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VYR-17 Shelf life extension of a batch of medicinal product manufactured before the approval of the appropriate variation to the registration

This guideline replaces guideline VYR-13 as of July 1, 2001.

1. Introduction

Due to the problem in practical application of some of the requirements listed in guideline VYR-13, revision thereof has been prepared.

Extension of the shelf-life of a medicinal product is possible only on the basis of long-term stability studies (see REG-49) after the approval of the relevant variation to the registration. Shelf-life can be extended also for products manufactured prior to the approval of the relevant variation to registration if they comply with the below stipulated conditions and if the State Institute for Drug Control (SUKL) is notified to this effect, so that consistent information about the situation on the market, necessary for control purposes, be maintained. SUKL does not issue any decisions on these matters, the extension of shelf-life for batches manufactured prior to the approval of the relevant variation to the registration are entirely within the responsibility of the registration decision holder who has direct access to all information necessary for quality assurance of the medicinal product and its compliance with the documentation submitted within the registration procedure.

2. Conditions governing the shelf-life extension of the medicinal products manufactured prior to the approval of the variation to registration relevant to the extended shelf-life

The extension of shelf-life for batches of medicinal products manufactured prior to the approval of the relevant variation to the registration is entirely within the responsibility of the registration decision holder and it can be carried out where compliance with the following conditions has been achieved:

- Change of shelf-life was already approved within the processing of the application for the relevant variation to registration;
- The manufacture of the batches of medicinal products, whose shelf-life is being extended, was executed under the same conditions as of those medicinal products for which a long-term stability study was submitted within the application for a variation to registration;
- All packages of the medicinal products in question were evidently stored in compliance with prescribed conditions thereof;
- Measures preventing the occurrence of other packages of the same batch of the medicinal product labelled with a different shelf-life on the market have been adopted;
- New shelf-life is clearly marked both on immediate and outer packaging (and, where applicable, in the package leaflet);
- Re-labelling of all packages of the medicinal products has been made by the licensed manufacturer under the conditions of good manufacturing practice;
- The registration decision holder shall inform the SUKL in writing about the extended shelf-life of batches of medicinal products manufactured prior to the approval of the relevant variation to registration (including batch numbers and number of packages of medicinal products whose shelf-life will be extended, and including the reference number and date of the decision pertaining to the variation to the registration on the basis of which the shelf-life of the relevant batches of medicinal products was extended);
- Where needed, the registration decision holder can prove re-labelling of the product to distributors, pharmacies, and any other entities operating in the area of medicinal products supply by the decision on the variation to registration or by a reference to the lists of variations published by SUKL in the Bulletin (Věstník) or on its homepage.

Note: Written information about extended shelf-life of a medicinal product manufactured prior to the approval of a variation to the registration and any related queries and comments are collected and handled by the Inspection Branch of SUKL.