SUB02 The European Centralised Procedure (CP)

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

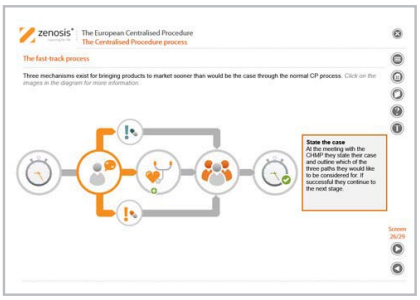
Audience: Regulatory

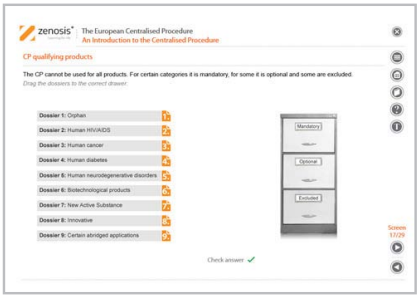
Category: Regulatory Submissions

Region: Europe

CPD Points: 1.5

Module outline
- Module overview
- An introduction to the CP
- The Centralised Procedure Process
- Assessment





The Centralised 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. In the CP, one successful application leads to a marketing authorisation being issued by the European Commission that applies throughout the EEA. The CP is mandatory for certain types of products.

This module describes the various players in the procedure, the sequence and duration of the stages involved, and the requirements on content, format and timing of submissions.

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 CP process.
- Identify which products may/must use the CP
- For products for which the CP is optional, outline the advantages and disadvantages of the CP compared with other routes to marketing authorisation.
- Describe requirements on content, format and timing of submissions.
- Specify the sequence and duration of the stages of the CP and the responsibilities of the participants.
- Describe the role of the European Medicines Agency and its relevant competent committee.
- Outline fast-track provisions.
- Describe the appeals procedure.

Module outline

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

An introduction to the Centralised Procedure
This session provides background information. It specifies the types of product for which the CP is mandatory and those for which it is optional. It discusses the types of Marketing Authorisation Application, and characteristics of the application procedure.

The Centralised Procedure process
This session takes you through the entire process from pre-submission to what happens after an Opinion has been received.

Assessment
Multiple-choice mastery assessment.