COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 15 December 2025 T-MED (2025) LD2

COMMITTEE OF THE PARTIES TO THE MEDICRIME CONVENTION

(MEDICRIME COMMITTEE)

LIST OF DECISIONS
10TH Plenary Meeting
Strasbourg, 9-10 December 2025

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

1. Opening of the meeting

- to **take note** of the information provided by Mr Rafael BENITEZ, Director of the Social Rights, Health and Environment Directorate, who welcomed the **16 States Parties, 7 signatories countries, 4 countries** not yet Parties, participants and observers to the MEDICRIME Convention reflecting the growing interest and relevance of the topic. He also informed that the MEDICRIME Convention is now integrated into the Health Division and underlined the key messages of the 2025 Conference on the Protection of Health held on 15 October 2025, in particular: the need to safeguard reliable medical products, the serious yet often silent impact of pharmaceutical crime, the Council of Europe's (hereinafter, CoE) strong commitment and the importance of ratifying and implementing the MEDICRIME Convention. He also noted the substantive agenda of this meeting, including presentations from Türkiye and France, and underlined the value of close cooperation with other CoE bodies and committees. He also recalled the Republic of Moldova's interest, in its capacity as current Presidency of the Committee of Ministers, in hosting the next Plenary meeting of the Committee of the Parties in Chișinău;

- to **have** a question-and-answer discussion with the Director following his address, in particular on the possibility for the MEDICRIME Committee to conduct on-site visits in States Parties to monitor the implementation of the Convention and to underline the political will to combat the falsification of medical products, on the proposal to extend plenary meetings to 3 days and on the suggestion to invite customs authorities to future plenary meetings;

- to **thank** Ms Laurence LWOFF, Head of the Health Division, for her kind welcoming words and her introduction. She also presented the new composition of the Health Division, highlighted by the reinforcement of the Unit with the incorporation of the MEDICRIME and Santiago de Compostela Conventions and encouraged the representatives of the States Parties to liaise with their permanent representations and representatives of their country in other committees to reinforce visibility;

- to **welcome** the new representative of the Republic of Moldova, Mr Constantin NEDELEA, Deputy Director General of the Medicines and Medical Devices Agency, who invited the CoP to hold the forthcoming MEDICRIME Committee plenary meeting in Chișinău in the framework of the Republic of Moldova's Presidency of the Committee of Ministers of the Council of Europe;

2. Adoption of the agenda and the order of business

- to **adopt** the draft agenda of the meeting without amendments (the list of participants and the agenda appear in Appendices I and II respectively);

3. Information by the Chair and the Secretariat

- to **take note** of the list of decisions of the last Plenary meeting (31 March – 1 April 2025);

- to **take note** of the information provided by its Chair and its Executive Secretary, Dr. Oscar Alarcón, on the outcomes of the multiple activities undertaken since the last CoP plenary meeting, such as: the Bureau meetings, the Joint Expert Group on organised crime relating to drug trafficking, the Conference on the protection of health, the 19th Ministerial Conference of the Pompidou Group, the Working Group meeting on Unauthorised Removal, including theft, from the medical supply chain of medical products as well as opportunities to promote the Convention (a delegation's visit of Egyptian prosecutors, a capacity-building activity for customs authorities and a study visit from Northeastern University students);

4. 2025 Conference on the Protection of Health

- to **take note** of the outcome document of the Conference which highlights the promotion of a CoE's holistic rights based approach to protect public health and to explore how this approach can be strengthened in a changing public landscape marked by different challenges;

- to **take note** that the Chair addressed the Committee of Ministers in the margins of this conference;

5. Exchange of Information / Tour de table

- to **take note** of the information provided by the States Parties on the most recent developments in their national frameworks, which will be reflected in Appendix III;

6. Monitoring of the MEDICRIME Convention and future work

6.1 Country Profile Questionnaire

- to **take note** of the current state of play and of the latest replies to the Country profile Questionnaire (hereinafter, CPQ) from all States Parties, noting the remaining replies from Belarus and Albania, as well as the replies received from signatory countries;

- to **take note** that a draft Summary Report was previously adopted by the CoP and that the additional replies received may be incorporated into this report;

- to **agree** to update this report and to **instruct** the Secretariat to do so by introducing all latest replies received;

- should signatories wish to submit their replies to the CPQ, to **agree** on an extended deadline and to request those interested to inform the Secretariat;

6.2 1st Thematic Monitoring round: *The protection of public health through the MEDICRIME Convention in times of pandemics*

- to **take note** of the latest status of play of the answers received to the 1st thematic monitoring questionnaire;

- to **take note** that **Albania, Belarus, Guinea and Niger** will be reminded of their obligation to submit their responses to the 1st thematic monitoring round;

- following the adoption of the 1st monitoring round report, to **take note** of its executive summary as well as of a document compiling the different recommendations of the report, sorted by country;

- to **welcome** the draft compliance procedure drafted by the Secretariat to follow the implementation of the recommendations included in the 1st monitoring round report and the according timeline drafted in line with the Rules of Procedure;

- to **invite** States Parties to submit their comments on the draft concept note to the Secretariat by 27 January 2026 ;

- to **take note** of the three draft Country factsheet templates prepared by the Secretariat and instruct the Secretariat to send them to the States Parties for possible comments on the structure;

- to **instruct** the Secretariat to draft Country Factsheets for all States Parties for their adoption at the forthcoming Plenary meeting;

6.3 2nd Thematic Monitoring round: *Deposit and destruction measure of seized counterfeit medical products, active substances, excipients, parts, materials, and accessories*

- to **take note** of the latest status of play of the answers received to the 2nd thematic monitoring questionnaire and its timeline and thank the independent experts for their input in this monitoring round;

- to **recall** the different phases of this monitoring round and the corresponding deadlines with which States Parties must comply:
  - Phase 1: 30 May 2025
  - Phase 2: 28 November 2025
  - **Phase 3: 29 May 2026**

- to **remind** those States Parties that have not yet done so of their obligation to submit their responses for the 1st and 2nd phase of the second monitoring round;

- to **take note** that answers to the 3rd Phase are due for May 2026;

6.4 Follow-up to the survey on falsification of medical products for veterinary use

- to **take note** of the success and positive results of the report entitled "VETMEDICRIME Survey report" and the status of play of the answers received to the survey on falsification of medical products for veterinary use;

- to **thank** Mr Andrés GARCIA CAMPOS, representative of the World Organisation of Animal Health (hereinafter, WOAH) for its presentation on WOAH's Programme on Substandard & Falsified Veterinary Products. The presentation outlined the global threat posed by substandard and falsified veterinary products and described the organisation's coordinated international programme, including surveillance initiatives like VSAFE and the forthcoming TRUVET system designed to assess risks, strengthen detection and reporting and promote cross-sectoral collaboration to protect animal health;

- to **consider** a follow-up to both the VETMEDICRIME Survey report and the WOAH's presentation and **instruct** the Bureau to undertake this at its next Bureau meeting;

6.5 MEDICRIME Strategy

- to **take note** of the limited number of proposals received and the need for greater commitment from States Parties and to **invite** all the observers and participants to the CoP to submit further proposals to the Secretariat with the aim of drafting a coherent and consolidated global strategy against falsified medical products;

- to **call** States Parties to provide the Secretariat with any additional proposal for the draft of such MEDICRIME Strategy taking into consideration the main dimensions highlighted in the current Strategy (the promotion of the Convention, the prevention and prosecution/investigation of falsified medical products);

- to **take note** of the additional deadline for providing the Secretariat further proposals by 15 February so that a draft Strategy can be discussed at the next plenary meeting;

- to **instruct** the Secretariat to send reminders;

6.6 Working Group: unauthorised removal, including theft, from the supply chain of medical products

- to **take note** of the information provided by the Secretariat on recent developments on this topic and **thank** the independent experts Mr Hugo BONAR, Mr Mark JACKSON, Ms Lynda SCAMMELL and Dr Asier URRUELA MORA for their presentation and preparing the questionnaire;

- to **take note** of the Working Group's roadmap and encourage not only States Parties but also signatories to liaise with all relevant national actors in order to provide answers to the questionnaire;

- to **instruct** the Secretariat to update the roadmap in accordance with the new deadlines and distribute the questionnaire to all countries clearly informing them that the established deadline for responses is 27 February 2026 ;

6.7 Gender-specific impact of falsified medicines and medical products: focus on women

- to **take note** that the previous Gender Equality rapporteur is no longer a member of the CoP and to **underscore** the continued importance of this topic for the Committee's work

- to **thank** Ms Tatiana SALEM for her presentation on the Gender Dimensions in the implementation of the MEDICRIME Convention and **take note** of the information provided, which underscored the essential role of a gender perspective for effective implementation. It detailed the specific vulnerabilities of women, men and youth to counterfeit medical products and outlined a proposal, questionnaire, and toolkit designed to generate gender-disaggregated data, improve prevention and protection measures, and enhance policy coherence to strengthen countries' responses;

- to **instruct** the Secretariat to distribute the prepared questionnaire to all States Parties with the objective of receiving their responses during the first semester of 2026;

- to **thank** Ms Lynda SCAMMELL for her complementary presentation on Gender Equality in the framework of the previous project and **take note** of the relevant additional information provided on this topic;

- to **take note** of the need raised by the Secretariat;

6.8 Artificial Intelligence

- to **thank** Prof. Fernando MIRÓ LLINARES for presenting the preliminary draft report "*The MEDICRIME Convention in the Age of AI: Challenges and Opportunities*". The presentation outlined how artificial intelligence is transforming the digital landscape simultaneously amplifying the risks of medical-product counterfeiting and creating new avenues for detection and enforcement. It underscored the need to clarify how the MEDICRIME Convention applies to AI-driven scenarios, including the potential to establish AI use as an aggravating circumstance, while strengthening cooperation with online platforms;

- to **request** that Parties review the report thoroughly and submit their comments and considerations to the Secretariat on the drafting of a Guidance Note for the Bureau's consideration;

- to **take note** of the suggestion by the Hungarian representative, Dr Ivan AKOS BUJDOS, to incorporate the AI topic into the MEDICRIME Strategy, a proposal that will be further discussed at the next Bureau meeting;

- to **agree** in principle to adopt this report at the next plenary meeting and to **consider** drafting a recommendation on this topic;

6.9 24/7 Network

- to **note** that, to date, only 7 participants have been designated by 5 States Parties for the 24/7 Network and to **instruct** the Secretariat to issue formal reminders to all States Parties, signatories and other countries present at this plenary meeting;

- to **agree to convene** the Network's first meeting online in early 2026, followed by an in-person meeting after the summer break of 2026;

7. Exchange of information, experiences and good practices

7.1 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 (hereinafter, CD-P-PH/CMED)

- to **take note** of the information provided by Mr Chris McGUIRE, Chair of the CD-P-PH/CMED. He provided an overview of recent activities, highlighting emerging trends in falsified and illegally diverted medical products, ongoing cooperation with international partners and progress on key activities such as guidance on falsified medicines, online advertising and waste-management initiatives. He outlined upcoming workshops (scheduled for September 2026), updates on draft recommendations and efforts to strengthen the prevention, detection and reporting of medicine falsification across Europe;

7.2 Cooperation with the Monitoring Group of the Anti-Doping Convention (T-DO)

- to **take note** of the information provided by Ms Liene KOZLOVSKA, representative of the Anti-Doping unit (T-DO), on its work and potential avenues for cooperation with the MEDICRIME Committee. She also informed of the upcoming international Conference on *Limiting the Availability of Doping Substances in Europe: A Shared Responsibility* scheduled to be held in Paris on 27 May 2026;

7.3 National efforts and achievements in the fight against falsified medical products - Türkiye

- to **thank** Mr Burak CIHAN ÜRKMEZ, Trade Expert, Ministry of Trade, and Mr Kürşat ÇİLEK, Colonel Gendarmerie, Branch Chieffor their presentations on Türkiye's national efforts and achievements in combating falsified medical products, which outlined Türkiye's robust legal framework, enforcement strategies, major seizure cases and ongoing challenges such as online sales, border vulnerabilities and the need for increased technical capacity and cooperation;

7.4 The landscape of law enforcement and judicial actors – France

- to **thank** Ms Annaïck LE GOFF, Première vice-présidente chargée de l'instruction, and Mr Aissam AIMEUR, Assistant spécialisé pharmacien, Pôle santé Publique de Marseille, for their comprehensive presentation on law enforcement and judicial structures in France. Their intervention detailed the organisation and regional mandates of the specialised public health and environment jurisdictions established in Paris and Marseille in 2002, the corresponding referral procedures and the potential use of special investigative techniques for the most serious offences involving health products;

- to **thank** LCL Laurent DOUREL, Adjoint au chef de la Division de Stratégie et Opérations, Commandement pour l'environnement et la santé (CESAN), for his presentation on the

role and activities of the CESAN (Gendarmerie Nationale's Specialised Central Office for Attacks on the Environment and Public Health) in combating pharmaceutical crime including current trafficking trends in medical products;

- following the Spanish, French and Türkiye's example, to **invite** States Parties to provide the Secretariat with a comprehensive member list of their National Platform to allow smooth collaboration among them and activate the platform's full potential;

7.5 Presentation of relevant activities by international governmental organisations and other observers

- to **thank**:
  - Mr Zdeněk POLANSKÝ, representative of EUROPOL for his presentation on the SHIELD operation, which detailed EUROPOL's coordinated efforts against counterfeit and misused medicines, highlighting significant arrests, product seizures, and the importance of cross-border collaboration to address evolving pharmaceutical crime;

  - Ms Xie GUIQIU, representative of INTERPOL, for her presentation on INTERPOL's response to illicit pharmaceuticals, which emphasised the international dimension of pharmaceutical crime and INTERPOL's global operations such as Operation Pangea to combat the online and cross-border trade in counterfeit medicines;

  - Ms Sophie ROBERT, representative of Fight the Fakes Alliance, for her presentation on the objectives, actions and events of the Fight and Fakes Alliance, which underscored their multi-stakeholder approach to raising awareness, advocating for policy change, and collaborating globally to combat substandard and falsified medicines through campaigns, education, and active engagement with international organizations;

  - Ms Pernette BOURDILLON-ESTÈVE, representative of WHO, for her presentation on WHO's work to combat substandard-falsified medical products, which highlighted the WHO's global strategy for prevention, detection, and response, including surveillance systems like GSMS, capacity building and international collaboration to protect public health;

  - Mr Mike ISLES, representative of ASOP EU, for his presentation on their activities, which showcased initiatives to make online medicine purchases safer, including awareness campaigns, verified pharmacy domains, and digital surveillance tools;

- to **take note** of the written message to the CoP from Mr Quentin DUTEUIL, representative of OPALS, and **instruct** the Secretariat to deliver to the States Parties;

7.6 Borderline products

- to **thank** Ms Lynda SCAMMELL for the information provided on the situation in the United Kingdom concerning borderline products and for outlining the role and attention that the MEDICRIME Convention should accord to this topic;

- to **take note** that a network on this topic operates under the aegis of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and that a presentation to introduce its work may be considered for a future session;

7.7 Innovation: portable tool to detect substandard and falsified medicines

- to **note** and **welcome** the presentation from the University of Brighton (United Kingdom), where Professor Bhavik PATEL and Dr. Ricoveer SHERGILL are developing a portable tool for detecting substandard and falsified medicines;

- to **engage** in an exchange of views with them on bringing this academic perspective into the CoP's deliberations and to thank them for their innovative initiative.

8. Voting

8.1. Observer status to the MEDICRIME Committee

- to **take note** of the Chair's information concerning ongoing Bureau discussions to prepare a non-paper on the role and contributions of observers to the MEDICRIME Committee. This work aims to clarify how observers can best contribute, including potential reporting obligations, and to review their current level of support to the Committee;

- to **take note** of the presentation by Ms. Jolanta BILINSKA, Founding Director of the World Patients Alliance (hereinafter, WPA), on behalf of the WPA, regarding its application for observer status within the CoP;

- to **take note** of the presentation by Mr. Matisse JUBB, Operations Support Coordinator, on behalf of the European Medicines Verification Organisation (hereinafter, EMVO) regarding its application for observer status within the CoP;

- following a successful vote, to **grant** observer status to both the WPA and the EMVO;

8.2. Gender Equality Rapporteur

- to **elect** Ms Salimata DAGNOKO (Ivory Coast) as the new Gender Equality Rapporteur (GER);

8.3. Amendment proposal article 22 Rules of Procedure

- to **take note** of the Secretariat's update on the status of financial contributions from States Parties;

- for the purpose of improved internal monitoring by the CoP's representatives, to **instruct** the Secretariat to send third countries the correspondence regarding financial contributions (including letters from the Finance Department previously sent to Embassies in Paris) directly to the designated national focal points;

- to **vote** in favour of amending Article 22 of the CoP's Rules of Procedure with the understanding that this amendment shall enter into force on 1 January 2027;

9. Information points

9.1 Events

- **to take note** that AIDF will extend an invitation to the Executive Secretary of the MEDICRIME Convention to promote the MEDICRIME Convention in their 3rd Congress to be held in Tunisia mid-October 2026;

9.2 Website information

- to **welcome** the significant, user-friendly development of the MEDICRIME website, which members have praised for its intuitive design, in particular regarding the monitoring procedure, the calendar of activities and news sections;

- to **note** the planned creation of a secure, restricted space for States Parties and Bureau members to facilitate the sharing of documents including during plenary meetings and instruct the Secretariat to proceed with its implementation;

- to **thank** the Secretariat for all this effort;

9.3 Accession of new countries

- to **take note** and **welcome** the recent ratification of the MEDICRIME Convention by the National Assembly of Chad on 26 November 2025, and to acknowledge that the Treaty Office of the CoE awaits receipt of the formal instrument of ratification to proceed with Chad's recognition as a fully State Party;

- to **encourage** signatory countries to complete their national processes and formally accede to the Convention without delay;

9.4 Promotion of the MEDICRIME Convention

- to **take note** that data and results from the online HELP training course on pharmaceutical crime and the MEDICRIME Convention will be presented and discussed at the next plenary meeting;

10. Any other business

- to **take note** of the information provided by the Secretariat regarding the rules for the reimbursement of travel expenses, and in particular of the requirement that any State Party representative seeking coverage for his or her travel must obtain prior approval from the Secretariat;

11. Dates of the next plenary meeting

- to **take note** of the dates and locations of the forthcoming plenary meetings, to be held over three days instead of two:
  - 28–30 April 2026 in Chisinau, Republic of Moldova (11th plenary meeting)
  - 23–25 September 2026 in Strasbourg, France (12th plenary meeting).

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➢ **Appendix I – List of Participants**	**See below**
➢ **Appendix II- Agenda of the meeting**	Agenda
➢ **Appendix III- Tour de table - Presentation of the Parties**	**See below**

APPENDIX I

LIST OF PARTICIPANTS

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

ARMENIA / ARMÉNIE
Mr Mkrtich SHAKARYAN, Head, Inspection Department, The Scientific Centre of Drug and Medical, Technology Expertise, Ministry of Health

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

BENIN / BÉNIN
Dr Yossounon CHABI, Directeur Général, Agence béninoise du Médicament et des autres produits de santé

Mr Marius Janvier DOSSOU-YOVO, Chef de la cellule juridique, Agence béninoise du Médicament et des autres produits de santé (Apologised, *Excusé*)

Ms Nathalie MIGAN, Présidente du Conseil de Surveillance du sous-secteur pharmaceutique au Bénin

Ms Nelly NOUTAIS, Assistante du Directeur Général (Apologised, *Excusée*)

Mr Jean-Pierre WANGBE, Chef de la cellule juridique, Ministère de la Santé, Président du Conseil d'administration de l'ABMed

BOSNIA AND HERZEGOVINA / BOSNIE-HERZÉGOVINE
Vice - Chair / Vice - Présidente
Ms Verica Trbic, Expert adviser, Directorate for Coordination of Police Bodies of Bosnia and Herzegovina NCB INTERPOL

BURKINA FASO / BURKINA FASO
Ms Kotim YAMÉOGO, Magistrat, Conseiller Technique du ministre de la Santé du Burkina Faso

Dr Innocent Armel SAWADOGO WINDWAOGA, Pharmacist specialising in pharmaceutical regulation, head of legal affairs unit at the National Agency for Pharmaceutical Regulation

CROATIA / CROATIE
Dr Rajka TRUBAN ŽULJ, Deputy Head for Operations, Mpharm Croatian Agency for Medicinal Products and Medical Devices (HALMED)

CYPRUS / CHYPRE
Mr Efraim OLYMPIOS, Police officer

Ms Theodora PAPAMICHAEL, General Laboratory of the Ministry of Health of Cyprus (Apologised, *Excusée*)

FRANCE / FRANCE
M. Aissam AIMEUR, Assistant spécialisé pharmacien, Pôle santé Publique de Marseille (online, *en ligne*)

LCL Laurent DOUREL, Adjoint au chef de la Division de Stratégie et Opérations (DSO), Commandement pour l'environnement et la santé (CESAN) (online, *en ligne*)

Ms Annaick LE GOFF, Première vice-présidente chargée de l'instruction

Chair / Président
Mr Christian TOURNIÉ, Conseiller pour les Affaires Européennes et Internationales, Commandement pour l'Environnement et la Santé (CESAN), Direction Générale de la Gendarmerie Nationale

GUINEA / GUINÉE
Dr Aly BADARA CAMARA, Armed Forces forensic doctor, Expert approved at the Court of Appeal of Conakry, Inspector General of Health And Public Hygiene (Apologised, *Excusé*)

Dr Thierno BAH, Director General of the Itinerant Institute for Integrated Training and Prevention against Drugs and Other Addictive Behaviors (IIFPIDCA), (Apologised, *Excusé*)

HUNGARY / HONGRIE
Dr Ivan AKOS BUJDOS, Deputy State Secretariat for Criminal Law Codification, Ministry of Justice

IVORY COAST / COTE D'IVOIRE
Dr Assane COULIBALY, Directeur Général, Autorité Ivoirienne de Régulation Pharmaceutique (AIRP), (Apologised, *Excusé*)

Dr Salimata DAGNOKO, Pharmacien, Cheffe du Service Surveillance marche et lutte contre PMQIF, AIRP

Mr Ismaël SANOGO, Responsable du Service Affaires Règlementaires et du Contentieux, AIRP

REPUBLIC OF MOLDOVA/ RÉPUBLIQUE DE MOLDOVA
Mr Constantin NEDELEA, Deputy Director General of the Medicines and Medical Devices Agency (MMDA) (online, *en ligne*)

MORROCCO / MAROC
Mr Mohammed AZZOUZI, Direction de la Police Judiciaire, Direction Générale de la Sûreté Nationale

Mr Younes ESCAYD, Chef d'unité des crimes régies par des textes particuliers, ministère public marocaine

NIGER / NIGER
Dr Barira DAN NOUHOU, Director General, Niger Pharmaceutical Regulatory Agency (ANRP) (Apologised, *Excusé*)

PORTUGAL / PORTUGAL
Mr Afonso SALES, Criminal Investigation Coordinator, Criminal Police (UNCC), (Apologised, *Excusé*)

SLOVENIA / SLOVENIE
Ms Doroteja NOVAK-GOSARIČ Secretary, Directorate for Health Care Other Health Activities Division, M.Pharm Republic Of Slovenia, Ministry Of Health, (Apologised, *Excusée*)

SPAIN / ESPAGNE
Mr Pedro ALBERTO ÁLVAREZ, Head of Unit of the Madrid Regional Area, Customs Surveillance Service

Mr Juan Pablo ARMENTEROS GENEROSO, General Commissariat of Judicial Police, Co-operation Division

Mr Juan José CASTRO GARCÍA, Chief Inspector, National Police, Head of the Consumption, Environment and Doping Section (Apologised, *Excusé*)

Mr Carlos David GEA MÉNDEZ, Head of International Relations and Cooperation, A.E. Spanish Anti-Doping

Commission in Sport (online, *en ligne*)

Mr Miguel Ángel MARCOS SÁNCHEZ, Brigadier, Guardia Civil (Apologised, *Excusé*)

Ms Frieda SAN JOSE Magistrate Advisor to Advisor to the Cabinet of the Secretary of State to Justice, Ministry of Justice

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

Dr Richard EHMANN, Investigator-in-charge Penal Division (Apologised, *Excusé*)

TÜRKIYE / TÜRKIYE
Mr Cenk BURAK ALTAY, Head of Department, Ministry of Trade

Mr Burak CIHAN ÜRKMEZ, Trade Expert, Ministry of Trade

Mr Kürşat ÇİLEK, Colonel Gendarmerie, Branch Chief

UKRAINE / UKRAINE
Ms Iryna FEDENKO, Head of International Cooperation and Communication Division, State Service of Ukraine on Medicines, and Drugs Control

2. SIGNATORY STATES TO THE MEDICRIME CONVENTION / *ETATS SIGNATAIRES A LA CONVENTION MÉDICRIME*

CHAD / TCHAD
Dr Ayoub Moussa ABDERAMAN, Directeur général de la pharmacie du Médicament et des laboratoires du Tchad

Mr Michel AMARO, Directeur des relations institutionnelles mobilisé par le gouvernement tchadien

Mr Gilbert Léon GLESS, Consul honoraire du Tchad à Strasbourg

Azzedine Moussa MAHAMAT SALEH, Chargé de Mission au Consulat du Tchad à Strasbourg

Prof. Choua OUCHEMI, Conseiller Santé à la Présidence du Tchad

CHILE / CHILI
Ms Lorena REBOLLEDO LATORRE, Deputy Director of the Organized Crime and Drugs Specialized Unit (online, *en ligne*)

REPUBLIC OF THE CONGO / REPUBLIQUE DU CONGO
Ms Amélia Flore Régine DZIA LEPFOUNDZOU, Conseillère au Service Médico-Social, Ambassade de la République du Congo en France

ISRAEL / ISRAEL
Dr Ronny BERKOVITZ, Head of enforcement and inspections Ministry of Health

ITALY / ITALIE
Mr. Salvatore PRIMAVERA, Marshal, Carabinieri Unit, Italian Regulatory Agency for medicines (online, *en ligne*)

Mr. Federico RUZZI, Marshal, Carabinieri Unit, Italian Regulatory Agency for medicines (online, *en ligne*)

LUXEMBOURG / LUXEMBOURG
M. Olivier MOES, Pharmacien-inspecteur, Division de la pharmacie et des médicaments, Ministère de la Santé et de la Sécurité sociale, Direction de la santé

SLOVAK REPUBLIC / RÉPUBLIQUE SLOVAQUE
Mr Dominik CESNEK, Expert, Head of Handling of Medicines and Medical Devices Unit, Pharmacy Divisions, Ministry of Health of the Slovak Republic (online, *en ligne*)

Mr. Marian JASZBERENYI, Senior Officer Specialist, National Drug Enforcement Unit, Police Force of Slovak Republic

Ms Zuzana JAVORSKÁ SAXOVÁ, expert, Ministry of Justice of the Slovak Republic (online, *en ligne*)

Ms Martina HROMÁDKOVÁ, Director, Pharmacy Division, Pharmacy and Drug Policy Department (online, *en ligne*)

Ms Gabriela ŠVECOVÁ CVEKOVÁ, Head of Handling of Medicines and Medical Devices Unit, Pharmacy Division (Apologised, *Excusée)*

Ms Ivana PANKUCHOVÁ, Head of Drug Registration Department (Apologised, *Excusée*)

TUNISIA / TUNISIE
Ms Maryem BETTOUMIA, Tunisian Ministry of Health

Ms Safa CHERNI, Assistante de Projets, Bureau du Conseil de l'Europe à Tunis

3. OTHER COUNTRIES / AUTRES PAYS

BURUNDI / BURUNDI
M. Jean Bosco HITIMANA, Avocat auprès des Cours et Tribunaux du Burundi, Ancien Ministre de la Décentralisation et Réforme Institutionnelle (Apologised, *Excusé*)

CAMEROUN / CAMEROUN
M. Guy Parfait AYE NGONG, Chef Service de la Formation et des Stages du ministère de la justice (Apologised, *Excusé*)

CZECH REPUBLIC / REPUBLIQUE TCHEQUE
Ms Johana STEJSKALOVA, Enforcement Inspector, State Institute for Drug Control (Apologised, *Excusée*)

ROMANIA / ROUMANIE
Mr Răzvan-Gabriel APRODU, First Secretary, Deputy to the Permanent Representative, Permanent Representation of Romania (Apologised, *Excusé*)

SENEGAL / SENEGAL
M. Ibrahima BA, fonctionnaire du Ministère de l'intégration Africaine et des Affaires étrangères du Sénégal (Apologised, *Excusé*)

UNITED KINGDOM / ROYAUME-UNI
Ms Lynda SCAMMELL, Head of Borderline Products, Healthcare Quality and Access, MHRA

EGYPT / EGYPTE

Ms Asma ABDEL JALIL ABDEL DAEM, Counselor, President of Appeal and Director of the International cooperation Department

Mr Karim Ibrahim Ahmed EL-SAYED TARKHAN, Attorney General of the Judicial Inspection

Mr Amr Mohamed Anwar EL-DESOUKI, Chief Prosecutor at the Technical Secretariat for Judicial Inspection

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

AIDF
Ms Paule ONOUVIET, Attaché douanier à l'ambassade du Gabon à Bruxelles

Mr Crépin NAMDENGANANA, Inspecteur des douanes, RCA

Mr Rodrigue BOUBOU KAMDEM, expert OMD contrefaçon et piratage, Cameroun

ASOP
Mr Mike ISLES, Director Alliance for Safe Online Pharmacy EU (online, *en ligne*)

EMVO
Mr. Matisse JUBB, Operations Support Coordinator

Mr Kai MJAANES, General Manager

EUROPOL
Mr Zdeněk POLANSKÝ, Specialist in the Counterfeiting Team, Analysis Project Copy (online, *en ligne*)

Mr Gianluca SABATINO, Counterfeiting Team Senior Specialist, Head of Analysis Project Copy (Apologised, *Excusé)*

FEDEFARMA
Ms Carmen DA SILVA, Cluster Director (Apologised, *Excusé*)

Mr Eduardo VALVERDE, Illegal activities coordinator (Apologised, *Excusé*)

Mr Fernando VIZQUERRA, Cluster Director (Apologised, *Excusé*)

Fight the Fakes Alliance
Ms Sophie ROBERT, Focal Point, Secretariat of Fight the Fakes Alliance (online, *en ligne*)

INTERPOL
Ms Xie GUIQIU, Operations Coordinator, Criminal Networks, Public Health and Pharmaceutical Crime

OPALS
Dr Quentin DUTEIL, Pharmacien (Apologised, *Excusé*)

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

LEEM
Ms Caroline ALLHEILY, Responsable des Affaires internationales, Direction des Affaires publiques – Direction de l'Engagement (online, *en ligne*)

Ms Nina GASQUET, Alternante Juridique (online, *en ligne*)

Mr Cédric OTSE-MAWANDZA, Conseiller en affaires internationales, zone Afrique (online, *en ligne*)

Ms Lucie TUDES, Chargée d'Affaires internationales (*online, en ligne*)

WOAH
Dr Andrés GARCIA CAMPOS, Project manager for the Antimicrobial Resistance & Veterinary Products Department, World Organisation for Animal Health (online, *en ligne*)

World Health Organization
Ms Pernette BOURDILLON-ESTÈVE, Technical Officer, Data governance and analyses, Market Surveillance and Control team (online, *en ligne*)

Mr Naseem HUDROGE, Analyst, Incident Management and Response, Market Surveillance and Control team (Apologised, *Excusé*)

Mr Rutendo KUWANA, Team Lead, Market Surveillance and Control team, (Apologised, *Excusé*)

World Patients Alliance
Ms Jolanta BILINSKA, Founding Director of WPA (online, *en ligne*)

5. EXPERTS / *INTERVENANTS*

Independent experts / Experts independents

Mr Hugo BONAR, Independent Expert

Mr José Maria ESTEBAN, Independent expert (Apologised, *Excusé*)

Mr Mark JACKSON, Independent expert

Mr Fernando MIRO, Independent expert (online, *en ligne*)

Mr Bhavik Anil PATEL, Professor of Clinical and Bioanalytical Chemistry (online, *en ligne*)

Ms Tatiana SALEM, Consultant

Mr Ricoveer SHERGILL, School of Applied Sciences & Centre for Lifelong Health, University of Brighton, UK

Mr Sigitas SIRIUKAITIS, Independent expert (Apologised, *Excusé*)

Dr Asier URRUELA MORA, Professor of Criminal Law, University of Zaragoza, Spain

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

DGI - HUMAN RIGHTS AND RULE OF LAW /
DGI - DROITS HUMAINS ET ÉTAT DE DROIT

Directorate of Social Rights, Health and Environment/ *Direction des droits sociaux, de la santé et de l'environnement*

Mr. Rafael BENITEZ, Director of Social Rights, Health and Environment / *Directeur des Droits Sociaux, Santé*

et Environnement

Ms Laurence LWOFF, Head of Health Division / *Cheffe de la Division Santé (*online*, en ligne)*

Dr iur. Oscar ALARCÓN-JIMÉNEZ **Executive Secretary to the Committee of the Parties of MEDICRIME Convention** / ***Secrétaire Exécutif du Comité des Parties de la Convention MEDICRIME***

Ms Rachel VAN DER BEEK, Junior Programme Manager (online, *en ligne*)

Ms Emma JEANNOEL, Assistant Administrative / *Assistante* Administrative

Ms Léa KREMER, Trainee / Stagiaire

Directorate of Security, Integrity and Rule of Law / Direction de la sécurité, de l'intégrité et de l'État de droit

The Monitoring group of the Anti-Doping Convention (T-DO)
Ms Liene KOZLOVSKA, Senior Programme Manager, Anti-Doping Unit, Sport Division

PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE / ASSEMBLÉE PARLEMENTAIRE DU CONSEIL DE L'EUROPE

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

Mr Dan ALDRIDGE, Représentant, Député, Labour, House of Commons, Royaume-Uni

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM) / DIRECTION EUROPEENNE DE LA QUALITE DU MEDICAMENT & SOINS DE SANTE (DEQM)

Mr Gwenael CIREFICE, Head of the Pharmaceutical and Consumer Care Section

Ms Ines DU PLESSIS, Program Manager, Committee of Experts on Falsified Medical Products, CD-P-PH/CMED (Apologised, *Excusée*)

Mr François-Xavier LERY, Co-ordination and Scientific Support

Mr Chris McGUIRE, Chair of the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes, CD-P- PH/CMED

Ms Marta MIQUEL, European Directorate for the Quality of Medicines and HealthCare, Market Surveillance (Apologised, *Excusée*)

Ms Silvia RAVERA, Secretary to the CD-P-PH Committee

Interpreters / Interprètes
Ms Barbara GRUT

Ms Corinne McGEORGE

Ms Amanda LARIVIERE

APPENDIX III

TOUR DE TABLE – PRESENTATIONS OF THE PARTIES

1. RESPONSES RECEIVED FROM THE PARTIES (following the 10th plenary meeting of the COP)

	COUNTRIES / *PAYS*	TOUR DE TABLE WRITTEN CONTRIBUTIONS / *TOUR DE TABLE CONTRIBUTIONS ECRITES*
1	ALBANIA / *ALBANIE*	
2	ARMENIA / *ARMÉNIE*	
3	BELARUS/ *BÉLARUS*	
4	BELGIUM / *BELGIQUE*	
5	BENIN / *BÉNIN*	
6	BOSNIA AND HERZEGOVINA / *BOSNIE HERZÉGOVINE*	
7	BURKINA FASO / *BURKINA FASO*	12/12/2025
8	CROATIA / *CROATIE*	09/12/2025
9	CYPRUS / *CHYPRE*	
10	FRANCE / *FRANCE*	
11	GUINEA / *GUINÉE*	
12	HUNGARY / *HONGRIE*	09/12/2025
13	IVORY COAST / *CÔTE D'IVOIRE*	09/12/2025
14	REPUBLIC OF MOLDOVA / *RÉPUBLIQUE DE MOLDOVA*	
15	MOROCCO / *MAROC*	10/12/2025
16	NIGER / *NIGER*	
17	PORTUGAL / *PORTUGAL*	
18	RUSSIAN FEDERATION / *FÉDÉRATION DE RUSSIE*	
19	SLOVENIA / *SLOVÉNIE*	
20	SPAIN / *ESPAGNE*	
21	SWITZERLAND / *SUISSE*	10/12/2025
22	TÜRKIYE / *TÜRKIYE*	
23	UKRAINE / *UKRAINE*	

ALBANIA / *ALBANIE*	Not present

ARMENIA / *ARMÉNIE*	Contribution received on:

BELARUS / *BIÉLORUSSIE*	Not present

BELGIUM / *BELGIQUE*	Contribution received on

BENIN / *BÉNIN*	Contribution received on

BOSNIA AND HERZEGOVINA / *BOSNIE-HERZÉGOVINE*	Contribution received on

BURKINA FASO / *BURKINA FASO*	Contribution received on 12/12/2025

Les principales mesures législatives ou autres prises en application de la Convention Medicrime pour lutter contre la contrefaçon de produits médicaux et les infractions similaires menaçant la santé publique dans notre pays sont :

- Au titre des structures de lutte contre la contrefaçon de produits médicaux et les infractions similaires menaçant la santé publique, on peut citer :

• l'Agence Nationale de la Régulation Pharmaceutique dont le rôle principal est de réguler le secteur pharmaceutique au Burkina et de contribuer à la lutte contre la contrefaçon de produits médicaux et les infractions similaires menaçant la santé publique.

• La Coordination Nationale de Lutte contre la Fraude dont le rôle est de lutter contre la fraude y compris la fraude dans le domaine pharmaceutique.

• La Coordination Nationale de Lutte contre la Drogue qui contribue également à cette lutte.

• Les pôles spécialisés dans la répression des infractions économiques et financières et de la criminalité organisée auprès des tribunaux de grande instance de Ouagadougou et de Bobo-Dioulasso. Les tribunaux contribuent à la lutte contre la contrefaçon de produits médicaux et les infractions similaires menaçant la santé publique par les poursuites (parquet) et le jugement des personnes impliquées dans ces types d'infractions.

- Au titre des mesures législatives de répression de la contrefaçon de produits médicaux et les infractions similaires menaçant la santé publique. On peut citer :
- le code pénal en 2018,
- le code des drogues,
- la loi portant régime général des importations et des exportations,
- le code des douanes.
- le code de la santé publique

Il faut signaler également le projet de loi portant prévention et répression des infractions en matière de trafic de faux médicaments et autres produits médicaux.

CROATIA / *CROATIE*	Contribution received on 09/12/2025

The Ministry of Health adopted the Ordinance on the conditions for the distance retail sale of medicines via the Internet in July this year. Although the distance sale of medicines without a prescription was provided for in the 2013 Medicines Act, it was necessary to additionally prescribe the conditions for the opening and operation of e-pharmacies through an appropriate regulation.
New Act on Veterinary Medicinal Products and Veterinary Medical Devices is now in the final correction before submitting to the Government session for approval.
This new Act, in addition to the definition of a counterfeit veterinary medicinal product, defines the SPOC for counterfeit veterinary medicinal products and obligations of wholesalers, marketing authorisation holders and veterinary doctors to notify the contact point, the Croatian Veterinary Institute, in the event of counterfeit veterinary medicinal product.
The Act also includes a chapter on veterinary medical devices and in this chapter also defines the obligation to notify the contact point in the event of a counterfeit medical device.

CYPRUS / *CHYPRE*	Contribution received on

FRANCE / *FRANCE*	Contribution received on

GUINEA /. *GUINÉE*	Not present

HUNGARY / *HONGRIE*	Contribution received on 09/12/2025

1. The next considerable legislative and practical challenge in terms of the Medicrime Convention will be the setting up of the 24/7 network. It is going to be an effort of multiple stakeholders, including the Ministry of Justice, the Ministry of Interior, law enforcement agencies and practitioners of law.
2. As far as the 2nd monitoring round of the Medicrime Convention is concerned, the 2nd phase of the questionnaire is being finalised at the moment; it will be sent to the Secretariat shortly, as soon as it is ready.

IVORY COAST / *CÖTE D'IVOIRE*	Contribution received on 09/12/2025

Au cours du tour de table, la Côte d'Ivoire a eu l'occasion de présenter la situation actuelle quant aux activités relatives à la lutte contre les produits médicaux de qualité inférieure et falsifiés (PMQIF). Vous trouverez ci-dessous comme convenu le point écrit de l'intervention de la côte d'Ivoire:

- **Situation actuelle** :
La Côte d'Ivoire dispose de plusieurs textes juridiques lui permettant d'encadrer le secteur pharmaceutique, notamment la loi n°2017-543 du 03 août 2017 relative à la régulation du secteur pharmaceutique. Cette loi qui met en place l'Autorité Ivoirienne de Régulation Pharmaceutique (AIRP), contient des dispositions pour la répression du trafic des PMQIF. La Côte d'Ivoire a ratifié la Convention MEDICRIME en 2023 (juillet 2023).

Suite à la ratification de ladite Convention, la Côte d'Ivoire a bénéficié de l'appui technique du Conseil de l'Europe pour la rédaction d'un texte spécifique à la convention MEDICRIME ce qui permettra au pays de renforcer la répression du trafic des PMQIF et de ses infractions assimilées, et ce processus a aboutit à la rédaction d'un avant-projet de loi spécifique à la Convention MEDICRIME en attente d'adoption par la pays.

Dans le cadre de la lutte, l'AIRP a mis en place et anime un groupe multisectoriel (Police, Gendarmerie, Douanes, Justice, société civile, acteurs pharmaceutiques) pour renforcer la collaboration nationale entre les différentes parties prenantes.

Proposition de recommandation:

Au titre de la coopération, la Côte d'Ivoire sollicite une visite du bureau du comité des parties afin d'organiser une visite sur son territoire.
L'objectif principal de cette mission est de **promouvoir la Convention MEDICRIME** auprès des **ministères stratégiques** (Santé, Justice, Affaires étrangères, etc.)
Cette visite sera également l'occasion de souligner le **rôle décisif des décideurs** dans la lutte contre les produits médicaux de qualité inférieure et falsifiés (PMQIF), de **catalyser l'adoption** de l'avant-projet de loi MEDICRIME, et de **faciliter concrètement** la mise en œuvre des activités de lutte contre ces produits.

REPUBLIC OF MOLDOVA / *REPUBLIQUE DE MOLDOVA*	Contribution received on

MOROCCO / *MAROC*	Contribution received on 10/12/2025

Mesdames et Messieurs,
Conscients de la gravité du phénomène de la contrefaçon et de la vente illicite de produits pharmaceutiques, qui menace non seulement les économies nationales mais aussi la santé publique, le Royaume du Maroc, à travers ses différents départements et institutions compétentes, s'engage pleinement dans la lutte contre ce fléau. Cette mobilisation se décline en deux axes majeurs : le renforcement du cadre réglementaire et des mécanismes de contrôle, et l'intensification des actions répressives pour arrêter et traduire en justice les auteurs des infractions connexes.
Premièrement, sur le plan réglementaire, il convient de souligner que le Ministère de la Santé Marocain a publié, le 3 octobre 2025, une circulaire destinée à rappeler à tous les acteurs du secteur pharmaceutique l'impérieuse nécessité de respecter les textes législatifs et réglementaires en vigueur. Cette circulaire insiste notamment sur :

- Le respect strict du circuit légal de vente et de distribution des médicaments et produits de santé ;
- L'assurance d'une traçabilité complète, de la fabrication à la dispensation, avec mention obligatoire du numéro de lot et de la date de péremption ;
- L'interdiction de la remise d'échantillons gratuits contenant des substances psychotropes ou stupéfiantes ;
- Le strict respect des exigences législatives relatives aux substances vénéneuses ;
- L'interdiction de vendre des médicaments à des entités non autorisées, y compris certaines associations, cabinets médicaux ou groupements de cliniques ; et
- L'interdiction formelle du colportage pharmaceutique, ainsi que de la vente via Internet, réseaux sociaux ou tout autre moyen non autorisé.

Deuxièmement, sur le volet répressif, les services de sécurité marocains déploient des

efforts majeurs pour lutter efficacement contre ce phénomène et protéger la santé publique. De même, les services de Police marocains collaborent étroitement, via le canal du Bureau Central National (BCN Rabat), avec le Secrétariat Général d'Interpol et participe à des opérations internationales. À titre d'exemple, entre le 16 décembre 2024 et le 16 mai 2025, ils ont pris part à la 17ème édition de l'opération « PANGEA », organisée par l'OIPC-Interpol en partenariat avec l'Organisation Mondiale des Douanes, et visant la lutte contre la vente illicite des produits pharmaceutiques en ligne. Les investigations cybernétiques et sur le terrain menées, durant la période considérée, ont permis l'identification et l'arrestation de plusieurs individus s'adonnant à cette activité illicite, avec la saisie de quantités conséquentes de produits pharmaceutiques, dont notamment des produits de soins et compléments alimentaires, des stimulants sexuels, ainsi que des inflammatoires et produits abortifs.
Finalement, je tiens à rappeler que le Royaume du Maroc restera toujours déterminé à poursuivre sa collaboration avec ses partenaires internationaux notamment le Conseil de l'Europe, et ce, afin de lutter efficacement contre ce phénomène et garantir la sécurité sanitaire de ses citoyens.

NIGER / *NIGER*	Not present

PORTUGAL / *PORTUGAL*	Not present

RUSSIAN FEDERATION / *FÉDÉRATION DE RUSSIE*	Not present

SLOVENIA / *SLOVÉNIE*	Not present

SPAIN / *ESPAGNE*	Contribution received on

SWITZERLAND / *SUISSE*	Contribution received on 10/12/2025

On behalf of Switzerland
Swissmedic
Swiss Agency for Therapeutic Products
Penal Division
Hallerstrasse 7, 3012 Bern - Switzerland

First, a quick summary of legislative developments in therapeutic products law:

Following various previous revisions to the Therapeutic Products Act (TPA), Parliament and the Federal Council once again saw a need for revision in

- the areas of medication safety for patients,
- electronic prescribing via e-prescriptions, and
- drug safety in paediatrics.

So-called advanced therapy medicinal products (abbreviated ATMPs) are now also regulated more appropriately and clearly in the TPA. The development of ATMPs is increasing worldwide, as is their importance in medical practice.
Finally, in the area of veterinary medicinal products, equivalence with the new EU veterinary medicinal products legislation is to be achieved as far as possible

- in order to prevent trade barriers,
- prevent the development of antibiotic resistance and
- ensure market access for advanced therapy medicinal products in veterinary medicine.

The message on the draft of the revised TPA was submitted to the Swiss Parliament at the beginning of September 2025. It is not yet known when the parliamentary debate on this will take place.
From a criminal law perspective, it is significant that the revision transfers transplant products and the associated penal provisions from the Transplantation Act to the Therapeutiv Products Act. As this addition would have made the existing penal provisions convoluted, Swissmedic took the opportunity to restructure these penal provisions to make them clearer for those who apply the law.

Second, a brief overview about some action that was done in Switzerland in the last year in relation with combatting medical crime:

1. In collaboration with the inspectorates, the Swissmedic conducted a focused action on licensed wholesalers trading with suppliers from non-EU countries . With that targeted campaign, Swissmedic responded to former cases of falsified medicinal products with stricter controls. The results were published in March 2025. No new cases of trade in falsified medicines were detected, but a few shortcomings in the control systems of the companies were uncovered.

2. After several observations of illegally imported “GLP-1” weight loss medicinal products, the OMCL analysed products and market control investigated offers. Three trends were identified as especially harmful, a warning against falsified and misleading “GLP-1” weight loss products was published end of august 2025, it resulted in a good media coverage.

3. From a criminal law perspective, also worth mentioning is Swissmedic’s recent success before the Federal Supreme Court, where Swissmedic won an appeal against a decision by the Zurich High Court. The subject matter was the question of the distinction between the Narcotics Act (NarcA) and the Therapeutic Product Act (TPA) in the area of therapeutic substances containing narcotics. According to the applicable legal provisions, the TPA applies in cases of therapeutical use, unless the NarcA imposes equally strict or stricter regulations for a specific area (e.g. import).

While Swissmedic took the position that an abstract view should be taken to answer this question, the Zurich High Court considererd a concrete approach to be appropriate. The Federal Supreme Court fully concurred with Swissmedic's position.

Third, some updates regarding Swissmedic’s active role in the field of training in therapeutic products law:

Swissmedic organizes information events on current topics, particularly on important developments in the regulation of therapeutic products, for representatives of our stakeholders. These include, for example, roundtables, training sessions, workshops, symposia, or conferences. The primary focus lies on the efficient provision of information and communication with various stakeholders on the topic of therapeutic products, with the aim of simplifying mutual understanding and the exchange of information.
Swissmedic also offers hands-on training courses for National Regulatory Authorities (NRAs) in low- and middle-income countries, with the aim of building their capacities and

supporting them in performing their mandates more efficiently and effectively. In 2025, among others, we hosted the following events:

- Haemovigilance workshop targeted at subject matter experts covering reporting types, legal bases, and the practical implementation of haemovigilance in Switzerland
- "Train the Trainer" Symposium on Clinical Trials providing an overview of the latest regulatory updates related to clinical trials as well as GCP inspections
- Multi-day GMP Training for Inspectors focusing on manufacture and controls of biologicals with participants from international regulatory authorities, Swiss Regional Medicines Inspectorates and Swissmedic

Additionally, our employees regularly give presentations at events organized by other organizations upon request, for example, as part of training and continuing education programs, at associations, or with partner authorities. In this context, Swissmedic also plays a significant role in the training programs of the Central European Society for Regulatory Affairs (MEGRA), thereby contributing to the education and training of individuals working in the pharmaceutical industry or service sector in regulated areas such as marketing authorization, clinical research, technical expertise and quality assurance, pharmacovigilance, or advertising, as well as employees of authorities. As of November 19th, a total of 134 presentations and participations in panel discussions by our the experts of the Swiss Agency of therapeutiv Products have been registered for 2025.

And last but noch least Swissmedic hosted the annual Swiss Medicrime Meeting on September 9th, 2025, for all cantonal and federal regulatory authorities, law enforcement, prosecutors, the customs and border Security with the aim to strengthening collaboration between various authorities with differing laws in the fight against illegal therapeutic products - totally in line and in the spirit of the Medicrime Convention.

TÜRKIYE / *TÜRKIYE*	Contribution received on

UKRAINE / *UKRAINE*	Contribution received on