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 (Text with EEA relevance)

Article 2

Transitional provisions

1 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 **[**X1 21 July 2012**]** as from either:

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

[X1 b) 21 July 2015**]**

whichever is earlier.

2 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 **[**X1 21 July 2012**]**.

3 With regard to the obligation on the part of the marketing authorisation holder to submit information on suspected adverse reactions electronically to the Eudravigilance database, provided for in Article 107(3) of Directive 2001/83/EC as amended by this Directive, the Member States shall ensure that this obligation applies as from 6 months after the functionalities of the database are established and have been announced by the Agency.

4 Until the Agency can ensure the functionalities of the Eudravigilance database as specified in Article 24 of Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010[(1)] of the European Parliament and of the Council, marketing authorisation holders shall report, within 15 days of the day on which the holder concerned gained knowledge of the event, all serious suspected adverse reactions that occur in the Union, to the competent authority of the Member State on whose territory the incident occurred and shall report all serious suspected adverse reactions that occur on the territory of a third country to the Agency and, if requested, to the competent authorities of the Member States in which the medicinal product is authorised.

5 Until the Agency can ensure the functionalities of the Eudravigilance database as specified in Article 24 of Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, the competent authority of a Member State may require marketing authorisation holders to report to it all non-serious suspected adverse reactions that occur on the territory of that Member State, within 90 days of the day on which the marketing authorisation holder concerned gained knowledge of the event.

6 During this period, Member States shall ensure that the reports referred to in paragraph 4 that relate to events that occurred in their territory are promptly made available to the Eudravigilance database, and in any case within 15 days of the notification of suspected serious adverse reactions.

7 With regard to the obligation on the part of the marketing authorisation holder to submit periodic safety update reports to the Agency as provided for in Article 107b(1) of Directive 2001/83/EC as amended by this Directive, the national competent authorities shall ensure that this obligation applies as from 12 months after the functionalities of the repository have been established and have been announced by the Agency.

Until the Agency can ensure the functionalities agreed for the repository of the periodic safety update reports, the marketing authorisation holders shall submit the periodic safety reports to all Member States in which the medicinal product has been authorised.

Editorial Information

X1 Substituted by 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 (Official Journal of the European Union L 348 of 31 December 2010).

(**1**) See page 1 of this Official Journal.