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Benefits of testing MRP/DCP products

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Benefits of the post-marketing surveillance scheme for the testing of mutual recognition/decentralised procedure products

Introduction

The testing scheme for post-marketing surveillance (PMS) of Mutual Recognition Procedure (MRP) products was initiated in late 2000 by the General European OMCL (Official Medicines Control Laboratory) Network (GEON) and the EDQM, the Network's secretariat. Following the implementation of the Decentralised Procedure (DCP) in 2005, the scope was extended to include products authorised under that marketing authorisation procedure.

It is a voluntary scheme, available to OMCLs from EU/EEA member states. The main objective is achieving a better co-ordinated surveillance approach for these medicines. The scheme is subject to ongoing development and improvement work.

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 in the field of independent official control of MRP/DCP products.

The scheme also includes testing of active substances (APIs) where OMCLs can share API samples and data on tested APIs and other substances for pharmaceutical use.

Benefits of the scheme

The value of this surveillance scheme is demonstrated by the number of OMCLs and member states that regularly participate. Since 2014, around 25-30 OMCLs from 20-25 member states have participated in the scheme each year.

Since it is designed around the principles of work-sharing and sharing of test results, the scheme helps to make best use of available laboratory resources and capacity across the OMCL Network. When planning their testing programmes, OMCLs can check whether the MRP/DCP product has recently been tested with satisfactory results by another OMCL and then decide to focus instead on MRP/DCP products that have not been tested recently. It is a practical approach to avoid duplicate testing of the same product and/or the same product batches in different member states. The scheme also has the added benefit of providing a tool that facilitates sampling of medicinal products in several markets at the same time.

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.

Another benefit of sample exchange collaboration between OMCLs is the knowledge gained about the different analytical competences and techniques available in the OMCLs, which is very useful for crisis management.

IT support and data distribution

The EDQM has developed and installed an IT SharePoint database, the MRP/DCP Product Testing Database, to support the scheme. It allows for co-ordination of planning, sampling

and reporting with respect to the surveillance of MRP and DCP products and also serves as a platform for information exchange on follow-up actions for non-satisfactory test results.

It also adds value in terms of data security and confidentiality. Access to the database is restricted to OMCLs actively involved in the scheme. However, read-only access to the surveillance data is granted to users of the Communication and Tracking System (CTS), staff members of drug regulatory departments and pharmacovigilance units in National Competent Authorities (NCAs), and to GMP/GDP inspectors.

Statistical evaluation of the scheme

The following statistics show the extent of usage of the scheme, as well as results and benefits:

By the cut-off date of 16/12/2022, a total of 17 284 surveillance projects had been recorded in the MRP/DCP Product Testing Database, and each year the number has grown by more than 1 200. A project is equivalent to the testing of one MRP/DCP product. Several batches can be tested in the same project; this often occurs when samples are exchanged between OMCLs. More than one OMCL might be involved in the testing of one product or a product group, for example where test parameters are split between OMCLs due to different competences. Sometimes a project has to be cancelled, for example if samples are not available.

Once product testing has been completed, the scheme enables rapid and widespread availability of market surveillance data to health authorities on the quality of medicinal products in their territories and across the EU.

Most MRP/DCP products are chemical products for human use, and the MRP/DCP surveillance scheme reflects this. Around 15% of the medicinal products tested in 2022 were veterinary vs 85% human, and about 98% contained chemical active ingredients.

The 10 most frequently tested APIs in 2022 were: Rosuvastatin, Tadalafil, Ramipril, Amlodipine, Ezetimibe, Olanzapine, Fipronil, Amoxicillin, Hydrochlorothiazide and Atorvastatin.

Out-of-specification results occurred in only about 2% of the products tested in 2022. This indicates a generally high level of quality and shows that procedures in place for assuring the quality of medicines on the European market, such as authorisation procedures and PMS testing, work well.

In addition, the scheme shows that it can facilitate continual improvements in the control of medicines across the EU. In about 2% of the projects registered in 2022, OMCLs identified issues with the authorised analytical methods used by the quality control laboratories of manufacturers. As it is not always possible to identify such issues during assessment of the marketing authorisation dossiers, the MRP/DCP scheme adds value in this area by allowing issues to be addressed and corrected by the MAHs concerned in a timely manner. Ensuring that well evaluated and suitable test methods are used by companies for the medicines that they produce contributes to the protection of public and animal health.

When comparing the total number of tested products marketed in member states to the number of products tested by each participating member state, there is an average gain of 9. This means that for each product a member state tests within the scheme, they can access results for 9 other products on their market. In addition to the national benefits,

the results of the scheme also provide information on the quality of medicines in the EU/EEA as a whole.

Outlook

One of the main goals of this testing scheme is to facilitate the exchange and testing of samples in targeted campaigns by individual OMCLs on behalf of the Network.

Despite several global crises in the early 2020s, the OMCLs have been able to maintain a high level of contribution to the scheme.

Sample exchange is beneficial for the participating member states; it allows OMCLs lacking certain analytical techniques necessary for the testing of a product to still have them in their testing plan. Analysing a series of samples from other countries together with samples from one's own national market is both cost-effective and labour-saving.

In 2020, new information related to the risk of product quality defects as well as testing recommendations from quality assessors became available via the MRP/DCP Product Testing Database (RATemp Tool). This contributes to a risk-based selection of products for PMS testing and strengthens the dialogue, in particular between assessors and OMCLs.

When registering a project, the OMCL has to open the related risk-based score template and is informed about the test recommendations made by the quality assessors, if any. As more MRP/DCP products have this template available, OMCLs will be able to improve their control planning taking into account the pre-authorisation risk-based score.

In the future, a post-marketing risk-based scoring system is planned to help OMCLs take into consideration all types of risk and focus their control testing on products presenting a higher risk. The ultimate objective is to improve the quality of medicinal products on the market.

The testing scheme is described in more detail in the document Co-operation in Post-marketing Surveillance of Mutual Recognition/Decentralised Procedure Products (PA/PH/OMCL (06) 116) in its current version, available on the EDQM website at https://www.edqm.eu/en/mrp/dcp-post-marketing-surveillance-scheme.

Note: This document represents a snapshot of the situation at the end of 2022. The figures given in the document are based on the statistics from that time and may change from one year to another.