

OMCL Network of the Council of Europe

GENERAL DOCUMENT

PA/PH/OMCL (08) 04 12R

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

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 12R
Document type	Terms of Reference
Legislative basis	Council Directive 2001/83/EC and 2001/82/EC, as amended
Date of first adoption	June 2008
Date of original entry into force	June 2008
Date of entry into force of revised document	July 2011
Previous titles/other references	This document replaces document PA/PH/OMCL (08) 04 6R (internal document)
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 present and future
members of the GEON**

Introduction to the questionnaire (full and associated members)

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 new 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 complete 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. If the external assessment is not part of an MJA by the OMCL network, the completed questionnaire as well as the outcome of the assessment (attestation/certificate and scope of assessment) should be returned to EDQM for its review by the AdG-GEON and the Secretariat. In addition the questionnaire should be filled in and sent to EDQM whenever the status of an OMCL changes.
- 3) The information provided in this questionnaire should be in line with the data available on the OMCL inventory database (only applicable to existing 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
Signature	
Last date the OMCL Status questionnaire was answered	

THE FOLLOWING ITEMS ONLY NEED TO BE CONSIDERED IN CASE OF CHANGES SINCE THE LAST COMPLETION OF THE QUESTIONNAIRE

*Please add a **recent organigram** of your organization.*

*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 candidate members

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.***

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*Please provide an **Activity Report** of the last year.*

*Please attach a **list of test methods/techniques** performed in your laboratory.*

*In addition please add a **recent organigram** of your organisation.*

*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.*

*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 (<i>please specify which one</i>)	<input type="checkbox"/>
An integral part of the National Medicines Agency	<input type="checkbox"/>
An independent governmental body	<input type="checkbox"/>
A nominated medicines control laboratory as part of a larger institute with other testing and control activities (<i>if box is ticked, please specify</i>)	<input type="checkbox"/>
Others (<i>please specify</i>)	<input type="checkbox"/>
Is the laboratory financially independent from the Pharmaceutical Industry (Marketing and Manufacturing) and from publicly owned manufacturers of medicines?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Please further specify your answer</i>	
Can conflict of interest be excluded?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Please provide evidence such as a “conflict of interest register” for the organisation or for the individual staff members¹</i>	
Is confidentiality of external documents guaranteed?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Please further specify your answer</i>	
Is the laboratory strictly performing regulatory activities in the fields of medicines?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>If “no”, please specify, which non-medicinal products are tested</i>	

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.

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

LIST OF ACTIVITIES PERFORMED BY THE LABORATORY

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

CAP (including ad hoc testing)	<input type="checkbox"/>
MRP / Decentralised Products	<input type="checkbox"/>
National Surveillance	<input type="checkbox"/>
OCABR	<input type="checkbox"/>
Counterfeits / illegal drugs	<input type="checkbox"/>
Others (<i>please specify</i>)	<input type="checkbox"/>

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

CAP (including ad hoc testing)	<input type="checkbox"/>
MRP / Decentralised Products	<input type="checkbox"/>
National Surveillance	<input type="checkbox"/>
Counterfeits / illegal drugs	<input type="checkbox"/>
Others (<i>please specify</i>)	<input type="checkbox"/>

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

CAP (including ad hoc testing)	<input type="checkbox"/>
MRP / Decentralised Products	<input type="checkbox"/>
National Surveillance	<input type="checkbox"/>
OCABR	<input type="checkbox"/>
Counterfeits / illegal drugs (enforcement analysis)	<input type="checkbox"/>
Analysis of Suspected Defective Medicines	<input type="checkbox"/>
Testing in the context of Pharmacovigilance issues	<input type="checkbox"/>
Pre-authorisation testing (testing during licensing or variation applications)	<input type="checkbox"/>
MSS	<input type="checkbox"/>
Ad Hoc Collaborative Studies	<input type="checkbox"/>
Others (<i>please specify</i>)	<input type="checkbox"/>

In which other fields of activities is the laboratory involved?

Participation in Pharmacopoeia monograph development / validation or establishment of CRS (Ph.Eur. and national)	<input type="checkbox"/>
Participation in the BSP programme	<input type="checkbox"/>
Development within the regulatory frame work of medicinal products ² (e.g. development of new tests such as alternative to in-vivo tests)	<input type="checkbox"/>
<i>If box above is ticked, please specify funding of this activity in detail</i>	
Research within the regulatory frame work of medicinal products ²	<input type="checkbox"/>
<i>If box above is ticked, please specify funding of this activity in detail</i>	
Others (<i>please specify</i>)	<input type="checkbox"/>

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

Testing activities (including batch release, stability testing) - <i>please fully explain and specify</i>	<input type="checkbox"/>
Development of analytical methodologies (<i>please fully explain and specify</i>)	<input type="checkbox"/>
Research (<i>please fully explain and specify</i>)	<input type="checkbox"/>
Others (<i>please fully explain and specify</i>)	<input type="checkbox"/>

² Development/research within the regulatory frame work of medicinal products means work done with respect to the marketing authorisation of medicinal products and their surveillance after introduction on the market.

QMS status of the laboratory

QMS in place according to ISO/IEC 17025 and relevant OMCL guidelines	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<i>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. In case you hold an accreditation, please provide the latest certificate and the scope of assessment.</i>		
Regular external assessment of QMS (every 3-5 years) – <i>please state intervals</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Regular participation in PTS (covering all aspects of testing competence) – <i>in case of “yes”, please further specify</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<i>In case of “yes”, which providers are used?</i>	EDQM <input type="checkbox"/>	Other <input type="checkbox"/>
<i>In case of “other”, please further specify</i>		

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 Date of last participation	<input type="checkbox"/>
Annual Meeting of the EEA CAP Network	<input type="checkbox"/>
Meetings of the EEA MRP/DCP Network	<input type="checkbox"/>
GEON Advisory Group	<input type="checkbox"/>
CAP Advisory Group	<input type="checkbox"/>
OCABR human Advisory Group	<input type="checkbox"/>
OCABR veterinary Advisory Group	<input type="checkbox"/>
Drafting Group for Human Vaccines	<input type="checkbox"/>
Drafting Group for Blood Products	<input type="checkbox"/>
OMCL Expert Group of Gene transfer medicinal products (GTMPs)	<input type="checkbox"/>
Other Ad-hoc Drafting/Working/Expert Groups (<i>please specify</i>)	<input type="checkbox"/>
Mandated for Participation in QMS Activities of the Network	
MJA/MJV as auditee	<input type="checkbox"/>
MJA/MJV as auditor	<input type="checkbox"/>
QMS training programme as trainee	<input type="checkbox"/>
QMS training programme as trainer	<input type="checkbox"/>
EDQM PTS studies (<i>for GEON members free of charge</i>)	<input type="checkbox"/>

Mandated for Participation in Testing Activities of the Network	
MSS	<input type="checkbox"/>
Ad-hoc Collaborative Studies	<input type="checkbox"/>
CAP Sampling and Testing Programme (<i>including ad hoc testing</i>)	<input type="checkbox"/>
MRP / Decentralised Product Post-Marketing Surveillance Scheme	<input type="checkbox"/>
OCABR human (<i>mutual recognition</i>)	<input type="checkbox"/>
OCABR vet (<i>mutual recognition</i>)	<input type="checkbox"/>
Counterfeit / Illegal drug programme (<i>e.g. APIC/EDQM trial phase</i>)	<input type="checkbox"/>
Mandated for Access to Network data / databases	
CombiStat (<i>for GEON members free of charge</i>)	<input type="checkbox"/>
OMCLnet	<input type="checkbox"/>
CAPnet	<input type="checkbox"/>
OCABRnet	<input type="checkbox"/>
MRPnet	<input type="checkbox"/>
OMCL inventory database	<input type="checkbox"/>
MRP / DCP-product testing database	<input type="checkbox"/>
OCABR human database	<input type="checkbox"/>
Who is defining the extent of the mandate? (<i>please complete</i>):	
Ministry (<i>please specify which one</i>)	<input type="checkbox"/>
National Medicinal Agency	<input type="checkbox"/>
Other body (<i>please specify</i>)	<input type="checkbox"/>

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