



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Changes to the preparation of the Paediatric Annual Report to the EC

Industry R&D Stakeholder Platform meeting, 5 December 2022

Presented by Isabel Sanchez
Paediatric Medicines Office, Scientific Evidence Generation (H-EG)

An agency of the European Union



Annual report to the European Commission

Art 50(1) Regulation (EC) No 1901/2006 (Paediatric Regulation)

Two parts of the report to list:

- **Companies/products that have benefited from any of the rewards and incentives** and the
- **Companies that have failed to comply with any of the obligations** in this Regulation

on an annual basis.



Rewards and incentives

- Free paediatric scientific advice or protocol assistance (art 26)
- Extensions of the supplementary protection certificate following completion of an agreed PIP (art 36)
- Orphan market exclusivity extension following completion of an agreed PIP (art 37)
- Paediatric use marketing authorization (PUMA) protection periods (art 38)

Obligations

- Timely submission of PIP and Waiver applications (art 16)
- Placing on the market for medicinal products authorised for a paediatric indication following completion of an agreed PIP (art 33)
- Completion of the PIP as agreed in EMA Decision
- Annual Report by applicants to EMA as progress update of deferred paediatric studies (art 34.4)

Annual Report preparation process:

Potential for optimisation for the preparation of the Annual Report has been recognised both by the Agency (EMA-EC action plan) and Applicants (EFPIA proposal).

Challenges

Communication challenges

Potential for enhanced clarity

Justifications and extra revisions

Amendments of the Annual Report

Increase demand of resources and time on all sides

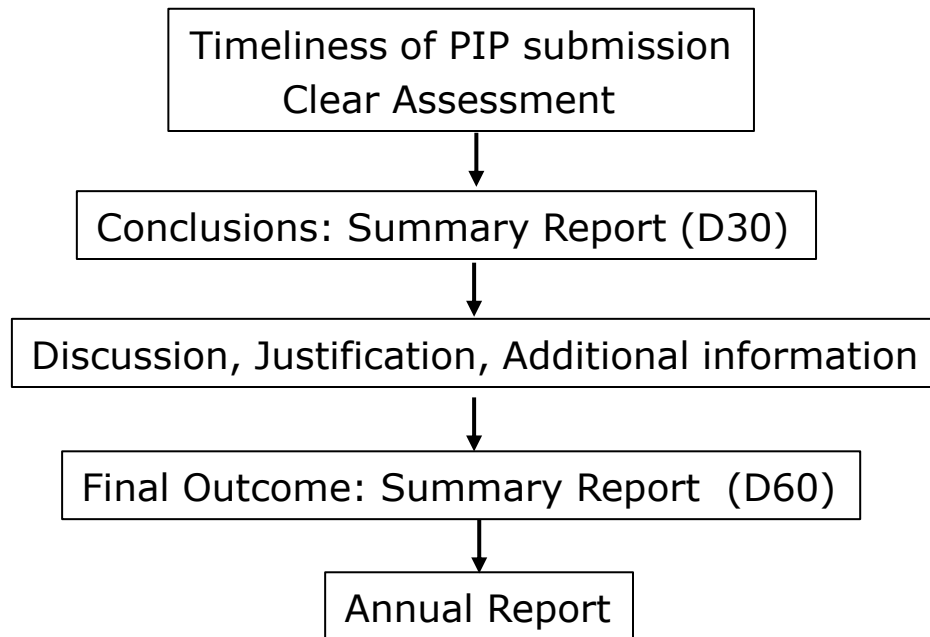
Reputational harm on all sides

Focus on optimisation of operational aspect of timing of PIP submission

Optimisation of the process - Principles.

- Improve implementation of the **current requirements** of the paediatric regulation ensuring timely communication and collaboration between all involved parties.
- **Streamline the process** of the Annual Report preparation to ensure a consistent approach for the evaluation of the correspondent parts of the PIP and the subsequent annual reporting to the European Commission.
- Engage in **early interaction**.
- Achieve clear conclusions and outcomes of the evaluations during the PIP assessment phase
- Clear communication of the outcomes allowing initial clearness of the data to be included in the Annual Report.
- Avoid retrospective revisions, recurring loops and amendments of the Annual Report.

Optimised process:



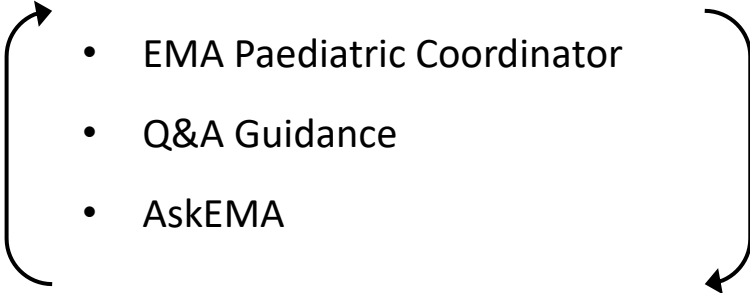
➤ Timelines

- Start of the implementation phase: 2022.
- Ongoing transition period where information on previous assessments might need to be communicated via contact with MAH.
- Expected finalization and procedure to be fully in place for the 2023 Annual Report.

Call for collaboration :

- **Applicants**
 - Provide sufficient and accurate information and context in the PIP/Waiver submissions
 - i.e. stage of the development, studies conducted, dates and justifications for potentially late submission
- Interaction with **PME office** as early as possible if needed (e.g. further clarifications (Day 30))
- **PDCO** - to strive to reach clear conclusion ideally by D60

Available Resources

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- EMA Paediatric Coordinator
 - Q&A Guidance
 - AskEMA

Future steps:

- Continue optimisation of the Annual Report process focusing on other sections such as the placing on the market (article 33)
- Update of guidance
- Revision of the Paediatric Legislation