

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)

- Objectives
 - To obtain consistent (between NCAs) and timely
 - implementation of Art 30 SmPC harmonisation EC Decisions in all MSs
 - start of MRP procedure
 - To avoid duplication of reviews
- Request
 - Agreement on and adherence to a SOP or Best Practice Guide for NCA and Industry on specifics of Article 30 post-CHMP opinion
 - CMDh website to be updated to clarify/supplement current referrals Recommendations
 - FAQ on Art 30 Referral post-CHMP Opinion
 - Best Practice Guidance

1. Agreement on RMS & allocation of MRP number
2. Adoption of EC decision into national MAs
3. Optional CMC harmonisation during Art 30 referral
4. Inclusion of MRP renewal
5. Inclusion of safety assessments & PSURs
6. Inclusion of paediatric worksharing

- **ISSUE:**

- Inconsistent and, in some cases, time-consuming process to get agreement on RMS and MRP number following harmonisation

- **PROPOSAL:**

- Immediate notification from EMA to CMDh following CHMP Opinion adoption
- MAH sends choice of RMS (standard form) to CMDh within 7 days of CHMP Opinion
- CMDh actions in CMDh meeting following Opinion
 - Timely Appointment of RMS (choice of MAH or nominated by CMDh if none proposed) & allocation of MRP number
 - Notification Letter (standard form) from CMDh to MAH including
 - Confirmation of RMS and name of a contact person
 - MRP number

- **ISSUE:**

- Inconsistent requirements (variation type I and II, different administrative requirements, resubmissions of parts of dossiers, comparison tables,...) and timelines in different NCAs in order to get the Art 30 EC Decision implemented in the national MAs

- **PROPOSAL:**

- Harmonisation of requirements to one simple administrative process in all MS with sufficient resources provided by MSs
 - Guideline on categories of variations indicates that change in product information in accordance with referral is Type IA_{IN} (change C.I.1.a)

- **ISSUE:**

- Alignment of national MAs with the Art 30 referral EC Decision in most resource efficient way

- **PROPOSAL:**

- Option to allow MAH to request CMC harmonisation in parallel to Art 30 procedure. Updated Module 3 in eCTD format to be submitted at Day 2 of Art 30 procedure
- CMC FUMs as included in Letter of Undertaking
 - Submissions occur in line with the MRP Variation Guideline within agreed timelines and/or amended timelines agreed with RMS, but not earlier than 30 days after EC Decision

- **ISSUE:**

- MRP renewal is required at next national renewal (even if the harmonisation has just finished a month earlier). If MRP renewal not initiated by the company, national MA renewals are still required to be completed, risking de-harmonisation

- **PROPOSAL:**

- Art 30 SmPC harmonisation can be considered to satisfy main review requirements of renewal procedure
- In case of renewal post-referral, harmonised MA should automatically be renewed under simplified procedure

- **ISSUE:**

- During harmonisation, the totality of the safety of a product is re-examined. However PSUR worksharing procedures may start soon post-CHMP harmonisation and not necessarily with the RMS as coordinator

- **PROPOSAL:**

- Ensure MRP RMS and PSUR worksharing coordinator are same
- Improve coordination of referral and PSUR worksharing assessments for efficiency gains and to achieve single integrated outcome

- **ISSUE:**
 - Coordinator for paediatric worksharing may be different from the RMS and/or Art 30 Referral
- **PROPOSAL:**
 - Coordinator for the paediatric worksharing is same as RMS
 - If Worksharing coordinator is appointed prior to appointment of RMS, but worksharing procedure has not yet been initiated, the coordinator role for the paediatric worksharing will automatically move to RMS

- Selection of molecules for harmonisation - Seek clear and transparent criteria
 - Limit number of harmonisations per year to important public health issues
- CMC Harmonisation
 - Resources need to be planned at new RMS if CMC harmonisation not in parallel with SmPC harmonisation
 - CMC harmonisation process needs to be simplified
 - Real mutual recognition of RMS assessment is required
 - Aligned with requirements for generic procedures where no filing history exists
- New RMS should take leadership in all EU procedures (including workshares)