EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Conclusions and next steps

EMA/EC multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation

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What were the objectives of today's workshop?

Multi-stakeholder discussion how to better apply the paediatric legislation to boost development of medicines for children

- Engagement across different stakeholders to facilitate listening and common understanding
- Opportunity to discuss potential improvements to the implementation of the regulatory framework specific for paediatric medicines
- Development of a shared vision for detailed actions to address the identified shortcomings

Joint workshop as crucial step for the development of a concrete plan to address the challenges identified

What have we learned?

Experiences and ideas regarding criteria and methodologies that could be used to identify diseases/conditions of unmet paediatric medical needs

Ideas on measures to proactively address obstacles to timely completion of paediatric investigation plans (PIPs)

Operational challenges in relation to paediatric procedures and exchange ideas for process improvements

Which will be the next steps?

Transparency and continuous engagement:

- Report from the workshop and presentations published in May
- Action plan based on today's input to be established by mid-2018
- Reporting on the progress with the actions

Expectation that all stakeholders need to contribute to boosting development of medicines for children