

OMCL Network of the Council of Europe

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**Complementary Mutual Joint Audits in OMCLs
accredited against ISO/IEC 17025**

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Position Paper of the GEON

Introduction

According to the terms of reference of the General European OMCL Network (GEON), the voluntary sharing of work, competences and results relies on the principles of mutual confidence and recognition and is based on a common approach regarding the quality management system and on the acceptance of harmonised working procedures. The same document lists among the responsibilities of members of the Network, *“Acceptance of external audits covering ISO/IEC 17025 and specific Official Medicines Control Laboratory (OMCL) Network guidelines including an appropriate evaluation of both the technical level and managerial level covering aspects of independence, confidentiality and conflicts of interest for all internal and subcontracting activities”*. In addition, the European Pharmacopoeia is another commonly agreed standard of the Network.

To become and stay member of the GEON, an OMCL has to conform to the above quality standards. An OMCL has currently two alternative ways, accreditation or Mutual Joint Audit (MJA), to present its conformance. It is up to an OMCL if the accreditation, the MJA or a combination of both is chosen. In ideal cases, but no mandatory, each OMCL being a member of the Network should have undergone an MJA once, whenever the accreditation system is preferred as regular surveillance tool.

Accreditation and MJA

Accreditation

Accreditation is performed according to Regulation (EC) 765/2008 by national accreditation bodies (NABs). Accreditation has a legal basis, is internationally well-known and recognised also outside the OMCL Network. Some OMCLs are obliged by national law to undergo accreditation. An OMCL under accreditation has to provide evidence to the accreditation body that it conforms to the ISO/IEC standard 17025 and to other standards which are part of the QMS (including the specific guidelines elaborated and adopted by the Network and the Ph. Eur.).

From the OMCL Network point of view, exclusive accreditation has some weaknesses:

- The OMCL Network documents are not the main focus of an accreditation audit and are not necessarily taken into consideration.
- The national accreditation bodies have to deal with a large range of areas and products. This means that the NABs need a vast range of expertise and experts for the various audits and might have difficulties finding suitable auditors for OMCLs.

Mutual Joint Audit

The MJA is an OMCL-specific assessment that focuses more on the tasks characteristic of an OMCL but is also based on the above mentioned standards. The system of MJAs is well-known within the OMCL Network and is therefore regarded as the best adapted and cost effective tool to demonstrate the competence of a laboratory to the peers within the Network and thus obtain and maintain a documented quality status within the Network.

The MJA audits reflect the various scopes and specific obligations of the OMCLs which are members of the Network. MJAs performed by the EDQM together with auditors coming from the OMCL Network are highly accepted by the OMCLs due to the auditors' in-depth knowledge of the specific scopes of the audited OMCLs. This is extremely important for the technical part of the audit. Since the MJA-auditors come from other OMCLs and from the EDQM, the diversity of assessments is expected to be less than among those performed by the national accreditation bodies. It is also advantageous that the MJA auditors are trained at EDQM to harmonise the decision making process during MJAs. Therefore, MJAs are supposed to ensure a higher level of harmonisation in the application of quality standards and guides within the OMCL Network.

From the OMCL Network point of view, exclusive MJA has some weaknesses:

- the MJA auditors are not necessarily aware of specific national regulations and the communication language is not necessarily the official one of the OMCL.
- MJA is not widely known and recognised outside the Network.

Mutual recognition of Accreditation and MJA

Both accreditation and MJA have their advantages and some laboratories of the Network have either accreditation or MJA, whereas others have undergone both assessments on a voluntary basis.

In order to rationalise the assessment by the two systems (accreditation and MJA), negotiations between OMCLs, the EDQM Secretariat and representatives of the European Cooperation for Accreditation (EA) have re-started in 2012 aiming at combining the benefits of accreditation and MJA in an optimal way to avoid duplication of work by joining forces of the two. To support these efforts a position paper has been established by two members of the Advisory Group of the GEON (*PA/PH/OMCL (12) 63*) to be used in the discussions with the EA¹. Meanwhile the Laboratory Committee, which is a body of the EA, and to which the EDQM has observer status, has signalled "to support developing cooperation between the NABs and the EDQM based on the sharing of audit results. Common audits could also be performed when the scheduling allows them and the assessors are qualified by both the NAB and the EDQM, that is to say when the team composition is agreed by both the NAB and the EDQM."²

¹ This document is available to the Network members via OMCLnet.

² Extract from the minutes of the 24th EA Laboratory Committee Meeting, 19th-20th September 2012, Oslo, Norway.

For OMCLs such joint audits could become a resource effective way to demonstrate the reliability of their work for customers and authorities both within and outside the OMCL Network. Thus, the OMCLs are encouraged to start the discussion with their national accreditation bodies to foster joint audits.

Complementary MJA for Accredited OMCLs

Within the Network accreditation and MJA are acknowledged as equivalent. Nonetheless, with the adoption of Annex 5 of the Terms of Reference, *PA/PH/OMCL (10) 93* in its current version, which regulates measures to monitor the membership of OMCLs of the Network, gaps of some accredited Network members with respect to transparency have become evident. It should be pointed out, that transparency within the Network, based on open and detailed communication between the OMCLs and with the EDQM regarding the QMS is a prerequisite of mutual recognition of results and effective information exchange within all cooperation tools. In this context, some hurdles still need to be overcome:

- Although it is stated in the terms of reference that 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 the Network/EDQM for transparency purposes. Currently this is not always followed by some Network members.
- The same applies to the questionnaire to query the OMCL status of present and future members of the GEON, Annex 4 of the ToR, *PA/PH/OMCL (08) 04* in its current version, which is used as a working document in preparation for MJAs, but, although requested, is not necessarily completed on a regular basis by accredited OMCLs.
- In addition, accredited OMCLs are not obliged to send their accreditation audit reports to the EDQM, which would be an important tool to monitor the QMS of Network members. These reports are issued by the NABs and as (co-)property of the NAB and the OMCL are often not intended for further distribution.
- Experiences in the last years with accredited OMCLs which volunteered to pass an MJA have shown that the audits by NABs in Europe are not yet harmonised. In addition, in a number of OMCLs the scope of accreditation is too restricted to cover the obligations of OMCLs with respect to independent testing of medicines. Finally, for OMCLs which are embedded in complex organisational structures, it is not always evident to which extent the units, which represent the OMCL, have been audited during accreditation audits of the whole organisation and whether the specificities of testing of medicines have been sufficiently taken into account.

Conclusion

For all these reasons, accredited OMCLs of the Network are invited to negotiate with their NABs to perform joint audits which is in line with the agreements made with the EA, and where this is not possible, to try to target at least one separate MJA.