



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Paediatric Committee (PDCO): Work Plan 2022

Adopted by the Committee on 21 January 2022

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The activities outlined in the PDCO work plan for 2022 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2022-2024.

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1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Development of Therapeutic Areas strategies

Key objectives

- Define strategies on how to approach PIPs for identified therapeutic areas or certain paediatric developments.

Activities in 2022

PDCO activities to achieve the objectives set for this area:

- Contribution to Multi-stakeholder paediatric oncology strategy forum on BRAF/MEK inhibitors (TBC) in Q1 2022; with a second meeting in Q2 and a third meeting in Q3 2022 (both topics TBC)
- Publication of the outcome of above workshop

PDCO topic leader: Koen Norga

- C4C (Conect4children) activities on future topics (e.g. paediatric psychiatry- unmet need in symptom of irritability, atopic dermatitis)

PDCO topic leaders: Fernando de Andres Trelles (Psychiatry), Sabine Scherer (atopic dermatitis)

- 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 leaders: Koen Norga, Sabine Scherer

1.1.2. Real world evidence

Key objectives

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

Activities in 2022

- 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)
- Test the feasibility of processes
- Evaluate the usefulness of the RWE provided
- More specific: at which stage of a procedure request are likely, type of data sources needed, test templates, time needed

PDCO topic leader: Sylvie Benchetrit, Nanna Borup Johansen.

2. Horizontal activities and other areas

2.1. Committees and Working parties

2.1.1. 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 clinical trials.

Activities in 2022

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 leaders: Anette Solli Karlsen, Sabine Scherer, Maria Fernandez Cortizo

2.1.2. Monitoring of CHMP procedures on PIP studies

Key objectives

- To follow CHMP procedures on PIP studies;
- To provide input to CHMP if needed /requested and to regularly inform the PDCO on issues identified during assessment of paediatric data, especially in cases where issues with the studies included in the PIP opinion were identified that require further discussion on PDCO's approach.

Activities in 2022

PDCO activities to achieve the objectives set for this area:

- Re-discuss the current approach to come to a more structured way of involvement.
- PDCO rapporteurs to follow their procedures at the time of MAA.
- PDCO rapporteurs to provide feedback to the PDCO/CHMP on issues identified during assessment of paediatric data.

PDCO topic leaders: Siri Wang, Sabine Scherer, Agnes Guyrasics

2.1.3. Partners and stakeholders

Key objectives

- To increase interactions with stakeholders (including patients/public and HTA) and raise awareness of the work by the PDCO.

Activities in 2022

PDCO activities to achieve the objectives set for this area:

- To explore ways to improve communication on topics discussed during PDCO meetings, raise awareness on the work of PDCO and inform relevant stakeholders about important topics including new paediatric medicines.
- Improve communication with HTA bodies on topics relevant to the PDCO such as formulation.

PDCO topic leaders: Helena Fonseca, Brian Aylward, Karl-Heinz Huemer, Sabine Scherer