EXPLANATORY MEMORANDUM

Ladies and gentlemen,

The main objective 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 – is to formalise the framework needed to combat shortages of medicinal products and medical devices. The provisions in this text shall apply when a public health emergency is recognised under the conditions laid out in 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 final.

This text pursues two main objectives: one, to facilitate research and development into medicinal products used to treat, prevent or diagnose illnesses at the origin of health crises and, two, to reconcile the rules on monitoring shortages of medicinal products and medical devices.

To achieve the first objective, an Emergency Task Force is created within the European Medicines Agency (the Agency). It should:

– provide free opinions on scientific questions relating to the development of treatments and vaccines for the disease causing the public health emergency, without prejudice to the opinions of the Agency's scientific committees as to marketing authorisation;

– provide scientific and administrative support to facilitate clinical trials to be carried out within the Union for medicinal products that seek to prevent, diagnose or treat the disease causing the public health emergency, especially those initiated in several Member States, and issue an opinion on the protocols of the clinical trials proposed within the framework of a clinical trial application submitted to the competent authority of a Member State, which must duly take it into account.

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal

products for human use, was adopted on the basis of Articles 168(4)(c) and 114 of the Treaty on the Functioning of the European Union (TFEU). It provides that the scientific evaluation of applications for clinical trials is made by a reporting Member State and, if it gives its approval, then this authorisation is valid in all other Member States. This scientific evaluation is followed by an ethical evaluation performed by each Member State concerned. Article 6 of Regulation (EU) No 536/2014 specifies the elements that Member States must take into account for the scientific evaluation of the application. The Proposal for a Regulation COM(2020) 725 adds the scientific opinion of the task force. Therefore, this provision is not in breach of the principle of subsidiarity.

The second objective is to perpetuate and oversee the measures developed to confront the COVID-19 pandemic, especially concerning the monitoring and notification of stocks of medicinal products. The Member States and holders of market authorisations will now be required to notify the Agency of information about a potential or actual shortage during a recognised emergency situation. This information is specified, and the methods of transmission standardised.

The Proposal for a Regulation COM(2020) 725 provides for the creation of two steering groups within the Agency, one for medicinal products and the other for medical devices. In case of a recognised emergency situation, each must provide a list of critical products to be monitored. If there is a potential or actual shortage, these steering groups may issue recommendations to mitigate the impact of this shortage. Member States must take these recommendations into account. The Commission can also take all the necessary measures within its responsibilities to mitigate the impact of potential or actual shortages. Member States must respect these measures.

The Commission does not specify in this text the scope of the measures that it can take. For example, on 8 April 2020, the Commission published a communication that presented its guidelines for an optimal and rational supply of medicinal products to avoid any shortages during the COVID-19 pandemic. In this communication, the Commission recommended lifting export prohibitions and restrictions and implementing measures to manage stocks at a national level with a reassignment of stocks to the

hospitals that need them most and to restrict sales in pharmacies. However, these last two measures fall within the responsibilities of Member States.

Given the lack of specificity about the measures that the European Commission can take to mitigate the impact of a potential or actual shortage, the European Affairs Committee has adopted the following draft resolution:

EUROPEAN DRAFT RESOLUTION DELIVERING A REASONED OPINION

① The Proposal for a Regulation COM(2020) 725 provides for the creation of two steering groups, one for medicinal products and the other for medical devices. In case of a health crisis, each must provide a list of critical products to be monitored. If there is a potential or actual shortage, these steering groups may issue recommendations to mitigate the impact of this shortage. Member States must take these recommendations into account. The Commission can also take all the necessary measures within its responsibilities to mitigate the impact of potential or actual shortages. Member States must respect these measures.

② Having regard to Article 88-6 of the French Constitution,

③ 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,

④ The Senate makes the following observations:

⑤ – The legal basis for the Proposal for a Regulation COM(2020) 725 is Article 114 of the Treaty on the Functioning of the European Union (TFEU). This allows the European Parliament and the Council to adopt measures to harmonise legislative, regulatory and administrative provisions of the States, which have as their object the establishment and functioning of the internal market. When these measures concern health, the Commission takes as a base a high level of protection in its proposals;

⑥ – The Commission also relies on Article 168(4), which provides that the European Parliament and the Council can adopt

measures setting high standards of quality and safety for medicinal products and devices for medical use;

⑦ – 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. These responsibilities include the allocation of resources, especially financial resources assigned to care;

⑧ – The European Commission wants to be able to take all necessary measures, within the limits of the responsibilities granted to it, to mitigate the impact of potential or actual shortages of medicinal products or medical devices considered critical during a health emergency;

⑨ – However, such measures can have an impact on the provision of health services and medical care, which falls within the responsibilities of Member States in accordance with Article 168(7) of the TFEU;

⑩ For this reason, the Senate considers that Articles 11(4)(b), 12(b), 25(4)(b), and 26(a) of the Proposal for a Regulation COM(2020) 725 do not respect the principle of subsidiarity.