HERA: what’s new in pandemic preparedness?

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HERA –
what’s new for the next pandemic

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The aim remains in place

- need to further invest in our EU-wide and global coordination for health preparedness and response

- protecting public health while keeping society and economy open and resilient
Better health preparedness for the EU

**EU VACCINES & COVID-19 THERAPEUTICS STRATEGIES**
- To effectively tackle the current COVID-19 pandemic in a coordinated manner

**CREATION OF HERA**
- To strengthen coordination at EU-level when facing cross-border health threats

**EXTENDED EMA MANDATE**
- To provide stronger surveillance, scientific analysis and guidance before and during a crisis

**EXTENDED ECDC MANDATE**
- To modernise the regulatory framework and support research and technologies that reach patients

**UPDATED REGULATION ON SERIOUS CROSS-BORDER THREATS TO HEALTH**

**PHARMACEUTICAL STRATEGY FOR EUROPE**
- To effectively tackle the current COVID-19 pandemic in a coordinated manner
Mission

- Addressing **serious cross-border health threats** in an all-threat approach (e.g. biological, chemical, environmental threats of natural, accidental or intentional origin)
- Addressing vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of **medical countermeasures**

**Medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health, such as: vaccines, antibiotics, antitoxins, chemical antidotes, therapeutics, diagnostics, medical equipment and supplies**

- Contributing to reinforcing the **global health emergency preparedness and response** architecture
Budget and staff

Operational budget: **EUR 6bn** from MFF 2021-2027

EU4Health, Horizon Europe, UCPM/rescEU

2022 Total budget: EUR 1.3 billion

Staff: up to **120 FTEs**

Crisis operations: **Emergency Support Instrument**
Some lessons learned and translation into action

1. Contribute to better surveillance and epidemic intelligence
2. Ensure better coordination on EU level
3. Ensure better coordination internationally
4. Reinforce resilient supply chains for critical equipment and medicines
5. Ensure that sufficient and agile manufacturing capacities for vaccines are kept operational
6. Speed up significantly the approval of clinical trials of vaccines and therapeutics
7. Establish flexible financing facilities to boost pertinent research projects and enable swift and targeted procurement
8. Invest in health care systems, public health functions and capacities by providing key funding opportunities
9. Invest in health security preparedness and resilient health and social protection systems
HERA main tasks

- **Preparedness mode:**
  - Threat assessments and intelligence gathering
  - Advanced research and development capacities for medical countermeasures
  - Production capacities for medical countermeasures
  - Procurement, stockpiling, and distribution capacities for medical countermeasures
  - Knowledge and skills capacity building

- **Crisis mode:**
  - Monitoring of crisis-relevant countermeasures
  - Procurement, purchase and manufacturing of crisis-relevant medical countermeasures
  - Activation of EU FAB facilities
  - Activation of emergency research and innovation plans
  - Establishment of an inventory of crisis-relevant medical countermeasures production facilities
  - Activation of emergency funding

International engagement to ensure availability and access of critical medical countermeasures both for the Union and for third countries
Threat assessments and intelligence gathering

- Develop methodologies and IT platforms for:
  - intelligence gathering and analysis
  - anticipatory threat assessment
  - mapping medical countermeasures and raw material availability (incl. stockpiling) and production capacity

- Regular prioritisation exercise to identify **three high-impact threats** to be addressed in the course of 2022 and relative list of MCM

- Extend epidemic surveillance support programmes

- Draft and present the EU’s State of Preparedness Report
Promoting advanced R&D of medical countermeasures and related technologies

- Support the development of next generation vaccines and the pre-clinical development of the next generation of immunotherapies
- Horizon scanning for potential medical countermeasures and innovative technologies against emerging pathogens
- Gap analysis and needs assessment for AMR medical countermeasures
- Contribution to CEPI and EDCTP3 (clinical trials)
- Create a common strategic EU research and innovation agenda for pandemic preparedness
International dimension

- Close collaboration with global partners to address international supply chain bottlenecks and expanding global production capacity.

- Conduct a gap analysis and develop methodologies for data collection to reinforce global surveillance.

- Support the functioning of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R).

- Support manufacturing capacity for LMIC countries.
Addressing market challenges and failures and boosting the Union’s open strategic autonomy

- Facilitate the development of a prototype for a mapping platform on COVID-19 therapeutics (and key raw materials)
- Implement a flexible (multi technology) EU manufacturing and innovation capacity (EU FAB) for medical countermeasures
- Rapidly reorganise production process chains in case of need
- Close interplay with IPCEI Health (esp. on AMR and emerging health threats)
- Series of matchmaking events for medical countermeasure manufacturers
- Close cooperation with civil society stakeholders (Civil Society Cooperation Forum) and with industry (Joint Industrial Cooperation Forum)
Ensuring medical countermeasures provision

- Promote wider use of **procurement and reservation contracts**, for instance for vaccines against infectious disease threats such as pandemic influenza vaccines and COVID-19 vaccines and therapeutics.

- Develop a **methodology to map antimicrobials and APIs** most needed within the EU and assess the gaps in access.

- Develop an **IT platform for stockpiling management**.

- Establish a **list of medical and CBRN countermeasures** for stockpiling and deployment.
Clinical trials

- **EU-wide networks for clinical trials**
  - Work with EMA to create a long-term and large-scale EU platform for multi-centre clinical trials and corresponding data platforms
  - On COVID-19: EU-wide networks for vaccines (VACCELERATE) and for therapeutics

- **Third programme of the European & Developing Countries Clinical Trials Partnership (EDCTP3)**
  - The EU–Africa Global Health Partnership will support international research partnerships accelerating the clinical evaluation of drugs, vaccines and diagnostics for key infectious diseases affecting sub-Saharan Africa, as well as novel approaches for surveillance and control of emerging/re-emerging infections
Identify major knowledge gaps in the field of medical countermeasures and provide trainings accordingly.

Assist all Member States in organising a national/regional assessment process of public procurement practices in the health sector with all relevant stakeholders.

**TASK 5**

**Strengthening knowledge and skills**

**EUR 5 million**
Conclusion: HERA

a streamlined, sustainable, institutional approach to

- conduct health threat assessments and intelligence gathering
- promote advanced R&D of medical countermeasures and related technologies
- address market challenges and failures and boost the Union’s open strategic autonomy
- ensure the provision of medical countermeasures
- and strengthen knowledge and skills

→ Better prepared for next pandemic?