



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Paediatric Committee (PDCO) Work Plan 2021

Adopted on 11 December 2020

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The activities outlined in the PDCO work plan for 2021 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2021-2023.

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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 or certain paediatric developments.

Activities in 2021

- Multi-stakeholder paediatric oncology strategy forum (CAR T cell) in Q2 2021.
PDCO topic leader: Koen Norga
- Publication of the outcome of above workshop.
PDCO topic leader: Sylvie Benchetrit
- 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: Koen Norga, Sabine Scherer
- Explore possibilities for a PIP model that allows in certain situations to develop PIPs progressively as more evidence becomes available over time (linked to EC/EMA action plan).
PDCO topic leader: Koen Norga, Sabine Scherer

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 2021

- Review of the procedure for interactions between PDCO and CAT.
PDCO topic leader: Koen Norga

2.1.2. Real world evidence

Key objectives

- To identify how real-world evidence can support paediatric development.

Activities in 2021

- Identify use cases where the evidence from real word data can support the scientific assessment (e.g. identify unmet needs, identify needs in children to support waivers and deferrals).
- Agree key principles for a pilot of real-world data analytics to support a proof of concept study to inform the pilot in 2022.

PDCO topic leader: Sylvie Benchetrit

2.1.3. Collaboration with 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 2021

- 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