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 Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom in respect of Northern Ireland as well as in Cyprus, Ireland and Malta **(first reading)** - Adoption of the legislative act

1. On 17 December 2021 the Commission sent its proposal[1], based on Article 114 and Article 168(4)(c) TFEU, to the Council.

2. The European Economic and Social Committee delivered its opinion on 24 February 2022[2].

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

4. The European Parliament adopted its position at first reading on the Commission proposal on 7 April 2022. 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 15189/21.
2 Not yet published in the OJ.
3 7828/22.

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 7/22, as an 'A' item at a forthcoming meeting.

6. The statement for the minutes of the Council meeting is set out in Addendum 1 to this note.

7. 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.