CMDh QUESTIONS & ANSWERS
PHARMACOVIGILANCE LEGISLATION
REGULATION (EU) NO 1235/2010 AND DIRECTIVE 2010/84/EU

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Question 1 (June 2012)

As of 21 July 2012, new requirements for marketing authorisation applications are introduced in Directive 2001/83/EC as amended, e.g. with regard to the change from Detailed Description of the Pharmacovigilance System (DDPS) to Summary of Pharmacovigilance System Master File (PSMF) and the requirement of Risk Management Plans (RMP) for all applications. Is it possible to submit an MRP or repeat-use application to (new) CMS after 21 July 2012 without prior update of these requirements during a transitional period?

Yes, until 31 December 2012 it will be acceptable that MRP and repeat-use applications are submitted to CMS, without prior update of the above described changes. The MAH should commit to submit the appropriate variations within 2 months after the end of the MRP/RUP.