

European Directorate for the Quality of Medicines & HealthCare Council of Europe



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

EU OMCL network experience contributes to method implementation and reduced animal use

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AFSA – IABS Conference about Animal testing replacement for vaccines: A One Health View: global outlook and future strategy

2-5 December 2025



EDQM

- ★ **Directorate** of the Council of Europe
- ★ 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



* EU: European Union; TFDA: Taiwan Food and Drug Administration; WHO: World Health Organization

Four policy areas & a wide portfolio of activities



Medicinal
products

Official standards for manufacture and quality control of pharmaceuticals

European Pharmacopoeia (documentary & 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 & safety standards

Biovigilance, data collection and harmonisation

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

Addressing SoHO supply



Pharmaceutical
care

Policies & 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)

Official Medicines Control Laboratories (OMCLs)



Official Medicines Control Laboratories are:

- Independent public laboratories
- Established and nominated by National Authorities
- Analysing medicinal products, already or to be marketed, for human and veterinary use

They work according to a harmonised quality management system applying the ISO/IEC 17025 standard and in compliance with European Pharmacopoeia, supported by OMCL quality guidelines and GEON quality programmes e.g. audits, trainings, PTS

OMCLs' main activities:

(Pre)- and Post-marketing test programmes:

- Sampling and Analysis
e.g. Official Control Authority Batch Release (OCABR), market surveillance

Emergency (“for-cause”) testing e.g. in case of adverse reactions of medicines

Laboratory testing of medicines & active ingredients:

- Innovator medicines
- Generic medicines and biosimilars
- Extemporaneous and stock preparations
- Suspected falsified/illegal medicines

Packaging and labelling controls

OMCLs adopt a risk-based approach in all their planned testing activities

Work sharing, mutual recognition of results and use of specialised centres is critical to success

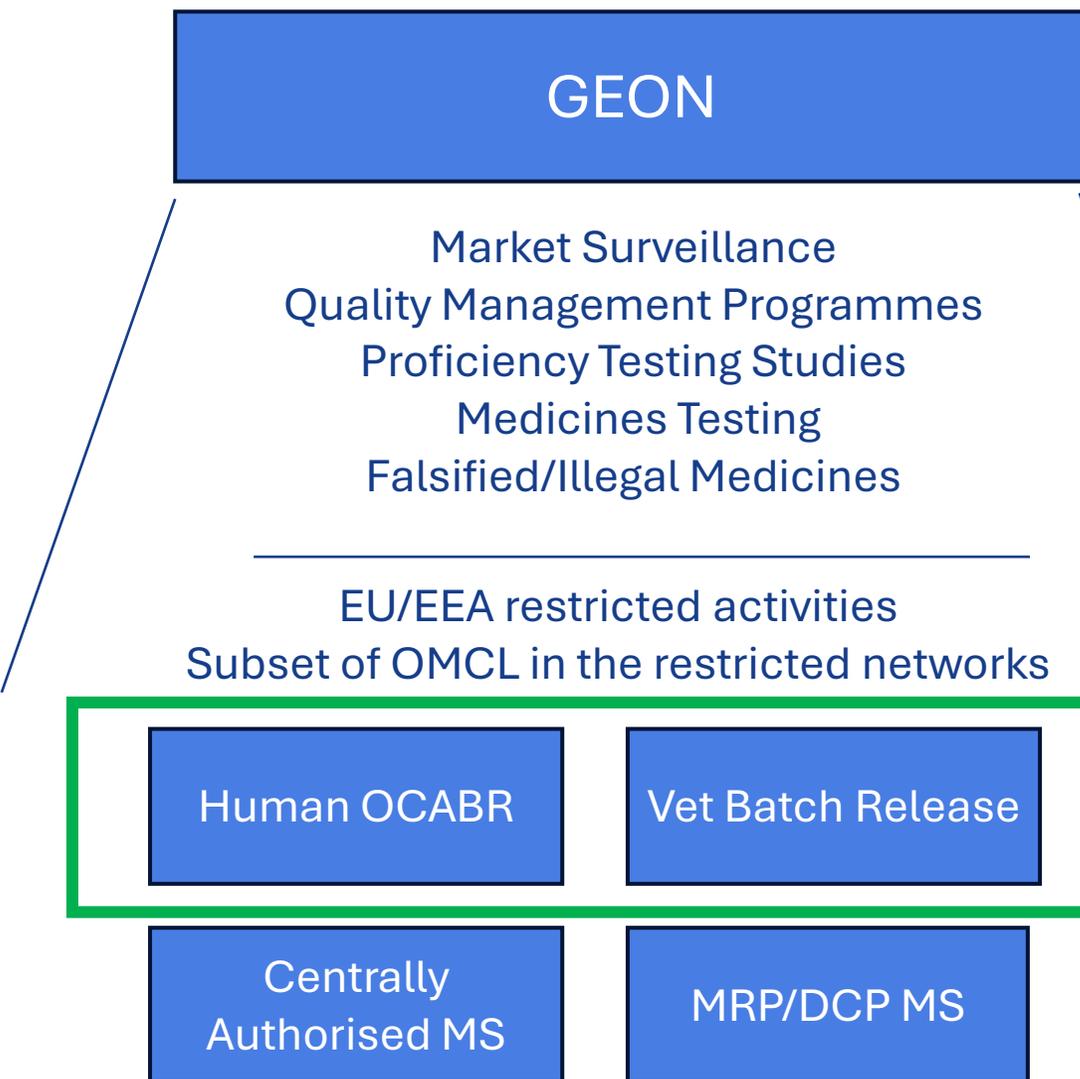


Network Organisation

Co-funded
by the European Union



Co-funded and implemented
by the Council of Europe



Almost 70 **OMCLs** from over **40 countries**
Members and Observers of the European Pharmacopoeia Convention

- **Full or associate membership**
- **Plenary meeting 1/year**
- **EDQM is the secretariat**

Each Network/restricted network has its own:

- Terms of reference
- Advisory Group
- Activity program

All have access to support through exchange, training databases, quality programmes

Each of the restricted networks focuses on specialised activities and includes a subset of OMCLs from the GEON

Participation linked to:

- EU/EEA membership
- Specific competencies within the OMCL

OCABR Activity – based in EU legislation



- Member State (MS) **MAY** require OCABR, MS **MUST** recognise results from another MS
- Testing and protocol review of each batch according to the procedure and product specific guideline before release on to the market
- 1 batch – 1 testing - 1 **certificate** – **recognised** throughout the OCABR network and used by **reliance** in other countries

This is achieved through:

- Adherence to common rules
- Transparency/Communication
- Work sharing



Mutual Confidence

Contributes to reduced testing including in vivo tests

Work sharing for OCABR

Contributes to efficient method implementation and competence building

- ★ Specialised centres responsible for testing – emphasise use of at least 2 OMCLs for business continuity
- ★ Identify OMCLs with potential competence – through network communication/databases and provide contact lists and relevant information with involved manufacturers
- ★ Early contact with manufacturers– encourage open dialogue
 - ★ Provision of SOPs, receipt of critical reagents and reference material
 - ★ Technical exchanges and logistical considerations
 - ★ Forecasts for timelines and expected volume of lots per year
- ★ Favour common meetings with all involved OMCLs and the company – shared experiences
- ★ Consider staggered implementation if relevant
 - ★ All OMCLs involved in discussions
 - ★ One OMCL may begin implementation first followed by the second – allows ‘inter-OMCL’ training, assures at least one OMCL is ready
 - ★ Possibility to visit an OMCL already performing the method
- ★ Training opportunities if the test is more widely implemented
 - ★ e.g. OMCL network training on cell-based assays



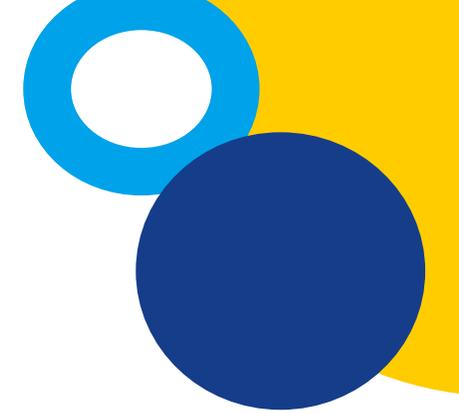
Points to consider ⁽¹⁾

When implementing validated methods

- ★ The exercise is to verify the method implementation at the OMCL
- ★ It is not the goal of the OMCL to re-validate the method of the company

In particular for non-animal alternatives

- ★ It is not necessary to repeat animal tests as part of the method implementation at the OMCL if the method is already validated by the manufacturer
- ★ In some cases OMCLs develop/validate their own animal-free or animal reduced/refined method
 - ★ In these cases method validation is required and may necessitate some comparison between the old and new methods HOWEVER the principles of Ph. Eur. chapter 5.2.14 should be applied in particular a direct head-to-head comparison of in vitro and in vivo tests may not be relevant
- ★ OMCLs openly collaborate where possible in consortium like VAC2VAC for a common approach to method development and participate in method validation projects like the EDQM Biological Standardisation Programme – this also provides experience and develops competence in the new methods



Points to consider (2)

★ Responsibilities of the manufacturers

- ★ Identify viable opportunities and pro-actively develop in vitro testing strategies
- ★ Complete validation packages in line with ICH Q2 guideline and local requirements
- ★ Communicate early with regulators, seek regulatory advice, share protocols and critical reagents with independent control laboratories to facilitate implementation

★ Responsibilities of the NCA/NCL

- ★ Keep up to date with regard to the appropriate knowledge and expertise to assess and implement in vitro tests
- ★ Be open to the use of in vitro approaches that have been adequately validated and scientifically justified
- ★ Have mechanisms to allow their authorisation and promote consistent regulatory application and implementation at independent control laboratories

★ Other facilitating factors

- ★ International exchange of information and data to promote acceptance, and international alignment of requirements
- ★ Consortium projects/collaborative studies with industry, independent control laboratories and academia in the service of a common goal
- ★ Regulatory reliance and associated regulatory strengthening including reliance on the tests carried out by another reference regulatory authority as part of independent lot release testing

Next: Practical case study from EU OMCL in presentation from Lorenzo Tesolin, Sciansano, BE

More information

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

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