The FRENCH REPUBLIC

SÉNAT

EUROPEAN AFFAIRS COMMITTEE

Paris, 12 November 2021

POLITICAL OPINION

On the establishment of the HERA, the Health Emergency Preparedness and Response Authority and the proposal for a Council Regulation establishing a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (COM(2021) 577 final)

The European Affairs Committee of the French Senate,

Having regard to Articles 114, 122 and 168 of the TFEU,

Having regard to the Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level dated 16 September 2021 (COM(2021) 577 final),

Having regard to the Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union dated 16 September 2021 (COM(2021) 576 final)

Having regard to the Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (C(2021) 6712 final),

Having regard to 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 dated 11 November 2020 (COM(2020) 725 final) and the Senate Resolution N° 69 (2020-2021) of 23 February 2021 giving a reasoned opinion on this text,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) N° 851/2004 establishing a European Centre for disease prevention and control of 11 November 2020 (COM(2020) 726 final) and the Senate Resolution N° 68 (2020-2021) of 23 February 2021 giving a reasoned opinion on this text,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision N° 1082/2013/EU of 11 November 2020 (COM(2020) 727 final) and the Senate Resolution N° 67 (2020-2021) of 23 February 2021 giving a reasoned opinion on this text,

Having regard to the Communication from the Commission the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats dated 11 November 2020 (COM(2020) 724 final)

Having regard to Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health (the "EU4Health Programme") for the period 2021-2027, and repealing Regulation (EU) 282/2014,

Having regard to Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union,

Having regard to Regulation (EU) 2021/836 of the European Parliament and of the Council of 20 May 2021 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism,

Having regard to the Communication from the Commission the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pharmaceutical Strategy for Europe dated 25 November 2020 (COM(2020) 761 final),

Having regard to the European Parliament Resolution of 17 September 2020 on the shortage of medicines - How to address an emerging problem,

Having regard to the Communication from the Commission to the European Parliament, the European Council and the Council of 17 February 2021 “The HERA Incubator – Anticipating COVID-19 variants” (COM(2021) 78 final),

Having regard to the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices of 15 October 2021 (COM(2021) 627 final),

Having regard to the conclusions of the European Council of 21 and 22 October 2021,

Having regard to the information report of the Assemblée nationale concerning the coordination by the European Union of national measures to manage the health crisis (N° 4327 - fifteenth parliamentary term) - 7 July 2020 - by Ms Marietta Karamanli and Mr Thierry Michels, made on behalf of the European Affairs Committee of the Assemblée nationale, and the European Resolution of the Assemblée nationale N° 4329 (fifteenth parliamentary term) of 25 August 2021 on the coordination by the European Union of national measures to manage the health crisis,

- *On the creation of HERA*

Whereas the COVID-19 pandemic has highlighted the need for an Authority capable of preparing the European Union for a health crisis and reacting rapidly to such a crisis by coordinating the

action of the Member States and the various EU agencies in order to ensure the supply of medical countermeasures;

Whereas public health emergencies such as the COVID-19 pandemic have repercussions for all EU Member States and no Member State has the capacity to ensure that the necessary medical countermeasures are available in sufficient quantities and in good time;

Whereas HERA, the Health Emergency Preparedness and Response Authority, was established on 16 September 2021 within the services of the European Commission;

Whereas the legal basis for the Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level can be found in Article 122 of the Treaty on the Functioning of the European Union (TFEU);

Whereas Article 122 of the TFEU provides that the Council, acting on a proposal from the Commission, may decide, in a spirit of solidarity between Member States, on appropriate measures where serious difficulties arise in the supply of certain products;

Whereas the Commission plans a review of the status, governance and tasks of HERA, as well as the framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level in 2025;

Whereas the global nature of the COVID-19 pandemic requires an international response;

Whereas in the event of a health crisis, public confidence is essential to promote medical countermeasures such as vaccines against COVID-19;

Emphasises the need for a coordinated response, in a spirit of solidarity, by Member States in the event of a health crisis affecting several Member States;

Supports the creation of HERA;

Approves the framework of the missions assigned to HERA in the preparation phase and to the Commission in the event of a public health emergency;

Calls for the European Parliament to be closely involved in HERA’s work;

Notes that the revision of the texts establishing HERA planned for 2025 includes an evaluation of its status and governance, and calls for this evaluation to reflect the views of the Member States;

Calls for HERA to be able to develop cooperation within its field of competence with international organisations such as the World Health Organisation (WHO) or third countries;

Stresses the need for HERA to ensure a high level of transparency in its work and to make specific provisions to avoid conflicts of interest;

- *On the role of Member States in the preparation phase*

Whereas there is a need to have production capacity and stocks of medical countermeasures required in the event of a crisis;

Whereas the identification of priority threats and the establishment of a common strategic research agenda are particularly important strategic choices for the health security of the Member States;

Whereas it is important to develop clinical trial networks of sufficient size;

Whereas, as part of the preparation phase for health emergencies, the European Commission has assigned an advisory role to the Member States in the governance of HERA through a Committee chaired by the Managing Director of HERA;

Calls for the Member States to be more closely involved in HERA’s work during the preparation phase, in particular as regards identifying priority threats, establishing the common strategic research agenda and negotiating FabEU contracts, as well as compiling stocks to ensure better coordination between HERA's activities and those of the Member States;

Recalls the need to develop EU-wide clinical trial networks, in coordination with the Member States, in order to avoid a lack of capacity;

- *On the role of Member States in the event of a public health emergency*

Whereas the Health Crisis Board is composed of representatives of the Member States and must be consulted when

implementing the measures provided for in the proposed Regulation COM(2021) 577 final;

Whereas, when awarding contracts, the Commission acts on behalf of the Member States;

Whereas the proposal for a Regulation COM(2021) 577 final does not specify the operating procedures and rules governing decision-making within the Health Crisis Board, which should be involved in drawing up the negotiating mandate for awarding contracts;

Whereas the provision of medical countermeasures is also the responsibility of the Member States;

Whereas there is a need for greater coordination between the Member States and the Union;

Whereas research can make an essential contribution to optimising the preparation for and response to health emergencies;

Considers that the Health Crisis Board should be established in the event of a public health emergency;

Calls for clear rules on the Health Crisis Board’s decision-making process;

Calls for the terms of the negotiating mandate drawn up by the Commission on behalf of the Member States when awarding public contracts for medical countermeasures to be approved by the Health Crisis Board;

Considers that Member States do not need to consult the Health Crisis Board when making decisions on the purchase of medical countermeasures, but should inform it of such decisions as soon as possible;

Calls for the Health Crisis Board's opinion on the monitoring mechanism for critical medical countermeasures, the inventory of stocks and production capacities to be duly taken into account;

Considers that the criteria for establishing the list of critical medical countermeasures should be approved by the Health Crisis Board;

Requests that the content of the research aspect of health crisis preparation and response plans be specified in the proposed Regulation COM(2020) 577 final;

- *On the risk of the same tasks being carried out by several agencies or committees*

Whereas the tasks entrusted to HERA and the Commission under Decision C(2021) 6712 final and the proposal for the Regulation COM(2021) 577 final may appear to be identical to those entrusted to other EU agencies or committees;

Whereas the European Medicines Agency and the European Centre for disease prevention and control are independent agencies whose expertise cannot be subordinated to economic or supply imperatives;

Calls for a rapid conclusion of the discussions on the "European Health Union package" in accordance with the principle of subsidiarity and thus to clarify the tasks of the European Medicines Agency and the European Centre for disease prevention and control;

Points out the need to respect the independence of these two agencies, whose opinions must not be influenced by procurement considerations;

Requests that HERA's activities do not duplicate those carried out by other agencies or committees following the adoption of the "European Health Union package" or the reform of the Union Civil Protection Mechanism;

Recommends that the same information be collected only once from industries using existing national schemes;

- *On the need to guarantee HERA's funding*

Whereas the Commission plans to provide HERA with a budget of €6 billion from the "Horizon Europe" programme, the "European Health Union" programme and the funds dedicated to the Union Civil Protection Mechanism;

Whereas the "European Health Union" programme has a budget of €5.1 billion, of which €2.8 billion is expected to be allocated to HERA;

Considers that a budget of €6 billion will provide HERA with sufficient financial capacities;

Points out, however, that the programmes planned to finance HERA have their own governance rules and therefore calls on the Commission to guarantee the HERA budget by means of other

funding, if necessary, or to establish mutually beneficial synergies between the various funded projects;

Requests that this financial effort in favour of HERA should not be made to the detriment of the other “European Health Union” programme objectives, in particular the cancer plan;

- *On the development of production capacities for medical countermeasures within the EU*

Whereas the EU was faced with export restrictions imposed by non-EU countries during the COVID-19 pandemic;

Whereas there are structural difficulties in the supply of medicinal products within the Union;

Whereas there is a lack of competent bodies that can certify medical devices in accordance with the provisions of Regulations (EU) 2017/745 and (EU) 2017/746;

Whereas there is a need to increase the production of medical countermeasures within the Union in order to promote the Union’s strategic independence in health matters;

Encourages the development of major projects of common European interest in the field of health in order to encourage innovation;

Supports the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices of 15 October 2021,

Calls for consideration to be given to ways of avoiding a supply disruption of medical devices associated with the implementation of Regulation (EU) 2017/745 of 5 April 2017 on medical devices;

Calls for the identification of health technologies in which the EU has a clear competitive advantage and for the identification of health technologies in which the EU should have more independence in terms of supply and for the production of these technologies in the EU to be promoted on a permanent basis;

Recommends supporting the production of medical countermeasures within the EU by including security of supply as a selection criterion in public procurement and by offering financial incentives in line with State aid rules;

Reiterates the need to ensure continuous communication with the pharmaceutical and medical industries and calls for the establishment of an exchange platform with a single point of contact that can assess the industrial constraints of the pharmaceutical and medical device sectors.