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NOTE

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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee |
| No. Cion doc.: | 12972/20 |
| Subject: | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control <i>- Mandate for negotiation with the European Parliament</i> |

I. BACKGROUND

1. On 11 November 2020, the Commission submitted the proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control to the Council and to the European Parliament¹. 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.
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 12972/20

3. The proposal aims to reinforce the capacities of the ECDC on the prevention and control of communicable diseases and risk assessment with a view to future cross-border health threats through: strengthening its collaboration with Member States; rapid digitalisation of integrated surveillance systems; strengthening the ability to anticipate and forecast; developing prevention and response plans against future epidemics and capacities for an integrated rapid response to epidemic and outbreaks; strengthening its capacity to provide non-binding recommendations for risk management; developing its capacity to implement, mobilize and deploy an EU Health Task Force for rapid intervention to support the response in Member States; enhancing monitoring and assessment of the ability of national health systems for diagnosis, prevention and treatment of specific communicable diseases as well as of patient safety; creating a new network of Union reference laboratories for public health and a new network of national services supporting transfusion, transplantation and medically assisted reproduction; strengthening its cooperation with third countries and collaboration with WHO; and ensuring complementarity with other Union and international instruments, thereby avoiding duplication of efforts.
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.

² 8384/21

³ 8965/21

6. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file and MEP Joanna Kopcińska (ECR, PL) was appointed as Rapporteur. The ENVI Committee adopted its report on 29 June 2021 and a plenary vote is scheduled for September.

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 11 May 2021, with the aim to address the main issues raised by delegations during the examination of the original proposal at technical level: the Centre's task of monitoring health systems' capacities; the nature of recommendations issued by the ECDC; the auditing of preparedness and response planning; the EU Health Task Force. This was further revised in light of comments from delegations, in particular regarding: data protection; health systems' monitoring; the EU Health Task Force; the role of the Management Board; the reporting obligations of the Member States; the coherence with the proposed Regulation on serious cross-border threats to health.
9. The latest Presidency compromise text⁵ was examined by the WP at the meeting on 13 July 2021 and received broad support from delegations. A number of changes were made during the meeting with a view to addressing some remaining concerns from delegations, while others could not be included due to lack of support from most delegations.

⁴ 9620/21

⁵ 10543/21

10. 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.
11. Some additional comments were received in writing following the WP. The Presidency decided to slightly amend its latest compromise text to take on board some of the comments referring to data protection and the European Public Prosecutor's Office, as well as to clarify the text. Following discussions in the WP meeting on 16 July 2021 on the compromise text on the proposed Regulation for serious cross-border threats to health, further slight amendments were made to ensure consistency with that text. The resulting overall compromise text is available in document 10804/21.

III. CONCLUSION

12. In the light of the above, the Permanent Representatives Committee is invited to:
- examine the overall compromise text, as set out in document 10804/21 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 amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control.

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.