

# OMCL Network of the Council of Europe

## GENERAL DOCUMENT

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**Terms of Reference for the General European OMCL Network (GEON)  
of the Council of Europe**

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<b>Concerned Network</b>	GEON

**TERMS OF REFERENCE  
FOR THE GENERAL EUROPEAN OMCL NETWORK (GEON)  
OF THE COUNCIL OF EUROPE**

## **1. Introduction**

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With a view to creating a pool of resources which provides technical expertise and a possibility of work sharing for the testing of medicines, a general European Network of Official Medicines Control Laboratories (OMCLs), as defined in **Annex 1** – “Definition of an OMCL and OMCL Status within the GEON”, in its current version, was formed in the mid-nineties under the aegis of the Council of Europe. It was created at the joint initiative of the European Commission (EC) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe.

The present Terms of Reference include the core document and all its annexes as indicated in the text.

## **2. Regulatory framework and objectives of the GEON**

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The regulatory framework and common operating mechanisms of the GEON are based on the following standards:

- European Pharmacopoeia
- Relevant Articles of the European Union (EU) Code for Human and Veterinary Medicines and of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA)<sup>1</sup>
- Commonly agreed guidelines
- Commonly agreed Quality Management Systems (QMS).

The activities of the OMCLs of the GEON are derived from this framework.

The objectives of the Network are

- to co-ordinate the technical activities of OMCLs
- to foster exchange of data and results obtained within the context of the OMCL activities (e.g. market surveillance testing, pre-authorisation testing, official batch release testing, counterfeit and illegal medicines testing)
- to promote future development through harmonised common standards, based on the legal requirements for testing medicinal products for the benefit of the human patient and/or animals.
- to offer a discussion platform for sharing scientific information and strategies.

The voluntary sharing of work and competence relies on the principles of mutual confidence and recognition and is based on a common approach to the QMS and on harmonised working procedures.

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<sup>1</sup> Code for Human Medicines: Directive 2001/83/EC, as amended, Articles 19, 111, 114;  
Code for Veterinary Medicines: Directive 2001/82/EC, as amended, Articles 23, 80, 82;  
Regulation (EC) No 726/2004, Articles 7, 57.

### 3. Composition of the GEON

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#### 3.1. Representation in GEON

While the GEON is composed primarily of OMCLs, representatives of Competent Authorities may also be members of the GEON. The second option is applicable for Member States in which the Competent Authority has mandated a control laboratory to act as its OMCL within the OMCL Network, but where, in accordance with Section 2 of **Annex 2** to the GEON Terms of Reference (ToR) – “Factors for determining OMCL status within the GEON”, in its current version, the Competent Authority in question has retained within the regulatory organisation certain specific duties and responsibilities. In such situations, the Competent Authority should have provided this control laboratory with a clear mandate as to its responsibilities and duties, and the control laboratory acting as an OMCL must meet the criteria outlined in Sections 2 of **Annex 2** to the GEON Terms of Reference and Chapter 8 of the ToR. It must also meet the definition of an OMCL as laid out in **Annex 1**. If the second option is applied it should be defined in advance if the Competent Authority or the OMCL represents the member state.

The GEON is composed of full and associated members.

#### 3.2. Full members of the GEON

All OMCLs of member states that have signed the European Pharmacopoeia Convention and that fulfil

- the definition given in **Annex 1**
- the criteria given in **Annex 2**

may become full members of the GEON upon decision of the GEON Advisory Group (see ToR of the AdG-GEON for details). A list of all current full members of the GEON can be found in **Annex 3**. The presence in the list authorises the OMCL to use the GEON logo for official correspondence.

#### 3.3. Associated members of the GEON

All OMCLs of other member states of the Council of Europe or countries that are observers to the European Pharmacopoeia Commission and that fulfil

- the definition given in **Annex 1** and
- the criteria given in **Annex 2**

may become associated members of the GEON upon decision of the GEON Advisory Group.

In exceptional cases other OMCLs of member states of the Council of Europe, which are full members to the European Pharmacopoeia Commission, might be given the status of associated members of the GEON, in cases where they do not, in all respects, fulfil certain criteria of **Annex 1** and/or **Annex 2** (e.g. the mandating Competent Authority is not part of the Ministry of Health/Agriculture or the National Medicines

Agency etc.). Decision on the acceptance as associated member is made on a case-by-case basis by the GEON Advisory Group.

The associated members of the GEON do not participate in any voting procedure and are not eligible for any Network financial support.

A list of all current associated members of the GEON can be found in **Annex 3**. The presence in the list authorises the OMCL to use the GEON logo for official correspondence.

#### **4. Accession to the GEON**

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Membership in the GEON is taken in consideration after a formal request from the relevant authorities for each OMCL and the completion of a standardised questionnaire (document “Questionnaire to query the OMCL Status of present and future members of the GEON” in its current version) challenging the OMCL status of the future member (see **Annex 4**). The request and the completed questionnaire are sent to the Secretariat (for Secretariat see Chapter 10).

The GEON Advisory Group and the Secretariat check whether the conditions are fulfilled and will approve or reject the request. Following the decision taken, the applicant is informed officially by EDQM and, in case of a positive opinion, can then participate in the following annual meeting and all relevant activities.

Further details are explained in the internal document “New Membership to the GEON – Procedures for AdG GEON and EDQM”.

#### **5. Activities of the Network**

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The activities of the Network in the various fields are differentiated as follows:

##### **5.1. General activities**

Elaboration of common Network strategies, such as risk-based approach for post-market sampling and testing, contribution in combating counterfeits and illegal medicines, establishment of centres of expertise, improvement of communication etc.

General QMS activities including the Mutual Joint Visit/Mutual Joint Audit (MJV/MJA) programme and the Proficiency Testing Scheme (PTS)

Market Surveillance Studies (MSS) and collaborative studies

Educational programmes

Applied analytical research and regulatory development.

##### **5.2. Activities based on the European Union (EU) “acquis communautaire”**

Centrally Authorised Product (CAP) testing

Official Control Authority Batch Release (OCABR)

Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP)-product testing.

## **6. Participation Rights to Activities of the Network**

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### **6.1. Participation Rights to General Activities**

#### **Participation of Members of the Network**

Members are eligible to participate in any of the activities for which they have the relevant competencies, interest and mandate.

#### **Participation of Laboratories Outside the OMCL Network in European Market Surveillance Studies**

The Competent Authorities of the member states may have a laboratory outside the OMCL Network act as their control laboratory for a given European market surveillance study. In such cases the Member State informs the EDQM and ensures that the commonly agreed standards (ISO/IEC<sup>2</sup> 17025) are in place. The participation of such a laboratory in European market surveillance studies is subject to a confidentiality agreement between this subcontracted laboratory<sup>3</sup> and the Competent Authority and a declaration of non-interest for the product covered by the study. In these cases the Competent Authority takes the responsibility for interaction with the GEON with respect to the exchange of organisational and decision making information regarding the programme and its follow-up.

#### **Participation of Laboratories Outside the OMCL Network in Other Activities**

The activities of the Network not related to product surveillance are open to laboratories outside the Network. This includes QMS activities such as general trainings, audits and PTS. Participation to these activities is subject to a fee.

### **6.2. Participation Rights to EEA Activities**

These activities of the OMCL Network are restricted to OMCLs and Competent Authorities from European Union/European Economic Area (EU/EEA) countries (e.g. CAP, MRP) and to countries for which a relevant Mutual Recognition Agreement (MRA) exists (e.g. OCABR).

## **7. Responsibilities of the GEON**

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The responsibilities of the GEON will be to:

- 7.1. within the legal framework develop, set up and carry out programmes for common sampling and testing of active substances and medicinal products on the market in the GEON such as MSS, testing of counterfeits and illegal medicines, collaborative studies;
- 7.2. develop and maintain appropriate databases for information, communication and exchange of results within the GEON;

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<sup>2</sup> International Organisation for Standardisation / International Electrotechnical Commission .

<sup>3</sup> In this document and its Annexes it is understood that a subcontracted laboratory is a control laboratory not belonging to the network, which is used by the Competent Authority or an OMCL for occasional testing restricted to a specific analytical technique or product. It does not refer to arrangements between OMCLs or National Competent Authorities from the Network, where subcontracting on specific activities may be required in the interest of work sharing (e.g. OCABR or counterfeit identification).

- 7.3. develop and implement a common approach for Quality Management System within the GEON based on ISO/IEC 17025 including the programmes for PTS and peer reviews based on the QMS procedure for MJV/MJA;
- 7.4. develop guidance and policy documents for the activities of the GEON.

## **8. Responsibilities of members of the Network**

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Members of the OMCL Network have the following responsibilities:

- 8.1. Cooperation with and provision of relevant information to the Network and participation in Network activities following the principle of work sharing, wherever possible.
- 8.2. Compliance with the rules and application and/or implementation of guidelines of the Network.
- 8.3. The scope of activities should be made transparent to the Network and be updated, when applicable (OMCL inventory database).
- 8.4. Acceptance of external audits covering ISO/IEC 17025 and specific OMCL Network guidelines including an appropriate evaluation of both the technical level and managerial level covering aspects of independence, confidentiality and conflicts of interest for all internal and subcontracting activities; if the external assessment is not part of an MJA by the OMCL Network, the outcome of the assessment (attestation/certificate and scope of assessment) should be made available to Network/EDQM.
- 8.5. The laboratory must ensure that where applicable a statement of independence, confidentiality and absence of any conflicts of interest is made available to the responsible Competent Authority and, upon request, to the Network/EDQM.
- 8.6. Each control laboratory shall have a clearly defined policy for the maintenance of any confidential information received or generated.
- 8.7. A clear separation between OMCL and non-OMCL activities has to be guaranteed in case of additional activities outside the regulatory framework.
- 8.8. Major structural re-organisations affecting the status in the Network should be communicated.

## **9. Meetings of the GEON**

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- 9.1. Registration to meetings of the GEON are open to representatives of OMCLs and/or representatives of Competent Authorities from member states, the official control laboratories of which fulfil the definition as stated in **Annex 1** and accession criteria as stated in **Annex 2** (as full or associated member). EDQM (representing the Council of Europe) participates in the meetings and provides the Secretariat of the GEON.

In addition, the following parties may participate in the meeting without voting rights:

- The EU Commission
  - The EMA
- 9.2. Meetings of the GEON shall normally be held once a year and upon convocation when necessary in the case of emergency or special need, at the request of the Secretariat or by a majority of 2/3 of the member states. The Annual Meeting of the GEON shall be held in one of its member states preferably applying the principle of rotating location.
- 9.3. Meetings of the GEON are only open to those noted in 9.1 and to experts invited for specific topics, who are nominated by the relevant Advisory group/EDQM. In addition representatives from candidature countries to the Network and from other organisations (e.g. World Health Organisation - WHO) might be invited to join certain sessions of the meeting either to provide their expertise or to be informed about the activities of the Network. The participation and role of attendance will be discussed and determined by the GEON Advisory Group and communicated through official correspondence by EDQM. The applications should be substantiated by a detailed summary of their activities and their potential contributions to the GEON.
- 9.4. The chairs of the Annual Meeting of the GEON shall be members of the hosting OMCL together with members of the EDQM Secretariat and the chairperson of the AdG-GEON.
- 9.5. The first draft agenda and any paper for which a decision is needed shall be prepared by the Secretariat in close collaboration with the Advisory Group and preferably sent to the members of the GEON at least 3 weeks before the meeting.
- 9.6. The agenda shall be adopted at the beginning of each meeting.
- 9.7. Each member of the GEON prepares, dependent on the scope of activities, an Annual Report based on the documents “Model Format and Content of the OMCL’s Annual Reports (non-OCABR Activities)” or “Control Authority Batch Release of Vaccines and Blood Products – Annex V” / OCABR Vet: Annual Report Model. These reports shall be circulated to the other members of the respective specific networks following the appropriate access restrictions at least 2 weeks before the Annual Meeting.
- 9.8. Within the 4 weeks following the date of the meeting, the minutes shall be circulated to all participants for comments and adopted by written procedure. If relevant comments are made, these shall be dealt with at the next meeting of the Advisory Group.
- 9.9. All final documents will be circulated to the whole Network and placed on the corresponding Extranet sites and, where relevant, on public websites.

## **10. Operating mechanism**

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- 10.1. The work programme on basis of proposals from the Advisory Group will be defined at the Annual Meeting of the GEON. If applicable, additional proposals can be made by any Network member during the year in written form.
- 10.2. Decisions within the GEON shall be allowed only if a majority of the member countries represented in the Network, are present.
- 10.3. Decisions are taken whenever possible by consensus. In case it becomes necessary to vote the same principles as laid down in document “Policy for electing members of the Advisory groups or any other committees” apply. Associated members as well as EDQM, EC and EMA representatives are not entitled to vote.
- 10.4. The GEON adopts and updates its Terms of Reference at the Annual Meeting based on the principles laid down in the document “Implementation and Management of Guidance and Policy Documents”.
- 10.5. The GEON creates an Advisory Group, which is elected at the Annual Meeting (see document “Policy for electing members of the Advisory groups or any other committees”). Between the Annual Network Meetings, the Advisory Group prepares and implements the work programme based on the proposals of the GEON. It reports back to the Network about the achievements during the year on the occasion of the Annual Meeting.
- 10.6. Within the GEON, there exists subgroups (specific networks) for specific purposes such as the EU/EEA CAP testing, the EU/EEA MRP/DCP-product testing and the OCABR for human and veterinary medicinal products. These specific networks may have restricted access criteria for members as defined by their activity, e.g. EU/EEA members only (see also Chapter 5). Each subgroup decides on its specific activities during its annual meeting and based on this, a work programme is established and implemented during the year. Topics of general interest are referred to the GEON. For each subgroup a separate Advisory Group is created, if required. Each specific network through its Advisory Group prepares its own Terms of Reference. The Advisory Groups of the specific networks shall hold their meetings in Strasbourg unless otherwise justified. These meetings shall be held as closed sessions.
- 10.7. For the elaboration of specific technical documents a drafting group (or working groups) composed of representatives of the affected subgroup with particular expertise in the respective field might be established. The result of the work as a rule is passed through the appropriate Advisory Group before formally adopted by the corresponding specific network or GEON as the case may be.

## **11. Cooperation with external partners**

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The GEON or its specific networks may decide to hear the representatives of associations including industrial ones, or scientific institutions.

If required, co-operation with other relevant organisations (e.g. WHO) may be sought.

## **12. Duties of the Secretariat (EDQM-DBO/Section OMCL Network)**

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The Secretariat is provided by the EDQM – Department Biological Standardisation, OMCL Network & HealthCare (DBO – Section OMCL Network).

The Secretariat shall provide all administrative support necessary to co-ordinate the activities of the GEON. On behalf of the GEON

- 12.1. It shall liaise with the relevant national authorities and, where applicable, with European Institutions and International Organisations and with Marketing Authorisation Holders, manufacturers and industry associations in general within the framework of the activities related to the GEON;
- 12.2. It shall organise the Annual Meeting and any specific meetings or scientific symposia, and be responsible for establishing minutes and taking any necessary follow-up measures as outcome of decisions made during the meetings;
- 12.3. It shall co-ordinate the annual programmes, peer reviews and studies on topics of particular interest and follow up all decisions taken;
- 12.4. It shall assist in fulfilling the responsibilities of the GEON as described under Chapter 7;
- 12.5. It shall issue an Annual Report of its activities as part of the activity report of EDQM, which is published in Pharmeuropa;
- 12.6. It shall make documents elaborated by the GEON public, if endorsed by the Network.

## **13. Ownership of data**

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The Secretariat is not responsible for deciding about the property of results of tests performed within the frame of the GEON or specific network activities (unless otherwise defined). As a rule, and provided that nothing else has been decided in advance (e.g. in the case of sample exchange), it is the responsibility of the Competent Authority of the Member State in which the results were generated to follow the European legislation in place to deal with this matter or to define rules in case there is not an existing legal frame. It is up to the relevant Competent Authority to take legal measures and to follow them up in case there are infringements of the rules governing medicines.

## **14. Finances**

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The expenses of co-ordinating and running the activities of the GEON are borne by a financial contribution of the EC and the Council of Europe.

## **15. Structure of the Network**

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Below the current structure of the GEON and its specific networks is summarised in a chart.

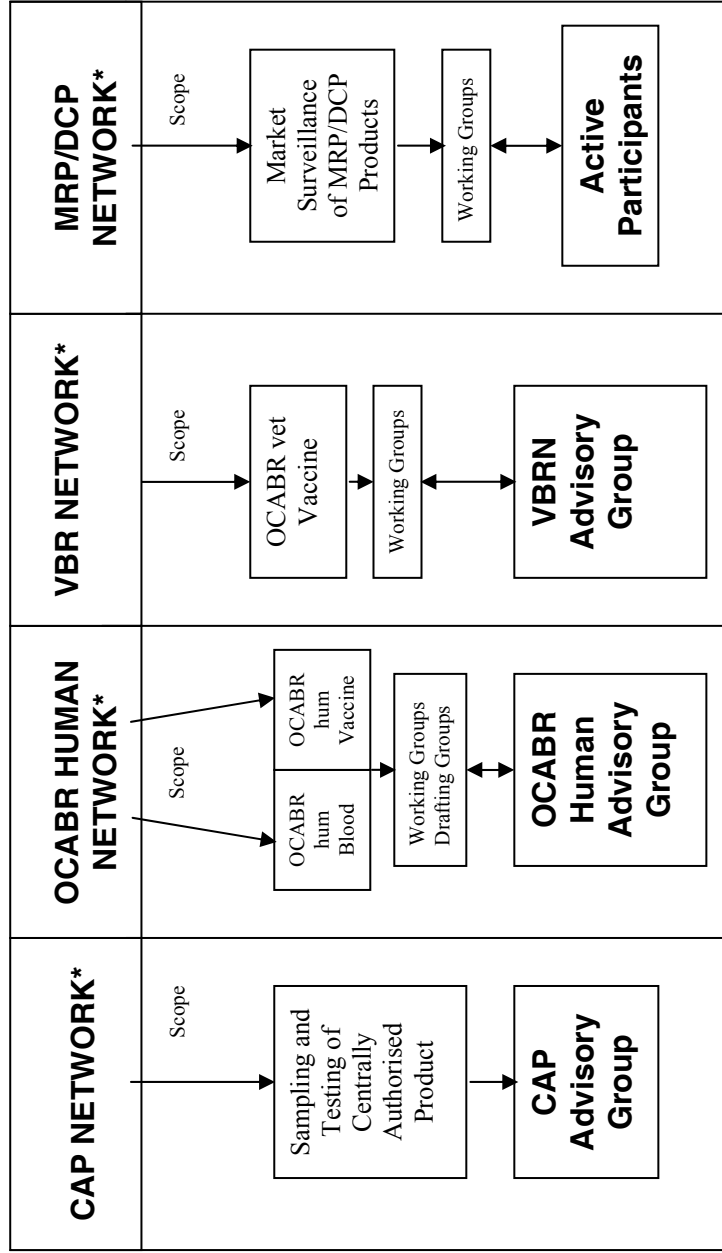
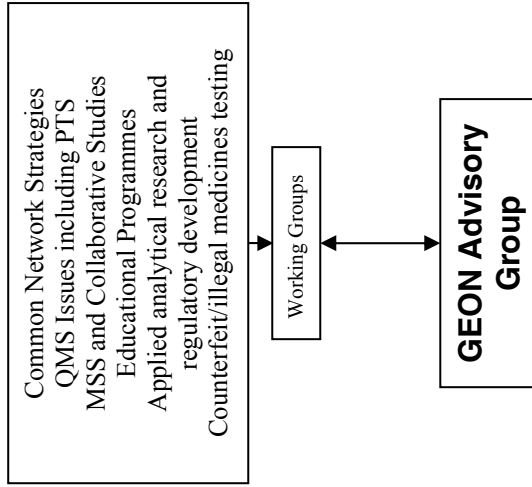
## **16. Glossary**

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CAP: Centrally Authorised Product  
DBO: Department Biological Standardisation, OMCL Network & HealthCare  
DCP: Decentralised Procedure  
EC: European Commission  
EDQM: European Directorate for the Quality of Medicines & HealthCare  
EEA: European Economic Area  
EMA: European Medicines Agency  
EU: European Union  
GEON: General European OMCL Network  
IEC: International Electrotechnical Commission  
ISO: International Organisation for Standardisation  
MJA: Mutual Joint Audit  
MJV: Mutual Joint Visit  
MRA: Mutual Recognition Agreement  
MRP: Mutual Recognition Procedure  
MSS: Market Surveillance Study  
OCABR: Official Control Authority Batch Release  
PTS: Proficiency Testing Scheme/Study  
QMS: Quality Management System  
ToR: Terms of Reference  
VBRN: Veterinary Batch Release Network  
WHO: World Health Organisation

# GENERAL EUROPEAN OMCL NETWORK

Scope



\* EU specific activities restricted to EEA community members and Mutual Recognition Agreement (MRA) partners where relevant