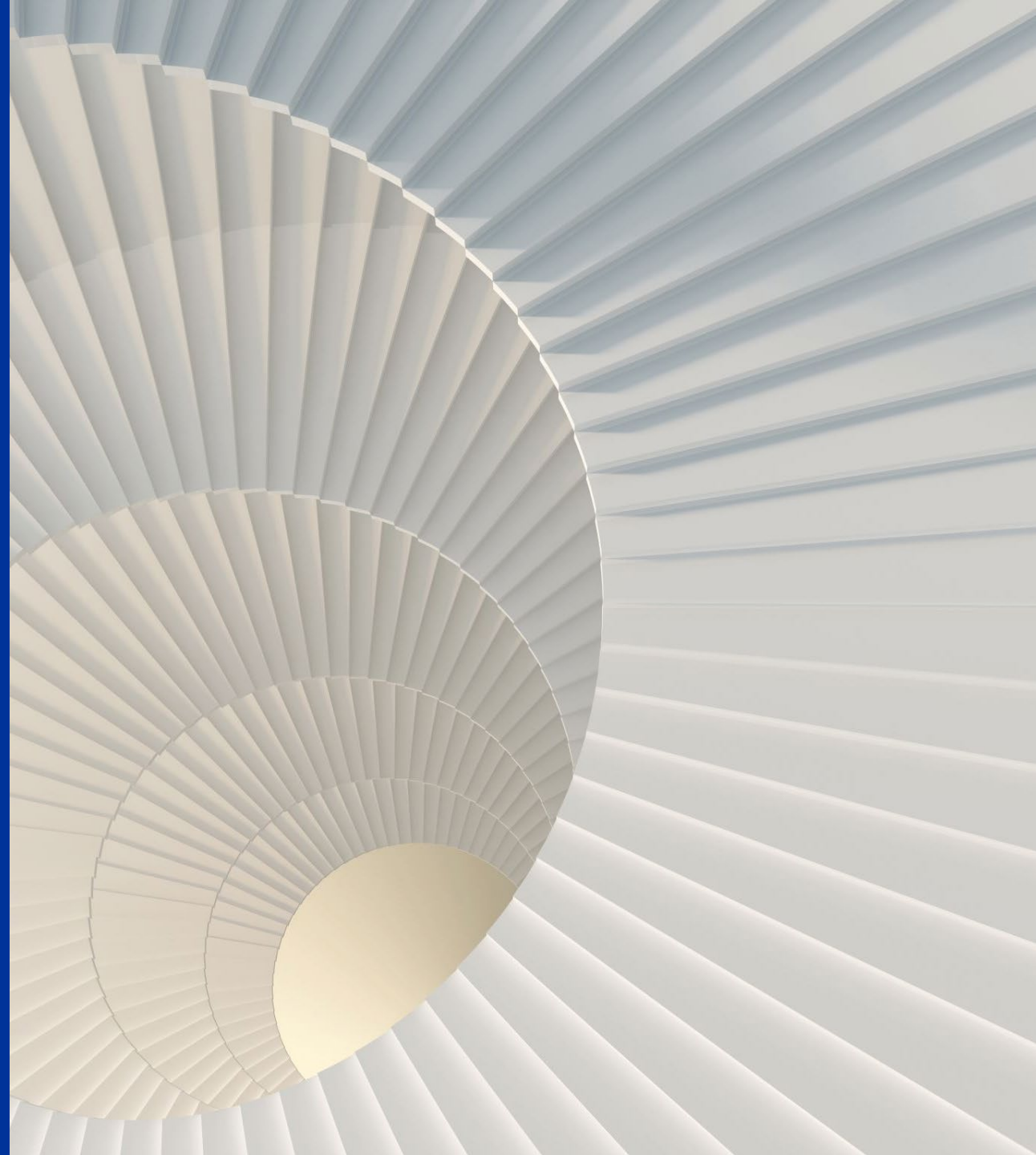


Stepwise PIP

Update on the stepwise PIP pilot

14th R&D industry stakeholder platform July 2025
Presented by Chrissi Pallidis Senior Scientific Officer,
Paediatric Medicines



Stepwise PIP pilot - reminder

- In general, it is expected that all **PIP measures** can be agreed upon at the time of the **initial PIP application**
- For the rare cases when **crucial data are not yet available** to sufficiently define the key elements (KEs) of the planned measure at the time of the initial PIP application → **stepwise PIP approach** → **Opinion on a plan not yet fully defined**
- **KEs that cannot be defined** → **data required for defining them and by when**
- **Minimum set of data** (condition, age subsets, preliminary outline of planned studies and completion date) required
- The sPIP will be modified when relevant data available as agreed in milestones → **fully developed PIP at the end** (same details as for conventional PIP)
- **Paediatric development must not be delayed**

Requests

Pilot concluded once the cut-off of 8 PIP opinions was reached.



Number of requests: 28 (no information on therapeutic area for 2 requests)



Submitted sPIPs: 15



Refused during PDCO discussion: 1



Opinions adopted: 8

Stepwise PIP lifecycle

- sPIPs include conditions/milestones for re-discussion of missing elements
- first modification opinion of an sPIP adopted in June 2025
- elements updated: sample size and stratification according to age groups, study duration, dose, endpoints, statistical plan, date of completion
- updates were based on results of a completed dose-finding study

Next steps

- Revision of the Pharmaceutical Legislation foresees the implementation of the stepwise PIP concept – learning from the pilot for later implementation
- Conclusion of pilot and moving to established procedure
- Discussion and agreement by PDCO
- Update of guidance
- Facilitate process



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Thank you

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