



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2014
EMA/124017/2014
Press Office

Organisational matters

CHMP meeting 22-25 April 2014

The Committee welcomed Dr. Filip Josephson as new alternate member from Sweden and Dr. George Aislaitner as new alternate member from Greece.

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

- The election of the BWP Vice chair and due to tie-in elections carried out twice (March and April CHMP meeting), the Committee appointed Dr. Ilona Reischl from Austria and Nanna Aaby Kruse from Denmark as BWP Vice chairs.
- Presentation by the European Commission on the Delegated Regulation to determine situations when Post-Authorisation Efficacy Studies (PAES) may be needed. The Regulation has been published on 10th April and has entered into force 10 days later. The Committee was reminded that PAES are an exceptional instrument and should not be used as justification for premature granting of a marketing authorisation and will be initiating the drafting of relevant scientific guidance. To that effect, the Committee agreed to set up a drafting group with EMA, PRAC and CHMP representatives together with expert consultation planned in the future.
- Follow-up discussion on the definition of "medical diagnosis" at the request of the European Commission with comments transmitted accordingly.
- Information about a survey on identification and traceability of biosimilar medicinal products. The members were updated on a reflection paper on pharmacovigilance considerations for biologicals as well as biological qualifiers agreed by the INN Committee in April 2014.
- Information regarding pre-submission activities. In the future, quarterly reports of planned MAAs with already appointed Rapporteurs will be circulated to members in an attempt to offer more accurate information regarding anticipated MAA submissions.

EMA message

As part of the rolling review of assessment report templates, the EMA has updated pre-authorisation and post-authorisation assessment report templates. The updated templates will be published on the EMA website in the coming weeks.

