European Commission - Press release





European Health Emergency preparedness and Response Authority (HERA): Getting ready for future health emergencies

Brussels, 16 September 2021

STATE OF THE UNION 2021

Today, the European Commission is <u>launching the European Health Emergency preparedness and Response Authority</u> (HERA) to prevent, detect, and rapidly respond to health emergencies. HERA will anticipate threats and potential health crises, through intelligence gathering and building the necessary response capacities. When an emergency hits, HERA will ensure the development, production and distribution of medicines, vaccines and other medical countermeasures – such as gloves and masks – that were often lacking during the first phase of the coronavirus response. HERA is a key pillar of the European Health Union announced by President **von der Leyen** in her 2020 State of the Union address and will fill a gap in the EU's health emergency response and preparedness.

Before crises: preparedness

Before a health crisis, in the "preparedness phase", HERA will work closely with other EU and national health agencies, industry and international partners to improve the EU's readiness for health emergencies.

HERA will carry out threat assessments and intelligence gathering, develop models to forecast an outbreak and, by early 2022, identify and act on at least three high impact threats and address possible gaps in medical countermeasures.

HERA will also support research and innovation for the development for new medical countermeasures, including through Union-wide clinical trial networks and platforms for the rapid sharing of data.

In addition, HERA will address market challenges and boost industrial capacity. Building on the work done by the Task Force for Industrial Scale up of COVID-19 vaccines, HERA will establish a close dialogue with industry, a long-term strategy for manufacturing capacity and targeted investment, and address supply chain bottlenecks for medical countermeasures.

The authority will promote procurement and tackle challenges related to their availability and distribution and increase stockpiling capacity to avoid shortages and bottlenecks in logistics.

HERA will also strengthen knowledge and skills on all aspects of medical countermeasures in Member States.

During a health crisis: emergency response

In case a public health emergency at EU level is declared, HERA can quickly switch to emergency operations, including swift decision making and the activation of emergency measures, under the steer of a high-level Health Crisis Board. It will activate emergency funding and launch mechanisms for monitoring, new targeted development, procurement and purchase of medical countermeasures and raw materials.

The EU FAB facilities, a network of ever warm production capacities for vaccines and medicines manufacturing, will be set in motion to make available reserved surge manufacturing capacities, as well as emergency research and innovation plans in dialogue with Member States.

The EU production of medical countermeasures will be boosted and an inventory will be established of production facilities, raw materials, consumables, equipment and infrastructure in order to have a clear overview of EU capacities.

Resources

HERA activities will rely on a budget of €6 billion from the current Multiannual Financial Framework for the period 2022-2027, part of which will come from the NextGenerationEU top-up.

Other EU programmes such as the Recovery and Resilience Facility, REACT-EU, Cohesion Funds and the InvestEU Progamme inside the EU, and the Neighbourhood, Development and International Cooperation Instrument outside the EU, will also contribute to support the resilience of health systems. Together with the above €6 billion the total support will thus amount to almost €30 billion under the next financing period and even more if we consider investments at national level and in the private sector.

Next steps

To ensure a swift launch and building on the HERA incubator launched in February 2021, HERA will be set up as an internal Commission structure. It will be fully operational early 2022. Its functioning will be reviewed and adapted on an annual basis until 2025, when a full review will be carried out.

The proposed Council Regulation on a framework of measures related to medical countermeasures in the event of a public health emergency at Union level will be discussed and adopted by the Council.

In the next days, the Commission will publish a Prior Information Notice to provide advance information to vaccine and therapeutics manufacturers about the EU FAB call for competition, planned for early 2022.

Members of the College said:

President of the European Commission, Ursula **von der Leyen**, stated: "HERA is another building block of a stronger Health Union and a major step forward for our crisis preparedness. With HERA, we will make sure we have the medical equipment we need to protect our citizens from future health threats. HERA will be able to make swift decisions to safeguard supplies. This is what I promised back in 2020, and this is what we deliver."

Vice-President for Promoting the European Way of Life, Margaritis **Schinas**, said: "HERA has a clear mission: ensuring the availability, access and distribution of medical countermeasures in the Union. HERA is the EU's response for both anticipating and managing emergencies. HERA will have the clout and budget to work with industry, medical experts, researchers and our global partners to make sure critical equipment, medicines and vaccines are swiftly available when and as necessary. We now know: To fight the COVID-19 pandemic and future health emergencies, cooperation is the only way forward."

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: "HERA is a crucial centerpiece of a strong European Health Union. With HERA we will be able to anticipate threats through horizon scanning, coordinate our actions to respond in a timely fashion through the development, procurement, and distribution of critical medical countermeasures at EU level. It is a unique health security structure allowing us to be ahead of the curve. Health security is becoming a collective endeavor in the EU. After almost two years of a devastating pandemic, HERA is a symbol of the mindset-shift on health policy that we should all rally behind – it is when we act together that we are stronger and able to make a real difference for the health security of our citizens."

Mariya **Gabriel**, Commissioner for Innovation, Research, Culture, Education and Youth, said: "Medical counter-measures are key to combat health threats. The Commission has been at the forefront of tackling the pandemic but more must be done to ensure that we are better prepared for the next crisis. Research and innovation will be a central piece in HERA, as the new authority sets out to promote and support the development of medical technologies and their production."

Thierry **Breton**, Commissioner for the Internal Market, said: "With HERA, we draw the lessons learned from the crisis: we cannot ensure our citizens' health without industrial capacity in the EU and well-functioning supply chains. We succeeded in upgrading COVID-19 vaccine production in record time, for Europe and the rest of the world. But we need to be better prepared for future health crises. HERA will establish new, adaptable production capacities and secure supply chains to help Europe react fast when needed."

For More Information

State of the Union Address by President von der Leyen

<u>Communication on Introducing the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union</u>

Annex to the Communication

Commission Decision establishing the Health Emergency Preparedness and Response Authority

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)

Q&A on the European Health Emergency preparedness and Response Authority (HERA)

European Health Union website

EU Coronavirus response

IP/21/4672

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