COMMISSION IMPLEMENTING DECISION (EU) 2015/1057

of 1 July 2015

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)

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) Israel requested, by letter dated 9 May 2012, to be listed in accordance with Article 111b(1) of Directive 2001/83/EC. The equivalence assessment by the Commission concluded that the requirements of that Article were fulfilled. In exercising this equivalence assessment, account was taken of the agreement on conformity assessment and acceptance of industrial products ([2]), as referred to in Article 51(2) of that Directive, between Israel and the Union.

(3) Brazil requested, by letter dated 4 October 2012, to be listed in accordance with Article 111b(1) of Directive 2001/83/EC. On the basis of a review of relevant documentation and two on-site reviews, and taking due account of the action plan proposed by Brazil on 12 March 2015, the equivalence assessment by the Commission concluded that the requirements of that Article were fulfilled.

(4) Commission Implementing Decision 2012/715/EU ([3]) should therefore 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.

([1]) OJ L 311, 28.11.2001, p. 67.

([2]) Council Decision 2013/1/EU of 20 November 2012 on the conclusion of a Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, on Conformity Assessment and Acceptance of Industrial Products (CAA) (OJ L 1, 4.1.2013, p. 1).

([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 (OJ L 325, 23.11.2012, p. 15).

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, 1 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

'ANNEX

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

Third country	Remarks
Australia	
Brazil	
Israel ([1])	
Japan	
Switzerland	
United States of America	

([1]) Hereafter understood as the State of Israel, excluding the territories under Israeli administration since June 1967, namely the Golan Heights, the Gaza Strip, East Jerusalem and the rest of the West Bank.'