

Module 7



Aim:

The purpose of this module is to provide students with an awareness of the strategic issues to be considered in relation to submissions for products containing established active substances, whether these are line extensions, 'me-toos' or generics.

Regulatory Strategy for Submissions for Established Active Substances

Learning outcomes

- Students will be able to describe the differing types of abridged applications possible in the EU and to identify situations when the use of each of these is appropriate.
- Students will be able to develop and evaluate strategies for submissions in EU markets for products containing established active substances.
- Students will have an insight into the routes to approval in the USA for products containing established active substances, sufficient to aid discussions with colleagues in this market.

The module will cover the following topics

- The commercial importance of abridged applications
- The type and range of abridged applications in Europe
- The legal background to abridged applications including essential similarity, marketing exclusivity and patent protection
- The impact of the Commission interpretation of Directive 2001/83 Article 10, use of the mutual recognition procedure and implications for the harmonisation of the SmPC
- Use of abridged applications versus variations
- Planning strategy for abridged applications from the development of the formulation to submission
- Processing of abridged applications by the Regulatory Authorities
- Particular issues for generics and over-the-counter (OTC) products
- Routes to approval of products containing established active ingredients in the USA, a comparison with the EU

Links with other modules

- Module 8 is designed to complement this module.
- Module 11 provides more detail on submissions for established active substances in the USA.



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by the
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