27 February 2013
EMA/CHMP/109953/2013
Press Office

Organisational matters

CHMP meeting 18-21 February 2013

The Committee welcomed Joseph Emmerich as new CHMP alternate member for France who replaced Philippe Lechat in this role.

The main organisational topics addressed during the February 2013 CHMP meeting related to:

- The adoption of revised CHMP and Rapporteur's Assessment Report (AR) templates and related guidance documents to reflect the involvement of PRAC in the assessment of Risk Management Plans. The updated templates for initial marketing authorisation applications and post-authorisation procedures will be published shortly on the Agency's website.
- The presentation of the SmPC Advisory Group's second activity report. Activities have included the creation of the public interface of the EudraSmPC webpage with presentations, FAQs and videos on how to prepare and review SmPC. The report recommends to formalise the quality assurance system of product information review.
- The information on recent changes introduced into the template for EPAR summaries, which serve to improve the overall structure and editorial flow of the summary. The updates take account of independent feedback and were consulted with patient and healthcare professional organisations. In particular, the updated template aims to make the purpose of the summary clearer and the information easier to follow, it contains standard text in simpler language and it includes new information on the Risk Management Plan.
- The presentation of the updated dossier requirements table for submission of applications to the EMA and Members of CHMP, CAT and PRAC. These requirements were revised with a purpose to align with the implementation of the Pharmacovigilance legislation, the creation of the PRAC and the possibility of electronic submission through dedicated portals. The document will be available soon on the Agency's website.

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