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Co-operation in Post-Marketing Surveillance of MRP/DCP Products

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CO-OPERATION IN POST-MARKETING SURVEILLANCE OF MUTUAL RECOGNITION/DECENTRALISED PROCEDURE PRODUCTS

Introduction

Within the EU/EEA countries of the OMCL Network (GEON), a voluntary post-marketing surveillance (PMS) scheme exists for medicinal products that have received a marketing authorisation via the Mutual Recognition Procedure (MRP) or the Decentralised Procedure (DCP).

Once placed on the market, responsibility for quality surveillance of these products lies with each member state. However, since marketing authorisations are based on identical dossiers (including specifications), there is scope for co-operation at EU/EEA level regarding independent official control of MRP/DCP products.

The main purpose of the PMS scheme is to improve surveillance work through two core principles:

1. Work-sharing by sharing in advance the market surveillance projects and per se avoiding as much as possible testing the same product in different countries. This also facilitates exchanges of samples when possible.

2. The sharing of test results provides individual member states and other relevant bodies (e.g. Heads of Medicines Agencies) with a better overview of the quality of MRP/DCP products on the EU/EEA market. By benefitting from the surveillance work already done on MRP/DCP products by other OMCLs, it also allows individual member states to allocate more resources to the testing of other medicinal products.

Confidence in the reliability of testing results is necessary for the fruitful sharing of work and results. This is assured by the fact that the GEON maintains a quality management system (QMS) that is harmonised for all OMCLs and implemented in accordance with the ISO/IEC 17025 standard.

A risk-based approach is encouraged when selecting products for testing. A risk-assessment and test recommendation tool, developed by an HMA working group involving OMCL representatives, has been available since 2020. It currently focuses on pre-authorisation risk factors but will be extended to incorporate post-marketing risk factors, sourced, for example, from assessments of variations, GMP inspections, quality defect reports, pharmacovigilance activities and findings from testing of similar products from assessments of variations, GMP inspections, quality defect reports, pharmacovigilance activities and findings from testing of similar products.

Scope

This document is a reference document describing the principles of the MRP/DCP product surveillance scheme related to:

- elaboration of Periodic Surveillance Work Programmes (PSWP),
- sampling and testing,
- reporting and sharing results,
- follow-up activities.

Elaboration of Periodic Surveillance Work Programmes

The participating OMCLs enter their testing plans into the MRP/DCP product testing database by listing MRP/DCP products they intend to test during the forthcoming surveillance period.

Testing plans can be accessed online at any time by OMCL database users with access rights and can be discussed between participants to avoid unnecessary overlaps/repetitions and to make other organisational arrangements. When a product is on the market of the reference member state (RMS) or a member state where crucial production steps take place, testing of the product in the OMCL of that member state will facilitate follow-up activities related to the dossier or inspections, respectively.

By directly amending the relevant information in the database, participants can communicate any adjustments to the periodic surveillance programme.

Additional products can be added, and the testing of already entered products can be amended, cancelled or put on-hold.

Sampling and Testing

The testing OMCL can set up a sampling acceptance deadline in the database and allow other member states to report their interest in sending products from their market for testing. Sample size, testing parameters, schedule for testing, etc. are agreed upon bilaterally.

Sampling in more than one member state is encouraged, because it gives a broader view of the quality of the products on the EU/EEA market and at the same time makes optimal use of resources since only one OMCL has to set up the method. Furthermore, sending samples for testing permits OMCLs that might lack certain techniques necessary for the testing of a product to still have it in their testing plan.

Because the testing laboratory receives no economic compensation for the work of analysing extra samples, it is essential that each laboratory takes care to maintain a good balance between samples sent out and samples received for testing. Ideally, the average number of

samples sent out to other OMCLs for testing over a number of years should equal the number of samples tested for other OMCLs to maximise the benefits of the PMS scheme.

OMCLs test the products using approved MAH methods or other methods validated in accordance with OMCL Network QA principles, such as pharmacopoeial methods but also screening methods.

Reporting and Follow-up

At the end of the testing, a full test report is sent to the sample providers. As soon as possible after completion of the testing, the testing OMCL also inserts results for all samples into the MRP/DCP product testing database.

Any issues identified during testing are summarised by the testing laboratory in the database and follow-up actions and decisions can be added by the sampling and/or testing OMCL.

In general, follow-up activities are the responsibility of the national competent authority (NCA) of the member state where the product was sampled, but participants are encouraged to inform each other, where appropriate, of such activities.

In the case of issues concerning the content of the marketing authorisation dossier (unclear test procedure, mistake in a mathematical formula, etc.) the RMS for the procedure should be informed by the member state of the testing OMCL, unless otherwise agreed with the OMCLs that have provided samples for testing.

If, as an outcome of a testing campaign, a pharmacopoeial issue is identified, the European Pharmacopoeia Department (EPD) of the EDQM is contacted either by the NCA or the secretariat for further action.

Participants are also encouraged to report results from testing of MRP/DCP products even if not shared in advance as a periodic programme in the database.

Meetings

The progress and development of the MRP/DCP product surveillance scheme and the current periodic surveillance work programme are followed and discussed at one or more GEON meetings per year.

MRP/DCP Product Testing Database

The secretariat is the co-ordinator of the MRP/DCP product testing database, which contains product and test related information necessary to run the surveillance scheme. The product information is sourced from the common MRP/DCP database of the EU/EEA authorities, the Communication and Tracking System (CTS) used to coordinate MRP and DCP procedures.

The EDQM initiates and the OMCLs maintain for their own organisation a list of the MRP/DCP product surveillance contact persons, who act as administrative, sampling and testing contacts, etc. and who are also registered users of the database.

Users have access to the data via a secure portal. In addition, read-only access to the database is granted to quality assessors, inspectors and members of the pharmacovigilance units of NCAs of EU/EEA member states upon request.

Ownership of data, confidentiality and data protection

The NCA of the member state responsible for sourcing a sample is the owner of the data generated for this sample.

The information generated in the programme should only be used within the framework of shared responsibility for regulatory purposes.

In the case of external use/publication, the owner(s) of the data must be contacted to obtain an agreement.

Care has been taken to ensure that the database is compliant with EU General Data Protection Regulation 2016/679 (GDPR).

Glossary

Administrative contact: Person within an OMCL who serves as a contact point for general information related to the MRP/DCP product surveillance scheme.

Communication and tracking system (CTS): IT tool for licensing authorities to implement and run the mutual recognition and decentralised procedures.

GEON: General European OMCL Network.

MRP/DCP products = Mutual Recognition Procedure or Decentralised Procedure Products: Medicinal products that have been authorised in more than one EU/EEA member state using the procedures laid down in Article 27ff of Directive 2001/83/EC, as amended, or Articles 48 to 53 of the 2019/6 regulation (EU), as amended.

MRP/DCP product surveillance period **or** *testing period*: The time between finalisation of subsequent surveillance work programmes. Normally a calendar year.

MRP/DCP product testing database: A computer application that has been developed by the OMCL Network and the EDQM to serve as a common data tool for running the MRP/DCP product surveillance scheme.

OMCL: Official Medicines Control Laboratory.

Participant: OMCL participating in, contributing to or by other means being involved in the post-marketing surveillance scheme for MRP/DCP products described in this document. With respect to the MRP/DCP product testing database, the term participant comprises all

registered OMCLs (active and passive participants). The abbreviation used in this context is POMCL ("Participating OMCL").

***Periodic surveillance work programme*:** Compilation of testing plans from all participating OMCLs after potential duplication of work has been eliminated as far as possible.

Reference member state: The EU member state that leads the review of an application in a mutual recognition procedure or decentralised procedure.

***Secretariat*:** The secretariat of the Department of Biological Standardisation, OMCL Network & HealthCare (DBO) at the EDQM.

***Testing laboratory*:** OMCL that, according to the periodic surveillance work programme, will test an MRP/DCP product. The abbreviation used in this context is TOMCL ("Testing OMCL").

***Testing plan*:** OMCL plan for the surveillance of MRP/DCP products.