EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Procedural announcements

CMHP meeting 17-20 October 2011

Submission of Type IA, Type IAin and Quality Type IB variations in December 2011

Please note that the EMA will be closed between 23 December 2011 and 2 January 2012 (inclusive).

Marketing Authorisation Holders are therefore advised, where possible, not to submit Type IA and Type IAin variation applications to the EMA after 28 November 2011 because the 30-day timeframe for the Agency to acknowledge the validity of the submitted Type IA and Type IA in variation(s) (see article 14 of Commission Regulation (EC) No 1234/2008) would coincide with the official closure of the EMA.

Marketing Authorisation Holders intending to apply for Quality Type IB variations in December 2011 are encouraged to liaise with the EMA prior to their submission.

Quality of Opinions exercise: follow-up information for all applicants and marketing authorisation holders on new proceedings for post-authorisation measures

As previously announced in the context of an ongoing quality of opinion exercise, the Agency, through its Scientific Committees, has introduced a classification system for post-authorisation measures into their appropriate legal framework since June 2011 for initial marketing applications.

After the successful implementation of this system of classification, all post-authorisation procedures for centrally authorised products receiving a CHMP opinion as of November 2011 will be handled accordingly. Therefore, any new or changed post-authorisation measures arising from these procedures will be classified either as Conditions in Annex II (Obligations to fulfil post-authorisation measures), as Additional Pharmacovigilance Activities in the Pharmacovigilance Plan of the Risk Management Plan or as Recommendations for further development. As a consequence, procedural templates have been updated to reflect these changes and the practice of a Letter of Undertaking ceases to exist.

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