Advanced therapy medicinal products

2005/0227(COD) - 13/11/2007 - Corrigendum to final act

PURPOSE: **corrigendum** to Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83 /EC and Regulation (EC) No 726/2004 (Regulation initially published in the Official Journal L 324 of 10 December 2007).

The aim of the Regulation is to establish specific rules concerning the authorisation, supervision and pharmacovigilance of advanced therapy medicinal products.

The corrigendum relates to **Article 28 of the Regulation** (Amendments to Directive 2001/83/EC, point 4):

- in Article 6(1), the first subparagraph shall be replaced by the following: “No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 1394/2007.