



European Federation of Pharmaceutical  
Industries and Associations

# CMDh Meeting with Interested Parties – EFPIA contributions

20 September 2010

- Different procedures for submission of data under Art.46 based on whether Centralised or DCP/MRP
  - Divergent processes create unnecessary issues for companies' internal compliance systems
  - EFPIA strongly recommends one consistent regulatory process, regardless of registration route
- EFPIA shortly starting survey of members to gather quantitative data on experiences with Paediatric Regulation, including Art.45 and 46 procedures. Results to be available 1Q2011