

OMCL Network of the Council of Europe

GENERAL DOCUMENT

PA/PH/OMCL (10) 93 R12

GEON Terms of Reference

Annex 5: Maintenance of Membership to the GEON

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1. Introduction

The General European OMCL Network (GEON) is composed of full and associated members that fulfill the agreed rules of the Network as well as laboratories with observer status. The document Terms of Reference of the GEON, in its current version, and its annexes define, amongst others, the rights and responsibilities of members and observers to the Network. The considerations and criteria for membership are applicable for both new applicants and existing members. While applicants to the GEON shall demonstrate their legitimacy to become member of the Network following a defined application procedure (see document “Annex 6 to the GEON Terms of Reference: Application for New Membership to the GEON” in its current version), existing members of the GEON must prove their competence and their compliance with the rules of the GEON, in particular their independence from commercial organisations, on a regular basis. For this purpose, different monitoring instruments are in place.

The present guideline¹ details the critical membership criteria, consequences of non-compliance for Network members and the different instruments allowing a regular monitoring of compliance with the criteria. As a general rule, the Secretariat shall monitor the compliance of membership criteria and forward significant non-compliances (e.g. related to essential criteria or annual reporting obligations) to the Advisory Group GEON (AdG-GEON).

The AdG-GEON shall review the concerned information and determine a GEON position in case of non-compliance. In case that an AdG member is from the same country as the “discussed case”, conflicts of interest are excluded by requiring that AdG-GEON member to leave the room during that discussion.

Some of the criteria also apply to observers of the GEON. The basis is defined in the core document of the ToR and elements are also highlighted below.

2. Membership criteria

In the context of maintenance of membership, the membership criteria are classified in 2 groups, namely primary (essential) criteria and secondary indicators. The consequences of non-complying to essential criteria will be more severe than the consequences of non-complying to secondary indicators.

2.1 Primary (essential) criteria

- a) Independence of testing and control. This relates to impartiality, absence of conflicts of interest and confidentiality of data and also applies to observers to the GEON.
- b) Quality of work. This relates to the scientific and technical competence according to the ISO/IEC 17025 standard. This aspect has an impact on the mutual recognition of

¹ The guideline does not cover the situation where OMCLs are excluded from the GEON due to loss of membership or observership status of the corresponding member state to the European Pharmacopoeia Commission.

results, one of the main binding elements of the GEON (see also Annex 7 of the GEON Terms of Reference).

2.2 Secondary indicators

- a) Regular confirmation of the OMCL status.
- b) Regular maintenance of the own OMCL inventory database records.
- c) Submitting an Annual Report for relevant activities in line with the approved model templates, e.g. GEON, OCABR and Veterinary Batch Release Network (VBRN).
- d) Regular participation in Network activities (e.g. test programmes, working groups, attendance at the Annual Meeting...) and provision of relevant information (including test result data and relevant methodologies).
- e) Correct use of GEON and/or MJA logo.

3. Consequences of non-compliance

3.1 Non-compliance regarding primary (essential) criteria

- a) Non-compliance regarding *Independence*:

This will lead to the suspension of the membership.

In case of this decision the AdG-GEON should take into consideration that exclusion of an OMCL from the GEON may result in loss of access to unique expertise necessary for essential activities (e.g. OCABR).

The name of the suspended member shall be mentioned during the next GEON Annual Meeting and listed in the corresponding meeting report. Suspended members are also listed in Annex 3 of the GEON Terms of Reference and cannot apply for observer status.

- b) Non-compliance regarding *Quality of work*:

This can lead to exclusion of results and / or exclusion of participation in GEON programmes in case the non-compliance is not resolved within a certain time frame. This time frame must be agreed between the AdG-GEON and the member with reconsideration on an annual basis.

The status of the non-complying member regarding Quality of work shall be changed to observer.

Change of the status within the Network should be considered in case the member cannot present within 3 years documented proof that the quality of work is again conforming to the ISO/IEC 17025 standard.

In this case the GEON will give support to the affected laboratory in order to allow the OMCL to regain compliance to ISO/IEC 17025.

3.2 Non-compliances regarding secondary indicators

An overview of non-compliances and the nature of non-compliances are presented by the chairperson of the AdG-GEON or the Secretariat on a regular basis on the occasion of the GEON Annual Meeting without mentioning the name of the concerned members. In case the non-compliances of a member (accumulated non-compliances related to secondary indicators e.g. failure to provide annual reports on a regular basis, regular participation in Network activities) is not resolved within a certain time frame, possible sanctions should be discussed and decided in the AdG-GEON (e.g. suspension of financial contributions to meetings, trigger of an MJA etc.).

3.3 Suspension of membership

In case a suspension of the membership to the GEON is decided, all privileges as defined in the GEON Terms of Reference are suspended and an application as observer is not accepted.

3.4 Change to observer status

In case a change of the membership to observer status is decided, the privileges are restricted to those defined in the GEON Terms of Reference (see Core document, chapter 3.5 Table on membership rights and obligations).

In all cases mentioned above significant non-compliances shall be discussed in the AdG-GEON as soon as possible, keeping in mind the current contributions of the non-complying member in relation to GEON activities and the possible consequences on results or conclusions of that GEON activity. This discussion must include the necessity and urgency to inform stakeholders following a decision of the AdG-GEON.

4. Monitoring instruments

4.1 OMCL status

Background

The “questionnaire to query the OMCL status of present and future members and observers of the GEON” is used for new applicants to provide a first overview of the status of the applicant and as monitoring instrument for members. In the latter case a one-page declaration on the validity of the OMCL status replaces the detailed questionnaire which should already be available for all members. Rules for the use of this document are detailed in the preamble of the questionnaire.

The current version of the questionnaire template forms Annex 4 of the GEON ToR and can be downloaded from www.edqm.eu.

Role of the EDQM Secretariat

The Secretariat shall keep track of received OMCL status questionnaires and declarations which are directly uploaded on the OMCL inventory database.

The Secretariat shall launch an official email to the Network members as a rule every three years with the request to issue an OMCL status declaration. The Secretariat shall check on a regular basis which OMCLs are due to provide a declaration and contact those that did not provide this information.

4.2 External assessment of the QMS

Background

In the GEON Terms of Reference it is stated that the members of the OMCL Network must accept external audits covering ISO/IEC 17025, specific OMCL Network guidelines and the Ph. Eur. requirements, where applicable, 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/accreditation) must be made available to the OMCL Network/EDQM.

Role of the EDQM Secretariat

The Secretariat shall keep track of all information with respect to external assessments of the QMS of members as defined in the Terms of reference. This information should be uploaded by the concerned OMCLs in the respective domain of the OMCL inventory database.

A list of OMCLs that failed to submit the necessary proof shall be established and forwarded to the AdG-GEON for discussion in one of the following meetings.

4.3 OMCL inventory database

Background

In the GEON Terms of Reference, it is stated that the scope of activities should be made transparent to the Network and be updated, when applicable (OMCL inventory database; <http://omcldb.edqm.eu>). For this purpose, the Network members shall submit a conformity statement on a regular basis to confirm that the information available on the database is up to date. Network observers have no access to the OMCL-DB and hence are not obliged to provide the statement.

Role of the EDQM Secretariat

The Secretariat shall launch the campaign (as a rule once per year) and shall define the deadline for issuing the “declaration of conformity”. The form can be downloaded by the OMCL members individually from the OMCL inventory database (domain “OMCL”, rider “Print”) and after signature should be uploaded onto the respective document section of the database.

The Secretariat shall keep track of the available declarations.

4.4 Annual Report

Background

The delivery of an annual activity report is part of the obligations of all Network members as stated in the GEON Terms of Reference. The “non-OCABR/OBPR reports” should be made available on a yearly basis ahead of the Annual Meeting of the GEON to the concerned Networks by uploading files on the OMCL inventory database; details about the structure of the report are described in the document Model Format and Content of the OMCLs’ Annual Reports (other than OCABR/OBPR Activities) in its current version. With respect to human OCABR and VBRN separate policies for establishing and sharing annual reports are in place.

Role of the EDQM Secretariat

The Secretariat shall keep track of the distributed Annual Reports.

A list of OMCLs that did not provide the Annual Report(s) over a longer period of time (e.g. more than 3 years) shall be established and forwarded to the AdG-GEON for discussion in one of the following meetings. In case of Annual Reports of human OCABR and VBRN activities the respective specific Advisory Groups should be involved in the discussion.

4.5 Accumulated Non-compliances

Finally, the AdG-GEON could be involved in cases of “accumulated non-compliances” over a longer period (e.g. combination of failures to provide OMCL status declarations and declarations of conformity, lack of participation in Network programmes and annual meetings for more than 3 years etc.). This might trigger an MJA of the non-compliant OMCL laboratory.

5. Evaluation of and decision about membership

The AdG-GEON shall decide on the action to be taken towards members that do not comply with the Terms of Reference. Before taking a final decision on the consequences following a significant non-compliance of membership, in all cases the Secretariat must contact the concerned member (OMCL and/or National Competent Authority) and ask for an explanation. The member shall submit a written statement concerning this issue or might be invited to a meeting to give an oral explanation of the situation.

If a sufficient answer is not received within 60 days after the formal request of the Secretariat (which could be co-signed by the chairperson of the AdG-GEON), the AdG-GEON shall decide about appropriate actions. In all cases the member must be informed about the decision in an official letter sent by the Secretariat and co-signed by the chairperson of the AdG-GEON.

6. Restoring Membership

Suspension of membership or the change of full / associated membership to observer status can be lifted provided that the reasons which have led to the suspension or membership change are eliminated. If the restoration is not linked to the successful finalisation of an MJA, an official

application letter including a written proof of the changed situation must be sent by the concerned OMCL to the Secretariat. The case shall be discussed and decided in the following AdG-GEON meeting. The OMCL shall be informed on the decision and mentioned in the next Annual Meeting.

7. Obtaining status

An observer status can be given to the following laboratories:

- OMCLs from CoE member states
- OMCLs which failed to become member of the GEON after application (refusal not linked to lack of membership/observer status in the Ph. Eur. Committee)
- OMCLs from EDQM focus regions
- OMCLs which failed to meet the primary and secondary criteria (except for Independence).

Out of these potential observer's groups the triggers to support GEON observer status and / or GEON associated/ full membership result from:

- Strategic orientation of EDQM to support membership applications on international level
- Suspension of membership status (in some specific cases only as per Chapter 3)
- Failure to maintain membership status.

The situations indicated might be the reason for individually decided support (e.g. trigger for a MJA) of the observer requesting for full/associated membership.

8. Reporting and communication to interested parties

The chairperson of the AdG-GEON or the Secretariat should present on a regular basis at the Annual Meeting the results of the review of provided and pending membership questionnaires/declaration of validity and Annual Reports without mentioning names.

The same applies to the information about external assessment of the QMS and the receipt of declarations of conformity of the inventory database records.

The decisions taken and the consequences of these reviews, like changes in membership status shall also be communicated to the Annual Meeting plenum by the chairperson of the AdG-GEON.