

COMMISSION IMPLEMENTING DECISION

of 24 April 2013

amending Implementing Decision 2012/715/EU establishing a list of third countries with a regulatory framework applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union

(Text with EEA relevance)

(2013/196/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾, and in particular Article 111b(1) thereof,

Whereas:

- (1) In accordance with Article 111b(1) of Directive 2001/83/EC a third country may request the Commission to assess whether its regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union in order to be included in a list of third countries ensuring an equivalent level of protection of public health.
- (2) Australia requested, by letter dated 18 September 2012, to be listed in accordance with Article 111b(1) of Directive 2001/83/EC. The equivalence assessment by the Commission confirmed that the requirements of that Article were fulfilled. In exercising this equivalence assessment, account was taken of the agreement on mutual recognition ⁽²⁾ as referred to in Article 51(2) of that Directive between Australia and the Union.

- (3) Commission Implementing Decision 2012/715/EU of 22 November 2012 establishing a list of third countries with a regulatory framework applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union, in accordance with Directive 2001/83/EC of the European Parliament and of the Council ⁽³⁾ should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision 2012/715/EU is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 24 April 2013.

*For the Commission**The President*

José Manuel BARROSO

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 229, 17.8.1998, p. 3.

⁽³⁾ OJ L 325, 23.11.2012, p. 15.

ANNEX

'ANNEX

Third country	Remarks
Australia	
Switzerland'	