



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2014
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Press Office

Organisational matters

CHMP meeting 17-20 November 2014

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

- The appointment of Mary-Ann Eichmann from Germany as a new core member replacing Vera Luetgendorf in Blood Products Working Party.
- Information on the adjustment of timetable for procedures in phase outcome in December 2014/January 2015. CHMP were informed that procedural deadlines concerning the CHMP, which fall into the period of 26.12.14 – 02.01.2015, will be postponed to 05.01.2015.
- Update on the benefit-risk workshop. The workshop will be held on 23rd January 2015. The expected outcome of the workshop is to share the ideas and principles of the whole benefit-risk methodological background and guidance.
- A status update on changes to the initial MAA process.
- Information on participation of the centralised procedure in the Information Sharing Pilot for generic medicinal products (IGDRP) pilot. Under the pilot, all assessment reports (from D80 to D210) will be shared with participating non-EEA agencies, for selected applications of generic medicinal products. The anticipated start date is January 2015, first assessment reports are expected to be shared by the agency from May 2015.
- Discussion on initiative on patient registries: tools to improve the quality, consistency and utility of data and information from patient registries. Registries are requested to Marketing Authorisation Holders in the context of risk management plans and as regulatory requirements, e.g. for advanced therapies, medicinal products for paediatric use and orphan products. However, the current approach is not optimal from scientific and efficiency perspectives. In particular, there is a potential to better use existing data sources in place of new registries. The CHMP members were informed of the approach proposed to identify existing data sources (in collaboration with current projects at European and national levels), of the proposal for a pilot phase on 2-4 products and of the proposal to establish a Cross-Committee Advisory group in order to develop a strategy paper. It was agreed that an email would be sent by EMA to CHMP members to ask for volunteers for this group.
- Information on presentations given at the CHMP, CAT and COMP joint Italian Presidency meeting, 29 – 30 October 2014 in Rome.

