Council of the European Union

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POLCOM 131

PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	10 April 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2026) 130 final
Subject:	Proposal for a 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 adoption of a decision concerning 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

Delegations will find attached document COM(2026) 130 final.

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Brussels, 10.4.2026
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Proposal for a

COUNCIL DECISION

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EXPLANATORY MEMORANDUM

1. SUBJECT MATTER OF THE PROPOSAL

This proposal concerns the decision establishing the position to be taken on the Union's behalf in the Joint Committee established under the Comprehensive Economic and Trade Agreement ('CETA' or 'the Agreement') between Canada, of the one part, and the European Union and its Member States, of the other part ('the Parties'), in connection with the envisaged adoption of a decision concerning the inclusion of active pharmaceutical ingredients ('API') as medicinal products or drugs listed in paragraph 2 of the Annex 1 to Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products.

2. CONTEXT OF THE PROPOSAL

2.1. The Comprehensive Economic and Trade Agreement

The CETA aims to liberalise and facilitate trade and investment, as well as to promote a closer economic relationship between the Union and Canada. The Agreement was signed on 30 October 2016 and has been provisionally applied since 21 September 2017.

The Agreement contains the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices ('GMP') for pharmaceutical products to the Comprehensive Economic and Trade Agreement ('the GMP Protocol'), which aims to strengthen the cooperation between the authorities of the Parties in ensuring that medicinal products and drugs meet appropriate quality standards through the mutual recognition of certificates of GMP compliance.

2.2. The CETA Joint Committee

The CETA Joint Committee is established under Article 26.1 of the Agreement and comprises representatives of the Union and Canada. The CETA Joint Committee is responsible for all questions concerning trade and investment between the Parties and the implementation and application of the Agreement.

In accordance with Article 26.1(5)(c) of the Agreement, the CETA Joint Committee 'may consider or agree on amendments as provided in this Agreement'. Relatedly, Article 30.2 of the Agreement provides that 'the CETA Joint Committee may decide to amend the protocols and annexes of this Agreement', which includes the GMP Protocol. Pursuant to Article 26.3(3) of the Agreement, such decision shall be made by mutual consent of the Parties.

In accordance with Rule 10.2 of the Rules of Procedure of the CETA Joint Committee, in the period between meetings, the CETA Joint Committee may adopt decisions or recommendations by written procedure if the Parties to the Agreement decide by mutual consent. For that purpose, the text of the proposal will be circulated in writing from the co-chairs to the members of the CETA Joint Committee pursuant to the correspondence requirements under Rule 7 of the Rules of Procedure of the CETA Joint Committee, with a time limit within which members will make known any concerns or amendments they wish to make. Adopted proposals will be communicated pursuant to the same correspondence requirements once the time limit has elapsed and recorded in the minutes of the next meeting.

2.3. The envisaged act of the CETA Joint Committee

The paragraph 1 of Annex 1 of the GMP Protocol lists APIs as medicinal products or drugs within the scope of the GMP Protocol, but does not yet include them in its operational scope, pending assessment by the Parties. Article 15(6) of the GMP Protocol states that the Joint

Sectoral Group will review the operational scope of medicinal products or drugs, with a view to including those listed in Annex 1.

By letter dated 1 October 2018, Canada requested to be included in a list of third countries ensuring an equivalent level of protection of public health as regards the regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities, in accordance with Article 111b(1) of Directive 2001/83/EC[1]. To decide on Canada's request, the Commission reviewed the relevant documentation and conducted an on-site audit in Canada in June 2022.

Based on this assessment, the annex to Implementing Decision 2012/715/EU was amended by Commission Implementing Decision (EU) 2023/172 of 24 January 2023 to include Canada in the list of third countries for importation of active substances. As a consequence, pursuant to Article 46b(3) of Directive 2001/83/EC, the importers of APIs manufactured in Canada are no longer required to provide a written confirmation, as foreseen under Article 46b(2)(b) of that Directive.

From the Canadian side, Heath Canada assessed the competent authorities of the Member States by means of a questionnaire. The conclusion of the assessment and the subsequent recognition of all 24 assessed Member States was published in a report by Health Canada in February 2023.

Based on the reciprocal assessments described above, the Joint Sectoral Group, established under Article 15 of the GMP Protocol, considered on 15 December 2022 that both the EU and the Canadian regulatory framework and supervision system applicable to APIs were equivalent. Therefore, on that occasion, the Joint Sectoral Group recommended that APIs be included as medicinal products or drugs listed in the operational scope of the GMP Protocol. Such inclusion would require Canada to recognise EU GMP certificates for APIs, thus reciprocating the benefits it already derives from its inclusion in the list of recognised countries under Implementing Decision 2012/715/EU.

Against this backdrop, the CETA Joint Committee is to adopt a Decision concerning the inclusion of APIs as medicinal products or drugs listed in Annex 1 to the GMP Protocol ('the envisaged act'). The envisaged act will become binding on the Parties in accordance with Article 26.3.2 of CETA, subject to the completion of any necessary internal requirements and procedures.

3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

The envisaged act aims to expand the operational scope of the GMP Protocol by including APIs. This would allow the mutual recognition of inspections and acceptance of official documents, reduce the costs resulting from duplicative inspections and free capacity of EU and Canadian authorities to focus on inspections of higher risk manufacturers in other countries.

It is therefore appropriate to establish the position to be taken on the Union's behalf in the CETA Joint Committee as supporting the adoption of the envisaged act in order to ensure the effective implementation of the Agreement.

The proposed position fits in with other policies, rules or initiatives of the Union.

[1] OJ L 311, 28.11.2001, p. 67.

4. LEGAL BASIS

4.1. Procedural legal basis

4.1.1. Principles

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for decisions establishing '*the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement*.'

The concept of '*acts having legal effects*' includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are '*capable of decisively influencing the content of the legislation adopted by the EU legislature*'[2].

4.1.2. Application to the present case

The CETA Joint Committee is a body set up by an agreement, namely CETA.

The envisaged act constitutes an act having legal effects. The envisaged act will be binding under international law in accordance with Article 26.3.2 of the Agreement.

The envisaged act does not supplement or amend the institutional framework of the Agreement.

Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU.

4.2. Substantive legal basis

4.2.1. Principles

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in respect of which a position is taken on the Union's behalf. If the envisaged act pursues two aims or has two components and if one of those aims or components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(9) TFEU must be founded on a single substantive legal basis, namely that required by the main or predominant aim or component.

4.2.2. Application to the present case

The main objective and content of the envisaged act relate to the common commercial policy.

Therefore, the substantive legal basis of the proposed decision is the first subparagraph of Article 207(4) TFEU.

4.3. Conclusion

The legal basis of the proposed decision should be the first subparagraph of Article 207(4) TFEU, in conjunction with Article 218(9) TFEU.

5. PUBLICATION OF THE ENVISAGED ACT

As the act of the CETA Joint Committee will amend the operational scope of the GMP Protocol, it is appropriate to publish it in the *Official Journal of the European Union* after its adoption.

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[2] Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

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THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Whereas:

(1) Council Decision (EU) 2017/37[3] 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 ('the Agreement'). The Agreement was signed on 30 October 2016.

(2) Council Decision (EU) 2017/38[4] provides for the provisional application of parts of the Agreement, including the establishment of the CETA Joint Committee. The Agreement has 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 as provided in this Agreement.

(4) Article 30.2 of the Agreement provides that the CETA Joint Committee may decide to amend the protocols and annexes of this Agreement. Pursuant to Article 26.3(3) of the Agreement, such decision shall be made by mutual consent of the Parties.

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

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[3] 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).

[4] 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).

(6) The Joint Sectoral Group has on 15 December 2022 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 be included as 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 the Union's behalf in the CETA Joint Committee on the basis of the attached draft decision of the CETA Joint Committee,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the CETA Joint Committee as regards the adoption of a decision concerning the inclusion of active pharmaceutical ingredients as medicinal products or drugs listed in Annex 1 to the GMP Protocol to CETA shall be based on the draft act of the CETA Joint Committee attached to this Decision.

Article 2

This Decision is addressed to the Commission.

Done at Brussels,

For the Council
The President