

International Conference, 19-21 September 2022



Collaboration, Innovation and Scientific Excellence: the European Pharmacopoeia 11th Edition

Open Debate: Unmet needs?

Moderator: Tobias Godschan

Swissmedic

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

Open debate Unmet needs?

Moderator: Tobias Gosdschan, Swissmedic, Switzerland

Ph. Eur. monograph elaboration/revision: to summarise

Monographs are based on quality described for approved products

Invitation of interested parties to participate

Interested parties can check the feasibility for authorised products

Responding to the Pharmeuropa enquiry is a must

Industry, OMCLs, assessors



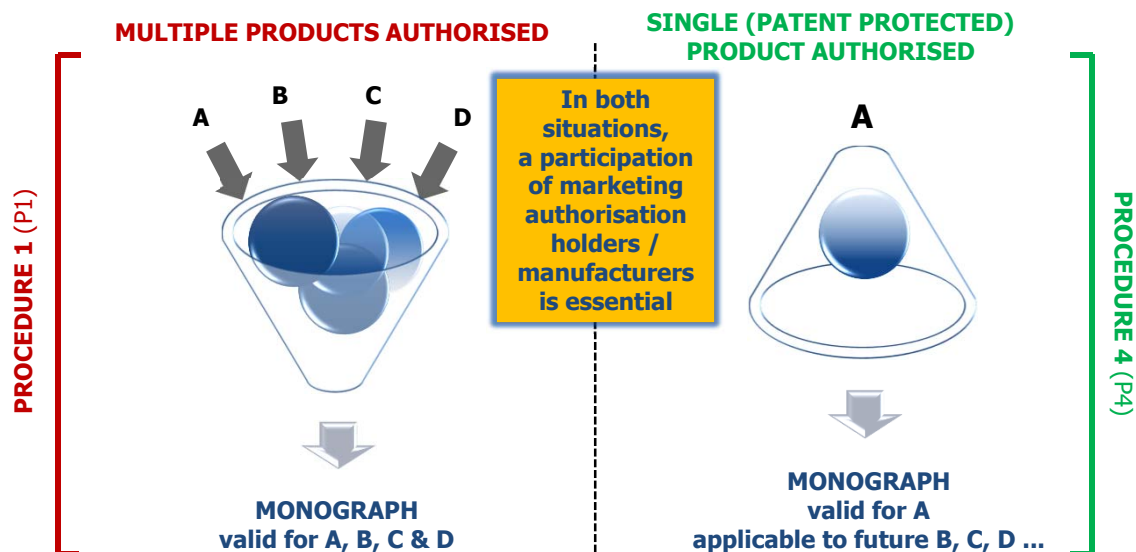
- **Data package** (current specifications, analytical procedures; validation data; batch and stability data)
- **Material** for testing
- *Candidate material for RS establishment*

- **Review** of data package
- **Laboratory study/ collaborative testing**
- **Draft** new or revised monograph

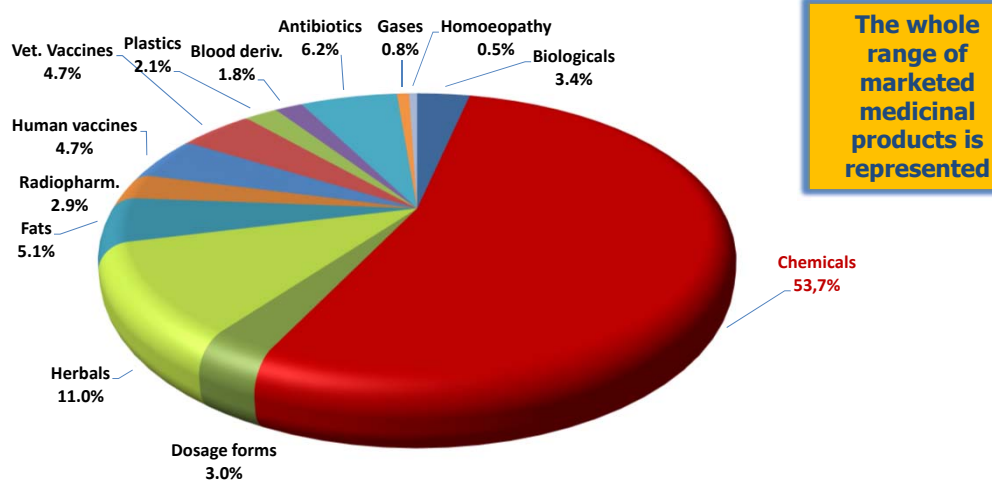
- **Draft published for comments** (3 months commenting period)
- **Evaluation of stakeholder feedback** (technical comments, data)

Once a monograph is published, MAHs of authorised products have to ensure that their products meet the requirements of the monograph ... *at the implementation date at the latest*

Main situations for the elaboration / revision of texts



Contents of the European Pharmacopoeia



Unmet needs

- The information given as introduction shows how things are done at the moment and the topics currently covered by the Ph. Eur.
- Now, you have the opportunity to inform us
 - on ideas how things could be done better
 - on topics which are not / not appropriately covered from your perspective
 - on fields where you have a lack of information
 - on any other unmet needs
 - or even on points that you particularly appreciate (and that you wish to keep)
- Your input will be highly appreciated by the Ph. Eur. Commission and the EDQM for further consideration. If you need further explanations, please do not hesitate to ask.

The floor is yours !

Thank you for your attention



Stay connected with the EDQM

EDQM Newsletter: <https://go.edqm.eu/Newsletter>
LinkedIn: <https://www.linkedin.com/company/edqm/>
Twitter: [@edqm_news](https://twitter.com/edqm_news)
Facebook: [@EDQMCouncilofEurope](https://www.facebook.com/EDQMCouncilofEurope)