



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Organisational matters

CHMP meeting 29 March - 1 April 2016

The main organisational topics addressed during the March meeting related to:

- Discussion on joint CHMP-PDCO membership: 4 mandates of joint CHMP/PDCO membership are expiring in May 2016 and joint CHMP/PDCO memberships for another three-year mandate are needed.
- Information on the review of composition of working parties in regards to working parties' 2016 work plan objectives to be achieved and also reminding the Rules of Procedure for the temporary working parties and drafting groups.
- Information on draft reflection paper which outlines a framework for the extrapolation of clinical trial data from adults to children to support the authorisation of new medicines for children. EMA is organising a workshop on 17-18 May 2016 to gather the views from experts and stakeholders on the topic. These discussions will contribute to the further development of the draft reflection paper which is expected to be released for public consultation by the end of July 2016.
- Information about the agenda topics of the upcoming Strategic Review and Learning meeting that will be held in Utrecht, 30 May-1 June 2016 under the Netherland's Presidency of the Council of the European Union. This meeting will be held, in part, jointly with the COMP.
- Changes in the procedural documents planned to be implemented in February. From February 2016, the Agency started to implement a number of changes in the procedural documents for centrally authorised medicines. The MAHs and applicants are therefore informed that the information contained in the Opinion cover letters will be reduced, and part of the text will be moved to the Eudralink message, opinion, assessment report and/or translation timetable.
- Type II variations, PSURs and IB-Worksharing. Following the changes in procedural documents implemented in February, the MAHs are informed that, for PSUR single assessment (PSUSA) and Type II and IB-WS variation procedures, the opinion MAH cover letter, in word format, has been discontinued, and the Eudralink mail message will be the cover communication to the MAH. Information previously included in the MAH cover letter has been moved to the recommendation, opinion, assessment report or translation timetables documents. For any detailed questions on the procedure, the MAHs are advised to contact the procedure manager.



- Requests for supplementary information: Type II Variations, Annual reassessments, 1 and 5 year renewals, and Work sharing. In line with the recent changes implemented since February and March, the Marketing Authorisation Holders (MAHs) are informed that, for the above procedures, the MAH's RSI cover letter, in word format, has been discontinued, and the Eudralink mail message will be the cover communication to the MAH. For any detailed questions on the procedure, the MAHs are advised to contact the procedure manager.
- Appointment of Heidi Meyer new member to replace Michael Pfeleiderer and appointment of new alternate Matthias Renner from Germany to Biologics Working Party.
- Appointment of Eva Macri from Sweden as new member to replace Anders Lindblom to Blood Products Working Party.
- Nomination of Anna Nordmark from Sweden as expert to Pharmacokinetics Working Party.
- Nomination of Zoran Simic from UK as observer to Central Nervous System Working Party.
- Nomination of Ingrid Schellens from Netherlands as observer to Infectious Diseases Working Party.
- Nomination of Marina Fertek from Czech Republic as observer to Pharmacokinetics Working Party.
- Nomination of Fati Kirakoya from Belgium as observer to Biostatistics Working Party.