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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 Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products **(first reading)** - Adoption of the legislative act

1. On 28 May 2018 the Commission sent the above proposal[1], based on Article 114 TFEU, to the Council.

2. The European Economic and Social Committee delivered its opinion on 20 September 2018[2].

3. On 17 April 2019 the European Parliament adopted its position at first reading on the Commission proposal. The outcome of voting in the European Parliament reflects the compromise agreement reached between the institutions and should, therefore, be acceptable to the Council[3].

1 9485/18.
2 OJ C 440, 6.12.2018, p. 100.
3 8442/19.

4. 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 52/19, as an "A" item at a forthcoming meeting, with Denmark, Malta, Sweden and the United Kingdom voting against and Austria and Czechia abstaining;

   – decide that the statements in the addendum to this note be entered in the minutes of that meeting.

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

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