29 April 2016
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Press Office

Organisational matters

CHMP meeting 25-28 April 2016

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

- Information on the PSUR Repository project, which is due to move to the mandatory phase on the 13 June 2016. There will a group of NCA Communication Contact Points established which will act as liaisons between the EMA and MAHs at national level. EMA is in the process of designing an engagement plan for NCA Communication Contact Points, which will be shared in the coming weeks. A kick-off webinar will be arranged to welcome the NCA Communication Contact Points to the PSUR Repository change network by the end of May.
- Discussion on 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.
- Information on the revision of Guideline on safety and efficacy follow-up – RMP of ATMPs. CHMP, PRAC and CAT members are involved in the revision. The guideline should be revised so that it provides adequate guidance based on past ATMPs applications. The CHMP also agreed on the work plan to be used for the guideline revision.
- Information on Best Practice Guide for operating CHMP plenaries more efficiently. This guidance document is meant for members, alternates, experts and assessors for preparing CHMP plenary discussions.
- Appointment of Isabelle Bekeredjian-Ding (PEI(DE)), Svein Rune Andersen (NO), Agustín Portela Moreira (ES) and Nele Berthels (BE) as core members to the Vaccines Working Party.
- Nomination of Kaatje Smith (BE) as expert to the Vaccines Working Party.
- Appointment of Theodoros Karampinas from Greece as new member to the Blood Products Working Party.
- Nomination of Anja Schiel from Norway and Cecilia Hedlund from Sweden as experts to the Biostatistics Working Party.
- Nomination of Claudia Gramiccioni (IT) as observer to the Vaccines Working Party.
- Changes in the procedural documents planned to be implemented since 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

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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.