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Press Office

Organisational matters

CHMP meeting 18-21 July 2016

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

- Election of CHMP Co-opted members - Jean-Louis Robert and Sol Ruiz were re-elected as Co-opted members to CHMP in the area of Quality (non-biologicals) and Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies).
- Information on follow-up actions from the CHMP Strategic Review and Learning meeting in Utrecht held in May 2016.
- Information on CHMP 2016 work plan mid-year report.
- Information on changes in procedure for appointment of co-opted members in CHMP, CVMP and HMPC. Main changes are related to the inclusion of HMPC; Committee may choose one or more possible areas of scientific expertise per co-opted member position – nominee should have expertise in at least one of the areas; Existing co-opted members may participate in discussions and decisions on scientific expertise and number of co-opted members; If less than 5 co-opted members, quorum should be adjusted accordingly.
- Information on EMA survey on Initial Marketing Authorisation Application 2016. A web-based will be performed between September 2016 - February 2017. The scope of the survey is Centralised (human), Initial Marketing Authorisation procedures (MAA) targeting: Content & Procedural Questions. The survey will be completed by EMA, Applicants and Rapporteurs. 40-50 IMAA applications are expected to be surveyed at 3 key steps of the centralised evaluation: 1) after validation (EMA/Applicants); 2) late in clock-stop (Rapporteurs) or after LoQ response (Applicants/EMA); 3) after opinion (EMA/Applicants/Rapporteurs).
- Information and feedback from ICH Lisbon meeting held in June 2016.
- Information on new timetable proposal for type II variations involving the PRAC: the specific 'weekly' timetable finishing on the Thursday of the PRAC for the majority of type II variations involving the PRAC. This excludes variations to be discussed at the CHMP (i.e. extensions of indication) as well as variations leading to an immediate EC Decision (as per current practice). The proposal only applies to non-controversial variations rarely discussed in practice in either committee. There will be 2nd monthly linguistic review after PRAC.

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- Information on new Day 210 CHMP Assessment Report Template to be used for opinions of line extensions. So far these opinions have been prepared based on the initial MAA CHMP AR template. This new template will facilitate a great deal the preparation of the CHMP AR and avoid inconsistencies.
- Reminder to CHMP members and NCAs to complete the survey on service and support provided by CHMP Secretariat.
- Information on the timetable for the August 2016 CHMP written procedure.
- Appointment of Caoimhin Concannon from Ireland as new member to the Safety Working Party.
- Appointment of Francesca Luciani from Italy as new member to the Biologics Working Party.
- Appointment of Regine Lehnert and Ellen Pantke from Germany as new members to the Infectious Diseases Working Party.
- Appointment of Mario Miguel Rosa from Portugal as new core member to the Central Nervous System Working Party.
- Nomination of Gaby Wangorsch from Germany as observer to the Modelling and Simulation Working Group.
- Nomination of Mika Kastarinen from Finland as observer to the Cardiovascular Working Party.
- Nomination of Ana Jurić from Croatia as observer to the Pharmacokinetics Working Party.
- Nomination of Kastytis Šmigelskas from Lithuania and Dariusz Krajewski from Poland as observers to the Biostatistics Working Party.