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NOTE

From: General Secretariat of the Council
To: Council

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
- Progress report

Delegations will find in Annex a progress report on the proposal mentioned in the subject above, due to be presented at the EPSCO (Health) Council on 15 June, with a view to inviting the Council to take note of it.

The present report has been drawn up under the responsibility of the Presidency and is without prejudice to particular points of interest or further contributions of individual delegations. It sets out the work done so far in the Council's preparatory bodies and gives an account of the state of play in the examination of the above mentioned proposal.

Information from the Presidency on the progress achieved in the examination of the Proposal for a Regulation on the mandate of the European Centre for Disease Prevention and Control (ECDC)

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 Control¹. 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. The proposal is based on Article 168(5) of the Treaty on the Functioning of the European Union (ordinary legislative procedure, qualified majority voting).
2. 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.

¹ 8531/21

3. 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.
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. The German Presidency organized four virtual meetings of the members of the Working Party on Pharmaceuticals and Medical Devices, dedicated to the presentation and examination of the proposal.
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. A draft report was presented on 23 March 2021 and further amendments to the proposal were tabled on 13 April 2021. The ENVI Committee is expected to vote on the file during its June meeting.

Progress during the Portuguese Presidency

7. During the Portuguese Presidency, eight virtual meetings of the members of the Working Party on Pharmaceuticals and Medical Devices were held. Detailed discussions took place on several topics, some in connection with other proposals in the Health Union Package, in order to ensure consistency and coherence between the proposals: the Early Warning and Response System; data usage; the newly created network for substances of human origin; the new vaccine monitoring platform; the European Union Health Task Force, and the possible inclusion of liaison officers; monitoring and assessment of national health systems capacities - and the first examination of the proposal was concluded. Based on the discussions in the Working Party and on written comments from delegations, the Presidency tabled a revised text in May, which was examined in two virtual meetings at technical level.

² 8384/21

³ 8965/21

8. The Presidency has clarified the meaning of the term "monitoring" by including in the proposal a definition, and modified the text concerning the monitoring and assessment of health systems capacity to ensure the task would be performed collaboratively by the ECDC and Member States. Regarding the provision of recommendations for risk management by the ECDC, the Presidency included language to clarify that such recommendations are non-binding and based on scientific evidence. The Presidency also modified the language related to the auditing of preparedness and response planning, to more clearly state the supporting role of the ECDC in revising the Member States' plans. The Presidency proposed to extend the tasks of the EU Health Task Force to maintaining country knowledge and providing recommendations on preparedness and after action reviews and proposed that the structure of the Task Force be decided by implementing act.
9. Most delegations welcomed the Presidency revised text in general. Several delegations supported the Presidency's modified text regarding the monitoring and assessment of health systems capacity, while some requested that the initial wording in the proposal be kept. Several delegations requested that the structure of the European Health Task Force, be defined not in an implementing act, but in the Regulation; several Member States have requested the inclusion of liaison officers in the structure of this Task Force, while some others have raised concerns regarding a permanent Task Force. Some delegations asked for a specific article dedicated to compliance with the General Data Protection Regulation (GDPR) and Regulation (EU) 2018/1725 (EUDPR) to be added. Several delegations reiterated requests made also on the original proposal that the revised text should state that communication to the general public on certain issues should not be done directly by ECDC, but to be decided together with Member States. Some delegations have requested for the text to more explicitly state that recommendations by the ECDC are non-binding.
10. During the examination of the revised text at technical level, further detailed discussions took place on the issues of monitoring and assessing national health systems' capacity, communication to the public, and the ECDC's funding related to new competencies, namely the future structure of the European Health Task Force. Several delegations reiterated their support to the Presidency's modified text regarding the monitoring and assessment of health systems capacity, while some reiterated their request that the initial wording in the proposal should be kept. Following clarifications regarding ECDC's communication to the public, delegations did not reprise their earlier objections to the text.

11. Based on discussion in the Working Party as well as the delegation's written comments on the first revised text, the Presidency is due to table a second revised text, to be further discussed at technical level under the future Slovenian Presidency.

Conclusions

12. The Presidency considers that the revised text, which was well-received by delegations, reflects the positions expressed by delegations at technical level and constitutes a good basis for continued discussion.
13. The Presidency believes that further discussion at technical level would be necessary, in particular on the structure of the EU Health Task Force as well as on the proposed health system monitoring and assessment tasks of the ECDC.
