



Building a European Health Union: Stronger crisis preparedness and response for Europe

Brussels, 11 November 2020

Today, the European Commission is taking the first steps towards building the European Health Union announced by President **von der Leyen** in her State of the Union address. The Commission is putting forward a set of [proposals](#) to strengthen the EU's health security framework, and to reinforce the crisis preparedness and response role of key EU agencies. In order to step up the fight against the COVID-19 pandemic and future health emergencies, more coordination at EU level is needed. Drawing lessons from the current crisis, today's proposals will ensure stronger preparedness and response during the current and future health crises.

President of the European Commission, Ursula **von der Leyen** stated: *"Our aim is to protect the health of all European citizens. The coronavirus pandemic has highlighted the need for more coordination in the EU, more resilient health systems, and better preparation for future crises. We are changing the way we address cross-border health threats. Today, we start building a European Health Union, to protect citizens with high quality care in a crisis, and equip the Union and its Member States to prevent and manage health emergencies that affect the whole of Europe."*

Vice-President for Promoting the European Way of Life, Margaritis **Schinias**, said: *"Today, we are taking a big, meaningful step towards a genuine EU Health Union. We are strengthening our common crisis management to prepare and respond to serious cross border threats to health. Our EU agencies need to be equipped with stronger mandates to better protect EU citizens. To fight the COVID-19 pandemic and future health emergencies, more coordination with more efficient tools at EU level is the only way forward."*

Stella **Kyriakides**, Commissioner for Health and Food safety said: *"Health is more than ever an essential concern for our citizens. In times of crisis, citizens rightfully expect the EU to take a more active role. Today we are reinforcing the foundations for a more secure, better-prepared and more resilient EU in the area of health. This will be a significant change for the capacity to respond collectively. The European Health Union is all about preparing for and facing up to common health threats together, as a Union. We need to do this in order to meet the expectations of our citizens."*

Today's proposals focus on revamping the existing legal framework for serious cross border threats to health, as well as reinforcing the crisis preparedness and response role of key EU agencies, namely the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

A stronger EU health security framework

To create a more robust mandate for coordination by the Commission and EU agencies, the Commission is today proposing a **new Regulation on serious cross-border threats to health**. The new framework will:

- **Strengthen preparedness:** EU health crisis and pandemic preparedness plan and recommendations will be developed for the adoption of plans at national levels, coupled with comprehensive and transparent frameworks for reporting and auditing. The preparation of national plans would be supported by the European Centre for Disease Prevention and Control and other EU agencies. The plans would be audited and stress tested by the Commission and EU agencies.
- **Reinforce surveillance:** A strengthened, integrated surveillance system will be created at EU level, using artificial intelligence and other advanced technological means.
- **Improve data reporting:** Member States will be required to step up their **reporting of health systems** indicators (e.g. hospital beds availability, specialised treatment and intensive care capacity, number of medically trained staff etc.).
- The **declaration of an EU emergency situation** would trigger increased coordination and

allow for the development, stockpiling and procurement of crisis relevant products.

Stronger and more operational EU Agencies

The European Centre for Disease Control and Prevention and the European Medicines Agency have been at the forefront of the EU's work to address COVID-19 since the outbreak of the pandemic. However, COVID-19 has shown that both agencies need to be reinforced and equipped with stronger mandates to better protect EU citizens and address cross border health threats.

The **ECDC's mandate** will be reinforced so that it may support the Commission and Member States in the following areas:

- epidemiological surveillance via integrated systems enabling real-time surveillance
- preparedness and response planning, reporting and auditing
- provision of non-binding recommendations and options for risk management
- capacity to mobilise and deploy EU Health Task Force to assist local response in Member States
- building a network of EU reference laboratories and a network for substances of human origin

The **European Medicines Agency's mandate** will be reinforced so that it can facilitate a coordinated Union-level response to health crises by:

- monitoring and mitigating the risk of shortages of critical medicines and medical devices
- providing scientific advice on medicines which may have the potential to treat, prevent or diagnose the diseases causing those crises
- coordinating studies to monitor the effectiveness and safety of vaccines
- coordinating clinical trials.

The Commission is also today setting out the main elements of the future Health Emergency Response Authority (HERA), to be proposed by the end of 2021. Such a structure would be an important new element to support a better EU level response to cross-border health threats.

For More Information

[European Health Union website](#)

[Questions and Answers](#)

[Factsheet – A European Health Union – tackling health crises together](#)

[Factsheet – A European Health Union – the role of agencies](#)

[Communication: Building a European Health Union: preparedness and resilience](#)

[Proposal for a Regulation on serious cross-border threats to health](#)

[Proposal to extend the mandate of the European Medicines Agency](#)

[Proposal to extend the mandate of the European Centre for Disease Prevention and Control](#)

[EU Coronavirus response](#)

[Overview of the Commission's response](#)

[State of the Union speech](#)

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