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Stockpiling of Medicines – Monitoring – General Considerations

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Stockpiling of Medicines – Monitoring - General Considerations

Background/Introduction

Individual member states might stockpile medicines to be used in cases of pandemics or other crises. As long as stockpiled medicines are stored under adequate storage conditions no quality problems are anticipated before their expiry date. Nevertheless most of these stockpiled medicinal products will not be used up within their shelf life for the treatment of patients. The question can be raised: what about the pharmaceutical quality, safety, and efficacy, when these medicines reach the end of their shelf life, knowing that the medicines may still be suitable for use in many cases? A discussion is going on in many member states and it was thought to be worthwhile to address this important issue from a technical/scientific point of view in order to achieve a common approach.

The responsibility for the stockpiled product should be clearly established (Government, National Competent Authorities, …), since the Marketing Authorisation Holder (MAH)/manufacturer is responsible only during the shelf life of the product as approved in the Marketing Authorisation and given on the container label (this responsibility includes batch recalls, pharmacovigilance follow-ups, etc.…). The responsible authorities should consider establishing a policy for stockpile replacement, based on scientific/technical criteria.

Scope

The scope of this document is to identify the technical issues in relation to the monitoring of stockpiled medicines (chemical + biological), that will help to make decisions when the shelf life has expired. The document aims to highlight to 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, to replace current sampling and testing programmes of marketed medicines (EMA/EDQM programmes) or to decide the selection of products for stockpiling.

It is the intention of the Network to define general guidance for OMCLs on testing stockpiled medicines. In such a context, there is a need for elaborating a common document to clarify/specify the role of OMCLs. On the basis of this core document, a technical annex has been developed (Monitoring of Stockpiled Medicines – Development of Technical Guidelines PA/PH/OMCL (09) 94, in its current version). Additional annexes might follow at a later point in time.

Role of OMCLs

In order to monitor the quality of a medicine stockpile, an OMCL would have to test samples of the medicinal product and to verify its quality with reference to the approved specifications expected throughout the shelf life. The shelf life of a medicine is the time period during which it is expected to fulfil the approved specifications, provided that it has been 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 already competent and have personnel trained to test medicines available on the market on a routine basis. OMCLs have the expertise and the necessary equipment (within their organisation or within the Network) and they work under an approved quality management system, which is independently assessed by the mutual joint audit (MJA) programme and/or by a national accreditation body. Monitoring of medicines stockpiles does not generally require any additional expertise.

In a preliminary meeting in 2008, the following consensus was reached:

- To deal with medicines with (e.g. final medicinal products) and without (e.g. active substance, bulks) Marketing Authorisation;
- Active substance (bulk): re-test date and testing in accordance with 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

In order to achieve a harmonised and consistent approach in monitoring stockpiled medicines within the Network there is a need to set up common guidance documents. Common documents 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 separate documents[1]:

1. Selection of medicines to be monitored:
   - Evaluation from a scientific and/or technical viewpoint; e.g. stability considerations, technical feasibility;
   - Investigate the possibility of extending the period during which the products are suitable for use.

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

   Elaboration of basic principles for 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 conditions to be required, inspection of storage location.
4. Exchange of data: ownership has to be clarified.
5. Clarification of an extension to medical devices and other relevant products for public health (e.g. disinfectants/biocides).
6. Biological products.

[1] The topics are covered in the corresponding guideline “Monitoring of Stockpiled Medicines – Development of Technical Guidelines”.