Medicinal products for human use: pharmacovigilance of products

2008/0260(COD) - 15/12/2010 - Corrigendum to final act

PURPOSE: Corrigendum to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (originally published in OJEU L 348 of 31 December 2010).

CONTENT: the corrigendum relates to Article 2 which relates to transitional provisions. The text should read as follows:

With regard to the obligation on the part of the marketing authorisation holder to maintain and make available on request a pharmacovigilance system master file in respect of one or more medicinal products provided for in Article 104(3)(b) of Directive 2001/83/EC as amended by this Directive, the Member States shall ensure that that obligation applies to marketing authorisations granted before 21 July 2012:

a) the date on which those marketing authorisations are renewed; or

b) the expiry of a period of 3 years starting from 21 July 2015,

whichever is earlier.

The Member States shall ensure that the procedure provided for in Articles 107m to 107q of Directive 2001/83/EC as amended by this Directive applies only to studies which have commenced after 21 July 2012.