SUB11 The Decentralised Procedure (DCP)

Approximate study time: 2 hours

Level: Introductory/Intermediate

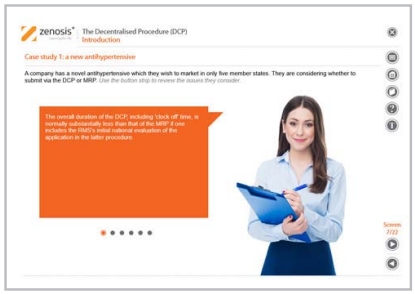
Audience: Regulatory

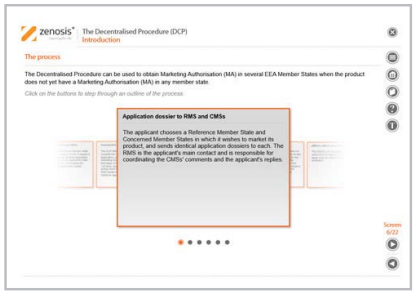
Category: Regulatory Submissions

Region: Europe

CPD Points: 2

Module outline
- Module overview
- An introduction to the DCP
- DCP Step 1
- DCP Step 2
- Generics and the DCP
- Assessment





The Decentralised 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. It can be used only for a product which has no existing marketing authorisation in any member state. It is similar to the Mutual Recognition Procedure (MRP) but with earlier involvement of the Concerned Member States in the assessment by the Reference Member State. The Coordination Group for Mutual Recognition and Decentralised Procedures (CMD) 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 DCP.

Who will benefit from this module?

This module is primarily aimed at regulatory affairs 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 DCP 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.

An introduction to the Decentralised Procedure
This session provides background information. It covers products for which the DCP can be used, the types of Marketing Authorisation Application, and characteristics of the application procedure.

The DCP Step 1
This session takes you through the pre-procedural step and the first assessment stage of the DCP, as far as day 120.

The DCP Step 2
This session takes you through the second assessment stage and the final step of issuing national licences. Referral of issues to the CMD, and the arbitration process, are also covered.

Generics and the DCP
This session gives a brief introduction to generics and the special issues facing generics in the DCP.

Assessment
Multiple-choice mastery assessment.