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COMMISSION DECISION

of 16.9.2021

establishing the Health Emergency Preparedness and Response Authority

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Whereas:

- (1) The COVID-19 pandemic demonstrated the need for coordinated action at Union level to respond to health emergencies, including monitoring the needs, swift development, manufacturing, procurement and equitable distribution of medical countermeasures.
- (2) The European Parliament, the European Council and the Council have called for proactive Union action and for ensuring preparedness and the ability to act jointly to respond to health crises.
- (3) In light of the experience with the first months of the COVID-19 pandemic, the President of the Commission called in the 2020 State of the Union address to draw lessons from the current crisis and to build a European Health Union, including a dedicated European structure for biomedical advanced research and development to support capacity and readiness to respond to cross-border health threats and emergencies – whether of natural, accidental or deliberate origin.
- (4) As set out in the Communication ‘Building a European Health Union: Reinforcing the Union’s resilience for cross-border health threats’¹ adopted in November 2020, the Health Emergency Preparedness and Response Authority (‘HERA’) will be a key element for the establishment of a stronger European Health Union, together with a strengthened cross-border health threats legal framework, and with extended and improved crisis related mandates for the European Centre for Disease Prevention and Control, the European Medicines Agency and the Pharmaceutical Strategy for Europe.
- (5) The bio-defence preparedness plan ‘HERA Incubator’², established to tackle the threats posed by the emerging SARS-CoV-2 variants as the vanguard for HERA, is successfully facilitating contacts and cooperation between regulatory authorities of the Member States, other public authorities and the industry, and between the industry players involved in the supply chain. This work is synergetic with the Structured Dialogue on security of medicines supply by providing insight into the functioning of the pharmaceutical value chains and will help identify their bottlenecks.
- (6) Nevertheless the task of ensuring supply and access in the area of medical countermeasures, such as vaccines, medicines, medical equipment and diagnostics, has

¹ Communication from the Commission to 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“. COM(2020) 724 final.

² Communication from the Commission to the European Parliament, the European Council and the Council “HERA Incubator: Anticipating together the threat of COVID-19 variants.” COM(2021) 78 final.

until now been shattered between different policy frameworks and funding programmes of the Union. The need to increase the effectiveness of preparedness and response to health emergencies requires the establishment of a dedicated central structure, HERA as a Commission service, complementary to and in synergy with the existing Union structures and mechanisms, including the Union's crisis preparedness and management system.

- (7) HERA should extensively coordinate and cooperate with Member States. For that purpose, Member States should be represented in the HERA Board, to contribute to the identification of Union priorities, mutualise efforts and leverage existing resources. To enable information exchange, knowledge generation and cooperation, HERA should bring together Member States experts from the area of health research at the technical level and industrial sectors within the HERA Advisory Forum.
- (8) As set out in the Communication on the Health Emergency Preparedness and Response Authority, HERA will be tasked with two functional 'modes': preparedness and crisis response following a recognition of a public health emergency at Union level,

HAS DECIDED AS FOLLOWS:

Article 1

The Health Emergency Preparedness and Response Authority

The Health Emergency Preparedness and Response Authority ('HERA') is hereby established as a Commission service.

Article 2

Mission and tasks

1. HERA shall work to improve preparedness and response to serious cross-border threats in the area of medical countermeasures, in particular by:
 - (a) strengthening health security coordination within the Union during preparedness and crisis response times, and bringing together Member States, the industry and the relevant stakeholders in a common effort;
 - (b) addressing vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures;
 - (c) contributing to reinforcing the global health emergency preparedness and response architecture.
2. HERA shall be responsible for the following tasks:
 - (a) assessment of health threats and intelligence gathering relevant to medical countermeasures;
 - (b) promoting advanced research and development of medical countermeasures and related technologies;
 - (c) addressing market challenges and boosting the Union's open strategic autonomy in medical countermeasures production;
 - (d) swift procurement and distribution of medical countermeasures;

- (e) increasing stockpiling capacity of medical countermeasures;
- (f) strengthening knowledge and skills in preparedness and response related to medical countermeasures.

These tasks shall be exercised in close cooperation with Member States.

Article 3

Organisation

HERA shall be composed of:

- (a) the Head of HERA;
- (b) the Coordination Committee;
- (c) the HERA Board;
- (d) the HERA Advisory Forum.

Article 4

Head of HERA

HERA shall be under the authority of the Head of HERA, ranked as Director-General.

The Head of HERA shall be appointed by the Commission.

The Head of HERA shall be assisted by a Deputy Head, and ranked as Director, and appointed by the Commission.

The Head of HERA shall take all measures necessary for the efficient functioning of HERA, in close coordination with the Directorate-General for Health and Food Safety.

The Head of HERA shall:

- (a) prepare a multiannual strategic plan for HERA and an annual draft work programme for HERA's various fields of activity, taking into account the programming cycle calendar of contributing Union programmes;
- (b) negotiate and conclude procurement and other contracts related to medical countermeasures with third parties;
- (c) be responsible for the implementation of HERA's activities and for the financial administration. HERA's activities shall respect the governance of contributing Union programmes, in particular EU4Health, Horizon Europe and Union Civil Protection Mechanism;
- (d) determine the internal organisation of HERA, within the constraints of the budget allocated to it by the budgetary authority;
- (e) report to the Member of the Commission in charge of Health.

The tasks described under points a) to d) shall be exercised in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council³ and the

³ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU)

Commission internal rules on the implementation of the general budget of the European Union⁴.

Article 5

Coordination Committee

A Coordination Committee shall provide political steering on the planning and implementation of HERA's tasks, without prejudice to the prerogatives of the College of Commissioners.

1. The Coordination Committee shall be composed of:
 - (a) the Vice-President of the Commission in charge of Health;
 - (b) the Member of the Commission in charge of Health; and
 - (c) the Members of the Commission in charge of the Internal Market, Innovation and Research and Crisis Management.
2. The Coordination Committee shall be co-chaired by the Vice-President and the Member of the Commission in charge of Health.
3. The Head of HERA and the Director General in charge of Health and Food Safety shall attend meetings *ex officio*.
4. The Coordination Committee shall meet regularly and at least four times a year.

Article 6

The HERA Board

1. The HERA Board shall be composed of one high-level representative from each Member State, appointed by the Commission on the basis of nominations by the relevant national authorities. All HERA Board members shall be appointed for a two-year term, renewable once.
2. The HERA Board shall be chaired by the Head of HERA.
3. A representative of the European Centre for Disease Prevention and Control and a representative of the European Medicines Agency may participate as observers in the meetings of the HERA Board.

Representatives of the Emergency Response Coordination Centre, other Union decentralised and relevant executive agencies and other bodies relevant to public health emergencies may participate as observers in the meetings of the HERA Board upon invitation by the Commission.

The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the HERA Board on an *ad-hoc* basis.

No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

⁴ Commission Decision C(2018) 5120 of 3 August 2018 on the Internal Rules on the implementation of the general budget of the European Union (European Commission section) for the attention of the Commission departments

A representative of the European Parliament may participate as observer in the meetings of the HERA Board.

4. The HERA Board shall assist and advise the Commission in the formulation of strategic decisions concerning HERA and having regard to the need to develop close cooperation between HERA and Member States, ensuring that Member States' resources and capacities are leveraged as much as possible towards HERA's joint goals, in particular in the following fields:
 - (a) the functions of HERA within the Union's crisis preparedness and response management, research and innovation as well as industrial strategy in the area of medical countermeasures;
 - (b) the scientific/technical management of HERA;
 - (c) the performance of the tasks entrusted to HERA.
5. The HERA Board shall deliver opinions in particular on:
 - (a) the proposals for activities to be implemented by HERA as well as proposals for new tasks to be assigned to HERA, including:
 - (i) threat assessment, modelling and forecasts of medical countermeasures;
 - (ii) monitoring the supply and demand of medical countermeasures;
 - (iii) procuring and deploying medical countermeasures;
 - (iv) promoting research and development of medical countermeasures and provisions and platforms for the rapid sharing of data;
 - (v) support for capacity building for Member States for preparedness and response related to medical countermeasures;
 - (b) the coherence of the activities with relevant Union programmes;
 - (c) the multiannual strategic planning covering all HERA activities, and each year, not later than by 31 December, the corresponding annual work plan to be adopted by the Commission;
 - (d) the formulation of proposals for the annual budget of HERA and the monitoring of its implementation.
6. The HERA Board shall discuss the annual activity report drawn up by the Head of HERA.
7. The HERA Board shall meet at least four times a year.
8. The Commission shall provide the secretariat for the HERA Board.
9. The Commission may set up working groups to support the HERA Board in its work for the purpose of examining specific questions on the basis of the tasks defined in paragraphs 4 and 5.

Article 7

HERA Advisory Forum

1. The HERA Advisory Forum ('Forum') shall constitute a mechanism for an exchange of information on preparedness and response in the area of medical countermeasures and the pooling of knowledge. It shall ensure close cooperation between HERA and

the competent bodies in the Member States, in particular on the planning and implementation of scientific, health and industrial activities of HERA.

2. The Forum shall be composed of members from technically competent bodies designated by each Member State. Members of the Forum shall not be members of the HERA Board.
3. The Forum shall support the HERA Board in providing scientific and technical advice.
4. The HERA Board may set up sub-groups of the Forum for the purpose of examining specific questions in the fields of science, research or industrial matters. In particular, a subgroup named 'Joint Industrial Cooperation Forum' composed of the representatives of the industry and Member States shall be set up.

The sub-groups shall report to the Forum. They shall be dissolved as soon as their mandate is fulfilled.
5. The Forum and its sub-groups shall be chaired by a representative of the Commission. It shall meet regularly upon the invitation of the Head of HERA and at least four times per year.
6. Representatives of the Commission's departments may participate in the work of the Forum.
7. The Commission shall provide the secretariat for the Forum.
8. The Head of HERA may invite experts or representatives of professional or scientific bodies, or non-governmental organisations with recognised experience in disciplines related to the work of HERA to cooperate in specific tasks and to take part in the relevant activities of the Forum.

Article 8

Review

1. By 2025, the Commission shall carry out an in-depth review of the implementation of the operations of HERA, including its structure and governance.

The review shall address in particular any need to modify the mandate of HERA and the financial implications of any such modification.
2. The Commission shall report to the European Parliament, to the Council and to the HERA Board on the findings of the review referred to in paragraph 1. Those findings shall be made public.

Article 9

Entry into force

This Decision shall enter into force on 16 September 2021.

Done at Brussels, 16.9.2021

For the Commission
Stella KYRIAKIDES
Member of the Commission