REG-80 version 1

Inclusion of a medicinal product previously authorized in the Czech Republic in the Mutual Recognition Procedure or, where applicable, in the Decentralised Procedure

This Guideline supersedes guideline REG-80 with the effect from 10 November 2008.

The inclusion of a medicinal product in the Mutual Recognition Procedure (MRP) has to comply with the procedure stipulated by Section 41 of Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to some Related Acts (the Act on Pharmaceuticals) on the basis of a submitted application for marketing authorisation by Mutual Recognition Procedure (REG-70), and the process has to be completed by the issue of a new marketing authorisation. If the medicinal product has been previously authorised in the Czech Republic and the applicant wishes to maintain the same name of the product, the same MA number as well as the same SÚKL codes, SÚKL shall allow for such procedure in order to avoid unnecessary variations made for purely administrative reasons.

As the terms and conditions of marketing authorisation in the reference Member State (RMS) have to be strictly observed within the MRP, including all product packagings (both package sizes and types of packaging), as well as the same manufacturers, it may happen that the new MRP authorisation shall apply to a different number of package sizes or types of packaging of the product or possibly even other manufacturers compared to the original, national marketing authorisations. These differences may imply the need to assign new SÚKL codes or to cancel some of the existing ones. In order to avoid confusion which would delay the MRP it is necessary for the applicant not only to highlight in a cover letter submitted together with the application for the MRP marketing authorisation the fact that he wishes to maintain the same product name, MA number, and SÚKL codes, but also to provide a summary table of all presentations of the product covered by the original national MA, and of product presentations which are included in the submitted MRP, as per the specimen provided below.

It is not possible to authorise a medicinal product at the same time on a national level and by the MRP under the same product name and MA number. Therefore, the name of the product, its MA number, and SÚKL codes can be maintained after inclusion in the MRP only on condition that the applicant applies for revocation of the original national MA as of the date of the issue of the new marketing authorisation. This application may be submitted in the course of the MRP at the moment when the procedure is drawing to a successful conclusion (Day 90). Should there be any pending applications for variations or renewal as part of the original national MA, it is necessary, at the same time, to provide a letter announcing to the Institute that the applicant no longer wishes to pursue these procedures and withdraws these applications. As part of the revocation of the original national MA it is not necessary to deal with gradual recall as the product remains identical. It, however, should be borne in mind that unless all pack sizes authorised by the original national MA are authorised in the MRP, the SÚKL codes for certain packagings shall be cancelled together with the marketing authorisation revocation as of the effective date of the decision on the revocation of the original national marketing authorisation. Those codes shall no longer be included in the database of authorised products (list of codes) and their placing on the market will be possible.

Product name, strength, pharmaceutical form			
MA number			
MRP number			
NATIONAL MARKETING AUTHORISATION			
SÚKL code	Pack size	Type of immediate packaging	Manufacturer responsible for batch release
Manufacturer of the active substance			
Manufacturing chain of the medicinal product (without releasing manufacturer)			
MRP			
SÚKL	Pack size	Type of	Manufacturer responsible for batch release

code*		immediate packaging	
Manufacturer(s) of the active substance			
Manufacturing chain of the medicinal product (without releasing manufacturer)			

* Please state SÚKL code assigned as part of the national MA, if the code is to be maintained for the relevant product presentation.