EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 669

PHARMACEUTICAL COMMITTEE
22 October 2014

Subject: **State of play of the preparations for the application of the Clinical Trials Regulation**

Agenda item 2c

EMA update

Background

The Clinical Trial Regulation was published on 27 May 2014. The Agency has been given the task to develop the EU Portal and database (articles 80 to 82 of the Regulation), as well as introduce changes to the EudraVigilance Clinical Trial Module and electronic reporting of Annual Safety Reports. The Regulation will come into force no earlier than 28 May 2016, after the EU Portal and database have been developed and audited. When the Agency Management Board has verified that the EU portal and database have achieved full functionality and the systems meet the functional specifications it will inform the Commission. Once satisfied that the required conditions are met the Commission will publish a notice in the Official Journal. The Regulation will apply as from 6 months after the publication of the notice.

State of play

The Agency has prepared the draft Functional Specifications together with the expert group of Member States as previously agreed. Additionally, following an invitation to all Member State Permanent Representatives for nominations, the Agency has formed a group the aim of which is to discuss and endorse key requirements, including the Functional Specifications (which the Agency prepares in collaboration with the Member States and the Commission in accordance with article 82).

This group held the first meeting on 11 September 2014 during which it agreed to the release of the functional specifications for public consultation, subject to the changes agreed. The document is undergoing consultation as agreed, with plans for a short public consultation during October 2014. The text will then be revised in cooperation with the expert group and a final text will be circulated for endorsement by all Member States during a further meeting on 28 November 2014 at the Agency. The Functional Specifications will then be submitted to the Agency Management Board on 18 December 2014 before signoff and publication by the Agency.

The Agency will continue progressing with the detailed design of the system and its development in 2015. Quarterly meetings will be held with the full group of Member States, monthly meetings with the expert group and fortnightly or more often with the subgroups formed to address specific aspects (the latter meet by teleconference or Adobe connect). Monthly meetings are also held with Stakeholder groups (sponsors (commercial and non-commercial), patients and consumers and health care providers).

One of the key elements the experts are looking into is the definition of the data and document models and labelling to enable their exchange via an interface with Member States. This will be done in the early phase of the design since it is a crucial step in the Agency and MS system planning.

Action to be taken:

For information