



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Organisational matters

CHMP meeting 23-26 June 2014

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

- The re-election of Jean-Louis Robert as chair of the Quality Working Party.
- The appointment of Pablo de Felipe as new BWP member and of Susana Rojo as new BWP alternate from Spain. Furthermore Panagiota Tsantili from Greece was appointed as new BWP alternate.
- A report from the EMA-EDQM workshop held 27-28 November 2013 regarding “Characterisation of novel clotting factor concentrates (FVIII, FIX) with respect to potency assays used for labelling and testing of post infusion samples”. A public report will be published on the EMA and EDQM websites.
- Discussion on an action plan from the CHMP informal meeting under the Greek presidency held in Uppsala on 26 – 28 May 2014.
- An update on the EMA policy on publication of clinical trial data with more user-friendly amendments that was endorsed by the Management Board at its June meeting.
- The adoption of a timetable to reflect that the August CHMP plenary will be replaced by a CHMP written procedure.
- Follow-up discussion regarding the mandate, objectives and rules of procedures for establishing a new Inter-Committee ad hoc Ethics Advisory Group.
- Follow-up discussion on an action plan to improve the quality of opinions issued by EMA scientific Committees.
- Discussion on process improvement for initial MAA, PIQ/QRD, linguistic accuracy, referral and scientific processes in partnership with National Competent Authorities. While the improvements primarily cover how EMA internally supports these procedures, there are interfaces areas where input of NCAs is expected.
- Follow-up discussion on the benefit/risk project and the report on a pilot phase for the 2nd part of the project which consisted looking into the added value of creating an effect table. The purpose of such table would be to facilitate the communication of the key benefits and risks described in the benefit-risk section of the CHMP assessment report. Further discussion on this topic is anticipated in the coming months.



- Discussion on the CHMP work plan for 2015 which will be aligned to the objectives described in the European Medicine Agency's [Road Map to 2015](#) and the associated implementation plan "[From Vision to Reality](#)".
- Follow-up discussion on the pilot phase to involve patients in benefit/risk discussions at CHMP meetings. The discussion focused on practical criteria defined for such involvement (type of documents to review, when to involve patients, how to involve them etc...).
- Additional information on the move of the EMA to Churchill Place in July 2014.