EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 679

PHARMACEUTICAL COMMITTEE
17 March 2015

Subject: **Legal and Regulatory news (New pieces of legislation, COM guidelines)**

Agenda item 1c

➢ **New legislation/regulatory texts published**

The following legislation and regulatory texts have been published since the last meeting of the Pharmaceutical Committee:

- Delegated Regulation (EU) No 1252/2014 with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products
- Guidelines for good manufacturing practices: New versions of Chapter 3 and Chapter 5 have been published providing transitional arrangements for toxicological evaluation. The chapters are otherwise unchanged – apart from an editorial correction of footnote 2 in Chapter 5 – and will become operational on 1 March 2015 for all other aspects.

Action to be taken:

For information