

Coronavirus: preparing Europe

Increased threat of variants

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USPA NEWS - Today, the Commission is proposing immediate action to prepare Europe for the increased threat of coronavirus variants. The new European bio-defence preparedness plan against COVID-19 variants called "HERA Incubator"^[1] will work with researchers, biotech companies, manufacturers and public authorities in the EU and globally to detect new variants, provide incentives to develop new and adapted vaccines, speed up the approval process for these vaccines, and ensure scaling up of manufacturing capacities.

Taking action now is important as new variants continue to emerge and challenges with scaling up vaccine production are arising. The HERA Incubator will also serve as a blueprint for the EU's long-term preparedness for health emergencies.

Key actions to boost preparedness, develop vaccines for the variants and increase industrial production:

1). Detect, analyse and assess variants

Developing specialised tests for new variants, and to support genomic sequencing in Member States with at least €75 million in EU funding;

Reaching the target of 5% of genome sequencing of positive tests to help identify variants, monitor their spread in populations, and screen their impact on transmissibility;

Stepping up research and data exchange on variants with €150 million funding;

Launching the VACCELERATE COVID-19 clinical trial network, bringing together 16 EU Member States and five associated countries including Switzerland and Israel to exchange data and progressively also include children and young adults as participants in clinical trials.

2). Speed up regulatory approval of adapted vaccines: based on the annual influenza vaccine model, the EU will provide accelerated approval for adapted COVID-19 vaccines by:

Adapting the regulatory framework, such as amending the regulatory procedure to enable the approval of an adapted vaccine with a smaller set of additional data submitted to EMA on a rolling basis;

Providing guidance on data requirements for developers from the European Medicines Agency so that the requirements for variants are known in advance;

Facilitating certification of new or repurposed manufacturing sites through early involvement of regulatory authorities;

Considering a new category of emergency authorisation of vaccines at EU level with shared liability among Member States.

3). Ramp up production of COVID-19 vaccines: the EU will:

Update or conclude new Advance Purchase Agreements to support the development of new and adapted vaccines through EU funding, with a detailed and credible plan showing capability to produce vaccines in the EU, on a reliable timescale. This should not prevent the EU from considering sources from outside the EU if needed, provided they meet the EU safety requirements;

Work closely with manufacturers to help monitoring supply chains and addressing identified production bottlenecks;

Support the manufacturing of additional vaccines addressing new variants;

Develop a voluntary dedicated licensing mechanism to facilitate technology transfer;

Support cooperation between undertakings;

Ensure the EU's manufacturing capacity by building up the "EU FAB"^[2] project.

The actions announced today will go hand-in-hand with global cooperation via the World Health Organisation and global initiatives on vaccines. They will also prepare the ground for the European Health Emergency Preparedness and Response Authority (HERA). HERA will build on the actions launched today and provide a permanent structure for risk modelling, global surveillance, technology transfers, manufacturing capacity, supply chain risk mapping, flexible manufacturing capacity and vaccine and medicine research and development.

Members of the College said:

President of the European Commission, Ursula von der Leyen, said: "Our priority is to ensure that all Europeans have access to safe and effective COVID-19 vaccines as soon as possible. At the same time, new variants of the virus are emerging fast and we must adapt our response even faster. To stay ahead of the curve, we are launching today the HERA Incubator. It brings together science, industry and public authorities, and pulls all available resources to enable us to respond to this challenge."

Margaritis Schinas, Vice-President of the European Commission, said: "In our fight against the virus we are anticipating problems and acting proactively to mobilise all means to address the impact of variants. With our new bio-defence preparedness plan "HERA Incubator', we are tackling parallel or subsequent series of pandemics deriving from the variants. Today's proposal is the perfect example of what the EU is best at: pooling efforts and complementing them by funding. This is the way to get out from the crisis, ready to adapt to new circumstances and united in action - ensuring solidarity across the EU and the world."

Stella Kyriakides, Commissioner for Health and Food Safety, said: "Europe is determined to stay ahead of the threat of new coronavirus variants. The HERA Incubator is an exercise in foresight, anticipation and united response. We can meet the dual challenge of addressing new variants and increasing our vaccine production capacity. It will build bridges between research, industry and regulators to speed up the processes - starting from the detection of variants all the way to the approval and production of vaccines. We need significant investments now and for the future and the HERA Incubator is a crucial part of our response."

Thierry Breton, Commissioner for the Internal Market, said: "The Task Force for ramping-up vaccine production is already engaging on a daily basis with industry to better address and anticipate potential bottlenecks. With this increased cooperation, we will ensure that the industrial phase of vaccine production allows manufacturers to meet their commitments while anticipating our future needs and adjusting vaccine production to future variants. Today, with HERA incubator, we are providing a strong structural response. This is not only about short term fixes: it will contribute to a higher level of autonomy in the area of health in the near future for our Continent."

Mariya Gabriel, Commissioner for Innovation, Research, Culture, Education and Youth, said: "Research and innovation continue to be crucial in fighting the continuing challenges of this pandemic. The HERA Incubator and the reinforcement of European infrastructures and networks, supported by additional funding from Horizon 2020 and Horizon Europe programmes, will help us deal with any variants and be better prepared for future outbreaks."

Background

The EU Vaccine Strategy has secured access to 2.6 billion vaccine doses as part of the broadest global portfolio of safe and secure COVID-19 vaccines. Less than a year since the virus appeared for the first time in Europe, vaccination has started across all Member States. This is a remarkable achievement of European and global advanced research and vaccine development, condensing what usually takes 5-10 years in just over 10 months.

At the same time, there are challenges to scale-up industrial vaccine production to keep pace. In order to boost production capacity in Europe, a much closer, more integrated and more strategic public-private cooperation with industry is needed. In this spirit, the Commission has set-up a Task Force for Industrial Scale-up of COVID-19 vaccines to detect and help respond to issues in real-time.

Europe now also needs to stay ahead of the curve as new and emerging threats continue to appear in the present or on the horizon. The most immediate of these are emerging and multiplying variants already spreading and developing in Europe and across the world. Presently, authorised vaccines are considered effective against the variants we are aware of. However, Europe must be ready and prepared for the possibility of future variants being more or fully resistant to existing vaccines.

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