

# CMDh Meeting with Interested Parties – EFPIA contributions

**15 November 2010**

- **Variations (3):**
  - Preliminary feed back on experience of MRP/ DCP variations.

## **Issue:**

- Type IA variations affecting several MRPs

## **Proposal:**

- Allow submission of type IA variations affecting several MRP products as one single group, even if the RMSs are different
  - Particularly true for IA (IN), the others can be handled in Annual Reports.
  - Decrease the number of submissions.
  - Those variations are minor, and do not require any in-depth assessment.
    - e.g.: change of address of a MAH in 1 country affecting many MRP products.

**Issue:**

- Difficulties in triggering Worksharing (WS) procedures

**Proposal:**

- For Worksharing including original product and clones
  - No need to ask for agreement on the use of WS for each submission once WS for original product is agreed.
  - Have an easy & quick process in place to get the WS number (not linked to CMD(h) meeting).
- For Worksharing including one type IB (ex: for original product and clones)
  - Allow 30-days timetable instead of 60 days.

- MRP Application Form (AF) and Cover Letter (CL)
  - Decrease administrative burden by removing all national specific requirements.
    - No translations of AF/CL.
    - No use of national systems for AF.
    - No reference to national laws in CL.
    - Be allowed to use EU AF and CL as in the CP.
- MRP translations
  - Ensure that all NCA have adapted their process for translations review to avoid any comments after the 30-day period.

## Issue:

- Type IB and II variations
  - Use of Worksharing to have 1 common Application Form/Cover Letter and reduced fees.
  - However not always possible due to timing issue:
    - It requires variation to be planned long in advance.
    - It leads to longer review time for type IB variations.

## Proposals:

- Allow use of a common CL and AF covering original product and duplicates if WS not used (submissions done in parallel).
- Have WS time reduced to 30 days for IB variations in WS (at least for a IB affecting an original product and the duplicates).

**Issue:**

- Potentially unfair fees approach

**Proposal:**

- Fees
  - EMA: for a group of variations accross products, the fees should be decreased, as a single change is reviewed once: same principle as for Worksharing.

## Additional PROPOSAL on variations:

- Reduce the time taken to reach an Article 5 recommendation, and make the procedure more attractive as an alternative to Type II.
- The timetables in the Annex II to the EMA Guide (588416/2008) should be re-examined with a view to reducing the time from submission to approval to 30 days. Recognising that there may be a requirement to apply some conditions on Industry to achieve this:
  - time can be reduced if EMA don't have to consult CMD(h).
  - or only one body has the responsibility to make the assessment whatever the type of authorisation – so this could be CMD(h) for all types.
- Clarify the requirements for the very high level classifications by relating the guidance to impact. The interpretation of major/minor is determined by whether the change has significant impact on product quality/safety as any of the Type II changes described or as minor as the Type IBs or Type IAs described.