EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 617

PHARMACEUTICAL COMMITTEE
27 March 2013

Subject: **Preparation of a Delegated Act on Post-Authorisation Efficacy Studies**

Agenda item 1

The new pharmacovigilance legislation (Directive 2010/84/EU and Regulation No 1235/2010) refers to 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]

In preparing this delegated act, the Commission wishes to consult experts from the national authorities of all the Member States, which will be responsible for implementing the delegated acts once they have been adopted.

The structure of the meeting will follow the public consultation document[2] which shall also serve as working document for the meeting.

The main points to be discussed are the following:

- Is a delegated act on the situations in which post-authorisation efficacy studies may be required of added value? (cf. consultation item No 1 in the public consultation document)

- Should Post-authorisation efficacy studies focus on generating efficacy data? (cf. consultation item No 2 in the public consultation document)

[1] Article 10b of Regulation(EC) No 726/2004 and Article 22b of Directive 2001/83/EC.
[2] http://ec.europa.eu/health/files/pharmacovigilance/2012_11_28_pc_paes.pdf.

- In which situations a competent authority may ask for a post-authorisation efficacy study? (cf. consultation item No 3 in the public consultation document)

Each of the three points will be preceded by a short introduction of the topic by the Commission on the basis of the replies the Commission received in the context of the public consultation. The Commission intends to make these replies public prior to the meeting.[3]

Action to be taken:

For Discussion

[3] http://ec.europa.eu/health/human-use/pharmacovigilance/developments/index_en.htm.