SUB03 The Mutual Recognition Procedure (MRP)

Approximate study time: 2 hours

Level: Introductory/Intermediate

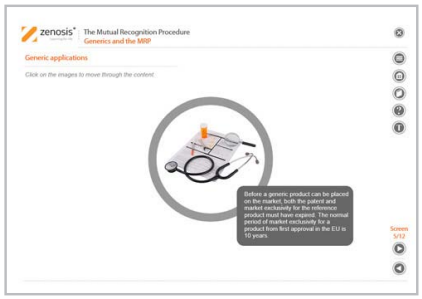
Audience: Regulatory

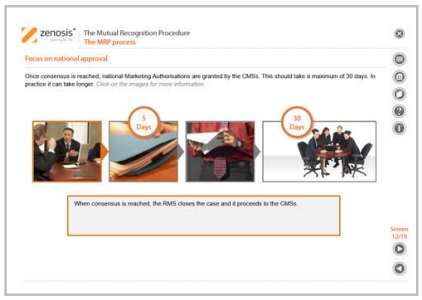
Category: Regulatory Submissions

Region: Europe

CPD Points: 2

Module outline
- Module overview
- Introduction
- The MRP process
- Generics and the MRP
- Assessment





The Mutual Recognition Procedure is one of three routes available to applicants to gain multinational Marketing Authorisation within the European Economic Area (EEA) on the basis of a single application. A national authorisation is converted to harmonised authorisations issued in a number of other member states chosen by the applicant.

The MRP is similar to the Decentralised Procedure but with later involvement of the Concerned Member States in the assessment by the Reference Member State. The Coordination Group for Mutual Recognition and Decentralised Procedures provides guidance and acts to facilitate agreement among the participating states.

This module describes the roles of the various players in the procedure, the sequence and duration of the stages involved, and the requirements on content, format and timing of submissions. It discusses the special issues that apply to generic products in the MRP.

Who will benefit from this module?

This module is primarily aimed at regulatory rffairs professionals dealing with marketing authorisation applications and related submissions for regulatory approval in Europe. More generally, it will also be of interest to all those involved in the development and registration of medicinal products.

Learning objectives

- Provide an overview of the MRP process.
- Describe the pre-submission and submission actions in relation to timeline deadlines.
- Specify the responsibilities of the Reference Member State (RMS), the Concerned Member States (CMSs) and the applicant.

Module outline

Module overview
Provides an overview of the content of the module and outlines related Zenosis modules.

Introduction
This session provides background information. It covers products for which the MRP can be used, the types of Marketing Authorisation Application, and characteristics of the application procedure.

The MRP process
This session takes you through the entire process from initial national authorisation by the RMS to the issuing of national licences by the CMSs. Referral of issues to the CMD, and the arbitration process, are also covered.

Generics and the MRP
This session gives a brief introduction to generics and the special issues that apply to generic products in the MRP.

Assessment
Multiple-choice mastery assessment.