EMWA Professional Development Programme

DDA31 Orphan Medicinal Products

Advanced (3.5 hours)

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Pre-workshop assignment

Objective
The objective of this pre-workshop assignment is to provide an understanding of orphan designation in Europe.

Content and instructions
Medicinal products become orphan medicinal products once they have been granted orphan designation. Read the following from the European Medicines Agency (EMA) website for an understanding of orphan designation and the associated incentives:

Orphan designation: https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation
Orphan incentives: https://www.ema.europa.eu/en/human-regulatory/research-development/orphan-designation/orphan-incentives
Market exclusivity: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/orphan-medicines/market-exclusivity-orphan-medicines
Activities after orphan designation: https://www.ema.europa.eu/en/human-regulatory/research-development/orphan-designation/activities-after-orphan-designation

Assessment criteria
This is a reading exercise, and will provide a framework for the workshop.

Resources and materials
EMA website (see specific links in the Content section).

Time required
1 hour

Deadline or other information about bringing the assignment to the workshop
This assignment is preparatory reading; there is no material to return prior to the workshop.