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)

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)

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) Switzerland requested, by letter dated 4 April 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. In exercising this equivalence assessment, account was taken of the agreement on mutual recognition[(2)] as referred to in Article 51(2) of that Directive between Switzerland and the Union,

HAS ADOPTED THIS DECISION:

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*.

[F1ANNEX

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

Textual Amendments

F1 Substituted by 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).

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**) OJ L 114, 30.4.2002, p. 369.

Changes to legislation:
There are currently no known outstanding effects for the 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).