Commission Implementing Decision (EU) 2019/769 of 14 May 2019 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)

COMMISSION IMPLEMENTING DECISION (EU) 2019/769

of 14 May 2019

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) The Republic of Korea requested, by letter dated 22 January 2015, 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 the Korean competent authorities, the Ministry of Food and Drug Safety, on 12 February 2019, the equivalence assessment by the Commission concluded that the requirements of that Article were fulfilled.

(3) Commission Implementing Decision 2012/715/EU[(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, 14 May 2019.

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[a]	
Japan	
Republic of Korea	
Switzerland	
United States of America	

a 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.

(**1**) OJ L 311, 28.11.2001, p. 67.

(**2**) 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).