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

Co-funded by the European Union

EUROPEAN UNION

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Co-funded and implemented by the Council of Europe

General European OMCL Network (GEON)
GENERAL DOCUMENT

PA/PH/OMCL (22) 110 R1

Benefits of the GEON MSS Programme

Full document title and reference	Benefits of the GEON MSS Programme, PA/PH/OMCL (22) 110 R1
Document type	Position Paper
Legislative basis	Council Directive 2001/83/EC and 2001/82/EC, as amended
Date of first adoption	**May 2023**
Date of original entry into force	**May 2023**
Date of entry into force of revised document	-
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

BENEFITS OF THE GEON MSS PROGRAMME

POSITION PAPER FOR OMCLs

Introduction

A Market Surveillance Study (MSS) is a specific type of surveillance programme operated by the General European OMCL Network (GEON). MSSs are collaborative studies organised within the GEON, in which a number of different Official Medicines Control Laboratories (OMCLs) test marketed medicines containing a defined active substance, using products available on their national markets. Such products may have a Marketing Authorisation (MA) issued under the national, Mutual Recognition or Decentralised Procedure (MRP/DCP), or in exceptional cases under the centralised procedure (CAP).

While MSSs are mainly focused on medicinal products, over the years the scope of the MSS programme has expanded to include active pharmaceutical ingredients (APIs, e.g. Clopidogrel, Telmisartan, Pramipexole, Liothyronine), herbal drugs (e.g. Liquorice root, Matricaria flower, Equisetum stem) and medical devices (e.g. Hyaluronic acid-based dermal fillers, Eye drops and Nasal preparations).

Since 1999, more than 60 MSSs have been organised within the Network and more than 4470 finished medicinal product samples have been tested in order to control the quality of medicines available on the European market.

Methods used in MSSs

The analysis of samples in an MSS is carried out according to a common protocol with screening methods for selected test parameters. The screening methods are usually developed by one OMCL and are intended to be suitable for a wide variety of different medicinal products containing the same active substance, sometimes across a number of different dosage forms. Thus, the ability of the sample preparation steps in the test method to extract the active substance from the matrix and get it into solution is important.

An initial method feasibility study is carried out by the scientific advisor for the MSS, based on the OMCL guideline on Validation and Verification of Analytical Procedures (PA/PH/OMCL (13) 82); this person is an expert from an OMCL that is participating in the MSS. The purpose of the feasibility study is to assess the suitability of the proposed screening method for use in the MSS, taking into account the range of medicinal products and dosage forms that may be involved. Where a proposed MSS method is based on the European Pharmacopoeia (Ph. Eur.) or on another pharmacopoeia, a feasibility study is still performed, as sometimes problems are identified with those methods and this can ultimately lead to the revision, and hence improvement, of those pharmacopoeial methods.

Benefits of the MSS programme

Quality control of medicines on the European market

The MSS programme has shown that the quality of medicines available on the European market is very good. At the same time, the programme has occasionally helped to identify quality issues with products (e.g. Amoxicillin powders in sachets or tablets for which subdivision is authorised).

Availability of screening methods for market surveillance testing

MSSs have contributed to the development of a number of screening methods within the Network, and these methods can then be used by OMCLs for their own market surveillance testing activities, outside of the MSS programme. The methods may be considered for establishing finished product monographs of the Ph. Eur.

Updating of MA methods

When a sample is found to be non-compliant using the MSS screening method, OMCLs usually revert to using the manufacturer's test method as registered in the MA. Sometimes, the use of such test methods has been problematic, with method deficiencies being identified by the OMCL. These issues have sometimes triggered the revision, and hence the improvement, of the manufacturer's test method and a corresponding update of the MA dossier.

Revision of Ph. Eur. and other compendial monographs

Where MSS methods are based on compendial test methods, the feasibility studies performed or the results of the MSSs have sometimes triggered the revision of the corresponding monographs or pharmacopoeia chapters. Examples include:

- Linseed Ph. Eur. monograph (addition of a test on cadmium)

- Subdivision of tablets (revision of the Ph. Eur. test following a number of out-of-specification results that were related to how the test method was described)

- Levothyroxine tablets, Sildenafil tablets (improvement of the analytical procedure for dissolution and the test for related substances of the associated compendial monographs)

Synergies with other GEON surveillance programmes

The MSS programme has a number of synergies with other surveillance programmes. For example:

- Over the past ten years, various MSSs have been organised as a continuation of the surveillance programme applied to generic products authorised via the CAP.

- Where MRP/DCP products or APIs are analysed in an MSS, the test results can be included in the MRP/DCP/API database operated by the EDQM and the OMCL Network, which captures the results of surveillance testing on such products, and this information adds to the available surveillance findings about those products.

- Collaborations with the 'fingerprinting' surveillance programme operated by the OMCL Network API Working Group have also taken place (e.g. for Sildenafil and Tadalafil).

- In addition, the Market Surveillance of Suspected Illegal Products (MSSIP) programme, in which OMCLs analyse products such as slimming food supplements and food supplements advertised as sexual potency enhancers, illegal anabolic steroids, medicines in disguise, or illegal products containing "non-INN" APIs, was launched as an extension of the general MSS programme.

Qualify the performance of the OMCL

As stated in ISO17025:2017 (7.7.2), the laboratory “shall monitor its performance by comparison with results of other laboratories”, by participating in proficiency testing schemes (PTS) or other inter-laboratory comparisons. MSSs (which include a common test sample) can be a good way of making such comparisons and qualifying performance, especially where no PTS (even commercial) is available. This may be particularly the case for techniques that are not frequently used or that concern only a few OMCLs (inductively coupled plasma (ICP) spectrometry, examination for visible or sub-visible particles, control of inhalers, etc.).