



European Parliament

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5 PROMOTING OUR EUROPEAN WAY OF LIFE

EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY (HERA) [  EXPECTED ARRIVALS ]

## CONTENT

On 16 September 2020, the President of the European Commission, Ursula von der Leyen, urged the need of a biomedical advanced research and development agency (BARDA) in the context of building a stronger European Health Union. The new agency would support the EU's capacity and readiness to respond to cross-border threats and emergencies. According to von der Leyen, the Union needs strategic stockpiling in order to address supply chain dependencies, notably for pharmaceutical products. In the letter of intent, which accompanied President von der Leyen's State of the Union speech, the Commission announced to publish a legislative proposal in order to establish the new European Biomedical Research and Development Agency.

On 19 October 2020, the annexes accompanying the work programme of the European Commission for 2021 announced a legislative proposal to establish a new European biomedical research and development agency.

On 11 November 2020, the European Commission published the communication 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats'. The Commission emphasised the fact that the EU lacks access to relevant medical countermeasure stockpiles. It also hinted to the vulnerability of EU supply chains for these critical medical countermeasures. Moreover, the EU lacks a coordinated and systematic approach to support development, production and procurement of necessary medical countermeasures.

Two weeks later, in the European Commission's Communication Pharmaceutical Strategy for Europe, however, the name Biomedical Advanced Research and Development Authority (BARDA), was replaced by European Health Emergency Response Authority (HERA). According to the Commission, 'HERA will fill a major structural gap in the EU's crisis preparedness and response infrastructure, and will strengthen the coordination of operations across the whole value chain and develop strategic investments for research, development, manufacturing, deployment, distribution and use of medical countermeasures. This will require the assembly of ecosystems of public and private capabilities that jointly enable a rapid response when the need arises.' In her 1 December 2020 speech at the EU Health Summit, President von der Leyen slightly changed the HERA term into European Health Emergency preparedness and Response Authority.

On 31 March, the Commission launched an online public consultation on the HERA. The consultation had run until 12 May 2021. In parallel to the public consultation, the Commission also held talks with Member States and stakeholders.

The HERA is 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 equitable distribution of key medical countermeasures. HERA will anticipate threats and potential health crises, through intelligence gathering and building the necessary response capacities, during "preparedness phase". When an emergency hits, HERA will ensure the development, production and distribution of medicines, vaccines and other medical countermeasures.

Member States will be involved in the governance of HERA: during the preparedness phase, one representative per Member State sits on the HERA Board and 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.

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.

HERA will rely on €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.

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.

HERA decision was formally adopted on 16 September 2021 by the College of Commissioners and the legislative proposal unveiled the same date.

## References:

- European Commission, Communication [Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union](#), COM(2021) 576
- European Commission, [Decision establishing the Health Emergency Preparedness and Response Authority](#), 16 September 2021
- European Commission, [State of the Union Address by President von der Leyen at the European Parliament Plenary](#), 16 September 2020

- European Commission, [Letter of Intent to President David Maria Sassoli and to Chancellor Angela Merkel](#), 16 September 2020
- European Commission, [2021 Commission Work Programme](#), dedicated website
  - European Commission, [Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats](#), COM(2020) 724
  - European Commission, [Questions and Answers: Building a European Health Union: Stronger crisis preparedness and response for Europe](#), 11 November 2020
- European Commission, Communication [Pharmaceutical Strategy for Europe](#), COM(2020) 761
- European Commission, [Speech by President von der Leyen at the EU Health Summit](#), 1 December 2020

### Further reading:

- EPHA, Discussion [Getting it right: Recommendations for a European BARDA](#), dedicated website

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#### HYPERLINK REFERENCES

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