The 2018 EMA-EC action plan to improve the implementation of the Paediatric Regulation

7th ACCELERATE Paediatric Oncology Conference
Brussels, 14-15 February 2019

Presented by Ralph Bax
Head of Paediatric Medicines, Product Development Scientific Support Department, European Medicines Agency
1. More medicines authorised for children
2. Better product information
3. More paediatric trials and research

goals

analysis

Workshop 3/2018

Action plan 10/2018
Workshop to improve implementation of Paediatric Regulation

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

Paediatric medicines

The report on the Paediatric Regulation workshop is now available. Check out EMA’s factsheet and video for insights and views on the impact of this regulation.

Find out more...
# EMA-EC action plan 2019-2020

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Identifying paediatric medical needs

- Raise awareness for paediatric medical needs
  - Input from all stakeholders
  - Multi-stakeholder focus groups and workshops
  - ‘Paediatric Landscape Reports’
- Structured assessment in PIPs

| 3 | Establish framework for collaboration of EMA/PDCO with the U.S. FDA’s Oncology Center of Excellence Pediatric Oncology Program regarding the assessment of relevant molecular targets in paediatric cancers. | To maximise synergies and share expertise in the assessment of relevant molecular targets and to address medical needs with a global perspective. | In progress. | 12/2019 |
Strengthening of international cooperation

- Initiatives to further increase regulatory paediatric cluster interactions
- Contribution of investigators and other stakeholders
  - Clinical Trial Facilitation Group
  - Regulatory paediatric cluster activities (enhanced integration and transparency)
  - Increase global interactions between EMA/PDCO and other stakeholders including networks.
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:
  - Recommendations 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).
Improving the handling of PIP applications

- Exploring ways of adapting PIPs to the evolution of scientific knowledge
- Enhance possibilities of communication with PIP applicants
- Improvement of guidance, administrative requirements
Work is ongoing!

**EC/EMA Action plan to cover period until 2020**

- Time lines for action items according to priority
- Working groups with stakeholders have already started

**Follow-up and outcome**
Thank you for your attention

Further information

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