



EUROPEAN COMMISSION

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C(2022) 1574 final*

*Miloš VYSTRČIL
President of the Senát
Valdštejnské náměstí 17/4
CZ – 118 01 PRAGUE 1*

Dear President,

The Commission would like to thank the Senát for its Opinion on the package on the European Health Emergency Preparedness and Response Authority (HERA):

- the Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union {COM(2021) 576 final} and*
- the proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level {COM(2021) 577 final}.*

On 11 November 2020, the Commission put forward its plans to build a European Health Union¹, a new health security framework fit for the health challenges of tomorrow. The European Health Union will better protect the health of the citizens, equip the EU and its Member States to better prevent and address pandemics and improve the resilience of Europe's health systems. A strong European Health Union will allow all Member States to prepare and respond together to health crises, ensure availability of medical supplies, and improve prevention, treatment and aftercare. The core of the European Health Union consists of a stronger health security framework established by a regulation on cross border health threats, as well as the strengthening of two key agencies: the European Centre for Disease Prevention and Control and the European Medicines Agency.

A key component of a strong European Health Union is the recently established HERA. On 16 September 2021, the Commission put forth the so-called 'HERA package'

¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM(2020) 724 final.

consisting of a Communication introducing HERA², a Commission decision establishing HERA³ and a proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level⁴.

The Commission is pleased that the Sénat agrees with the importance of a coordinated response, in a spirit of solidarity, between Member States in the face of cross-border health crises and supports the creation of HERA.

HERA was set up to strengthen Europe's ability to prevent, detect and rapidly respond to cross-border health emergencies, by facilitating the development, manufacturing, procurement and distribution of key medical countermeasures.

The core mission of HERA will be:

- to strengthen health security coordination within the EU during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort;*
- to address vulnerabilities and strategic dependencies within the EU related to the development, production, procurement, stockpiling and distribution of medical countermeasures;*
- to contribute to reinforcing the global health emergency preparedness and response architecture.*

The Commission's decision to create HERA as an internal service, was driven by the urgency of the situation and by financial constraints. Establishing a new agency would have taken several years, while an operational response to the current crisis is needed now. As described in the Commission Decision establishing HERA, HERA's organisation consists of the following: a Coordination Committee providing political steering on planning and implementation of HERA's tasks, without prejudice to the prerogatives of the College of Commissioners; a HERA Board composed of high-level representatives from each Member State, assisting and advising the Commission in the formulation of strategic decisions concerning HERA; and an Advisory Forum supporting the HERA Board in providing scientific and technical advice.

Moreover, there is no specific budget allocated to a new agency in the current multiannual financial framework. On the contrary, by establishing HERA as an internal Commission's service, existing programmes such as EU4Health, Horizon Europe and the Union Civil Protection Mechanism could be mobilised. As a service of the Commission, HERA's budget will be subject to the scrutiny of the budgetary authority. In addition, as explained in the Commission Decision, the Commission will carry out an in-depth review of HERA by 2024, including on its structure and governance, and will report to the

² COM(2021) 576 final

³ C(2021) 6712 final

⁴ COM(2021) 577 final

European Parliament, to the Council and to the HERA Board on the findings of the review, which will be made public.

The Commission would like to reassure the Senát that duplication of activities carried out by different institutions and agencies will be avoided. In addition, external actors with relevant expertise in the field of pandemic preparedness and response may be involved in the activities of HERA, for instance through the Advisory Forum.

As regards the negotiation process for the purchase of vaccines, the Commission will ensure the utmost transparency and inclusion when stepping up preparedness and availability of medical countermeasures in the EU. The decision-making process for future vaccine contracts is envisaged to mirror the current arrangements among Member States and the Commission, and will be in line with the future governance mechanisms of HERA.

Concerning the requests advanced by the Senát, the Commission highlights that a comprehensive mapping of the interplay between HERA and relevant EU committees and entities, such as the Health Security Committee, the European Centre for Disease Prevention and Control, the European Medicines Agency, the Integrated Political Crisis System, was shared with the Council on 21 October 2021⁵.

As regards the creation of the future European Chief Epidemiologist, mentioned in the Communication ‘Drawing the early lessons from the COVID-19 pandemic’⁶ from June 2021, President von der Leyen asked on 1 December 2021 Professor Peter Piot to be the Commission’s Chief Scientific Advisor for Epidemics, within his existing mandate⁷. He is closely cooperating with HERA and other relevant entities.

To conclude, the Commission notes that it is a shared priority to create a robust health security framework enabling the EU and all Member States to protect the health of European citizens and collectively respond to cross-border health crises.

The Commission hopes that the answers provided in this reply address the questions and concerns raised by the Senát and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*

*Stella Kyriakides
Member of the Commission*

⁵ Non-paper “Mapping on the functions of the Health Emergency preparedness and Response Authority (HERA), WK 12276/2021 INIT.

⁶ COM(2021) 380 final

⁷ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_6473