

Preparing Europe for COVID-19 variants: HERA incubator

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The European Union is working at full speed to ensure that **all Europeans have access to COVID-19 vaccines** as soon as possible. The authorised vaccines are effective against the current virus.

At the same time, we must be prepared to **tackle new variants** of the virus and to rapidly develop and produce on a large scale vaccines effective against those variants.

This is why the European Commission is launching the **HERA incubator**. It will bring together science, industry and public authorities, and leverage all available resources to enable Europe to respond to this threat.



KEY ACTIONS TO BOOST PREPAREDNESS AND INCREASE THE CAPACITY TO DEVELOP VACCINES ADAPTED TO VARIANTS



1. DETECT AND ANALYSE NEW VARIANTS OF THE VIRUS

Boost **capacity to characterise** the variants (genome sequencing)

Enable seamless **sharing of information** on new variants with all stakeholders working on the development of adapted or new vaccines Identify and **agree on escape variants** of high concern



2. DEVELOP VACCINES AGAINST NEW VARIANTS OF THE VIRUS FOR WHICH EXISTING VACCINES MAY NOT BE SUFFICIENTLY EFFECTIVE

Support companies working on the adaptation of vaccines or development of new vaccines Facilitate clinical trials: launch of EU-wide network of clinical trials (VACCELERATE) Support new technologies to develop adapted or new vaccines



3. PRODUCE AT SCALE AND SPEED VACCINES ADAPTED TO VARIANTS

Upgrade existing Advanced Purchase Agreements

(APAs) or **conclude new APAs** with manufacturing companies working on adapted vaccines

Companies to present credible plan

showing real capacity to produce vaccines in EU and supply required quantities sufficiently fast

TO DELIVER, THE EU WILL:

SPEED UP REGULATORY PROCEDURES

- Accelerate approval of adapted vaccines
- Explore introduction of emergency authorisation of vaccines at EU level
- Provide guidance on data requirements
- Support research to include children in clinical trials

RAMP UP INDUSTRIAL PRODUCTION

- Monitor supply chains, address production bottlenecks
- Support manufacturing of vaccines against new variants
- **Develop a voluntary licensing mechanism** to facilitate technology transfer
- Enhance manufacturing capacity through the "EU Fab" project

This emergency programme will tackle the short to medium-term threat and simultaneously prepare for the future. It will serve as the vanguard for the **European Health Emergency Preparedness and Response Authority** (HERA). HERA will provide a structural system to enable the EU to anticipate and tackle better future pandemics.

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