

# CMDh Meeting with Interested Parties – EFPIA contributions

21 June 2010

- MRP/DCP Resources (2)
- Variation Regulation (4)
  - Type 1A implementation (AOB)
- Art 30 Harmonisation (AOB)
- Paediatric Art 45/46 workshares (AOB)

- Seek clear and transparent criteria for prioritisation of products for inclusion in list of Article 45 procedures
  - Possibility for companies to propose inclusion to allow for better planning of resources?
- Recommendations on paediatric worksharing (CMDh/141/2009) not always followed (e.g. requests from assessors for additional studies)
  - Respectfully request that Recommendations are followed
- Over 140 molecules included in list of active substances for Art.45 worksharing
  - How many worksharing procedures have been started?
  - What impact do these procedures have on Regulatory Agency resources?

- 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