



*Making Medicines Affordable*



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# Experience with Variations Regulation

# Worksharing and Art 5.

- **Still relatively limited experience**
  - Procedure at CMD level works well (nomination of RMS, number etc..) but RMS was able to start only in 4 months
- **No experience with Art 5- unforeseen variations**
  - CMD(h) table- examples not very detailed
    - It may be an issue of know-how to be protected?
    - Transposition during the next revision of classification guideline?

# Grouping

- Even if grouping is clearly allowed based on the annex or CMD paper, the MS still request the official agreement to group
  - Unnecessary administrative step
  - Feedback on grouping was fast but seems to have slowed down recently
- Varying advice about grouping API and Finished Dosage Form variations together.

# Grouping versus Consequential Variations

- Some authorities have stated that consequential variations are no longer possible, only grouping
  - Grouping becomes very expensive
  - Some variations should be still allowed to be submitted as consequential (although they can be also submitted as grouping)

# Type IA

## ■ Reporting within 12 months

- Open question about use in practice..
- Due to document management system, companies submit on an on-going basis

# Type IB by default

- **Safeguard clause- positive experience until now**
  - No too many upgrades to type II
- **Validation time not respected- no feedback on valid application on time**



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# Issue of implementation

- Date of implementation- when introduced in company's system as stated in QA document
- Implementation in a company is a process, not an overnight action!
- No withdrawal of existing batches from warehouse and supply chain!
  - Pragmatic approach urgently needed in some MS
- Where the official documents are involved (MA, PIL, SmPC, packaging), official authorisation still requested in some MS before implementation

# Date of revision of the text- proposal

## ■ Type IA, IA<sub>IN</sub>

- Date of implementation by MAH

## ■ Type IB

- Date of the RMS acceptance

## ■ Type II

- 30 days after the date of the RMS acceptance