REG-80 version 2 Inclusion of a medicinal product previously authorized in the Czech Republic via national procedure into the Mutual Recognition Procedure or, where applicable, into the Decentralised Procedure

This Guideline supersedes REG-80 version 1 with the effect from 14 April 2025.

The Guideline is issued in accordance with the provision of Section 41 of Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to some Related Acts.
The Guideline is for recommendation.

The inclusion of a medicinal product into 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 Associated Acts ("Act on Pharmaceuticals"), as amended, on the basis of a submitted application for marketing authorisation ("MA") by Mutual Recognition Procedure, 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 via national procedure 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. This procedure can be used only if the legal basis of the national authorised medicinal product is the same as the legal basis of the medicinal product authorised via mutual recognition procedure or decentralised procedure. At the time of submission of an application for inclusion of a medicinal product in MRP, no ongoing variations or renewal of the marketing authorisation should be pending.

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 presentations (both pack 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 pack sizes or types of packaging of the product or possibly even other manufacturers compared to the original national marketing authorisation. 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 of all presentations of the product covered by the original national MA, and of product presentations which are included in the submitted MRP along with other necessary information.

Summary

Medicinal product cannot be authorised 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 into 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 once the procedure is drawing to a positive opinion (Day 60/90). More information on a revocation application here. As part of the revocation of the original national MA it is not necessary to deal with gradual recall as the product remains identical. However, it is important to note that if all pack sizes authorised under the original national MA are not authorised in the MRP, the authorisation status of SÚKL codes for non-authorised pack sizes will be changed to "B", which means that they can be only marketed for a maximum 180 days after the approval of the inclusion.

A similar approach can be applied to certain applications for the decentralized procedure. However, this only applies to cases where the medicinal product submitted via decentralized procedure is a duplicate of a nationally authorised medicinal product, and the future marketing authorization holder wishes maintaining only the newly authorised product with the same product name, the same MA number and SÚKL codes.

Annex 1 – Summary