



# Health emergency preparedness and response authority (HERA)

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HERA-02 – Intelligence gathering, analysis and innovation

*4 July 2023  
PROMIS Summer school*

# European Health Union

- New EU legislative framework to improve EU-level protection, prevention, preparedness and response against serious cross-border threat to healths

## European Health Security Framework – crisis preparedness and response

**Regulation on serious  
cross-border threats to  
health**

**Reinforced mandate of  
EMA**

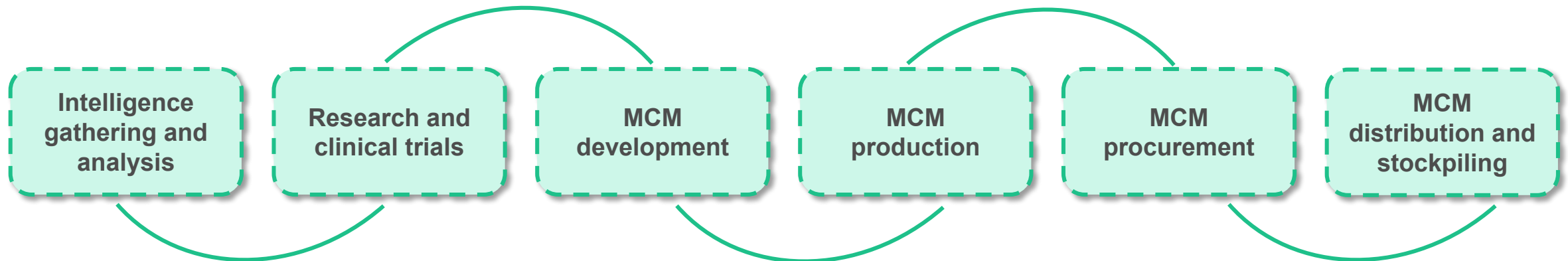
**Reinforced mandate of  
ECDC**

**Creation of HERA and  
Emergency Framework  
Regulation**

# HERA mission

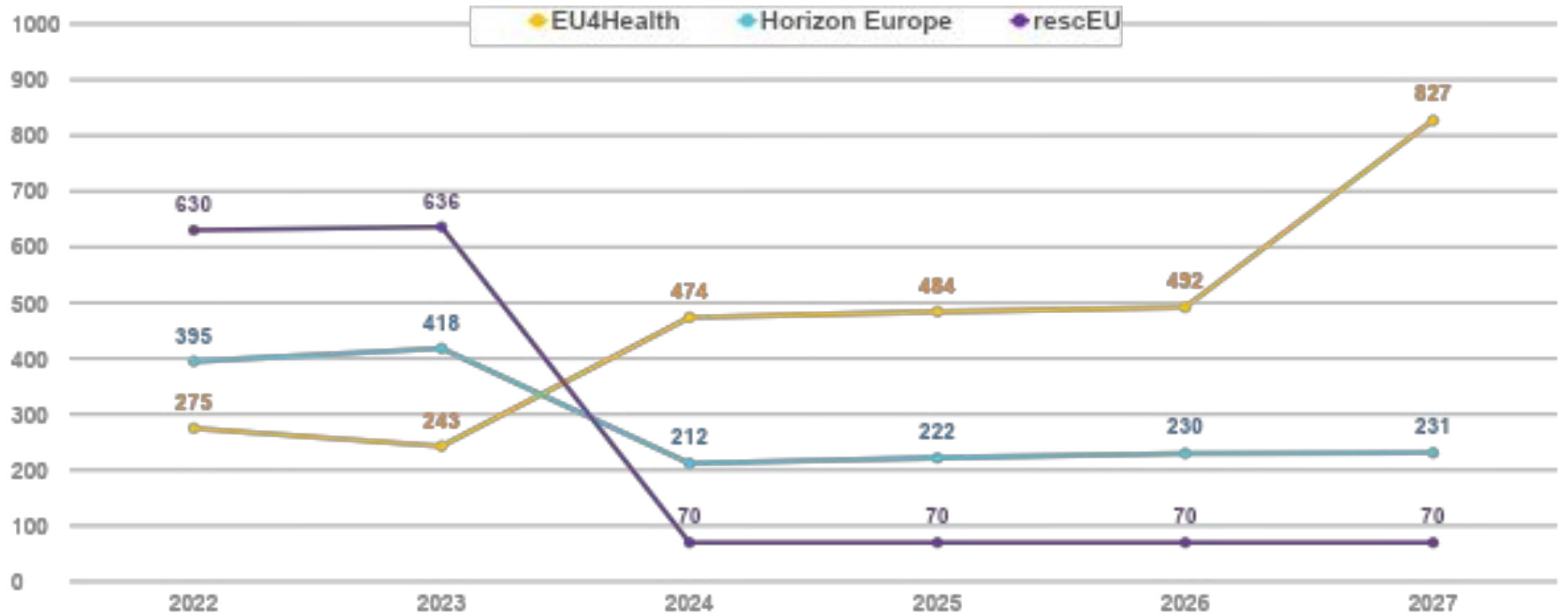
- ❖ **When?** Created on 16 September 2021
- ❖ **Budget:** EUR 6 billion over 2022-2027
- ❖ **Mission:** strengthening Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the availability of and access to key **medical countermeasures** (MCM) by looking at the **whole value chain**

*= medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health*



**CROSS-SECTOR, MULTI-ACTOR AND INTERNATIONAL COLLABORATION**

# HERA budget : 3 EU funding programmes





# HERA priority threats

- ◆ **3 serious cross-border health threats to prepare against**
  - ◆ ‘All hazards approach’
  - ◆ Consultation with EU Agencies, international partners experts and HERA Board members
  - ◆ Aligned with Member States’ priorities



Chemical, biological,  
radiological and nuclear



Antimicrobial  
Resistance

# HERA main tasks

## PREPAREDNESS MODE



Threat assessments and intelligence gathering



Advanced research and development capacities for MCMs



Production capacities for MCMs



Procurement, stockpiling, and distribution capacities for MCMs



Knowledge and capacity build

## INTERNATIONAL COLLABORATION

## CRISIS MODE



Monitoring of crisis-relevant MCMs



Procurement, purchase and manufacturing of crisis-relevant MCMs



Activation of EU FAB facilities



Activation of emergency research and innovation plans



Establishment of an inventory of crisis-relevant MCM production facilities



Activation of emergency funding

# The 5 flagship initiatives for 2023

Budget

EUR ~1.3 billion

- EU4Health (EUR 243 million)
- Horizon Europe (EUR 418 million)
- UCPM/rescEU (EUR 636 million)

5 flagships



Establish ATHINA – the health threats and medical countermeasures intelligence **IT platform**



Support the R&D of medical countermeasures - **Vaccines 2.0 Strategy, broad spectrum of antivirals, innovative diagnostics and PPE**



Reserve manufacturing capabilities for vaccines with **EU FAB**



Establish **HERA INVEST**, a new financing tool for medical countermeasures



Establish **strategic stockpiles** of medical countermeasures

**Expanding collaborations** with third countries, relevant stakeholders, innovators, international organisations

# Threat assessment and intelligence gathering relevant to medical countermeasures



# Threat assessment and intelligence gathering

## Threat prioritisation exercise

Agents with  
pandemic  
potential

CBRN

AMR

List of critical  
medical countermeasures,  
*template for data collection*  
*mapping of supply and demand*

ATHINA : IT platform for  
intelligence gathering  
*epidemic & MCM intelligence;*  
EIOS *technological and*  
*community development*

Support for **interoperability**  
between Member States' IT  
platforms and HERA IT tool

## Establishment of the HERA laboratory network (DURABLE)

Support to Member States' **capacity  
building for WGS and PCR**

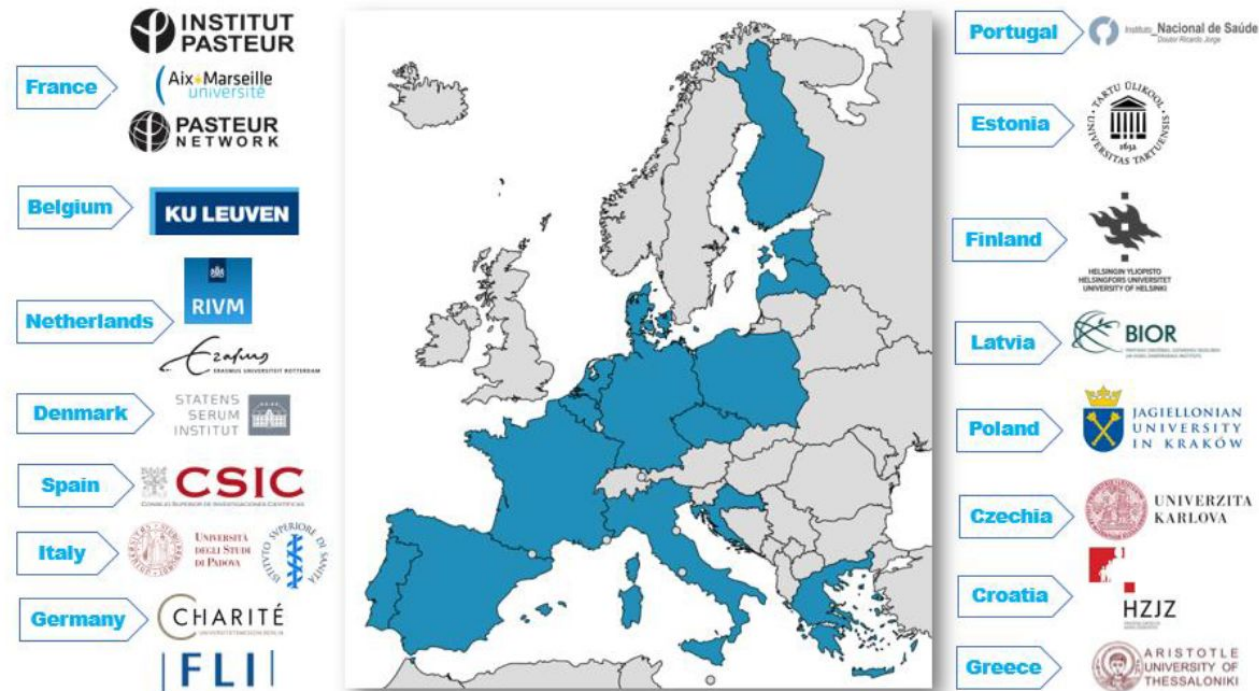
Strengthening of **wastewater  
surveillance  
beyond COVID-19**

Studies : AMR ; **innovative  
diagnostic solutions**



# HERA Laboratory network - DURABLE

- EU4Health-funded project – € 25 Mio | 48 months
- “Delivering a Unified Research Alliance of Biomedical and public health Laboratories against Epidemics”
- Consortium of 20 biomedical and research institutes led by “Institut Pasteur”
- **Experimental capacities** for the detection and characterisation of pathogens relevant to inform MCM preparedness
- Strong **global reach**

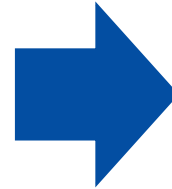


# Support to Member States' capacity building for WGS and PCR

- EU4Health-funded projects, HERA-ECDC collaboration
- Expand capacity for genomic sequencing **in the EU** (EUR 39 M – 21 grants to MS)
  - Enhancing whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities **beyond** COVID-19
- Expand capacity for genomic sequencing **in Africa** (EUR 10 M)
  - WHO AFRO for laboratory capacities (lab capacities, human resources, data management), WHO Hub for epidemics (information system architecture, analytics, training)
  - Pathogen genomic initiative (Africa CDC) extension beyond COVID-19

# Joint Action on wastewater surveillance

1. Definition of wastewater surveillance strategies
2. Definition of technical procedures
3. Establishment of governance framework
4. Communication
5. Sustainability and financial viability of the wastewater surveillance



- Increased surveillance capacities **including metagenomics** for (pandemic) preparedness and control of **infectious diseases and AMR**
- Integration of wastewater surveillance systems into other types of routine surveillance focusing on complementarities
- Extended implemented systems for monitoring and early warning for future outbreaks of other health threats.

This joint action will be complemented by establishment of an **EU sentinel system** that will leverage samples from MS to get early signals around EU. Discussion with global partners to establish a **global consortium on wastewater monitoring** and establish a global sentinel system

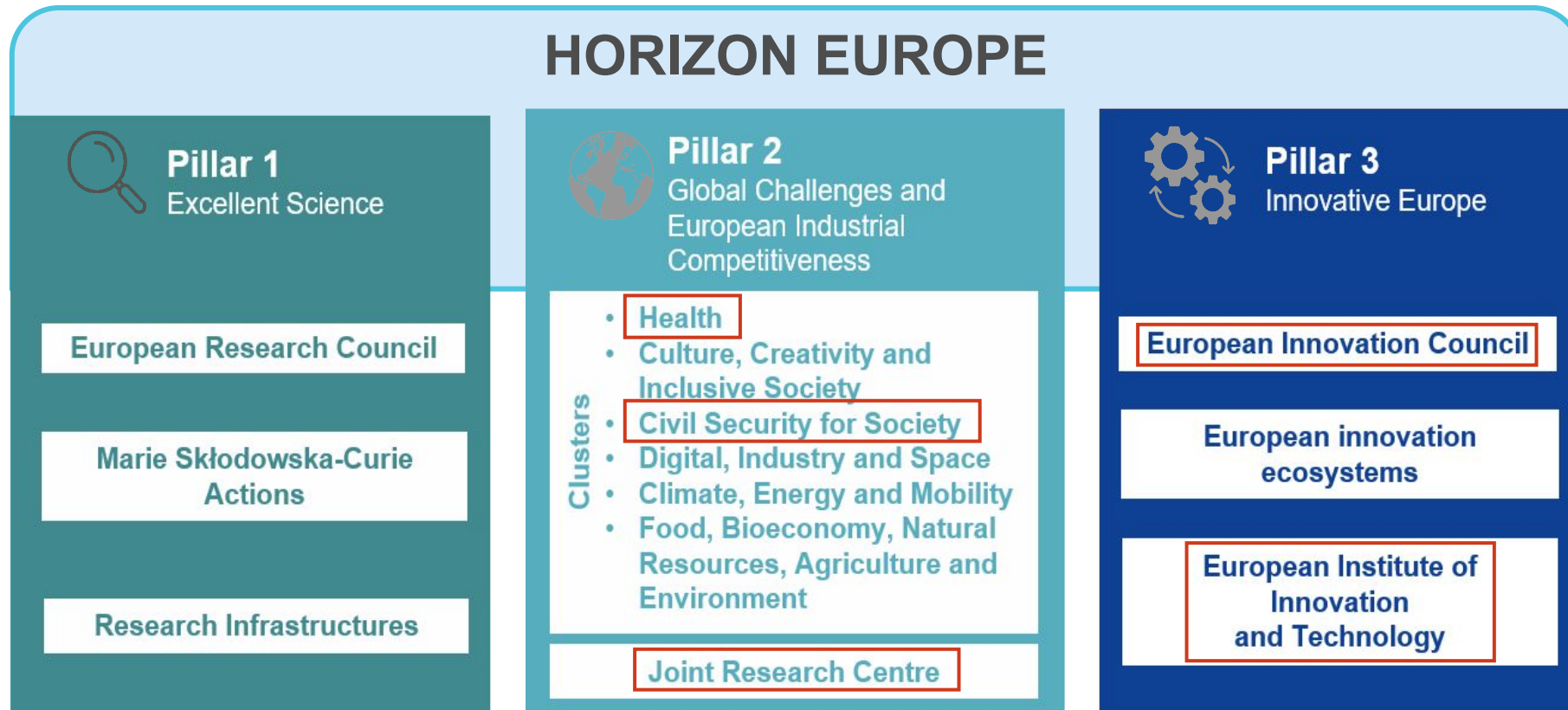
# Advanced research and development for medical countermeasures



# Research, Innovation and Development

## Aim:

promoting pandemic preparedness research to support the development of safe and effective medical countermeasures for serious cross-border health threats







# R&I actions for 2023

HERA budget: EUR 384 m

## Health Cluster:

- ❖ Broad spectrum **anti-viral therapeutics** for infectious diseases with epidemic potential: EUR 50 m
- ❖ Sustaining established coordination mechanisms for European **adaptive platform trials** and/or for **cohort networks**: EUR 3 m
- ❖ Understanding **vaccine-induced immunity**: EUR 20 m
- ❖ **Immunogenicity** of viral proteins of viruses with epidemic and pandemic potential: EUR 50 m
- ❖ **In vitro diagnostic devices** to tackle cross-border health threats: EUR 40 m
- ❖ Contribution to **CEPI**: EUR 70 m
- ❖ **Emergency funds**: EUR 1 m

Coalition for Epidemic Preparedness Innovations

## Civil Security for Society Cluster:

- ❖ Operability and standardisation in response to **biological toxin incidents**: EUR 6 m
- ❖ Internationally coordinated networking of training centres for the validation and testing of **CBRN-Explosive tools and technologies** in case of incidents: EUR 4 m

## European Innovation Council (EIC):

- ❖ EIC Accelerator Challenge: evidence-based technologies to realise pandemic-resilient economies, enable social interaction and support mental health: EUR 75 m

## Institutionalised partnerships:

- ❖ **EDCTP3**: EUR 40,15 m
- ❖ **IHI**: EUR 30,21 m

European and Developing Countries Clinical Trials Partnership

Innovative Health Initiative

# Promoting innovation for MCM against AMR

- **Priority signaling** - funding WHO for maintaining global priority pathogens lists & pipeline analyses ; establishing own EU mapping and prioritizing
- Contribute to and coordinate **push funding** for AMR MCM (One Health AMR partnership for early development, support to translational research, ECRAID, GARDP)
- Design and implement **EU multi country pull incentives**
- The EU Commission proposed a comprehensive toolbox for pull incentives for antimicrobials
  - Indirect pull incentives in the EU pharma legislation in form of Transferable data protection vouchers
  - Direct pull incentives implemented through HERA (milestone payment, market entry reward, revenue guarantee) in articulation with vouchers



# Manufacturing, procurement, stockpiling, distribution of medical countermeasures

# Some HERA's tools to ensure MCM availability

## Joint procurement

e.g. for COVID therapeutics and new Dynamic Purchasing System pilot for PPE

## ATHINA

*HERA IT platform*

to monitor the availability and accessibility of critical medical countermeasures



## Capacity reservations mechanism

e.g. EU FAB; study looking at flexible manufacturing options for vaccines and therapeutics in the EU

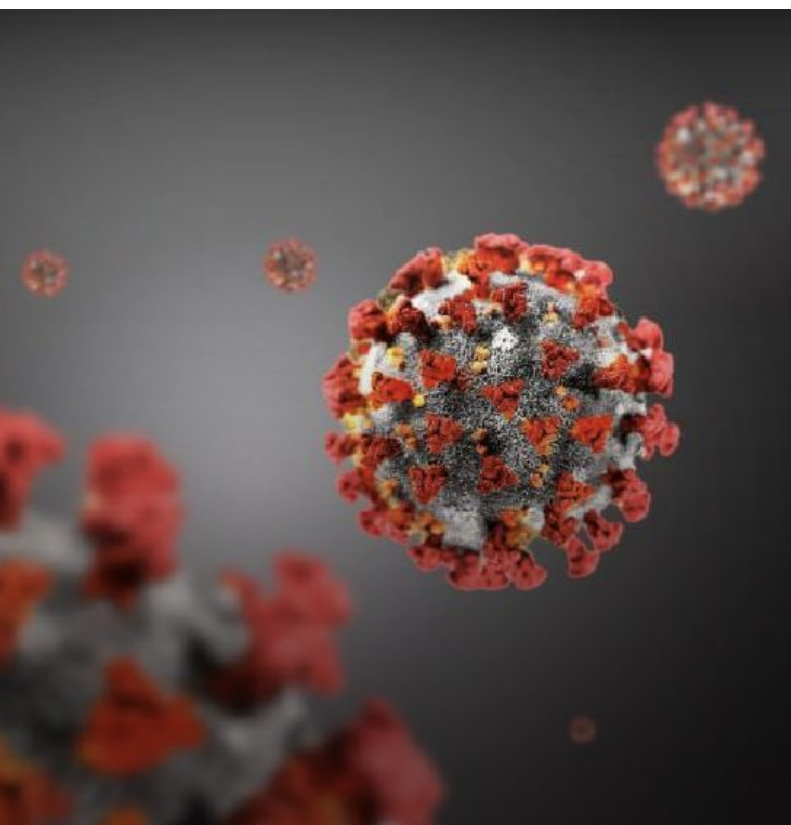
## Joint Industrial Cooperation Forum

to identify and find solutions to supply chain bottlenecks and vulnerabilities for medical countermeasures and raw materials

# HERA response

## RESPONSE

## COVID-19



**7 Advance Purchase Agreements**

signed with **7 vaccine manufacturers**

**3 Purchase Agreements**

**over 1.4 billion doses**

of **COVID-19 vaccines** (incl. adapted vaccines) already distributed to EU/EEA

**over 512 million doses**

of COVID-19 vaccines **shared with third countries** via COVAX and bilaterally

**around 6 million doses**

of **COVID-19 therapeutics** secured through 3 Joint Procurement framework contracts

# HERA response

## RESPONSE

### Other crises



#### Ukraine

Support to the **donation of medicines and vaccines** for medical needs with DG ECHO

#### MPOX

Mobilisation of funds for **clinical trials and cohort studies** (EUR 17 million)

Purchase and donation to Member States of 334,540 doses of **vaccines**

Purchase of 10,000 treatment courses of **tecovirimat**

Secured a framework contract for the purchase of up to 2,000,000 doses of vaccines on behalf of 14 countries

#### Sudan Ebolavirus

Mobilisation of funds to support clinical trials for **appropriate MCMs** (EUR 5 million)

Thank you