25 September 2015
EMA/38597/2015
Press Office

Organisational matters

CHMP meeting 21-24 September 2015

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

- Dr Tomas Salmonson was re-elected as CHMP Chairman for a second 3-year mandate.
- The CHMP discussed on the area of expertise for the 5th co-opted member. Further discussions on the area of expertise are expected during upcoming meetings.
- Information on changes to the rapporteurship and eligibility outcome letters from September 2015 onwards: Abolition of handwritten signatures and cessation of delivery by post. The EMA Head of Committees Secretariat will no longer physically sign outcome letters on CHMP/CAT/PRAC rapporteurship and eligibility for evaluation under the centralised procedure sent out to the applicants. In addition, the printed letters will not be sent by post anymore. The distribution will only be done electronically via EudraLink. Both changes are in line with legal requirements.
- Information about the draft agenda topics of the upcoming Strategic Review and Learning meeting that will be held in Luxembourg, 26-28 October 2015 under the Luxembourg Presidency of the Council of the European Union. This meeting will be held, in part, jointly with the PRAC.
- Update on current status of EMA cooperation with FDA. There will be new clusters on patient engagement and on paediatric development in rare diseases created. Furthermore, cooperation on pharmacovigilance inspections is explored.
- Update on recent confidentiality arrangements with World Health Organization (WHO) and Swissmedic. A confidentiality arrangement between the EMA, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) and WHO has been in place since 1 September 2015. This complements cooperation between these organisations in the context of global networks and initiatives. EMA and Swissmedic have extended their confidentiality arrangement for a year.
- Information on enhanced early dialogue to foster development and facilitate accelerated assessment (PRIME). There will be detailed guidance developed for eligibility criteria. The key feature is early rapporteur appointment, which enables continuity with life-cycle approach.
- Nomination of Dr Eadaoin Griffin from Ireland as new member to the Safety Working Party.
- Nomination of Wilhelm Johan de Waard from Netherlands as additional expert to the Safety Working Party.

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- Nomination of Dagmar Pospisilova from Czech Republic as alternate member to the Biologics Working Party.