



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2012
EMA/CHMP/732293/2012
Press Office

Organisational matters

CHMP meeting 10-13 December 2012

Dr Bengt Ljungberg was appointed as the new Swedish alternate member as of November 2012 CHMP meeting.

The main organisational topics addressed during the December 2012 CHMP meeting related to:

- The adoption of 2013 Work Programmes for Quality Working Party, Safety Working Party, EMA Human Scientific Committees Working Party with Patients and Consumer Organisations, CHMP Working Group with Health Care Professionals, Biosimilar Medicinal Product Working Party, Biologics Working Party, Blood Products Working Party, Pharmacogenomics Working Party, Cardiovascular Working Party, Biostatistics Working Party, Central Nervous System Working Party, Oncology Working Party, Infectious Diseases Working Party, Pharmacokinetics Working Party, Rheumatology/Immunology Working Party, Vaccine Working Party, Gastroenterology Drafting Group, Respiratory Drafting Group, Radiopharmaceutical Drafting Group, Urology Drafting Group. The documents will be published shortly on the Agency's website.
- The renewal of mandate for 2012-2015 and nomination of SAG Cardiovascular core group.
- The endorsement of the Questions-and-Answers on phosphates used as excipients in eye drops (EMA/795914/2012) which was prepared in the context of a wider revision of the guideline on excipients (Excipients in the label and package leaflet of medicinal products for human use CPMP/463/00). The objective of this revision is to update the safety concerns of some excipients already listed in Annex of the above guideline and add new excipients to the list. Because of the significant number of excipients to be reviewed and consequently the long expected timeframe needed, information on excipients reviewed will be progressively published in this Q&A document for public information prior completion of the guideline revision.
- The launch of the revised EudraSmPC webpage. This revision has been prepared in view of the upcoming public interface and proposes new features including video on demand and new or upgraded training presentations (e.g. FAQs based on the experience of the SmPC Advisory Group, 'SmPC: What is it and what does it contain', 'SmPC and older population').



- The adoption of revised Quality Review of Documents (QRD) human product information template. The purpose of this revision was to implement the new provisions from the pharmacovigilance legislation.