

Variations

CMDh meeting with Interested
Parties

15 November 2010, EMA

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IA, annual report and grouping

- **IA** – no definition of „immediate notification“ so far
- **„Annual reports‘** – a lot of grouped IA applications has extremely reduced the number of single variations
- **Grouping**
 - more examples published in October 2010
 - further examples (clin) will follow early 2011
 - consequential changes mostly replaced by grouping
 - approach for further simplification by CMDh

Worksharing

- only limited experience (ca. 20 applications for only MRP)
- simplified procedure for only one RMS under discussion
- shorter announcement phase possible if reference authority agrees (decision in next CMDh plenary meeting after application)
- 30 day timetable possible if reference authority agrees