



European Network of Paediatric Research at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feedback from EC/EMA-FDA bilateral on paediatric research

Presented by Peter Karolyi on 16 May 2016
Scientific Officer, Paediatric Medicines, EMA

An agency of the European Union



EU-US strategic bilateral on the future of paediatric medicines

- intensify collaboration
 - increase compatibility
 - identify future challenges
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- 28 September 2016
 - Co-Chaired by Florian Schmidt, European Commission and Sandra Kweder, FDA

Participants

- European Commission: 3
- EMA: 16 (D Division, Paediatrics, Legal, Regulatory, Pharmacovigilance, PDCO Chair, etc)
- FDA: 5 in person (OPT, Paed and Maternal Health, FDA Europe)
7 by phone (Divisions)

Areas of discussion

- Harmonisation / Streamlining
- Evolving Science in Paediatric Research: role of regulators
- Collaboration of all stakeholders
- Looking ahead

Key conclusion

- 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.

Goals

- The EMA/FDA Common Commentary process shall also incorporate input from regulators in Canada, Japan and Australia
- Disease-specific working groups and joint public workshops
- Further exploring providing joint high-level, early scientific feedback on targeted areas, 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
- Evolving science, a mechanism of action based approach and consideration of real-world data shall be integrated into and inform paediatric product development programmes, which shall be adaptable to new information over time

Published report

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/12/WC500218004.pdf

Thank you for your attention

Further information

European Network of Paediatric Research at the European Medicines Agency
([Enpr-EMA](#))

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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