



HERA HEALTH EMERGENCY
PREPAREDNESS AND
RESPONSE AUTHORITY
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FUNDING AND OPPORTUNITIES IN THE FRAMEWORK OF AWP 2024

Date: 17 April 2024



European Health Union

to improve EU-level protection, prevention, preparedness and response against human health hazard

European Health Security Framework – crisis preparedness and response

Regulation on serious cross-border threats to health

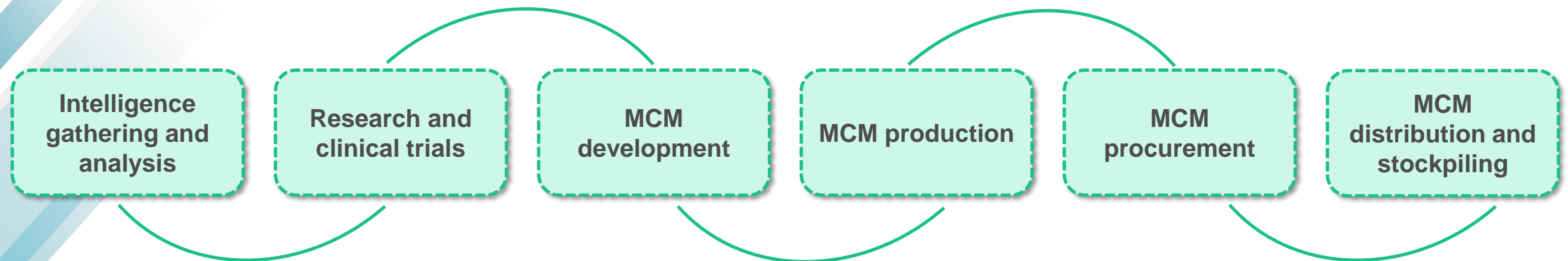
Reinforced mandate of EMA

Reinforced mandate of ECDC

**Creation of HERA and
Emergency Framework
Regulation**

- 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

EU4HEALTH programme

- Annual programmes for EU action in the field of **health**, incl. crisis preparedness and health resilience
- Total budget 2021-2027: EUR 5.3 billion
- HERA budget 2022-2027: **EUR 2.8 billion**
- Operating through **grants and procurement**

HORIZON EUROPE programme

- Biannual work programmes for EU action on **research and innovation** (esp. early-stage research)
- Total budget 2021-2027: EUR 95.5 billion
- HERA budget 2022-2027: **EUR 1.7 billion**
- Operating through **grants** (mostly open calls)

rescEU / EU Civil Protection Mechanism

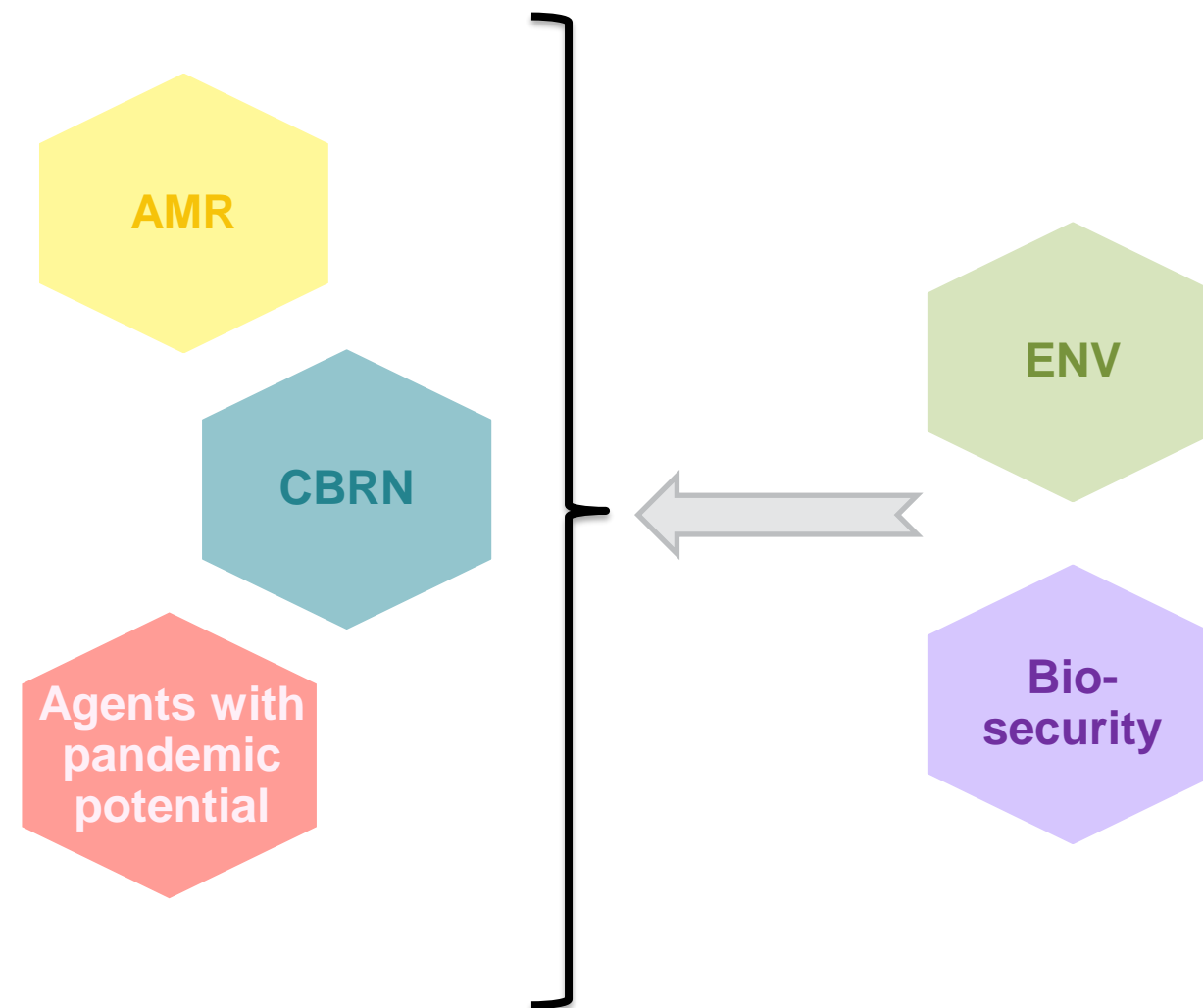
- Multiannual work programmes for EU action to **protect citizens from disasters** and **manage emerging risks**
- Total budget 2021-2027: EUR 3.32 billion
- HERA budget 2022-2027: **EUR 1.26 billion**
- Operating through **grants and procurement**

- ❖ Identification of overarching health threat categories



- ❖ Prioritisation of MCMs

- ❖ Catalogue of 500+ threat-specific/horizontal MCMs
- ❖ Lists of priority MCMs for:
 - ❖ Stockpiling
 - ❖ Monitoring the supply chain
 - ❖ R&D support activities



LABORATORY CAPACITIES

- ❖ Strengthening **sequencing** capacities in EU Member States and Africa
- ❖ Strengthening of environmental monitoring including **wastewater-based surveillance**
- ❖ Multidisciplinary consortium of world-class basic and translational research and biomedical institutes (**DURABLE**)

DIGITAL CAPACITIES

- ❖ **ATHINA**
- ❖ Epidemic intelligence from open sources (**EIOS**)
- ❖ Partnerships with WHO, Africa CDC to support digitalisation of health data
- ❖ Support for interoperability between MS' IT platforms and HERA IT tool (**EU-HIP**)

- ❖ HERA promotes advanced research and innovation to develop effective, safe and affordable countermeasures:
 - ❖ Academic research through **Horizon Europe**
 - ❖ Late-stage innovation through **EU4Health**
- ❖ Partnerships with CEPI, EIB (HERA Invest), US BARDA, FIND, GARDP,...

HERA Invest: leveraging public funding to incentivise private investment

- **EUR 100 million top-up** to EIB funding programme “**InvestEU**”
- InvestEU = venture loans at preferential interest rates, usually ranging between EUR 20-40 million (those need to be repaid)
- When investing, EIB covers a **maximum of 50% of investment costs**, i.e. public or private investors will need to finance the other half of the investment
- HERA Invest is de-risking private investment: in case of failure, HERA Invest would cover losses first, before other investors

EU FAB

- ❖ Guarantee access to vaccines production lines in the event of a health emergency
- ❖ EUR 160 million / year to keep **manufacturing capacities** for different vaccine types operational
- ❖ Capacity to produce in the EU up to **325 million vaccines per year**

JOINT PROCUREMENT

- ❖ Procurement by the Commission on behalf of the participant countries order and purchase a given MCM
- ❖ **37 participating countries:** all EU and EEA countries, the UK, Albania, Montenegro, North Macedonia, Serbia and Bosnia and Herzegovina, as well as Kosovo
- ❖ Current active contracts: e.g. Pandemic Influenza vaccines, C-19 therapeutics, C-19 vaccines, mpox vaccine, etc.

STOCKPILING

- ❖ **EUR 1.2 billion** to establish stockpiles of medical countermeasures under the rescEU programme
- ❖ The stockpiles serve as a **safety net** and can be accessed by countries through the Union Civil Protection Mechanism if an event overwhelms the national capacity to respond
- ❖ Specific focus on pathogens with high pandemic potential, antimicrobial resistance and **CBRN countermeasures**

BOOSTING SECURITY OF SUPPLY WITH A CRITICAL MEDICINES ALLIANCE

- ❖ On 24 October 2023, the Commission published a Communication on *Addressing medicine shortages in the EU*

Key objectives

- **Prevent and mitigate critical shortages** at EU level in a coordinated manner
- Assure security of supply for the most **critical medicines** for EU citizens and health systems



Three-step action plan

- 1) Immediate actions for this winter 2023-24
- 2) Mitigate critical shortages for next winter
- 3) Improve structural capacity for the mid-term

CRITICAL MEDICINES ALLIANCE

- ❖ set up to develop recommendations for industrial policy and for coordinated actions against shortages of medicines
- ❖ The Alliance will focus on a limited number of **critical medicines** with the highest risk of shortages and impact on healthcare systems, resulting from the vulnerability analysis of supply chains bottlenecks
- ❖ The Alliance will gather Member States' representatives of health industrial policy, industry, patients, health professionals, actors of the supply chain and the Commission to **identify key challenges** and propose solutions to address such vulnerabilities

THE DIFFERENCE BETWEEN PROCUREMENT AND GRANTS

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- Grants are an EU contribution:
 - carrying out an action, helping to achieve Union policy objective, e. g. **action grants**
 - financing the functioning of a body pursuing objectives part of Union policy, e. g. **operating grants**

HERA GRANT OPPORTUNITIES UNDER EU4HEALTH AWP 2024

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- **Indicative call opening: 23 May**
- **Deadline: 5 September**
- **Additional info session for detailed questions**
- **2024 EU4Health annual work programme**
 - CP-g-24-10 Call for proposals on the European Hub for vaccine development
 - CP-g-24-11 Call for proposals for next-generation respiratory protection
 - CP-g-24-12 Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production
 - CP-g-24-105 Call for proposals to support the development of novel antivirals
 - CP-g-24-13 Direct grants to Member States' authorities: Support to the development of sustainable, forward-looking national and Union stockpiling strategies

CALL FOR PROPOSALS ON THE EUROPEAN HUB FOR VACCINE DEVELOPMENT

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- Indicative budget: **102 million**
- Manufacturing capacities should be paired with the best R&D capacities for vaccines
- To establish a comprehensive European Hub for vaccine development
- **Applicants targeted: consortia comprised of vaccine developers involving both publicly funded and industrial entities.**

CALL FOR PROPOSALS FOR NEXT-GENERATION RESPIRATORY PROTECTION

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- Indicative budget: **20 million**
- Fundamental role of respiratory protection is saving lives in health emergencies
- Critical in the stages of outbreaks, before vaccines and therapeutics available
- the development of next-generation respiratory PPE
- Applicants propose a detailed plan to design, prototype, validate and CE mark innovative, cost-effective and sustainable next-generation respirators
- Feasibility for rapid production scale-up in health emergency
- **Applicants targeted: private and public bodies active and with relevant expertise**

CALL FOR PROPOSALS TO SUPPORT INNOVATIVE MANUFACTURING TECHNOLOGIES AND PROCESSES IN THE UNION FOR MEDICINES PRODUCTION

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- Indicative budget: **17 million**
- improved manufacturing technologies and processes that allow for a more effective, less expensive, easier to scale-up, more sustainable and cleaner production of medicines
- Innovations to allow rapid scale-up of Union pharmaceutical production in health emergencies or to prevent critical shortages
- **Applicants targeted: economic operators and applied research stakeholders who can develop these technologies and processes.**

CALL FOR PROPOSALS TO SUPPORT THE DEVELOPMENT OF NOVEL ANTIVIRALS

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- Indicative budget: **10 million**
 - Biggest pandemic threat
 - crucial to mitigating virus transmission
 - This action aims to diversify and advance the pipeline of broad-spectrum antiviral candidates.
-
- **Applicants targeted: private, academic and public bodies active and in the field of innovation and with adequate expertise in drug development**

SUPPORT TO THE DEVELOPMENT OF SUSTAINABLE, FORWARD- LOOKING NATIONAL AND UNION STOCKPILING STRATEGIES

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- Indicative budget: **10 million**
- Direct grant with MS nominating the relevant authorities
- 2024 Strategy on stockpiling of MCMs
- MSs should align the stockpiling strategies
- Different national stockpiling strategies
- **Applicants targeted: Member States' authorities**

“Procurement’ means the acquisition by means of a contract of works, **supplies or services** and the acquisition or rental of land, buildings or other immovable property, by one or more contracting authorities from economic operators chosen by those contracting authorities”

Financial Regulation

“The objective of public procurement is to **increase the choice of potential contractors to public bodies**, thereby allowing achieving a most economically advantageous tender, while at the same time developing **market opportunities** for companies

Vademecum of public procurement

Open procedures

Competitive procedures

Negotiated procedures

Direct contracts

Framework Contracts

Requests for Service



Intelligence gathering



Innovation



Purchase of MCMs (Emergency)



Availability and Accessibility

HERA PROCUREMENT OPPORTUNITIES UNDER EU4HEALTH AWP 2023

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CP-p-23-14 Support to the Commission on identifying priority threats and medical countermeasures

...This call for tenders aims at supporting the intelligence gathering and horizon scanning function of HERA in particular through providing essential information that can be used as an input by HERA to carry out its activities in the field of intelligence gathering on cross-border health threats and medical countermeasures...

Multiple Framework Contracts in cascade for support services to the European Commission on gathering intelligence on priority threats and medical countermeasures

HADEA/2024/OP/0009-PIN

EUR 15 000 000

TED: [37/2024 00107375-2024](#)



CP-p-23-16 - Support innovation and access to antimicrobials

...Action to support innovation and access to tuberculosis paediatric formulations...

The subject of this call for tenders is to conclude a service contract for purchasing services to speed up availability and access in the EU to age-appropriate anti-tuberculosis medicines. To achieve this goal, the selected contractor will need to carry out clinical and/or non-clinical services for finalising the development and submitting the market authorization for the concerned products for their commercialisation in the EU...

Speed-up the development, availability and access to anti-tuberculosis medicines for children

HADEA/2023/OP/0052

EUR 5 000 000

TED: [47/2024 00137572-2024](#)



CP-p-23-20 Continuous support to existing wastewater activities including the establishment of an EU sentinel system

...this action should cover testing of wastewater samples on the request of the Commission through: PCR analysis of SARS-CoV-2, PCR analysis of influenza and other pathogens, Next Generation Sequencing, with the specification of the platform to be used and Samples management (controlled deliveries from collection points to the analytical facilities)..

TBD

HERA PROCUREMENT OPPORTUNITIES UNDER EU4HEALTH AWP 2023

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- CP-p-24-14 Ever-warm facilities (EU FAB) for vaccines production – the Commission's Health Emergency Preparedness and Response Authority (HERA)
- *CP-p-24-19 Purchase, innovation and deployment of medical countermeasures in emergency situations (HERA)*



- CP-p-24-15 Support to speed up the development of access to and/or uptake of medical countermeasures including critical medicines (HERA)
- CP-p-24-16 Support innovation, supply capacity and access to critical medicines and antimicrobials (HERA)



- CP-p-24-17 Support to the Commission on gathering intelligence on priority threats and medical countermeasures
- CP-p-24-18 Establishment of a global wastewater sentinel system (HERA)
- CP-p-24-90 HERA's training and exercise programme for management of medical countermeasures

THANK YOU!