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Paediatric Clinical Research

The Commission's perspective

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Health

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The Paediatric Regulation

Milestones

- 2004: Commission legal proposal
- 2006: Adoption of Regulation (EC) No 1901/2006
- 2007: First meeting Paediatric Committee
- 2009: The first marketing authorisation based on a completed Paediatric Investigation Plan (PIP)
- 2011: The first Paediatric Use Marketing Authorisation (PUMA)
- 2013: Commission progress report

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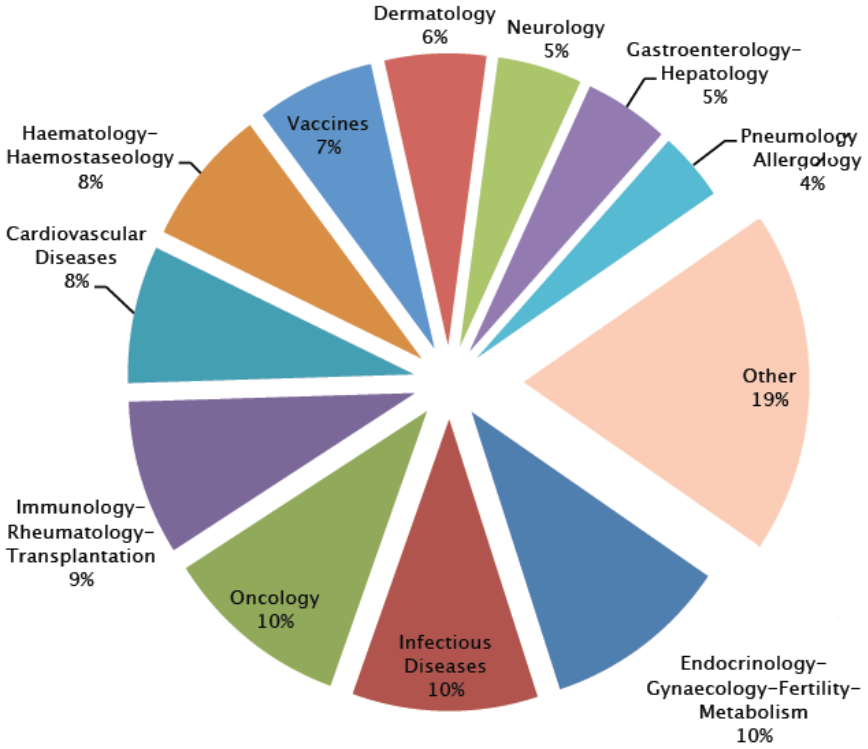
Achievements

- Aim of the Regulation: reduce off-label use, increase knowledge on paediatric use
- After 7 years: Paediatric development now integral part of product development
- However, in view of the development cycles for medicinal products, full impact can only be judged in the years to come
- Promising product pipeline
- More data in previously neglected age groups (neonates)
- More age-appropriate forms



Therapeutic areas covered by paediatric investigation plans

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Clinical research

- The changes in the legal framework mirror a change in the approach with regard to paediatric research
- *Previous 'paradigm':* children should be protected from clinical research
- *Nowadays*: The health and safety of children is better protected if the use of medicines in children is based on evidence rather than experience. This implies more clinical research with children.

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Challenges

- Clinical research in children is complex
- Sponsors of paediatric clinical trials often report problems of methodological, ethical or budgetary nature
- Low number of paediatric patients participating (recruitment)

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Participation in research

- Key role of patients, parents and health professionals
- Concerns/perceptions?
- National initiatives
- View of the PCWP/HCPWP: What is your experience?