EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 722

PHARMACEUTICAL COMMITTEE
18 October 2016

Subject: **Report from the Commission on pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)**

Agenda item 3i

Article 29 of Regulation (EC) No 726/2004[1] and Article 108b of Directive 2001/83/EC[2] require regular reporting on the performance of pharmacovigilance tasks by the European Medicines Agency (EMA) and the Member States respectively.

On 8 August 2016 the Commission adopted a report on the pharmacovigilance related activities of Member States and the EMA concerning medicinal products for human use[3] with an accompanying Staff Working Document[4] describe the activities of the EU's networked and collaborative system for monitoring and controlling the safety of human medicines. While the legislation foresees different timelines for reports on tasks of the Member State and of the EMA, reporting on the EMA tasks was brought forward in order to allow a joined-up overview of the tasks of the EU network.

Action to be taken:
For information

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.
[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.
[3] COM(2016) 498 final – http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1475187754964&uri=CELEX:52016DC0498
[4] SWD (2016) 284 final - http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1475187964607&uri=CELEX:52016SC0284