PCWP/HCPWP joint meeting-Committee feedback
HCP PDCO Presentation

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March 3, 2023

Boosting the development of medicines for children: Closing report of the European Medicines Agency and European Commission (DG Health and Food Safety) action plan on pediatrics (PDF/2.17 MB)

Identifying pediatric medical needs: Workshops, Accelerate Pediatric Strategy Forums

Strengthening of cooperation of decision makers: FDA, Enpr-EMA, Human HTA bodies

Ensuring timely completion of pediatric investigation plans (PIPs): Trial preparedness, Reflection papers, Extrapolation, structured Guidance (DM)

Improving the handling of PIP applications: Stepwise PIP, pilot started, Waiver/Deferral scrutiny

Increasing transparency around pediatric medicines: Community registry for medicines and trials

Guidance for Stepwise PIP pilot (PDF/240.73 KB) (new), First published: 06/02/2023/EMA/768685/2022

Adapting regulatory processes to better support innovation

Launch of a pilot phase for a ‘stepwise PIP’ agreement

Certain cases to agree on a partial development program, conditional on the development of a full PIP once evidence becomes available over time (partial age waivers)

Allow agreeing on PIPs for innovative medicines where crucial information is not yet available (no validated biomarkers/PD endpoints)

Planning the conditions and milestones for companies to return to EMA’s pediatric committee (PDCO) and discuss the uncertainties once more data are available

Stepwise development with fixed steps and deadlines avoiding modifications