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CEP 2.0: the regulatory authorities perspective – Swissmedic, Swiss Agency for Therapeutic Products

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Legal Background

- Switzerland is not a member of either the European Union (EU) or the European Economic Area (EEA)

However,

- Switzerland has been a member of the Council of Europe since May 6, 1963
- Switzerland was a founding member of the “Convention on the Elaboration of a European Pharmacopoeia” on July 22, 1964
- The Ph. Eur. is legally binding in Switzerland for medicinal products (Swiss Therapeutic Products Act (HMG; Heilmittelgesetz))
- Swissmedic Quality Assessors evaluate CEP applications as EDQM External Experts since the 1990ies

Major Advantages of the CEP 2.0 from Swissmedic perspective

- National generic drug applications that include a CEP instead of an ASMF significantly reduce the amount of work required for assessment
  - Our Quality Assessors love CEPs
  - CEPs are an excellent example of longstanding and successful international work-sharing
- Quality of water used in the last steps of the synthesis is specified
  - Important to know if a non sterile drug substance is used in a sterile drug product
- Specification approved by the EDQM is appended
  - It is clear which specifications have been reviewed and approved
  - The use and approval of an alternative analytical procedures is transparent from the specification which mentions that an “in-house” analytical procedure is used

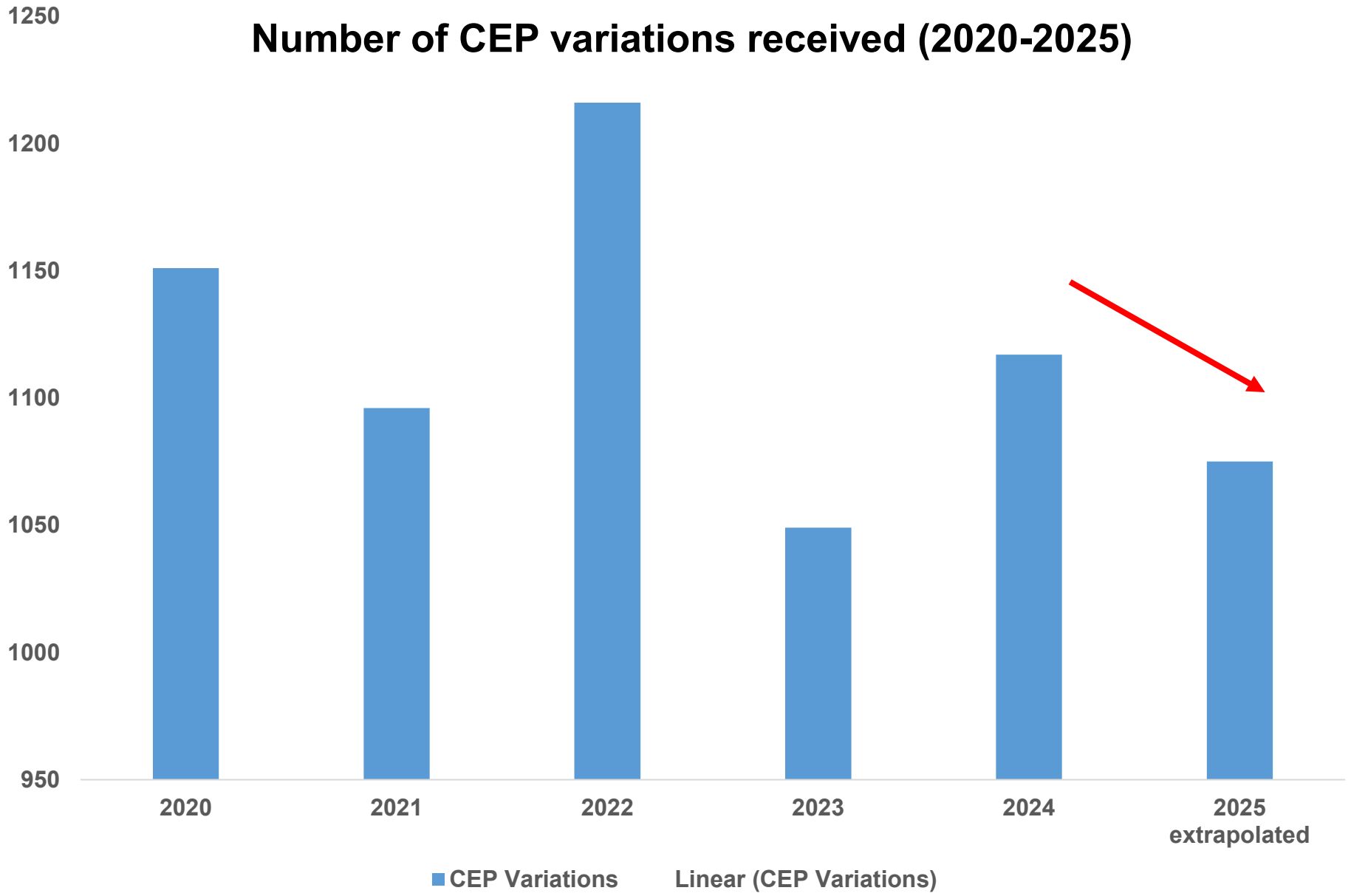
Major Advantages of the CEP 2.0 from Swissmedic perspective

- Additional analytical procedures approved by the EDQM are appended
  - Additional analytical procedures have been reviewed and approved

- Data on micronisation, particle size, microbiological controls, etc. are not included in the CEP dossier or must be removed if no corresponding specific grade is requested
  - The CEP dossier, the assessment performed and the approved specifications are now fully aligned

- Reduction of revisions of CEPs
  - The CEP is not revised if its content is not impacted by the changes proposed to the dossier (even when major)
  - We welcome the reduction of variation applications (B.III.1)
  - Up to now we see a slight reduction compared to 2024 (next slide)

Number of CEP variations received (2020-2025)



Frequent deficiencies by the MAH

- The applicant's part of the ASMF should NOT be included in the dossier
- 3.2.S.4 of the finished product manufacturer: Define clearly which analytical procedures are used in order to avoid unnecessary assessment, i.e. Ph. Eur. monograph, attached to CEP or in-house?
- In case of physical grades not stated on CEP: Submit all necessary information, e.g. details of the micronisation step and name and address of the micronisation site, stability data of micronised substance etc.
- Quality control sites should be provided in Section 3.2.S.2.1