28 February 2019
EMA/PDCO/598684/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

PDCO work plan 2019

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The activities outlined in the PDCO work plan for 2019 have been agreed taking into consideration the Agency's business continuity plans (BCP) due to the preparations for the consequences of the UK's exit from the EU, both in terms of impact on the Agency's operations and the physical relocation of the Agency's current premises in the UK to the new premises in the Netherlands.
The Agency is currently implementing its phase 3 BCP, which will be complemented with an additional set of temporary suspensions/reductions as of 1 January 2019, the latter to be launched as part of phase 4 of the BCP. Temporary scaling back of activities is currently scheduled to last until 30 June 2019, see enclosed link for additional information.

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1. Evaluation activities for human medicines

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

Key objective

Foster optimal cooperation with the European Commission to ensure implementation of the EC/EMA action plan developed based on the conclusions from the EC 10-year report on Paediatric Regulation and the multi-stakeholder workshop held at EMA in Q1 2018.

Activities in 2019

PDCO activities to achieve the objectives set for this area:

- 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 2019

PDCO activities to achieve the objectives set for this area:

- Publication of the outcome of the Multi-stakeholder paediatric oncology strategy workshop held in September 2018
- Multi-stakeholder paediatric oncology strategy forum in Q2 2019.

PDCO topic leader: Koen Norga

- Review of the experience acquired by the PDCO in evaluating PIPs in Duchenne Muscular Dystrophy in order to identify gaps and potential solutions to address them

PDCO topic leader: Sylvie Benchetrit

2. Horizontal activities and other areas

2.1. Committees and Working parties

2.1.1. Collaboration with CAT

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 2019

PDCO activities to achieve the objectives set for this area:

- Review of the procedure for interactions between PDCO and CAT.

PDCO topic leader: Dirk Mentzer

2.1.2. Collaboration with CTFG

Key objectives

Prepare the grounds for future interaction with CTFG in 2020.

Activities in 2019

PDCO activities to achieve the objectives set for this area:

- Strengthen dialogue between PDCO and CTFG and establish the process for future interactions.
- Elaborate on criteria for joint adolescent-adult early phase clinical trials.

PDCO topic leader: Dirk Mentzer

2.1.3. Non-clinical working group

Key objectives

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

Activities in 2019

PDCO activities to achieve the objectives set for this area:

- Publication of the outcome 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