EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 648

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: **Delegated act on post-authorisation efficacy studies**

Agenda item 3a

The 2010 pharmacovigilance legislation (Directive 2010/84/EU and Regulation No 1235/2010) provides for the possibility of requesting the marketing authorisation holder to conduct post-authorisation efficacy studies (PAES) complementing efficacy data that are available at the time of the initial authorisation. In order to determine the situations in which post-authorisation efficacy studies may be required, the Commission is mandated to adopt, by means of a delegated act, measures supplementing the provisions of Directive 2001/83/EC and Regulation (EC) No 726/2004.[1]

End of 2012 the Commission has conducted a public consultation on this delegated act, followed by expert group discussions with experts nominated by Member States and the European Medicines Agency. During those discussions general agreement was achieved on the way forward and on the situations to be covered by post-authorisation efficacy studies.

On 3 February 2014 the Commission adopted a Delegated Regulation on post-authorisation efficacy studies. This Delegated Regulation has not yet entered into force, as it is subject to the right of the European Parliament and of the Council to express objections, in accordance with Article 290(2) of the Treaty on the Functioning of the European Union.

The Pharmaceutical Committee will be updated on the state of play and the content of the Delegated Regulation.

Action to be taken:

For information

[1] Article 10b of Regulation (EC) No 726/2004 and Article 22b of Directive 2001/83/EC.