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COMMISSION IMPLEMENTING DECISION

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

(Text with EEA relevance)

(2012/715/EU)

(OJ L 325, 23.11.2012, p. 15)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Decision 2013/196/EU of 24 April 2013	L 113	22	25.4.2013
► <u>M2</u>	Commission Implementing Decision 2013/262/EU of 4 June 2013	L 152	52	5.6.2013
► <u>M3</u>	Commission Implementing Decision 2013/301/EU of 11 June 2013	L 169	71	21.6.2013

**COMMISSION IMPLEMENTING DECISION****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

(Text with EEA relevance)

(2012/715/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) Switzerland requested, by letter dated 4 April 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 Switzerland and the Union,

HAS ADOPTED THIS DECISION:

Article 1

The list of third countries referred to in Article 111b(1) of Directive 2001/83/EC is 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*.

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 114, 30.4.2002, p. 369.

▼ M3*ANNEX*

Third country	Remarks
Australia	
Japan	
Switzerland	
United States of America	