



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Organisational matters

CHMP meeting 19-22 October 2015

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

- Dr Jan Willem Van Der Laan was re-elected as Chairman to the Safety Working Party.
- The CHMP discussed on the area of expertise for the 5th co-opted member. Nominations are awaited from following areas of expertise: Statistics and methodology, Epidemiology, Geriatrics and Pharmacology.
- Information on updated Assessment Report templates: template for annual re-assessments and annual renewals have been updated to align them with the newly implemented process for 5 year renewals: Single Joint Assessment Report which evolves from submission to final opinion will be introduced. The intention is to start using the updated template from the end of the year.

Furthermore the specific section "3.5. Special populations: the elderly" has been introduced in the CHMP D80 AR for issues specific to the elderly. The pilot will be run on the new template.

- Information on Direct Oral Anticoagulants (DOACs) Workshop to be held on 23 November 2015. Experts and stakeholders will be brought together to discuss the utility of PK and PD measurements in the clinical use of the direct oral anticoagulants.
- Information about GCP inspection findings on CHMP opinions. The review showed that depending on the nature of the critical findings and the possibility to correct the issues revealed by the inspections, more applicants decided to withdraw their MAA following a triggered GCP inspection than following a routine inspection. It was emphasized that the good collaboration between assessors and GCP inspectors need to continue, as well as regular exchange of information on GCP inspections with other regulatory authorities.

