

OMCL Network of the Council of Europe

GENERAL DOCUMENT

PA/PH/OMCL (09) 83 R9

GEON Terms of Reference

Annex 6: Application for New Membership to the GEON

| | |
|--|---|
| Full document title and reference | Annex 6 to the GEON Terms of Reference: Application for New Membership to the GEON PA/PH/OMCL (09) 83 R9 |
| Document type | Terms of Reference |
| Legislative basis | Council Directive 2001/83/EC and 2001/82/EC, as amended |
| Date of first adoption | July 2010 |
| Date of original entry into force | July 2010 |
| Date of entry into force of revised document | February 2025 |
| Previous titles/other references / last valid version | This document replaces document PA/PH/OMCL (09) 83 8R |
| Custodian Organisation | The present document was elaborated by the OMCL Network / EDQM of the Council of Europe |
| Concerned Network | GEON |

Introduction

The GEON welcomes any OMCL that fulfils the agreed requirements to become a member of the Network. The document “*Terms of Reference of the General European OMCL Network (GEON)*”, in its current version, defines in general terms the considerations and criteria regarding applications for membership of the Network. These considerations and criteria for membership apply to both applicants, members and observers. Moreover, members of the GEON have to prove their scientific competence and their compliance with the rules of the GEON on a regular basis. Here, the steps to be taken to apply for membership of the GEON are detailed.

As defined in “*Terms of Reference of the General European OMCL Network (GEON)*”, PA/PH/OMCL (07) 79, in its current version, members must conform to the Chapter “Responsibilities of Members of the Network” of the core document, as well as to “*Annex 1 of the GEON Terms of Reference: Definition, role and status of OMCLs of the GEON*”, PA/PH/OMCL (07) 89, and “*Annex 2 of the GEON Terms of Reference: Factors for Determining OMCL Status within the OMCL*”, PA/PH/OMCL (07) 90, in their current versions. The GEON Advisory Group and the Secretariat check whether all required conditions are fulfilled and then decide on the membership.

Application step

Potential applicants can contact the Secretariat for information on the application procedure and/or for information, on an informal basis (e.g. via email, during visits to the EDQM), on the chances of gaining membership to the Network (**Step 1**). The Secretariat will provide this information including an editable version of the questionnaire “*Annex 4 of the GEON Terms of Reference: Questionnaire to Query the OMCL Status of Present and Future Members of the GEON*”, PA/PH/OMCL (08) 4, in its current version. In cases where the applicant does not fulfil one of the criteria or shows evidence of an accumulated non-compliance to primary and secondary indicators (as defined in the “Terms of Reference” and its annexes), e.g. if the applicant is a private control lab, the country of the applicant is already represented in the Network by another OMCL performing similar activities or is not a member / observer of the European Pharmacopoeia Commission, following decision steps have to be considered: The Secretariat may immediately inform the applicant about the impossibility of becoming a member of the Network but may make the applicant aware about the possibility of reaching observer status in the Network as defined in the “Terms of reference” and its annexes. In case of doubt, potential applicants are advised to apply formally in writing (**Step 2**).

The formal membership application starts when the applicant contacts the Secretariat in writing, requesting admission to the GEON (**Step 3**). This is done by an official letter (application letter), which is signed and dated by the person responsible from the relevant National Competent Authority (NCA) or Medicines Agency. This letter must be accompanied by:

- the completed questionnaire (*Annex 4 of the GEON Terms of Reference*);
- written statements and other applicable documentation as detailed in Annex 4 of the GEON Terms of Reference.

Evaluation and decision step

The next step is an administrative check by the Secretariat of the documents provided (preferably translated into English). This check is performed within 30 days following receipt of all required documentation. If information is missing, the applicant will be asked to provide the missing data within an appropriate timeframe (**Step 4**). If it is evident that an applicant does not fulfil the core criteria as defined in the Terms of Reference and its Annexes 1, 2 and 5, *e.g.* the applicant is a private control lab (see **Step 2**), the Secretariat will inform the applicant of the negative outcome. The Secretariat will also inform the GEON Advisory Group of the result of this check (**Step 5**).

Where the outcome is positive, the next step is a discussion of the application within the GEON Advisory Group.

The application letter, the completed questionnaire and the additional documentation provided by the applicant are distributed to the members of the GEON Advisory Group with a request to examine the application and, if necessary, to identify points for clarification (**Step 6**). The Advisory Group members respond within 60 days following receipt of the documentation from the Secretariat. If necessary, a list of questions (LoQ) or a list of additional documents that need to be submitted by the applicant is established by the Secretariat and sent to the applicant. The applicant has 3 months to respond and can request an extension to 6 months, where justified. If no response is received within this time, and after sending a last reminder providing a short deadline for responding, the Secretariat will inform the applicant that a positive decision is not currently possible. Otherwise, the Secretariat sends the reply, and the additional information received from the applicant to the Advisory Group members (**Step 7**).

As soon as all the questions have been answered and the additional documentation has been received and depending on when the application and the amendments were filed, the “membership case” is discussed, preferably at the following Advisory Group meeting or, alternatively, in urgent cases, by means of telecommunication (**Step 8**). If the GEON Advisory Group decides that the status of the applicant remains unclear and/or the documentation is unsatisfactory, a representative of the applicant laboratory might be invited to join an Advisory Group meeting or teleconference/videoconference to explain the points still outstanding. The Advisory Group can request that the EDQM performs an MJA (Mutual Joint Audit) at the premises of the applicant lab, paying particular attention to the items of the application still pending, *e.g.* questions of conflicts of interest, impartiality and confidentiality, scope of activities / sub-contracted activities, level of testing competency etc. The group members should reach a final decision by consensus either during an Advisory Group meeting or by means of telecommunication (**Step 9**). In case of an MJA, the outcome of the audit replaces the final decision of the Advisory Group.

Follow-up

As soon as a final decision is made, the applicant is officially informed by the Secretariat in writing about the outcome (within 30 days after the meeting or, in case of an MJA, at the latest after the issuance of the audit attestation).

In case of a negative decision, the reason for the rejection is explained in detail. *A negative decision does not exclude future applications for membership if the organisational structure or other relevant conditions change in favour of the applicant.*

In case of a positive decision, the status in the GEON (full, or associated or alternatively, observer) and extent of participation is specified, where applicable, e.g. access to specific networks based on their competencies and member state status (relationship to EU/EEA) (**Step 10**). In addition, the OMCL is included in the official list of GEON members (*“Annex 3 of the GEON Terms of Reference: List of Members and Observers”, PA/PH/OMCL (09) 45, current version*) and representatives of the OMCL are invited to participate in the next annual meeting of the GEON. The new member will also be requested to enter necessary information into the OMCL inventory database and depending on the status in the GEON, will be granted access to relevant Network computer applications – e.g. Extranet (**Step 11**).

Reporting to the GEON

The chairperson of the GEON Advisory Group has a duty to report all membership applications processed during a mandated year to the following Annual Meeting of the General European OMCL Network (**Step 12**).

Annex: Summary of the steps of the application procedure

A: Applicant

S: Secretariat

AdG-GEON: Advisory Group of the GEON

- Step 1:** *A* requests information from *S*.
- Step 2:** *S* provides information and sends editable version of Annex 4 or informs *A* if membership cannot be granted and if applicable, about observer option.
- Step 3:** *A* sends application data (letter, statements, completed questionnaire) to *S*.
- Step 4:** *S* performs administrative check on completeness of the application (< 30 days after receipt).
In the case of missing data: *S* requests *A* to complete data; *go to Step 3*.
If everything is in order: *go to Step 5*.
- Step 5:** *S* performs check on fulfilment of basic membership criteria.
In case of non-conformity: *S* informs *A* and *AdG-GEON*.
In case of conformity: *go to Step 6*.
- Step 6:** *S* sends application data to *AdG-GEON* for checking.
- Step 7:** *AdG-GEON* members perform final check on documentation (response < 60 days).
In case of incompleteness of dossier / need for clarification: *AdG-GEON* members send remarks to *S*. *S* compiles remarks from *AdG-GEON* members in list of Questions (LoQ) and sends it to *A* (response < 3+3 months): *go to Step 3*.
In case of completeness of dossier: *AdG-GEON* members inform *S*: *go to Step 8*.
- Step 8:** *S* includes application on agenda of next meeting of *AdG-GEON* or, alternatively, organises a teleconference/videoconference.
- Step 9:** *AdG-GEON* discusses the membership application and makes a decision.
- Step 10:** *S* informs *A* of the decision within 30 days. The decision can be as follows:
- Immediate acceptance of membership on basis of the dossier: *go to Step 11*;
 - Acceptance of membership following an MJA after the issuance of the audit attestation: *go to Step 11*;
 - Immediate rejection of membership on basis of the dossier; the reason for rejection is given;
 - Rejection of membership following evidence of non-compliance concerning the membership during an MJA; the reason for rejection is given.¹
- Step 11:** *S* adds the new member into GEON ToR; *Annex 3* and informs new member about benefits and duties (e.g. access to OMCL IT tools, obligation to populate applicable Network databases).
- Step 12:** The chair of the *AdG-GEON* reports on decisions regarding new applications at the Annual Meeting.

¹ *A negative decision does not exclude future applications for membership if the organisational structure or other relevant conditions change in favour of the applicant. Alternatively, an observer status could be offered to the failed applicant.*