



EUROPEAN COMMISSION

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*Cc : Mr Gérard LARCHER  
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*Dear President,*

*The Commission would like to thank the Sénat for its Opinion on 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 {COM(2021) 576 final} and 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 {COM(2021) 577 final}.*

*On 11 November 2020, the Commission put forward its plans to build a European Health Union<sup>1</sup>, a new health security framework fit for the health challenges of tomorrow. The European Health Union will better protect the health of the citizens, equip the EU and its Member States to better prevent and address future pandemics and improve the resilience of Europe's health systems. A strong European Health Union will allow all Member States to prepare and respond together to health crises – making medical supplies available, affordable and innovative – and to work together to improve prevention, treatment and aftercare. The core of the European Health Union consists of a stronger health security framework, established by a regulation on cross-border health threats, as well as the strengthening of two key agencies: the European Centre for Disease Prevention and Control and the European Medicines Agency.*

*Another key component of a strong European Health Union is the recently established Health Emergency Preparedness and Response Authority (HERA). On 16 September 2021, the Commission put forth the so-called 'HERA package' consisting of a*

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<sup>1</sup> Communication from the Commission to the European Parliament, the Council, the European Council, the 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 – COM(2020) 724 final

*Communication introducing HERA<sup>2</sup>, a Commission decision establishing HERA as an internal Commission department<sup>3</sup> and a 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<sup>4</sup>.*

*The new HERA was set up to strengthen Europe's ability to prevent, detect and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement and distribution of key medical countermeasures.*

*HERA builds upon the work launched by the HERA Incubator and the biodefence preparedness plan set up in February 2021, which brought together researchers, biotech companies, manufacturers, regulators and public authorities to rapidly detect and characterise new variants, adapt vaccines as necessary and scale up existing production capacities.*

*The core mission of HERA is to:*

- strengthen health security coordination within the EU during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort;*
- address vulnerabilities and strategic dependencies within the EU related to the development, production, procurement, stockpiling and distribution of medical countermeasures;*
- contribute to reinforcing the global health emergency preparedness and response architecture.*

*The COVID-19 pandemic revealed significant vulnerabilities in the European health preparedness and response to public health emergencies. The European Health Union proposals were put forward precisely to close the gap and equip the EU with tools and mechanisms to improve the current EU health security architecture, making health security a collective endeavour. Overall, HERA will improve the EU's development, manufacturing, procurement and distribution of key medical countermeasures within the EU.*

*The measures set out in the proposal 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 will complement the capacities of the Commission to address cross-border threats once they occur. The proposal aims to put in place a framework of measures to be activated in case of a public health emergency by enabling the EU to take the necessary measures for a sufficient and timely availability and supply of crisis-relevant medical countermeasures, including diagnostic tests, vaccines, therapeutics and personal protective equipment.*

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<sup>2</sup> COM(2021) 576 final

<sup>3</sup> C(2021) 6712 final

<sup>4</sup> COM(2021) 577 final

*The Commission is pleased that the Sénat supports the creation of HERA and welcomes the opportunity to provide a number of clarifications and further explain the plans for HERA in the attached annex.*

*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,*

*Maroš Šefčovič  
Vice-President*

*Stella Kyriakides  
Member of the Commission*

## *Annex*

*The Commission has carefully considered each of the issues raised by the Sénat in its Opinion and is pleased to offer the following clarifications.*

### *On the creation of HERA*

*The Commission takes in high consideration the role of the European Parliament in the context of health emergency management and counts very much on its contribution to the work of HERA.*

*Besides working to ensure that the EU and Member States are better able to act in the face of a cross-border crisis, HERA will have a strong international dimension. On a global level and within its remit, HERA will contribute to facilitating close collaboration with global partners – such as the World Health Organisation, the Coalition for Epidemic Preparedness Innovations, philanthropic organisations, Africa Centres for Disease Control and Prevention and the African Medicines Agency, COVAX – to address international supply chain bottlenecks, expanding global production capacity and reinforcing global surveillance.*

*The Commission is committed to take every step needed to guarantee a high level of transparency in the work of HERA and avoid any conflict of interest.*

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

*As regards the governance of HERA, Member States are full members of its Board. This is an unprecedented degree of involvement of Member States in the Commission's work, which aims to ensure complementarity between the EU and national actions in the field of health preparedness and response. Without prejudice to the institutional prerogatives of the Commission, Member States are contributing to the operations of HERA by assisting and advising the Commission, including for the choice of priority threats, the establishment of the common strategic research agenda and the implementation of the HERA operations to avoid fragmentation and duplication.*

### *On the role of Member States when the emergency framework is activated*

*To respond better and in a timely manner to cross-border health crises, the Commission presented a proposal for a Council Regulation for measures ensuring the supply of crisis-relevant medical countermeasures. The Commission would like to express its gratitude to the support given by France throughout the negotiations that led to the political agreement reached by the Council on 20 December 2021.*

*The Commission shares the hope of the Sénat regarding a swift adoption of all the proposals presented as part of the European Health Union package to ensure that an adequate framework for health security at EU level will be in place soon. As the Sénat is aware, discussions on the Commission proposals to reinforce the mandates of the European Centre for Disease Prevention and Control and European Medicines Agency were recently concluded at political level. The subsidiarity principle as well as the need*

*to respect the independence of these two agencies were firmly observed during the negotiations and reflected accordingly.*

*On the risk of the same missions being done by various agencies or committees*

*The Commission would like to ensure the Sénat that HERA will supplement the activities of the European Centre for Disease Prevention and Control and the European Medicines Agency with particular focus on the supply and availability of medical countermeasures, including medicines, medical devices, diagnostics and personal protective equipment for health emergencies.*

*On the need to ensure the financing of HERA*

*Concerning the budget, the Commission will ensure that the rules governing the programmes financing HERA's operations (e.g. EU4Health, Horizon Europe, rescEU/UCPM) are fully respected and synergies between projects already in the development phase will be maximised. Moreover, by no means will HERA jeopardise the resources allocated for the main health priorities of the Commission, such as the Europe's Beating Cancer Plan.*

*On supply chain vulnerabilities and strategic autonomy*

*Building on the report on strategic dependencies and capacities adopted in March 2020<sup>5</sup>, the Commission has developed six in-depth reviews of strategic areas, including for active pharmaceutical ingredients, providing further insights on the origin of strategic dependencies and their impact., As announced in the Pharmaceutical Strategy for Europe<sup>6</sup>, the Commission is working on the identification of the causes and drivers of potential vulnerabilities in order to address long-term challenges. This includes dependencies in the often global and complex supply chains of critical medicines, their raw materials, active pharmaceutical ingredients and intermediates. In this context, the Commission published a study on medicines shortages in the EU<sup>7</sup>, which will feed into the on-going work, including on the upcoming revision of the pharmaceutical legislation at the end of 2022.*

*Building upon the initiative from France, the Commission acknowledges growing interest by a number of Member States to implement and support Important Projects of Common European Interest to address health related challenges and important market failures.*

*The Commission strongly encourages an open and inclusive dialogue between Member States when jointly designing the scope of an integrated, cross-border Important Project of Common European Interest, with positive spill over effects on the internal market and the society as a whole, in a manner that does not to lead to undue distortions of competition.*

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<sup>5</sup> SWD(2021) 352 final

<sup>6</sup> COM(2020) 761 final

<sup>7</sup><https://op.europa.eu/en/publication-detail/-/publication/1f8185d5-5325-11ec-91ac-01aa75ed71a1/language-en/format-PDF/source-245338952>

*The Commission recently revised the State aid rules on Important Projects of Common European Interest (IPCEI Communication)<sup>8</sup> and, on this basis, will continue to provide support, for the ongoing efforts by Member States to design such proposed projects. Member States are obviously in the lead for such initiatives involving State aid.*

*In its Communication on the ten early lessons learnt from the COVID-19 crisis from 15 June 2021<sup>9</sup>, the Commission identified the need for reinforced public-private partnerships. The COVID-19 crisis emphasised the need to ensure innovative capacities to respond to health needs. The Commission therefore welcomes the combination of public and private efforts to incentivise breakthrough research, development and innovation in the health and pharmaceutical sector, making it more resilient, including via an Important Project of Common European Interest focused on developing novel generations of pharmaceutical products or breakthrough manufacturing technologies.*

*On the development of production capacities of medical countermeasures in the EU*

*One of the main tasks of HERA is to address market challenges and failures and boost the EU's open strategic autonomy. In this context, HERA will identify and contribute to ensuring the availability of critical technologies and production sites for medical countermeasures in the EU capable of increasing their production in times of need, including through support of breakthrough innovation. To do so, it will be important to systematically map and monitor supply chains, manufacturing capacities and ever-warm production sites. In this regard, 'EU FAB' – a network of ever-warm production capacities for vaccines and therapeutics – will play a critical role in ensuring that reservation capacities are in place in preparedness times so that they can rapidly be activated in case of an emergency. HERA is planning to set up a Joint Industrial Cooperation Forum, as a subgroup of the HERA Advisory Forum, for regular and systematic exchanges with the industry, based on the experience gained from the Task Force for Industrial Scale-up of COVID-19 vaccines and therapeutics. The Forum should be designed as an agile, dynamic and permanent mechanism in order to be able to detect disruptions fast and provide solutions even faster.*

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<sup>8</sup> C(2021) 8481 final

<sup>9</sup> COM(2021) 380 final