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POLCOM 133

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Draft DECISION OF THE CETA JOINT COMMITTEE as regards the inclusion of active pharmaceutical ingredients as the medicinal products or drugs listed in paragraph 2 of the Annex 1 to the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products

DRAFT

DECISION No …/2026
OF THE CETA JOINT COMMITTEE

of …

as regards the inclusion of active pharmaceutical ingredients as the medicinal products or drugs listed in paragraph 2 of the Annex 1 to the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products

THE CETA JOINT COMMITTEE,

Having regard to Article 26.1 of the Comprehensive Economic and Trade Agreement (CETA) between Canada, on the one part, and the European Union and its Member States, on the other part, done at Brussels on 30 October 2016 (the 'Agreement'),

Whereas:

(1) Under the provisions of Article 30.7.3(a) of the Agreement, the Agreement has been provisionally applied since September 21, 2017.

(2) Article 26.1.5(c) of the Agreement provides that the CETA Joint Committee may consider or agree on amendments as provided in the Agreement.

(3) Article 30.2.2 of the Agreement provides that the CETA Joint Committee may decide to amend the protocols and annexes of the Agreement.

(4) Article 15 paragraphs 5 and 6 of the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products (the 'Protocol') provides that the Joint Sectoral Group is to review the operational scope of medicinal products or drugs under paragraph 2 of Annex 1, with a view to including those medicinal products or drugs listed in paragraph 1 of Annex 1.

(5) The European Commission and Health Canada have conducted evaluations of the applicable Canadian and EU Good Manufacturing Practices programs for active pharmaceutical ingredients and have concluded that their respective regulatory and enforcement frameworks in this area are equivalent.

(6) The Protocol, on the recommendation of the Joint Sectoral Group to the CETA Joint Committee, should therefore be amended by including active pharmaceutical ingredients as medicinal products or drugs listed in paragraph 2 of Annex 1 to the Protocol.

(7) The entry into force of this Decision does not require any further procedure under the European Union legal order,

HAS ADOPTED THIS DECISION:

Article 1

Operational scope of medicinal products or drugs

Paragraph 2 of Annex 1 to the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products shall be amended as follows:

(a) at the end of the entry for point (f), the word ‘and’ shall be removed;

(b) at the end of the entry for point (g), the full stop shall be replaced by ‘; and’; and,

(c) after the entry for point (g), the following entry shall be added: ‘(h) active pharmaceutical ingredients.’.

Article 2

Legal status of the amendment

Upon entry into force of this Decision, the amendment set out in Article 1 will become part of the Protocol. The Parties recognize that since the Agreement, including the Protocol, is provisionally applied, the amendment will also be provisionally applied until the Agreement enters into force.

Article 3

Authentic texts

This Decision is drawn up in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each version being equally authentic.

Article 4

Entry into force

This Decision shall enter into force on the first day of the second month following the date Canada has provided to the European Union a written notification certifying that it has completed its internal requirements and procedures necessary for entry into force.

Done at …, …

For the Joint Committee

The Co-chairs