

CMDh Meeting with Interested Parties – EFPIA contributions

21 June 2010

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

- Too early to tell as Regulation only entered into force Jan 2010, however...
- Challenges for Industry to implement periodic notifications
 - Need for internal tracking system – needed final guidance to do this, delayed as complex system
 - Full applications (including all supporting data and replacement pages etc), no reduction in administration
 - No significant reduction in fees (fee per change still in many Member States)
 - e-CTD challenge
 - Need proof of “authorisation” of variation for submissions in export markets/CADREAC
 - Need prior approval for variation in some Member States, until Type IA periodic notification fully implemented for national MAs