European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

# OMCL Network of the Council of Europe
# GENERAL DOCUMENT

## PA/PH/OMCL (08) 04 16R

### Annex 4 to GEON ToR: Questionnaire to Query the OMCL Status

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|---|---|
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| **Custodian Organisation** | The present document was elaborated by the OMCL Network / EDQM of the Council of Europe |
| **Concerned Network** | GEON |

# Annex 4 to GEON Terms of Reference: Questionnaire to query the OMCL Status of applicants to and members of the GEON

**Introduction to the questionnaire**

The present questionnaire, which is in line with the core document of the General European OMCL Network, "GEON: Terms of Reference", current version and its other Annexes should be used as follows:

1) **For applicants** to the Network it should be filled in by the applicant at the time of application and forms part of the supportive documents, which are evaluated by the Advisory Group GEON (AdG-GEON) and the EDQM Secretariat; thus the questionnaire is a pre-requisite for accomplishing membership to the GEON.

2) **All members of the Network** should revisit the questionnaire at least every 3 years or on the occasion of preparation for the next regular external assessment of the Quality Management System against ISO/IEC 17025 and other complementary specific guidelines of the OMCL Network Quality Book by an internationally recognised body or by peers within the OMCL Network (Mutual Joint Audit, MJA), whichever comes first. In the case there are no changes, the validity of the originally submitted questionnaire should be confirmed by the OMCL by signature. Provided that additional questions have been added to the questionnaire since last completion, a new completed questionnaire should be submitted. If the external assessment is not part of an MJA by the OMCL network, the completed questionnaire or the confirmation of validity of the submitted version as well as the outcome of the assessment (attestation/certificate and scope of assessment) should be returned to the EDQM for its review by the AdG-GEON and the Secretariat. In addition the questionnaire should be filled in and sent to the EDQM whenever the status of an OMCL changes (essential changes of the organisational structure). This has to be communicated immediately also by the concerned National Competent Authority (NCA), where applicable.

3) The information provided in this questionnaire should be in line with the data available on the OMCL inventory database (only applicable to members of the network).

# QUESTIONNAIRE

**OMCL/Laboratory information**

**For members of the GEON**

| | |
|---|---|
| **Name of the OMCL / the Laboratory** | **Official OMCL code** |
| **Name and position of signing person** | **Place and Date** |
| **Last date the OMCL Status questionnaire was answered** | |
| **Changes since the last OMCL Status questionnaire has been completed**<br>Yes ☐ No ☐<br>If yes, please continue below. | |
| **Signature** | |

**IN ADDITION TO THE QUESTIONNAIRE, THE FOLLOWING 2 ITEMS NEED TO BE CONSIDERED IN CASE OF CHANGES SINCE THE LAST COMPLETION OF THE QUESTIONNAIRE**

1. *Please add a **recent organigram** of your organization.*
2. *In addition please attach a **written statement (in English)** from the responsible National Competent Authority (NCA) confirming the scope of mandate of your OMCL/Laboratory or alternatively*

   *an **English translation of a binding document** (e.g. national law, decree etc.) where the mandate of your laboratory is detailed.*

**For applicants**

| **Name of the OMCL / the Laboratory** | **Place and Date** |
|---|---|
| **Name and position of signing person** | |
| **Signature** | |

*Please **shortly introduce your control laboratory** to the network including the **main fields of activities**.*

| |
|---|
| |

1. *Please provide an **Activity Report** of the last year.*
2. *Please attach a **list of test methods/techniques** performed in your laboratory and the frequency of performance (per week, per month or per year).*
3. *In addition please add a **recent organigram** of your organisation.*
4. *Please also include a **written statement (in English)** from the responsible National Competent Authority (NCA) confirming that your OMCL/Laboratory will represent your country for the defined field of activities in the OMCL Network; the writing should also include the official **nomination of a contact person** within the Laboratory.*
5. *Finally please attach a **written statement (in English)** from the responsible National Competent Authority confirming the **scope of mandate** of your OMCL/Laboratory or alternatively*

   *an **English translation of a binding document** (e.g. national law, decree etc.) where the mandate of your laboratory is detailed.*

## GENERAL INFORMATION

**Is the laboratory…?**

| | |
|---|---|
| An integral part of a Ministry *(please specify which one)* | ☐ |
| An integral part of the National Medicines Agency | ☐ |
| An independent governmental body | ☐ |
| A nominated medicines control laboratory as part of a larger institute with other testing and control activities *(if box is ticked, please specify)* | ☐ |
| Others *(please specify)* | ☐ |

| | |
|---|---|
| Has the laboratory arrangements in place to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work? | Yes ☐ No ☐ |
| Has the laboratory policies and procedures in place to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity? | Yes ☐ No ☐ |
| *Please further specify your answers (e.g. no direct contracts with industry, fees fixed by law etc.)* | |
| Can conflict of interest be excluded? | Yes ☐ No ☐ |
| *Please provide evidence such as a "conflict of interest register" for the organisation or for the individual staff members*[1] | |
| Is confidentiality of external documents guaranteed? | Yes ☐ No ☐ |
| *Please further specify your answer* | |
| Is the laboratory strictly performing regulatory activities in the fields of medicines? | Yes ☐ No ☐ |
| *If "no", please specify, which non-medicinal products are tested* | |

[1] A document (or part of a document) where the conflicts of interest of the organisation / the individual conflicts of interest of at least all key staff members of an OMCL are registered.

| | |
|---|---|
| Is the laboratory only accepting requests from (inter)governmental institutions? | Yes ☐ No ☐ |
| *If "no", please specify for which type of non-governmental clients (such as consumer associations, anti-doping associations…) tests are performed* | |
| Does your laboratory apply the provisions laid down in the Ph. Eur. as common mandatory standard? | Yes ☐ No ☐ |
| What (other) pharmacopoeias do you apply? | |
| How many staff members of your OMCL/Laboratory are involved in testing activities?<br>*(please provide the approximate figure to get an idea about the size of your organisation)* | |
| **ONLY APPLICABLE FOR MEMBERS OF THE GEON**<br><br>Annual reports<br><br>Which type of reports do you produce?<br>On OCABR (Official Control Authority Batch Release) / OBPR (Official Batch Protocol Review) activities ☐<br>On non-OCABR/OBPR activities ☐<br><br>Date the last report was issued to the Network | |

## LIST OF ACTIVITIES PERFORMED BY THE LABORATORY

**Please indicate for which of the following activities the laboratory establishes working plans (national level)**

| | |
|---|---|
| CAP (Centrally Authorised Products) testing (including ad hoc testing) | ☐ |
| MRP (Mutual Recognition Procedure / Decentralised Product testing | ☐ |
| National Post-marketing testing | ☐ |
| API (Active Pharmaceutical Ingredient) testing | ☐ |
| Counterfeits / illegal product testing (enforcement analysis) | ☐ |
| Others *(please specify)* | ☐ |

**Please indicate in which of the following sampling activities the laboratory is involved**

| | |
|---|---|
| CAP testing (including ad hoc testing) | ☐ |
| MRP / Decentralised Product testing | ☐ |
| National Post-marketing testing | ☐ |
| API testing | ☐ |
| Counterfeits / illegal product testing (enforcement analysis) | ☐ |
| Others *(please specify)* | ☐ |

**Please indicate in which of the following testing activities the laboratory is involved**

| | |
|---|---|
| CAP testing (including ad hoc testing) | ☐ |
| MRP / Decentralised Product testing | ☐ |
| MSS (Market Surveillance Studies of the OMCL Network) | ☐ |
| OCABR/OBPR | ☐ |
| National Post-marketing testing | ☐ |
| API testing | ☐ |
| Counterfeits / illegal product testing (enforcement analysis) | ☐ |
| Analysis of Suspected Defective Medicines | ☐ |
| Testing in the context of Pharmacovigilance issues | ☐ |
| Pre-authorisation testing (testing during licensing or variation applications) | ☐ |
| Test on importation | ☐ |
| Ad Hoc Collaborative Studies | ☐ |
| Others *(please specify)* | ☐ |

**In which other fields of activities is the laboratory involved?**

| | |
|---|---|
| Participation in Pharmacopoeia monograph development / validation or establishment of reference standards (Ph.Eur. and national) | ☐ |
| Participation in the BSP (Biological Standardisation Programme of the EDQM) | ☐ |
| Development within the regulatory frame work of medicines[2] (e.g. development of new tests such as alternative to in-vivo tests) | ☐ |
| *If box above is ticked, please specify funding of this activity in detail* | |
| Research within the regulatory frame work of medicines[3] | ☐ |
| *If box above is ticked, please specify funding of this activity in detail* | |
| Others *(please specify)* | ☐ |

**In which activities with the pharmaceutical (or other) industry/university institutes/hospitals etc. is the laboratory involved?**

| | |
|---|---|
| Testing activities (including batch release, stability testing) - *please fully explain and specify* | ☐ |
| Development of analytical methodologies *(please fully explain and specify)* | ☐ |
| Research *(please fully explain and specify)* | ☐ |
| Others (*please fully explain and specify)* | ☐ |

[2] Development work done with respect to the marketing authorisation of medicines and their surveillance after introduction on the market.
[3] Research work done with respect to the marketing authorisation of medicines and their surveillance after introduction on the market.

**QMS status of the laboratory**

| | |
|---|---|
| QMS (Quality Management System) in place according to ISO/IEC 17025 and relevant OMCL guidelines | Yes ☐ No ☐ |
| *In case of "yes", please include details of inspections/audits (i.e. by National Accreditation Service, peer audit within the OMCL Network or other internationally recognised bodies) and provide the date of the last audit/inspection.*<br>*In case you hold an accreditation, please provide the latest certificate and the scope of assessment.* | |
| Regular external assessment of QMS (every 3-5 years) – *please state intervals* | Yes ☐ No ☐ |
| Regular participation in PTS (Proficiency Testing Scheme; covering all aspects of testing competence) – *in case of "yes", please further specify* | Yes ☐ No ☐ |
| *In case of "yes", which providers are used?* | EDQM ☐ Other ☐ |
| *In case of "other", please further specify* | |

**MANDATE OF THE LABORATORY WITHIN THE NETWORK**

**Please specify the mandate of the laboratory defined by your NCA**

| **Mandated for Participation in Network Meetings** | |
|---|---|
| Annual Meeting of the GEON<br>Date of last participation | ☐ |
| Annual Meeting of the EEA CAP Network | ☐ |
| Meetings of the EEA MRP/DCP Network | ☐ |
| GEON Advisory Group | ☐ |
| CAP Advisory Group | ☐ |
| OCABR human Advisory Group | ☐ |
| VBRN (Veterinary Batch Release Network) Advisory Group | ☐ |
| Drafting Group for Human Vaccines | ☐ |
| Drafting Group for Blood Products | ☐ |
| OMCL Expert Group of Gene transfer medicinal products (GTMPs) | ☐ |
| Other Ad-hoc Drafting/Working/Expert Groups *(please specify)* | ☐ |
| **Mandated for Participation in QMS Activities of the Network** | |
| MJA/MJV (Mutual Joint Audit/Visit programme of the EDQM) as auditee | ☐ |
| MJA/MJV as auditor | ☐ |
| QMS training programme as trainee | ☐ |
| QMS training programme as trainer | ☐ |
| EDQM PTS studies *(for GEON members free of charge)* | ☐ |

| **Mandated for Participation in Testing Activities of the Network** | |
|---|---|
| MSS | ☐ |
| Ad-hoc Collaborative Studies | ☐ |
| CAP Sampling and Testing Programme *(including ad hoc testing)* | ☐ |
| MRP / Decentralised Product Post-Marketing Surveillance Scheme | ☐ |
| OCABR human *(mutual recognition)* | ☐ |
| OCABR veterinary/OBPR *(mutual recognition)* | ☐ |
| Counterfeit / Illegal product testing programmes *(e.g. APIC/EDQM trial phase)* | ☐ |
| **Mandated for Access to Network data / databases** | |
| CombiStat *(for GEON members free of charge)* | ☐ |
| OMCLnet (GEON document depository) | ☐ |
| CAPnet (CAP document depository) | ☐ |
| OCABRnet (human OCABR document depository) | ☐ |
| VETnet (VBRN document depository) | |
| MRPnet (MRP/DCP document depository) | ☐ |
| OMCL inventory database | ☐ |
| MRP / DCP-product testing database | ☐ |
| OCABR human database | ☐ |
| **Who is defining the extent of the mandate? *(please complete)*:** | |
| Ministry *(please specify which one)* | ☐ |
| National Medicinal Agency | ☐ |
| Other body *(please specify)* | ☐ |

**Note: Participation might be restricted due to the <u>nature of activity</u> (CAP testing, MRP/DCP testing for EEA OMCLs only; OCABR for EEA OMCLs and Switzerland only etc.) and/or due to the <u>fields of activities</u> the OMCL is dedicated to (human, veterinary medicinal products; appointed OMCL for OCABR human activities etc.)**