EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 681

PHARMACEUTICAL COMMITTEE
17 March 2015

Subject: **Clinical Trials Regulation: update on the implementation**

Agenda item 2c

Update from the Commission

The implementation process for the new Clinical Trial Regulation (EU) 536/2014, which entered into force on 16 of June, is currently ongoing. The Commission is drafting the texts for the required Delegated and Implementing Acts, as well as steering the process for the update of the related guidelines.

A meeting was held on 1 December 2014 with the *ad hoc* group, established under the Directive 2001/20/EC. During the meeting the Commission presented a working document on the detailed arrangements for the inspection procedures including qualification and training requirements of inspector, in preparation for an Implementing Regulation by the Commission. It was drafted with the intention to carry over, to the extent possible, the relevant provisions of Commission Directive 2005/28/EC on Good Clinical Practice, as agreed during the last ad hoc group meeting, and adapting the text to the legal form of a Regulation.

The Commission also presented a working document on Good Manufacturing Practices for Investigational Medicinal Products, in preparation for a Delegated Regulation by the Commission. This was drafted on the basis of the provisions on investigational medicinal products of Directive 2003/94/EC.

Both working documents have been updated following comments received from the *ad hoc* group. The Commission is currently consulting the GCP IWG and GMP/GDP IWG of EMA on both working documents.

During the *ad hoc* meeting preliminary discussions were held with the group on some aspects of the Q&A document, which is currently being updated to incorporate Q&As related to the requirements of Clinical Trials Regulation as well as on other relevant information such as on substantial modifications and safety information. This will be a "living" document with further Q&As being added and updated as necessary.

A representative of DG SANTE F5, Food and Veterinary office (FVO) put forward for discussion some preliminary ideas on how the union controls (art 79 of Clinical Trial Regulation) could be organised and performed, in particular as regards the planning and frequency of the controls (both in the Member states and in the third countries), their scope, and potential voluntary participation of the national experts/inspectors from the Member States.

During the next meeting of the *ad hoc* group, which will be held on 9 March, the group will be updated on the development of the EU Portal and Database, will be presented clarifications on certain issues regarding procedures and rules related to the implementation of the Regulation and will discuss the work plan of the group's involvement in the amendment of the existing guidelines and preparation of new ones.

The Commission continues to closely follow the work of other bodies and groups involved in the preparation of the application of the new Regulation, also through the EU Clinical Trials Regulation Coordination Group.

May we remind those Member States who have not yet informed COM of the contact point for the facilitation of the functioning of the procedures related to the Clinical Trial Regulation (Art 83 of the Regulation), to send this information to COM as soon as possible. Please note that the contact point will also be the member on the Clinical Trials Advisory Group (CTAG) (art 85 of the Regulation).

Action to be taken:
For information/For follow-up