



European Directorate for the Quality of Medicines & HealthCare

Council of Europe

edqm
European Directorate
for the Quality
of Medicines
& HealthCare

Direction européenne
de la qualité
du médicament
& soins de santé

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CONSEIL DE L'EUROPE

Committee of experts on falsified medical products CD-P-PH/CMED – latest activities

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European Directorate for the Quality of Medicines & HealthCare



Council
of Europe

Council of Europe

- ★ Established in **1949**
- ★ **46 member states**
- ★ Based in **Strasbourg**
- ★ Founded on three main values:
**human rights, democracy
and the rule of law**

Protection of human rights
includes **access to good
quality medicines and
healthcare - EDQM**



EDQM

- ★ Founded in **1964**
- ★ Partial agreement (39 member states & the EU + 33 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities

Our vision

Together for better health, for all

Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders



Four policy areas and a wide portfolio of activities



Medicinal products

Official standards for manufacture and quality control of pharmaceuticals

European Pharmacopoeia (documentary and reference standards), Biological Standardisation Programme (BSP)

Certificates of Suitability confirming compliance with European Pharmacopoeia and inspections

Certification of suitability

Control of medicines
Network of Official Medicines Control Laboratories (OMCLs)



Substances of human origin

Quality and safety standards

Biovigilance, data collection and harmonisation

Improving quality system / capacity building of Blood and Tissues and Cells Establishments

Addressing SoHO supply



Pharmaceutical care

Policies and model approaches for the safe use of medicines

Cooperation to combat falsification of medical products



Consumer health

Safety standards for cosmetics, tattoo inks and food contact materials

Control of cosmetics
Network of Official Cosmetics Control Laboratories (OCCLs)



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What (who) is CD-P-PH/CMED ?



Intergovernmental committee of experts, framework given by the Council of Europe and more specifically the Ph. Eur.

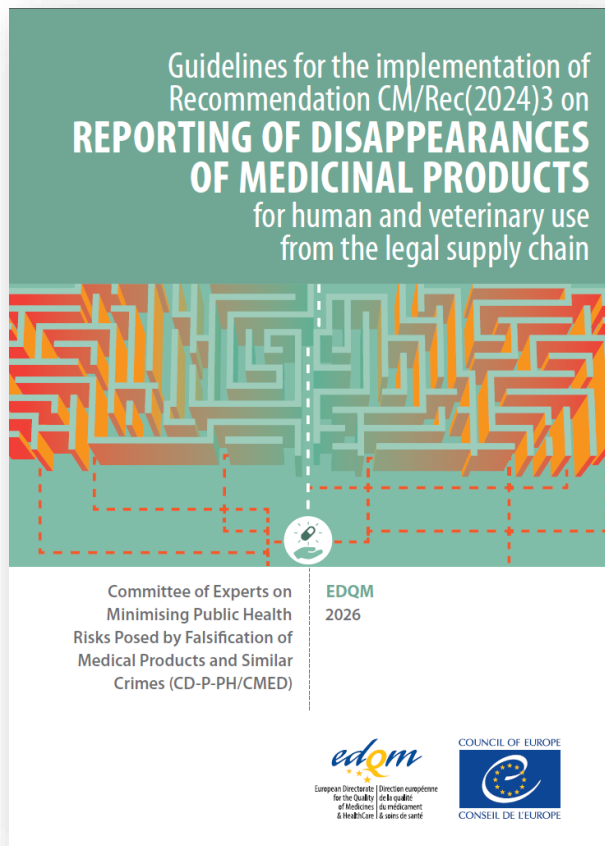
- ★ **European Pharmacopoeia member states** (plus some other CoE countries)
- ★ **Health regulatory authorities** (Law Enforcement and Customs)

Theft, loss & diversion of medicines



Council of Europe Recommendation CM/Rec(2024)3

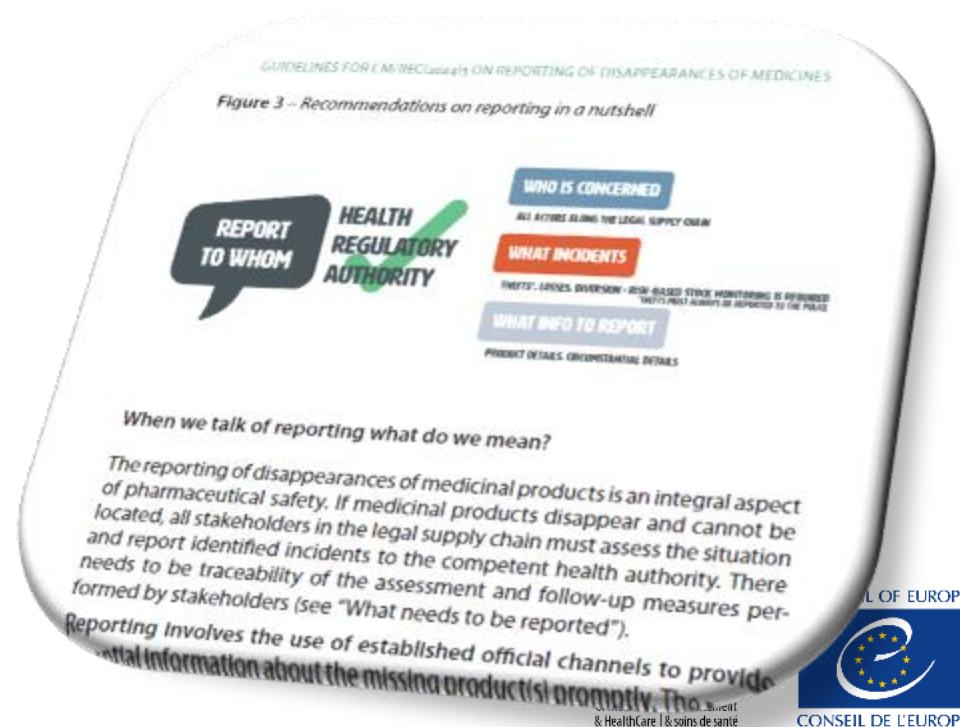
https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=0900001680af31ee



Guidelines for CM/Rec(2024)3

<https://freepub.edqm.eu/publications/PUBL-49/detail>

- Focus on reporting, data collection and co-operation
- Advice on implementation and on tools available

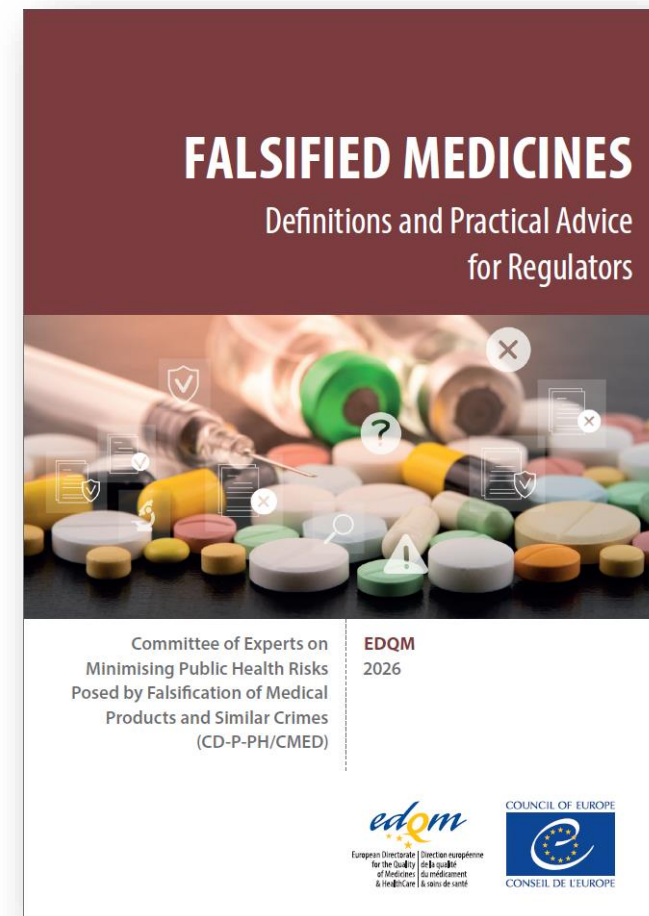


Guide “Falsified Medicines – Definitions and Practical Advice for Regulators”



provide a practical tool for decision taking on which specific falsification practices should be considered as falling under the broad legal definition of ‘falsification’.

Publication foreseen end of 2026



Guide “Falsified Medicines – Definitions and Practical Advice for Regulators”

Framework: applicable relevant definitions, importance of definitions and their understanding, methodology

Case scenarios: 17 cases provided by regulatory authorities – explained, assessed and evaluated acc. to the 3 relevant definitions

Falsification in context: Pharmaceutical supply chain, Threats & Risks, Customs & Law enforcement, Co-operation

 World Health Organization	 European Union - FMD	 CoE MEDICRIME
IDENTITY Name Labelling or packaging Documents supporting authenticity COMPOSITION Any ingredient or component	IDENTITY Name Packaging and labelling Composition as regards Any ingredients including excipients and the strengths of those ingredients	IDENTITY Name Packaging and labelling Composition regarding Any ingredient, including excipients and their strengths, or components
SOURCE Name and address of Marketing authorisation holder Manufacturer Importer/Exporter Distributor/Retailer	SOURCE includes Marketing authorisation holder Manufacturer Country of manufacture Country of Origin HISTORY Records and documents relating to the distribution channels	SOURCE shall include Marketing authorisation holder Manufacturer Country of manufacture Country of Origin Supply and distribution history, e.g. records and documents relating to the distribution channels including identification of the above

Recommendation CM/Rec(2026)7 on best practices for the remote and online provision of medicines

<https://search.coe.int/cm?i=09125948802b8d9e>

Appendix

- I. Scope, definitions and general principles
- II. Authorised remote and online providers of medicines
 - A. General recommendations applicable to any remote and online provider of medicines
 - B. Pharmacies
 - C. Non-pharmacy outlets
- III. Healthcare professional regulatory and representative bodies
- IV. Member States
- V. Online marketplace platforms and social media marketplace platforms
- VI. Cross-border aspects



Soon to be published

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Publications on falsified medical products and related crimes



Social media best practices for health authorities: *A compilation of best practices to help national authorities optimise their use of social media (2021)*

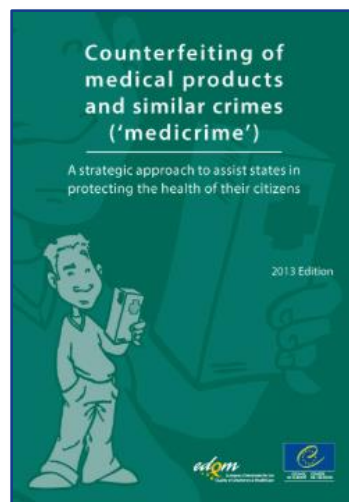
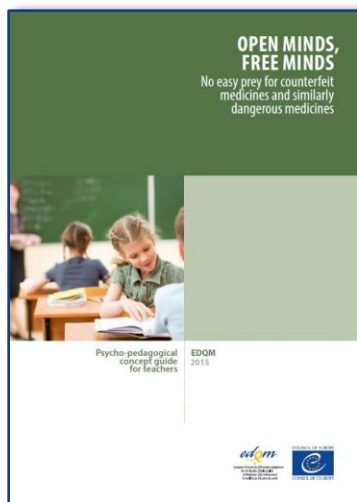
MEDICRIME vs Volcano: *A practical case study on how the Council of Europe Convention could improve the fight against pharmaceutical crime (2019)*

Open minds, free minds – No easy prey for counterfeit medicines and similarly dangerous medicines (2015): *Interactive concept guide to support training and education in schools*

Counterfeiting of medical products and similar crimes: *A strategic approach to assist states in protecting the health of their citizens (2013)*

Counterfeit Medicines: Facts and practical advice: *Root causes, types of counterfeit products, distribution paths, current legislation and the role of national and international institutions are examined through real case studies.*

Counterfeit Medical Products and Similar Crimes: Risk communication : *This publication discusses risk communication from the angles of both pharmaceutical and communication sciences.*



1. To expand reach

By providing an active hub for information and interaction on social media, organisations can broaden their reach and provide citizens with a channel to engage on specific topics. This is especially important with regard to communicating on falsification issues, as the right information needs to be disseminated as widely as possible.



<https://www.edqm.eu/en/publications-on-falsified-medical-products-and-related-crimes>

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More information

 www.edqm.eu

 <https://go.edqm.eu/Newsletter>

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