EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 668

PHARMACEUTICAL COMMITTEE
22 October 2014

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

Agenda item 2c

Update from the Commission

Regulation (EU) 536/2014 entered into force on 16 June 2014 and will apply once the EU Clinical Trials Portal and Database, developed by EMA, are fully operational.

Before the entry into application of the new Clinical Trial Regulation (CTR) the Commission will prepare and adopt the required Delegated and Implementing Acts, as well as steer the process for the update of the related guidelines.

The Regulation gives the Commission legal basis to adopt:
- A Delegated Act to specify the principles and guidelines of Good Manufacturing Practice (GMP) and detailed arrangements for inspections of investigational medicinal products (Article 63 of the Regulation);
- An Implementing Act on detailed arrangements for inspections procedures on Good Clinical Practice (GCP), including qualifications and training requirements for inspectors (Article 78 of the Regulation);
- Detailed guidelines for GMP (Article 63 of the Regulation);
- Guidelines on voluntary sharing of raw data (Article 37(4) of the Regulation);

The Regulation also empowers the Commission to adopt an Implementing Act on cooperation between Member States in the assessment of the information on safety reporting (Article 44 of the Regulation). The adoption of this act is at the Commission's discretion.

The Commission's priority is the adoption of the Delegated Act on GMP and of the Implementing Act on GCP inspections, as well as the update of GMP guidelines. The guidelines on voluntary sharing of raw data will be prepared with an input from DG Research and Innovation (RTD) at a later stage. With respect to the cooperation in the

assessment of safety reporting the Commission is following related discussions within the Clinical Trials Facilitation Group (CTFG) and will consider the necessity of an Implementing Act.

In executing its tasks the Commission would like to continue to work with the *ad hoc* group, established under the Directive 2001/20/EC. The first meeting of the *ad hoc* group on clinical trials after the entry into force of the new Regulation took place on 6 June 2014. The objective of the meeting was to identify and prioritise the necessary actions and to start discussions on the new Implementing and Delegated Regulations on the GMP and GCP inspections.

During the meeting the Commission proposed to base the new Delegated and Implementing Regulations, to the extent possible, on the provisions of Commission Directives (EC) 2003/94 and 2005/28 that are relevant to the new Regulation. The comments received after the meeting will be taken into account by the Commission in the preparation of the proposals, which will be presented to the *ad hoc* group during the next meeting. The Commission intends to adopt both the Delegated and Implementing Regulations by mid-2016. It will involve in the process the relevant European Medicines Agency (EMA) Inspectors Working Groups (IWGs) and is considering the possibility of launching public consultations. As regards the GMP guidelines, the Commission will work closely with Good Manufacturing Practice and Good Distribution Practice IWGs of EMA.

The *ad hoc* group concluded that the majority of the guidelines will require update or revision, in consultation with other groups such as the GCP IWG, where relevant. It also suggested various aspects to be included in the updated Q&A document.

The next *ad hoc* group meeting will take place in November 2014 (date to be confirmed). In addition, to the continuation of the discussion on the Implementing and Delegated Regulations, the Commission would like to include on the agenda, a detailed work plan of the group's involvement in the amendment of the existing guidelines.

Independently of its own activities, the Commission is closely following the work of other bodies involved in the preparation of the application of the new Regulation. Together with EMA and CTFG, the Commission forms part of the EU Clinical Trials Regulation Coordination Group which was established in order to enable regular exchanges to monitor implementation activity in relation to the CTR, identify critical issues and find solutions, to ensure no duplication of work by the various groups involved as well as to review impact on resources in the Member States and address. The Group reports regularly to the Heads of Medicines Agency.

Action to be taken:
For information