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'A' ITEM NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices **(first reading)** - Adoption of the legislative act

1. On 12 November 2020 the Commission sent its proposal[1], based on Articles 114 and 168(4) TFEU, to the Council.

2. The European Economic and Social Committee delivered its opinion on 27 April 2021[2].

3. The European Committee of the Regions delivered its opinion on 5 May 2021[3].

[1] 12971/20.
[2] OJ C 286, 16.7.2021, pp. 109–120.
[3] OJ C 300, 27.7.2021, pp. 87–92.

4. On 10 November 2021, the Permanent Representatives Committee endorsed the agreement reached with the European Parliament and authorised the Chair to send a letter to the Chair of the ENVI Committee stating that should the European Parliament adopt its position at first reading in the form set out in that letter, subject to revision by the legal linguists of both institutions, the Council would approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position.

5. The European Parliament adopted its position at first reading on 20 January 2022[4].

6. At its meeting on 19 January 2022, the Permanent Representatives Committee agreed to invite the Council to approve the European Parliament's position at the first reading as set out in PE CONS 76/21 as an 'A' item at a forthcoming meeting.

7. The statement by Hungary for the minutes of the Council meeting is set out in Addendum 1.

8. The Council is invited to approve the European Parliament's position at the first reading as set out in PE-CONS 76/21.

9. If the Council approves the European Parliament's position, the legislative act will be adopted in the wording which corresponds to the European Parliament's position.

   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*.

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[4] 5408/22.