DECISION OF THE EEA JOINT COMMITTEE

No 158/2013

of 8 October 2013

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

(1) Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products [1], as corrected by OJ L 201, 27.7.2012, p. 138, is to be incorporated into the EEA Agreement.

(2) 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 [2], as corrected by OJ L 21, 25.1.2011, p. 8 and OJ L 276, 21.10.2011, p. 63, is to be incorporated into the EEA Agreement.

(3) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter XIII of Annex II to the EEA Agreement shall be amended as follows:

1. The following text is inserted after the words 'Committee on Orphan Medicinal Products (COMP)' in the 13th paragraph of the introductory text:

', the Pharmacovigilance Risk Assessment Committee (PRAC)'

2. Point 15q (Directive 2001/83/EC of the European Parliament and of the Council) shall be amended as follows:

(i) The following indent is added:

'— **32010 L 0084**: Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 (OJ L 348, 31.12.2010, p. 74), as corrected by OJ L 21, 25.1.2011, p. 8 and OJ L 276, 21.10.2011, p. 63.'

(ii) The adaptation text is replaced by the following:

'The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptations:

(a) Liechtenstein shall not be obliged to participate in the decentralised procedure (DCP) and in the mutual recognition procedure (MRP) and shall, therefore, not be obliged to issue the corresponding marketing authorisations. Instead, Austrian marketing authorisations within the DCP and the MRP shall be valid for Liechtenstein upon request of a marketing authorisation applicant.

(b) The EFTA States may initiate the urgent Union procedure pursuant to Section 4 of Chapter 3 of Title IX of the Directive.

(c) With respect to Title IX, the obligations of Liechtenstein will be executed by Austria. Liechtenstein will however, as far as applicable to Liechtenstein:

— operate a pharmacovigilance system in accordance with Article 101(1);

— perform a regular audit of its pharmacovigilance system in accordance with Article 101(2);

— designate a competent authority for the performance of its pharmacovigilance tasks in accordance with Article 101(3),

— take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the national competent authority in accordance with Article 102(a);

[1] OJ L 348, 31.12.2010, p. 1.
[2] OJ L 348, 31.12.2010, p. 74.

— facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats in accordance with Article 102(b);

— impose an obligation on a marketing authorisation holder to operate a risk management system, as referred to in Article 104(3)(c), if there are concerns about the risks affecting the risk-benefit balance of an authorised medicinal product in accordance with Article 104a(2). For the imposition of such obligation Liechtenstein will base itself on a corresponding decision of the Austrian authorities;

— set up and maintain a national medicines web-portal which shall be linked to the European medicines web-portal in accordance with Article 106;

— record all suspected adverse reactions that occur in its territory which are brought to its attention from healthcare professionals and patients and ensure that reports of such reactions may be submitted by means of the national medicines web-portals or by other means in accordance with Article 107a(1), and

— submit reports in accordance with Article 107a(4).

(d) The following subparagraph shall be added to Article 107c(5):

"Swiss marketing authorisation for a medicinal product taking effect in Liechtenstein by virtue of Liechtenstein law on the basis of the Customs Union between the Principality of Liechtenstein and the Swiss Confederation shall not be considered as a first authorisation to place a product on the market for the purposes of this paragraph." '

3. The following indent is added in point 15zb (Regulation (EC) No 726/2004 of the European Parliament and of the Council):

'— **32010 R 1235**: Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ L 348, 31.12.2010, p. 1), as corrected by OJ L 201, 27.7.2012, p. 138.'

4. The following is added in point 15zh (Regulation (EC) No 1394/2007 of the European Parliament and of the Council):

', as amended by:

— **32010 R 1235**: Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ L 348, 31.12.2010, p. 1), as corrected by OJ L 201, 27.7.2012, p. 138.'

Article 2

The texts of Regulation (EU) No 1235/2010, as corrected by OJ L 201, 27.7.2012, p. 138, and Directive 2010/84/EU, as corrected by OJ L 21, 25.1.2011, p. 8 and OJ L 276, 21.10.2011, p. 63, in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 9 October 2013 or on the day following the last notification under Article 103(1) of the EEA Agreement, whichever is the later (*).

For Liechtenstein, this Decision shall enter into force on the same day or on the day of entry into force of the amendments to the Agreement between Liechtenstein and Austria laying down the technical details for Liechtenstein's recognition of Austrian marketing authorisations within the decentralised procedure (DCP) and the mutual recognition procedure (MRP), whichever is the later.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 8 October 2013.

For the EEA Joint Committee

The President

Thórir IBSEN

(*) Constitutional requirements indicated.