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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	12973/20 INIT + ADD 1
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU <i>- Mandate for negotiation with the European Parliament</i>

I. BACKGROUND

1. On 11 November 2020, the Commission submitted the proposal for a Regulation on serious cross-border threats to health¹. It 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.
2. The proposal is based on Article 168(5) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.

¹ 12973/20

3. The proposal aims to strengthen the framework for health crisis preparedness and response at EU level, particularly through: the development of an EU health crisis and pandemic preparedness plan and of requirements for corresponding national plans, coupled with a framework for reporting and auditing; rules for strengthening and integrating the epidemiological surveillance system at EU level, supported by improved data collection tools and artificial intelligence; rules for the surveillance of novel pathogens and for the reporting of health systems data and other relevant data for the management of cross-border threats; increased EU and Member States capacity for accurate risk assessment and response; provisions for designation and funding of EU reference laboratories for public health; rules on the recognition of emergency situations, and for the activation of Union emergency mechanisms for the management of health crises.
4. The French Senate submitted a reasoned opinion, raising subsidiarity concerns. The Italian, Portuguese and Spanish Parliaments submitted positive assessments of the proposal. The Czech Senate delivered a resolution on the three proposals of the European Health Union Package whereby, while supporting certain elements of the proposals, it also raised a number of questions.
5. On 27 April, the European Economic and Social Committee adopted its opinion on the proposal². On 7 May, the European Committee of the Regions also adopted its opinion on the proposal³.
6. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file and MEP Véronique Trillet-Lenoir (Renew, FR) was appointed as Rapporteur. The ENVI Committee adopted its report on 13 July 2021 and a plenary vote is scheduled for September.

² 8384/21

³ 8965/21

II. STATE OF PLAY

7. The technical examination of the proposal in the Council started under the German Presidency and continued under the Portuguese Presidency. In total thirteen virtual meetings of the members of the Working Party (WP) on Pharmaceuticals and Medical Devices were organised. On 15 June 2021, the Council (EPSCO) was informed about the progress of discussions⁴. The Slovenian Presidency further organised two meetings of the WP in July.
8. A first draft revised text was presented on 17 May 2021, with the aim to address the main issues raised by delegations during the examination of the original proposal at technical level: the structure of the Health Security Committee (HSC); the ECDC's task of auditing national preparedness and response plans and the delegated acts for adopting the procedures, standards and criteria required for performing the task; the frequency of Member States' reporting obligations; the participation of certain non-EU countries in joint procurement of medical countermeasures.
9. During the technical examination, several delegations raised legal concerns regarding the proposal and requested a written opinion from the Council Legal Service (CLS), notably on whether the exclusion of harmonisation of laws and regulations of the Member States, as stated in Article 168 (5) TFEU, is safeguarded, particularly with respect to proposed requirements that national plans reach consistency, coherence and interoperability with the Union preparedness and response plan.
10. The latest Presidency compromise text⁵ focused on addressing several outstanding issues: the definition of medical countermeasures and the joint procurement of such countermeasures; data protection; respecting national competencies with regards to preparedness and response planning; and the structure of the HSC. The text was examined by the WP at the meeting on 16 July 2021 and received broad support from delegations.

⁴ 9622/21

⁵ 10699/21

11. The CLS presented its opinion at the same meeting, concluding that while some provisions in the Commission proposal may go beyond the limitations of the proposed legal basis, the latest Presidency text ensures that those limitations are respected.
12. A number of changes were made during the WP meeting on 16 July 2021 with a view to addressing some remaining concerns from delegations, regarding in particular: avoiding overlap of reporting and reviewing activities on preparedness and response planning and implementation; voting rules in the HSC; the recognition of public health emergency situations at Union level; and cooperation with the World Health Organization.
13. 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. It further indicated that the Permanent Representatives Committee would be invited to examine this text on 23 July 2021 with a view to mandate the Presidency to enter into negotiations with the European Parliament.

III. CONCLUSION

14. In the light of the above, the Permanent Representatives Committee is invited to:
- examine the overall compromise text, as set out in document 10807/21 and confirm its agreement on it;
 - mandate⁶ the Presidency to enter into negotiations with the European Parliament on the basis of this text in view to reach an agreement at first reading on the proposal for a Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

⁶ In accordance with the approach on legislative transparency endorsed by the Permanent Representatives Committee on 14 July 2020 (doc. 9493/20), and in full consistency with Regulation (EC) No 1049/2001 and the Council's Rules of Procedure, the agreed mandate will be made public.