Variations & worksharing

An industry perspective

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Variations - Regulation

- **Commission Regulation (EU) No 1234/2008**
  - Since 1 January 2010
  - Applicable to CAPs and MRP/DCP products

- **Amendment 712/2012**
  - Since 2 November 2012
  - Extended to NAT products (with transition period)
  - Changes to “implementation” & amendment MA

Variations – Commission Guidelines

- **Commission guidelines**
  - 2010: Procedures & categories
  - 2013: Combined/updated guideline

- **Public consultation**
  - Article 4: *"The commission shall, after consulting the Member States, the Agency ~~and interested parties~~, draw up guidelines…."*
  - Short time line (1 month)
  - Industry comments/suggestions reviewed by EC

Variations – Commission Guidelines

- **Increased complexity**
  - Categories: high level, 107 (+10); total, 313 (+43)
  - More stringent conditions to allow for type IA
  - Introduction certain terms/expressions

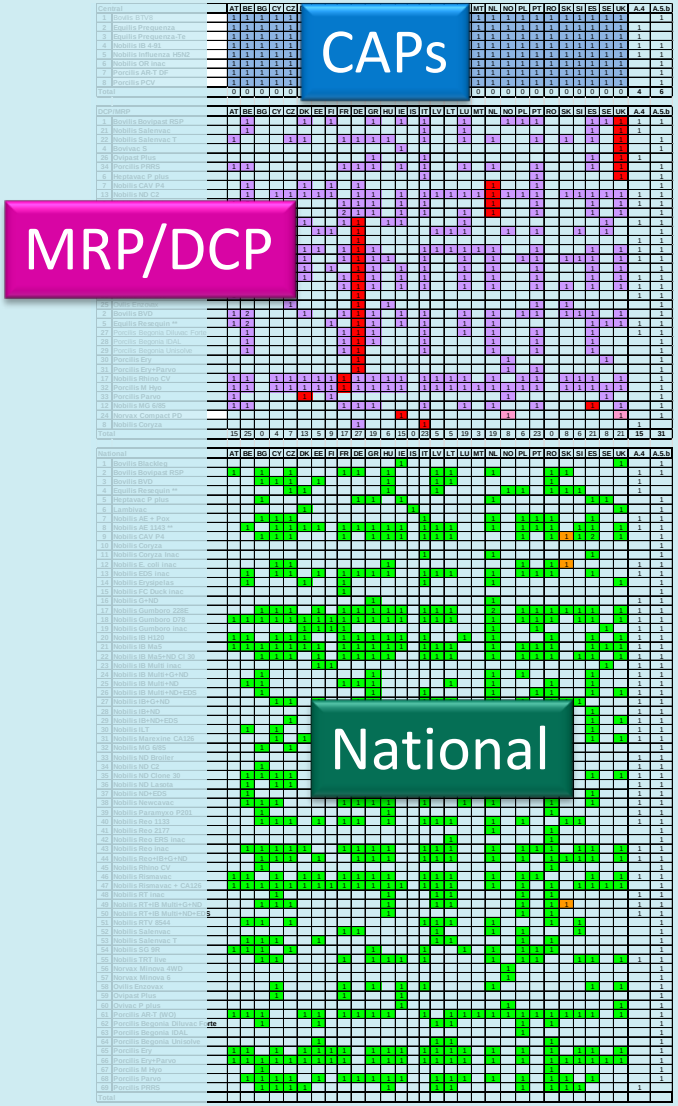
- **Possible consequences**
  - Increased administrative burden
  - Discussions between applicants and regulators
  - Re-classifications and delayed procedures
  - Delay improved/upgraded products to the EU market

Variations – Commission Guidelines

- **Areas requested for change by industry**
  - Administrative changes
  - Pharmacovigilance
  - Change to 1 national MAH not applicable to other member states in DCP/MRP
  - "Type II umbrella" concept (*slight modifications to the manufacturing process/testing without significant impact on quality/safety/efficacy*)
  - Single notification for change covering all MAs per CA (*notification removal TABST*)

→ ***Example of an "administrative" change***

Variations - Example



Name change of a manufacturing site

- Two classifications:
  - Active substance (A.4), type IA
  - Finished product (A.5), Type IA
- 78 products (A.4., A.5, A.4+A.5)
- Three different types of registration

>1000 variations

Variations – Commission Guidelines

- **Immunologicals**
  - Changes with no impact on quality, safety or efficacy remain classified as type II
  - New/upgraded categories on TSE certificates, which may lead to confusion and discussion

→ ***Examples***

Variations – Updated guideline on categories

Europe IFAH
Representing the European Animal Health Industry

TSE certificates

B.III.1.b	Condition	Type
2. New certificate for a starting material, reagent, intermediate or excipient from a new or an already approved manufacturer	~~X~~, 6, 9	~~X~~ IB
4. New/updated certificate from an already approved/new manufacturer <u>using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required</u>		II
Conditions		
3. The manufacturing process does not include the use of materials of human or animal origin for which an assessment of viral safety data is required.		

New

Variations – Updated guideline on categories

TSE certificates

B.III.1.b	Condition	Type
3. Updated certificate from an already approved manufacturer	~~X~~ 9	~~I~~ X IB
4. New/updated certificate from an already approved/new manufacturer <u>using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agents is required</u>		II
Conditions		
7. There has been no <u>change in the source of material</u>		

New

Can lead to request for risk assessment (?)

Worksharing

- One variation or same group of variations of type II or IB for more than one MA (line extension excluded)
  - Apply 3 months in advance at EMA or CMDv
  - All changes **must** be the same
  - By default: 60 days procedure

- NAT products:
  - Until August 2013: excluded
    - CMDv proactive on informal WS
    - NAT member states can step out (...*and they did?*)
  - After August 2013: included, all member states shall approve the change(s)

it may get a bit bumpy…. ***…but we'll get there***

Thank you