

# CMDh Meeting with Interested Parties – EFPIA contributions

**15 November 2010**

- CMDh contribution to Task Force on resources (2):
  - Changes in pharmacovigilance system.
  - E-submissions.

## Issue:

- Changes to the PV system are made often, either triggered by the sponsors or by recommendations from Competent HA.
- Despite pragmatism from some agencies around the classification of such changes e.g. being type 1A or type 1A IN vs. type 2, we still face significant administrative burden.
- Although the change is unique per company, different procedures are required depending on registration route.

## Proposal:

- Better co-ordination and worksharing including EMA & CMD/h irrespective of route of authorisation e.g.:
  - Worksharing (for type 2 variation).
  - Or potentially grouping (for type 1A/IAN).

- Situation is improving:
  - There is a greater consistency between the map and the statement of the requirements, the release of new requirements explicitly used the map colour scheme to identify each country and what e-submission and paper requirements they have.
  - We still have a concern about one aspect of the information that is not included, which is whether a country can still request a paper copy of the submission if they choose. This essentially negates any gain by submitting electronic-only if we still have to prepare for the possibility of a request for paper.
  - We also continue to have a concern about the speed in making updates to the published information to reflect changes in national requirements.