

Brussels, 22 April 2026  
(OR. en)

8358/26

SAN 228  
PHARM 59  
MI 361  
COMPET 451  
DELECT 76

**'I/A' ITEM NOTE**

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From: General Secretariat of the Council  
To: Permanent Representatives Committee/Council

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No. Cion doc.: 7571/26

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Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 20.3.2026  
amending Regulation (EU) 2017/745 of the European Parliament and of  
the Council as regards the list of implantable devices and class III devices  
exempted from the obligation to perform clinical investigations  
*- Intention not to raise objections to a delegated act*

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1. The Commission has submitted the above delegated act<sup>1</sup> to the Council in accordance with the procedure set out in Article 290 TFEU and with Article 61(8) of Regulation (EU) 2017/745 on 20 March 2026. The Commission having notified the delegated act with regard to the list of implantable devices and class III devices exempted from the obligation to perform clinical investigations on 20 March 2026, the Council may object to it until 21 June 2026.
2. The Working Party on Pharmaceuticals and Medical Devices has examined the delegated act and agreed that there are no grounds for the Council to object to it.

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<sup>1</sup> ST 7571/26.

3. It is therefore suggested that Coreper recommend that the Council confirm that it has no intention to object to the delegated act and that the Commission and the European Parliament are to be informed thereof. This implies that, unless the European Parliament objects to it, the delegated act shall be published and enter into force in accordance with Article 61(8) of Regulation (EU) 2017/745.
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