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Press Office

Organisational matters

CHMP meeting 27-30 May 2013

The Committee welcomed Radka Montoniová as new CHMP alternate member for the Czech Republic who replaced Miloslav Salavec in this role.

The main organisational topics addressed during the May 2013 CHMP meeting related to:

- The re-nomination of Agnes Gyurasics, Romaldas Mačiulaitis, Jacqueline Genoux-Hames, Nela Vilceanu together with their respective alternates as CHMP representatives to the PDCO.
- The nomination of Bruno Sepodes as CHMP representative to the CAT.
- The nomination of Dinah Duarte as CHMP representative to the EMA Human Scientific Committees Working Party with Healthcare Professionals Organisations (HCPWP).
- The election of Markus Paulmichl as the Pharmacogenomics Working Party Vice-Chair.
- The presentation of the first Annual Report on EudraVigilance for the European Parliament, the Council and the Commission for 2012 in accordance with the new pharmacovigilance legislation. The report provides information on the activities undertaken in 2012 in terms of development of new functionalities, data collection and quality, data analysis, transparency, communication and training. It will soon be available on the Agency's website.
- The establishment of the joint CVMP-CHMP antimicrobial advice ad hoc expert group (AMEG). The group will provide scientific advice on the impact of the use of antibiotics in animals on public health and animal health at the request by the European Commission. The work will be led by the CVMP and its experts in close collaboration with the CHMP.
- The Active Substance Master File (ASMF) submission requirements. These requirements will apply to centralised applications for marketing authorisations and variations starting from August 2013. After implementation of the new submission requirements ASMFs and their updates will only be required to be submitted once to the EMA and National Competent Authorities. Upon request by ASMF holders a sequential EMEA/ASMF/XXXXX number will be allocated. The ASMF number should be referenced in all applications where the source of active substance is used, eliminating the need for repeated submissions of the same data. The number allocation will run in parallel with the voluntary ASMF work sharing pilot starting in October 2013. This new practice with regards to

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ASMFs will align the EMA with the submission requirements already in place at the National Competent Authorities. Instructions on how to request the EMEA/ASMF/XXXXX number and information on changes to procedure will soon be available on EMA's website.

- The adoption of the amended mandate, objectives and rules of procedure for the CHMP Geriatric Expert Group (GEG).
- The Cardiovascular Working Party's (CVS WP) review of external comments received in January 2013 in relation to the definition of hypoglycaemia in the updated EMA Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus (CPMP/EWP/1080/00 Rev.1) adopted at the May 2012 CHMP meeting. The comments raise that the cut-off of 3.0 mmol/l (54 mg/dl), which was included in the previous version of the guideline, is considered clinically more relevant as definition than the cut-off of 3.9 mmol/l (70 mg/dl) (ADA definition) which is given as an example in the current version.

  The intention of the guideline is to provide one recommended approach for a definition of hypoglycaemia in order to facilitate global clinical development but does not exclude the use of other definitions, if justified.

  The CVS WP agreed that it is not needed to update the guideline but will consider an additional specification of a lower cut-off in a future revision.