EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Action Plan on Paediatrics – holistic approach

Annual Enpr-EMA workshop
07 June 2018

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Workshop to improve implementation of Paed Regulation

- Date: 20 March 2018
- Multi-stakeholder meeting (~160 participants):
  - Patients/carers
  - Academia (incl. networks)
  - Health Care Professionals
  - Industry
  - FDA
  - CTFG
  - WHO
  - Ethics committees
  - EMA/PDCO/EC

Topic areas of Action Plan

1. Identifying paediatric medical needs
2. Strengthening of international cooperation between regulators
3. Ensuring timely completion of Paediatric Investigation Plans (PIPs)
4. Improving the handling of PIP applications
5. Increasing transparency around paediatric medicines

Identifying paediatric medical needs

- Input of all stakeholders
- Alignment of actions by national and international partners

Strengthening of international cooperation

- Initiatives to further increase regulatory cluster interactions
- Contribution of investigators and other stakeholders

Ensuring timely completion of PIPs

- Optimisation of development programmes from early stages onwards:
  - Knowledge/information sharing between all relevant stakeholders (patients, academia/research, networks, industry)
  - Consideration and early regulatory discussions of trial designs and methodologies
  - Optimisation of the estimation of patient availability
  - Involvement of patients and young people along the drug development process
- Clinical trials:
  - Guidance for planning clinical trials
  - Sustainable infrastructure and funding
- Training and exchange of information between assessors of clinical trials (NCAs), ethics committees and regulators (involved in PIP-process and marketing authorisation).

Development of Action Plan

EC/EMA Action plan to cover period until 2020

- Working groups (EC,EMA & PDCO) on topic areas
- Discussion and finalisation at PDCO meetings

Publication of Action Plan planned by end of July