EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 February 2018
EMA/PDCO/566046/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

PDCO work plan 2018

adopted by the Committee on 15 December 2018

Table of Content

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. Evaluation activities for human medicines

1.1. Facilitate patients access to medicinal products specifically authorised for children

Key objective

The PDCO will foster optimal cooperation with the European Commission to ensure the development of an action plan and its implementation based on the conclusions from the EC 10-year report on Paediatric Regulation.

Activities in 2018

PDCO activities to achieve the objectives set for this area:

- PDCO contribution to prepare the EC/EMA action plan based on the conclusions from the EC 10-year report on Paediatric Regulation.

PDCO topic leader: Dirk Mentzer

- Contribution to a multi-stakeholder workshop to finalise the action plan in Q1/2018

PDCO topic leader: Dirk Mentzer

- Review of the criteria to determine paediatric therapeutic needs, and initiate a pilot in identified therapeutic areas.

PDCO topic leader: Karl-Heinz Huemer

1.2. Development of Therapeutic Areas strategies

Key objectives

Define strategies on how to approach PIPs for identified therapeutic areas.

Activities in 2018

PDCO activities to achieve the objectives set for this area:

- Review of the experience acquired by the PDCO in evaluating PIPs in 2 therapeutic areas or conditions (to be determined based on paediatric medical need and/or difficulties to progress with paediatric developments) in order to identify gaps and potential solutions to address them.

PDCO topic leader: Dirk Mentzer

- Multi-stakeholder paediatric oncology strategy workshop

PDCO topic leader: Koenraad Norga

1.3. Other specialised areas and activities

1.3.1. Neonatology group

Key objectives

To actively work with stakeholders in the neonatology field to leverage their experience on questions related to clinical studies of investigational medicinal products for neonates and reflect on the current regulatory guidance, the recent progress in science and the experience acquired by the PDCO in evaluating PIPs involving neonates.

Activities in 2018

PDCO activities to achieve the objectives set for this area:

- Finalise the revision of the EMA neonatal guideline;
- Continue working in collaboration with the International Neonatal Consortium, in specific areas (e.g. neonatal seizures, bronchopulmonary dysplasia, neonatal pharmacology).

PDCO topic leader: Dina Apele-Freimane

1.3.2. Modelling and Simulation

Key objectives

Continue to integrate modelling and simulation expertise into the work of the PDCO and ensure that methodological approaches are consistently applied by the PDCO in coordination with the Modelling and Simulation Working Group (MSWG).

Activities in 2018

PDCO activities to achieve the objectives set for this area:

- Update, in collaboration with the MSWG, the required information on Modelling and Simulation in PIP Summary Reports and in the key binding elements in the PIP opinions.
- Define criteria for MSWG involvement (in reviewing modelling and simulation studies) and translation into a PIP Opinion key binding element measure.

PDCO topic leader: Sylvie Benchetrit

2. Horizontal activities and other areas

2.1. Committees and Working parties

2.1.1. Collaboration with PRAC

Key objectives

Ensure that the needs of the paediatric population are systematically considered in the medicinal products development and assessment.

Reinforce cooperation with other EMA Scientific Committees with a view to supporting the continuity of the paediatric safety and efficacy assessment throughout the lifecycle of medicines.

Activities in 2018

PDCO activities to achieve the objectives set for this area:

- Within the PRAC-PDCO Working Group, discuss the approach when a PIP study becomes a post-authorisation study as part of the RMP.

PDCO topic leader: Dirk Mentzer

2.1.2. Non-clinical working group

Key objectives

To contribute to a global non-clinical strategy to support paediatric studies.

To evaluate the value of juvenile toxicity studies in the therapeutic areas of neurology and psychiatry.

Activities in 2018

PDCO activities to achieve the objectives set for this area:

- Contribution to relevant International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines, such as ICH S11 'Nonclinical Safety Testing in Support of Development of Paediatric Medicines' and ICH S5(R3) 'Detection of Toxicity to Reproduction for Human Pharmaceuticals';
- Finalisation of the review of the significance of juvenile toxicity studies included in PIPs in the therapeutic areas of neurology and psychiatry (i.e. central nervous system active drugs);

PDCO topic leader: Karen Van Malderen

2.1.3. Formulation working group

Key objectives

To contribute to a revised guideline on excipients to support paediatric formulations.

Activities in 2018

PDCO activities to achieve the objectives set for this area:

- Contribution to the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00).

PDCO topic leaders: Brian Aylward, Ann Marie Kaukonen

2.2. Partners and stakeholders

2.2.1. Strengthen dialogue with all stakeholders

Key objectives

Strengthen dialogue with external stakeholders (patients, healthcare professionals (HCP), academia, industry).

Activities in 2018

- In coordination with Patients' and Consumers' Working Party (PCWP), to collaborate on the implementation of the EMA Principles on the involvement of young patients/consumers within EMA activities, to facilitate and promote involvement of young patients within PDCO activities as needed.

PDCO topic leader: Helena Fonseca

- To increasingly use European network of paediatric research at the EMA (Enpr-EMA) and its working groups as platform for discussion among academia and industry with the PDCO

PDCO topic leaders: Angeliki Siapkara, Marek Migdal