

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

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Fight against the counterfeiting of medicinal products in the OMCL Network

<https://www.edqm.eu/en/testing-of-falsified/-illegal-medicines>

Marta Miquel (EDQM-ICND)

31 March - 1 April 2025



OMCL = Official Medicines Control Laboratory

- OMCLs are **public institutions** which support (or are part of) regulatory authorities in controlling the quality of medicinal products for human and veterinary use (pre-authorisation phase and/or post-marketing phase)
- OMCLs test medicinal products **independently** from manufacturers

OMCL is a recognised term in the EU legislation



OMCL NETWORK (GEON)

<https://www.edqm.eu/en/omcl-network>

- Devised in **1994** by the EU Commission & CoE
- To promote the **collaboration of OMCLs across Europe** (and beyond) in the area of quality control of marketed medicinal products for human and veterinary use
- Set up in **1995** by the EDQM
- Network activities are **co-financed** by the EC (on basis of a contribution agreement)
- **68** members from **42** countries
- **Annual work programmes** decided together with National Competent Authorities (NCAs) and the European Medicines Agency (EMA)
- EDQM: **Secretariat and co-ordination** of the Network activities and joint surveillance programmes



GEON Composition*

- 26 out of the 27 EU countries (except Malta)
- 7 European non-EU countries: Bosnia & Herzegovina, Republic of Moldova, Republic of North Macedonia, Serbia, Türkiye, Ukraine, United Kingdom
- Norway (EEA) & Switzerland (MRA)
- 7 non-European partners (Australia, Canada, Israel, Kazakhstan, Morocco, Singapore and Taiwan FDA): associate members as observers to Ph. Eur. Convention



*Status: March 2025

Creation of the Falsified Medicines WG

- **Early 2000s:** many OMCLs analysing falsified/illegal medicines on behalf of customs, police, health authorities, inspectors, courts => **authenticity testing** and **screening for unknown products**.
- **2005:** decision taken by the OMCL Network to better **coordinate** the work of the individual OMCLs in the field of falsified/illegal medicines testing.
- **October 2006:** Data repository set up by the EDQM to post test reports, facilitating a rapid exchange of information on testing activities in the field of falsified medicines. **March 2014:** replaced by the **Know-X database**.
- **Since 2007:** the EDQM organises the programme “**Suspicious Unknown Products**” (**SUP**). The aim is to evaluate whether the OMCLs are able to identify (and, where possible, quantify) unknown active pharmaceutical ingredients (APIs) in a “blind” sample.
- **December 2010:** adoption of MEDICRIME convention by Committee of Ministers of the Council of Europe.
- **June 2011:** DIRECTIVE 2011/62/EU of the European Parliament and of the Council, relating to the prevention of the entry into the legal supply chain of falsified medicinal products.
- **2011:** creation of the **Falsified Medicines WG of the OMCL Network**.

How the OMCL Network supports the NCAs in the implementation of MEDICRIME ?

Document available on the EDQM website [here](#)

- **Article 17 – National measures of co-operation and information exchange** => the OMCL Network uses IT platforms that facilitate a rapid dissemination of information; OMCLs collaborate with customs, police and other governmental agencies at national level.
- **Article 18 - Preventive measures** e.g. take the necessary legislative and other measures to establish the quality and safety requirements of medical products => OMCLs help NCAs monitoring the quality and safety of medicines (whether PRE or POST marketing) & active substances.
- **Article 22** => international co-operation on prevention and other administrative measures => Networking is a key element for OMCLs for an effective co-operation at international level: exchange of information, training activities, regular meetings, collaborative programmes, mutual assistance, etc.
- **Article 25** => the Committee of Parties (CoP) should monitor the implementation of the Convention => the EDQM is represented in the CoP => facilitates communication between the CoP and the OMCL Network.

OMCLs are explicitly mentioned in the Explanatory Report to the Medicrime convention



- The OMCL Network FM WG was established in 2011 with the aim of **reinforcing the collaboration** between OMCLs in the field of testing of falsified/illegal medicines, to foster a **coordinated approach** and to draw up a **work programme**.
- The WG is composed of representatives from 24 OMCLs and they meet twice per year.

Work programme of the FM WG:

- **Exchange of information** related to analysis on suspect samples:
 - Via IT platforms (Know-X) and regular meetings (2/year)
 - Contacts with other Authorities in the same field (e.g. customs labs, enforcement officers, etc)
- **Identification of training needs:** hands-on **training** sessions and **SUP** studies.
- **Market surveillance programmes (MSS)** on falsified and illegal products:
 - **MSSIP:** Market Surveillance on Suspected Illegal Products
 - **MSSFP:** Market Surveillance Study - Type FingerPrint
- **Know-X database:** assistance with its establishment, maintenance and further development.

1. Data Pooling



Know-X Database

- Exchange of information in the field of falsified medicinal products and similar crimes.
- Allows issuing Rapid Alerts, observance of trends, encourages collaboration between stakeholders, sharing of analytical information, etc.
- In 2024, **293** cases were reported by OMCLs in Know-X, of which **183** concerning **anabolic steroids**.

MSSIP – Market Surveillance Studies on Suspected Illegal Products

- 7 finalised, 1 ongoing
- MSSIP focus on **specific product groups** e.g. slimming food supplements, sexual potency enhancers, anabolic steroids, etc.
- **Conclusions shared :**
 - with all OMCLs of the OMCL Network
 - published on EDQM website
 - reported in Know-X
 - sent to the EU Commission
 - publication in scientific journals.

MSSFP – Market Surveillance Studies – type Fingerprint

- 5 finalised, 1 ongoing
- MSSFP focus on **API testing**: quality + authenticity of sources.
- Conclusions **shared** as above.

Market Surveillance Studies on Suspected Illegal Products (MSSIP)



- Focus on **specific product groups** e.g. slimming food supplements, sexual potency enhancers, anabolic steroids.
- Collection of **retrospective and prospective data**, over a defined period of time.
- The objective is to **map the extent of the presence of such products** in member states of the OMCL Network and to **raise awareness** of this phenomenon to public and the EU Commission.
- Participating OMCLs **sample the products** directly on their own (from pharmacies, herbal shops, gyms, internet, etc) or receive them via inspectors/customs/police, then **analyse** them with the analytical methods of their choice.

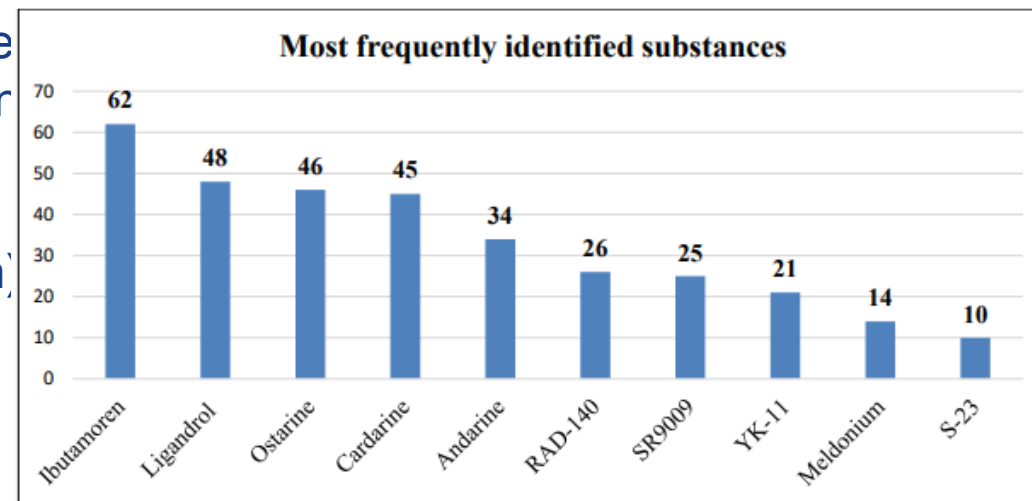
Conclusions/results:

- Shared within the whole **OMCL Network**.
- Published on **EDQM website**.
- Reported in **Know-X** by the participating OMCL.
- Shared with the **EU Commission** (final report).
- Published in **scientific journals**. For example: MSSIP005 *The occurrence of non-anatomical therapeutic chemical-international non-proprietary name molecules in suspected illegal or illegally traded health products in Europe: A retrospective and prospective study*, 2021, doi: 10.1002/dta.3001.

MSSIP (cont.)

MSSIP006 on SARMs, Metabolic Modulators and small molecule Growth Hormone Secretagogues used as Performance Enhancing substances.

- 14 participating OMCLs.
- Scientific Advisor: Magnolia Mendoza Barrios (AEMPS, Spain).
- 324 samples.
- [Final Report](#) available online.
- Report sent to the [EU Commission](#) in January 2024.
- [Status: scientific article](#) drafted – under review by OMCLs.



MSSIP007 on Nootropics

- 12 participating OMCLs
- Scientific Advisors: Eric Deconinck and Céline Vanhee (Sciensano, Belgium).
- 159 samples.
- Products in scope: natural, semi-synthetic and synthetic nootropics.
- [Status: Finalised](#) – Draft report under review by the OMCLs.
- [Scientific article](#) under preparation.

Top 3 reported molecules:

- melatonin (33)
- modafinil (25)
- levodopa (L-Dopa) (21)

MSSIP (cont.)

MSSIP008 on Antibiotics from illegal sources

- Scientific Advisor: Andreas Blomgren (MPA, Sweden).
- 8 registered OMCLs.
- Objective: to identify any deviation from label claim of the products, with focus on API identity, and to raise awareness of the problems concerning self-diagnosis and self-medication using antibiotics.
- Status: Ongoing. No results collected yet.
- Timeframe: January 2024 to September 2025.

Proposals for future MSSIPs:

- **Anaesthetic creams** containing lidocaine or similar APIs
- **Melatonin**
- GLP-1 receptor agonists
- Abortion pills
- HIV prophylactic medicines
- Botox

MSS on Suspected Illegal Products - MSSIP



European Directorate for the
Quality of Medicines & HealthCare

[Home](#) [EDQM](#) [Medicines](#) [Substances of human origin](#) [Consumer health](#) [Products & services](#) [Events & training](#) [Contact](#)

You are here: [European Directorate for the Quality of Medicines & HealthCare](#) > [Medicines](#) > [OMCL Network](#) > [Working group activities](#) > [Testing of falsified / illegal medicines](#)

Testing of falsified / illegal medicines

Within the General European OMCL Network (GEON)

- > [Background](#)
- > [Work plan of the OMCL Falsified Medicines Working Group](#)
- > [Market Surveillance Studies on Suspected Illegal Products \(MSSIP\) within the Network](#)
- > [OMCL Monoclonal Antibody Testing Group](#)

RELATED LINKS

- > [MEDICRIME Convention](#)
- > [Bundesamt für Sicherheit im Gesundheitswesen \(BSG\)](#)

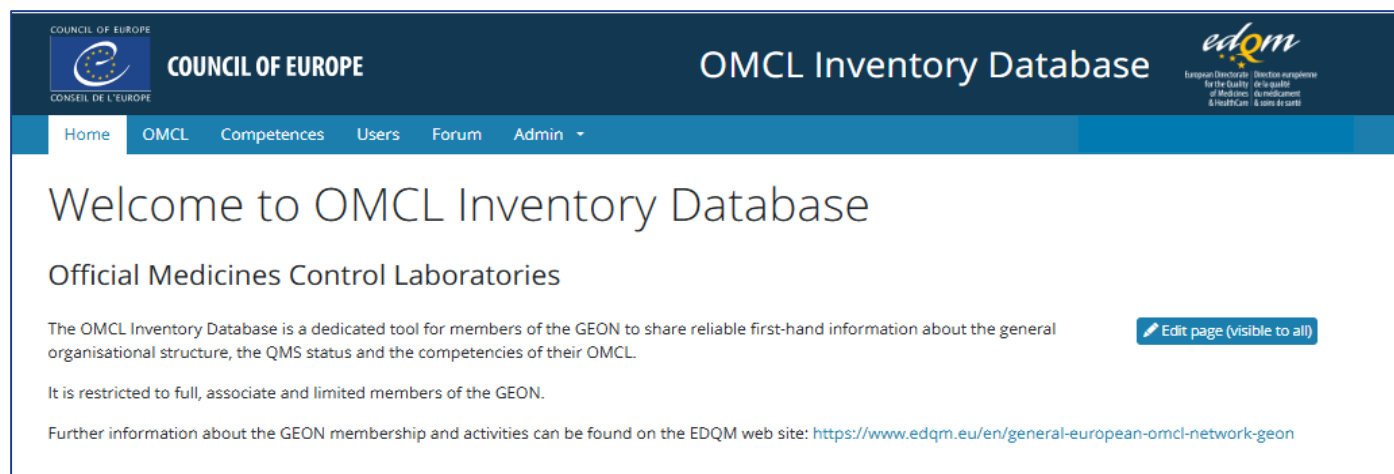
BACKGROUND

In the first decade of the 21st century, many OMCLs started testing (with products selected according to risk-benefit) on behalf of other authorities such as customs, police, etc.

Summaries of the study reports are available.

- [Download the study report on Illegal Products containing “non-INN” APIs](#)
- [Download the study report on Slimming dietary supplements](#)
- [Download the study report on Dietary Supplements advertised as Sexual Potency Enhancers](#)
- [Download the study report on Illegal Anabolic Steroids](#)
- [Download the study report on Medicines in disguise](#)
- [Download the study report on SARMs, metabolic modulators and small molecule growth hormone secretagogues used as performance enhancing substances](#)

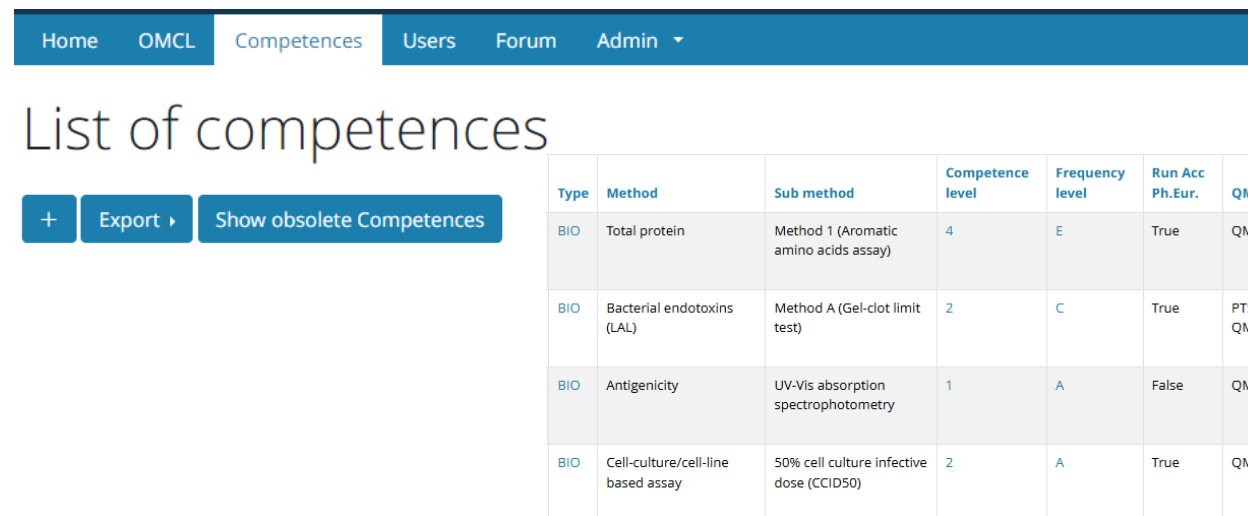
2. Competence Pooling



The screenshot shows the homepage of the OMCL Inventory Database. It features the Council of Europe logo and the EDQM logo. The main heading is "Welcome to OMCL Inventory Database" followed by "Official Medicines Control Laboratories". A paragraph explains that the database is a dedicated tool for GEON members to share information about their organizational structure, QMS status, and competencies. It also mentions that access is restricted to full, associate, and limited members of the GEON. A link to the EDQM website is provided for further information.

OMCL Inventory Database

- The OMCL Inventory Database is a tool to share information about the **analytical competences** of OMCLs => OMCLs not having specific competences/equipment to perform certain tests can send samples to another OMCL.



The screenshot shows the "List of competences" page. It includes a navigation bar with "Home", "OMCL", "Competences", "Users", "Forum", and "Admin". Below the navigation bar, there are buttons for "+", "Export", and "Show obsolete Competences". The main content is a table listing various competences.

Type	Method	Sub method	Competence level	Frequency level	Run Acc Ph.Eur.	QMS/Prog	Spec
BIO	Total protein	Method 1 (Aromatic amino acids assay)	4	E	True	QMS	
BIO	Bacterial endotoxins (LAL)	Method A (Gel-clot limit test)	2	C	True	PTS/OCABR/ QMS	P
BIO	Antigenicity	UV-Vis absorption spectrophotometry	1	A	False	QMS	
BIO	Cell-culture/cell-line based assay	50% cell culture infective dose (CCID50)	2	A	True	QMS	

3. Training and Know-how Exchange

Symposia on combating falsified and other illegal medicines

4 symposia organised since 2011, each with around 100 participants. 5th Symposium will be held in **June 2026 in Prague**. Hosted by the **Czech OMCL SUKL**.

Bring together stakeholders working in the field of falsified/illegal medicines: OMCLs, health authorities, police, forensic laboratories, customs and the European Commission. Press Releases

Hands-on training sessions (20 since 2012)

- **Practical technical training** of OMCL personnel by partner OMCLs experienced in certain techniques.

SUP – Ssuspicious Unknown Product Test Programme

- 14 finalised, 1 ongoing.
- Similar to a Proficiency Test Scheme (PTS).
- The aim is to **test the competency** of the laboratories to **identify** the active ingredient in an unknown sample.
- Use of **blind** samples: commercially available medicines and APIs or real falsified/illegal samples
- Participants: 25 – 30 OMCLs.

Joint meetings with other stakeholders

- **CLEN** (Customs Laboratories European Network)
- **WGEO** (Working Group of Enforcement Officers)
- **CMED** (Committee of Experts on minimising the public health risks posed by falsified medical products and related crimes)

Hands-on training sessions for OMCLs

202
5

Cell-based potency assay testing of mAbs

Host: OMCL INFARMED, Lisbon, PT

31 March to 3 April 2025

7 participants

Peptide and protein testing

Host: OMCL Sciensano, Brussels, BE

5 to 7 May 2025

7 participants

202
6

Falsified/Illegal Medicines Testing

Host: OMCL National Medicines Institute, Warsaw, PL

April 2026

Training in 3 techniques: 1. LC-HRMS, 2. XRPD, 3. NMR

15 participants

Date to be confirmed:

Falsified/Illegal Medicines Testing

Host: Medical Products Agency, Uppsala, SE

A general approach for analysing unknown samples using LC-QTOF-MS/MS and NMR spectroscopy

4. Targeted Communication

Documents

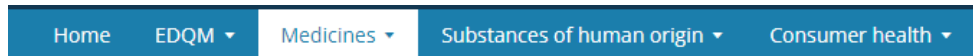
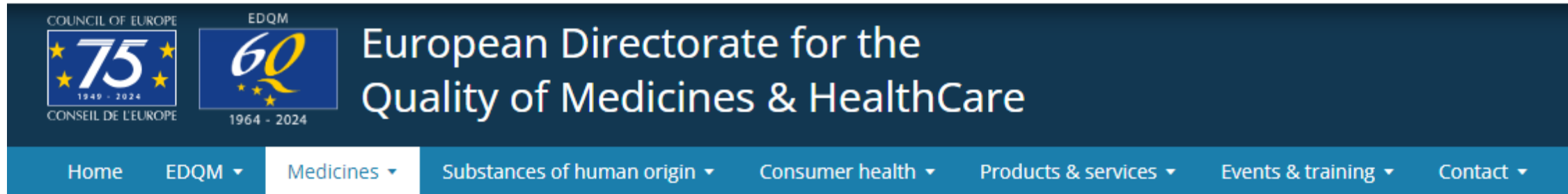
- [How the OMCL Network supports the implementation of the Council of Europe MEDICRIME Convention](#)
- [An “aide-mémoire” for the testing of suspected illegally traded and falsified medicines](#)
- [Aide-Mémoire: How to identify a Falsified Monoclonal Antibody / Antibody containing Fusion Protein](#)
- [Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health \(or MEDICRIME Convention\)](#)

Publications

- [The occurrence of non-anatomical therapeutic chemical-international non-proprietary name molecules in suspected illegal or illegally traded health products in Europe: A retrospective and prospective study](#), doi: 10.1002/dta.3001 (2021).
- [European fingerprint study on omeprazole drug substances using a multi analytical approach and chemometrics as a tool for the discrimination of manufacturing sources](#); Journal of Pharmaceutical and Biomedical Analysis, Vol. 208 (2022) (10.1016/j.jpba.2021.114444)
- [GEONs API fingerprint project: Selection of analytical techniques for clustering of sildenafil citrate API samples](#); Talanta, Vol. 239 (2022) (10.1016/j.talanta.2021.123123)
- [Clustering of Tadalafil API Samples According to their Manufacturer in the Context of API Falsification Detection](#); Journal of Pharmaceutical Sciences, Vol. 112 (2023) (10.1016/j.xphs.2023.05.015)

For more information on the GEON...

Please consult the section “OMCL Network” on www.edqm.eu



You are here: [European Directorate for the Quality of Medicines & HealthCare](#) > [Medicines](#) > [OMCL Network](#)

OMCL Network

[GEON Brochure](#)

[OMCL video](#)



More information



www.edqm.eu



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

Follow us on



[edqm](https://www.linkedin.com/company/edqm)



[@edqm_news](https://twitter.com/edqm_news)



[EDQMCouncilofEurope](https://www.facebook.com/EDQMCouncilofEurope)



edqm
European Directorate
for the Quality
of Medicines
& HealthCare | Direction européenne
de la qualité
du médicament
& soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE