State of Paediatric Medicines in the EU

Access to Paediatric Medicines

IPOPI 11th PID Forum
27 June 2018, Brussels

Health and Food Safety

European Commission

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

More research

PROGRESS REPORT ON 10 YEARS OF EU PAEDIATRIC REGULATION

The proportion of clinical trials that include children has INCREASED

by 50% in 2007-2016

from 8.25% to 12.4%.

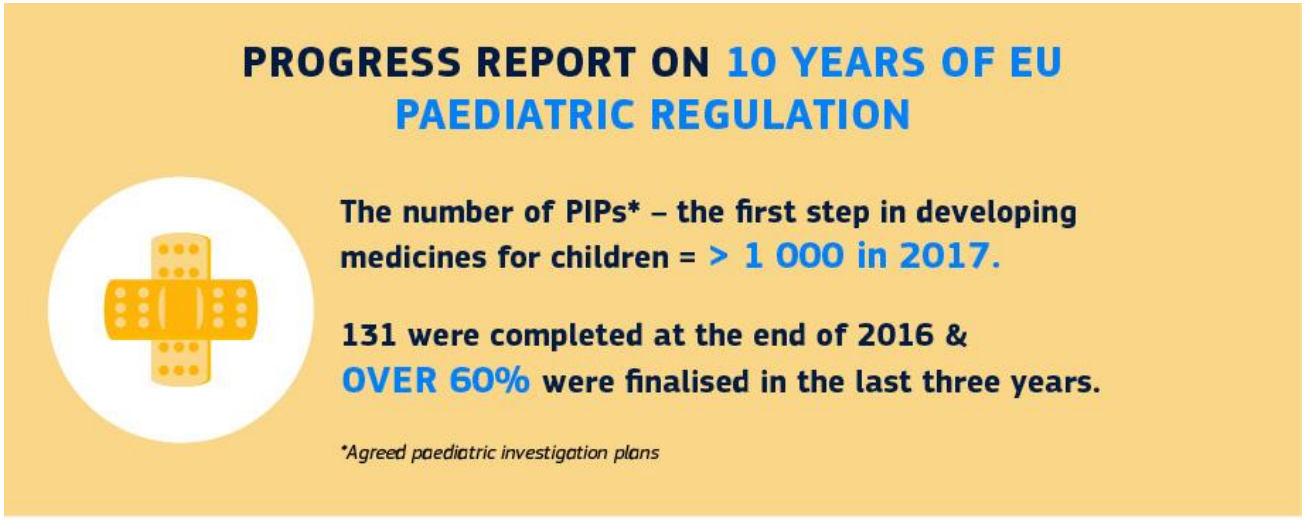
of the total number of clinical trials conducted in Europe

European Commission | Health and Food Safety

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

European Commission

More paediatric information



European Commission | Health and Food Safety

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

European Commission

More authorised products

European Commission | Health and Food Safety

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

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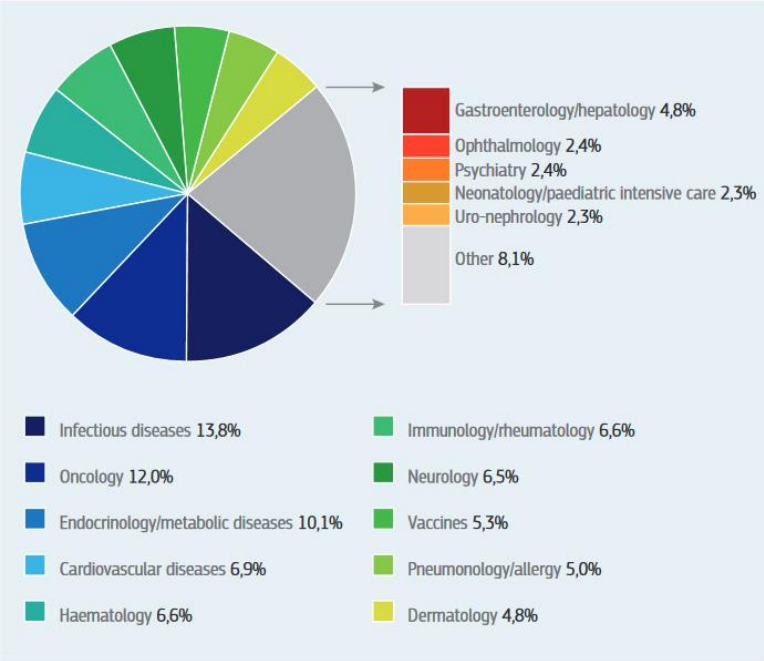
The report in a nutshell

Improvements

- More paediatric research
- More authorised products for children
- More information on the products

Challenges

- Differences between the various therapeutic areas
- Overlaps with the orphan legislation are problematic
- Completion of PIPs
- Rewards not always "working"



Source: EMA database (PedRA)

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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.

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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


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2016
EMA/49414/2018
Human Medicines Research and Development Support Division

EMA/EC multi-stakeholder workshop to further improve the implementation of the Paediatric Regulation

20 March 2018

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

Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

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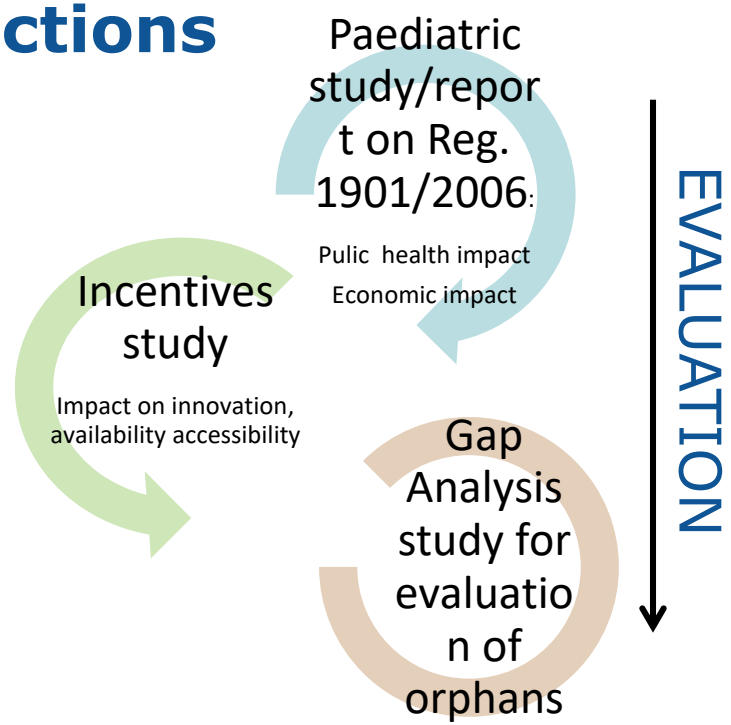
Next steps

Medium term actions



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TIMELINE

2017

Roadmap

4-week public consultation

2018/2019

Study on orphans

Various stakeholders consultations

2019

Evaluation

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More information:

http://ec.europa.eu/health/human-use/index_en.htm

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