EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Organisational matters

CHMP meeting 15-18 December 2014

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

- The appointment of CHMP representatives to the CAT: the current members (Sol Ruiz, Romaldas Maciulaitis, Bruno Sepodes, John Borg, Jean-Louis Robert) confirmed their willingness to continue the cross Committee membership to the CAT.
- The appointment of Claudia Gramiccioni from Italy as a new alternate member replacing Paola Bernard in Blood Products Working Party.
- Update on Multinational Teams Scheme – extended to CHMP/CAT Rapporteurships: starts from January 2015 on and applies only for the initial MAA assessment.
- Information on Initiative to enhance early dialogue with applicants to foster better development of products. The objectives of the initiative are to raise awareness of regulatory requirements earlier in development to enable sponsors to optimise and accelerate medicines development; improve data submission quality; reinforce regulatory predictability to stimulate R&D investment; foster and facilitate interaction with the Agency & the network; improve planning and optimise resource allocation across the network.
- Information to committee members to submit e-DoI version 2 by 30 Jan 2015.
- Information on the Benefit-risk communication to medicines users (workshop report): How can regulators best meet the information needs of patients and healthcare professionals? Series of workshops were held involving representatives of patients and healthcare professionals together with members of EMA staff and scientific committees and other interested stakeholders. The objectives of the workshops were to review current practice in communicating benefit-risk, to examine recent initiatives into how research can help inform best practice, to discuss the role of communications in risk minimisation and to explore how they can aid patients and healthcare professionals in making decisions throughout the therapeutic journey.
- Discussion on Draft Benefit-Risk Effects Table Guidance. The purpose of Benefit-Risk Effects Table is to improve consistency, transparency, and communication of the benefit-risk assessment for initial submissions of new active substances by summarising the key benefits and risks together with their uncertainties.
- Discussion on PSUR repository implementation plan. The starting date is 12.03.2015.

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- Information on follow-up actions from the Italian Presidency meeting 29-30 October 2014 in Rome.
- Discussion on CHMP meeting in the first half of year 2015 under the Latvian EU presidency.
- Update on the Risk Management Process: the schedule for the implementation of the revised RMP assessment process was presented. For the new MAAs this will be implemented starting from February 2015.
- Discussion on follow-up on general aspects regarding SmPC labelling (indication wording).
- Information on Data gathering initiative, Pilot Exercise. In March 2014, the project was initiated in order to gather evidence needed by European Commission in drafting future legislative proposal on fees. The objective is to assemble evidence about time spent on procedures at EMA and national competent authorities. The Pilot Exercise will be conducted to validate the time collection methodology and to extend the refined collection process to formal exercise addressing the major activities areas of the network.
- Discussion on the process for agreement of Working Parties' Work Programmes 2015. Existing WPs/DGs will be asked to prepare a work programme 2015 based on the 2014-agreed paper, highlighting in track-change any updates and deadlines. Draft 2015 Work Programmes will be presented to the CHMP plenary in either January or February for adoption.