
Under Article 6 of the Protocol (No 2) on the application of the principles of subsidiarity and proportionality, national parliaments may, within eight weeks of the date of transmission of a draft legislative act, send the Presidents of the European Parliament, the Council and the Commission a reasoned opinion stating why they consider that the draft in question does not comply with the principle of subsidiarity.

The French Senate has sent the attached reasoned opinion on the aforementioned proposal for a regulation.

Under Parliament’s Rules of Procedure the Committee on Legal Affairs is responsible for matters relating to compliance with the subsidiarity principle.
Dear Mr President,

Pursuant to Article 6 of the Protocol (No 2) on the application of the principles of subsidiarity and proportionality annexed to the Treaty on the Functioning of the European Union, I enclose three reasoned opinions of the Senate on:

- the 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 (COM(2020)725);


- 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),

setting out the reasons why the Senate does not consider them to comply with the principle of subsidiarity.

As these reasoned opinions were considered by the Committee on European Affairs, I am also forwarding the minutes of its meeting on the subject of 4 February 2021.

Yours sincerely,

Encl.:

Jean-François RAPIN
Mr David SASSOLI
President of the European Parliament
European Parliament
Rue Wiertz 60
B-1047 BRUSSELS

No 69
SENATE

ORDINARY SESSION, 2020-2021
23 February 2021

EUROPEAN RESOLUTION WITH REASONED OPINION
on the compliance with the subsidiarity principle of the 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, COM(2020)725 final

Pursuant to Rule 73g, paragraphs 4 and 5, of the Senate’s Rules of Procedure, the resolution
adopted by the Senate’s Committee on Social Affairs, worded as follows, has become a
Senate resolution:

The 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, COM(2020)725 final, provides for the setting-up of
two steering groups within the Agency, one for medicinal products and the other for medical
devices. In a health crisis, each will be required to provide a list of critical products to be
monitored. The steering groups may make recommendations to mitigate the impact of a
potential or actual shortage. Member States will be required to take these recommendations
into account. The Commission may also take all necessary measures, within the limits of its
powers, to mitigate the impact of actual or potential shortages. Member States will be
required to comply with these measures.

Having regard to Article 88-6 of the Constitution,
Having regard to the wording of the letter sent by the First Vice-President of the European Commission to the President of the Senate on 11 October 2019, according to which the period from 20 December of a given year to 10 January of the following year is excluded from the eight-week period referred to in Protocol No 12008E/PRO/02 on the application of the principles of subsidiarity and proportionality annexed to the Treaty on the Functioning of the European Union (TFEU),

The Senate makes the following comments:

- the legal basis for the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)725 final is Article 114 TFEU. It empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. Where such measures relate to health, in its proposals the Commission takes as a basis a high level of protection;

- the Commission also relies on Article 168(4) TFEU, which provides that the European Parliament and the Council may adopt measures setting high standards of quality and safety for medicinal products and medical devices;

- however, Article 168(7) TFEU states that Union action must 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. These responsibilities include the allocation of financial resources assigned to care;

- the Commission wishes to be able to take all necessary measures, within the limits of the powers conferred on it, to mitigate the impact of actual or potential shortages of medicinal products or medical devices regarded as critical in a health emergency;

- however, such measures may have an impact on the provision of health services and medical care, which falls within the sphere of competence of the Member States, in accordance with Article 168(7) TFEU;

For these reasons, the Senate considers that Articles 11(4)(b), 12(b), 25(4)(b) and 26(a) of the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)725 final do not comply with the principle of subsidiarity.

This text became a Senate resolution on 23 February 2021.

The President,

Signed: Gérard LARCHER
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No 68

SENATE

ORDINARY SESSION, 2020-2021

23 February 2021

EUROPEAN RESOLUTION WITH REASONED OPINION


Pursuant to Rule 73g, paragraphs 4 and 5, of the Senate’s Rules of Procedure, the resolution adopted by the Senate’s Committee on Social Affairs, worded as follows, has become a Senate resolution:


The text therefore incorporates a provision from the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)727 final, which provides for the involvement of the Centre in the assessment of national preparedness and response plans to counter serious cross-border threats to health.

Having regard to Article 88-6 of the Constitution,

Having regard to the wording of the letter sent by the First Vice-President of the European Commission to the President of the Senate on 11 October 2019, according to which the period from 20 December of a given year to 10 January of the following year is excluded from the eight-week period referred to in Protocol No 12008E/PRO/02 on the application of the principles of subsidiarity and proportionality annexed to the Treaty on the Functioning of the European Union (TFEU),

The Senate makes the following comments:

- the legal basis for the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)727 final is Article 168(5) TFEU. That article provides that the European Parliament and the Council can take incentive measures ‘to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health (...), excluding any harmonisation of the laws and regulations of the Member States’.
- as regards subsidiarity, the Commission relies on Article 2(5) TFEU, which provides that, in the field of health, the Union has competence to carry out actions to support, coordinate or supplement the action of the Member States, without replacing their competence in those areas;

- the Commission wishes to involve the Centre in the assessment of national preparedness and response plans to counter serious cross-border threats to health. The objective of this assessment is to guarantee the interoperability of national plans with that of the European Union;

- such interoperability necessarily calls for the harmonisation of laws and regulations, which is not consistent with Article 168(5) TFEU, which rules out such harmonisation;

- similarly, the legal basis for Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 is Article 152(4) of the Treaty establishing the European Community. That article rules out any measure to harmonise the laws and regulations of the Member States. Therefore, the Centre cannot be given this task;

- the impact assessment did not reveal whether the Centre would be able to carry out the task of evaluating and auditing operational plans, which seems far removed from the scientific tasks for which the Centre was set up;

For these reasons, the Senate considers that Article 1(6) of the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)726 final does not comply with the principle of subsidiarity.

This text became a Senate resolution on 23 February 2021.

The President,

Signed: Gérard LARCHER
EUROPEAN RESOLUTION WITH REASONED OPINION

on the compliance with the subsidiarity principle of the proposal for a regulation of the European Parliament and of the Council on Regulation on serious cross-border threats to health repealing Decision No 1082/2013/EU, COM(2020)727 final

Pursuant to Rule 73g, paragraphs 4 and 5, of the Senate’s Rules of Procedure, the resolution adopted by the Senate’s Committee on Social Affairs, worded as follows, has become a Senate resolution:

The proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision 1082/2013/EU, COM(2020)727 final provides for a new legal framework for the implementation of measures to prepare for and respond to serious cross-border threats to health.

The text proposes to strengthen the role of the Health Security Committee (HSC), which will be able to formally adopt by simple majority guidelines and opinions, addressed to the Member States, to improve the coordination of measures taken in response to a serious cross-border threat to health. The Commission must specify by means of implementing acts the procedures required to implement this provision. If it considers that the degree of coordination is insufficient, the Commission may adopt recommendations for joint and temporary public health measures addressed to the Member States.

The Commission also proposes to draw up a binding European plan for preparedness and response to health crises and pandemics. This plan will be complemented by Member States’ plans, adopted at national or local level, which must be interoperable with that of the Union. The Commission must establish by means of an implementing act the models to be used when providing information on preparedness and response planning. It will also lay down by means of delegated acts the procedures, standards and criteria for audits to assess preparedness and response planning at national level, the conclusions of which could determine whether EU financial support is granted for national plans.

Having regard to Article 88-6 of the Constitution,

Having regard to the wording of the letter sent by the First Vice-President of the European Commission to the President of the Senate on 11 October 2019, according to which the period from 20 December of a given year to 10 January of the following year is excluded from the eight-week period referred to in Protocol No 12008E/PRO/02 on the application of the
principles of subsidiarity and proportionality annexed to the Treaty on the Functioning of the European Union (TFEU),

The Senate makes the following comments:

- the legal basis for the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)727 final is Article 168(5) TFEU. That article provides that the European Parliament and the Council can take incentive measures ‘to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health (...) excluding any harmonisation of the laws and regulations of the Member States’.

- as regards subsidiarity, the Commission relies on Article 2(5) TFEU, which provides that, in the field of health, the Union has competence to carry out actions to support, coordinate or supplement the action of the Member States, without replacing their competence in those areas;

- 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. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them’;

On measures to improve coordination:

- the Commission should specify in the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)727 final, and not in an implementing act, the extent to which the opinions of the HSC could be binding on the Member States. This will ensure that the Member States’ competences are respected, in accordance with Article 168(7) TFEU;

- the Commission recommendations, although not binding, are to be taken into account by national courts, in particular where they provide guidance on the interpretation of national provisions adopted in order to implement such recommendations, or where they are intended to supplement Community provisions of a binding nature. Accordingly, the Commission should specify in the above-mentioned proposal for a Regulation of the European Parliament and of the Council COM(2020)727 final the subjects which these recommendations may cover, in order to ensure that the Member States’ competences are respected, in accordance with Article 168(7) TFEU;

Pending these clarifications, the Senate considers that Articles 21(4) and 22 of the above-mentioned proposal for a regulation of the European Parliament and of the Council COM (2020) 727 final do not comply with the principle of subsidiarity.

On the preparedness and response plans:

- the Commission refers to an implementing act as the basis for identifying the areas covered by these plans, which makes it impossible to assess whether the Member States’ competences have been respected;
- in order to guarantee the interoperability of national plans with the Union plan, harmonisation of provisions of a legislative and regulatory nature will be necessary, which is ruled out by Article 168(5) TFEU;

- it must be possible for national plans to contain provisions, which may or may not be classified and which are specific to each Member State, concerning in particular the organisation and provision of health services and medical care, in accordance with Article 168(7) TFEU;

For these reasons, the Senate considers that Articles 6 and 7 of the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)727 final do not comply with the principle of subsidiarity.

On the assessments and audits of national plans:

- in accordance with Article 168(5) TFEU, which rules out any harmonisation of laws and regulations, these assessments and audits may not lead to national laws and regulations being challenged with a view to ensuring the interoperability of national plans with that of the Union;

- these assessments and audits may not involve the disclosure of classified information concerning national preparedness and response plans;

For these reasons, the Senate considers that Articles 8 and 9 of the above-mentioned proposal for a regulation of the European Parliament and of the Council COM(2020)727 final do not comply with the principle of subsidiarity.

This text became a Senate resolution on 23 February 2021.

The President,

Signed: Gérard LARCHER