EUROPEAN COMMISSION

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Dear Chair,

The Commission would like to thank the Sénat for its Opinions on the three legislative proposals of the European Union Health package:

- Proposal for a Regulation of the European Parliament and of the Council on the reinforced role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices {COM (2020) 725 final},

- 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 {COM (2020) 726 final} and

- 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 final}.

The Commission takes very seriously the concerns expressed by the Sénat in its reasoned Opinions as regards the principle of subsidiarity. The Commission believes that the proposals comply with this principle and is pleased to have this opportunity to provide a number of clarifications regarding the proposals, trusting that these will allay the Sénat's concerns.

1) Proposal for a Regulation of the European Parliament and of the Council on the reinforced role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

The Sénat draws attention to the fact that, according to the proposal, "the European Commission wishes to be able to take all the necessary measures, within the limits of the powers conferred on it, to mitigate the effects of actual or potential shortages of drugs or medical devices considered as critical in a context of health emergency". However, the Sénat considers that such measures may have an impact on the provision of health and medical care services that fall under the competence of the Member States, in accordance with Article 168(7) of the Treaty on the Functioning of the European Union.

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For this reason, the Sénat wonders whether the proposal respects the principle of subsidiarity.

The Commission does not see that the proposed Regulation would disrespect the responsibilities of the Member States under Article 168(7) of the Treaty on the Functioning of the European Union. Indeed, the Commission would like to highlight that public health emergencies of the magnitude of the COVID-19 crisis have repercussions on all Member States, which, by themselves, are not able to provide a sufficient response, as it became evident notably in the first months of the COVID-19 pandemic. Actual or potential shortages of medicinal products (centrally and nationally authorised) and medical devices in times of crisis can lead to the risk that Member States build up disproportionate stocks or put in place restrictions on the movement of these goods in the internal market. A coordinated response at European Union level to monitor and mitigate the risk of shortages can help Member States to better prepare for a sudden surge in demand, to avoid export restrictions within the European Union or to prevent the creation of excessive and disproportionate reserves. This will make it possible to allocate resources more efficiently at national and European levels, to maintain the proper functioning of the single market and to ensure an overall positive impact on public health.

In addition, the proposal aims to strengthen the role of the European Medicines Agency in providing scientific advice on medicines that may treat, prevent or diagnose diseases causing health crises, in coordinating studies aimed at controlling the efficacy and safety of vaccines and in coordinating clinical trials.

The current health situation calls for accelerating the process of strengthening all the institutional and legislative measures necessary to respond, in a coordinated and effective manner, to public health challenges. The proposal reflects this need.

2) 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

The Sénat notes that the aim of the European Centre for Disease Prevention and Control's review of national preparedness plans is to ensure that the national plans are "interoperable" and suggests that this implies a harmonisation of the laws and regulations of the Member States, which is not allowed under Article 168(5) of the Treaty on the Functioning of the European Union.

The Commission does not share the view that the proposed Regulation would encroach on Member States' competences in the definition of their health policy under Article 168(5) of the Treaty on the Functioning of the European Union. The proposal aims at enhancing the capacity of the European Centre for Disease Prevention and Control to provide the required scientific and technical expertise to the Member States to support actions that are relevant to the prevention, preparedness, response planning and combating serious cross-border threats (recital 5 and Article 1(6) of the proposal). The European Centre for Disease Prevention and Control shall support the Member

States in several ways, including through contributing to the development, regular review and updating of preparedness plans and blueprints. The provision of such support does not entail the harmonisation of national preparedness plans.

The Commission would like to stress that, in pursuing its mission, the European Centre for Disease Prevention and Control shall take full account of the responsibilities of the Member States, the Commission and other European Union bodies or agencies, and of the responsibilities of international organisations active within the field of public health, in order to ensure comprehensiveness, coherence and complementarity of action (Article 1(2) of the proposal). Therefore, the Commission believes that the proposal respects Member States' competences in the definition of their health policy (Article 168 of the Treaty on the Functioning of the European Union).

3) 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

The Sénat considers that, to ensure the interoperability of national plans with the European Union plan, harmonisation of provisions of laws and regulations of Member States will be necessary, which is excluded by Article 168(5) of the Treaty on the Functioning of the European Union.

As regards the Sénat's concern that the proposal would entail harmonisation of the laws and regulations of Member States, the Commission would like to stress that Articles 6 and 7 of the proposal do not prescribe that the national plans must be "interoperable" nor do they require harmonisation of the laws and regulations of the Member States[1]*. Therefore, the Commission considers that the proposal respects Member States' competences in the definition of their health policy (Article 168 of the Treaty on the Functioning of the European Union).*

In relation to Articles 21 and 22 of the proposal, the Sénat points out that the Commission should specify in the proposal, and not in an implementing act, to what extent the opinions of the Health Security Committee could bind the Member States. Moreover, the Sénat argues that the Commission should specify in the proposal to which topics the recommendations may relate in order to ensure that the competences of the Member States are respected, in accordance with Article 168(7) of the Treaty on the Functioning of the European Union.

The Commission would like to recall that Article 21(3) of the proposal provides that the Commission shall adopt, by means of implementing acts, the procedures necessary for the uniform implementation of the information exchange, consultation and coordination provided for in paragraphs 1, 2 and 3. Thus, the implementing measures merely concern procedures and neither do they attribute additional powers to the Health Security Committee nor do they render binding the Health Security Committee Opinions. As

[1] Article 6 of the proposal refers to "*coordination*" and does not prescribe the content of national plans. The decision that is currently in force already envisages the coordination of planning (see Article 4 of Decision No 1082/2013/EU on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293, 5.11.2013, p. 1).

regards the Sénat's concerns on the recommendations, Article 22(2)(b) of the proposal expressly provides that the recommendations, which in any event are not binding acts, 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. This ensures that the competences of the Member States, in accordance with Article 168(7) of the Treaty on the Functioning of the European Union, are respected.

The Sénat also expressed concerns with regard to the potential disclosure of classified information (Article 7). In this regard, the Commission would like to recall that the proposal does not expressly require the disclosure of classified information by Member States but, even if such disclosure were necessary, this does not affect the respect of the subsidiarity principle by the proposal.

Finally, in relation to Articles 8 and 9 of the proposal, the Sénat points out that the proposed audits and reports may lead to the harmonisation of legislative and regulatory provisions. The Sénat rightly notes that Article 168(5) of the Treaty on the Functioning of the European Union excludes any harmonisation of the laws and regulations of the Member States. However, neither Article 8 nor Article 9 of the proposal, directly or indirectly (through audits and reports), require the harmonisation of the laws and regulations of Member States.

The Commission would like to stress that European Union action in areas that do not fall within the European Union's exclusive competence, is in accordance with the subsidiarity principle if and insofar as its objectives cannot be sufficiently achieved by the Member States, which is the case here.

The points made in this reply are based on the initial proposals presented by the Commission, which are currently in the legislative process involving both the European Parliament and the Council.

The Commission hopes that the clarifications provided in this reply address the issues raised by the Sénat and looks forward to continuing the political dialogue in the future.

Yours faithfully,

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Vice-President

Stella Kyriakides
Member of the Commission