

27 March 2013 EMA/CHMP/127956/2013 Press Office

Organisational matters

CHMP meeting 18-21 March 2013

The Committee noted the appointment of Kersti Oselin as a new CHMP alternate member for Estonia who replaced Irja Lutsar in this role.

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

- The adoption of Rapporteur's Assessment Report template for paediatric studies submitted in accordance with article 46 of regulation (EC) No1901/2006 which will be published shortly on the <u>Agency's website</u>. The outcome of article 46 procedures, through publication of assessment reports, will be made publicly available upon finalisation of the procedure.
- The recent changes aimed to increase transparency with respect to refused and withdrawn new marketing authorisation applications for human medicinal products. It would imply the same level of transparency is applied to these applications as to applications that receive a positive opinion and equally the same documents would be published in such cases.

