



Making Medicines Affordable

Experience with Variations Regulation

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London, 15 November 2010

Grouping

- Even if grouping is clearly allowed based on the annex or CMD paper, the MS still request the official agreement to group or even disagree with group (!)
 - Unnecessary administrative step
- Room for improvement for obtaining grouping number
 - CMD(h) help appreciated

Grouping versus Consequential Variations

■ ASMF

- Varying advice about grouping API and FP variations
- Changes to AMSF

■ Some authorities have stated that consequential variations are no longer possible, only grouping

- Grouping is more expensive than consequential variations
- Some variations should be still allowed to be submitted as consequential (although they can be also submitted as grouping)

Type IB by default

- 14 days validation time not respected
 - no timely notification of valid application to calculate possible date of implementation after 30 days

Implementation of changes to PIL, SmPC

- Reluctance to implement changes by companies before formal acceptance by the CA, although the law allows it.
 - comments from some CMS after 30 days; the SmPC/PIL would have been already printed
 - if correction is needed, it should be allowed to correct with next printing run only
 - it should not be lead to withdrawal product from the market