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POLCOM 133

## LEGISLATIVE ACTS AND OTHER INSTRUMENTS

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Subject: COUNCIL DECISION on the position to be taken on behalf of the European Union within the CETA Joint Committee established under the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part, as regards the inclusion of active pharmaceutical ingredients as medicinal products or drugs listed in 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

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**COUNCIL DECISION (EU) 2026/...**

**of ...**

**on the position to be taken on behalf of the European Union  
within the CETA Joint Committee  
established under the Comprehensive Economic and Trade Agreement (CETA)  
between Canada, of the one part,  
and the European Union and its Member States, of the other part,  
as regards the inclusion of active pharmaceutical ingredients  
as medicinal products or drugs listed in 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**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the Article 207(4), first subparagraph, in conjunction with Article 218(9), thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Council Decision (EU) 2017/37<sup>1</sup> provides for the signing on behalf of the European Union of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part<sup>2</sup> (the ‘Agreement’). The Agreement was signed on 30 October 2016.
- (2) Council Decision (EU) 2017/38<sup>3</sup> provides for the provisional application of parts of the Agreement, including the establishment of the CETA Joint Committee. Parts of the Agreement have been provisionally applied since 21 September 2017.
- (3) In accordance with Article 26.1(5)(c) of the Agreement, the CETA Joint Committee may consider or agree on amendments to the Agreement.
- (4) Article 30.2 of the Agreement provides that the CETA Joint Committee may decide to amend the protocols and annexes of the Agreement. Pursuant to Article 26.3(3) of the Agreement, such decision is to be made by mutual consent of the Parties.

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<sup>1</sup> Council Decision (EU) 2017/37 of 28 October 2016 on the signing on behalf of the European Union of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part (OJ L 11, 14.1.2017, p. 1, ELI: <http://data.europa.eu/eli/dec/2017/37/oj>).

<sup>2</sup> OJ L 11, 14.1.2017, p. 23, ELI: [http://data.europa.eu/eli/agree\\_internation/2017/37/oj](http://data.europa.eu/eli/agree_internation/2017/37/oj).

<sup>3</sup> Council Decision (EU) 2017/38 of 28 October 2016 on the provisional application of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part (OJ L 11, 14.1.2017, p. 1080, ELI: <http://data.europa.eu/eli/dec/2017/38/oj>).

- (5) Pursuant to Article 15(5) of the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products to CETA (the ‘GMP Protocol’), the Joint Sectoral Group is to review the Annexes the GMP Protocol at the request of the Parties to the Agreement and develop recommendations for their amendment for consideration by the CETA Joint Committee.
- (6) Pursuant to Article 15(6), on 15 December 2022 the Joint Sectoral Group reviewed the operational scope of the GMP Protocol and recommended that active pharmaceutical ingredients which are currently listed in paragraph 1 of Annex 1 to the GMP Protocol, and for which the GMP requirements and compliance programmes of both Parties are equivalent, also be included in the list of medicinal products or drugs listed in paragraph 2 of Annex 1 to the GMP Protocol.
- (7) The CETA Joint Committee is to adopt a decision on the inclusion of the active pharmaceutical ingredients in the operational scope of medicinal products or drugs listed in Annex 1 to the GMP Protocol.
- (8) It is therefore appropriate to establish the position to be taken on behalf of the Union within the CETA Joint Committee on the basis of the attached draft decision of the CETA Joint Committee as regards the inclusion of active pharmaceutical ingredients as medicinal products or drugs listed in paragraph 2 of Annex 1 to the GMP Protocol,

HAS ADOPTED THIS DECISION:

*Article 1*

The position to be taken on behalf of the Union within the CETA Joint Committee as regards the inclusion of active pharmaceutical ingredients as medicinal products or drugs listed in paragraph 2 of Annex 1 to the GMP Protocol to the Agreement shall be based on the draft decision of the CETA Joint Committee attached to this Decision.

*Article 2*

This Decision shall enter into force on the date of its adoption.

Done at ..., ...

*For the Council*  
*The President*

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