EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
**Medicinal products – authorisations, EMA**

PHARM 662

**PHARMACEUTICAL COMMITTEE**
**22 October 2014**

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

**Agenda item 1b**

➢ **New legislation/regulatory texts published**

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

- Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use
- Regulation (EU) No 658/2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities
- Delegated Regulation (EU) No 357/2014 on post-authorisation efficacy studies
- Implementing Regulation (EU) No 699/2014 on a common logo for internet pharmacies
- New Commission guideline on paediatric investigation plans
- New Commission guideline on orphan designation

**Action to be taken:**

For information