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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 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (First reading) - Adoption of the Council's position at first reading and of the statement of the Council's reasons

1. On 28 September 2012 the Commission sent the above proposal¹, based on Article 114 and point (c) of Article 168(4) TFEU, to the Council.
2. The European Economic and Social Committee delivered its opinion on 14 February 2013².
3. The European Parliament adopted its position at first reading on 2 April 2014³.

¹ 14499/12.

² OJ C 133, 9.5.2013, p. 52.

³ 8009/14.

4. At its 3484th meeting on 20 September 2016, the General Affairs Council reached a political agreement on the Council's position at first reading on the above Regulation⁴.
5. Following the political agreement, it became clear that certain provisions, in particular the transitional provisions, could have led to certain unintended consequences both for the industry and for patients and regulators. At the initiative of a number of Member States, and in line with suggestions from certain Members of the European Parliament, it was decided to clarify the intention of the political agreement in this regard. The resulting technical clarifications of the text of the political agreement have been informally agreed upon by all the Member States, the European Parliament and the Commission, and inserted into the text during legal-linguistic finalisation. The relevant provisions are listed in paragraph 12 of the draft statement of the Council's reasons set out in 10729/16 ADD 1.
6. The Permanent Representatives Committee could suggest that the Council:
 - adopt, as an 'A' item at a forthcoming meeting, the Council's position at first reading as set out in 10729/16 and the statement of reasons as set out in 10729/16 ADD 1;
 - order that the statements in the addendum to this note be entered in the minutes of that meeting.

⁴ In accordance with the letter of 16 June 2016 sent by the Chair of the European Parliament's Committee on the Environment, Public Health and Food Safety to the Chair of Coreper, the European Parliament should, at second reading, approve the Council's position at first reading without amendment.