

EXPLANATORY MEMORANDUM

Ladies and gentlemen,

The 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 – COM(2020) 727 – provides for a new legal framework for the implementation of measures to prepare for and respond to serious cross-border threats to health. To ensure that it is applied uniformly throughout the Union, this new framework is established by a regulation.

Whereas the current provisions provided for in Decision No 1082/2013/EU have not allowed for sufficient cooperation and coordination between Member States, the European Commission proposes to improve coordination and cooperation between Member States on the one hand, and develop the Union's preparedness and response capabilities on the other.

Two sets of provisions have been analysed in light of the principle of subsidiarity.

Firstly, the Proposal for a Regulation makes provisions to reinforce the role of the Health Security Committee (HSC), established by Decision No 1082/2013/EU and comprised of representatives from Member States. When a public health emergency is declared, Member States should coordinate their reactions and communications within the framework of the HSC and in liaison with the Commission. When a Member State intends to adopt or does adopt emergency public health measures to fight a serious cross-border threat to health, it informs and consults other Member States and the Commission about the nature, the subject and the scope of these measures. The HSC can adopt opinions on these measures.

The Commission must specify the procedures necessary to the implementation of the provisions in an implementing act. The rapporteurs consider that, while the HSC's role should be strengthened to foster the exchange of information and the

coordination of the measures taken, especially in border areas, their opinions must not bring into question the prerogatives of Member States in the area of health as defined in Article 168(7) of the Treaty on the Functioning of the European Union (TFEU). However, the Proposal for a Regulation does not specify the extent to which the opinions of the HSC are binding on the Member States.

If the Commission considers the coordination of national public health measures to be insufficient to ensure an adequate response from the Union, it can adopt recommendations pertaining to shared and temporary public health measures. These must be founded on the recommendations of the Union's agencies, should not undermine Member States' responsibilities and be proportionate to the threat. However, the Court of Justice of the European Union regularly recalls that national judges must take the recommendations into consideration, especially when they inform the interpretation of national provisions taken to implement these recommendations or when their purpose is to complement binding Community provisions (Case No C-322/88, for example). Thus, these recommendations can have an impact on national disputes in which the measures that fall within the responsibilities of Member States are contested.

Secondly, the Commission proposes to draw up a binding European plan to prepare and respond to health crises and pandemics. The word "binding" is used in European Commission Communication COM(2020) 724 published at the same time as this draft regulation. This plan, which must be adopted by a simple majority of Member States within the Health Security Committee (HSC), will be complemented by Member States' plans, adopted at the national or local level, and required to be interoperable with those of the Union. The Commission must define in an implementing act the models to use when providing information pertaining to preparedness and response planning. Thus, it will define the nature of this information and the sectors concerned. These elements are essential to assessing the scope of this Proposal for a Regulation with regard to the principle of subsidiarity. Furthermore, to allow national plans to be interoperable with the Union's plan, measures seeking to harmonise legislative and regulatory provisions will be essential.

In addition, in order to determine the implementation status of national preparedness plans and their coherence with the Union's plan, the Commission can adopt delegated acts to define the procedures, standards, and criteria pertaining to audits that seek to evaluate preparedness and response planning at the national level. This audit process will be directed and coordinated by the Commission, while the technical implementation will mainly be carried out by the European Centre for Disease Prevention and Control. However, the communication of the European Commission COM(2020) 724 specifies that the conclusions of these audits will be used to ensure an optimal use of the financial support that the Union may provide for the implementation of national plans interoperable with the Union's plan. Thus, they may condition Member States' access to budget appropriations from the "health" programme.

Consequently, the European Affairs Committee considered that these two sets of provisions do not respect the principle of subsidiarity and has adopted the following draft resolution:

EUROPEAN DRAFT RESOLUTION DELIVERING A REASONED OPINION

- ① The Proposal for a Regulation of the European Parliament and of the Council pertaining to the serious cross-border threats to health and repealing Decision No 1082/2013/EU – COM(2020) 727 – provides for a new legal framework for the implementation of measures to prepare for and respond to serious cross-border threats to health.
- ② The text proposes to strengthen the role of the Health Security Committee (HSC), which will be able to formally adopt guidelines and opinions by simple majority for Member States to strengthen the coordination of measures taken in the event of a serious cross-border health threat. The Commission must specify the procedures necessary to the implementation of this provision in implementing acts. If it considers that this coordination is insufficient, the Commission can adopt recommendations concerning shared and temporary public health measures for Member States.
- ③ The Commission also proposes to draw up a binding European plan to prepare and respond to health crises and pandemics. This plan will be complemented by Member States' plans, adopted at the national or local level and required to be interoperable with those of the Union. The Commission must define in an implementing act the models to use when providing information pertaining to preparedness and response planning. It will also use delegated acts to determine the procedures, standards and criteria related to the audits to assess preparedness and response planning at the national level. The conclusions of these audits could condition the Union's financial support to national plans.

- ④ Having regard to Article 88-6 of the French Constitution,
- ⑤ 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 evaluation by national parliaments of the conformity of the Commission's draft legislative acts with the principles of subsidiarity and proportionality,
- ⑥ The Senate makes the following observations:
 - ⑦ – 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;
 - ⑧ – 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 carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas;
 - ⑨ – However, Article 168(7) of the TFEU states that Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. Member States' responsibilities include the management of health services and medical care and the allocation of the resources assigned to them;

- ⑩ – **Concerning the measures to reinforce coordination**
- ⑪ - The Commission should specify, in the Proposal for a Regulation and not in an implementing act, the extent to which the opinions of the HSC could be binding on the Member States. This would ensure that Member States' responsibilities are respected in accordance with Article 168(7) of the TFEU;
- ⑫ - The Commission's recommendations, while not binding, are taken into consideration by national judges, especially when they inform the interpretation of national provisions taken to implement these recommendations or when their purpose is to complement binding Community provisions. Given this, the Commission should specify in the Proposal for a Regulation which subjects these recommendations may address in order to ensure that Member States' responsibilities are respected, in accordance with Article 168(7) of the TFEU;
- ⑬ Pending these clarifications, the Senate considers that Articles 21(4) and 22 of the Proposal for a Regulation COM(2020) 727 do not respect the principle of subsidiarity;
- ⑭ – **Concerning preparedness and response plans**
- ⑮ - The Commission refers the determination of the domains covered by these plans to an implementing act, which does not allow the respect for Member States' responsibilities to be assessed;
- ⑯ - To guarantee national plans' interoperability with the Union's plan, a harmonisation of legislative and regulatory provisions will be necessary, which is excluded by Article 168(5) of the TFEU;
- ⑰ - National plans must be able to contain provisions, which may or may not be classified, specific to each Member State, especially concerning the organisation and provision of health services and medical care in accordance with Article 168(7) of the TFEU;

⑱ For these reasons, the Senate considers that Articles 6 and 7 of the Proposal for a Regulation COM(2020) 727 do not respect the principle of subsidiarity;

⑲ – **Concerning the audits and assessments of national plans**

⑳ - These audits and assessments may not lead to national laws and regulations being called into question with a view to ensuring the interoperability of national plans with that of the Union, in accordance with Article 168(5) of the TFEU, which excludes any harmonisation of laws and regulations;

㉑ - These evaluations and audits may not involve divulging classified information related to national preparedness and response plans;

㉒ For these reasons, the Senate considers that Articles 8 and 9 of the Proposal for a Regulation COM(2020) 727 do not respect the principle of subsidiarity