



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Procedural announcements

CHMP meeting 14-17 November 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.

Updated Commission Note on Multiples - Implications for validations of new marketing authorisation applications with a target start day in December 2011

The Agency would like to draw your attention to the [updated note from the European Commission](#) with regards to multiple applications as published on 6/10/2011.

In light of the clarified definition of "same medicinal product" and "same applicant" there is a need to reconfirm in writing that your application does not fall under the clarified definition of a multiple in accordance with Art. 82 of Regulation (EC) 726/2004 within the centralised procedure.

Should you not be able to confirm that your application does not fall within the clarified definition of a multiple, please contact the EC via their functional mailbox SANCO-PHARMACEUTICALS@ec.europa.eu to request authorisation to submit a multiple application.

Kindly note that the Agency will only be able to validate your application and start its procedure based either on your confirmation in writing that your application does not fall within the clarified definition of a multiple or upon the receipt of your authorisation to submit a multiple by the EC, as applicable.

Applicants should contact their Product Team Leader in case of further questions.

