



European Federation of Pharmaceutical  
Industries and Associations



European Confederation of  
Pharmaceutical Entrepreneurs AISBL

## Industry perspective and proposals for action plan 2018-2019

Authors: Lene Rose Arfelt, Tillmann Taube, Martine Dehlinger-Kremer



Annual Meeting of Enpr-EMA  
members and Coordination Group  
meeting  
Friday, 08<sup>th</sup> June 2018



# Industry Perspective & Proposal for action plan 2018/2019

## - Optimisation of PIP development & realisation (1/2)

- Enpr-EMA WG 3&5 Recommendation that companies should contact selected network very early in drug development process & before preliminary PIP and to keep in contact with network until MAA and beyond
  - Company to contact Enpr-EMA as step 1
  - Enpr-EMA to propose a network to the company. Company to contact network (step 2)
    - Enpr-EMA to have adequate resources to identify the appropriate network.
    - Networks to have adequate description of services offered
- Publish the recommendation of Enpr-EMA WG 3&5 asap
- Start to apply the process for all new PIP's. Propose to not wait the outcome of the pilot from Enpr-EMA WG 3&5

# Industry Perspective & Proposal for action plan 2018/2019

## - Optimisation of PIP development & realisation (2/2)

- Enpr-EMA to be included in informal early discussions with PDCO/EMA and Industry on paediatric development plans
- A new pilot similar to “Early dialogue for paediatric development plans” from 2015-2017 could be started and include Enpr-EMA together with PDCO/EMA and Industry

# Perspectives on action plan 2018/2019 as per discussion of meeting dated 07 June 2018 (1/2)

- Establish international collaboration between regulators (EMA, FDA, Canada, PMDA) and networks (e.g. Enpr-EMA representing Europe) - like an ICH set-up
  - Initiative would be beneficial for global drug development and global trials
- Best practice to looking at standard of care
  - Very important for development of new therapies for children
  - Enpr-EMA in role of facilitator/integrator
- Parents - how to share good practice
  - Parents/Patients organisations to be involved in Enpr-EMA (cat. 4 network)
    - Support development parent/patients “friendly” protocols and thus improve recruitment and retention
    - Motivate parents to get positive towards paediatric research

# Perspectives on action plan 2018/2019 as per discussion of meeting dated 07 June 2018 (2/2)

- Carry on work of all the existing working groups of Enpr-EMA
  - Important initiatives - need to ensure adequate sharing of the outcomes (written communication, conferences)
  - Ensure enough communication to ensure adequate collaboration and avoid duplication of efforts
    - GCP training: get support from companies specialised in training

# Perspectives on discussion of meeting dated 07 June 2018

- Parents and EC
  - Involve parents in ECs
- Access to medicines for children
  - Involve HTAs early on.
  - Alternative HTA exemption for pediatric

Thank You