EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinions on the three legislative proposals accompanying the Communication on the European Health Union, namely:

- *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},*
- *the 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*
- *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 final}.*

The Commission appreciates that the Senato della Repubblica decided to analyse these proposals and welcomes its conclusion that they comply with the principle of subsidiarity. The European Health Union package adopted by the Commission constitutes the first building block of a more secure, better-prepared and more resilient EU in the area of health. It consists of three legislative proposals aimed at improving the Union's ability to prepare for and manage future public health crises.

This includes a proposal to reinforce the role of the European Medicines Agency to monitor and mitigate potential and actual shortages of medicines and medical devices, facilitate the development of 'candidate' medicines with the potential to address the diseases causing public health crises, and provide a support framework for medical device expert panels.

The proposal reinforces existing mechanisms, which will facilitate dialogue and information sharing between the European Medicines Agency, national competent authorities and the pharmaceutical industry, in the event of a crisis. The processes

Ms Maria Elisabetta ALBERTI CASELLATI
President of the Senato della Repubblica
Piazza Madama, 1
IT –00186 ROMA

formally established in the proposal will ensure prompt and appropriate data gathering for critical medicines and medical devices to inform decision-making and identification of concrete recommendations.

The Steering Groups and the Emergency Task Force established in the proposal have clearly defined roles and responsibilities, linked to crisis preparedness and response. These do not replace existing European Medicines Agency structures but can complement and feed into these established structures, including the responsibilities and functioning in relation to the Committee for Medicinal Products for Human Use.

On the use of the European Medicines Verification System, the Commission proposal provides for IT tools that will facilitate the sharing of data on the state of supply and demand during and in preparation for crises. The Commission will consider additional approaches to data sharing and shortages mitigation and prevention under actions of the Pharmaceutical Strategy for Europe adopted in November 2020.

With respect to the obligations on Marketing Authorisation Holders (MAHs) and national competent authorities, the proposal intends to facilitate the monitoring of and reporting on potential or actual shortages of medicinal products and medical devices. It is important that the Agency should be able to ask and obtain information and data from the concerned MAHs, manufacturers and Member States through designated points of contact. This should not interfere with the obligation of MAHs under article 23a of the Directive 2001/83/EC to notify Member States when the product ceases to be placed on the market of that Member State and the obligation under article 81 of the Directive 2001/83/EC for MAHs and wholesale distributors within the limits of their responsibilities, to ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

The Commission welcomes the adoption by the Council of its general approach on the proposal at the Council of Health Ministers (EPSCO), on 15 June 2021. It is very positive that the Council text retains the level of ambition of the original proposal of the Commission and its policy objectives. In parallel, the preparations in the European Parliament for the legislative negotiations are also progressing.

The Commission also welcomes the Senato della Repubblica's broad support for the aims of the proposal amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control.

The Commission shares the view that strengthening the European Centre for Disease Prevention and Control will enable Member States to be better prepared in addressing cross-border health threats. Moreover, the Commission would like to recall the importance of using a modern approach to surveillance, relying on linking and integrating relevant surveillance systems, using electronic health records and harmonised datasets.

Finally, the Commission concurs with the Senato della Repubblica that the Regulation of the European Parliament and of the Council on serious cross-border threats to health

and repealing Decision No 1082/2013/EU will put in place an improved robust health security framework that will better protect EU citizens in the face of health crises.

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

Yours faithfully,

Maroš Šefčovič
Vice-President

Stella Kyriakides
Member of the Commission