COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 28 October 2025 WG URSC (2025) 01

WORKING GROUP MEETING

Unauthorised removal, including theft, from the supply chain of medical products (WG-URSC)

(MEDICRIME CONVENTION)

1st MEETING REPORT

Paris (France), Wednesday 22 October 2025

I. Opening of the meeting

1. The first meeting of the Working Group meeting on "Unauthorised removal, including theft, from the supply chain of medical products" was held in Paris, France, on 22 October 2025 in hybrid format. It was opened by the Executive Secretary of the Committee of the Parties (hereinafter, CoP) to the MEDICRIME Convention, Dr. Oscar Alarcón-Jiménez. In his opening remarks, he warmly welcomed all participants to the Working Group (hereinafter, WG) and referred to the important role that the CoP should play in removing obstacles to the implementation of the MEDICRIME Convention and in advising on the best ways to translate its provisions into effective laws and policy measures.

2. Dr. Alarcón-Jiménez continued by recalling the WG's key objective as included in the Terms of Reference adopted by the CoP, namely to both prepare a report on the

topic for its adoption by the CoP and a Guidance Note based on the report's conclusions. Against this background, the MEDICRIME Committee will explore the possibility of preparing - seeking the opinion of the European Committee of Crime Problems - a recommendation for its submission to the Committee of Ministers of the Council of Europe in view of its adoption. He also highlighted that the WG meeting represented a valuable opportunity for open and constructive exchanges among stakeholders to advance this important work.

II. Adoption of the Agenda

3. The WG members adopted the agenda as it appears in Appendix I.

4. Dr Alarcón-Jiménez provided the CoP with practical information on the meeting. Given that some of the WG members and the observers did not know each other, he invited everyone to introduce her/himself in a tour de table.

III. Presentation on Concept Note and Terms of Reference (ToR)

5. After the presentation of all the participants, Dr Alarcón-Jiménez then introduced the Terms of Reference (revised) (T-MED (2025) 08) adopted by the CoP. He stressed that it facilitated the first discussions of the WG.

IV. Tour de table of the different WG members

6. The WG members were invited to provide information on the most recent developments in their jurisdictions about the topic of the WG:

7. The Belgian WG member mentioned the following:

- In Belgium, medicines agencies began identifying issues with medicines that were suspected of being falsified. These products, often of unknown origin and sometimes confirmed as stolen, were illicitly introduced into the legal supply chain.

- A significant gap was identified in the reporting of such incidents (theft or loss), which is not obligatory unless it refer to narcotics, making it difficult to qualify incidents and take appropriate action. To address this, fact-finding missions with other Member States (MS) and distributors were initiated to understand their procedures. A common challenge emerged: when a shipment is lost, stakeholders often do not know how to proceed or how to classify the event.

- Given the scale of the financial incentives and the potential for an increase in such cases, this issue required a high-level attention. Consequently, the idea of a recommendation was issued through the CD-P-PH/CMED, one of the EDQM intergovernmental committees. This recommendation, which was adopted by the Committee of Ministers, established that regulatory authorities are informed of such incidents and thefts are reported to the police. The implementation of this recommendation is now the key focus. While reporting theft is the most straightforward aspect, the challenge lies in gathering accurate data. Health Regulatory Authorities (hereinafter, HRA) are best positioned to collect this

information proactively. They are pleased to share their findings and believe the adopted recommendation serves as a solid foundation for further action. However, additional legal measures are expected to follow to reinforce this framework.

8. The WG member from Bosnia and Herzegovina mentioned the following:

   - The effective implementation of this Recommendation is crucial to legally combat this criminal activity. A significant legal gap has been identified: current legislation does not explicitly address the theft of medical products. To address this, a two-pronged approach is recommended:
     - Immediate Action: begin by implementing the current recommendation as an initial measure.
     - Subsequently, develop supplementary legal provisions to formally define and penalise the theft of medicines, thereby closing the existing legal loophole.

   - This issue is substantial. The theft of goods is a serious problem in itself, but the specific theft of medical products lacks a clear legal status, complicating prosecution. Therefore, a collaborative effort is essential. Success requires the close cooperation of all relevant authorities across the supply chain, including law enforcement, customs agencies, the medicines inspectorate, and border police.

   - Integrating these stakeholders into a unified framework -potentially using international networks like INTERPOL and secure communication platforms- is vital. This cooperation will enable the accurate identification and classification of incidents (e.g., as theft, diversion, or falsification) and ensure that the specialised input of each agency contributes effectively to combating this crime.

9. The Chair of the CoP pointed out that large-scale thefts occur not only in hospitals and pharmacies but also within pharmaceutical manufacturing companies. These thefts frequently target high-value medicines, such as cancer treatments, causing shortages and financial strain on health systems and patients. He stressed the need for systematic reporting of such cases, particularly when they fall within the scope of falsified medicines, as this could trigger investigations and strengthen cooperation between law enforcement authorities.

10. The representative from INTERPOL underscored that:

    - combating pharmaceutical crime relies on effective intelligence sharing and the establishment of secure communication channels. Dynamic analytical tools, which are instrumental in understanding criminal methodologies, have been developed. These tools have proven highly valuable to member States and have contributed to several operational achievements in recent years. The use of Purple Notices to inform Member Countries about criminal modus operandi, and Orange Notices to warn of imminent threats -such as the 2022 alert on COVID-19 medical device trafficking- were cited as key tools.

    - INTERPOL support to member countries is both operational and investigative. Through Project PANGEA, which targets illicit medical products, INTERPOL

coordinates transnational efforts, and invests in capacity building, particularly in Africa, to enhance detection and response. Collaboration with partners such as the MEDICRIME Convention and public awareness campaigns were also highlighted as integral components of their approach.

- While INTERPOL's focus on "illicit" products encompasses theft, current data suggests that the primary challenge in developing countries is smuggling, trafficking and theft. Ultimately, building and maintaining trust among all partners is fundamental to INTERPOL collective success.

11. The representative from WHO noted the following elements:

- While theft, stolen or diverted medical products falls outside the official WHO reporting scope, they remain a crucial factor as they facilitate the circulation of falsified medical products. WHO does recognise a significant importance of this issue, as these products leave the legitimate supply chain, often due to insecure storage, creating opportunities for their illicit re-entry. Theft and diversion significantly increase the risk of falsified medicines penetrating the legal market.

- The Fakeshare program, launched by the Italian Medicines Agency (AIFA) in response to incidents involving diverted and stolen products, was recalled as a database primarily focused on recording stolen products. Data were initially collected by Italy. The rationale was that stolen products are most likely to be reintroduced into the supply chain for commercial gain, making the database a useful tool for tracing and identifying them.

- However, key challenges identified in having such a database include:

  - securing sustainable funding for the relevant database (e.g. cloud hosting)
  - avoiding duplication of reporting efforts, which places additional burdens on staff
  - How is long-term sustainability ensured? Who is responsible for IT infrastructure costs?
  - How is secure access managed for relevant authorities?
  - How is reporting designed to avoid the challenge of dual reporting for entities?
  - What is the user experience for logging in and submitting data?
  - Is the collected information truly useful and actionable?
  - For investigations, the most valuable data concerns the transnational movement of products and the shipment methods used by criminal networks. For regulators, data on stock management anomalies is critical.

12. The representative from INTERPOL informed that for INTERPOL, actionable information includes the transnational aspects of a case, such as shipment routes and methods. This intelligence is essential, as it enables formal requests for collaboration to be sent to relevant countries. Possessing this level of detail is fundamental to effectively addressing the international dimension of these crimes.

13. The representative from the EDQM Secretariat observed that the Fakeshare platform is no longer active. The Italian Medicines Agency (AIFA) has since developed an intelligence-based platform in cooperation with the Italian Joint Research Centre on

Innovation and Crime (Transcrime) and others, named "MEDI-THEFT" (https://www.transcrime.it/en/projects/medi-theft/), whose strategic goal is to strengthen data collection, national infrastructures, and to facilitate cooperation between relevant stakeholders on a national and international level.

14. The Spanish Representative informed that:

- there are currently no systematic reports of routine thefts of medicinal products. It was noted that such thefts often follow specific patterns -for example, diversion of IPO infractions by clinics for treatment use outside the legal supply chain.

- At present, theft of pharmaceuticals is treated similarly to ordinary goods. These cases do not concern the typical theft of medicines; instead, the modus operandi involved the diversion of products, including Fentanyl and Oxycodone through clinics. Notably, these incidents were not captured by any official reporting system. This operation highlights a critical issue: the secure transport of high-risk medicines.

- There is a clear need to mandate specific security protocols for pharmaceutical logistics. The requirements for transporting medicines are fundamentally different and far more stringent than those for general cargo. Consequently, active discussions with national authorities are needed to establish these specialised security standards for pharmaceutical supply chains. He suggested that pharmaceutical logistics should be better integrated into legislation, with tailored security measures for transport operations.

15. The independent expert, Mr Hugo Bonar, emphasised the need to align with the Terms of Reference (ToR), highlighting Article 8 of the MEDICRIME Convention as a key provision. He pointed out that the MEDICRIME Convention was drafted to criminalise specific acts, raising a fundamental question: *should these crimes be integrated into general law*, or *should there be a formal recognition of a distinct category for medical product-related crime, in particular, medicinal products*?

16. He moved forward saying that a significant challenge related to the reporting and recording of medical product-related crime is the legal distinction between controlled substances (e.g., narcotics) and non-controlled medicines, despite both being medicinal products. This fragmentation, coupled with the fact that not all countries have implemented the Convention, makes comprehensive data collection almost impossible. It is important to note that while Article 8 of the MEDICRIME Convention criminalises the diversion of medical products, theft is generally addressed under broader criminal law. Therefore, he encouraged this WG to focus on reporting. However, he mentioned that without reliable data, informed decision-making is severely hindered. The core problem is under-reporting, which stems from several areas:

1. Regulatory requirements: most countries have administrative reporting obligations for product losses under licensing frameworks, though these are often not linked to criminal law.
2. Systemic gaps: a significant "unknown" factor exists due to poor supervision and governance within the distribution trade, meaning many incidents simply go

unrecorded.

17. He also noted that: 1) to address all these concerns the WG should: a) agree on what to report; b) how to classify these reports; 2) INTERPOL is a key stakeholder in this effort. Thus, subsequent actions and decisions will depend on the outcomes of this collaboration.

V. Election of a Chair

18. The WG elected Ms Verica TRBIC (Bosnia and Herzegovina) as Chair. Her appointment was welcomed by the participants, reflecting their confidence in her leadership and commitment to guiding the WG's work towards the preparation of a comprehensive report, Guidance Note and recommendation.

VI. Activity areas for consideration

19. An introductory report was presented by Mr Marck Jackson, consultant, providing valuable insights into the issues addressed by the WG and the availability of reliable information on the topic. The paper compiled and linked all relevant open sources identified from existing publications and released data, structured around several recurring themes.

20. Under the section on definitions, he highlighted key distinctions:

- **Loss**: situations involving regulatory or security failings where medical products have been removed from the legitimate supply chain, potentially due to breaches in security or quality control.

- **Diversion**: the unauthorised transfer of medical products from the legitimate supply chain to illegal or unregulated markets, or into legitimate markets where the medical products were not intended to be marketed.

21. In conclusion, the consultant's report underlined the current scarcity of comprehensive data and stressed the importance, within each country, of reaching a clear agreement on what data should be collected and by whom. Understanding the scale and origins of the problem was identified as a prerequisite for developing effective, long-term solutions. The consultant emphasised that strengthened cooperation between national authorities and across states will be essential to address this challenge in a coordinated and sustainable way.

V. General discussion

22. The Working Group reached a constructive agreement on its *modus operandi* and the next steps of its work. WG members agreed to prepare and circulate a focused questionnaire to better identify and analyse available data on theft and unauthorised removal of medical products within the legitimate supply chain. Developed with expert input and strictly aligned with the ToR, this tool will include a limited number of targeted questions and a clearly defined response timeframe.

23. The WG agreed to maintain the initiative within the framework of the MEDICRIME

Convention, the only legal instrument addressing this issue, ensuring coherence and legal consistency. The EDQM Secretariat was very supportive with the WG and shared its existing questionnaire as a useful reference.

24. The WG members requested the document be prepared in both English and French for presentation at the Plenary Session. This pragmatic and collaborative approach reflects the WG's commitment to building a solid evidence base that will support meaningful recommendations and strengthen cooperation among countries under both the MEDICRIME and the CoE framework.

VI. Dates of the next Plenary meeting

25. The Working Group confirmed that the next MEDICRIME Plenary Session will be held on 9–10 December 2025. Participants welcomed the opportunity to reconvene, noting that this meeting will provide an excellent occasion to present the WG's progress and discussion to the CoP, showcasing the valuable work carried out and setting the stage for further constructive discussions.

26. To broaden expertise and input, the WG members instructed the Secretariat to invite additional francophone State Parties to participate in its forthcoming meetings.

27. The Working Group (WG) members requested that the Secretariat present at the MEDICRIME Committee plenary meeting:
    - a **Roadmap** to provide a structured, clear, and sequential plan for guiding the implementation of the actions proposed in the Terms of Reference (ToR).
    - a **questionnaire** to be addressed to the WG members, the States Parties and signatories of the MEDICRIME Convention.

28. Following consultation with WG members on their availability and based on the responses received to the questionnaire, the Secretariat will determine the schedule for subsequent meetings, which will be held in a hybrid format (both online and in-person).

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Appendices	Title of the document
Appendix I	List of Participants

Appendix I: List of Participants

1. STATES PARTIES TO THE MEDICRIME CONVENTION

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

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

HUNGARY
Dr Ivan AKOS BUJDOS, member of the Bureau of the MEDICRIME Committee of the Parties, Deputy State Secretariat for Criminal Law Codification, Ministry of Justice of Hungary

SPAIN
Mr Juan José CASTRO GARCÍA, Chief Inspector, National Police, Head of the Consumption, Environment and Doping Section (CGPJ- UDEV Central), Madrid (Apologised)

Mr Santiago RIVERA JOFRE, Head of Health and Antidoping Group, Operative Central Unit (online)

Mr Javier VALDENEBRO TINAUT, Head of the drug trafficking group in the Criminal Investigation Central Unit (Apologised)

2. MEDICRIME COMITTEE OF THE PARTIES

Mr Christian TOURNIÉ, Chair of the MEDICRIME Committee of the Parties, Conseiller pour les Affaires Européennes et Internationales, CESAN - Commandement pour l'Environnement et la Santé, Direction Générale de la Gendarmerie Nationale

3. INDEPENDENT EXPERTS

Mr Hugo BONAR, Independent Expert (online)

Mr Mark JACKSON, Consultant to the MEDICRIME Committee (online)

Dr Asier URRUELA MORA, Professor of Criminal Law, University of Zaragoza, Spain, Independent Expert (online)

4. OBSERVERS TO THE MEDICRIME COMMITTEE OF THE PARTIES

INTERPOL
Mr Moussa THIOMBIANO, Criminal Intelligence Officer of IGGH (online)

Pharmaceutical Security Institute (PSI)
Mr Niall MCCARTHY, Regional Director EMEA (Apologised)

World Health Organization (WHO)
Ms Pernette BOURDILLON-ESTÈVE, Technical Officer in the Market Surveillance and Control

team in the WHO Health Systems, Access, and Data division (online)

5. COUNCIL OF EUROPE SECRETARIAT

DGI - HUMAN RIGHTS AND RULE OF LAW

Directorate of Social Rights, Health and Environment

Dr Oscar ALARCÓN-JIMÉNEZ, **Executive Secretary to the Committee of the Parties of the MEDICRIME Convention**

Ms Rachel VAN DER BEEK, Junior Programme Manager

Ms Léa KREMER, Trainee

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

Intergovernmental Committees and Networks Department (ICND)

Dr Gwenaël CIRÉFICE, Head of the Pharmaceutical and Consumer Care Section (online)

Dr Ines DU PLESSIS, Scientific Program Manager (online)