

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)

- EFPIA welcomes actions taken by CMDh and HMA:
 - The increased transparency at EU level on slot lead times in Member States
 - The increase in number of agencies volunteering as RMS

- However, some previous observations remain: even agreed MRP/DCP guidelines are not followed
 - Validation phase often prolonged beyond 15 days (e.g. CMS have divergent positions on legal basis of the dossier; requests for specific national requirements)
 - Prolongation of DCPs to full 210 days by maintaining differences in opinion to the very last moment or due to need for assessment by national committee(s) whose processes are not in line with MRP/DCP timelines
 - In some agencies, coordination role could be improved: key documents not being distributed within NCAs
 - Local implementation times after DCP/MRP remain far beyond 30 days in many countries

- Do not delay validation based on legal basis – discuss and agree during procedure
- Timely referral of divergent opinions to CMDh to ensure adherence to timelines
- Better coordination within NCAs to ensure timely involvement of national committees
- Companies committed to providing necessary information in timely manner

- Situation is improving but still has some way to go
 - EFPIA analysis shows inconsistency between the currently published HMA map and other sources, including CMDh e-submission requirements table and NCA websites
- EFPIA appreciates the on-going work to revise and re-issue CMDh table but would welcome opportunity to review table before being published
- EFPIA would appreciate establishment of consistency between CMDh e-submission requirements table and public information on NCA websites and HMA map
- Our on-going concern will be regarding the currency and consistency of information
 - And which source takes precedence if there is a discrepancy