Variations and Work-sharing – Regulatory perspective

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Areas to be covered:

- **Possibility to work-share**
- **Current situation - does it work now?**
- **4 August 2013 – what changes can be expected?**

Possibility to work-share

Aim was:

- to **reduce regulatory burden** **for industry**

- to **avoid duplication of work** **for competent authorities**

Possibility to work-share

- **Article 20** of Regulation (EC) No. 1234/2008
- From 1 January 2010 – work-sharing possible but **limited** to products authorised via the MRP/DCP and centralised routes
- **Reference authority is either EMA** (if centralised procedure) or **NCA** if not

Possibility to work-share

- Several marketing authorisations owned by the same holder
- Type IB, II
- Groups
- But no extensions

Possibility to work-share

- **Same change(s)** apply to the different medicinal products concerned, with either no or limited need for assessment of a potential product-specific impact
- Some frustration expressed by industry that very simple changes e.g. to DDPS cannot be work-shared across all procedures
- Despite current restriction to MRP/DCP and CAPs many marketing authorisation holders continue to request work-shares across all types of authorised products – but not possible until August!

Current situation - Does it work now?

- **CMDv** have offered a flexible approach where possible
- **CMDv** have completed some **30** “informal” work-sharing procedures (mainly manufacturing changes) during 2012 – an increase of some 20% on the 2011 figures
- Only **2** formal work-shared procedures during 2012

Current situation - Does it work now?

Work-shares **(centrally authorised products)**:

- Work-shares for Type IA variations (IG):

  11 since 2010
- Other work-sharing Type IB/II/Grouped:
  4 in 2011, **8** in 2012
- Work-sharing with MRP/DCP procedures:
  2 i.e. not many!

4 August 2013 – what changes can be expected?

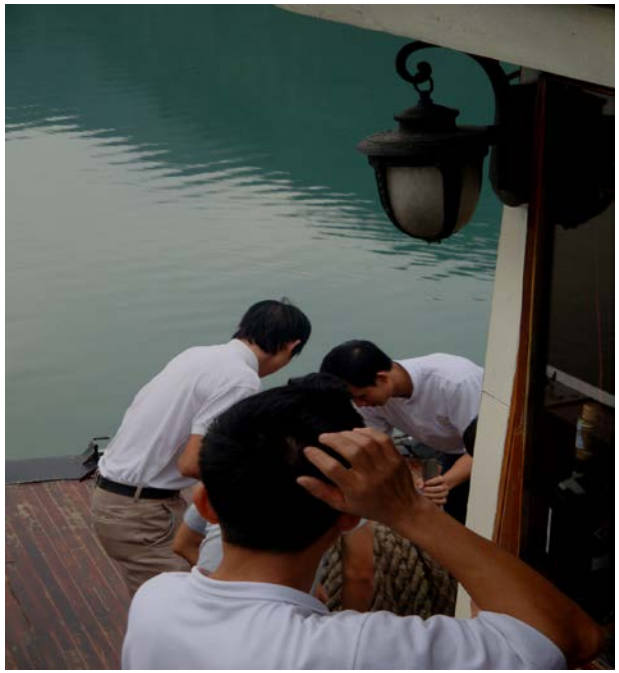
- Revised variations Regulation will allow work-sharing for products authorised by national, MRP/DCP and centralised routes
- More flexibility for industry ?
- More difficulties for industry and the regulator ?
- Expected take-up of national MAs in work-sharing? Formal work-sharing does not seem that attractive…..
- Will hear from Industry shortly……

4 August 2013 – what changes can be expected?

The Variations Regulation is still a challenge!

Many possibilities – can mean very complex applications

Discuss with the regulators in detail before submission



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Any queries for centrally authorised products?

Please send to vet.applications@ema.europa.eu and the team will be happy to help you!

Thank you for your attention!