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Press Office

Organisational matters

CHMP meeting 22-25 July 2013

The CHMP welcomed Ivana Mikačić as new CHMP Member and Ana Dugonjić as new CHMP Alternate Member from Croatia. The accession of Croatia brings the total number of CHMP members to 33 (including the co-opted members).

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

- The re-election of Sol Ruiz (expertise in Quality (biotech and biological)) and Jean-Louis Robert (expertise in Quality (non-biologicals) (synthetic chemicals)) as CHMP co-opted members with a 3-year mandate.
- The appointment of Blazenka Jurisic as new SWP member from Croatia
- A discussion on the first FDA-EMA pilot for parallel assessment of a Quality by Design applications. The aim of the pilot was to ensure consistent implementation between EU and US of ICH Q8, 9, 10, 11 guidelines in the assessment process and to facilitate sharing of regulatory decisions on new regulatory concepts. The members discussed the successful finalisation of the first EMA-FDA parallel assessment of quality by design elements on an initial marketing authorisation. A question-and-answer document will be published shortly on the EMA website.
- A call for nominations of chairpersons for the EMA temporary working parties (WPs) and drafting groups (DGs). After the establishment of new temporary WPS and DGs in September 2010, the 3-year term of the chairpersons comes to an end. The new appointment of chairpersons is scheduled for September 2013.

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Changes to Risk Management Plan in the European Union.

There are two important changes to RMPs in the EU.

Change to updates of the RMP
The European Medicines Agency and the National Competent Authorities in the Member States are adopting a risk based approach to updates of the RMP. There will no longer be an automatic requirement to update the RMP on a fixed time basis.

Instead, an updated RMP should be submitted:

- At the request of the European Medicines Agency or National Competent Authority
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as a result of an important (pharmacovigilance or risk minimisation) milestone being reached.

When justified by risk, the Competent Authority exceptionally may still specify a date for submission of the next RMP as a condition of the Marketing Authorisation.

If the date for the submission of a PSUR and the need to update a RMP coincide, they can be submitted at the same time.

Change to "Important missing information."
Article 12 of Regulation 726/2004 states that a MA should be refused if the MAA has not properly or sufficiently demonstrated the quality, safety or efficacy of their product. ICH E2E, and all EU risk management documents until now, use the terms *"important identified risks, important potential risks and important missing information"* to define what constitutes a safety concern in the RMP.

To prevent misunderstanding with regard to Article 12, we are removing the word *"important"* from *"important missing information"*.

The safety concerns will now be:

- *important identified risks*
- *important potential risks*
- ***missing information*.**

The concept of a safety concern has not changed, in that it is still missing information that could be clinically important that needs to be captured. The way the concept is expressed is the only change.

All the appropriate guidances on the format of RMPs have been updated to reflect this change. GVP Module V and GVP annex 1- Definitions will be updated in the Autumn. Please note that as part of the continuous improvement exercise, it is likely that there will be further revisions to the RMP formats in the Autumn to reflect the experience over the last year.