EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PDCO and SAWP interactions

2nd Paediatric Industry stakeholders platform – 15th April 2016

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REGULATION (EC) No 1901/2006, Art. 26

- Any legal or natural person developing a medicinal product intended for paediatric use may, **prior to the submission of a paediatric investigation plan and during its implementation**, request advice from the Agency on the design and conduct of the various tests and studies necessary to demonstrate the quality, safety and efficacy of the medicinal product in the paediatric population in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004.
- In addition, this legal or natural person may request advice on the design and conduct of pharmacovigilance and risk management systems as referred to in Article 34.
- The Agency shall provide advice under this Article **free of charge**.

Scientific Advice

- Scientific Advice is designed to facilitate the development and availability of high-quality, effective and acceptably safe medicines, for the benefit of patients.

- Scientific advice offers an opportunity to initiate a scientific dialogue on all aspects of the development of a medicine including clinical trial design.

EMA web site guidance

- Applicants may choose to request scientific advice first, to help in the preparation of a paediatric investigation plan;

- or to submit a paediatric investigation plan directly and follow it up with a request for scientific advice on, for example, combined adult and paediatric development in light of the paediatric investigation plan requirements.

- Parallel submission of an application for a paediatric scientific advice and an application for paediatric investigation plan **is discouraged**.

Paediatric Scientific Advice applications

The number of companies requesting paediatric scientific advice is increasing every year.

- 2007: 7.6% of scientific advices were related to paediatric matters
- 2015: 21.3%

The PDCO collaborates **closely** with the Scientific Advice Working Party (SAWP) to address questions on pharmaceutical, non-clinical and clinical development.

Why PDCO and SAWP collaborate?

- The collaboration between SAWP and PDCO ensures optimisation of the paediatric development and a link to CHMP and the marketing authorisation process.

- It is of particular importance when e.g., innovative trial designs and extrapolation approaches (informed also by high quality data from adult studies) are used.

How PDCO and SAWP collaborate?

- PDCO members are systematically involved as experts in SA/protocol assistance (PA) procedures in which paediatric questions are concerned.

- Although PDCO members and alternates have contributed to SA since 2007, this has only been formally documented since 2009.

- The PDCO provides paediatric expertise most often on clinical development but also on pharmaceutical and non-clinical development.

CHMP Scientific Advice and Protocol Assistance (including follow-up)

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total
Total number of advice procedures (Scientific Advice and Protocol Assistance)*	277	321	388	400	433	420	473	551	510	3773
Number of paediatric-only and mixed (adult and paediatric development questions) advice procedures*	21	32	74	80	57	91	96	97****	109*****	657
Number of paediatric-only or mixed advice procedures that involved a PDCO member(s)**	ND	ND	68	80	55	91	93	88	97	572

Source: EMA databases. * Year of advice letter. ** Year of start of procedure. ND = Not documented. ***including qualification of biomarker procedures **** including qualification of biomarker procedures and HTA parallel scientific advice

PDCO/SAWP interactions workplan for 2016

- To continue providing input to SAWP on parallel SAWP/HTA advice and on non-imposed Post-authorisation Safety Studies (PASS)

- Review experience gained with interaction process between PDCO and CHMP/SAWP for scientific advice/protocol assistance applications with potential paediatric development

- Transparency on PDCO involvement in scientific advice procedures

Early access and early dialogue pathways

- Adaptive design
- PRIME

➢ See EMA webpage

Apply to Paediatric development

Handeled the same way as the other eligible applications

Optimal use of the PIP and SA procedures

- ICH E11 and the Extrapolation reflection Paper are promoting an early planning of paediatric development at the same time as the adult development as it may be relevant to validate potential paediatric endpoints in the adult trials.
- Timing for discussion on paediatric development **will remain as early as possible**

Interactions should not lead to late submissions of paediatric development plans to SAWP, PDCO, or both, as it is important that the timelines foreseen in the paediatric regulation are respected".

Positive observations based on experience

- PIPs applications always benefit from SA before / after submission at PDCO, …if prospectively planned
- PDCO and SAWP expertise are complementary
- The procedure for PDCO input at SAWP is fully operational and monitored
- Regular procedural optimisation

Thank you for your attention

Further information

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