# General European OMCL Network (GEON)

## GENERAL DOCUMENT

**PA/ PH/ OMCL (19) 91 R3**

**Planning Market Surveillance Testing of Medicinal Products**

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<tr>
<th><strong>Full document title and reference</strong></th>
<th>Planning Market Surveillance Testing of Medicinal Products Position Paper for OMCLs, PA/PH/OMCL (19) 91 R3</th>
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<tr>
<td><strong>Document type</strong></td>
<td>Position Paper</td>
</tr>
<tr>
<td><strong>Date of first adoption</strong></td>
<td>November 2019</td>
</tr>
<tr>
<td><strong>Date of original entry into force</strong></td>
<td>November 2019</td>
</tr>
<tr>
<td><strong>Date of entry into force of revised document</strong></td>
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<tr>
<td><strong>Previous titles/ other references / last valid version</strong></td>
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<td><strong>Custodian Organisation</strong></td>
<td>The present document was elaborated by the OMCL Network / EDQM of the Council of Europe</td>
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<td><strong>Concerned Network</strong></td>
<td>GEON</td>
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PLANNING MARKET SURVEILLANCE TESTING OF MEDICINAL PRODUCTS
POSITION PAPER FOR OMCLs

1. SCOPE
This position paper discusses some of the general practices for the involvement of OMCLs in the planning of drawing samples from the market for the purpose of any kind of surveillance testing. It is intended to be of use to OMCLs and their associated inspectors or other colleagues who are involved in designing surveillance programmes. OMCLs are encouraged to discuss the content of this paper with their colleagues, as cooperative work in this area is important given the knowledge of the OMCL and the OMCL Network. It should be noted that “sampling” addressed in this position paper in context with market surveillance testing activities in OMCLs is not understood in the strict sense as for instance defined in chapter 7.3 of ISO/IEC 17025:2017 or the WHO Guidelines for Sampling of Pharmaceutical Products and Related Materials, No. 929, 2005, in particular with respect to sampling operations (e.g. randomised sampling, use of sampling tools etc.).

2. INTRODUCTION
The legal requirements for the sampling and testing of medicinal products are laid down in Directives 2001/83 Art 111 (Human Medicinal Products) and 2001/82 Art 80 (Veterinary Medicinal Products), Title XI, Supervision and sanctions.

Post-marketing sampling and testing is part of the overall supervision of medicinal products and is complementary to other important areas e.g. pharmacovigilance and inspection of manufacturers. The objectives of the post-marketing sampling and testing programmes are derived from the legal requirements:
- to supervise the quality of medicinal products placed on the market;
- to check compliance of the medicinal product placed on the market with its authorised specifications.

The OMCLs have a role within the medicines regulatory network to protect public health by detecting defective medicinal products on the market. This is achieved by testing of medicinal products, which have been sampled from the distribution chain (manufacturers, wholesalers and pharmacies).

3. ESTABLISHMENT OF A SAMPLE PLAN
A good surveillance programming procedure will be dependent on the risks, which have been identified in the selection model. Adoption of a risk based approach to market surveillance will allow the OMCLs to concentrate their limited resources on those areas considered most likely to pose a risk to human and animal health.

As a consequence, and in order to optimise the use of OMCL resources for surveillance studies, a risk based approach in the selection of products to be included in market surveillance studies is appropriate.

Such risk analysis would be based on findings at assessment of applications for marketing authorisation and variations, GMP inspections, pharmacovigilance activities, or findings in similar products. Selection criteria could include but are not limited to risks identified for active substance, patient profiles, poor stability of product, production process, pharmaceutical form and data from previous controls. Thus, close collaboration with inspectorates, licensing assessors and the OMCL, including up-to-date information on variations etc. are necessary and invaluable for a risk based approach to market surveillance.
Since the OMCLs are performing the testing, it is desirable that the OMCL has a role in the national surveillance programming strategy. If the OMCL is not involved in the planning, a good collaboration with the decision makers should be pursued so that the OMCL can contribute with experience and knowledge about identified risks.

Further details on a risk based market surveillance is described in position paper PA/PH/OMCL (06) 3, *Incorporation of a risk based approach in Market Surveillance testing at OMCLs*, in its current version.

Risk-based surveillance planning will (in the future) be covered by the *Pre-marketing Risk-based Model for Medicinal Product Testing* which has been developed by a HMA working group. Once the IT platform is in place, post-marketing risk factors can be implemented in the model.

4. SAMPLING

According to Directives 2001/83 Art 111 and 2001/82 inspections shall be carried out by officials representing the competent authority who shall be empowered to take samples including with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory designated for that purpose by a Member State.

The legal requirement may be further elaborated in national legislation. For example, that samples shall be provided free of charge and all information and materials including reference standards necessary for the control must be supplied to the national competent authority by the MAH.

The responsibility for sampling may vary between member states. The responsibility can lie with the OMCL, inspectors or others. However, when sampling is performed for the purpose of testing by an OMCL, a close collaboration with the sampler should be pursued. According to ISO 17025, the laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. This includes information on date and time of sampling and environmental or transport conditions.

The sample size will depend on the number of pharmaceutical dosage units needed per test procedure. Furthermore, the aspect of stability should also be addressed: the nearer to the end of shelf-life of a particular batch, the higher the risk of a quality defect (either batch or generally product related). At the same time, the OMCL should be able to test the product within the shelf life of a particular batch.

Depending on the type of product and the type of risk to be addressed, sampling can occur at any step of the production or distribution chain. For finished medicinal products, the sampling site should be chosen as closely to the patient as possible. The further down the distribution chain the sampling is performed, the higher is the chance of detecting inadequate storage, handling or tampering (e.g. repackaging and relabelling of parallel traded products). For the sampling of active pharmaceutical ingredients, please refer to PA/PH/OMCL (12) 51, *API surveillance – position paper for OMCLs*, in its current version.

When products are not requested from the MAH, it is advisable to have a voucher system in place to ensure rapid sample replacement and avoid challenges at the point of sampling. The vouchers should be signed by the MAH and exchanged at the point of sampling; the vouchers will then entitle to obtain from the manufacturer a quantity of product that corresponds to the units sampled.

National legislation regulates how cost of such OMCL testing is covered.