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Human Medicines Research and Development Support Division

EU-USA strategic meeting on the future of paediatric medicines

Meeting report

Executive summary

On 28 September 2016 EMA hosted an EU-US strategic bilateral meeting to discuss the future of paediatric medicines, intensify collaboration, increase convergence and identify future challenges.

Participants included representatives from the European Commission, the European Medicines Agency and the US Food and Drug Administration.

Processes were discussed to increase harmonization and further streamline global paediatric product development. The envisioned goal in the next few years is:

Aim for a convergent and harmonised paediatric development programme for each medicine, through:

- early and proactive collaboration to increase efficiency during paediatric product development;
- joint outreach programmes to identify high priority paediatric need areas and to facilitate related research and development;
- collaboration with all stakeholders to bring experts, researchers and industry together to address scientific issues in paediatric medicine development.

To conduct these activities, FDA and EMA will use existing venues of collaboration as the basis to expand proactive exchange of information between the agencies, with a focus on ensuring early dialogue and the organisation of joint initiatives and symposia to bring stakeholders together.

The well-established **Paediatric Medicinal Products Cluster**[1] is expected to serve as a key forum for continued discussion and resolution of scientific issues among regulators.

The EMA/FDA **Common Commentary** process will also incorporate input from regulators in Canada, Japan and Australia and will continue to be utilized to communicate the Paediatric Medicinal Products Cluster discussions to sponsors.

[1] A monthly teleconference between EMA and FDA, with the participation of regulators from Canada, Japan, and Australia, to discuss development of medicines for children and share information on regulatory science.

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Disease-specific **working groups** and **joint public workshops** will continue to serve as forums for the scientific discussions. All these forums will facilitate the development and publication of disease-specific model protocol templates.

Also in line with the above aims, the participants discussed further exploring providing joint high-level, early scientific feedback on targeted areas, in a manner that is more detailed than a Common Commentary for developers of medicines for children, with the **possibility of direct interaction with sponsors** when appropriate.

Ad-hoc **mutual participation** in the EMA Paediatric Committee (PDCO) and the FDA Paediatric Review Committee (PeRC) for high priority programmes is to be implemented. Furthermore, it was discussed that evolving science, a mechanism of action based approach and consideration of real-world data will be integrated into and inform paediatric product development programmes, which will be adaptable to new information over time. The participants agreed on the need to address emerging public health threats in paediatric development programmes; to focus on development of therapeutics in neonates and paediatric patients with rare diseases; to develop approaches to collect long-term paediatric safety data and foster collaboration of paediatric clinical trials networks.