the Chair and every Party or between the individual Contracting Parties, to instruct the Secretariat to provide a list of contacts of the CoP members;

**11. Dates of the next meeting**

- to take note that the next Plenary meeting will last 3 days and that the tentative dates for the forthcoming CoP meeting will be the week of 21 to 25 October 2024 (to be confirmed by the Bureau);
- to instruct the Secretariat to inform all Parties, participants and observers once the dates are agreed upon.

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**Annexes**

<b>Appendix I – List of Participants</b>	<i>(in process)</i>
<b>Appendix II – Agenda</b>	<a href="#">Click here</a>
<b>Appendix III – Report 24/7</b>	 T-MED (2023) 19 E 24-7 Network Capacit
<b>Appendix IV – MEDICRIME Strategy</b>	 T-MED (2024) 01 E - MEDICRIME Strategy ;
<b>Appendix V – ASOP EU presentation</b>	 Medicrime Convention CotP Bure