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

edqm

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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The “CEP of the Future” Project

The"CEP of the Future" project

Goal = design/update the CEP document according to stakeholders' needs: CEP holders/manufacturers, medicines manufacturers, regulatory agencies (worldwide)

The"CEP of the Future project"

Wide public consultation in 2020 via on-line survey

- Questions on various aspects connected to CEPs and open for free suggestions
- About 550 responses + seperate feedback received
- Summary report available: https://www.edqm.eu/en/-/-cep-of-the-future-project-update

Review of Feedback (1)

- Lack of knowledge of current EDQM policies on the content of the CEP (cf. EDQM policy document ˝How to read a CEP˝)
- Lack of knowledge and understanding of:
  - Duties of CEP holders/manufacturers and MAH/Drug Products manufacturers
  - Current regulations and how to use CEPs (e.g. what should be provided in marketing applications, etc.)

Review of Feedback (2)

- Expectations for more information on CEPs to increase transparency and clarity for users
- Wish to extend assessments in CEP dossier (e.g. stability)
- Requests to reduce revisions of CEPs (e.g. administrative changes)
- Enhance use of public database/IT tools

Work areas

5 work areas

Review information to be stated on the CEP

Reduce revisions of CEPs and facilitate handling of changes

Enhance digital tools and public databases

Foster information sharing between CEP holders and medicines manufacturers

Train users on content and use of CEP

Next Steps – July 2022 onwards

Design and preparation of CEP

Consultation with stakeholders (Sep 2022)

Deployment (May 2023)

Thank you for your attention

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