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8147/26

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POLCOM 132

'I/A' ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee (Part 2)/Council
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 in the list of 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
- Adoption

1. On 13 April 2026, the Commission submitted to the Council a 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 products¹.

¹ ST 8146/26 + ADD 1

2. On 23 April 2026, the Trade Policy Committee (Deputies) endorsed the draft 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).
 3. In light of the above, and subject to confirmation by the Permanent Representatives Committee, the Council is invited to:
 - adopt, as an "A" item on the agenda of one of its forthcoming meetings, the Council Decision on the position to be taken on behalf of the European Union within the CETA Joint Committee as finalised by the legal-linguistic experts and set out in document 8148/26 as well as the Draft Decision of the CETA Joint Committee 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 as finalised by the legal-linguistic experts and set out in document 8148/26 ADD 1;
 - decide to order the publication in the Official Journal of the European Union of the Decision of the EU CETA Joint Committee, as set out in document 8148/26 ADD 1, once adopted; and
 - note that the European Parliament will be informed in accordance with Article 218(10) TFEU, and that the Council Decision will be transmitted to the European Parliament.
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