

Health Emergency Preparedness and Response Authority

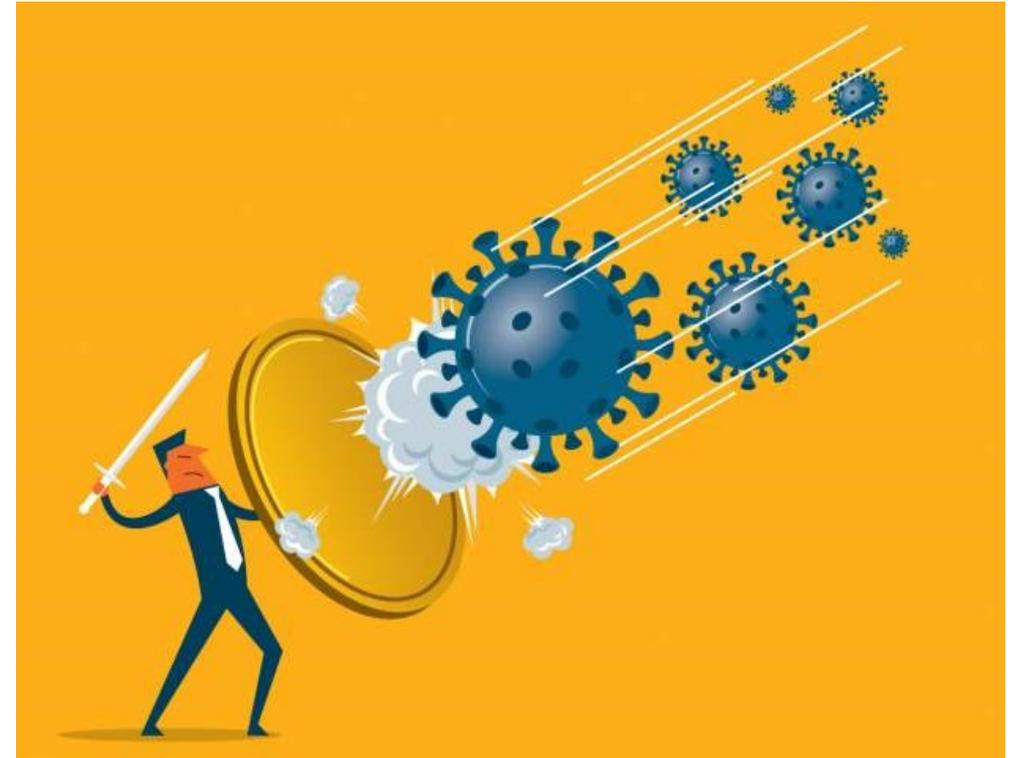
HERA

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European Commission
DG SANTE

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

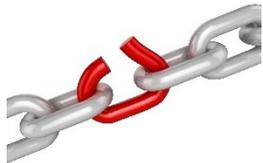


<https://www.eppgroup.eu/newsroom/publications/a-european-solidarity-pact-against-the-coronavirus-pandemic>

Building a European Health Union

Early lessons learned from COVID-19

- 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



Building blocks of the European Health Union (11 Nov 2020), set of proposals to:

- strengthen the EU's health security framework, **including AMR under Decision 1082**
- reinforce the crisis preparedness and response role of key EU agencies – ECDC and EMA
- **outline for the Health Emergency Preparedness and Response Authority (HERA)**

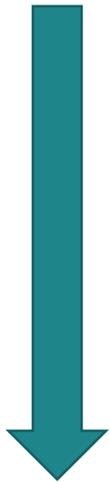


25 Nov 2020 – EU Pharmaceutical Strategy

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

HERA Incubator



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

Further Preparation of HERA: 'Preparatory Actions'

AMR

- Why intervene?
 - Antimicrobial resistance is responsible for at least 33,000 deaths per year and at least EUR 1.5 billion in additional health care costs.
 - “Initial research, looking only at part of the impact of AMR, shows that a continued rise in resistance by 2050 would lead to 10 million people dying every year and a reduction of 2% to 3.5% in Gross Domestic Product (GDP). It would cost the world up to 100 trillion USD.”(O’Neill report).
 - WHO declared AMR one of the top 10 global public health threats facing humanity
 - Commissioner Kyriakides’ mission letter defined the need to tackle the rise of highly infectious diseases, highlighting need to focus on implementation of the EU’s One Health Action Plan against AMR
 - EU Pharmaceutical strategy & EU Health Union

AMR

- What will the HERA preparatory action do?

- 2 Service contracts

1) Technological review of the latest AMR medical countermeasures, gap analysis and needs assessment in the Member States
Technological review of the latest AMR MCMs

→ 1 million euros

2) Feasibility study on AMR stockpiling to analyse the medical countermeasures most needed and means to stockpiling

→ 1 million euros

- Work should initiate in 2021 and completion in 2022
- HaDEA/SANTE 'Info day' including HERA 'preparatory actions' scheduled for mid-July