

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





The “CEP of the Future” Project



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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 + separate 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)



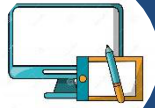
- Expectations for more information on CEPs to increase transparency and clarity for users
- Wish to extend assessments in CEP dossier (e.g. stability)
- Requests to reduce revisions of CEPs (e.g. administrative changes)
- Enhance use of public database/IT tools

Work areas

5 work areas



Review information to be stated on the CEP



Enhance digital tools and public databases



Train users on content and use of CEP

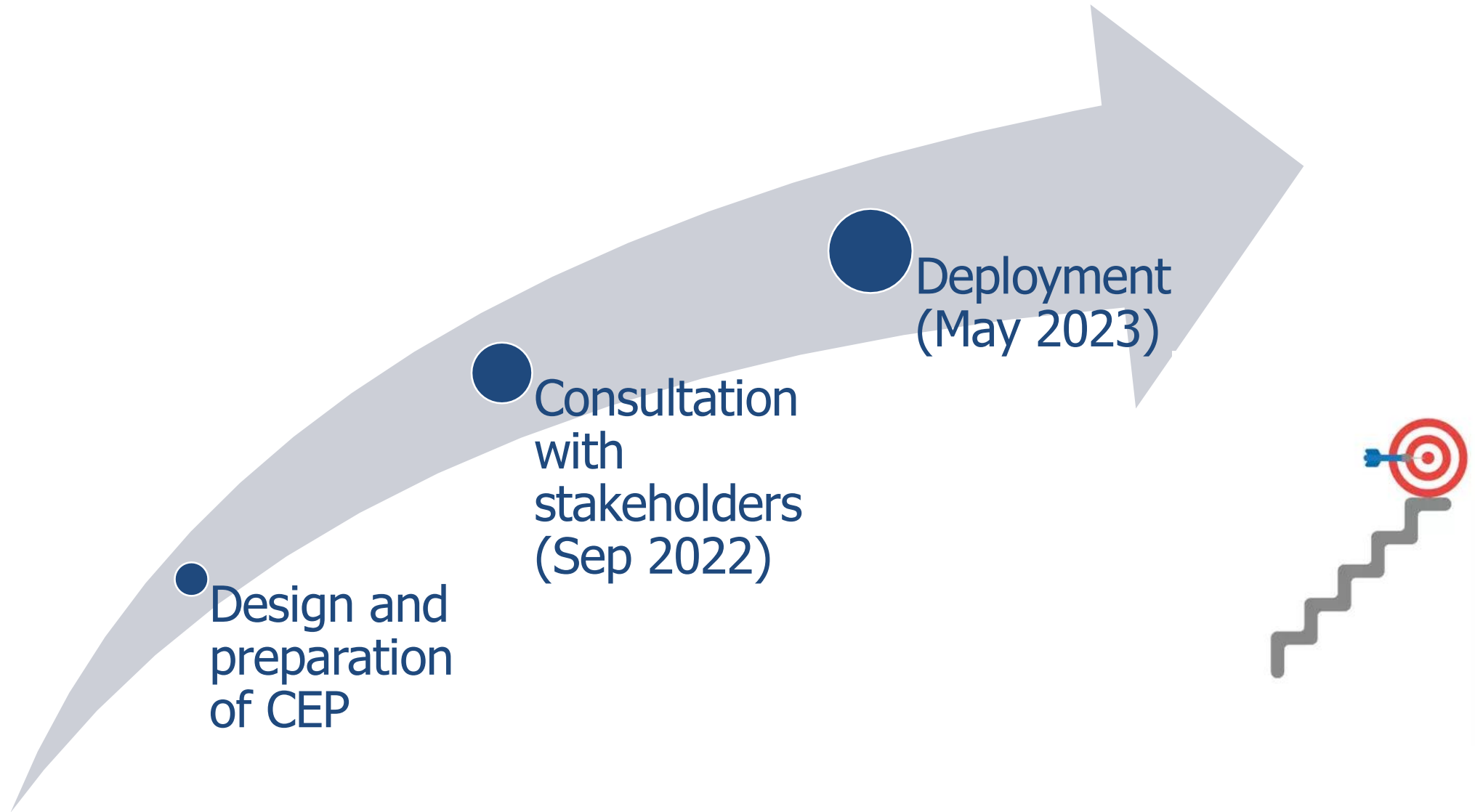


Reduce revisions of CEPs and facilitate handling of changes



Foster information sharing between CEP holders and medicines manufacturers

Next Steps – July 2022 onwards



Thank you for your attention



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