EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 657

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: **New Regulation on clinical trials, update from the Commission and EMA. EMA update**

Agenda item 2f

Background

The Committee of Permanent Representatives (COREPER) endorsed the compromise text of the Clinical Trial Regulation on 20/12/13. This compromise text provides the following responsibilities for the Agency:

- Set up and maintain the clinical trial Union portal and Union database in collaboration with the Member States and the Commission (Art 78.1).
- Requirements for electronic safety reporting (expedited and annual safety reporting)

Article 78a states the "*The Agency shall, in collaboration with the Member States and the Commission draw up the functional specifications for the EU portal and the EU database, together with the timeframe for their implementation".*

This Regulation will start to apply 6 months after the publication by the Commission in the Official Journal of the European Union, that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications referred to in article 78a, above, and on the basis of an independent audit report endorsed by the Management Board of the Agency.

In order to prepare for the implementation of this legislation, within very tight timelines, the Agency is holding workshops with an Expert Group previously established by the Commission. The Commission established this Expert Group in early 2013 for the specific purpose of starting preparation for the implementation of the clinical trial regulation requirements for the EU database and related EU clinical trial portal. The Commission formed the group by asking the Ad Hoc Commission Working Group on Clinical Trials for volunteers (that Ad hoc group had previously been nominated by the Member States via the Permanent Representatives). The expert group is composed of delegates, coming from National Competent Authority, or Health Ministry and Ethics committee functions, of the 10 volunteering Member States.

To date, two meetings have taken place at the Agency (on 30 Jan 2014 and 4 March 2014), and these follow two earlier meetings held by the Commission in 2013. Further meetings are taking place on a monthly basis.

The Agency will work with this Expert Group and will keep all Member States informed of progress through the Pharmaceutical Committee and the Clinical Trials Facilitation Group (CTFG). As soon as the Clinical Trial Regulation is adopted and enters into force the Agency will also make contact with the 'national contact points', to be designated by each Member State in line with article 79 of this Regulation, and all Member States will be consulted on proposals being developed. Workshops and consultation with stakeholder groups are also foreseen, once the final regulation has been adopted and published (representing

pharmaceutical industry and academic sponsors, healthcare professionals and patients and consumers).

Action to be taken:

For Information