COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 9 August 2023 T-MEDICRIME (2023) LD1

Committee of the Parties MEDICRIME Convention

6th Plenary meeting

List of Decisions

Strasbourg, 10-12 May 2023

The Committee of the Parties (hereinafter referred to as "the MEDICRIME Committee" or "the CoP") to the MEDICRIME Convention, under the vice-Chairmanship of Mr Christian Tournié (France), took the following decisions:

1. Opening of the meeting

- to take note of the welcoming address by Mr Christian Tournié, who welcomed all the Parties, participants, observers and independent experts to this CoP meeting, the first face-to-face meeting since 2019 and also the first after the break of 2022;
- to invite all the Parties, participants, observers and independent experts to a *tour de table* to introduce themselves;

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);

3. Information by the Vice-Chair and the Secretariat

- to take note of the information provided by the Executive Secretary to the MEDICRIME Committee, Dr Oscar Alarcón-Jiménez, on the most recent developments within the Council of Europe

(hereinafter, CoE), in particular the 4th Summit of Heads of State and Government of the CoE to be held on 16-17 May in Reykjavik (Iceland), which will be an opportunity for the CoE to refocus its mission in the light of the new threats to human rights, democracy and the rule of law and to support Ukraine following its aggression by the Russian Federation. The CoP was also informed about the work implemented by the CoE on both Artificial Intelligence (hereinafter, AI), mainly the zero Draft of the Framework Convention on AI, Human Rights, Democracy and the Rule of Law, and on the environment, in particular the drafting of a new Convention on the Protection of the Environment through Criminal Law;

4. Modalities of participation of both the Russian Federation and Belarus in the MEDICRIME Committee

- to take note of the information provided by the Secretariat in relation to the modalities of participation of both the Russian Federation and Belarus in the MEDICRIME Committee, in particular the new Rules of Procedure (hereinafter, RoP) of the CoP and the decisions adopted at the CoP Extraordinary meeting held on 16 March 2023;

5. Monitoring of the MEDICRIME Convention and future work

5.1 Country profile Questionnaire and its replies

- following Article 24 of the RoP, to invite those Parties which did not provide their replies to the Country Profile Questionnaire (more than nine Parties) to do so at their earliest convenience;
- to instruct the Secretariat to resend this questionnaire to those Parties (in both languages) requesting them to provide such a document by **2 October 2023**;

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

- to take note of the 1st Monitoring report and congratulate the independent experts for their excellent work carried out in drafting it;
- on the basis of the presentations made by the experts, to hold a debate on this item. In this regard, the purpose of this report is to collect specific information on the thematic implementation of the MEDICRIME Convention by the Parties to assist them towards its full thematic implementation;
- to preliminarily examine this report, to hold a debate about both the mandatory and optional questions included in this report;
- to note that only 9 out of 18 Parties replied to this monitoring report (in the meantime three more Parties joined the Convention). Against this background, to invite those Parties who did not provide their replies to the 1st Monitoring report (more than the half of the Parties) to do so at their earliest convenience;
- to invite its Bureau to discuss how to proceed with the publication of this 1st Monitoring report taking into consideration that some Parties already replied to it and others did not;
- to take note that Switzerland insisted on having first the French version of the draft monitoring report before providing comments to it. The reasons for such request were twofold: a) to highlight that the French language is one of Switzerland's official languages; and b) to properly implement Art 6 of the RoP where it is stated that the official languages of the MEDICRIME Committee shall be those of the Council of Europe (namely English and French.)
- to instruct the Secretariat to translate the 1st monitoring report into French (excluding the Annexes) and send it to the Parties;
- to invite the Parties that replied to this 1st monitoring report only to review the 1st monitoring report and provide their comments to the Secretariat (if any) by 27 November 2023 for the possible bilateral discussions with the Secretariat (if any) and its possible approval at the forthcoming Plenary meeting in 2024;
- to invite its Bureau to discuss the Guidance document explaining the monitoring procedure and its deadlines;

- to invite the Parties to provide the Secretariat with their proposals of possible theme(s) for the second monitoring round by 5 September 2023; in particular, this information from the Parties should be accompanied with a short rationale (context), the goals to achieve with this 2nd monitoring procedure and the aspects to be addressed with this 2nd monitoring round;

5.3 Definition of the term "counterfeit" vs. the term "falsified and substandard"

- to take note that a Working Group on this topic could not be organised given the political situation of the CoP; with a view to overcoming this situation, the Secretariat worked with independent experts on the drafting of a Guidance Note;
- to congratulate the experts on their excellent work carried out in drafting the Preliminary draft Guidance note;
- on the basis of the presentations made by the experts, to hold a debate on this item. In this regard, the goal of this Guidance Note is to avoid any misinterpretation in the use of terms and assist Parties when applying these terms. This Guidance note refers to the concept of "counterfeit", outlined in Art. 4 g of the MEDICRIME Convention, and excludes IPR issues.
- to invite the Parties to send their possible written comments to the Secretariat by **21 June 2023** for examination at the next Bureau meeting and approval at the next Plenary meeting;

5.4 Draft Strategy 2022-2024

- to take note and examine the Preliminary draft Strategy 2022-2024, which was already introduced to the Parties. In this regard, the Parties underlined the need to set a framework to promote standard-setting activities in human rights, democracy and the rule of law to protect public health. This requires close co-operation and coordination with other international organisations, member states and other countries. This draft strategy foresees four thematic strands (Promote accession to the Convention; Prevent the counterfeiting of medical products and similar crimes; Prosecute offenders, including enablers of trafficking and Protect victims from unforeseen events);
- to hold a debate on this preliminary draft Strategy and instruct its Bureau to both modify the length (the years) of the strategy and consider its implementation;
- to invite Parties to provide their comments to the Secretariat by **5 September 2023** for examination at its next Bureau meeting so that it could possibly be adopted at the forthcoming plenary meeting

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

- to take note of the information provided by the independent experts and thank them for their presentation. In this regard, whereas theft is a criminal behaviour covered by the Convention, a leakage is a regulatory breach, but a criminal offence covered by the Convention;
- to hold a debate on this concrete issue and confirm the adoption of the concept note;
- to mandate its Bureau to decide the procedure to be set-up for the drafting of both such a report and its recommendations;

5.6 Report on falsification of medical products for veterinary use

- given the impossibility of the expert to finally take part at the meeting, to postpone the presentation and discussion of this preliminary draft report to the forthcoming Plenary meeting;

- to invite all Parties to send their answers (to the survey) to the Secretariat if they did not do so, by **27 July 2023** at latest;

5.7 Requests received by the MEDICRIME Committee for comments:

- to take note of both legal documents, notably the draft CoE Recommendation *on reporting of unaccounted disappearances of medicinal products for human and veterinary use from the legal*

supply chain, and the draft CoE Recommendation *on best practices for the remote and online provision of medicines,* received by EDQM for comments;

- to hold a debate on both these draft legal instruments;
- to invite the CD-P-PH/CMED to provide both draft Recommendations in English and French version so that the CoP Secretariat could forward them to the Parties for their comments;
- to invite Parties to provide their comments to the Secretariat on both the draft CoE Recommendation *on reporting of unaccounted disappearances of medicinal products for human and veterinary use* and the CoE Recommendation *on best practices for the remote and online provision of medicines* by **3 July 2023;**
- to mandate its Bureau to examine the comments received from Parties, discuss them at their forthcoming meeting in September and draft an opinion on each legal instrument on behalf of the CoP by the end of September 2023;

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 exchange views with the Chair of the CD-P-PH/CMED, Ms Lynda Scammel, on the current activities carried out by the CD-P-PH/CMED, in particular: a) its workplan; b) the draft CoE Recommendation on disappearances of medicines; c) guidance on definitions; d) its transversal projects, mainly the draft Recommendation on best practices for the remote and online provision of medicines and its work on Borderline Products;
- on the basis of this presentation, to hold a debate with the Parties where the concepts of parallel import and diversion were raised;
- to reiterate the valuable role of CD-P-PH/CMED in its support to the MEDICRIME Convention but express some concerns on the CD-P-PH/CMED's current work programme, which may create confusion in the terminology and raise concerns in the implementation of the Convention;
- to invite both committees to discuss further co-operation to strengthen their common fight against the counterfeiting of medical products and similar crimes;

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

- to hold an exchange of views with the Chair, Mr Van Pararen, member of the Committee on Social Affairs, Health and Sustainable Development from the Parliamentary Assembly of the Council of Europe (PACE), on the current activities carried out by the PACE;
- to invite Mr Van Pararen to encourage his country to join the MEDICRIME Convention;

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

- to exchange views with the Mr Cedric Otse-Mawandza, from the Brazzaville Foundation, with observer status to the CoP, on its current activities, in particular, the 'Initiative de Lomé'. This was launched by six African Heads of State (Congo, Ghana, Niger, Senegal, Togo, Uganda) on 18 January 2020 and aims to fight counterfeit medicines. The Brazzaville Foundation encourages countries to join the MEDICRIME Convention. The Brazzaville Foundation will begin a pilot project in Africa during the 2nd semester this year; more information will be provided at the forthcoming plenary meeting;

7. Technical Co-operation activities

7.1 CRIMFAMED Global Programme

- to take note of the information provided by Ms Aroa Fandiño-Serrano, senior project manager, on the CRIMFAMED Project, which is financed by a French voluntary contribution. Concrete information was provided on the national platforms and the 24/7 Network initiative, which is an operational network. In this regard, a Working Group meeting on the 24/7 Network took place in

December 2021 but it could not gather in 2022 due to the political situation of the CoP. To overcome this situation, the MEDICRIME Secretariat considered that it was important to move forward with this portfolio regardless the "forced break" within the CoP. With a view to relaunching the issue in a more dynamic and efficient way, some elements of the 24/7 Network were developed within the project pending the forthcoming meeting of the WG. The results obtained within the project in the 24/7 Network activity will serve to feed the 2nd meeting of the WG where they will be introduced;

8. Information points

8.1 New accessions to the MEDICRIME Convention

- to take note that Togo and Norway signed the MEDICRIME Convention on 16 January and 12 April 2023 respectively;
- to take note that more than 19 countries (to date) signed the MEDICRIME Convention long time ago and have not yet ratified it;
- to invite the Bureau to discuss possible measures to both encourage signatory countries to ratify the MEDICRIME Convention and other European countries who have not done so to join it;
- to invite the CD-P-PH/CMED to encourage its members, signatory countries, to ratify the MEDICRIME Convention and other European countries who have not done so to join it;

8.2 Participation of the MEDICRIME Committee in outside events

- to instruct the Parties to inform the Secretariat of any possible event where the goals of the Convention may be introduced and promoted, regardless of the field (justice, health, law-enforcement, other);

9. Exchange of Information / Tour de table

- to invite the Parties to a *tour de table* to consider both technical co-operation and capacity-building activities as possible activities to be implemented by the CoP. Parties considered as a priority, in particular: the setting-up of national platforms, assistance in the drafting of national Action Plans, the setting-up of a 24/7 Network (and data base), the organisation of events (workshops, seminars) to promote the Convention, assistance in the drafting of national laws and organising capacity-building activities for the actors involved;
- to take note that African francophone countries are willing to host some events to be organised in their territories;
- to invite the Parties who have not done so to appoint their contact point for this CoP;
- to instruct the Secretariat to distribute a list of contacts from all Parties to Parties to properly strengthen the exchange of information, international co-operation as well as upgrade the role of the CoP;

10. Elections

- given that the Vice-Chair is applying for the position of Chair, to proceed with the election of Chair and Vice-Chair of the MEDICRIME Committee. In this regard:
  - given the absence in the room of other Bureau members, Ms Judith Voney (Switzerland) took the Presidency in order to implement the voting procedure;
  - 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 and Mr Van Pararen participated as electoral observer for this process;
  - the Chair of the CoP is Mr Christian Tournié (France), elected for two years renewable once;
  - the Vice-Chair of the CoP is Ms Verica Trbic (Bosnia and Herzegovina) elected for two years renewable once;

- to express its warmest thanks to Mr Sergey Glagolev (Russian Federation), the first and former Chair of the CoP, for the excellent way in which he had chaired the CoP since 2019 and the work implemented so far in the fight against counterfeiting of medical products and similar crimes;

11. Any other business

- to take note of the information on CoE gender equality strategy, which is one of the priorities of the CoE, and in particular of the role of Gender Equality Rapporteurs (hereinafter, GER);
- to recall that gender equality issues were dealt with under the NA-FAMED project;
- to elect Ms Lina Gudima (Moldova) as the GER within the CoP;
- following Article 23.5 of the Convention, to remind Parties who are not CoE member states to contribute to the financing of the CoP;

12. Dates of the next meeting

- to take note of the dates of the next meeting (**28-30 November 2023**);
- to take note of the dates of the next Bureau meeting (**21-22 September 2023**).

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COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

10 May 2023

MEDICRIME COMMITTEE / *COMITÉ MEDICRIME*

Committee of the Parties to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health /
Comité des Parties à la Convention du Conseil de l'Europe sur la contrefaçon des produits médicaux et les informations similaires menaçant la santé publique

List of participants / Liste des participants

6th Plenary Meeting of the MEDICRIME Committee /
6ème Réunion plénière du Comité MEDICRIME

In person, Room 6, Palais Building, 10-12 May 2023 /
Présentiel, Salle 6, Palais de l'Europe, 10-12 mai 2023

1. STATE PARTIES TO THE MEDICRIME CONVENTION – MEMBERS / *ETATS PARTIES A LA CONVENTION MÉDICRIME- MEMBRES*

ALBANIA / ALBANIE

Ms Diana SILA (STILLO)	Head of Sector, Ministry of Justice of Albania

ARMENIA / ARMÉNIE

Mr Mkrtich SHAKARYAN	Apologized / Excusé

BELGIUM / BELGIQUE

Ms Anja EBRAERT	Inspector, Division Distribution of the FAMHP Federal Agency for Medicines and Health Products

BENIN / BÉNIN

No nomination / Pas de nomination

BOSNIA AND HERZEGOVINA / BOSNIE-HERZÉGOVINE

Ms Verica TRBIC	Expert adviser, Directorate for Coordination of Police Bodies of Bosnia and Herzegovina NCB INTERPOL

BURKINA FASO / BURKINA FASO

Mr Boureima SAWADOGO	Vice-président du Tribunal de Commerce de Bobo-Dioulasso

CROATIA / CROATIE

Dr Siniša TOMIĆ (Apologized/ Excusé)	Head of Croatian Agency for Medicinal Products and Medical Devices
Ms Rajka Truban Žulj	Deputy Head for Operations, Mpharm, Croatia

FRANCE / FRANCE **Vice Chair / Vice - Président**

Mr Christian TOURNIÉ	Office central de lutte contre les atteintes à l'environnement et à la santé publique (OCLAESP)

GUINEA / GUINÉE

Mr Jean Baptiste GROVOGUI	Ministre Conseiller, Chargé des Affaires Politiques et Culturelles

HUNGARY / HONGRIE

Mr Ivan BUJDOS	Ministry of Justice, Deputy State Secretariat for

MORROCCO / MAROC

Mr Hicham BENMARK	Vice-Consul, Chargé des affaires politiques multilatérales Consulat Général du Royaume du Maroc à Strasbourg
Mr Younes ESCAYD	Chef d'unité des crimes régies par des textes particuliers, ministère public marocaine

NIGER / NIGER

Dr Barira Dan Nouhou	Directrice Générale de l'Agence Nigérienne de Réglementation du secteur Pharmaceutique (ANRP)

REPUBLIC OF MOLDOVA / RÉPUBLIQUE DE MOLDOVA

Ms Lina Gudima	Deputy General Director Medicines and Medical Devices Agency of the Republic of Moldova

PORTUGAL / PORTUGAL

Mr Afonso SALES	Criminal Investigation Coordinator Criminal Police (UNCC)

SLOVENIA / SLOVENIE

Ms Doroteja Novak-Gosarič	Secretary, Directorate for Health Care Other Health Activities Division, M.Pharm Republic Of Slovenia, Ministry Of Health

SPAIN / ESPAGNE

Ms Frida San Jose	Magistrate Advisor to the General Secretariat for Innovation and Quality of the Public Justice Service, Ministry of Justice
Mr Pedro Alberto Álvarez Otero	Regional Customs Surveillance Area Special Delegation
Mr Juan José CASTRO GARCÍA	Chief Inspector, National Police Head of the Consumption, Environment and

	Doping Section
Mr Carlos GEA	Apologized / Excusé

SWITZERLAND / SUISSE

Ms Judith S. VONEY	Head of Penal Division Swiss Agency for Therapeutic Products (SWISSMEDIC)

TURKEY / TURQUIE

No nomination / Pas de nomination

UKRAINE / UKRAINE

Mr Volodymyr CHEKALIN	Chief of the Department of State Market Supervision of Medical Devices

2. OBSERVERS TO THE MEDICRIME CONVENTION / *OBSERVATEURS A LA CONVENTION MÉDICRIME*

Mr Cédric OTSE-MAWANDZA	Chef de Mission, Initiative de Lomé Projet Pilote, Fondation Brazzaville
Ms Cyntia GENOLET (Apologized / Excusé)	Associate Director, Africa Engagement IFPMA
Mr Quintin DUTEIL (Apologized / Excusé)	Organisation Panafricaine De Lutte Pour La Sante
Mr Luc DUMONT (Apologized / Excusé)	International Association Of French-Speaking Customs Officers, AIDF

3. EXPERTS / *INTERVENANTS*

Independent experts / experts independents

Mr Hugo BONAR	Consultant
Mr José María Esteban Fernández	Apologized / Excusé
Prof. Dr. Carlos ROMEO CASABONA	Apologized / Excusé
Mr Sigitas Siriukaitis	Apologized / Excusé
Mr Asier URRUELA MORA	Professor of Criminal Law University of Zaragoza, Spain

4. COUNCIL OF EUROPE SECRETARIAT / SECRÉTARIAT DU CONSEIL DE L'EUROPE

DGI - HUMAN RIGHTS AND RULE OF LAW / DGI - DROITS DE L'HOMME ET ÉTAT DE DROIT

Information Society and Action against Crime Directorate / Direction de la Société de l'information et de la lutte contre la criminalité

Mr Carlo CHIAROMONTE	Head of Criminal Law Division / Chef de la Division du Droit pénal (Apologized/ Excusé)
Dr Oscar ALARCÓN-JIMÉNEZ	**Executive Secretary to the Committee of the Parties of MEDICRIME Convention / Secrétaire Exécutive de Comité des Parties de la Convention MEDICRIME**
Ms Aroa FANDINO-SERRANO	Project Manager / Chargée de Projet
Ms Ipek DEMIRBÜKER	Assistant Administrative / Assistante Administrative

DG II – DIRECTORATE GENERAL OF DEMOCRACY / DG II – DIRECTION GÉNÉRALE DE LA DEMOCRATIE

European Directorate for the Quality of Medicines & HealthCare (EDQM) / Direction Européenne de la Qualité du Médicament & Soins de Santé (DEQM)

Ms Lynda SCAMMELL	Chair of CD-P- PH/CMED Committee of Experts On Minimising Public Health Risks Posed By Falsification Of Medical Products And Similar Crimes
Ms Inès du PLESSIS	Program Manager Falsified Medical Products Borderline Products

Directorate General of Democracy and Human Dignity / Direction générale de démocratie et de la dignité humaine

Ms Cécile GRÉBOVAL	Programme Manager Gender Mainstreaming Senior Gender Equality Advisor, Gender Equality Division

SECRETARIAT OF THE PARLIAMENTARY ASSEMBLY / SECRETARIAT DE L'ASSEMBLEE PARLEMENTAIRE

Committee on Social Affairs, Health and Sustainable Development / Commission des questions sociales, de la santé et du développement durable

(Apologized/ Excusé) Ms Tanja KLEINSORGE	Head of the Secretariat, Committee on Social Affairs, Health and Sustainable Development,

	Secretariat of the Parliamentary Assembly / Chef du Secrétariat, Commission des questions sociales, de la santé et du développement durable, Secrétariat de l'Assemblée Parlementaire
Mr Bob van PARENREN	Committee on Social Affairs, Health and Sustainable Development Parliamentary Assembly of the Council of Europe

Interpreters / Interprètes

Chloé CHENETIER
Grégoire DEVICTOR
Corinne McGEORGE
Lisa WOJCIECHOWICZ