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Terms of Reference for the General European OMCL Network (GEON) of the Council of Europe

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1. Introduction

With a view to creating a pool of resources which provides technical expertise and a possibility of work sharing for the testing of medicines, a general European Network of Official Medicines Control Laboratories (OMCLs), as defined in **Annex 1** – "Definition, role and status of OMCLs of the GEON", in its current version, was formed in the mid-nineties under the aegis of the Council of Europe. It was created at the joint initiative of the European Commission (EC) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe.

The present Terms of Reference include the core document and all its annexes as indicated in the text.

2. Regulatory framework and objectives of the GEON

The regulatory framework and common operating mechanisms of the GEON are based on the following standards:

- European Pharmacopoeia
- Relevant Articles of the European Union (EU) Code for Human and Veterinary Medicines and of the Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA)[1]
- Commonly agreed guidelines
- Commonly agreed Quality Management Systems (QMS) according to ISO/IEC[2] 17025.

The activities of the OMCLs of the GEON are derived from this framework.

The objectives of the Network are

- to co-ordinate the technical activities of OMCLs
- to foster exchange of data (results and associated methodologies) obtained within the context of the OMCL activities (e.g. market surveillance testing, pre-authorisation testing, official batch release testing, falsified and illegal medicines testing)
- to promote future development through harmonised common standards, based on the legal requirements for testing medicinal products for the benefit of the human patient and/or animals
- to offer a discussion platform for sharing scientific information and strategies
- to publicise the work of the individual OMCLs and the GEON as a whole and by this or other means to raise awareness of the contributions of the OMCLs and the Network to public and animal health.

The voluntary sharing of work and competence relies on the principles of mutual confidence and recognition and is based on a common approach to the QMS and on harmonised working procedures. The principle of mutual recognition of test results is further discussed in **Annex 7**.

[1] Code for Human Medicines: Directive 2001/83/EC, as amended, Articles 19, 111, 114;
Code for Veterinary Medicines: Regulation (EU) 2019/6, as amended, Articles 29, 123, 128;
Regulation (EC) No 726/2004, Articles 7, 57.
[2] International Organisation for Standardisation / International Electrotechnical Commission.

3. Composition of the GEON

3.1. General

The GEON is composed of full members and associated members; an observer status is possible under certain conditions. Decisions on membership follow the procedures as described in Chapter 4.

A list of all current members of the GEON can be found in **Annex 3**.

3.2. Full members of the GEON

All OMCLs of member states that have signed the European Pharmacopoeia Convention and that fulfil

- the definition given in **Annex 1**
- the criteria given in **Annex 2** (Factors for determining OMCL status within the GEON and QMS requirements for OMCLs)

may become full members of the GEON upon decision of the GEON Advisory Group (see ToR of the AdG-GEON for details).

3.3. Associated members of the GEON

All OMCLs of other member states of the Council of Europe or countries that are observers to the European Pharmacopoeia Commission and that fulfil

- the definition given in **Annex 1** and
- the criteria given in **Annex 2**

may become associated members of the GEON upon decision of the GEON Advisory Group.

In exceptional cases other OMCLs of member states of the Council of Europe, which are full members to the European Pharmacopoeia Commission, might be given the status of associated members of the GEON, in cases where they do not, in all respects, fulfil certain criteria of **Annex 1** and/or **Annex 2** (e.g. the mandating Competent Authority in general is not responsible for public health or animal welfare etc.). Decision on the acceptance as associated member is made on a case-by-case basis by the GEON Advisory Group.

3.4. Observers of the GEON

The observer status is suitable for OMCLs that have a limited maturity with regards to QMS or have limited resources and are willing to participate in the Network goals.

OMCLs that do not fulfil the requirements of full and associated members may be eligible for observer status to the GEON upon decision of the GEON Advisory Group. To be considered they shall comply with

- the definition given in **Annex 1** and
- the criteria given in **Annex 2**.

The GEON will provide access to Network training in order to increase the maturity and QMS level of the observers. Details on profiles of the Network can be found in the Chapter 3.5 “Membership rights and Obligations” below.

3.5. Membership Rights and Obligations

A complete picture of the membership rights is given in the table below.

Summary of rights for members and observers

	Full member	Associated member	Observer	Applicant/Suspended OMCL
Voting rights	**Yes**	**No**	**No**	**No**
Participation in educational activities	**Yes**	**Yes**	**Conditional+**	**No***
Use of OMCL logo	**Yes**	**Yes**	**No**	**No**
Use of MJA logo	**Yes**	**Yes**	**No**	**No****
Access to confidential information / databases	**Yes**	**Yes**	**No**	**No**
Participation in GEON meetings (Annual Meeting / working groups)	**Yes**	**Yes**	**Yes*+**	**No*****
Free PTS participation	**Yes**	**Yes**	**No**	**No**
Participation in Network Market Surveillance testing programmes	**Yes**	**Yes**	**No*****	**No**
Reimbursement of registration, travel costs for attending meetings / educational activities	**Yes**	**No**	**No**	**No**
Financial support for MJA / MJV / training visits	**Yes**	**No**	**No**	**No***
Inclusion in GEON ToR Annex 3	**Yes**	**Yes**	**Yes**	**No**
Eligibility to Advisory Group	**Yes**	**No**	**No**	**No**

Participation to certain OMCL programmes has some restrictions (e.g. OCABR/OBPR, CAP, MRP/DCP)

*Including access to the respective programmes in case of suspension; **Decision about duration of using the MJA logo after suspension is taken on a case-by-case basis taking into account the audit scope; ***Only upon invitation; *+Not for all Sessions/Meetings and only upon invitation and in general virtual participation. +Based on space and budgetary considerations.

A complete picture of obligations for members and observes is given in the table "Summary of obligations" below.

Summary of obligations (see also Annex 5 to the GEON ToR, primary and secondary indicators)

	Full member	**Associated member**	**Observer**
Meets definition of an OMCL, Annex 1	Yes	Yes	Yes
QMS according to ISO/IEC 17025	Yes	Yes	Yes[++]
Regular information of the OMCL status	Yes	Yes	Yes
Regular maintenance of own OMCL inventory database records	Yes	Yes	No
Submission of Annual Reports	Yes	Yes	No
Annual follow-up reports from educational activities	No	No	Yes
Regular participation in Network programmes	Yes	Yes	No
Correct use of GEON and/or MJA logo	Yes	Yes	No

[++] Lower maturity level could be accepted.

3.6. Special Arrangements

While the GEON is composed primarily of OMCLs, representatives of Competent Authorities may also be members of the GEON. The second option is applicable for Member States in which the Competent Authority has mandated a control laboratory to act as its OMCL within the OMCL Network, but where, in accordance with Section 2 of **Annex 2**, in its current version, the Competent Authority in question has retained within the regulatory organisation certain specific duties and responsibilities. In such situations, the Competent Authority should have provided this control laboratory with a clear mandate as to its responsibilities and duties, and the control laboratory acting as an OMCL must meet the criteria outlined in Sections 2 of **Annex 2** to the GEON Terms of Reference and Chapter 8 of the ToR. It must also meet the definition of an OMCL as laid out in **Annex 1**. If the second option is applied, it should be defined in advance if the Competent Authority or the OMCL represents the member state.

3.7. Change of membership status

Any changes in the rights of members or observers to the European Pharmacopoeia Commission (e.g. change from signatory status to observer status or vice-versa, suspension from the European Pharmacopoeia Commission or re-admission, etc.) will impact the membership rights in the OMCL Network. In case of a suspension from the European Pharmacopoeia Commission (e.g. exclusion from the participation in meetings and programmes) which might be triggered by different factors including the loss of membership of a country to the Council of Europe, this will mean a loss of all OMCL Network membership rights as listed under item 3.5.

4. Application and Maintenance of Membership to the GEON

4.1. Application of Membership to the GEON

Membership of the GEON is taken into consideration after a formal request from the relevant authorities for each OMCL involved in the control of marketed medicines and the completion of a standardised questionnaire (document "Questionnaire to query the OMCL Status of members and applicants to the GEON" in its current version) challenging the OMCL status of the future member (see **Annex 4**). The request and the completed questionnaire are sent to the Secretariat (for Secretariat see Chapter 12). For new Member States the nomination of OMCLs is restricted to a maximum of three laboratories from separate entities covering the main fields of activities, chemical and biological testing of human and veterinary products.

The GEON Advisory Group and the Secretariat check whether the conditions are fulfilled and will approve or reject the request. Following the decision taken, the applicant is informed officially by the EDQM and, in case of a positive opinion, then is considered as full or associated member of the Network with all rights, as defined.

Further details are explained in **Annex 6** (Application for New Membership to the GEON).

4.2. Maintenance of Membership to the GEON

The compliance of members of the GEON with the criteria defined in the Terms of Reference is constantly monitored using different instruments such as the "OMCL status questionnaire", results from the external assessment of the QMS, the Annual Reports and the maintenance of the OMCL inventory database. Non-compliance with the ToR may lead to the suspension of the membership (suspended OMCL) or change from membership to observer status. Additionally, an MJA can be triggered to check the suitability of the OMCL. The latter applies as well to "passive" OMCL (OMCL not contributing to the Network) and those who do not meet anymore the definition of an OMCL as laid out in **Annex 1**.

Further details are given in **Annex 5**.

5. Activities of the Network

The activities of the Network in the various fields are differentiated as follows:

5.1. General activities

Elaboration of common Network strategies, such as risk-based approach for post-market sampling and testing, contribution in combating falsified and illegal medicines, establishment of centres of expertise, improvement of communication etc.;

General QMS activities including the Mutual Joint Visit/Mutual Joint Audit (MJV/MJA) programme and the Proficiency Testing Scheme (PTS);

Market Surveillance Studies (MSS) and collaborative studies;

Educational programmes, Training Visits;

Applied analytical research and regulatory development.

5.2. Activities based on the European Union (EU) "acquis communautaire"

Centrally Authorised Product (CAP) testing;

Human Official Control Authority Batch Release (OCABR);

Veterinary Official Control Authority Batch Release (OCABR) and Official Batch Protocol Release (OBPR);

Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP)-product testing.

6. Participation Rights to Activities of the Network

6.1. Participation Rights of Members of the Network to General Activities

Members are eligible to participate in any of the general activities for which they have the relevant competencies, interest, and mandate**.**

6.2. Participation Rights of Members of the Network to Activities based on the European Union (EU) "acquis communautaire"

These activities of the OMCL Network are restricted to OMCLs and Competent Authorities from European Union/European Economic Area (EU/EEA) countries (e.g. CAP, MRP, DCP) and to countries for which a relevant Agreement exists with the EU (e.g. MRA, ACAA) or a specific Memorandum of Understanding (MoU) exist (e.g. OCABR).

6.3. Participation of Laboratories outside the OMCL Network in European Market Surveillance Studies

The Competent Authorities of the member states may have a laboratory outside the OMCL Network act as their control laboratory for a given European market surveillance study. In such cases the Member State informs the EDQM and ensures that the commonly agreed standards (ISO/IEC 17025) are in place. The participation of such a laboratory in European market surveillance studies is subject to a confidentiality agreement and a declaration of non-interest for the product covered by the study. In these cases, the Competent Authority takes the responsibility for interaction with the GEON with respect to the exchange of organisational and decision-making information regarding the programme and its follow-up.

When an OMCL wishes to outsource testing activities to other organisations it refers to **the OMCL guideline "Externally provided products and services".**

6.4. Participation of Official Control Laboratories outside the OMCL Network in Other Activities

The activities of the Network not related to product surveillance are open to other official control laboratories (public labs) outside the Network. This includes QMS activities such as general training and audits. Participation to these activities is subject to a fee. PTS organised by the EDQM are open to public and private labs. Participation of official control laboratories outside the Network and private labs to this programme is subject to a fee.

7. Responsibilities of the GEON

The responsibilities of the GEON will be to:

7.1. within the legal framework develop, set up and carry out programmes for common sampling and testing of active substances and medicinal products on the market in the GEON such as MSS, testing of suspected falsified and illegal medicines, collaborative studies;

7.2. develop and maintain appropriate databases for information, communication and exchange of results within the GEON;

7.3. develop and implement a common approach for Quality Management System within the GEON based on ISO/IEC 17025 including the programmes for PTS and peer reviews based on the QMS procedure for MJV/MJA;

7.4. develop guidance and policy documents for the activities of the GEON.

8. Responsibilities of members of the Network

Members of the OMCL Network have the following responsibilities:

8.1. Cooperation with and provision of relevant information (including test result data and relevant methodologies) to the Network and participation in Network activities following the principle of work sharing, wherever possible.

8.2. Compliance with the rules of the Network (e.g. good use of the logos) and application and/or implementation of guidelines (e.g. OCABR guidelines).

8.3. The scope of activities should be made transparent to the Network and be updated, when applicable (OMCL inventory database).

8.4. Acceptance of external audits covering ISO/IEC 17025 and specific OMCL Network guidelines including an appropriate evaluation of both the technical level and managerial level covering aspects of impartiality, 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) should be made available to Network/EDQM.

8.5. The laboratory must ensure that where applicable a statement of impartiality, independence, confidentiality, and absence of any conflicts of interest is made available to the responsible Competent Authority and, upon request, to the Network/EDQM.

8.6. Each control laboratory shall have a clearly defined policy for the maintenance of any confidential information received or generated.

8.7. A clear separation between OMCL and non-OMCL activities has to be guaranteed in case of additional activities outside the regulatory framework.

8.8. Major structural re-organisations affecting the status in the Network should be communicated to the Network/EDQM.

9. Meetings of the GEON

9.1. Registration to meetings of the GEON is open to:

a) representatives of full members and associated members (observers only upon invitation);

b) experts invited for specific topics;

c) representatives from applicants to the Network upon invitation;

d) representatives from other organisations (e.g. World Health Organisation – WHO, Heads of Medicines Agencies - HMA), who might be invited to join certain sessions of the meeting either to provide their expertise or to be informed about the activities of the Network.

e) In addition, the following parties may participate in the meeting:

- The EU Commission;
- The EMA.

The participation and role of attendance of b) c) and d) will be discussed and determined by the GEON Advisory Group and communicated through official correspondence by the EDQM. The applications should be substantiated by a detailed summary of their activities and their potential contributions to the GEON.

9.2. The EDQM (representing the Council of Europe) participates in the meetings and provides the Secretariat of the GEON. Meetings of the GEON shall normally be held once a year and upon convocation, when necessary, in the case of emergency or special need, at the request of the Secretariat or by a majority of 2/3 of the member states. The Annual Meeting of the GEON shall be held in one of its member states preferably applying the principle of rotating location.

9.3 The chairs of the Annual Meeting of the GEON shall be members of the hosting OMCL together with the chairperson and other members of the AdG-GEON and representatives of the EDQM Secretariat.

9.4. The first draft agenda and documents for which a decision is needed at the meeting shall be prepared by the Secretariat in close collaboration with the Advisory Group and shall be sent to the OMCL contacts for comments. The Secretariat shall prepare a revised version of the document to be presented during the meeting, considering the comments received before the deadline. In case there are contradictory comments on an important aspect of the document, the AdG-GEON shall take a decision in consultation with the Secretariat.

The revised document shall be electronically distributed to the participants/contacts for information and presented at the Annual meeting for discussion. Additional concerns can be raised orally during the meeting and are considered for the finalisation of the document, which (as a rule) is redistributed within the Network for adoption after the meeting. The document is adopted by consensus (for definition see below).

Documents that are finalised far from the date of the Annual meeting may be adopted only by correspondence, without being tabled at the meeting. This is the common document adoption process.

9.5. The agenda shall be adopted at the beginning of each meeting.

9.6. Each member of the GEON prepares, dependent on the scope of activities, an Annual Report based on the documents "Model Format and Content of the OMCL's Annual Reports (non-OCABR/OBPR Activities)" or "Control Authority Batch Release of Vaccines and Blood Products – Annex V" / OCABR Vet/OBPR: Annual Report Model. These reports shall be circulated to the other members of the respective specific networks following the appropriate access restrictions at least 2 weeks before the Annual Meeting.

9.7. Within the 4 weeks following the date of the meeting, the meeting report shall be circulated to all participants for comments and adopted by written procedure. If relevant comments are made, these shall be dealt with at the next meeting of the Advisory Group.

9.8. All final documents will be circulated to the whole Network and placed on the corresponding IT platforms and, where relevant, on public websites.

10. Operating mechanism

10.1. The work programme on basis of proposals from the Advisory Group will be defined at the Annual Meeting of the GEON. If applicable, additional proposals can be made by any Network member during the year in written form.

10.2. Decisions within the GEON shall be allowed only if a majority of the member countries represented in the Network, are present.

10.3. Decisions are taken whenever possible by consensus. In conjunction with decisions taken in the remit of the OMCL Network, consensus means that there is a common agreement within the Network, which is understood as lack of an active opposition against the decision by any member state. If no agreement is reached the item has to be re-discussed. For further details see **Annex 8**.

In case that it is decided for a specific issue to vote, the principles as laid down in **Annex 8** apply. Associated members as well as the EDQM, the EC and EMA representatives are not entitled to vote.

10.4. The GEON adopts and updates its Terms of Reference either at the Annual Meeting or by correspondence based on the principles laid down in the document "Management of OMCL Network documents and records by the EDQM".

10.5. The GEON creates an Advisory Group, which is elected at the Annual Meeting (see document "Policy for electing members of the Advisory groups within the General European OMCL Network of the Council of Europe"). Between the Annual Network Meetings, the Advisory Group prepares and implements the work programme (work plan) based on the proposals of the GEON. It reports back to the Network about the achievements during the year on the occasion of the Annual Meeting.

10.6. Within the GEON, there exists subgroups (specific networks) for specific purposes such as the EU/EEA CAP testing, the EU/EEA MRP/DCP-product testing and the OCABR for human and veterinary medicinal products. These specific networks may have restricted access criteria for members as defined by their activity, e.g. EU/EEA members only (see also Chapter 5). Each subgroup decides on its specific activities during its Annual Meeting and based on this, a work programme is established and implemented during the year. Topics of general interest are referred to the GEON. For each subgroup a separate Advisory Group is created, if required. Each specific

network through its Advisory Group prepares its own Terms of Reference. The Advisory Groups of the specific networks shall hold their meetings in Strasbourg unless otherwise justified. These meetings shall be held as closed sessions. All members of OMCL Advisory Groups need to sign the document "Declaration of Interests and confidentiality undertaking of the European Directorate for the Quality of Medicines and HealthCare (EDQM) Group of Experts, Working parties, Committees and staff".

10.7. For the elaboration of specific technical documents, a drafting group (or working groups) composed of representatives of the affected subgroup with particular expertise in the respective field might be established. The result of the work as a rule is passed through the appropriate Advisory Group before formally adopted by the corresponding specific network or GEON as the case may be.

10.8. Where applicable, items identified as of common interest to all Advisory Groups and the GEON are exchanged between the groups to reach agreement on a document prior to circulation to the whole GEON.

10.9. In case of an incident[3] *, the OMCL Network Incident Management procedure,* PA/PH/OMCL (11) 159 in its current version*, could be applied and an Incident-Specific Working Group appointed.*

11. Cooperation with external partners

The GEON or its specific networks may decide to hear the representatives of associations including industrial ones, or scientific institutions.

If required, co-operation with other relevant organisations (e.g. WHO, HMA) may be sought.

12. Duties of the Secretariat (EDQM-ICND/OMCL Market Surveillance and QA Section)

The Secretariat is provided by the EDQM – Intergovernmental Committees and Networks Department (ICND – OMCL Market Surveillance and QA Section).

The Secretariat shall provide all administrative support necessary to co-ordinate the activities of the GEON. On behalf of the GEON

12.1. It shall liaise with the relevant national authorities and, where applicable, with European Institutions and International Organisations and with Marketing Authorisation Holders, manufacturers and industry associations in general within the framework of the activities related to the GEON;

12.2. It shall organise the Annual Meeting and any specific meetings or scientific symposia, and be responsible for establishing meeting reports and taking any necessary follow-up measures as outcome of decisions made during the meetings;

12.3. It shall co-ordinate the annual programmes (different testing programmes, MJV/MJA programme, PTS programmes...), peer reviews and studies on topics of particular interest and follow up all decisions taken;

[3] For definition of an "incident" see the procedure in question.

12.4. It shall assist in fulfilling the responsibilities of the GEON as described under Chapter 7;

12.5. It shall issue an Annual Report of its activities as part of the activity report of the EDQM which is published on the EDQM website;

12.6. It shall make documents elaborated by the GEON public, if endorsed by the Network.

13. Ownership of data, confidentiality, and personal data protection

13.1. Ownership of data

The Secretariat is not responsible for deciding about the property of results of tests performed within the frame of the GEON or specific network activities (unless otherwise defined).

Taking the above into account, as a rule, and provided that nothing else has been decided in advance by the involved parties (e.g. in context of sample exchange in the MRP/DCP product testing scheme or the CAP Sampling and Testing Programme, etc.), it is the responsibility of the Competent Authority of the Member State in which the results were generated to follow the applicable community or national legislation in place to deal with this matter or to define rules of responsibilities in case there is not an existing legal frame. It is up to the relevant Competent Authority to take legal measures and to follow them up in case there are infringements of the rules governing medicines or, where applicable, other relevant rules (e.g. with respect to medical devices).

13.2. Prohibition to disclose confidential information

Documents and data generated by or received from the OMCLs and Secretariat or received from third parties in the context of Network activities and shared with Network members are for confidential exchange within the Network and/or with Competent Authorities.

Persons receiving documents and/or data in the above context as well as other persons assisting the coordination of the Network are required to maintain confidentiality of the documents and/or data of the Network and parts thereof as well as of the information of which they have become aware at meetings. They shall not disclose it to any third persons not involved in the activities of the Network or persons who have not signed a relevant confidentiality agreement, unless the concerned group/OMCL(s) decide(s) otherwise, or they are openly available, or have been received, without restriction, via other channels. If all participants of a study or all concerned Network members that have produced a document agree unanimously, data and/or the document or their parts may be published on behalf of the GEON or the concerned group. In such cases the concerned group/OMCL shall determine the necessity to anonymise data sets/parts of text depending on the forum for publication.

13.3. Personal data protection rules

Where personal data is processed by EDQM within the framework of GEON activities, protections and rights will be applied in compliance with Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data or the enhanced Convention 108 or any other regulation for the protection of data as applied by the Council of Europe.

14. Finances

The expenses of co-ordinating and running the activities of the GEON are borne by a financial contribution of the EC and the Council of Europe.

15. Structure of the Network

Below the current structure of the GEON and its specific networks is summarised in a chart.

16. Glossary

ACAA: EU-Israel Conformity Assessment and Acceptance of Industrial Products
CAP: Centrally Authorised Product
DCP: Decentralised Procedure
EC: European Commission
EDQM: European Directorate for the Quality of Medicines & HealthCare
EEA: European Economic Area
EMA: European Medicines Agency
EU: European Union
GEON: General European OMCL Network
HMA: Heads of Medicines Agencies
ICND: Intergovernmental Committees and Networks Department
IEC: International Electrotechnical Commission
ISO: International Organisation for Standardisation
IVMP: Immunological Veterinary Medicinal Product
MJA: Mutual Joint Audit
MJV: Mutual Joint Visit
MoU: Memorandum of Understanding
MRA: Mutual Recognition Agreement
MRP: Mutual Recognition Procedure
MSS: Market Surveillance Study
OCABR: Official Control Authority Batch Release
PTS: Proficiency Testing Scheme/Study
OBPR: Official Batch Protocol Release
QMS: Quality Management System
ToR: Terms of Reference
VBRN: Veterinary Batch Release Network
WHO: World Health Organisation

17. List of Annexes of the GEON Terms of Reference

Annex 1: Definition, role and status of OMCLs of the GEON*; PA/PH/OMCL (07) 89 (current version).*

Annex 2: Factors for determining OMCL status within the GEON and QMS requirements for OMCLs*; PA/PH/OMCL (07) 90 (current version).*

Annex 3: List of GEON members*; PA/PH/OMCL (09) 45 (current version).*

Annex 4: Questionnaire to query the OMCL Status of members and applicants to the GEON*; PA/PH/OMCL (08) 04 (current version).*

Annex 5: Maintenance of Membership to the GEON*; PA/PH/OMCL (10) 93 (current version).*

Annex 6: Application for New Membership to the GEON*; PA/PH/OMCL (09) 83 (current version)*

Annex 7: Mutual Recognition of Test Results*; PA/PH/OMCL (16) 49 (current version)*

Annex 8: Policy in case of exceptional voting; *PA/PH/OMCL (15) 99 (current version).*

18. References

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

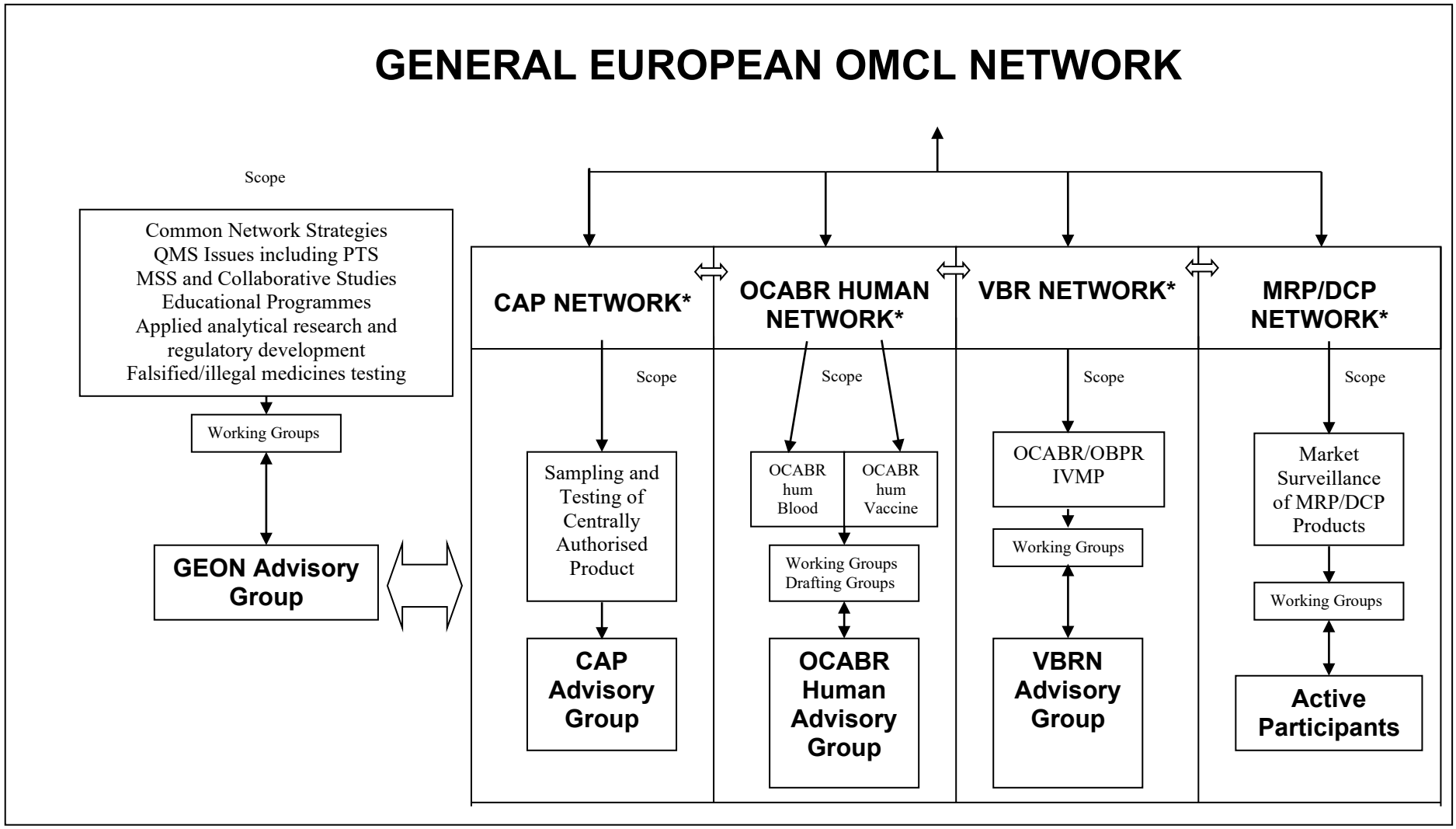
Flexibilisation of the accreditation area:

EA-2/15 M: 2023 (translation 2024): "Requirements of the EA for the accreditation of flexible scopes"

Cross-border accreditation procedures:

EA-2/13 M: 2019 (translation 2021): "EA policy on cross-border accreditation and procedures for cross-border co-operation of EA members"

Regulation (EU) 2018/1725 on the protection of natural persons



* EU specific activities restricted to EEA community members and Mutual Recognition Agreement (MRA) partners where relevant Indicate Interactions