



# HERA Incubator:

## Anticipating the threat of SARS-CoV-2 variants

5.1.2e

European Commission  
DG SANTE

11 March 2021

*Extraordinary NFP meeting for Microbiology*

# Outline

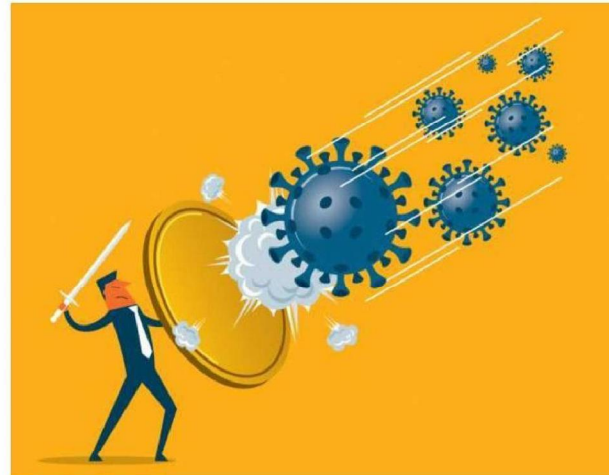
- Introducing HERA
- Launch of the HERA Incubator
- Focus on detection of SARS-CoV-2 variants
- Implementing specific actions to support MS

# Health Emergency Preparedness and Response Authority

## HERA

## SOTEU 2020 – President von der Leyen

- We need to build a **stronger European Health Union**
- Opportunities for **strengthening EU preparedness and response** to serious cross-border health threats
- Set up a “**European BARDA**” – an agency for biomedical advanced R&D to support capacities and readiness for response



<https://www.eppgroup.eu/newsroom/publications/a-european-solidarity-pact-against-the-coronavirus-pandemic>

# 11 Nov '20: Building a European Health Union

- A comprehensive **EU Health Security Framework** is in place (e.g. Decision 1082, EWRS, HSC, ECDC, EMA, Joint Procurement)
- However, pandemic has revealed **structural weaknesses**, such as:
  - Weak or suboptimal preparedness plans and modelling
  - Fragmentation of efforts in the EU
  - Market failures and lack of medical countermeasures
  - Vulnerabilities in global supply chains
  - Insufficient oversight of manufacturing capacities and research priorities



- There is need for strengthened **EU coordination** to improve **preparedness and response capability**

# EU Health Emergency Preparedness & Response Authority (HERA)

- **Mission:** Enable the EU and its MS to rapidly deploy the most advanced medical and other counter measures in the event of a health emergency
- Assembly of **ecosystems of public and private capabilities**
- This will be done by covering the **whole value chain** and by providing **end-to-end solutions**

*Flexible and resourced financing & procurement capacities*



**Knowledge generation:** horizon scanning, market intelligence, foresight

**Development:** late stage research, innovation and development

**Production:** flexible and scalable manufacturing capacities

**Deployment:** EU level stockpiling and distribution

**Use:** training programmes



# Timeline and next steps

- **Inception Impact Assessment**
  - Feedback period 27 Jan 2021 – 24 Feb 2021
  - Presentation of several policy options
  - Feedback will be taken into account for further development and fine tuning of the initiative
- **Legislative proposal:** second half 2021
- **Preparatory actions:** launch in 2021
  - Piloting HERA
  - E.g. HERA Incubator, AMR, vaccine and drug R&D, climate change and (re)emerging diseases
- **HERA to be operational:** latest 2023

# HERA Incubator

- 17 Feb – Commission Communication
- Launch of a new EU bio-defence preparedness plan against COVID-19 variants
- Key actions to boost preparedness, develop vaccines for the variants and increase industrial production
- The HERA Incubator will also serve as a blueprint for the EU's long-term preparedness for health emergencies





## Focus on 5 key action areas

### Rapid detection of new variants

- Sequencing capacities
- Exploring use of detection assays
- Data sharing and exchange
- Wastewater monitoring
- Support to low income countries

### Swift adaptation of vaccines

- Bringing together research and evidence on VOC
- Aligning research with existing/new vaccines and their technologies
- Vaccine development for children and adolescents

### Setting up a EU Clinical Trials network

- Launch of VACCELERATE
- Ensure MS involvement
- Streamline the process between clinical trials and the regulatory approval process

### Fast tracking of regulatory vaccine approval process

- Amending the regulatory procedure to accelerate vaccine approval
- Amending EU pharmaceuticals legislation
- Ensuring support to manufacturers

### Upscaling of vaccine production and swift delivery

- Creating the "EU-FAB" project
- Mapping of potential bottlenecks of vaccine production
- Exploring use of flexible production models
- Providing capacity support
- Facilitate technology transfer
- APAs

## EUCO meeting – 25 February



*“It is our task to detect and tackle as soon as possible, as fast as possible **variants**. That is the reason why we launched last week the HERA Incubator to build up our response to variants to stay ahead of the curve.*

*What we need to do is to **support the rapid detection** of new variants through cooperation with Member States, notably by increasing the sequencing.*

*For that, the European Commission is providing **EUR 200 million** because we have to detect on a regular basis how the virus is spreading and whether the variants are spreading and how they are developing.”*

# Action Area 1 – HERA Incubator

## Swift detection of SARS-CoV-2 variants

Current thinking on the activities to be launched and funded:

1. **Whole genome sequencing**
2. **Specialised RT-PCR**
3. **Wastewater monitoring**
  - Development of a web-based platform
  - Support MS capacities and infrastructures
  - Support EU Neighbourhood countries

# 1. Whole genome sequencing

- **Expand the ECDC Framework contract**
  - Ensure representative sampling
  - Increase sequencing quantity: 15.000/week (at least until Summer time)
- **Transport of viral samples for sequencing**
  - Strengthen logistics (internal transport from peripheral labs to central MS labs)
- **Development of MS capacities**
  - Addressing needs for materials and equipment for sequencing
- **Support to labs and standardisation of sequencing procedures**
  - Capacity building (training, setting standards, supplies)
- **Support to neighbourhood countries**

## 2. Specialised RT-PCR assays

- This approach can substantially increase the capacity of identifying known VOCs thus potentially reducing the volume of required sequences and enabling the timely implementation of response measures such as contact tracing
- However:
  - Specialised RT-PCR assays are only useful for the specific situation in the pandemic that we are in right now (not for longer-term objectives)
  - The overall strain on RT-PCR diagnostics due to the pandemic will probably subside once vaccines take full effect
- Funds could be used for:
  - Validation of such assays (RTD)
  - Swift deployment in case of demand

# What are your needs?

- ... in context of **whole genome sequencing?**
  - Where do you need support? Increasing sequencing capacities through ECDC FWC? Strengthening logistics/transport of vials? Other aspects?
  - What about longer-term objectives? How can we ensure that a sustainable sequencing framework is put in place (for post-pandemic public health surveillance purposes? Support for training, capacity building, setting standards, supplies, etc.? Other aspects?
- ... in context of **specialized RT-PCR assays?**
  - Would it be helpful to have EU funds ready for swift deployment of assays in case of demand?
  - Are there other aspects where EU support is needed?

Thank you

