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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
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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>Analysis of the final compromise text with a view to agreement</i>

I. INTRODUCTION

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.

¹ 12972/20

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.
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 2021 the European Economic and Social Committee adopted its opinion on the proposal². On 7 May 2021, the European Committee of the Regions also adopted its opinion on the proposal³.
6. On 23 July 2021, the Permanent Representative Committee agreed on a mandate⁴ for the Presidency to enter into negotiations with the European Parliament.
7. 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 report was voted by the ENVI Committee on 29 June 2021 and adopted by the plenary on 14 September.
8. After the start of negotiations, it became clear that additional flexibility would be necessary for the Presidency to move forward successfully the discussion with the European Parliament. At its meeting on 27 October 2021, the Permanent Representatives Committee approved a revised mandate⁵.
9. Three trilogues took place on 27 September, 27 October and 29 November 2021. In addition, twelve technical meetings were held on 28 September, on 8, 14, 15, 19 of October and on 11, 15, 17, 22, 25, 26 and 30 November 2021.
10. At the last trilogue, on which the Presidency briefed Coreper at its meeting of 1 December 2021, the co-legislators provisionally agreed on an overall compromise text, as set out in document 14516/21.

The main elements of this compromise text are outlined in Section II below. The Presidency considers that the overall compromise package reached with the European Parliament is balanced and that it respects the mandate the Presidency received.

² 8384/21
³ 8965/21
⁴ 11091/21
⁵ 13023/21

II. COMPROMISE PACKAGE

a) Amendments on non-communicable diseases

11. The negotiating teams agreed to add a new recital 5a, acknowledging the impact that major outbreaks have on health systems, including on patients with non-communicable diseases and to add a provision in Article 31(2) stating that the first external evaluation will examine the feasibility of extending the ECDC mandate to address the impact of cross-border health threats on non-communicable diseases.
12. The European Parliament negotiating team thus agreed to withdraw references to ECDC's tasks in the area of non-communicable diseases from all other amendments throughout the text, namely EP amendments 35, 36, 42, 43, 44, 51, 53, 54, 66, 70, 74, 76, 86, 93, 112, 122 and 141.

b) Amendments on the Centre's relation to Member States

13. The European Parliament negotiating team accepted to withdraw references to:
 - on-the-spot assessments by the ECDC of national health systems capacities (EP amendment 47) ;
 - the publication of the Centre's assessments and recommendations regarding preparedness and response planning (EP amendment 90/ Article 5b(1)(2)(c)) and health systems' capacities relevant for outbreaks of communicable diseases (EP amendment 94/ Article 5b(1)(2)(i)).

14. The negotiating teams reached compromises on:

- a substantial revision, in order to ensure the respect of Member States' prerogatives in the field of health, of the references to inspections at source organized by the ECDC in Member States (as initially proposed by the European Parliament) in order to monitor compliance with obligations on preparedness and response planning (EP amendment 48/ Article 3 (2) (ea));
- a revision of the reference to immediate notification of delays in data reporting by Member States (EP amendment 64/ Article 4 (1)(cc));
- a facilitating role for the ECDC in the self-assessment and external evaluation of national preparedness and response planning, when accepted by the Member State concerned (EP amendment 90/ Article 5b(1)(2)(c));
- a more active involvement of the Centre regarding preparedness gaps, where its task will be to assess, rather than monitor (Article 5b(1)(2)(d)).

15. The Presidency agreed:

- that the ECDC monitor health systems' capacities relevant for outbreaks of communicable diseases based on common indicators and indicators for preparedness (EP amendment 94/ Article 5b(1)(2)(i));
- to a more active role for the Centre in identifying population groups at risk in need of targeted measures (Article 5(4)(e)).

c) Amendments on data reporting

16. The European Parliament negotiating team agreed to withdraw its amendment 59 on the obligation for Member States to use common indicators to assess their own domestic health situation and to communicate them to the Centre.
17. The Presidency agreed to:
- the standardization of data collection procedures (Article 11(1));
 - withdraw the reference to reporting by Member States of available data on the surveillance of communicable diseases and serious cross-border threats to health (Article 4(1)(a)), as well as the reference to the use of available data by the ECDC in order to evaluate and monitor communicable disease prevention and control programmes (Article 5a(3)).

d) Amendments on tasks overlapping with those of other EU bodies and agencies

18. The European Parliament negotiating team agreed to withdraw references to:
- ECDC's role in providing recommendation for stockpiling of medical countermeasures (in EP amendment 52/ Article 3(2)(h));
 - requiring the Centre to include in its risk assessments a forecast of the demand for medical countermeasures (in EP amendment 112/ Article 8a(2)) as well as to collect data in order to forecast the demand for specific medicines, equipment and hospital capacity (in EP amendment 123/ Article 11(1a)(c)).

19. The Presidency agreed that ECDC include, in its risk assessments: a forecast of the evolution of a health crisis and the risk of a health emergency; recommendations on the capacity of health services necessary for the management of communicable disease threats; the identification of vulnerable groups in society.

e) Other issues

20. The negotiating teams reached a compromise regarding ECDC's role in regularly reviewing and updating the Union preparedness and response plan (Article 5b(1)(2)(a))

21. The Presidency agreed not to limit the development by the ECDC of exercises stress tests, in-action and after-action reviews only to the EU level.

22. Regarding the EU Health Task Force (Article 11a), the negotiating teams reached a compromise concerning its permanent and enhanced emergency capacities, the development of a framework to define the structure and use of the permanent capacity as well as the adoption of procedures for mobilisation of the enhanced emergency capacity by implementing act.

III. CONCLUSION

23. In the light of the above, the Permanent Representatives Committee is invited:

- to confirm its agreement on the compromise text set out in document 14516/21,
and
- to mandate the Presidency to send a letter to the Chair of the ENVI Committee of the European Parliament confirming that, should the Parliament adopt its position at first reading in accordance with Article 294(3) TFEU and in the exact form set out in document 14516/21 - subject to legal-linguistic revision - the Council would, in accordance with Article 294(4) TFEU, approve the European Parliament's position and the act would be adopted in the wording which corresponds to the European Parliament's position.