



## Questions and Answers: European Health Emergency preparedness and Response Authority – HERA

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# STATE OF THE UNION 2021

### 1. Why do we need a new authority to respond to health emergencies?

Outbreaks of infectious diseases are on the rise worldwide. Population growth and climate change put pressure on land use, food production and animal health, resulting in greater risk of emerging pathogens. While the COVID-19 pandemic is not over yet, Europe must be prepared for future cross-border health threats.

Coordination and cooperation between Member States and the Commission were absolutely crucial in dealing with the COVID-19 pandemic. The crisis stimulated public authorities at EU, national and local level to take an unprecedented series of measures to react to the crisis, in health as in other policy areas. However, measures were often taken on an *ad hoc* basis, were reactive to the circumstances and lacked an anticipatory overall management system. The new Health Emergency preparedness and Response Authority's (HERA) task will be to ensure that the EU and Member States are much more ready to act in the face of a cross-border crisis.

HERA will complement the work of existing EU health agencies. It will make sure crisis-relevant medical countermeasures (including vaccines, antibiotics, medical equipment, chemical antidotes, therapeutics, diagnostic tests or personal protective equipment such as gloves or masks) are available, help reduce strategic dependencies in the health industrial ecosystem by developing and supporting highly innovative flexible and modular production capacities, and contribute to the global health security infrastructure.

### 2. Will HERA only operate in health emergencies?

HERA is set up to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies.

The best way to master future health crises is to anticipate and prepare before they materialise. This is why HERA will operate in two different modes: a preparedness mode and an emergency mode. In the "preparedness phase", it will steer investment and action in strengthening prevention, preparedness and readiness for new public health emergencies. In the "crisis phase", HERA will be able to draw on stronger powers for swift decision-making and implementation of emergency measures.

In the preparedness phase, when there is no immediate health emergency, HERA will gather intelligence and assess threats together with Member states to identify potential emergencies early on; it will promote research and innovation to develop effective, safe and affordable medical countermeasures; it will also identify and ensure the availability of critical production sites for medical countermeasures capable of increasing their production in times of need; ensure the provision of medical countermeasures by increasing the use of stockpiling and EU procurement; and finally improve Member States' capacities in preparedness and response by fostering knowledge and skills through targeted training programmes in cooperation with Member State authorities.

HERA's "crisis phase" and ensuing emergency operations may be activated when a public health emergency is recognised at Union level and where appropriate to the economic situation.

### 3. How can HERA ensure quick decision-making in future health emergencies?

In the event of a public health emergency, the Council can immediately activate HERA's emergency phase where this is appropriate to the economic situation. During the emergency phase, the Health Crisis Board chaired by the President of the European Commission will be mandated to ensure

coordinated action by the Commission, the relevant Union agencies and bodies, and Member States to ensure the supply of and access to medical countermeasures.

The proposed regulation for medical countermeasures during a public health emergency at Union level is based on Article 122 TFEU for crisis situations and puts forward the key measures HERA will be able to take during emergencies, centred around the procurement, purchase and manufacturing of crisis-relevant medical countermeasures through emergency funding. HERA will also be able to draw upon reinforced international cooperation and support by working with HERA-like national agencies, third countries, the World Health Organisation and other global partners.

Furthermore, HERA will have powers concerning the surge capacity production of crisis-relevant medical countermeasures by industry.

#### **4. What can HERA do to support mobilisation of industry?**

COVID-19 has shown that public health and industrial autonomy are intrinsically linked. HERA will bring together EU Member States, industry and other stakeholders in a common effort to address the availability of medical countermeasures for health threats. Cooperation with industry will be key to developing, manufacturing, purchasing and distributing these countermeasures. A structured and agreed cooperation mechanism with EU industry players in the preparedness phase is vital to implement strategies for robust supply chains. A joint Industrial Cooperation Forum, composed of industry representatives and the Commission will be set up to offer channels for adequate feedback by the industry on capacities and bottlenecks. Additionally, HERA will encourage new industrial partnerships, facilitated by the organisation of pan-European matchmaking events, building on the work of the Task Force for Industrial Scale-up of COVID-19 vaccines and therapeutics (TFIS).

In crisis mode HERA may also invite experts with specific expertise to take part in the work of the Health Crisis board on an ad hoc basis.

HERA will also use tools such as the innovation partnership procedure, which promotes agile cooperation between public buyers and economic partners in procurement.

#### **5. How will HERA cooperate with Member States and with the European Parliament?**

HERA is a key pillar of the Health Union, which aims to equip the Union and its Member States with procedures, infrastructures and capacities to prevent and address future health emergencies in a structural manner in full respect of Member States' competences in the area of health. In line with Article 168 of the Treaty on the Functioning of the European Union (TFEU), HERA will ensure availability and access to medical countermeasures, by offsetting the inability of market forces to respond to a surge of demand in case of cross-border health threats.

Member States are closely involved in the governance of HERA. During the preparedness phase, one representative per Member State sits on the HERA Board. The Board assists and advises the HERA in the formulation of strategic decisions. During the emergency phase, Member States sit on HERA's Crisis Board together with the President of the European Commission, the Commissioner for Health and Food Safety and other members of the Commission as appropriate. It is the Member States through the Council that activates HERA's emergency powers, upon a proposal by the European Commission.

The European Parliament will be invited to designate an observer in the HERA Board. The Commission will also ensure a regular exchange with the European Parliament about the work of HERA.

#### **6. How will HERA cooperate with researchers and academia?**

Knowledge, research and innovation will be key to all areas of HERA's work, which will often deal with new and emerging threats. HERA's tasks encompass threat assessment and intelligence gathering as well as the promotion of research and development and coordination of clinical trial platforms.

HERA will have dedicated capacities for horizon scanning, foresight and efficient data-sharing mechanisms. It will promote data sharing and use the planned European Health Data Space, the European Science Cloud and their digital infrastructures. The knowledge that will be brought together will directly feed into the other HERA operations, including those related to research and innovation.

HERA will promote advanced R&D, relying on Europe's contribution to pool research and the EU Pandemic Preparedness Partnership to set up a common strategic research agenda for medical countermeasures across the EU. Moreover, the role of the existing European clinical trial networks for therapeutics and vaccines is key and these networks will be brought together during the preparedness phase into a large scale EU platform for multi-centre clinical trials to avoid

fragmentation. A close collaboration with EMA is key to guarantee that these clinical trials provide timely and relevant evidence for granting marketing authorisations for medicines.

HERA will also fund activities such as intelligence gathering and analysis, research and development, procurement, flexible manufacturing capacities, stockpiling, deployment and capacity building. The Authority will also be responsible for developing proposals for funding agreements aiming to support third countries to, for example, reinforce their surveillance capacities or their skilled workforce needed in times of a health crisis.

During the emergency phase, HERA can activate emergency research and innovation plans and EU-wide clinical trial networks and data sharing platforms. This will allow for the targeted development and validation of crisis-relevant medical countermeasures, both in pre-clinical and clinical research phases.

## **7. How will HERA work with other agencies?**

HERA's mandate is clearly geared towards health emergencies and the supply and availability of medical countermeasures. Whilst the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) have been at the forefront of the EU's response to the COVID-19 crisis, their mandates and tools limit their ability to protect EU citizens from cross-border health threats.

ECDC has a well-established specific mandate in the area of communicable disease threats. However, it has no mandate in the area of other health threats, nor on the procurement, development or production of medical countermeasures.

EMA is the regulatory body responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU

HERA will cooperate closely with the European Medicines Agency and the European Centre for Disease Prevention and Control and complement their work during and before emergencies in areas such as clinical trials, preparedness and response planning, and intelligence gathering.

HERA will have exclusive competence for procuring and distributing medical countermeasures as well as supporting their development and production.

As the scope of HERA will be beyond viral pandemics, EU agencies and bodies other than ECDC and EMA may be involved for their input and knowledge on preparedness and response in relation to relevant fields.

## **8. How will EU FAB contribute to be better prepared for future pandemics in view of manufacturing capacity, particularly for vaccines and therapeutics?**

Although the EU has substantially scaled up by now the manufacturing capacities for COVID-19 vaccines, it remains crucial that, after the current pandemic, sufficient and agile manufacturing capacities will be maintained for possible future health threats, even when there is no more demand on the market. EU FAB will make a network of 'ever-warm' production capacities for vaccine and medicine manufacturing available at European level, including availability of qualified staff, clear operational processes, quality controls and regular investments in infrastructure, thus allowing the EU to be better prepared and respond to future health threats.

In case of future health threats, EU FAB will be able to quickly and easily activate its network of manufacturing capacities, to meet demand for vaccines and/or therapeutics needs, until the market has scaled up production capacities.

A Prior Information Notice on the EU FAB project will be published very soon to provide advance information to vaccine and therapeutics manufacturers about the EU FAB call for competition, planned for early 2022.

## **9. How will HERA be financed?**

With the COVID-19 pandemic, the need for investing in health security and preparedness has become apparent. HERA will ensure effects of scale from bundling resources, funding and capacities across the EU for medical countermeasures. It will have €6 billion funding in 2022-2027 for preparedness and response from several EU programmes – mainly EU4Health, rescEU, Horizon Europe and NextGenEU. Emergency operations will be financed through the Emergency Support Instrument.

In addition, other EU programmes contribute directly and indirectly to health emergency preparedness in the EU, for instance the Recovery and Resilience Facility and REACT-EU inside the EU, and the work of the Neighbourhood, Development and International Cooperation Instrument

outside the EU. Together with the €6 billion foreseen for HERA directly, this will amount to almost €30 billion under the next financing period. Cohesion Funds and the InvestEU Programme complement this substantial investment in health systems' resilience. Finally, Member States devote large-scale resources from their own budgets to health preparedness and countermeasures.

HERA will also mobilise private funding, including through the use of financial instruments (such as loans, capital investment, budget guarantees) in cooperation with the European Investment Bank and other financial actors. National budgets may be mobilised through the launch of the important project of common European interest (IPCEI) on Health and multi-country projects.

## **10. What preparatory work has been done in the run-up to today?**

The HERA Incubator was launched in February 2021 with the mandate to detect and analyse new variants of the virus as well as develop and produce at scale and speed vaccines adapted to new variants. The Commission has funded new research projects, sped up the approval process for adapted COVID-19 vaccines and worked with industry to ramp up production.

In October 2020, the Group of Chief Scientific Advisors to the European Commission, the European Group on Ethics in Science and New Technologies (EGE) and the Special advisor to President Ursula **von der Leyen** on the response to the coronavirus and COVID-19 had already recommended to coordinate research and the development and implementation of medical countermeasures during a pandemic or other health threat.

In its Communication on the early lessons of the pandemic from June 2021 (COMM(2021)380), the Commission pointed out the huge knowledge gap at the start of pandemic in terms of manufacturing capacities and potential Member State demand, as well as the depth of reliance on global supply chains. It identified the need to be able to monitor and shape market priorities and capacities for essential health supplies at every stage, from research and development to production and supply.

The European Commission made €20 million available to fund key preparatory actions for HERA in the field of antimicrobial resistance (AMR), an EU mapping platform (prototype) for COVID-19 therapeutics and intelligence gathering, threat assessment and global disease surveillance. Results of this work will directly feed into HERA's strategic planning and preparedness work.

The EU-FAB project to create ever-warm production capacities and structured cooperation with industry have also fed into plans for HERA and will become an asset for HERA.

In addition to a number of past research actions related outbreaks and epidemics, the Commission also launched several special actions in 2020, as part of a €1 billion pledge for coronavirus research. These actions addressed epidemiology, preparedness and response to outbreaks, the development of diagnostics, treatments and vaccines, as well as the infrastructures and resources that enable this research. Many of the platforms and research developed under these actions can feed into HERA.

## **More Information**

[State of the Union Address by President von der Leyen](#)

[Communication on Introducing the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union](#)

[Proposal for a Council Regulation on a framework of urgent measures related to medical countermeasures in the event of a public health emergency at Union level](#)

[Factsheet – European Health Emergency preparedness and Response Authority \(HERA\)](#)

[Press Release on the European Health Emergency preparedness and Response Authority \(HERA\)](#)

[European Health Union website](#)

[EU Coronavirus response](#)

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