EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Transitional provisions for implementation of Commission Regulation (EU) No 712/2012 amending Variations Regulation (EC) No 1234/2008

Commission Regulation (EU) No 712/2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products entered into force on 24th August 2012. The new rules will apply in a stepwise approach, the majority of the provisions governing the variation of marketing authorisations granted under Regulation 726/2004 applying from 2nd November 2012. Provisions governing variations to national marketing authorisations and worksharing will apply from 4th August 2013.

It is appropriate to inform applicants of how the new rules will impact on pending variation procedures as well as applications submitted following a worksharing procedure:

- Applications for variations to the terms of marketing authorisations granted under Regulation (EC) No 726/2004 which do not follow a worksharing procedure and which have been submitted to the Agency but have not yet been the object of an opinion by the Agency before 2nd November 2012 will be processed in accordance with the changes introduced by the Commission Regulation (EU) No 712/2012. Consequently the new rules and timeframes for amendments to the Commission decision granting the marketing authorisation and for implementation of the respective variation, set out in Articles 23.1a and 24 will apply.
- Until 4th August 2013, applications for variations following a worksharing procedure will continue to be subject to the rules that applied prior to the adoption of Commission Regulation (EU) No 712/2012. However, the new rules and timeframes for amendments to the Commission decision granting the marketing authorisation will apply to variations following worksharing procedures for which a CHMP and CVMP opinion is adopted after 4th August 2013. In addition, purely national marketing authorisations can only be included as part of worksharing applications for which the Agency is the reference authority as of 4th August 2013.

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