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 (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) 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 (²) 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, 4 June 2013.

For the Commission

The President
José Manuel BARROSO

ANNEX

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<tr>
<th>Third country</th>
<th>Remarks</th>
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<tr>
<td>Australia</td>
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<td>Japan</td>
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<td>Switzerland</td>
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