



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

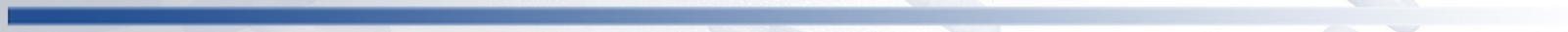


Making Medicines Affordable

Variations Regulation- Revised CMD(h) SOP procedure

Beata Stepniewska, EGA

London, 16th November 2009





Long discussion process comes to the end

- **Industry's early involvement in the process was highly appreciated**
 - Openness of the EC and of the Task Force Group to dialogue with the industry was welcome
- **1 January 2010- Time 0**
 - Practical implementation:
 - Learning process for both sides
 - Pragmatic approach and common understanding needed
- **Clear message how to deal with on-going and planned variations before 1 January?**
 - Cut-off date?



Final outcome in the context of the industry's objectives

- The overall final outcome is seen as positive
 - There is trust that the main objectives have in general been achieved
 - ↑ of predictability of the system
 - Harmonised requirements and harmonised assessment for all MAs
 - Reduction of administrative burden
 - Respected timeline
 - During the procedure itself
 - Implementation of changes at the same time in all MS
-



CMD(h) Revised SOP on procedure

- In general: clear and understandable
- Several technical issues highlighted by the EGA on various occasions were taken on board
- The final version of the EC guideline not yet known- some adjustments will be needed to keep consistency

Some technical points for further consideration

■ Type IA

- Fear of rejecting variations when the product is already on the market (withdrawal)
 - DE, AT, UK- Pragmatic way of dealing with incompliance to be shared with other MSs to avoid unnecessary withdrawals

■ Type IB: an upgrade to Type II

- Clarification on the process (page 16)
 - *Applicant has 21 days to update the application...*
 - *Once the variation is resubmitted as a type II*



Changes to Packaging Materials

- Possibility to implement the variations if no negative feedback from the RMS within 30 days or if the RMS opinion is positive
 - Changes to packaging
 - National translation must be provided within 5 days
 - Fear from the industry that some MS will still require an official approval for PIL before the implementation (reference to the national legislation)
 - Fear about additional changes at the national phase
-



Work sharing as a good tool to optimise resources

- **Timeline not very attractive for the applicant**
 - Information minimum 3 months in advance
 - But no information in advance in case of regular type II if worksharing is not used.
 - CMD(h) feedback about the “RMS” up to 2 weeks
 - **Possible to shorten timeline?**
-

Conclusion:

- Overall the EGA strongly supports the revised variation procedures as a significant step forward to improving the current system
- The continued role of the Task Force is welcome
 - EGA internal monitoring of the implementations
 - First feedback to the CMD and to the Task Force after 6 months?



Making Medicines Affordable

Thank you

