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COMPET 452
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'I/A' ITEM NOTE

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

No. Cion doc.: 7573/26

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 class IIb implantable devices exempted
from the obligation to perform an assessment of the technical
documentation for every device
- Intention not to raise objections to a delegated act

1. The Commission has submitted the above delegated act¹ to the Council in accordance with the procedure set out in Article 290 TFEU and with Article 52(5) of Regulation (EU) 2017/745 on 20 March 2026. The Commission having notified the delegated act with regard to the list of class IIb implantable devices exempted from the obligation to perform an assessment of the technical documentation for every device 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.

¹ ST 7573/26.

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 52(5) of Regulation (EU) 2017/745.
