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GEON Terms of Reference

Annex 2: Factors for determining OMCL status within the GEON and QMS requirements for OMCLs

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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 or observership to the GEON are outlined in the core document of the Terms of Reference, and further specified in its annexes.

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 or observership of the OMCL Network for an individual control laboratory are required to be met by both the current members/observers of the Network as well as by applicants. 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 and the GEON quality management guideline on Externally provided products and services, PA/PH/OMCL (20) 77 in its current version.

2. Criteria for "OMCL status within the Network"

The mandating Competent Authority of the member state must be assured that a control laboratory which acts as its OMCL should fulfil the following criteria to enable the control 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 safeguards independence and impartiality regarding the testing and control of medicinal products.
- 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.
- The control laboratory shall identify risks to impartiality, whatever the cause might be (own activities, relationship, personnel, contracts…), and it shall demonstrate how they are eliminated or minimised. A register of risks related to interests may be a useful tool in this respect.
- 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.
- Testing activities may be performed by another control laboratory on behalf of the OMCL. These activities should be clearly defined and subject to technical, impartiality and confidentiality agreements (in line with the requirements of ISO/IEC 17025 and the GEON quality management guideline on Externally provided products and services, PA/PH/OMCL (20) 77 in its current version) and where appropriate approved by the relevant authority.
- 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 Chapter 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 the GEON is a substantial element with respect to other potential activities.

For full and associate members, the following criteria must also be met:

- 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 control laboratory should have implemented the standard ISO/IEC 17025 in relation to OMCL activities.

3. Quality Management System requirements for OMCLs

The Quality Management System requirements that are applicable to the full and associated OMCL members within the OMCL Network are based on the ISO/IEC 17025 standard, the European Pharmacopoeia and GEON quality management guidelines. GEON quality management guidelines have been developed to interpret and support the application of ISO/IEC 17025 within the context of Official Medicines Control Laboratories.

The observer OMCL should follow the basic principles of the ISO/IEC 17025 standard and follow the GEON guidelines as appropriate according to the maturity level of the laboratory.

Accredited OMCLs will also have to satisfy the requirements of their national accreditation body.

Since OMCLs do not manufacture medicines, the guides to Good Manufacturing Practice (GMP) are not applicable to their work. However, elements of these guides as well as from other references (e.g. ICH, other ISO norms…) may be used on a voluntary basis by OMCLs, where considered useful/relevant for the establishment and further development of the OMCL's Quality Management System.