



2026/2347

26.10.2026

**COMMISSION IMPLEMENTING DECISION (EU) 2026/2347**

**of 23 October 2026**

**amending Implementing Decision 2012/715/EU as regards the inclusion of the Republic of Singapore  
in the list of third countries established by that Decision**

**(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 <sup>(1)</sup>, 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 that country's 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 Singapore requested, by letter dated 11 February 2025, to be listed in accordance with Article 111b(1) of Directive 2001/83/EC.
- (3) The Commission assessed the request by carrying out a review of the relevant documentation and an on-site review of Singapore's regulatory system from 18 to 25 March 2026. This assessment included two observed inspections and took due account of the responses, information and documentation provided during the audit by the Health Sciences Authority (HSA) of Singapore.
- (4) Based on that assessment, the Commission concluded that the requirements laid down in Article 111b(1) of Directive 2001/83/EC were fulfilled.
- (5) Commission Implementing Decision 2012/715/EU <sup>(2)</sup> 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.

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>.

<sup>(2)</sup> 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, ELI: [http://data.europa.eu/eli/dec\\_impl/2012/715/oj](http://data.europa.eu/eli/dec_impl/2012/715/oj)).

*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, 23 October 2026.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

## ‘ANNEX

**List of third countries with a regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union**

| Country               | Remarks |
|-----------------------|---------|
| Australia             |         |
| Brazil                |         |
| Canada                |         |
| Israel <sup>(1)</sup> |         |
| Japan                 |         |
| Singapore             |         |
| South Korea           |         |
| Switzerland           |         |
| Taiwan <sup>(2)</sup> |         |
| United States         |         |

<sup>(1)</sup> 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.

<sup>(2)</sup> This Decision should not be interpreted as reflecting any official position of the European Union with regard to the legal status of Taiwan.’