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NOTE

From:	Presidency
To:	Council
No. Cion doc.:	11956/21
Subject:	Council Regulation on the emergency framework regarding medical countermeasures - <i>Exchange of views</i>

I. BACKGROUND

1. On 16 September 2021, the Commission submitted the proposal for a Council Regulation on the emergency framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level¹. On the same day the Commission adopted its decision establishing the Health Emergency Preparedness and Response Authority (HERA).

¹ 11956/21

2. The proposal is one of the main pillars of the European Health Union. It is proposed in conjunction with the proposals put forward by the Commission in November 2020: the proposal for a Regulation on serious cross border threats to health and the extended mandates of the European Centre for Disease Prevention and Control (ECDC) European Medicines Agency (EMA).
3. The proposal is based on Article 122 (1) of the Treaty on the Functioning of the European Union (TFEU). The proposal was not accompanied by an impact assessment due to the urgency of the matter to strengthen the emergency framework in preparation for a future public health emergency. The key measures of the proposal are:
 - the establishment of a Health Crisis Board to ensure coordination and integration of approaches to crisis-relevant medical countermeasures at Union level in the event of a public health emergency;
 - the establishment of mechanisms for the monitoring, activation of emergency funding, procurement and purchase of crisis-relevant medical countermeasures and raw materials;
 - the activation of EU FAB facilities, the activation of emergency research and innovation plans, and the use of Union-wide clinical trial networks and provisions and platforms for the rapid sharing of data; and
 - measures concerning the production of crisis-relevant medical countermeasures.

II. STATE OF PLAY

4. Since 28 September 2021, the Slovenian Presidency has convened all together 9 meetings examining the proposal at technical level. On 12 November 2021, the Slovenian Presidency presented a draft text on the entire proposal, which was thoroughly examined by the Working Party. Based on the discussion and comments from the Member States, additional three revised versions of the draft compromise text were drafted. The latest Presidency's compromise text² was examined by the Working Party at the meeting on 23 November 2021.

Following the discussion at the last Working Party, the Presidency decided to further amend the text and take on board some of the written comments from delegations that aimed to clarify the text. The resulting draft compromise text submitted to the Permanent Representatives Committee on 1 December 2021³, aims at addressing the main issues highlighted by delegations in relation to the original proposal, in particular for enhanced involvement of Member States in the decision-making process.

The Permanent Representatives Committee discussed the latest compromise text on 1 December 2021 with a view to a possible political agreement at the EPSCO Council on 7 December. While a number of Member States supported the compromise text as a good basis for a political agreement, a group of Member States considered that further changes to the text were necessary to allow them to support a political agreement.

5. The main issue expressed by Member States in the discussions so far has been the need for stronger involvement of Member States in the decision-making process of the emergency framework, especially in periods of crisis. Therefore, the Presidency has introduced some key amendments aimed at ensuring the enhanced role of Member States in the governance structure. These include, among others, a strengthened role of the Health Crisis Board and the introduction of implementing acts into several provisions of the proposal.

² 14179/21

³ 14031/21

Another issue raised by some Member States was the interlinkages of this proposal with **the proposed Regulation on serious cross border threats to health**⁴. In the Presidency's opinion, the work on this proposal does not prejudice the discussions on the proposal for a Regulation on serious cross border threats to health and is subject to any adjustment of cross-references necessary to ensure coherence between the two acts. Once the final text of the Regulation on serious cross border threats to health is agreed upon, the necessary technical adjustments, notably the cross-references, will be introduced in the framework regulation before its final adoption by the Council.

6. Following the request of the European Parliament, expressed in the letter dated 25 October 2021, the **budgetary scrutiny procedure** will be launched in line with the joint declaration of the European Parliament, the Council and the Commission on budgetary scrutiny of new proposals based on Article 122 TFEU with potential appreciable implications for the Union budget⁵. The possible outcome of this procedure will be considered with a view to the final adoption of this proposal by the Council.

III. CONCLUSION

Ministers at the EPSCO Council (Health) on 7 December 2021 are invited to exchange views on the basis of the following question:

How in your view could the proposed emergency framework most efficiently contribute to the overall EU resilience in the event of a public health emergency?

⁴ 12973/21

⁵ 2020/C 444 I/05