

OMCL Network of the Council of Europe

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GEON Terms of Reference

Annex 1: Definition of an OMCL and OMCL Status within the GEON

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Annex 1 to GEON Terms of Reference: Definition of an OMCL and OMCL status within the 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” (Directive 2001/82/EC as amended).

The situation in Europe

To carry out national testing activities, the Competent Authority, which is part of the Ministry of Health/Agriculture 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 only performs laboratory testing for a Competent Authority, independently from the manufacturer, for medicinal products prior to and/or after marketing for the general surveillance of medicines in relation to the safety of human patient and/or animals.

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.

OMCL status within the Network

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

1. The laboratory is part of the Ministry of Health/Agriculture 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 fulfill 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.