



Council of the
European Union

Brussels, 9 June 2021
(OR. en)

9622/21

Interinstitutional File:
2020/0322(COD)

SAN 385
PHARM 121
PROCIV 70
COVID-19 256
CODEC 861

NOTE

From: General Secretariat of the Council
To: Council

Subject: Proposal for a Regulation on serious cross-border threats to health and
repealing Decision No 1082/2013/EU
- 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 serious cross-border threats to health

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. 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 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.
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.

¹ 8647/21

² 8384/21

³ 8965/21

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 organised two virtual meetings of the members of the Working Party on Pharmaceuticals and Medical Devices, dedicated to the presentation and examination of the proposal as part of the Health Union package.
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. A draft report was presented on 22 April 2021 and further amendments to the proposal were tabled on 29 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, ten 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 - the Early Warning and Response System; data usage; the newly created network for substances of human origin; preparedness and response plans and auditing; implementing and delegated acts; surveillance system in the frame of the European Health Data Space - and the first examination of the proposal was concluded.
8. Several delegations have raised subsidiarity concerns regarding the proposal and have requested a written opinion from the Council Legal Service 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.

9. Pending the Council Legal Service's written opinion and based on the discussions in the meetings and on written comments from delegations, the Presidency tabled a revised text in May, which was examined in two virtual meetings at technical level.
10. Regarding the structure of the Health Security Committee (HSC), the Presidency has maintained the high-level working formation introduced in the proposal, while changing its name from 'high-level working group' to 'high-level steering group', to reflect its mission and to better differentiate from the Committee's technical working groups. The Presidency has replaced the term 'audit', as used in reference to the periodical task performed by the ECDC with regards to national preparedness and response plans, with the term 'review', to clarify the nature of the process and its implications for Member States; in order to allow for more input from the Member States, the means of adoption of procedures, standards and criteria for these reviews was changed from delegated, to implementing act. In order to reduce the Member States' burden of various reporting obligations, the Presidency has reduced the frequency of these obligations. Building on recent pandemic experiences, the Presidency has included Andorra, Monaco and San Marino as participants in joint procurement of medical countermeasures.
11. In general, the proposal was well received by the delegations, who welcomed the amendments made by the Presidency, although considering it may still benefit from further changes. Several delegations expressed concerns regarding the HSC high-level group that would discuss topics of political importance, requesting that political issues be considered in the Council, while others support the two-tier structure. Some delegations requested that the HSC be co-chaired by a representative of the Presidency. Regarding the voting system for adopting guidance and opinions, some delegations requested that the simple majority rule be changed to a qualified or two-thirds majority, while others opposed the change. Several delegations asked for the term 'review', introduced in the revised text in reference to the periodical task performed by the ECDC with regards to national preparedness and response plans, to be replaced with 'analysis'. Several delegations expressed concerns regarding the extensive and burdensome reporting on preparedness and response planning. Some delegations requested for national discretion in adopting action plans that would address recommendations resulting from the review of their preparedness and response plans. Several delegations requested more flexibility regarding the exclusivity clause for joint

procurement of medical countermeasures. The establishment of an advisory committee for the recognition of public health emergencies at Union level was another topic of discussion for several delegations. A few delegations still expressed reservations regarding the network of substances of human origin established by the proposal.

12. During the examination of the revised text at technical level, further detailed discussions took place on the various platforms of the EU Health Security Framework under the proposal.
13. Based on discussion in the meetings as well as on the written comments from delegations 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

14. The Presidency considers that the main outstanding issues to be resolved concern: the structure of the HSC; the EU and national preparedness and response planning, including reporting and reviewing; the participation in the joint procurement of medical countermeasures; and the establishment of an advisory committee for the recognition of public health emergencies at Union level. Discussions and comments at technical level, as well as the expected opinion by the Council Legal Service, will provide a good basis for the further examination of the text in the Council.
