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Joint EA - EDQM Communication regarding cooperation when carrying out (joint) audits/assessments in Official Medicines Control Laboratories

PURPOSE

This publication provides comprehensive information on the agreed cooperation between EA and EDQM at avoiding duplication of assessments of OMCLs.

Authorship

This document has been written by the EA Laboratory Committee.

Official language

The publication may be translated into other languages as required. The English language version remains the definitive version.

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Further information

For further information about this document, contact the EA Secretariat. Please check the EA website for up-to-date information (http://www.european-accreditation.org).

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1. INTRODUCTION

Official Medicines Control Laboratories (OMCLs) operate as independent control authorities of the quality of medicines, in the framework of the Council of Europe convention on the elaboration of a European Pharmacopoeia and of the Directive 2001/83/EC ("human code") and Regulation (EU) 2019/6 ("veterinary code"), as amended.

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is responsible for the elaboration of the European Pharmacopoeia, a single reference work providing the legal and scientific basis for the quality control of medicines, mandatory through legal texts in the signatory states of the European Pharmacopoeia Convention.

The EDQM is also co-ordinating the work of the European Network of Official Medicines Control Laboratories (OMCLs), set up under the aegis of the Council of Europe with financial support of the European Commission.

The European co-operation for Accreditation (EA) is an association of national accreditation bodies in Europe that are officially recognised by their national Governments to assess and verify - against international standards - organisations that carry out evaluation services such as certification, verification, inspection, testing and calibration (also known as conformity assessment services).

EA has been formally appointed as the body responsible for the European accreditation infrastructure in Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, Article 14, paragraph 6. Prerequisite for the mutual acceptance of testing results by the OMCL Network laboratories and the fulfilment of their mission is their commitment to set up and maintain QM systems based on ISO/IEC 17025 and complementary documents (see below).

In order to ensure full compliance with this standard, the OMCLs have committed to undergo either national accreditation or to follow a commonly agreed peer review process (Mutual Joint Audit - MJA) operated by EDQM. In many cases OMCLs adhere to both processes. Considering that EA mission is to provide, through its members, effective and reliable accreditation service fulfilling at best the needs of the European economy and society, to consolidate and strengthen the Multilateral Agreement of its Members (MLA), and to promote the establishment of agreements on mutual recognition of accreditation activities at international level, both, EA and EDQM have established a recognized cooperation by a Recognized Stakeholder Agreement dated 03 July 2013. Meanwhile, regular exchange of experience with respect to (joint) audit/assessments performed in OMCLs have been established and several joint audit/assessments between NABs and EDQM have been carried out.

2. SCOPE

Further to the Recognized Stakeholder Agreement, this communication provides comprehensive information on the agreed cooperation between the two organizations aiming at avoiding duplication of assessments of OMCLs, while at the same time respecting EAs and EDQMs own rules and policies.

3. PRACTICAL MECHANISM FOR COOPERATION INCLUDING RESPONSIBILITIES AND ROLES FOR (JOINT) AUDIT/ASSESSMENTS

EDQM and EA encourage the conduct of joint audit/assessments, where this is feasible and accepted by the OMCL.

These joint audit/assessments are triggered upon proposal by the audited OMCL. EDQM and NAB aim at early communication to establish common grounds for a harmonized audit process, in terms of principles and administrative tasks.

Important practical considerations are listed in Annex 1.

Confidentiality policies of NAB and EDQM will apply to joint audit/assessment.

4. RELEVANT DOCUMENTATION FOR (JOINT) AUDIT/ASSESSMENTS CONDUCTED IN OMCLS

For any audit/assessment in OMCLs, the following references should be used.

The OMCL Network members are obliged to implement and maintain a quality management system based on ISO/IEC 17025. This means that for accredited laboratories policies and procedures of EA and NAB are applied, supplemented by a number of QM guidelines specifically developed and unanimously adopted by the OMCL Network. These guidelines can be downloaded in its enforced versions from the EDQM website: https://www.edqm.eu/en/quality-management-qm-documents

Moreover, the application of the legally binding texts of the European Pharmacopoeia has been agreed as common scientific-technical basis of the work of the OMCLs.

5. RESPONSIBILITIES AND ROLES FOR JOINT AUDIT/ASSESSMENT

The national accreditation body (NAB) as well as the EDQM remain solely responsible for their own audit/assessment process and the issuing of relevant accreditation certificates / MJA attestations.

However, where possible and agreed, both parties may benefit from sharing tasks throughout the preparation, audit and reporting process.

Where possible, non-conformities will be established and followed-up commonly. Cross-references to documents established by either party are considered acceptable.

6. REPORTS

After joint audit/assessments, the national accreditation body and the EDQM exchange their final reports, if done separately.

Agreement for this practice should be requested from the auditee, when joint audit/assessment requests are stated.

7. EXCHANGE OF INFORMATION AND COMMON TRAINING

EA and the EDQM share on a regular basis experiences on conducted joint audit/assessment during the meetings of the Laboratory Committee (LC).

Joint training programs for auditors could be organized by EDQM and the NABs.

Also exchange of information concerning suspension / withdrawal of accreditation of an OMCL is considered important.

ANNEX 1 – PRACTICAL CONSIDERATIONS

For the preparation and conduct of joint audit/assessments, the following points should be subject of discussion and agreement:

- ***Contact person*****:** assign a contact person from both parties and define who initiates the arrangements (the contact person should share the relevant information instantly and keep the other party in copy on the email exchanges).

- ***Audit/assessment date:*** a date for the audit/assessment should be agreed well in advance (ideally 6 months ahead).

- ***Scope of the audit/assessment:*** it needs to be clarified which type of audit/assessment the NAB is planning (Initial Assessment/Surveillance/Reassessment/Extensions) and which areas of the norm/techniques are covered.

- ***Duration and organization of the on-site assessment*** preparatory discussion between auditors before the audit can be conducted by meeting, teleconference or email. Typically EDQM carries out the audit in three days as follows:
  - Opening meeting ;
  - Two days of parallel QMS/technical audit/assessment ;
  - Compilation of non-conformities and drafting the report (including presentation in a closing meeting) on the 3rd day ;
  - Presence of the NAB team for whole audit/assessment to be confirmed. Ideally the joint audit/assessments should be organized when the NAB performs a full audit/assessment; for other audits/assessments at least the closing meeting should be conducted together.

- ***Team composition:*** The MJA audit team is typically composed of one coordinator from EDQM who is either a QMS auditor or a technical auditor and auditors from the OMCL Network. The number of auditors depends on the scope of the audit/assessment. The NAB decides about the size and composition of its team (appropriate to the scope of the assessment). In case the NAB opts for a reduced size team, it may recognize the EDQM QMS and/or technical auditors as qualified experts, according to NAB procedures. On a regular basis they perform MJAs within the OMCL Network. EDQM organizes in addition workshops for OMCL auditors. The potential inclusion of observers and trainees must be agreed by both parties (EDQM and NAB).

- ***Audit/Assessment agenda:*** the audit requests should be shared in order to sort out a common audit plan and draft a common agenda ahead of the audit, if possible.

- ***Preparatory documents:*** a common list of documents to be requested from the OMCL in preparation of the joint audit/assessment should be established. Reports from previous audits/assessments could be shared between the EDQM and NAB subject to the agreement by the audited OMCL.

- ***Language:*** EDQM conducts the audit and establishes the report in English, the NAB determines the language of its report, if different from the EDQM report.

- ***Reference documents:*** relevant EDQM documentation (see above). Applicable National Accreditation Body documentation has to be considered.

- ***Harmonization of non-conformities:*** consistency of non-conformities found by EDQM and NAB during the audit should be checked in order to achieve a common agreement, if possible before the closing meeting and reporting.

- ***Reporting:*** in order to facilitate the process (e.g. OMCL follow-up) drafting of a single audit report for an optimal use of resources/time (i.e. OMCL follow-up) is preferred; in the EDQM system only one report is produced on site with the possibility to make editorial amendments of the text within one month after the audit. In the situation of a joint audit/assessment, reporting is agreed between NAB and EDQM. However, wherever feasible, a common report should be the target.

- ***Agreement on proposed actions:*** in the EDQM audit system non conformities (NCs) are agreed at the closing meeting. Each NC is transcribed from the report into a NC form which is sent to the auditee (no later than one week after the audit), for the proposing actions within 4 weeks. These are sent to the auditors for approval. The procedures and policies of the NAB and EDQM will apply.

  For the submission and acceptance of actions a decision has to be made in advance to define if each party follows their own forms and timeframes or if it is possible to harmonize the procedures (e.g. agree to use the NC form of the other party or agree to use the more stringent deadline for the date of implementation).

- ***Responsibilities for follow-up:*** the actions taken as a result of non-conformities should be approved by the responsible auditor.

- ***Timelines for follow-up:*** EDQM releases the MJA attestation to the OMCL audited only after all the actions are implemented, which should typically occur within 8 months from the approval of the non-conformity forms (including respective actions). The procedures and policies of the NAB will apply. Ideally EDQM and NAB should ensure that the deadlines for implementation of actions are compatible to finalize both audit/assessment processes. In case of discrepancies in a joint audit/assessment situation, the policy of the party suggesting more stringent timelines for the implementation of NCs should be followed (see also item “agreement on proposed actions”).