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

Brussels, 11 November 2020

The COVID-19 pandemic has caused immense human suffering and pushed health systems to their limits. The measures needed to contain the pandemic and save lives have a huge impact on people's livelihoods, their jobs and their freedoms. From the beginning of the pandemic, solidarity has been real and tangible. Healthcare workers were at the forefront, working day and night to care for COVID-19 patients. EU Member States turned from unilateral measures to supporting each other, either by receiving COVID-19 patients from neighbouring countries or sending healthcare professionals and key medical equipment. Cooperation and coordination at EU level has become the norm.

EU Agencies also stepped in to support the EU, with the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) playing a key role in the response to the COVID-19 pandemic. Specifically, the ECDC continuously provided risk assessments and scientific guidance based on the epidemiological spread of the virus and the EMA has streamlined its assessment procedures to allow for a more efficient assessment of promising COVID-19 vaccines or treatments.

However, to fight the COVID-19 pandemic and future health emergencies, we need a reinforced framework of coordination and strengthening of existing structures and mechanisms for better EU level protection, prevention, preparedness and response against human health hazards. This is why the President of the Commission in her State of the Union address of 2020, called on Europe to draw lessons from the current crisis and build a **European Health Union**.

Why do we need a European Health Union?

The experience of the current pandemic shows that coordination and cooperation between Member States and the Commission are crucial. The pandemic is both an EU wide and global problem that can only be tackled if we work together. With the support of the European Parliament and the Council, the EU must therefore be better equipped to prevent, prepare for and manage health crises. Only a stronger Health Union, with all the societal and economic benefits it brings, is up to the task.

A strong European Health Union will protect our health, but also our ways of living, our economies and societies. Where our health is in danger, our economies are in danger. The close relation between saving lives and saving livelihoods has never been so clear. By building a stronger Health union, the proposals put forward today will contribute to a more resilient EU internal market and sustained economic recovery.

The Commission's ambitions for a Health Union are presented in the midst of a widespread resurgence of COVID-19 cases across Europe and the world. The EU and its Member States need to continue taking the necessary measures to contain and manage the pandemic on a day-to-day basis, for which coordinated EU-level action remain essential.

At the same time, however, improving preparedness and response for future outbreaks of communicable diseases is more pressing as such outbreaks become more likely. Indeed, long-term trends such as antimicrobial resistance, pressures on biodiversity and climate change, all associated with increasing communicable disease threats worldwide and in Europe, keep rising. This requires a systemic, foresight-based approach recognising the interaction between human and animal health and the environment to develop structural, future-proof solutions, coherent with a One-Health approach.

The first building blocks of a European Health Union presented today outline the lessons learnt from the first stage of the pandemic, and advocate the strengthening of existing structures and mechanisms to improve EU level protection, prevention, preparedness and response against human health hazards.

These first proposals are envisaged within the current Treaty provisions, particularly Article 168 (5) of the TFEU. By upgrading the EU framework for cross-border health threats, these first building

blocks of the European Health Union will bring greater overall impact, requiring the strongest commitment of the Member States, while fully respecting their competence in the area of health.

Why strengthen the EU health security framework in the middle of a pandemic?

The coronavirus pandemic has demonstrated that the EU needs to improve preparedness and response to manage serious cross-border health threats more effectively at both EU and Member State level. The gaps seen over the last months in our capacities to respond to a major health crisis call for a more consistent and coordinated approach to prepare for and manage such threats in the EU. This is why President **von der Leyen** announced new measures to create a European Health Union in her State of the Union speech.

Based on the lessons learned during the past nine months, the Commission is proposing a solid framework for EU preparedness, surveillance, risk assessment, early warning and response. Today's proposals will give the EU and Member States stronger tools to take quick, decisive and coordinated action together: new crisis mandates for the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), as well as a revamped cross-border health threat legal framework.

The COVID-19 pandemic is not over yet. Whilst the EU has made significant progress under the EU Vaccines Strategy and has signed three contracts with pharmaceutical companies for the access to future safe and efficient vaccines, there is currently no approved vaccine available, and treatments remain limited. That is why it is important to move ahead now to ensure stronger preparedness and response during the current and future health crises.

Will the European Health Union be limited to crisis management?

Today's proposals address crisis management, preparedness, response and resilience. It is the first step towards the European Health Union announced in the State of the Union speech, but the Health Union will go further.

The crisis has demonstrated how important cooperation is in fighting communicable diseases. Health systems need to be resilient and capable of responding to health emergencies as well as all other serious cross border health threats.

EU citizens consider health as a priority and expect Europe to do more in this area. That is why all future health policies will contribute to the goal of creating a European Health Union.

Today's proposals will be followed by two major Health Union initiatives: the Pharmaceutical Strategy for Europe and Europe's Beating Cancer Plan.

Do the proposals address COVID-19 or only future health crises?

The three proposed Regulations will now be negotiated by the Council and European Parliament. As soon as they are adopted, the Regulations will enter into force and be immediately applicable. The new structures build on existing legislation and practice during the COVID-19 emergency response and as such could be embedded quickly. It is important to continue using all existing resources to respond to the current crisis. These proposals support this and also provide the framework for preparing better for the next serious cross border threat to health.

How will the proposed cross-border health threats legislation strengthen crisis management?

The Commission is proposing a stronger and more comprehensive legal framework to prepare and respond to serious cross border threats to health. The changes are based on lessons learnt from the coronavirus crisis. Under the new Regulation, the European Union would be able to:

- adopt common measures at EU level to face future cross-border health threats;
- declare an EU-level public health emergency;
- strengthen preparedness planning, reporting and auditing at EU level;
- put in place an integrated EU monitoring system for infectious disease and other health threats.

Why are you changing the mandate of the European Centre for Disease Prevention and Control (ECDC)?

The ECDC plays an important role in crisis preparedness and response to infectious disease threats and outbreaks. The coronavirus outbreak has however highlighted weaknesses in its role. The agency could only issue technical guidance and was not able to provide analyses of the data it collected. The new extended mandate would allow it to:

- issue stronger recommendations on measures to control outbreaks;
- mobilise and deploy an EU Health Task Force to assist local response in Member States;
- step up analysis and modelling to support Member States in the control of outbreaks, for example by collecting and processing more data;
- build up the key competences for health protection in Member States through a new network of EU public health reference laboratories;
- reinforce the prevention of communicable diseases and specific health issues, e.g., antimicrobial resistance, vaccination and biosecurity.

Why is it necessary to strengthen the role of the European Medicines Agency (EMA)?

The EMA is vital to ensure the evaluation, approval and supervision of medicinal products available to treat patients in the EU. There needs to be a stronger EMA in times of crisis. During the coronavirus outbreak, cooperation with Member States' experts, assessments of potential treatments and vaccines were stepped up based on temporary and exceptional measures, to allow a response in line with the size of the challenge. Building on the experience of the current pandemic, the proposed Regulation would put these arrangements on a permanent footing and allow the EMA to:

- permanently monitor events which could lead to shortages of medicines during future crises;
- monitor and report on the risk of shortages of medicines and medical devices during a crisis;
- activate a dedicated crisis management structure;
- play a key role in the development and faster approval of medicines to treat or prevent a disease causing a public health crisis;
- fast-track scientific advice on clinical trial protocols and carry out rolling reviews of evidence from clinical trials and other studies;
- host medical device expert panels on a permanent basis.

Will the European Medicines Agency also regulate medical devices?

EMA will have a very limited role on medical devices, mainly during crisis. It is a pragmatic solution to ensure proper monitoring of the risk of device shortages. EMA will also provide a permanent structure for medical device expert panels. The Regulation would not give EMA a regulatory role in the field of medical devices.

Do the proposals respect Member States' competences in health?

The package is within the boundaries of the Treaty on the Functioning of the European Union. It will be based on both Article 168 on public health and Article 114 related to the internal market. The Regulation on serious cross-border threats to health will be based on Article 168(5) TFEU.*

Why do we need a new authority for biomedical preparedness?

Faced with a completely new pathogen, Europe lacked access to relevant medical countermeasure stockpiles and the vulnerability of EU supply chains for these critical medical countermeasures was highlighted. The EU also lacked a coordinated and systematic approach to support development, production and procurement of necessary medical countermeasures. Indeed, no one body comparable to the US Biomedical Advanced Research and Development Authority (BARDA) currently exists at EU level to coordinate and drive this work. In her 2020 State of the Union speech, President von der Leyen promised that the EU will 'build a European BARDA –for biomedical advanced research and development'. This new authority will support our capacity and readiness to respond to cross-border threats and emergencies – whether of natural or deliberate origin.

An EU authority would remediate structural gaps in the EU's health preparedness and response capacities with regard to biomedical development, production and surge capacity development. It will also provide a horizon scanning function, focusing on emerging biomedical technologies that can be scaled-up for real-world application during times of crisis. The authority will engage with industry, science, academia and clinical research organisation networks, with the aim of implementing successful public-private partnerships.

The preparatory work is ongoing and the Commission will make a proposal for the future agency in Q4, 2021.

Is there a link between today's proposals and the pharmaceutical strategy?

The coronavirus pandemic has shown vulnerabilities in pharmaceutical supply chain. Today's proposals include elements that concern medicines and medical devices, such as closer monitoring of supplies during emergencies, more coordinated clinical trials, and advice on repurposed medicines

during health emergencies. The proposals are designed for health crisis situations, whereas the pharmaceutical strategy will take a more long-term systemic view in these areas and thus complement efforts to ensure a steady supply of medicines and medical devices, during crises and beyond.

How will today's proposals be financed?

The majority of the actions are included in the Commission proposal for the 2021-2027 EU4Health programme. The EU4Health proposal includes a list of eligible support actions such as setting up a Union preparedness plan, supporting stress tests of national healthcare systems and preparedness exercises, training healthcare professionals and investing in digitalisation. Some of the work could be financed through other Union programmes such as InvestEU. Strengthening the EU agencies will require an increase in the agencies' budget that will be negotiated with the budgetary authorities.

* Updated at 15:50 on 11/11/2020.

QANDA/20/2042

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