EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 674

PHARMACEUTICAL COMMITTEE
22 October 2014

Subject: **Pharmacovigilance**

Agenda item 4 a, b

Report on the performance of pharmacovigilance tasks by the Member States

On 2 May 2014, under Article 29 of Regulation (EC) No. 726/2004, a report on the pharmacovigilance tasks of the European Medicines Agency completed during the first year of application of the EU's new pharmacovigilance legislation was made available on the Health and Consumer website[1].

Similarly, Article 108b of Directive 2001/83/EC foresees that the Commission shall make public a report on the performance of pharmacovigilance tasks by the Member States on 21 July 2015 at the latest and then every 3 years thereafter.

The Commission will update the Committee on the action for the preparation of the report on the Member States' activities on pharmacovigilance tasks.

Action to be taken:

For information/discussion

[1] http://ec.europa.eu/health/files/pharmacovigilance/2014_ema_oneyear_pharmacov_en.pdf

Update on Reports of Member States' pharmacovigilance audits

In accordance with Article 101 of Directive 2001/83/EC Member States shall perform a regular audit of their pharmacovigilance system. The Member States reported the results to the Commission for the first time in September 2013.

The Commission will update the Committee on the preparation of the overview report.

Action to be taken:

For Information and possible discussion