International Conference, 19-21 September 2022

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

Open Debate: Procedure P4

Moderator: Marija Malešević,
Chair of P4 Working Group

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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Procedure 4 (P4)
- Open Debate -

Marija Malešević, Chair of the P4 Expert Group
Medicines & Medical Devices Agency of Serbia

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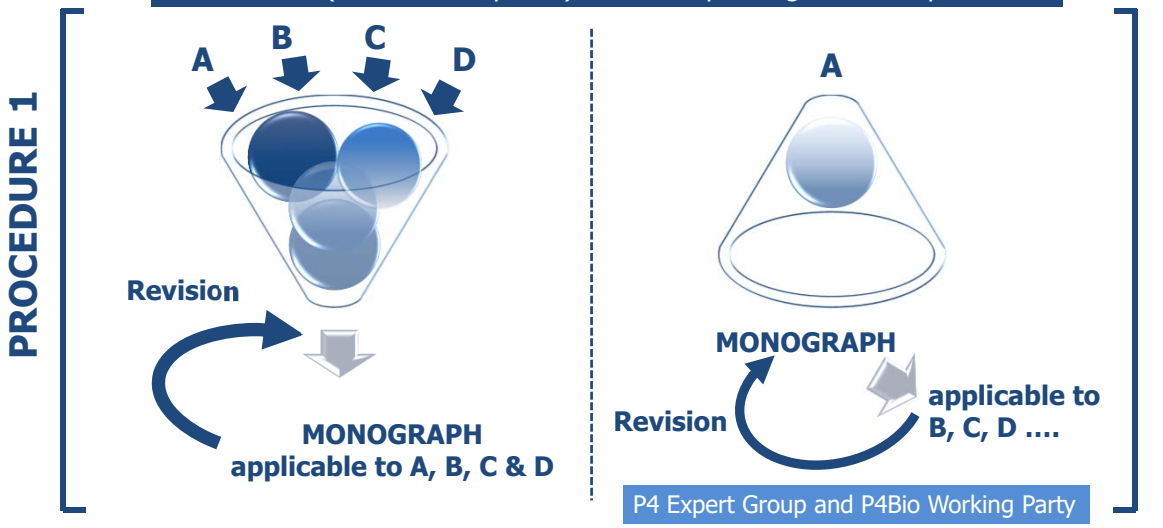
How are Monographs Elaborated / Revised?

Substances (APIs and excipients) and corresponding medicinal products



P4 Procedure: Expected advantages

For Innovator

- **regular and direct exchanges** with the EDQM
- **full transparency** about adaptation of the monograph
- **possibility to request a CEP** for chemical APIs immediately after adoption

For generic/biosimilar

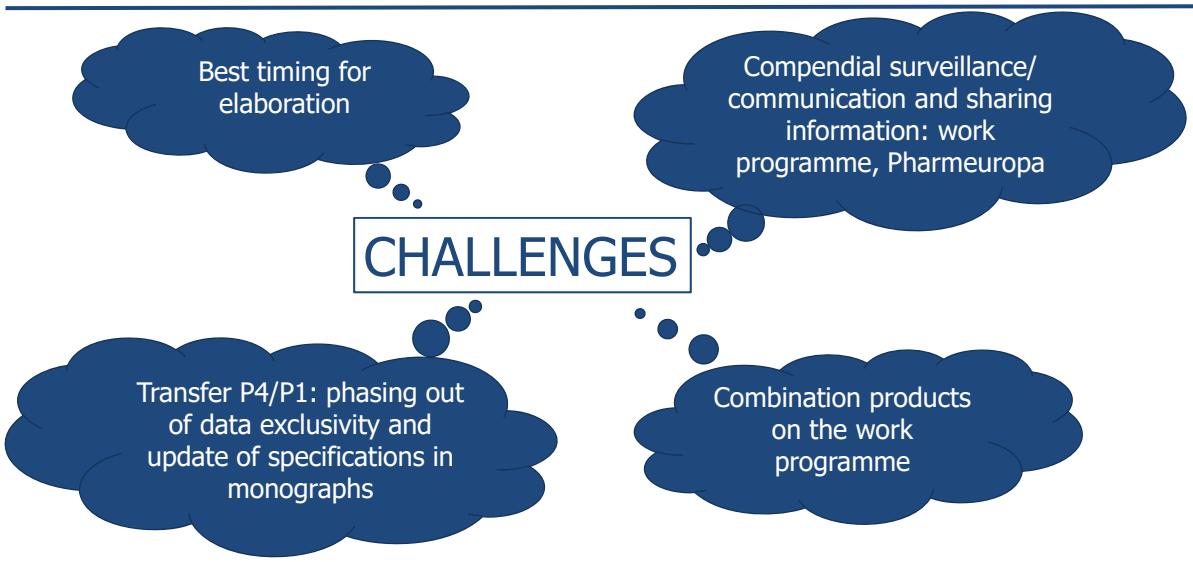
- **publicly-available** source of information
- availability of a monograph may **support the development** of generics/biosimilars

For authorities: licensing/OMCL

- **supporting** the assessment of Marketing Applications of generics
- **single official standard** for market surveillance studies (e.g. medicinal products monograph)

Do you agree ? Other? Your feedback is needed…

Open Discussion



Thank you for your attention

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