



Strasbourg, 11 February 2022

T-MEDICRIME (2021) LD 02_Rev

Online mode

Committee of the Parties MEDICRIME Convention

List of decisions

5th Plenary meeting

Teleconference, 1-3 December 2021

Council of Europe

The Committee of the Parties (hereinafter referred to as “the MEDICRIME Committee” or “the CoP”) to the MEDICRIME Convention meeting remotely via videoconference, under the Chairmanship of Mr Sergey Glagolev (Russian Federation) took the following decisions:

1. **Opening of the meeting**

- to take note of the welcoming address by Mr Glagolev who provided information on the current pandemic situation. He informed members of his address to the Committee of Ministers of the Council of Europe (held on 20 October 2021) to promote the work of the MEDICRIME Committee and call for further support for signatures and ratifications. He added that following this meeting, the Committee of Ministers adopted a Declaration on the occasion of the 10th anniversary of the MEDICRIME Convention. He thanked the Hungarian Presidency to the Committee of Ministers for its strong support to the anniversary event and the MEDICRIME Convention in particular in times of pandemic. He welcomed the progress achieved in the framework of the 2 years of activities by the CoP, including concrete activities, strategy and involvement of various

stakeholders. He welcomed the new representatives from North Macedonia and Mali who signed the MEDICRIME Convention recently.

- to take note of the opening remarks by Mr Jan Kleijssen, Director, Information Society - Action against Crime Department, who recalled the state of play of the signatures and ratifications. He noted that strengthened cooperation in addressing current health-care problems was regarded as a priority in the Council of Europe Strategic Framework for the next four years, as discussed at the 131st Session of the Committee of Ministers (Hamburg, May 2021). He also indicated that the European Commission issued the EU Strategy to tackle Organised crime 2021-2025 which supports both the accession to and ratification of the MEDICRIME Convention by more EU member States. He urged all member States that have not yet done so to sign and ratify the Convention. He stressed that co-operation among law enforcement authorities and others is essential and welcomed, among the items to be discussed, the future MEDICRIME Strategy for 2022-2025 which is in line with the 4-year strategy of the Committee of Ministers. He thanked international organisations for their participation and cooperation. He concluded by adding information about the 40 years milestone for the Convention on data protection, the 20 years anniversary of the Cybercrime Convention, and the 10 years of the MEDICRIME Convention, showing the Council of Europe is pioneering on new societal developments. He encouraged the MEDICRIME Committee to share information with and follow the work of the Committee on Artificial Intelligence (CAI) that is entering a process of negotiation for a treaty on the topic.

2. Adoption of the draft agenda

- to adopt the draft agenda of the meeting (the list of participants and the agenda appear in Appendices I and II respectively).
- to take note of the remarks by the Secretariat about the agenda and the annotated agenda.

3. Information by the Chair and the Secretariat

- to take note of the list of decisions of the last Plenary meeting held on 26-27 May 2021.
- to take note of the information by Mr Oscar Alarcón, Executive Secretary of the CoP, that contacts will be made with the new Committee of Ministers' Italian chairmanship to encourage attention is given to the MEDICRIME Convention.

4. Monitoring of the Convention and future work

4.1 Country Profile Questionnaire (CPQ) and replies by countries

- to take note of the presentation by the Chair on the CPQ and that the replies received by Parties were made public on the MEDICRIME website;
- to consider Bosnia and Herzegovina's reply to the CPQ;
- to take note of Mr Mkrtych Shakaryan (Armenia)'s reasons for the delay in replying to the CPQ;
- to take note of Albania, Armenia, Belarus, Benin, and Burkina Faso's lack of reply, and to instruct the Secretariat to address a letter signed by the Chair to the respective permanent representative/embassy asking for the submission of the CPQ;

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

- to take note of the 5 answers received from the Parties (Croatia, France, Hungary, Spain and Switzerland) to the 1st Monitoring round, which were provided by 30th November 2021, and to

invite those countries which have not yet replied to the questionnaire to do so at their earliest convenience;

- to take note that replies must be sent in English or French, that other languages will not be accepted and also that the replies will be made public;
- to examine both the draft Guidelines for monitoring the implementation of the MEDICRIME Convention and the Chronology provided for the first thematic monitoring round and agree to send any comments to these documents by February 2022;
- to highlight the availability of the Secretariat to answer any concrete question from Parties in relation to these documents and to instruct the Secretariat to facilitate the exchange of information between the experts and the Party(ies) should there be any comments;
- to take note that the descriptive part of the thematic report (which will include replies to the Questionnaire) will be considered at the spring 2022 plenary meeting.

4.3 Guidance note - Definition of “counterfeit” vs “falsified and substandard”

- to take note of the information provided by the vice-chair, Mr Christian Tournié (France), on the importance of clear definitions in the context of the work of the MEDICRIME Convention and the Council of Europe in general. He recalled the intense work carried out by delegates at the World Health Assembly on 29 May 2017 adopting the definitions of “substandard” and “falsified” medical products;
- to thank Ms Ana Salinas de Frías, Full Professor at the University of Malaga, for her report on the “Feasibility and the legal nature of a Guidance Note in the context of the MEDICRIME Convention” and her presentation. Her report concludes that the MEDICRIME Committee enjoys the capacity to issue guidance notes. She indicated that the CoP can express an opinion on any question concerning the application of the Convention, which may take the form of guidance note representing the common understanding of the Parties as to the use of the Convention. States and the European Court of Human Rights have taken into account such instruments and have given them a legally binding value. Guidance notes should be considered legally binding as they provide ordinary meaning to the terms of the treaty and express the will of the Parties, according to the Committee’s rules of procedure.
- to launch the drafting of a legally binding Guidance note on the definition of ‘counterfeit’, following the Bureau’s proposal. To instruct the Secretariat to convene a Working Group meeting, to which all members and observers will be invited to participate.

4.4 Draft Strategy 2022-2025

- to examine the preliminary Draft Strategy for the MEDICRIME Committee and thank the international consultants (Mr. Hugo Bonar, International Consultant (Ireland), Dr Carlos Romeo Casabona, Full Professor of Criminal Law, University of the Basque Country (Spain) and Dr Asier Urruela Mora, Full Professor of Criminal Law, University of Zaragoza (Spain)) for their presentations;
- to agree on the length of the Strategy (2022-2025);
- to take note of the comments on the draft Strategy on behalf of Switzerland, in particular the proposal to delete the fourth thematic pillar entitled “Protect” -proposed in the document- by including this topic in the other pillars (“Prevent” and “Prosecute”), leaving only three pillars (Promote, Prevent and Prosecute);
- to ensure that the Strategy includes the co-operation among all actors;
- to request the Parties to provide comments to this draft Strategy by February 2022;

- to instruct the Secretariat to compile a document including the comments received by Parties for its discussion at the Bureau and further adoption at the Plenary meeting;

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

- to examine the draft concept note on criminal activity resulting in leakages from the medical product supply chain and thank the experts (Mr. Hugo Bonar, International Consultant (Ireland), Dr Carlos Romeo Casabona, Full Professor of Criminal Law, University of the Basque Country (Spain) and Dr Asier Urruela Mora, Professor of Criminal Law, University of Zaragoza (Spain)) for their presentations;
- to take note of the discussion within the CoP about the different concepts: "leakage" and "diversion", the latter being frequently used; a clarification of the term "leakage" will be included in the document;
- to adopt this concept note, pending the introduction of a clarification in regard to the concept of "leakage";
- to instruct the Secretariat to take note of the interest of some members and observers to join the Working Group on leakages;
- to take note of the Parliamentary Assembly's Committee on Social Affairs, Health and Sustainable Development's imminent report on Securing safe medical supply chains (Rapporteur: Ms Jennifer De Temmerman, France, ALDE).

Report on the falsification of medical products for veterinary use

4.6

- to examine and discuss the survey and its replies on falsified veterinary medicines prepared by Dr José María Esteban Fernández, Member of the National Health Pharmaceutical Society (Spain) and Mr Sigitas Siriukaitis, Adviser, Veterinary Medicinal Products and Feed Division State Food and Veterinary Service (Lithuania);
- to take note that only 5 answers were received to the survey and to call on all CoP members to send their answers to the Secretariat if they did not do so, by 7 January 2022 at latest;
- to agree to both the publication of the data received in the survey and the preparation of a report, based on the answers received;
- to request Parties to provide the Secretariat with any information which may be of importance to draft the report;

Gap analysis study (risk mapping) on fraud and falsified medical products

4.7

- to examine, discuss and adopt the concept note relating to fraud and falsified medical products prepared by Ms. Sandrine Richard (Director of Business Ethics and Business Diplomacy, Cristal Group International) and thank her for her presentation;
- to welcome the development of a toolkit for national practitioners with a view to its incorporation in the preliminary Draft Strategy for 2022-2025;
- on the basis of the explanations provided, to give an additional delay to the expert to draft this report;

5 24/7 Network

- to take note that the first meeting of the Working Group on the implementation of the 24/7 Network was postponed to 16 December 2021;

- to instruct the Secretariat to send a reminder to the remaining Parties who did not reply to participate in this Working Group on the 24/7 Network at their earliest convenience;

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 welcome the work implemented by the CD-P-PH/CMED in supporting the MEDICRIME Convention and to recall the need to further strengthen synergies among both committees on common topics to achieve harmonisation of approaches;
- to take note of the presentation by Ms Lynda Scammell, Chair of the CD-P-PH/CMED and congratulate her for her new mandate. She presented CMED's work on "Social media best practices for health regulatory authorities", a "Recommendation regarding medicines irregularly leaving the legal supply chain", a Revision of Resolution ResAP(2007)2 on good practices for distributing medicines via mail order and the development of a "Guidance on falsified medicines;
- to request the CD-P-PH/CMED to invite the CoP to participate in the drafting exercise of the revision of the Resolution ResAP (2007)2 to make sure that the purpose and the content of the Convention are reflected in all other legal instruments developed by the Council of Europe;
- to encourage the CD-P-PH/CMED to participate in the work of the MEDICRIME Committee, namely the leakages report, the drafting of a Guidance note on definitions concerning the MEDICRIME Convention's terminology, and the survey of medical devices, and provide any additional information deemed useful and necessary to develop its tasks;
- to support Ms Scammel's plea for continued multidisciplinary and strategic collaboration between CD-P-PH/CMED and MEDICRIME Committee, and to instruct the Secretariat to set up a meeting between both Chairs (MEDICRIME Committee and CD-P-PH/CMED) at the Chairs' earliest convenience;

6.2 Presentation of relevant initiatives of the Parliamentary Assembly of the Council of Europe

- to take note of the presentation by Mr Luís Leite Ramos, Chair of the Committee on Social Affairs, Health and Sustainable Development regarding its latest work relevant to the MEDICRIME Convention namely a hearing in 2020 on "Securing safe medical supply chains" which resulted in an introductory note being drafted by Rapporteur Ms Jennifer De Temmerman. On 01 December 2021, the Committee adopted a report prepared by Mr Joseph O'Reilly on "Addiction to Prescription Medicine" which may often lead to the use of falsified medicine;
- to thank Mr Leite Ramos for his presentation and invite the PACE to participate in the work of the Working Group on leakages from the medical product supply chain to be organised by the CoP;

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

OPALS:

- to consider the concept note for a report on the falsification of medical devices, presented by Mr Quentin Duteil (OPALS). The OPALS Foundation and the Foundation of the French Academy of Surgery propose that the CoP consider carrying out a survey and, on the basis of the results, draft a report on the counterfeiting of medical devices in the Parties' jurisdictions. This report is aimed *inter alia* at making a more accurate assessment of this threat, the vulnerabilities in pharmaceutical distribution channels that may be exploited by traffickers, the level of awareness among the relevant stakeholders (health and legal professionals, the police, the customs

authorities, etc.), the legislative and regulatory weaknesses of the countries concerned and the advantages of the remedies offered by the Convention;

- to thank Mr Duteil for his presentation, adopt the proposal to draft such a report, welcome any contribution from any Party and observer on the issue and instruct the Secretariat to prepare a preliminary survey for its submission to the Bureau;
- to delegate the Bureau with a mandate to adopt this survey;

ASOP EU

- to take note of the information provided by Mr Mike Isles (ASOP EU) on a market research proposal currently being carried out by global partners on the behaviour and knowledge of patients around the internet, and invite ASOP EU to share relevant material on the issue; to take note of the important EU pending legislation known as the “Digital Services Act” to enhance the governance of those who buy medicine online;

PSI

- To take note of Ms Cecilia Fant (PSI)’s information about the extent of the problem regarding the use of empty vaccine vials and false labelling. To take note of her presentation on the latest data related to counterfeit vaccines (Covid-19, Pneumococcal, Influenza, Rabies) and work of the PSI;

Brazzaville Foundation

- to take note of the presentation by Ms Ariane Allin (Brazzaville Foundation) on the recent round table on stronger and more transparent drug supply chains, strong regulatory systems as well as equitable access to medical supplies, held on the 25 May 2021. She welcomed the cooperation with the MEDICRIME Committee, UNODC, OECD and African Union Special Envoy for the African Medicines Agency. The Brazzaville Foundation recently promoted the signature and ratification of the MEDICRIME Convention with several African countries;
- to request the Brazzaville Foundation’s support with regard to the signature and ratification of the MEDICRIME Convention by Congo;

7. Observer status to the MEDICRIME Committee

7.1 Requests received

- following the decision of the Bureau, to take note of the presentation of each organisation requesting observer status: LEEM, Association Internationale des Douaniers Francophones (AIDF) and Fight the Fakes; Given technical difficulties; to instruct the Secretariat to share the presentation of the AIDF with CoP members by email;
- to meet in camera and grant by consensus observer status to LEEM, Association Internationale des Douaniers Francophones, and Fight the Fakes after reviewing their application and taking note of their presentation;
- to recall that observers are important sources of information, to thank all applicants for their presentation and to welcome them in their new capacity.

8. Information points

8.1 Participation of the MEDICRIME Committee in outside events

- to take note of the different events to which the Chair, the Vice-Chair of the CoP and the Secretariat were invited, in particular:

- a conference on “Role of the Prosecutor’s Office in Protection of Individual Rights and Public Interest in light of Requirements of the European Convention on Human Rights” (8 July 2021, St Petersburg, Russian Federation);
- a regional workshop on the problem of sub-quality, counterfeit and falsified medicines in Africa (27-29 September 2021);
- the online International Conference on “*How to enhance integrity in the health sector in changing societies: tackling fraud, waste and corruption to ensure the right to health*” by the European Health and Fraud Corruption Network (18 October 2021);
- the meeting of the West African Central Authorities and Prosecutors Network (WACAP), organised by ECOWAS (8-12 November 2021, Senegal);
- the Emirates International Conference on falsified and substandard medical products (21-22 November 2021, Dubai, UAE);

8.2 10th anniversary of the MEDICRIME Convention

- in the light of the 10th anniversary of the MEDICRIME Convention, to take note of the programme of the public online anniversary event, held on the 2nd December 2021 presented by the Secretariat;
- to instruct the Secretariat to share with all members the press release issued on the Council of Europe website on the occasion of the anniversary;
- to thank all Parties that participated in the video on the occasion of the 10th anniversary and take note that their messages will be published on the MEDICRIME social media;
- to take note of:
 - a) the Switzerland’s initiative on the occasion of this anniversary, in particular, the issuing of a press release on the Swissmedic website;
 - b) the Russian Federation’s information that both a press release will be issued in the context of the anniversary and that a Russian-speaking online seminar will be held on 8 December 2021; to instruct the Secretariat to send any available information about this seminar to members by email;
 - c) the French’s information indicating that a francophone event will be organised in the context of the French Presidency of the European Union;
 - d) to take note that the Spanish-speaking event will take place in 2022;
- to call all members (Parties, participants and observers) to join the mini campaign on the Twitter account in the context of the anniversary called “I am a Medicrimer”, and thank all members for their active participation on the Convention’s social media;

8.3 New accessions to the MEDICRIME Convention

- to take note that Mali and North Macedonia signed the MEDICRIME Convention on 29 June 2021 and 9 September 2021, respectively;
- to take note and welcome Chile’s intention to sign the Convention;

9. Any other business

9.1 Election of Bureau members for 2022-2023

- to consider and adopt the memorandum on the elections for the Bureau members 2022-2023;
- to take note that all current Bureau members agree to be re-elected for the term 2022-2023;

- by consensus, to agree to renew the mandate of all the members of the Bureau;

9.3 Future work

- to invite Parties to send their priorities/proposals to the Secretariat;

9.4 Technical co-operation: NA-FAMED project

- to take note of the final result of the NA-FAMED project and the follow-up project called CRIMFAMED;
- to instruct the Secretariat to send a letter to all the Parties with the results and major information of the NA-FAMED project. The idea would be their further dissemination and information by the Parties to their Permanent Representatives to the Council of Europe for consideration of a voluntary contribution;

9.5 Other request

- to invite Parties to agree to send any proposals related to any topic the CoP should deal with to the Secretariat;
- to instruct the Secretariat to prepare a contact list of the Party members for its further dissemination among Party members;

10. Dates of the next meeting (2021)

- to take note of the forthcoming MEDICRIME Committee Plenary meeting (13-15 June 2022), pending the decision on its format and location, in accordance with budget and sanitary restrictions.

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