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Press Office

Organisational matters

CHMP meeting 16-19 December 2013

The CHMP noted that Helen Vella was appointed as the new CHMP Alternate from Malta, replacing Patricia Vella Bonanno in this role.

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

- The election of the Robert Hemmings as chair of the Scientific Working Party.
- An update on the latest discussions at ICH in Osaka in November 2013.
- The nomination of Daniel Brasseur as EU expert in the ICH Expert Working Group to develop a Concept Paper for updating the ICH Guideline E11 on Paediatric Drug Development.
- The appointment of Marie-Christine Annequin as member of the Biologics Working Party.
- The appointment of Pierre Demolis and Jan Mueller-Berghaus as new members of the Guideline consistency group.
- The publication of Risk Management Plan summaries as of this month (see procedural announcement below).

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Procedural announcement

The EMA will start publishing summaries of the risk management plan (RMP) for every new medicine that is evaluated centrally and receives a positive CHMP opinion as from December 2013. This is in line with Article 26 of Regulation (EU) 1235/2010.

RMP summaries are both a transparency and communication tool aimed at providing the public with information on risk minimisation activities for medicinal products. To this end, the lay public has been identified as a target audience, while the needs of other stakeholders (e.g. industry and independent researchers) will also be catered for.

RMP summaries have been designed to be clear and concise documents that are consistent with and complementary to the information in other published documents (e.g. product information, assessment reports and EPAR summaries).

The full RMP is submitted by the applicant and reviewed by the EMA during the evaluation of the marketing authorisation application. After the CHMP adoption of the full RMP, the applicant will be requested to submit a 'word version' of part VI.2 of the adopted RMP, which will form the basis for the RMP summary. Once ready, the EMA will share the final RMP summary with the applicant for information prior to its publication.

The RMP summary will be published as part of the EPAR (along with the other related documents such as the product information and EPAR summary). The RMP summary will only be available in English.

Updating RMP summaries

The RMP summary will be updated when major changes are made to the RMP. These may be:

- New indications;
- Restrictions of indication;
- New/updated contraindications;
- New important risks or important changes to a known risks;
- Any 'additional risk minimisation measure' which is added or removed.

For centrally authorised products for which a RMP summary does not exists (those that received a CHMP opinion prior to December 2013), the criteria above will be used to produce and publish a new RMP summary, as of January 2014.

The EMA will announce the publication of the first RMP summary on the EMA website.