



**SENATE
OF THE PARLIAMENT OF THE CZECH REPUBLIC
13TH TERM**

151st

RESOLUTION OF THE SENATE

Delivered on the 7th session held on 18th March 2021

on the Package of Proposals relating to the European Health Union

Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (Senate Print no. N 2/13, COM(2020) 725)

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 (Senate Print no. N 3/13, COM(2020) 726)

Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Senate Print no. N 4/13, COM(2020) 727)

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 (Senate Print no. K 5/13, COM(2020) 724)

The Senate

I.

1. Takes note

of the presentation of the package of proposals relating to the establishment of the European Health Union, which has the objective to update and complement the legislative framework on better coordination of the EU response to health crises, and relating to the support of early evidence-based decision-making and real-time situational awareness;

2. Supports

in this regard in particular measures which lead to:

- the introduction of a system for identifying and addressing shortages of key medicines and fast-tracking the provision of scientific advice from the European Medicines Agency (EMA), ensuring the timely development of high-quality, safe and effective key medicines to manage public health emergency,
- improving recommendations and the risk assessment mechanism of the European Centre for Disease Prevention and Control (ECDC) on the basis of more accurate and up-to-date data,
- the development of technologies for data and information sharing significant for the management of a health crisis;

3. Emphasizes, however,

that the proposals for regulations constitute long-term changes in the functioning of the EMA and the ECDC and in cooperation with the national competent authorities, which will remain in force even after the pandemic comes to an end;

4. Is therefore convinced

that such a comprehensive package of proposals, which extends the existing mandate of the EMA, strengthens the mandate of the ECDC and introduces fundamental changes in competences and new obligations for Member States, should have been presented together with an impact assessment;

5. Considers

that the absence of the impact assessment will prolong the legislative process, as a number of problem areas will need to be clarified, such as the duplication of reporting activities or overlaps of competencies, which could have been avoided if the impact assessment had been prepared;

6. Points out

that it is not entirely clear how the strengthening of the mandate of the Health Security Committee (HSC) to promote a coordinated response at EU level will affect Member States' cooperation within the IPCR (EU Integrated Political Crisis Response) mechanism;

7. Regrets

that the proposal to establish the EU Health Emergency Preparedness and Response Authority (HERA), which the Commission mentions in the accompanying Communication and which is to be presented at the end of 2021, was not introduced together with the package of proposals relating to the establishment of the European Health Union; at present, it is not clear how HERA will fit into the structure of the newly regulated functioning of the agencies and how it will complement their activities;

II.

1. Requests

the Government to inform the Senate no later than on 30 June 2021 about the way this Resolution was taken into account and about further development of negotiations of the proposals;