



## **EXPLANATORY MEMORANDUM**

Ladies and gentlemen,

The Proposal for a Regulation COM(2020) 726 of the European Parliament and of the Council modifies Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (the Centre). This Centre will have new responsibilities with a more operational role in both the preparedness and response to contagious diseases and in epidemiological surveillance in accordance with the provisions set out in the Proposal for a Regulation COM(2020) 727 of the European Parliament and of the Council on serious cross-border threats to health.

First, the Centre's expertise capabilities are reinforced, as is its capacity to guide and support the actions of Member States. Thus, in addition to providing scientific opinions, it will now provide recommendations pertaining to the actions to be taken to prevent and control threats related to contagious diseases and support the actions of Member States and the Commission. A Health Task Force is created under the Centre's responsibility. Its role is to provide field support for Member States' response by providing recommendations on the measures to take.

Additionally, the Centre must develop and ensure the interoperability of digital platforms used for epidemiological surveillance. Member States' notification requirements are reinforced with the requirement to share available scientific data and information and the response measures taken to combat the identified threat.

Finally, the Centre must contribute to the evaluation and surveillance of Member States' preparedness and response plans to combat health crises, as provided for in the Proposal for a Regulation COM(2020) 727. These national plans must complement those of the Union. This evaluation will serve to guarantee this interoperability. However, to ensure national plans complement those of the Union, measures to harmonise legislative and regulatory provisions will be necessary. Unlike the other provisions of this text, this one thus does not respect the principle of subsidiarity.

As a consequence, the European Affairs Committee has adopted the following draft resolution:

## **EUROPEAN DRAFT RESOLUTION DELIVERING A REASONED OPINION**

- ① The Proposal for a Regulation COM(2020) 726 modifies Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (the Centre). This Centre will have new responsibilities with a more operational role in both the preparedness and response to contagious diseases and in epidemiological surveillance in accordance with the provisions given in the Proposal for a Regulation COM(2020) 727.
- ② Thus, this text includes a provision from the Proposal for a Regulation COM(2020) 727 which stipulates that the Centre participate in national preparedness and response plans to combat serious cross-border threats to health.
- ③ Having regard to Article 88-6 of the French Constitution,
- ④ Whereas the terms of the letter addressed to the President of the Senate on 11 October 2019 by the First Vice-President of the European Commission, according to which the period from 20 December of a given year to 10 January of the following year is excluded from the 8-week period laid down in Protocol No 2 annexed to the Treaties for the assessment by national parliaments of the conformity of the Commission's draft legislative acts with the principles of subsidiarity and proportionality,
- ⑤ The Senate makes the following observations:
- ⑥ – The legal basis for the Proposal for a Regulation COM(2020) 727 is Article 168(5) of the Treaty on the Functioning of the European Union (TFEU). This article stipulates that the European Parliament and the Council can adopt incentive measures designed to combat major cross-border health scourges, measures to monitor serious cross-border health threats, warn in case of such threats and combat them, excluding any harmonisation of the laws and regulations of the Member States;

- ⑦ – The Commission's approach to subsidiarity is based on Article 2(5) of the TFEU, which provides that, in the field of health, the Union shall have competence to take action to support, coordinate or supplement the activities of the Member States, without thereby superseding their competence in these areas;
- ⑧ – The Commission wants to involve the Centre in the evaluation of national preparedness and response plans to serious cross-border threats to health. The objective of this evaluation is to ensure the interoperability of national plans with those of the European Union;
- ⑨ – This interoperability necessarily entails the harmonisation of legislative and regulatory provisions, which does not comply with Article 168(5) of the TFEU, which excludes this harmonisation;
- ⑩ – Similarly, Regulation (EC) No 851/2004 establishing the Centre has a legal basis in Article 152(4) of the Treaty establishing the European Economic Community. This article excludes any measures seeking to harmonise Member States' legislative and regulatory provisions. In light of this, the Centre cannot have this objective;
- ⑪ – The impact analysis was unable to shed light on the Centre's capability of taking on a mission to evaluate and audit operational plans, which seem to differ from the scientific missions for which the Centre was created;
- ⑫ For these reasons, the Senate considers that Article 1(6) of the Proposal for a Regulation COM(2020) 726 does not respect the principle of subsidiarity.