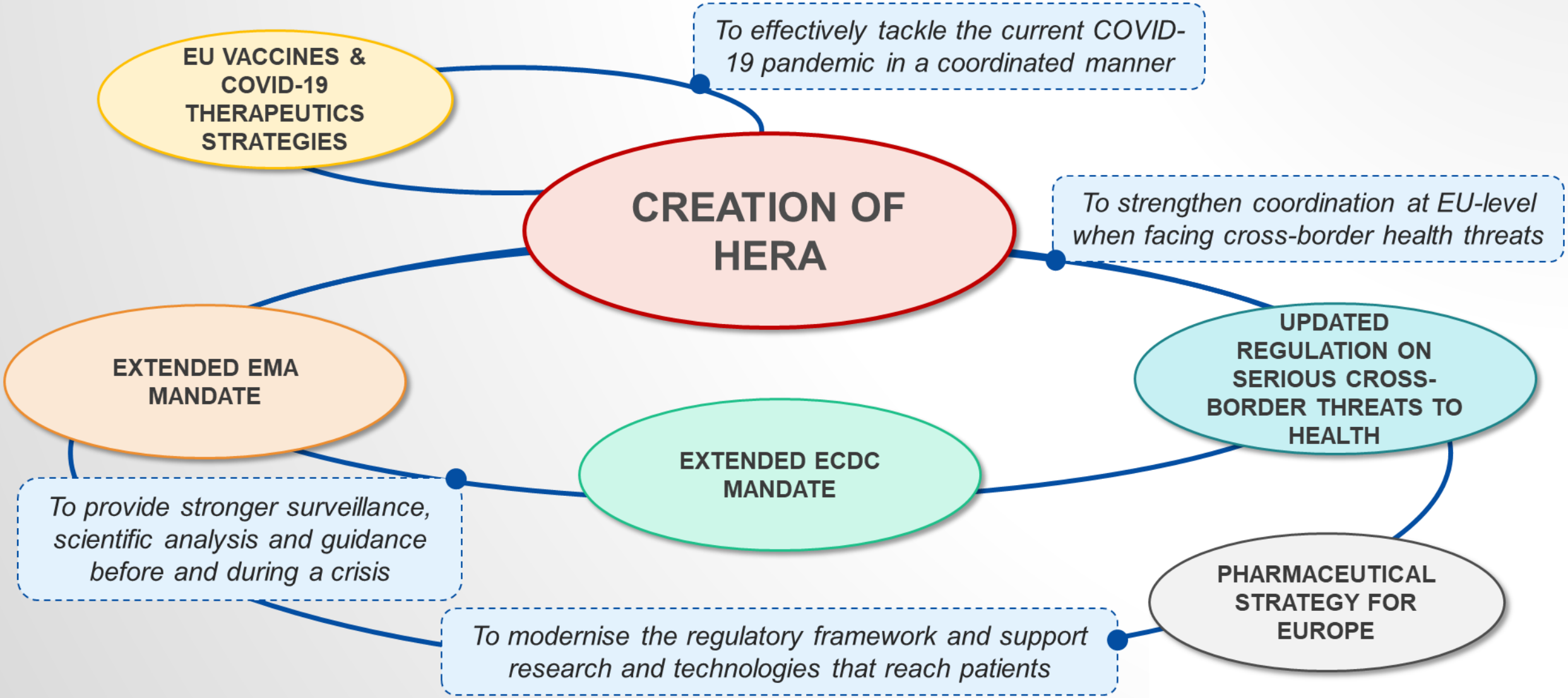
# The role of HERA in pandemic preparedness and response

# Improving European Union Preparedness

## Based on the COVID-19 experience, what needs to be improved?

1. Better **surveillance** and more interoperable and complete **data**
2. Clearer and more coordinated **scientific advice**
3. Further and more constant **investment** in preparedness
4. Availably of **emergency tools** to be activated rapidly
5. **Coordinated measures** at EU and between MS
6. Reinforced public-private partnerships and stronger **supply chains**
7. A pan-European approach to **clinical research**
8. Increased investment in resilience and **healthcare systems**
9. Pandemic preparedness **partnerships with key international partners**
10. Coordinated approach to **misinformation and disinformation**

# European Health Union



# The creation of HERA and its 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*

Intelligence gathering and analysis → Research and clinical trials → MCM development → MCM production → MCM procurement → MCM distribution and stockpiling

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

# HERA and its 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 skills capacity building

## 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

**International collaboration**

# HERA and its international dimension

❖ **Aim:** reinforcing **global health security** while ensuring availability and access to relevant MCMs

Reinforce **global surveillance and intelligence gathering**, threat detection, characterisation and assessment

Address **international supply chain bottlenecks** and expand global production capacity

Provide **access for low- and middle-income countries** to EU-funded or EU-procured MCMs

Build **expertise, develop local manufacturing and distribution capacities** in LMICs for relevant MCMs

bilateral cooperation with **third countries**

bilateral cooperation with relevant **international organisations**

engagement in **multilateral fora**

# Intelligence gathering and threat assessment

## PREPAREDNESS

## Threat assessments and intelligence gathering

**Threat prioritisation exercise**

- Agents with pandemic potential
- CBRN
- AMR

**Preliminary list of critical medical countermeasures**

Establishment of the **HERA laboratory network (DURABLE)**

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

Preparatory actions for the **IT platform for intelligence gathering** combining epidemic and MCM intelligence

Assessment of gaps and needs for the institutionalisation of **wastewater surveillance beyond COVID-19**

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

Study on market research on **innovative diagnostic solutions**

# DURABLE – HERA laboratory network

- 20 leading public health and academic institutions – led by Institut Pasteur
- Provides relevant data and information on **pathogen characterisation and MCM development** to enable effective policy decision-making, examples:
    - *How **damaging/lethal** is a pathogen to humans and animals?*
    - *Can a given pathogen **transmit via droplets**?*
    - *What outbreak **dynamics** can we **predict** based on lab-generated data?*
    - *What **diagnostics** are necessary for an optimal **emergency response**?*
- EUR 25 million over 48 months

European Commission

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

- Expand capacity for genomic sequencing **in the EU** (EUR 39 m)
  - 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 Initative (Africa CDC) extension beyond COVID-19

# Wastewater surveillance

- Joint Action **EU-WISH** (EUR 15 m)
  - Aiming at define wastewater surveillance strategies and technical procedures in order to institutionalise wastewater surveillance and strengthen national capacities
- Establishment of a **EU sentinel system** (EUR 2.5 m)
  - Collaboration with JRC for to allow for the testing of samples through centralised partner laboratories for a number of serious cross-border health threats
- Establishment of a **global consortium** for wastewater surveillance
  - Recent workshop in collaboration with several international stakeholders and Member States, to be followed by an International Conference in November 2023

Joint Research Centre JRC

World Health Organization

EIOS EPIDEMIC INTELLIGENCE FROM OPEN SOURCES

threat

MCM

Member States

Grants to MS for interoperability

ATHINA

EU-Databases and networks

ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

HERA-Labs

industry

## Identifying health threats requiring MCM response

- Identifying priority threats to prepare against
- Early identification of health events relevant for HERA
- Assessing and reporting on required MCM response

## Analysing and mapping MCM capacities, supply and demand

- Mapping of MCM on the market and in development
- Identification of gaps and needs
- Mapping and monitoring of supply chain, manufacturing and stockpiling capacities

## Modelling and forecasting

- Modelling MCM demand and needs, effect of MCM response
- Long-term horizon scanning / foresight

**MCM development, authorisation, manufacturing, purchasing, stockpiling deployment…**

# Research, Innovation and Development

+ DEFIS – MCMs for CBRNs

# EU4Health

**HERA budget: EUR 243 m**

- Use of research results to facilitate the uptake, scaling-up and deployment of health innovations
- Support to innovation, development and access to MCMs
- Priorities identified for 2023:

| | | |
|---|---|---|
| Threat identification and prioritisation | Support to epidemic intelligence | Support rapid and efficient clinical development |
| Support to product development, access and/or uptake | Actions supporting emergency actions including clinical trials | Pilot HERA fund |

# Pandemic Preparedness Partnership

| Pillar | Work package | Main objective |
|---|---|---|
| Pillar 1 – building the partnership | WP1: Management and secretariat | To ensure efficient coordination and management of the CSA and serve as secretariat of the future Partnership |
| | WP2: Development of partnership proposal | To draft the Partnership proposal and the future governance |
| Pillar 2 - SRIA | WP3: Research and Health | To identify needs, research gaps, obstacles and weaknesses in the development of an appropriate preparedness and response to pandemics |
| | WP4: Health & Biotech Research and Innovation | To identify key emerging health technologies and biotechnologies enabling innovative solutions to the main challenges of pandemic preparedness |
| Pillar 3 – synergies and engagement | WP5: Cooperation with the Commission including HERA | To establish coordination and collaboration with HERA to ensure complementarity and maximise R&I impact |
| | WP6: Synergies and EU-international alignment | To promote synergies and actively engage with relevant stakeholders and initiatives at EU and international level in the area of pandemic preparedness |
| | WP7: Dissemination, exploitation and communication | To increase the visibility of BE READY |

# Thank you!

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