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

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OMCL Network of the Council of Europe (GEON)
GENERAL DOCUMENT

PA/PH/OMCL (07) 89 R16

GEON Terms of Reference
Annex 1: Definition, role and status of OMCLs of the GEON

Full document title and reference	Annex 1 to the GEON Terms of Reference: Definition, role and status of OMCLs of the GEON PA/PH/OMCL (07) 89 R16
Document type	Annex to Terms of Reference
Legislative basis	Council Directive 2001/83/EC and 2001/82/EC, as amended
Date of first adoption	February 2000
Date of original entry into force	February 2000
Date of entry into force of revised document	February 2025
Previous titles/other references	This document replaces document Annex 1 to GEON Terms of Reference: Definition, role and status of OMCLs of the GEON, PA/PH/OMCL (07) 89 R15 Former titles/references: Definition of an OMCL and OMCL status within the GEON, PA/PH/OMCL (07) 89 9R European OMCL Network of the Council of Europe: Definition and Membership, PA/PH/OMCL (06) 01 DEF (internal document); PA/PH/OMCL (99) 23 DEF (internal document)
Custodian Organisation	The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
Concerned Network	GEON

Introduction

It is the right of the patient to receive medicines of good quality and the duty of the Competent Authorities (organisations, administrations, agencies) to ensure that the marketed products comply with the specifications laid down in the application file and in any other relevant compendial requirements, which these same authorities had approved. The aim of Official Laboratory Testing is to support the Competent Authorities in controlling the quality of medicinal products on the market for the benefit of the human patient and/or animals.

For EU member states, the respective rules for medicinal products are laid down in the "human code" (Directive 2001/83/EC as amended) and the "veterinary code" (Regulation (EU) 2019/6 as amended).

The situation in Europe

To carry out national testing activities, the Competent Authority, which is part of a Ministry, or the National Medicines Agency has access to a control laboratory within its own structure or, if not, it will contract the testing activities to one or more external laboratories. In the latter case, special care is taken to avoid a conflict of interest with the activities (present and future) of the contracted laboratory.

In Europe, the control of activities mandated by the Competent Authority can be performed by:

- governmental laboratories (public institutions/laboratories). Their activities are financed only by public resources (including fees for registration and/or control activities). Their independence is guaranteed by their status and independent funding. Independence *inter alia* means in this case that payment is not dependent on the results obtained.
- private/commercial laboratories and university laboratories. As a rule, their activities involve commercial contracts at least in part (e.g. from pharmaceutical companies).

In some countries the authority uses, or has the possibility to use, the competence of both. For all Network activities, if possible, preference should be given to use an OMCL according to the definition provided below rather than a private/commercial laboratory or a university laboratory.

Therefore, taking into account that:

1. *it is important to avoid conflicts of interest;*
2. *it is not permissible to discuss strategies, exchange confidential information or prepare programmes for market surveillance in the presence of commercial and university laboratories;*
3. *there are only limited resources available to the Secretariat of the Network (EDQM) and to the individual OMCLs;*
4. *public resources should not finance the development of commercial projects;*
5. *commercial and university laboratories could take advantage of membership in the OMCL Network for commercial reasons, i.e. when competing for contracts with pharmaceutical companies, it could have an unfair advantage over similar laboratories that are not members of the Network;*
6. *the role of an OMCL is not to serve as a substitute for a pharmaceutical company's Quality Control (i.e. to control the quality of product for the purpose of manufacturer's release) as this would result in a conflict of interest;*

the following proposal has been made for the purpose of the European OMCL Network:

Definition of an OMCL

An Official Medicines Control Laboratory (OMCL) is a public institution, which performs laboratory testing of medicinal products (and related materials, such as active substances, excipients, plasma pools, etc.) on behalf of competent authorities and in fulfilment of other national obligations, independently from the manufacturers or Marketing Authorisation Holders. Testing is carried out in the interest of official market surveillance of medicinal products in relation to the safety of humans and/or animals, prior to and/or after marketing of the respective medicines and is demonstrated to be free from conflicts of interest.

Nevertheless, where such institutions or specific technical competences are not available, the Competent Authorities or OMCL may have another laboratory act as their control laboratory, which does not necessarily give this laboratory the status of an OMCL within the Network. The laboratory should then sign a technical agreement as well as an impartiality and confidentiality agreement which also covers conflicts of interest.

Role of OMCLs

The involvement of the OMCLs is complementary to the evaluation of the application for marketing authorisation and part of the constant monitoring of the products marketed and shall ensure that the specifications set for the model are met in real production.
As this testing is performed **independently** from those who have been involved in the development, manufacturing and/or marketing of the product, it adds additional scientific knowledge of a medicinal product for the benefit of the patient.

National Role of OMCLs

At a national level the OMCL contributes to the protection of public and animal health and the regulatory function of Competent Authorities by providing their expertise and independent analytical data on medicines, active substances, excipients and other materials (e.g. plasma pools, etc.) that enable Licensing and Supervisory Authorities to make informed decisions on the quality of medicines. Areas of contribution include:

1. Support to the expertise in evaluation of the quality part of Marketing Authorisation files
2. Pre-authorisation analysis
3. Pre-marketing surveillance programme for medicinal product derived from human blood or plasma and immunological medicinal products (OCABR and OPBR)
4. Post-marketing surveillance programme
5. Analysis of unlicensed (unauthorised) medicines
6. Support of pharmacovigilance assessments
7. Support of GMP inspections
8. Evaluation of defect reports
9. Contribution in the elaboration of Ph. Eur. monographs and/or general chapters and methods and establishment of reference standards
10. Contribution in the Biological Standardisation Programme
11. Collaborative studies.

Other fields where certain OMCLs are active include, for example, the testing of:

1. Falsified and other illegal medicines including “medicines in disguise”
2. Primary packaging materials

3. Cosmetics
4. Food supplements
5. Pharmaceutical preparations
6. Stockpiled medicines
7. Medical devices and diagnostics
8. Feed
9. Allergens, gene therapy and cell therapy products.

European Role of OMCLs and Levels of Collaboration within the General European OMCL Network

Details of the European Role of OMCLs and levels of collaboration within the GEON are laid down in the GEON Terms of Reference and other GEON documents.

OMCL status within the Network

Status of an OMCL within the Network may be given provided that:

1. The laboratory is part of a Ministry or the National Medicines Agency or is an independent governmental body. Otherwise with respect to an external laboratory, it is funded only by the mandating relevant authority and acts exclusively as their control laboratory.
   Laboratories outside of these categories are excluded even if they fulfil the criteria outlined in **Annex 2** due to the lack of possibility of the Network to audit their absence of conflicts of interest, impartiality and confidentiality. As a consequence, private laboratories, and university laboratories as such cannot be given the status of an OMCL within the Network.
2. The Competent Authority transfers the responsibility for the given field of activity to that laboratory and the activity is not of an occasional nature or restricted to a specific analytical technique or product.
3. The laboratory meets the criteria outlined in Annex 2 to the GEON Terms of Reference.

Once status of an OMCL within the Network has been granted, the laboratory is considered an 'OMCL' in the context of the terms of reference.