EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 635

PHARMACEUTICAL COMMITTEE
23 October 2013

Subject: **Pharmacovigilance - Update**

Agenda item 4 a, b, c

➢ Directive 2012/26/EU as regards pharmacovigilance

Member States are required to adopt and publish the laws, regulations and administrative provisions necessary to comply with Directive 2012/26/EU by 28 October 2013 at the latest. On 1 October 2013 eight Member States have notified national execution measures.

➢ The delegated act on post-authorisation efficacy studies

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 has consulted experts nominated by the Member States.

The Pharmaceutical Committee will be updated on the state of play of preparatory works.

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

- **Additional monitoring and black symbol**

On 1 October a joint European Commission, European Medicines Agency and the Heads of Medicines Agencies fact sheet for patients on the black symbol/triangle was published. EMA have also produced a video.

- **Audits of national pharmacovigilance systems**

In accordance with Article 101 of Directive 2001/83/EC Member States shall perform a regular audit of their pharmacovigilance system and report the results to the Commission for the first time in September 2013 and then every 2 years thereafter.

The Commission will report on the submission of the reports and its further planning.

Action to be taken:

For Information