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Press Office

Organisational matters

CHMP meeting 22-25 February 2016

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

- From February 2016, the Agency has started to implement a number of changes in the procedural documents for centrally authorised medicines. The Marketing Authorisation Holders (MAH) 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 Marketing Authorisation Holders (MAHs) are informed that, for PSUR single assessment (PSUSA) and Type II and IB-WS variation procedures, the 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.
- Discussion on the revision of the benefit-risk assessment section of the CHMP assessment report template. The revision of the template is proposed in order to clarify the current benefit-risk template structure; in a subsequent step, training material (guidance, presentations) for assessors will be further developed.
- The draft Report on Pilot of Regulatory/HTA Parallel Scientific Advice was presented and endorsed. The report will be published in full shortly on the EMA website including the responses to the public consultation on the draft Best Practice Guide and the updated guidance.
- An interim report on the implementation of the Pilot Phase of the HMA Risk-Based Model for Medicinal Product Testing was presented to CHMP. The report looked at the risk-assessment templates received for the new centralised applications for human products, having a Day 0 between July and November 2015. There were a total of 31 new applications (for medicinal products for human use) during this period.
- Information on Review of experience with the revised RMP review process. Initial feedback from the committees has been positive and supportive. The CHMP noted the comments received.

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- Information about the draft 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.
- Nomination of Magnus Ingelman-Sundberg from Sweden as expert to Pharmacogenomics Working Party.
- Nomination of Cecilia Hedlund from Sweden, Philippe Zamia from France and Dana Marin from Romania as new observers to Biostatistics Working Party.
- Appointment of new core members Concepcion Prieto Yerro from Spain and Erika Fredriksson from Sweden to Respiratory Drafting Group, nomination of Susanne Kaul from Germany as an observer to Respiratory Drafting Group.