EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Organisational matters

CHMP meeting 23-26 March 2015

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

- The nomination of Dr Una Moore and Dr Sean Barry from Ireland as new core members at Biologics Working Party.
- Information about CHMP ORGAM meeting dates 2016-2018.
- Update on activities related to revised RMP Assessment process in 2015.
- Information about EU Network Training centre (http://euntc.eudra.org), which is European central platform for exchange of scientific and regulatory training information across the European Medicines Regulatory Network. The aim is to promote harmonisation of standards for assessment and to foster collaboration, sharing of best practices, and lessons learned across the Network.
- Information on update on Review and Reconnect implementation on Referrals. The updated process would benefit from earlier dialogue between national competent authorities and EMA on defining clear scope and establishing guidance on the best use of regulatory tools for handling an issue/procedure. Best use of network resources and support to (co-)rapporteurs and assessors will be provided together with involvement of a multidisciplinary team at EMA. Implementation is prioritised for pharmacovigilance (PhV) referrals which is now completed. The proposals for implementation include revised templates and process improvements such as strengthening (pre-) draft notification phase with early notification of the MAHs concerned, earlier Rapporteurship appointment for PhV referrals, preparation of the start of procedure, timelines, and a strengthening assessment phase. Training via webinar will be provided in April 2015.
- Information about the agenda of the upcoming Strategic Review and Learning meeting (previously known as 'Presidency/Informal meeting') that will be held in Ljubljana, Slovenia, 27-28 May 2015 under the auspices of the Latvian Presidency of the Council of the European Union. This meeting will be held, in part, jointly with the CAT. The agenda topics for the CHMP session include discussions on: labelling, biosimilars, developments in the regulatory framework, assessment of initial marketing authorisation applications and communication activities.

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