DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2023/172

of 24 January 2023

amending Implementing Decision 2012/715/EU as regards the inclusion of Canada 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 ([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 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) Canada requested, by letter dated 1 October 2018, to be listed in accordance with Article 111b(1) of Directive 2001/83/EC.

(3) The Commission has assessed the request by carrying on a review of the relevant documentation and an on-site review of Canada's regulatory system and an observed inspection and taking due account of the action plan proposed on 23 September 2022, by the Canadian competent authority, Health Canada/Santé Canada.

(4) The Commission has also assessed the regulations to extend Canada's drug establishment licensing framework and Good Manufacturing Practice requirements to establishments that conduct regulated activities with active substances intended solely for export ([2]), which are to enter into force on 8 December 2022.

(5) Based on that equivalence assessment, the Commission concluded that the requirements of Article 111(b) of Directive 2001/83/EC were fulfilled.

(6) Commission Implementing Decision 2012/715/EU ([3]) 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.

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) Canada Gazette Part II, Vol. 156, No 12/Gazette du Canada Partie II, vol. 156, no 12 p. 1521
([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, 24 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

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

Third country	Remarks
Australia	
Brazil	
Canada	
Israel ([1])	
Japan	
South Korea	
Switzerland	
United States	

([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 (OJ L 171, 2.7.2015, p. 24).'