



PHARMACEUTICAL COMMITTEE
27 March 2013

Subject: Legal and Regulatory news

Agenda item 3a

➤ **New legal texts published**

The following legal texts have been published in the Official Journal since the last meeting of the Pharmaceutical Committee:

- [Regulation \(EU\) No 1027/2012](#) of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance
- [Directive 2012/26/EU](#) of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance
- [Commission Implementing Regulation \(EU\) No 198/2013](#) of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring
- [Commission Guidelines on Good Distribution Practices](#) of Medicinal Products for Human Use
- [Commission Implementing Decision](#) of 23 January 2013 on the assessment of a third country's regulatory framework applicable to active substances of medicinal products for human use and of the respective control and enforcement activities pursuant to Article 111b of Directive 2001/83/EC of the European Parliament and of the Council

➤ **EudraLex on CD**

An updated version of [Eudralex on CD](#) has been published in February 2013.

Action to be taken:

For information