



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Continuous progress in the area of paediatrics

Review of status of the PDCO work plan delivery

Industry stakeholder platform on research and development support,
15 November 2017

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An agency of the European Union





Information on the status of some of the PDCO activities in the 2017 work plan

- Reinforced cooperation between PDCO and CHMP.
- Ongoing work on PIP overview by therapeutic area (in relation to findings on deferrals in the 10-year report to EC).
- Multi-stakeholder paediatric oncology strategy workshops (ACCELERATE):
 - [Paediatric Strategy Forum for anaplastic lymphoma kinase \(ALK\) inhibition in paediatric malignancies](#) (30-31 Jan 2017)
 - [Paediatric Strategy Forum for medicinal product development for mature B cell malignancies in children](#) (13-14 Nov 2017)



Information on the status of some of the PDCO activities in the 2017 work plan

- [EMA/FDA/Health Canada joint workshop addressing unmet needs of children with pulmonary arterial hypertension](#) (12-13 Jun 2017)
- Neonatology:
 - Ongoing revision of the EMA Guideline on the investigation of medicinal products in the term and preterm neonate
 - Ongoing work in collaboration with the International Neo Consortium, in specific areas (e.g. neonatal seizures, bronchopulmonary dysplasia, neonatal pharmacology).
- Contribution to the EMA [Reflection paper on the use of extrapolation in the development of medicines for paediatrics](#), for public consultation by 14 Jan 2018.



Information on the status of some of the PDCO activities in the 2017 work plan

- Contribution to the [Guideline on Good Pharmacovigilance Practice \(GVP\) chapter 'Product - or Population-Specific Considerations: Paediatric Population'](#), for public consultation until 13 Oct 2017.
- Contribution to relevant ICH guidelines:
 - ICH E11 Addendum
 - ICH S11 'Nonclinical Safety Testing in Support of Development of Paediatric Medicines'
- Contribution to the EMA [Principles on the involvement of young patients/consumers within EMA activities](#), published in July 2017.
- Enpr-EMA activities.