

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)

- Integration of national marketing authorisations as soon as possible is critical
- Guidelines from CMDh and EMA are very helpful
 - Limited time vis a vis entry into force of Regulation
- Grouping needs more pragmatic approach
 - Some CA only use Annex III example listing for acceptable groupings
 - CMD (h) guidelines could address some of these issues
- EFPIA survey data to be collected by end Nov 2010; results, to be available 1Q2011, will provide more quantitative feedback

- Not much experience from EFPIA members to date
- Timeline for announcement and preparation with CMDh is a concern for some variations, i.e. for labelling
- Type II timeline for workshare applications only containing Type IB's limits use for minor variations
- Real use will be when “pure” national marketing authorisations are included
- Efficiency gain mainly depends on duration of procedures

- For Worksharing including original product and clones/duplicates
 - Consider “master” agreement on worksharing concerning original and clone/duplicate products, so no need to ask for agreement on the use of Worksharing for each submission
 - Easy & quick process needed to get the WS number (not linked to CMDh meeting) as Worksharing concept approved previously
- For Worksharing including type IB’s as “highest” variation type
 - Allow 30-days timetable instead of 60 days

- Not much experience from responding EFPIA members to date
 - Excellent support and feedback from RMS and PTLs received for ambiguous classifications
 - Procedure is lengthy
 - Use of default type IB, if Type IA requirements not met, clarifies many initial questions so no need for Art.5 procedure in these cases
- CMDh policy to minimize the requests, to keep flexibility, is fully supported by EFPIA

- 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