



PHARMACEUTICAL COMMITTEE
22 October 2012

Subject: Legal and Regulatory news

Agenda item 1. d)

➤ **Corrigendum to Regulation (EU) No 1235/2010**

In July 2012 a corrigendum was published in the Official Journal rectifying a mistake in Regulation (EU) No 1235/2010, which amends Regulation (EC) No 726/2004. More precisely, it concerns Article 16 of the Regulation and clarifies that the legal basis for regulatory measures on variations was not deleted by Regulation (EU) No 1235/2010. The corrigendum led to a partial change of the numbering of the paragraphs in Article 16.

The corrigendum is available here:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0138:0138:EN:PDF>

➤ **Public consultation on experience acquired with the Paediatric Regulation**

In accordance with Article 50(2) of the Paediatric Regulation, in 2013 the Commission has to present to the European Parliament and the Council a general report on experience acquired as a result of the application of the Regulation. This report will include a detailed inventory of all medicinal products authorised for paediatric use since its entry into force. In preparation of this report, the Commission released in September 2012 a public consultation document which puts up for discussion certain 'lessons learnt'.

Member States are encouraged to participate in the public consultation, which is available here: http://ec.europa.eu/health/files/paediatrics/2012-09_publicconsultation_en.pdf.

➤ **New legal texts published**

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

- Commission Regulation (EU) No 488/2012 amending Regulation (EC) No 658/2007 concerning financial penalties
- Commission Implementing Regulation (EU) No 520/2012 concerning pharmacovigilance activities
- Commission Regulation (EU) No 712/2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations

Action to be taken:

For information