

Policy implications of the COVID-19 pandemic in Europe

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Broad spectrum antiviral workshop 22-23, November 2022

European response to the COVID-19 pandemic

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

- robust **preparedness** planning and a more integrated **surveillance**
- a better capacity for accurate risk assessment and targeted **response**
- **joint procurement** of medical countermeasures
- EU level **coordination** for future cross-border health threats

Reinforced mandate of EMA

Reinforced mandate of ECDC

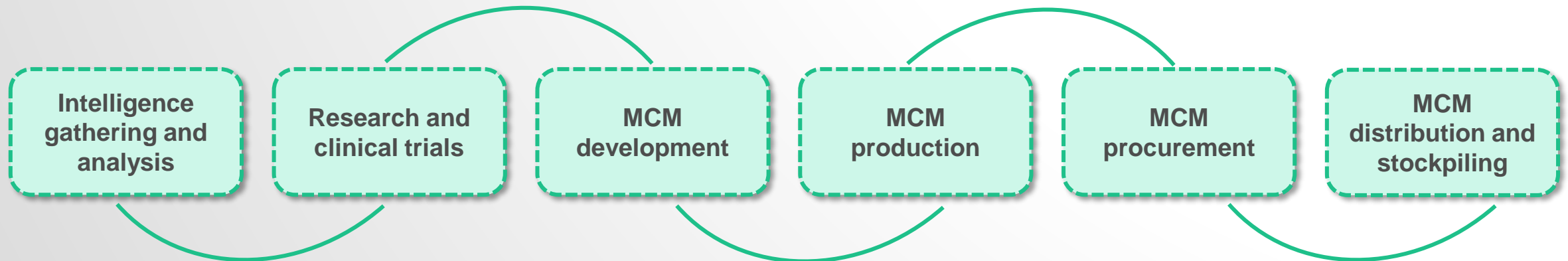
Creation of HERA and Emergency Framework Regulation

- establishment of the **Health Crisis Board** to coordinate the supply of and access to MCMs
- **extra powers** to HERA to set up monitoring mechanisms and enable the procurement and purchase of MCMs
- activation of EU FAB, emergency research and innovation plans, extra funding

The creation of HERA and its mandate

- ❖ **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 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 **European and 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

Boost MCM **availability** through **research and development**

Provide **access for LMICs** 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



Significance of broad spectrum antivirals in crisis preparedness and response

Broad spectrum antivirals

have the potential to act on several viral groups or families



potential to be used in crisis preparedness and response to several threats,
including emerging or unknown threats



following an **initial approval for a specific indication**,

the expected **versatility** and **stability** would facilitate **sustainable production** due
to the potentially broad interest for **procurement** for **use** and **strategic stockpiling**

Significance of broad spectrum antivirals in crisis preparedness and response

❖ Following an initial authorisation for a specific indication, **rapid deployment** of authorised products even for new indications, because of the:

- ✓ ideally, large-scale **production, access**
- ✓ well-known **safety profile**
- ✓ established **pharmacovigilance** system
- ✓ **existing clinical experience/RWD** with the product, including relevant **off-label uses**
- ✓ **regulatory familiarity** with the product file



e.g. use of remdesivir in SUDV Ebola – it has a marketing authorisation in Uganda for COVID-19 and there are no shortages

Enablers of the use of broad spectrum antivirals in crisis response

- ❖ rapid implementation of **clinical trials as part of the crisis response** and for **clinical data** collection for **future outbreaks**



e.g. pandemic trial platform helped the rapid submission/launching of MOSAIC trial for additional safety and efficacy data collection on Tecovirimat for monkeypox

- ❖ **flexible funding tools for clinical trials** and **planned coordinated procurements** for sustainable production via a cost-sharing model

- ❖ **early and coordinated engagement** between developers and regulators/funders



reinforced mandate of EMA, HERA to ensure availability and access of MCMs including their development

- ❖ **coordinated European and inter-regional/global actions**



e.g. EMA Emergency Task Force mandated to provide advice on cooperation// EU-RESPONSE therapeutic clinical trial platform// HERA core task to reinforce global health security

Proposed HERA strategy to identify antivirals for R&D funding

A vertical stack of four downward-pointing chevrons on the left side of the slide. The top chevron is light blue, the second is white, the third is medium blue, and the bottom is dark blue. They are arranged in a descending order of color and size, pointing towards the bottom of the slide.

Threat prioritization (concluded)

Largely RNA virus families with pandemic potential (Arena-, Bunya-, Corona-, Flavi-, Filo-, Orthomyxo-Paramyxo-, Picorna-, Pox- and Togaviridae viral families)

MCM prioritization for innovation (ongoing)

Strategic selection based on (amongst others) on availability (in Europe but also globally) and Member States' needs in cooperation with Member States and EMA

MCM selection for funding (planned)

Potential HERA funding mechanisms for antiviral R&D

EU4HEALTH programme

In 2023:

- CP-p-23-15 Support to speed up the development of, access to and/or uptake of innovative technologies and critical medicines
- CP-CA-23-25 Support to improve enhance intelligence gathering and clinical trials* in Africa - Strengthening Health Emergency Preparedness and Response
- CP- CA-23-09 Blending under the Thematic Innovation financial product implemented by the European Investment Bank under the InvestEU Fund (HERA)

HORIZON EUROPE programme

In 2023:

- HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential

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**

* e.g. clinical vaccine/treatment trials integrated in the crisis response to the ongoing SUDV outbreak in Uganda

creation of HERA

to strengthen Europe and global **resilience** against public health emergencies by ensuring access and availability of **key medical countermeasures**, including through innovation



Challenge: rapidly developing threat specific vaccines or treatments against every high priority pathogens



Possible solution: **broad spectrum of antivirals** as versatile, stable, affordable treatment option

what needs to be done?

- **mutualise European and global efforts and pool resources across competences to:**

support **research** from early phases through seminal clinical trials and regulatory submission to post-authorisation clinical data collection

identify needs to address **high-priority threats** where there is no available treatment option

facilitate coordinated and planned **purchase** of authorised products to de-risk innovation and support sustainable production

How to engage With HERA?

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Thank you!

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