

OMCL Network of the Council of Europe

GENERAL DOCUMENT

PA/PH/OMCL (07) 90 4R

GEON Terms of Reference

Annex 2: Factors for determining OMCL status within the GEON

| | |
|---|--|
| Full document title and reference | Annex 2 to the GEON Terms of Reference: Factors for determining OMCL status within the GEON PA/PH/OMCL (07) 90 4R |
| Document type | Annex to Terms of Reference |
| Legislative basis | Council Directive 2001/83/EC and 2001/82/EC, as amended |
| Date of first adoption | May 2007 |
| Date of original entry into force | February 2007 |
| Date of entry into force of revised document | June 2008 |
| Previous titles/other references | This document replaces document Annex 2 to GEON Terms of Reference: Factors for determining OMCL status within the GEON, PA/PH/OMCL (06) 79 DEF (former internal document) |
| Custodian Organisation | The present document was elaborated by the OMCL Network / EDQM of the Council of Europe |
| Concerned Network | GEON |

Annex 2 to GEON Terms of Reference: Factors for determining OMCL status within the GEON

1. Introduction

The definition of an Official Medicines Control Laboratory (OMCL) is laid down in **Annex 1** of document “Terms of Reference for the GEON of the Council of Europe”. Conditions of Membership to the GEON are outlined in sections 3 and 4 of the Terms of Reference document.

The current document further clarifies the conditions under which a control laboratory can reach the “Network OMCL status”. This applies to laboratories, which are officially mandated OMCLs by their national Competent Authority. The criteria for reaching the status of membership of the OMCL Network for an individual control laboratory are required to be met by both the current members of the Network as well as by new candidates. The intention of this document is to define a common basis of understanding of the status of an OMCL within the Network.

It should be emphasised that the document is not applicable to subcontracting activities, which are regulated by ISO/IEC 17025.

2. Criteria for “OMCL status within the Network”

The National Competent Authority must be assured that a laboratory which acts as its OMCL should fulfill the following criteria to enable the laboratory full access to the OMCL Network and thus to confirm its status as OMCL within the Network:

- The control laboratory should be organised in such a way, which confirms independence regarding the testing and control of medicinal products.
- Scientific judgement and conclusions on results of control activities need to be independent.
- The control activities of the laboratory should be publicly funded. Where fees for official activities are received these arrangements should be organised such that the payments do not affect the independence of the laboratory.
- Any possible conflicts of interest should be clearly stated and assessed and where necessary a register of interests should be prepared.
- The member state for which the control laboratory is performing testing shall have implemented the Ph.Eur. as a common standard in the national rules governing medicinal products.
- The Competent Authority should provide the control laboratories within the OMCL Network with a clear mandate as to their responsibilities and duties; in this context some Competent Authorities may wish to retain within the regulatory organisation certain specific duties.
- Any testing activities, which are subcontracted should be clearly defined and subject to technical, impartiality and confidentiality agreements (in line with the requirements of ISO/IEC 17025) and where appropriate approved by the relevant authority.
- Implementation of the ISO/IEC 17025 standard in relation to OMCL activities.

- If the control laboratory is not directly linked to the Competent Authority in the organisational structure, the activities of the laboratory should have a significant component related to the activities outlined in section 5 of the Terms of Reference for the GEON and in Annex 1 with respect to their own overall scope of activity. This does not imply that the laboratory must carry out all of the activities listed in both documents; it means only that within their own laboratory and adapted to the market volume of medicines on the respective national market, control activity related to GEON is a substantial element with respect to other potential activities.