



## EUROPEAN COMMISSION

*Brussels, 1.6.2021  
C(2021) 3965 final*

*Dear Presidents,*

*The Commission would like to thank the Cortes Generales 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 appreciates that the Cortes Generales decided to analyse these proposals and welcomes the broad support for their aims and the conclusion that they comply with the principle of subsidiarity.*

*Concerning 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, the Commission takes seriously the concerns expressed by the Cortes Generales as regards the application of the principle of subsidiarity and the choice of the Regulation as the legal instrument. The Commission is pleased to have this opportunity to provide a number of clarifications regarding the proposal and trusts that these will allay the Cortes Generales' concerns.*

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*The Cortes Generales find that the proposed approach, laid out in the explanatory memorandum, is debatable in two respects: 1) it is not evident whether the respect for the subsidiarity principle by the European Union in the exercise of its powers of support and coordination pursuant to Article 2(5) of the Treaty on the Functioning of the European Union (TFEU) can be claimed - and reviewed ex ante - unless Member States already exercise their competences; and 2) the Cortes Generales consider that a regime set out by decision can only exceptionally be covered by a Regulation.*

*The Commission would like to stress that the explanatory memorandum referred to a competence to support, coordinate or supplement Member State action in the sense of Articles 2(5) and 6 TFEU. The Commission believes that the Union can exercise such competence even if the Member States have not already exercised their own competence, as there is no such requirement of prior Member State action in the area concerned.*

*The Commission concurs with the Cortes Generales that Article 168 TFEU, stipulating a competence to support, coordinate or supplement Member State action in the sense of Article 2(5) TFEU, does not constitute a “shared competence” in the sense of Articles 2(2) and 4 TFEU.*

*As regards the Cortes Generales’ concerns on the choice of the instrument, the Commission believes that a regime set out by a Decision can generally be covered by a Regulation. The Commission would like to recall that the choice of the appropriate instrument is an issue of proportionality and has been motivated in the explanatory memorandum.*

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

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*

*Stella Kyriakides  
Member of the Commission*