EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Organisational matters

CHMP meeting 23-26 May 2016

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

- The election of Peter Mol (NL) and Kolbeinn Gudmundsson (IS) as vice-chairs to the Scientific Advice Working Party (SAWP).
- In view of the expiry of the current 3-year mandates for 2 of the CHMP Co-opted members in July 2016, the CHMP discussed and agreed on the areas of expertise: Quality (biotech and biological), with expertise in advanced therapies (gene, cell and tissue therapies), Quality (non-biologicals, synthetic chemicals) and Epidemiology (specialisation in post-marketing study design and registries).
- Information on EMA-ESMO Workshop on the use of Single Arm Trials, taking place at the EMA on the 30th June. The Workshop will debate the strengths and weaknesses of single-arm pivotal trials in marketing authorizations for oncology drugs. The views of different stakeholders including clinicians, patients, developers, regulators and HTAs will be explored, discussing different clinical scenarios and development approaches.
- The CHMP was informed on feedback from the joint EMA - HMA Task Force on timetables meeting with stakeholders. Uncertainty in the timing of submission of new MAAs or responses to List of Questions (LoQ)/List of Outstanding Issues (LoOI) creates resource planning difficulties for the EMA and National Competent Authorities (NCAs). A Task Force (TF) was set up by the HMA and EMA to address issues with timetables for applications in the CP, MRP and DCP procedures. Survey was performed among stakeholders and common problems were identified related to initial submissions and responses to LoQ/LoOI. Therefore A Best Practice Guide for regulators and industry will be developed to increase predictability in procedures and ensure quality. Preparation of the document involves consultation with the Committees and CMDs.
- The CHMP was informed on feedback from 3rd Industry stakeholder platform on the operation of the centralised procedure, held on 21 April 2016. Specific follow-up actions from the discussions with direct relevance for CHMP were presented: those were related to accelerated assessment and pre-submission meetings. There will also be an EMA survey on the Initial Marketing Authorisation Application, which provides opportunity for feedback also from rapporteurs / assessors on the applications through a specific and focused set of questions.
- Nomination of Koenraad Norga (BE) as expert to the Oncology Working Party.

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- Nomination of Mari Thorn (DE) as observer to the Gastroenterology Drafting Group.
- Information on several changes to the procedural documents: from February 2016, the Agency started to implement a number of changes in the procedural documents for centrally authorised medicines. The MAHs and applicants are therefore informed that the information contained in the Opinion cover letters will be reduced, and part of the text will be moved to the Eudralink message, opinion, assessment report and/or translation timetable. For any detailed questions on the procedure, the MAHs are advised to contact the relevant procedure manager (PM):

  Since June 2016: List of Questions (LoQ) and List of Outstanding issues (LoOI) cover letters to applicants and responses timetables (TT): Initial Marketing Authorisation Applications (MAAs), line extensions (LEs) and art. 58. The response TT document has been improved and the information guidance previously included in the applicant/MAHs' LoQ/LoOI cover letter can be found in the revised timetable. Subsequently, from June onwards, this cover letter, in word format, has been discontinued, and the Eudralink mail message will be the cover communication to the applicant/MAH.

  Since June 2016: Annual reassessment and 1 and 5 year renewals and Art. 58 Type II variations. The opinion cover letter to MAHs (in word format) for the referred procedures is to be discontinued, and the Eudralink mail message will be the cover communication to the MAH. Information previously included in the MAH cover letter has been moved to the opinion, assessment report or translation timetables documents.

  Since June 2016: Variation Type IBs. In line with the changes implemented in the Type II variation opinions in February, for Type IB variations with changes to annexes, the notification document will now include the statements on immediate/non immediate EC Decision. Consequently, these statements will be discontinued from the Eudralink message.

  Since May 2016: Requests for supplementary information (RSI): Type II Variations (including Type II art. 58), Annual reassessments, 1 and 5 year renewals, and Type II worksharing. In line with the recent changes, the MAHs are informed that, for the above procedures, the MAH's RSI cover letter, in word format, has been discontinued, and the Eudralink mail message will be the cover communication to the MAH.

  Since February 2016: Type II variations, PSURs/ PSUSA and IB-Worksharing (IB-WS). Following the changes in procedural documents implemented in February, the MAHs are informed that, for PSUR single assessment (PSUSA) and Type II and IB-WS variation procedures, the opinion MAH cover letter, in word format, has been discontinued, and the Eudralink mail message will be the cover communication to the MAH. Information previously included in the MAH cover letter has been moved to the recommendation, opinion, assessment report or translation timetables documents.