►**B**

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
►**M1**	Commission Implementing Decision 2013/196/EU of 24 April 2013	L 113	22	25.4.2013
►**M2**	Commission Implementing Decision 2013/262/EU of 4 June 2013	L 152	52	5.6.2013
►**M3**	Commission Implementing Decision 2013/301/EU of 11 June 2013	L 169	71	21.6.2013
►**M4**	Commission Implementing Decision (EU) 2015/1057 of 1 July 2015	L 171	23	2.7.2015
►**M5**	Commission Implementing Decision (EU) 2019/769 of 14 May 2019	L 126	70	15.5.2019

▼B

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(Text with EEA relevance)

(2012/715/EU)

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*.

▼**M5**

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	
Republic of Korea	
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.