

# OMCL Network of the Council of Europe

## GENERAL DOCUMENT

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### Stockpiling of Medicines – Monitoring – General Considerations

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<b>Concerned Network</b>	GEON

## **Stockpiling of Medicines – Monitoring - General Considerations**

### **Background/Introduction**

Individual member states might stockpile medicines to be used in cases of pandemic situations or other crisis. As long as the stockpiled medicines (under adequate storage conditions) are within their expiry date there are normally no quality problems. Nevertheless most of these medicinal products will not be used up for the treatment of patients within these dates. The question can be raised: what about the pharmaceutical quality, safety and efficacy, once these medicines have reached their expiring date, knowing that, in most cases, the medicines are still fit for use? A discussion is going on in many member states and it was thought to be worthwhile to address this issue from a technical/scientific point of view, also to achieve a common approach to this important issue.

The responsibility for the product should be established (Government, National Competent Authorities, manufacturers...), as the Marketing Authorisation Holder (MAH)/manufacturer is responsible during the MA registered shelf-life of the product which is stated by an expiration date placed on the container label (e.g., which is responsible for batch recalls, for pharmacovigilance follow-up...). The policy for stockpile replacement should be considered, and the scientific/technical criteria for requiring this should be established.

### **Scope**

The scope of this document is to identify the technical issues in relation to the monitoring of stockpiled medicines (chemical + biological), essentially when the shelf-life has expired. The document is to explain authorities the (technical) competence and potential contributions of Official Medicines Control Laboratories (OMCLs) in questions concerning the pharmaceutical quality, safety and efficacy of stockpiled medicines. This document is not intended to address legal issues or to replace current sampling and testing programmes of commercialised marketed medicines (EMA/EDQM programmes) or to prepare decisions for the selection of products for stockpiling.

It is the intention of the Network to define general guidelines for the OMCLs medicines stockpiles testing. In such context, there is a need for elaborating a common document to clarify/specify the role of OMCLs. On the basis of this core document, technical annexes might be developed at a later stage.

### **Role of OMCLs**

In order to monitor the quality of a medicine stockpile for use, an OMCL has to test samples of the medicinal product, and to verify its quality in reference to the approved shelf-life specifications. The shelf-life of a medicine is the time period during which a drug product is expected to remain within the approved shelf-life specification, provided that it is stored under the conditions defined on the container label. Analyses performed by the OMCL should be carried out according to control methods described in the MA file and/or in the European Pharmacopoeia.

OMCLs are trained and competent to control on routine basis medicines put on the market. They have the expertise and the availability of the necessary equipment within the Network and they have an approved quality assurance system in place recognised by the mutual joint audit (MJA) programme or by an accreditation body. Monitoring of medicines stockpiles does not generally require a different expertise.

In a preliminary meeting, the following consensus was reached:

- To deal with medicines with and without Marketing Authorisation;
- Active substance (bulk): re-test date and testing in accordance to pharmacopoeial or other respective regulations or as described in the marketing authorisation file;
- Medicinal product: testing on compliance with shelf-life specifications, as described in the application/marketing authorisation file.

### **Further discussion and future activities**

There is a need for setting up common procedures, in order to achieve a harmonised and consistent approach within the Network to monitor stockpiled medicines. These common procedures will also help to exchange information and experience between member states. Some of these guidelines need to be drafted in collaboration with the assessors. In all cases risk based principles should be considered.

The following topics could be considered in different guidelines:

1. Selection of medicines to be monitored
  - o Evaluation from a scientific and/or technical viewpoint; e.g. stability considerations, technical feasibility.

The actual product selection, based on pandemic or crisis considerations, will be done by member states.
2. Testing phase:
  - o Sampling issues
  - o Testing: selection of parameters to be tested

Elaboration of basic principles for a good testing practice; e.g. reference substances/materials, additives, packaging materials, testing methods, shelf-life specifications, toxicological evaluation of impurities/degradation products.
3. Storage of stockpiled medicines: e.g. minimum storage conditions to be requested, inspection of storage location.
4. Exchange of data: ownership has to be clarified.
5. Clarification of an extension on medical devices and other relevant products for public health (e.g. disinfectants/biocides).
6. Biological products.