European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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GENERAL DOCUMENT

PA/PH/OMCL (08) 04 R22

GEON Terms of Reference

Annex 4: Questionnaire to Query the OMCL Status of present and future members of the GEON

Full document title and reference	Annex 4 to GEON Terms of Reference: Questionnaire to query the OMCL Status of present and future members of the GEON PA/PH/OMCL (08) 04 R22
Document type	Terms of Reference
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Custodian Organisation	The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
Concerned Network	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 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 European Directorate for the Quality of Medicines & HealthCare (EDQM) Secretariat; thus the questionnaire is a pre-requisite for accomplishing membership to the GEON.

2) **All members of the Network** should issue an OMCL status declaration at least once every 3 years by filling in the template reproduced on page 11 of this document. A new declaration campaign is initiated by the Secretariat who will launch an official email request to the GEON contact points. The OMCLs are responsible for placing the completed declaration in the document section of the OMCL inventory database. Significant changes since the last declaration (e.g. essential changes of the organisational structure, changes in the mandate of the OMCL) should be listed in key words in the respective box. The responsible person in the OMCL confirms the validity of the content by signing the statement. In addition, crucial changes have to be communicated immediately to the Secretariat without waiting for the next campaign and should be accompanied by supportive documents, where applicable. The information in the OMCL inventory database should be aligned with these changes.

QUESTIONNAIRE

OMCL/Laboratory information

For applicants

Name of the OMCL / the Laboratory
Visiting address
Name and position of signing person
Place and Date
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 calendar 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 case your laboratory holds an accreditation certificate issued by your national accreditation body, please submit a **copy of the latest valid accreditation certificate** and a document detailing the **scope of accreditation**.*
4. *In addition please add a **recent organigram** of your organisation.*
5. *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.*
6. *Please attach a **written statement (in English)** from the responsible NCA confirming the **scope of mandate** of your OMCL/Laboratory or alternatively*
7. *A copy of the original (and a translation in English or, where sufficient, an English summary) **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)*		☐
Does the laboratory have 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 ☐	
Does the laboratory have 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? *(please provide the approximate figure of each group of employee (e.g. scientists, technicians, administrative staff) to get an idea about the size and composition of your organisation)*	

LIST OF ACTIVITIES PERFORMED BY THE LABORATORY

Please indicate for which of the following activities the laboratory <u>establishes working plans</u> (national level)

Centrally Authorised Products (CAP) testing*	☐
Mutual Recognition Procedure (MRP) / Decentralised Procedure (DCP) product testing*	☐
National post-marketing testing	☐
Active Pharmaceutical Ingredient (API) testing	☐
Counterfeit / illegal product testing (enforcement analysis)	☐
Others *(please specify)*	☐

Please indicate in which of the following <u>sampling activities</u> the laboratory is involved

CAP testing*	☐
MRP / DCP product testing*	☐
National post-marketing testing	☐
API testing	☐
Counterfeit / illegal product testing (enforcement analysis)	☐
Others *(please specify)*	☐

Please indicate in which of the following <u>testing activities</u> the laboratory is involved

CAP testing*	☐
MRP / DCP Product testing*	☐
National post-marketing testing	☐
Market surveillance testing campaigns *If ticked, please further specify*	☐ ☐
OCABR**	☐
API testing	☐
Counterfeit / 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; e.g. testing of medical devices, food supplements, cosmetics etc.)*	☐

* Only applicable to EU/EEA members
** Only applicable to EU/EEA members and officially recognised partners

In which other fields of activities is the laboratory involved?

Participation in Pharmacopoeia monograph development / validation or establishment of reference standards (Ph.Eur. and/or national)	☐
Participation in the Biological Standardisation Programme of the EDQM (BSP)	☐
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

Quality Management System (QMS) in place according to ISO/IEC 17025	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.		
Regular external assessment of QMS (every 3-5 years) – *please state intervals*	Yes ☐	No ☐
Regular participation in Proficiency Testing Scheme (PTS; 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

Who is defining the extent of the mandate? *(please complete)*:	
Ministry *(please specify which one)*	☐
National Medicinal Agency	☐
Other body *(please specify)*	☐

Note: Participation in the Network might be restricted due to the nature of activity (CAP Sampling and Testing Programme, MRP / DCP Product Post-Marketing Surveillance Scheme for EU/EEA OMCLs only; OCABR for EU/EEA OMCLs and officially recognised partners) and/or due to the fields of activities the OMCL is dedicated to (human, veterinary medicinal products; appointed OMCL for OCABR human activities etc.)

OMCL information

Declaration for members of the GEON

Name of the OMCL	**Official OMCL code**
Last date the OMCL Status questionnaire was completed	
Changes since the last OMCL Status questionnaire has been completed Yes ☐ No ☐ *If yes, please continue below and list significant changes in key words.*	
Place and Date	
Name and position of signing person	
Signature	

IN ADDITION TO THE DECLARATION, 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 organisation.*
2. *In addition please attach a **written statement (in English)** from the responsible NCA confirming the scope of mandate of your OMCL/Laboratory or alternatively*

   *A copy of the original (and a translation in English or, where sufficient, an English summary) **binding document** (e.g. national law, decree etc.) where the mandate of your laboratory is detailed. – highlighting the relevant paragraphs*

List of abbreviations:

AdG-GEON:	Advisory Group of the GEON
API:	Active Pharmaceutical Ingredient
BSP:	Biological Standardisation Programme of the EDQM
CAP:	Centrally Authorised Products
DCP:	Decentralised Procedure
EDQM:	European Directorate for the Quality of Medicines & HealthCare
EEA:	European Economic Area
GEON:	General European OMCL Network
MRP:	Mutual Recognition Procedure
NCA:	National Competent Authority
OBPR:	Official Batch Protocol Review
OCABR:	Official Control Batch Release
OMCL:	Official Medicines Control Laboratory
PTS:	Proficiency Testing Scheme
QMS:	Quality Management System