



European Federation of Pharmaceutical
Industries and Associations

CMDh Meeting with Interested Parties – EFPIA contributions

20 September 2010

- 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?

- Procedural Aspects
 - **Rapporteur designation**
Check that the reference product is authorised in the country of the Rapporteur to facilitate the review
 - **Timetable of the WS procedure**
Issue timetable immediately after submission of the dossier
 - **Preliminary Paediatric Assessment Report**
Send PPdAR to MAH for information
 - **Clock-stop**
Define a standard clock stop period (e.g. 2 months) which may be modified upon discussion and agreement between the Rapporteur and the MAH.
 - **Public Assessment Report**
Provide draft to the MAH for review prior to publication