The 10 years report on the EU paediatric Regulation

Fabio D'Atri
DG SANTE
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"The Commission shall present in 2017 a report to the European Parliament and the Council on the experience acquired as a result of the application of Articles 36, 37 and 38. The report shall include an analysis of the economic impact of the rewards and incentives together with an analysis of the estimated consequences for public health of this Regulation, with a view to proposing any necessary amendments."
Paediatric Regulation

- EMA 10-years Report to the European Commission
- Study on the economic impact of the paediatric Regulation
- EC Report to the Parliament and to the Council
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

More authorised products

PROGRESS REPORT ON 10 YEARS OF EU PAEDIATRIC REGULATION

260 new medicines for children were authorised between 2007 and 2016.

More paediatric information

**PROGRESS REPORT ON 10 YEARS OF EU PAEDIATRIC REGULATION**

The number of PIPs* – the first step in developing medicines for children = > 1 000 in 2017.

131 were completed at the end of 2016 & OVER 60% were finalised in the last three years.

*Agreed paediatric investigation plans

The Paediatric Report

Challenges

- 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.
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

- Expression of interests for patients representatives, academia, healthcare professionals associations. Deadline 14 February.

Next steps

- Medium term

- Paediatric study/report on Reg. 1901/2006:
  - Public health impact
  - Economic impact

- Incentives study
  - Impact on innovation, availability, accessibility

- Gap Analysis study for evaluation of orphans

EVALUATION
Study on orphan legislation

- **Orphan legislation dates back to 2000** – is it still fit for purpose?
- **2006 - report on the experience acquired** as a result of the application of the Orphan Regulation
- **2016 Council Conclusions**

Objectives reached?

Results at reasonable cost?
November 2017

Roadmap

2018/2019

Study on orphans

Various stakeholders consultations

2019

Joint Evaluation
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!

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