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*Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Decision of 4 June 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) (2013/262/EU). (See end of Document for details)*

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Commission Implementing Decision of 4 June 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) (2013/262/EU)

COMMISSION IMPLEMENTING DECISION

of 4 June 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)

(2013/262/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<sup>(1)</sup>, 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) Japan requested, by letter dated 6 December 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.
- (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<sup>(2)</sup> should be amended accordingly,

HAS ADOPTED THIS DECISION:

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*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, 4 June 2013.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX

ANNEX Third countryRemarksAustraliaJapanSwitzerland

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- (1) [OJ L 311, 28.11.2001, p. 67.](#)
- (2) [OJ L 325, 23.11.2012, p. 15.](#)

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