EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 601

PHARMACEUTICAL COMMITTEE
28 March 2012

Subject: **Pharmacovigilance legislation – state of play of ongoing preparatory work**

Agenda item 2a)

The application date of the new pharmacovigilance legislation (Directive 2010/84/EU and Regulation (EU) No 1235/2010 of 15 December) is now only a few months away.

The Pharmaceutical Committee is therefore a good opportunity to update each other on where we stand in the preparation process.

In this context, the Commission will inform Member States about the state of play in the adoption process for the Implementing Regulation as well as its plans concerning the delegated act on post-authorisation efficacy studies provided for by the new legislation.

Additionally, the Commission will give an update concerning transitional arrangements[1] and the process of appointing members (experts and patient/healthcare professional representatives) to the new Pharmacovigilance Risk assessment Committee.

Member States are invited to share the state of play as regards preparation at national level, especially if there is a risk as to the timely transposition of the new legislation.

Action to be taken:

For information/discussion

[1] http://ec.europa.eu/health/files/pharmacovigilance/2012_02_qa_phv.pdf.