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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a 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 - <i>General approach</i>

I. BACKGROUND

1. On 12 November 2020, the Commission submitted the proposal for a 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 to the Council and to the European Parliament¹.
2. The proposal is based on Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

¹ 12971/20

3. The proposal is part of a set of three proposals aiming to strengthen the EU's health security framework and to reinforce the crisis preparedness and response role of key EU agencies. Together they are the first building block of the European Health Union. The proposal was not accompanied by an impact assessment. The objectives of the proposal are to:
- monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address public health emergencies and other major events which may have a serious impact on public health;
 - ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing public health emergencies;
 - provide the structure for the functioning of expert panels that assess high-risk medical devices and provide essential advice in crisis preparedness and management.
4. Member States' National Parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity and proportionality. While the French Senate raised subsidiarity concerns, the Portuguese and the Spanish Parliaments considered that the proposal complied with the subsidiarity principle.
5. The European Economic and Social Committee and the Committee of the Regions were both consulted. The Committee of the Regions adopted its opinion² on the proposal during its 144th plenary session (5-7 May 2021). The European Economic and Social Committee has not yet sent its opinion on the proposal.
6. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file. The European Parliament has appointed MEP Nicolás González Casares (S&D, ES) as Rapporteur. The latter presented his draft report on 30 March 2021 and the deadline for amendments was set to 28 April 2021. The ENVI Committee is expected to vote on the file during its June meeting.

² 8920/21

II. STATE OF PLAY

7. The Portuguese Presidency convened 8 meetings of the members of the Working Party on Pharmaceuticals and Medical Devices via videoconference to examine the proposal at technical level.
8. On 18 May, the Portuguese Presidency presented a draft compromise text on the entire proposal. This draft compromise text aimed at addressing the main issues highlighted by the delegations on the original proposal during the technical examination including the preparation of a list of critical medicinal products; the triggering conditions for a monitoring of shortages of medicinal products and medical devices; the interoperability of IT systems to be developed both for medicinal products and medical devices; the composition and functioning of the Emergency Task Force; the handling of commercially confidential data; data protection and funding.
9. The members of the Working Party thoroughly examined the draft compromise text and its further revised versions at three meetings.
10. The latest Presidency compromise text³ was examined by the members of the Working Party at the meeting on 28 May 2021 and received a large support from delegations. A number of changes were made during the meeting with a view to addressing some remaining concerns from delegations, which, while broadly welcoming these changes requested additional time to be able to consult their Capitals.

³ 8903/21

11. In light of the above, the Presidency concluded the meeting by noting that there was broad support for the latest Presidency compromise text as revised during the meeting and indicated that the changes made during the meeting would be sent in writing to delegations for any possible comments by Monday 31 May in the morning. It further indicated that the Permanent Representatives Committee would be invited to examine the revised draft compromise text on 2 June 2021 with a view to subsequently submit it to the EPSCO Council (Health) and invite the latter to adopt a general approach on the text at its session on 15 June.
12. Some additional comments were received in writing by the end of the consultation period. The Presidency decided to further amend the text slightly to take on board some of these comments that aimed to clarify the text. However, regarding some of the changes to the definitions in Article 2, requested by a few delegations, the Presidency considered that despite the amendments it had already proposed for Article 30a (to provide for a review of definitions), given the diverging views presented, further discussion at Coreper would be useful. This is the case for the definition of '*major event*' on which on the one hand some delegations considered that the text should be revised to make its scope narrower, while on the other hand, others considered that the scope should be broad enough to ensure flexibility.
13. The Coreper is therefore invited to consider the views referred to above and identify the best way forward.

III. CONCLUSION

14. In the light of the above, the Permanent Representatives Committee is invited to:
 - a) discuss the issue referred to under points 12 and 13 above;
 - b) examine subsequently the latest compromise text as revised by the Presidency and set out in 9116/21, and confirm the agreement on this text;
 - c) agree to suggest to the Council to adopt a general approach on the text at its session on 15 June 2021.