Council of the European Union

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**'I/A' ITEM NOTE**

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| 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 the transitional provisions for certain medical devices and in vitro diagnostic medical devices **(first reading)**<br>- Adoption of the legislative act<br>- Decision to derogate from the eight-week period provided for in Article 4 of Protocol 1 on the role of national parliaments in the EU |

1. On 11 January 2023 the Commission sent 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 24 January 2023[2].

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

4. On 16 February 2023 the European Parliament adopted its position at first reading on the Commission proposal. The outcome of voting in the European Parliament reflects the agreement reached between the institutions on taking over the Commission proposal and should, therefore, be acceptable to the Council[3].

1 5139/23.
2 5897/23.
3 6292/23.

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 1/23 as an 'A' item at a forthcoming meeting;

   - derogate, on the basis of Article 3(3), second subparagraph, of the Council's Rules of Procedure, from the eight-week period referred to in the first subparagraph of that Article, in view of the urgency of the matter as set out in the preamble of the legislative act.

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*.