

# Paediatric regulation

Future developments in Belgium  
... the Pharma Industry view...



# Paediatric Regulation: the essentials

- A requirement at the time of marketing authorization applications for data on the use of the medicine in children
  - System of waivers from this requirement for medicines unlikely to benefit children
  - System of deferrals to ensure medicines are tested in children only when it is safe to do so and to ensure the requirements do not delay the authorization of medicines for adults



# Paediatric Regulation: the essentials

- A reward for studying medicines for children
  - New medicines
    - ▶ 6-months extension to the supplementary protection certificate - in effect, six-month patent extension;
  - Off-patent medicines
    - ▶ 10 years of data protection for new studies via a Paediatric Use Marketing Authorization



# Paediatric Regulation: the essentials

- Increased safety monitoring for children's medicines
  - Compulsory submission by industry of existing studies in children;



## How to achieve this at EU level

- EU inventory of the therapeutic needs of children
- EU network of investigators and trial centers to conduct the studies required
- Free scientific advice by EMEA



# EU CT Directive

- Trials on minors can be undertaken if
  - Research relates directly to condition and no alternatives available
  - Interest of minor prevails over those of science and society
  - Approval by Ethics Committee with paediatric expertise
  - Informed consent given by parents or legal representatives
  - Minor has received benefit/risk information
  - Explicit wish of minor if capable is followed
  - No financial benefits



## Belgian LEH (art.7)

- Experiments in children if
  - Informed consent of both the parents or a legal representative and Informed consent from child as soon as possible
    - ▶ Child's decision prevails
  - Therapeutic benefit
  - No other method available
  - Positive risk/benefit ratio expected
  - Favorable opinion EC
    - ▶ Should include or consult with at least 2 Paediatricians
  - No financial benefit



# Major Hurdles

- Limited experience with trials in children with all the stakeholders
  - Informed consent at level of children understanding
  - Handling difficult family situations
  - Logistics to be adapted
- Balance between regulatory requirements and feasibility



# What to do in future?

- Bring stakeholders together
  - Pharma Industry
  - Paediatrician investigators
  - Parents
  - Children
  - Ethics Committees + paediatrician experts
  - Competent Authorities



# What to do in future?

- Create a platform
  - Share expertise and know How
  - Develop together the environment
  - Facilitate exchange amongst stakeholders
  - Find solutions and develop framework
  - Prepare for the EU network Create platform

**Information  
Communication  
Training  
Discussion**

**Shape the environment**



# Why in Belgium?

- Belgium in general
  - Many studies
    - ▶ Good reputation
    - ▶ Excellent science
    - ▶ Favorable regulatory environment
  
- Belgium in paediatric research
  - Same goal
    - ▶ Point of interest for Belgian FAGG
    - ▶ Expertise available



# Final Goal

Serve the interest of paediatric patients and their families by speeding up the development of children specific medicines

