



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 December 2019  
EMA/PDCO/507899/2019  
Inspections, Human Medicines Pharmacovigilance and Committees Division

## Paediatric Committee (PDCO): Work Plan 2020

Adopted by the Committee on 11 December 2019

### Table of Contents

<b>1. Evaluation activities for human medicines .....</b>	<b>2</b>
1.1. Development of Therapeutic Areas strategies.....	2
<b>2. Horizontal activities and other areas .....</b>	<b>2</b>
2.1. Committees and Working parties.....	2
2.1.1. Collaboration with CAT .....	2
2.1.2. Collaboration with Clinical Trials Facilitation Group (CTFG) .....	2

**The activities outlined in the work plan for 2020 have been agreed taking into consideration that activities are gradually reinstated following a phase of business continuity.**

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



# **1. Evaluation activities for human medicines**

## ***1.1. Development of Therapeutic Areas strategies***

### **Key objectives**

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

### **Activities in 2020**

PDCO activities to achieve the objectives set for this area:

- Multi-stakeholder paediatric oncology strategy forum in Q1 2020
- Publication of the outcome of above workshop

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 (linked to EC/EMA action plan).

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 2020**

PDCO activities to achieve the objectives set for this area:

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

PDCO topic leader: Koen Norga

### **2.1.2. Collaboration with Clinical Trials Facilitation Group (CTFG)**

#### **Key objectives**

In line with the EMA/EC Action plan, to improve dialogue between EMA/PDCO and clinical trial assessors and facilitate mutual understanding of the interplay between assessment of PIPs and of clinical trials.

#### **Activities in 2020**

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: Anette Solli Karlsen