

EuropaBio's position on the Building of a European Health Union: stronger crisis preparedness and response for Europe

In November 2019, 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.”*

EuropaBio welcomes the European Health Union plan. The EU has indeed a critical role to play in public health and better crisis preparedness to address serious cross-border health threats and improving crisis management capacity.

European citizens have been increasingly clear on their expectations that the EU needs to have a more active role in protecting their health and well-being, particularly in protecting them from health threats that transcend national borders. The ongoing effort to fight the Covid-19 pandemic makes it clear that health challenges can only be tackled by working together across borders with increased coordination at EU level. Based on the strength of European science, the biotechnology industry has joined forces to partner on solutions and delivered on vaccines in unprecedented speed. This pivotal sector needs to be nurtured for the health and economic benefits of European citizens. Therefore, whilst EuropaBio recognises that most of the efforts are rightly targeted to avoid or counter future health emergencies more effectively, it also remains crucial that future Health Union initiatives include further stimulation of bioscientific research, rapid patient access and uptake of innovative treatments in Europe in the future. Creating the right incentives and rewarding innovation is critical to recovering European leadership position in life sciences.

A strong European Health Union needs public health measures that are consistent, coherent and coordinated to maximise their effect. These measures must be built on a strong life sciences and biotechnology ecosystem that can deliver the innovative vaccines, treatments or other health solutions needed. These public health measures must also be applied on improved, resilient and effective health systems that addresses challenges and structural weaknesses identified in the past. The best way to prepare and build the European Health Union is to foster strong innovation ecosystems in Europe and promote the right health systems infrastructures in EU countries not only for the next pandemic but for the long term.

EuropaBio, therefore, supports the proposals from the European Commission to change the mandate of the European Centre for Disease Prevention and Control (ECDC), to strengthen the role of the European Medicines Agency (EMA) and to create an EU Health Emergency Preparedness and Response Authority (HERA).

The ECDC could play a stronger role in crisis preparedness and response to infectious threats and outbreaks. Its new extended mandate should make sure the agency has full access to all relevant data from Member States and can increase its monitoring, surveillance, and risk assessment capacities to issue better recommendations on measures to control or prevent outbreaks. The ECDC also needs more resources – budget and personnel, if it is to function anything like the CDC in the US.

In the Covid-19 circumstances, the EMA has stepped up the cooperation with Member State experts and accelerated the assessments of potential treatments and vaccines thanks to applying exceptional

measures. Based on this unique experience, the EMA needs to consider maintaining regulatory adaptations, such as fast-tracking scientific advice on clinical trial protocols and maintaining rolling reviews of evidence, which proved effective to speed up patient access to critical novel therapies. The EMA should also be a core contributor to the creation of a European Health Data Space to streamline the use of real-world data in regulatory processes. In this context, strengthened access of EMA to health data should support its regulatory capacity and its broader role in the coordination and facilitation of clinical trials in the EU. Advancing acceptance of new sources of data of high-quality generation would enhance regulatory and HTA reviews. With the digital healthcare transformation, EuropaBio encourages unleashing the full potential of health data as a major tool for improving the efficiency and sustainability of healthcare systems for accelerating the move towards value-based healthcare models. This will ensure that Europe remains a leader in clinical research programs, the development of forward-thinking methodologies for value assessments and in advancing outcome-based payment models.

With respect to the proposal to involve the EMA in managing the risks of shortages of medicines, EuropaBio underlines that communication channels should be streamlined to avoid duplication with Member States reporting requirements and unnecessary burden on marketing authorisation holders. EuropaBio considers that the primary role of the EMA should be to ensure that the regulatory framework is future-proof, fit-for-purpose and centred on patients' needs.

The new Health Emergency Preparedness and Response Authority should remediate structural gaps in the EU's health preparedness and response capacities with regard to biomedical development, production and surge capacity development. The recent pandemic has shown how critical it is for the research community to speed up scientific discovery and for the biotechnology industry to accelerate technological innovation and build the production capacities required to save lives. EuropaBio encourages the European Commission to employ a holistic approach in its preparatory work to design the future HERA by engaging with all stakeholders from science, academia, clinical research networks and citizens. A primary goal should be to create the most competitive ecosystem for acceleration of biotechnology innovation that goes further than just the pandemic response. Europabio is ready to engage and contribute to this process.

Fostering R&D, coordinating public resources for healthcare research in an effective and efficient manner, funding research priorities that contribute to global research platforms, raise the need for complementary and joint action to ensure that research findings and elementary health data can be shared rapidly, openly, and effectively. This should pave the way for answering the need for a consistent interpretation of the GDPR across the Member States. Deploying the most advanced innovation and other measures in the event of a future health emergency can only be successful if the pre-existing European innovation ecosystem for clinical trials and data infrastructure is competitive and the health systems are fully prepared and aligned throughout the value chain from conception to delivery of care to citizens.

EuropaBio calls also for continued and increased cooperation at EU and international level as, for instance, through strengthened cooperation with the World Health Organisation. The implementation of the European Health Union will be largely dependent on clear division of competences between the EU and the Member States, good governance, and clarification of the future role of the Health Security Committee and the European agencies, to avoid unnecessary burden on stakeholders in the new structures and to deliver the added value to protect citizens from future health threats expected in this new operating mode.

EuropaBio invites the European Commission to make the best use of the upcoming Conference on the Future of Europe and the Global Health Summit scheduled in 2021 to fully grasp citizens' expectations

towards the Union and the evolution of the EU's role on health in the future. EuropaBio is looking forward to actively participating in the discussions around the role and extended mandates of the EU health agencies proposals in 2021.

More than ever, a strong Health Union is necessary in today's global world. For the next crisis EU and national institutions need to be robust and operate more effectively. The crisis also reminds us that a healthy society is needed in order for it to function and generate wealth for European citizens. European governments must continue to prioritise the health-care sector, regard innovation and the adoption of new technologies as a sound investment in the future and not simply as a variable cost which must be managed.