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

Funded by the European Union and the Council of Europe

EUROPEAN UNION

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Implemented by the Council of Europe

OMCL Network of the Council of Europe

GENERAL DOCUMENT

PA/PH/OMCL (16) 49 R2

GEON Terms of Reference
Annex 7: Mutual Recognition of Test Results

Full document title and reference	Annex 7 to the GEON Terms of Reference: Mutual Recognition of Test Results PA/PH/OMCL (16) 49 R2
Document type	Annex to Terms of Reference
Legislative basis	Council Directive 2001/83/EC and 2001/82/EC, as amended
Date of first adoption	May 2016
Date of original entry into force	May 2016
Date of entry into force of revised document	September 2021
Previous titles/other references / last valid version	/
Custodian Organisation	The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
Concerned Network	GEON

Annex 7 to GEON Terms of Reference:

Mutual Recognition of Test Results

Introduction

Mutual recognition of test results is one of the key principles of the OMCL Network and a key component of a collaborative approach to the sampling and analysis of medicinal products between Medicines Agencies / Competent Authorities (CAs). Sharing of workloads and acceptance of results is necessary for the success of this collaboration. It must be possible for CAs to take appropriate regulatory action on the basis of reports they receive from OMCLs without further confirmatory testing otherwise the concept of work sharing and collaboration fails.

Within the OMCL Network, mutual recognition of test results is based on the principles that Laboratories will operate common quality standards (ISO/IEC 17025 and OMCL network guidance documents as well as Ph. Eur. for full members), will be subject to external and peer audits (by National accreditation bodies and/or through the Mutual Joint Audit programme) and will share information and intelligence within the Network. These principles extend across the entire OMCL Network and generally enable mutual recognition of test results. For certain activities of the network, e.g. OCABR and inspection activities (outlined below), there are existing legally established principles within the EU/EEA member states.

The Legal Framework for Mutual Recognition of Control Results

OCABR

Mutual recognition of OCABR test results is established within the framework of Directive 2001/83 as amended by Directive 2004/27/EC in the context of the OMCL Network and the Official Control Authority Batch Release (OCABR) of human vaccines and medicinal products derived from human blood and human plasma. It is thus a legally based mutual recognition that applies in EU/EEA member states. It also applies in any countries with a formal agreement with the EU covering OCABR e.g. Mutual Recognition Agreement (MRA), Agreement on Conformity Assessment and Acceptance (ACAA). Article 114 of the Directive allows CAs to require that MA holders submit samples of individual batches of the products concerned to an OMCL or an equivalent designated laboratory for testing prior to release to the market. Furthermore, where such tests have been performed in one Member State, the results must be recognised in all other Member States.

A similar approach to the above is outlined in paragraphs 3-9 of Article 128 of Regulation (EU) 2019/6 on veterinary medicinal products, which replaces Article 82 of the Directive EC 2001/82 as amended. In addition Article 128, paragraph 1, which replaces Article 81 of that Directive, governs Official Batch Protocol Review (OBPR) of IVMPs and CA/OMCLs have agreed to mutually recognise the certificates based on this protocol evaluation.

Inspection activities

Article 111 of Directive 2001/83 as amended establishes the principle of surveillance of quality of medicines by means of GMP inspections. Within this article the CA is also empowered to take samples for independent analysis in an OMCL or equivalent designated laboratory. Information sharing and mutual recognition of inspections is achieved through certificates of GMP and the EudraGMP database as detailed in sub-paragraphs 6 and 7 of Article 111. Further requirements for communication of information from inspection reports, Article 40 manufacturing authorisations, Article 77 wholesale dealing authorisations and GMP certificates, are specified in Article 122 of the Directive.

Other than the OCABR batch release, and the inspection activities, there is currently no legislative provision for mutual recognition of laboratory testing.

CAP Sampling and Testing

The Centrally Authorised Product (CAP) sampling and testing programme is an annual post-marketing surveillance exercise sponsored by EMA, coordinated jointly by EMA and EDQM, and performed by OMCLs within the EU/EEA Network. It is based on EC Regulation n° 726/2004, Article 57, as amended and focuses on the quality testing of products which have undergone the centralised authorisation procedure. Test samples, which are collected from the EU/EEA market along the distribution chain, preferably as closely as possible to the patient, may include biological or chemical CAPs with the exception of human biologicals, which are covered by the Official Control Authority Batch Release (OCABR) Procedure and IVMPs from the restricted list of OCABR. Follow-up measures are coordinated by EMA.

The programme, which was implemented in 1998, is based on the principle of work sharing and mutual recognition of test results, and has been adopted by all 31 EU/EEA member states. For each product, as a rule one or two control laboratories carry out the tests, according to a fixed protocol based on the marketing authorisation application. The results are mutually recognised by all EU/EEA member states.

Cooperation in post-marketing surveillance of MRP/DCP products

The CAs can take advantage of work sharing for the sampling and testing of mutual recognition procedure (MRP) products and decentralised procedure (DCP) products by communicating work programmes and mutually recognising shared test results to confirm compliance with registered specifications covering the range of products on the different markets.

For these market surveillance activities of the Network (quality control of CAP, MRP, DCP products) mutual recognition works on basis of a goodwill agreement.

Exceptions to Mutual Recognition Policy

Mutual recognition has become possible due to the establishment of Quality Management Systems in the laboratories of the Network based on a commonly agreed standard which are regularly monitored by external experts. This reduces the duplication of effort and should be encouraged. However, there will be situations where it is necessary to perform additional analysis or to confirm the results of the original analysis when regulatory action needs to be taken against a manufacturing, wholesale dealing or marketing authorisation. As with inspection reports sharing of analytical reports should nevertheless be established for these situations.

The one area where sharing of samples and mutual recognition of results may not be possible is for forensic or illegal samples. Continuity of evidence is of major importance with such samples and laboratories handling such samples need to be familiar with and comply with these requirements. Under these circumstances it is sensible and logical for such samples to be handled within the control system of individual Member State so that the individual legal requirements in Member States are met. If it is necessary to transfer such samples between OMCLs then it is the responsibility of the parties concerned to ensure that the requirements are complied with.