Council of the European Union

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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices **(first reading)** - Adoption of the legislative act

1. On 23 January 2024 the Commission submitted its proposal[1], based on Article 114 and Article 168(4), point (c), TFEU, to the Council.

2. The European Economic and Social Committee delivered its opinion on 20 March 2024[2].

3. The Committee of the Regions was consulted and decided not to issue an opinion.

4. On 25 April 2024 the European Parliament adopted its position at first reading on the Commission proposal[3]. The outcome of voting in the European Parliament reflects the compromise agreement reached between the institutions and should, therefore, be acceptable to the Council.

[1] 5712/24.
[2] 8102/24.
[3] 9237/24.

5. The Permanent Representatives Committee is therefore asked to confirm its agreement and to suggest that the Council approve the European Parliament's position, as set out in PE-CONS 54/24 + COR 1, as an "A" item at a forthcoming meeting.

6. If the Council approves the European Parliament's position, the legislative act will be adopted.

   After being signed by the Presidents of the European Parliament and of the Council, the legislative act will be published in the *Official Journal of the European Union*.