EU Paediatric Regulation 10 yrs

Results and expectations

Fabio D'Atri, European Commission – DG SANTE

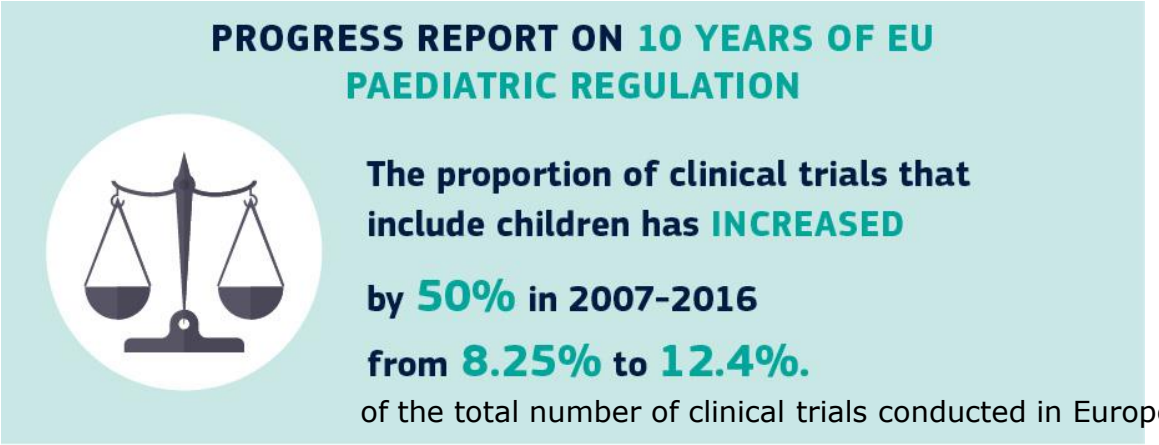
The Paediatric Report

- EC Report to the Parliament and to the Council (October 2017)
  - Study on the economic impact of the paediatric Regulation (December 2016)
  - EMA 10-years Report to the European Commission (August 2017)

European Commission

The Paediatric Report

More research



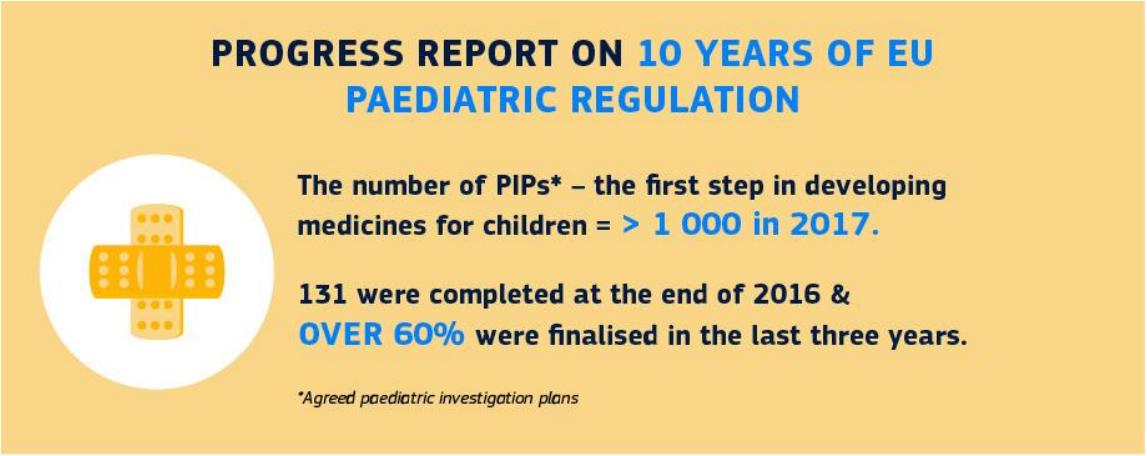
European Commission | Health and Food Safety

https://ec.europa.eu/health/human-use/paediatric-medicines_en

European Commission

The Paediatric Report

Increased development



European Commission

The Paediatric Report

More authorised products

European Commission

The Paediatric Report

Challenges identified

- Differences between the various therapeutic areas (paediatric only, like many cancers);
- Overlaps with the orphan legislation;
- Completion of PIPs;
- Rewards not always "working".

Next steps

- Short term actions;
- Medium term vision.

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Next steps

Short term actions

- Discuss paediatric needs in an open and transparent dialogue with all interested parties;
- analyse the experience with use of deferrals; speedier completion of PIP;
- handling of PIP applications; if necessary adapt Comm. Guidelines;
- provide additional transparency of new products authorised with paediatric indications;
- deliver regular updates about development and trends of the paediatric medicines landscape fostering international cooperation and harmonisation;
- foster international cooperation.

Next steps

Short-term actions

- EC-EMA Multi Stakeholders workshop 20 March 2018
  - Methodologies to identify paediatric needs
  - Strengthening international cooperation
  - Ensuring timely completion of PIP
  - Improving the handling of PIP applications
  - Increasing transparency

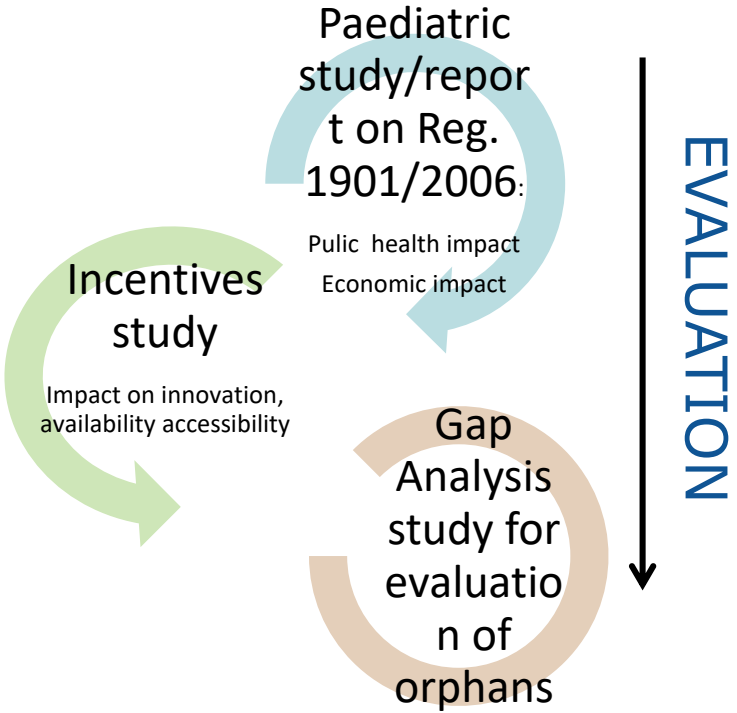
Next steps

Short-term actions

- EC-EMA Multi Stakeholders workshop 20 March 2018
  - Report of the meeting: May 2018
  - 2 years action plan: Summer 2018

Next steps

Medium term



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Next steps

Medium term

November 2017

Roadmap

2018/2019

Study on orphans

Various stakeholders consultations

2019

Joint Evaluation

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Evaluation

- Identify the problems;
  - Strengths and weaknesses of paediatric and orphan legislations alone and combined
  - How incentives have been used
- Propose possible solutions/options for solutions.

Thank you for your attention!

Disclaimer: The views and opinions expressed in these PowerPoint slides are those of the presenter; they do not necessarily reflect the opinion of the European Commission.