

Health Security in the EU



COVID-19 lessons learned and looking
ahead to ensure a stronger EU Health
Security Framework

Emergency Framework Regulation

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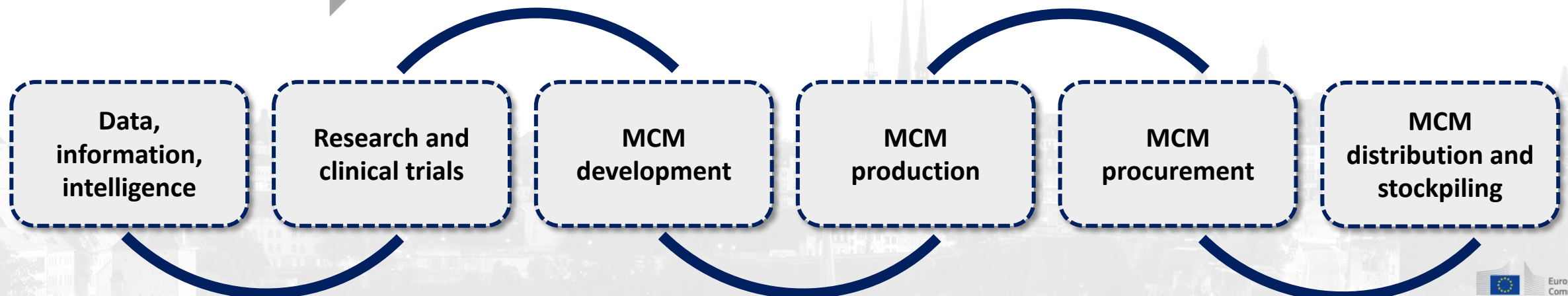


The creation of HERA and its mission

HERA was created on 16 September 2021 through a Communication introducing HERA and a Commission internal decision, accompanied by a proposal on an **Emergency Framework Regulation**

Overarching mission

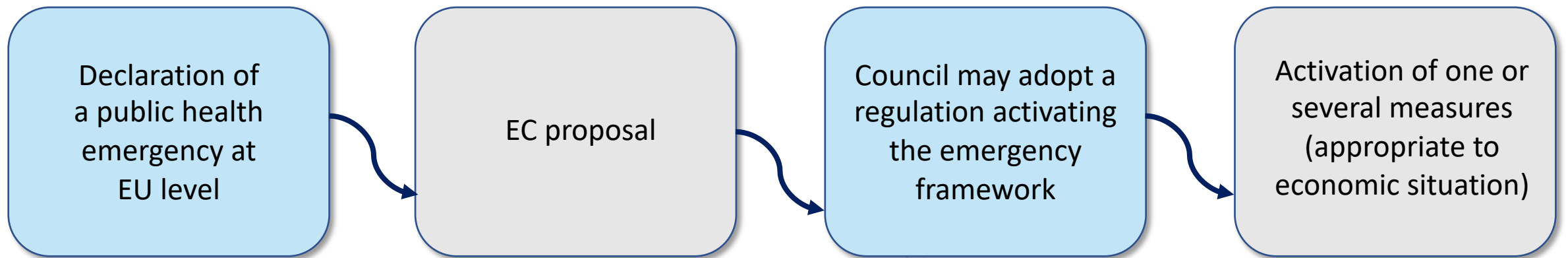
strengthening Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the availability of and access to key **medical countermeasures** (MCM) by looking at the **whole value chain**



Synergies and differences

	HERA	EMA	ECDC
MANDATE	supporting R&D, manufacturing, procurement, and distribution of medical countermeasures for health emergencies	ensuring appropriate evaluation, supervision and pharmacovigilance of medicinal products	identifying, assessing and communicating emerging health threats to human health posed by infectious diseases
MAIN OUTCOME	availability and access to appropriate medical countermeasures	safe, efficacious and of quality medical countermeasures	regularly updated information about emerging threats and associated risks
IMPROVED EU HEALTH SECURITY FRAMEWORK			

Activation of the Emergency Framework



Emergency Framework

Establishment of a
Health Crisis Board

(Articles 5 & 6)

Monitoring, procurement and
purchase of crisis-relevant
medical countermeasures
and crisis-relevant raw
materials

(Articles 7 & 8)

Activation of emergency
research and innovations
plans, incl. the use of Union-
wide clinical trial networks
and data-sharing platforms

(Article 9)

Measures concerning the
production, availability and
supply of crisis-relevant
MCMs, incl. the establishment
of an inventory of crisis-
relevant MCMs

(Articles 10, 11 & 12)

Emergency union funding

(Article 13)

HERA's mandate in Preparedness mode vs Crisis mode under the Emergency Framework


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

INTERNATIONAL COLLABORATION

CRISIS MODE under the Emergency Framework



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

Health Crisis Board



Central structure for guiding decision-making on medical countermeasures

Co-chaired by the Commission and the Member State holding the rotating presidency of the Council of the EU



Composed by Commission and MS representatives. EMA, ECDC and EP as observers

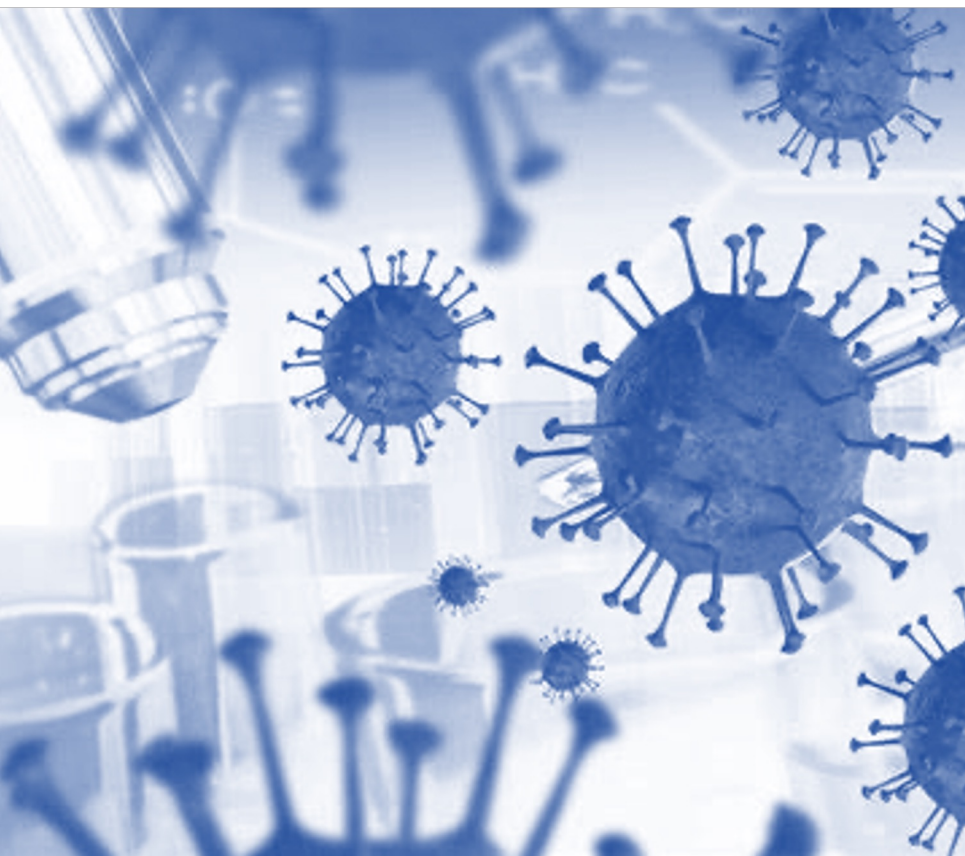
EMA and ECDC Directors to provide regular updates on the monitoring of MCMs, including their demand and supply, and on epidemiological surveillance



HERA to provide a comprehensive overview of the needed crisis-relevant MCMs as well as the Union's capacity to meet those needs

HERA's progress in 2022

Threat assessments and intelligence gathering



Identification of **three high-impact threats** to be addressed and draw up of the relative **list of MCMs**

Support Member States' **capacity building for WGS and PCR** (39 million)

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

Establishment of the **HERA laboratory network** (25 million)

HERA's progress in 2022

Promoting advanced R&D for MCMs



Direct grant to CEPI for **vaccines R&D** (35 million)

Grants to develop **next-generation vaccines** (40 million)

Grants to support research on **pathogen X** (10 million)

Support to **clinical trials** in sub-Saharan Africa via the **EDCPT3** (20 million)
and for AMR via the **GARDP** initiative (5 million)

Study on market research on **innovative diagnostic solutions** (1 million)

HERA's progress in 2022

Ensuring availability of MCMs



Establishment of the **ever-warm network EU FAB** for vaccines production (160 million)

Study on **flexible manufacturing** for MCMs (3 million)

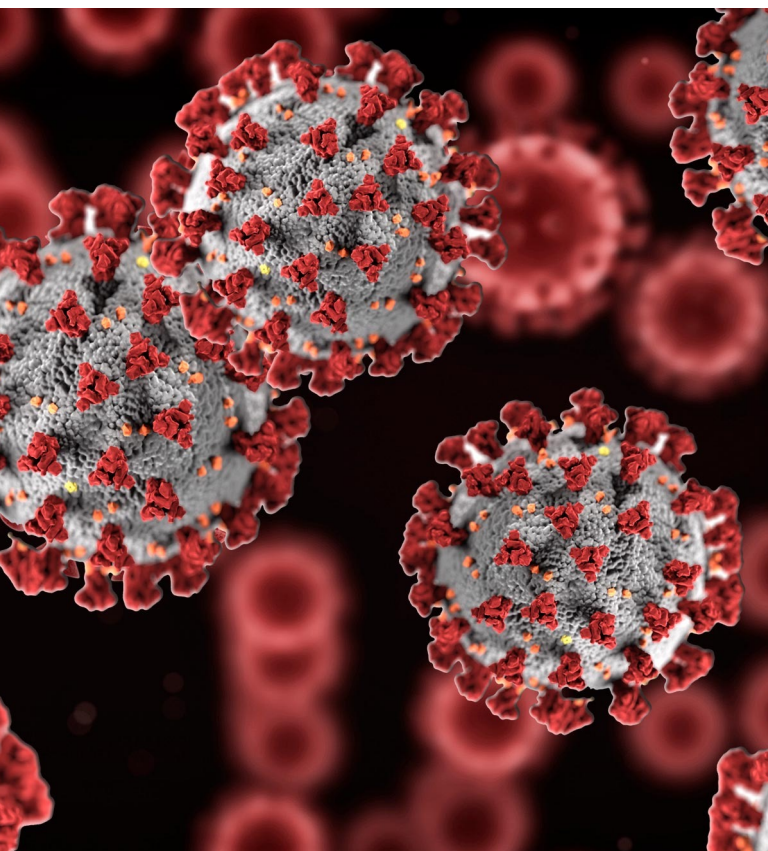
Studies to identify options to bring innovative **AMR MCMs** on the market and for stockpiling (2 million)

Support to the **SECURE** initiative to expand sustainable access to antibiotics (1 million)

Establishment of urgently needed **CBRN stockpiles** (up to 1.2 billion)

HERA's progress in 2022

Response to COVID-19



7 Advance Purchase Agreements

signed with **7 vaccine manufacturers**

3 Purchase Agreements

over 1.2 billion doses

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

over 482 million doses

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

2.5 million doses

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

HERA's progress in 2022

Response to other crises



Ukraine

Stockpile of priority items for medical needs and private donations scheme with DG ECHO

Monkeypox

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**

Sudan Ebolavirus

Ongoing discussion with international partners to support R&D for **appropriate MCMs**

Collaborations to improve preparedness

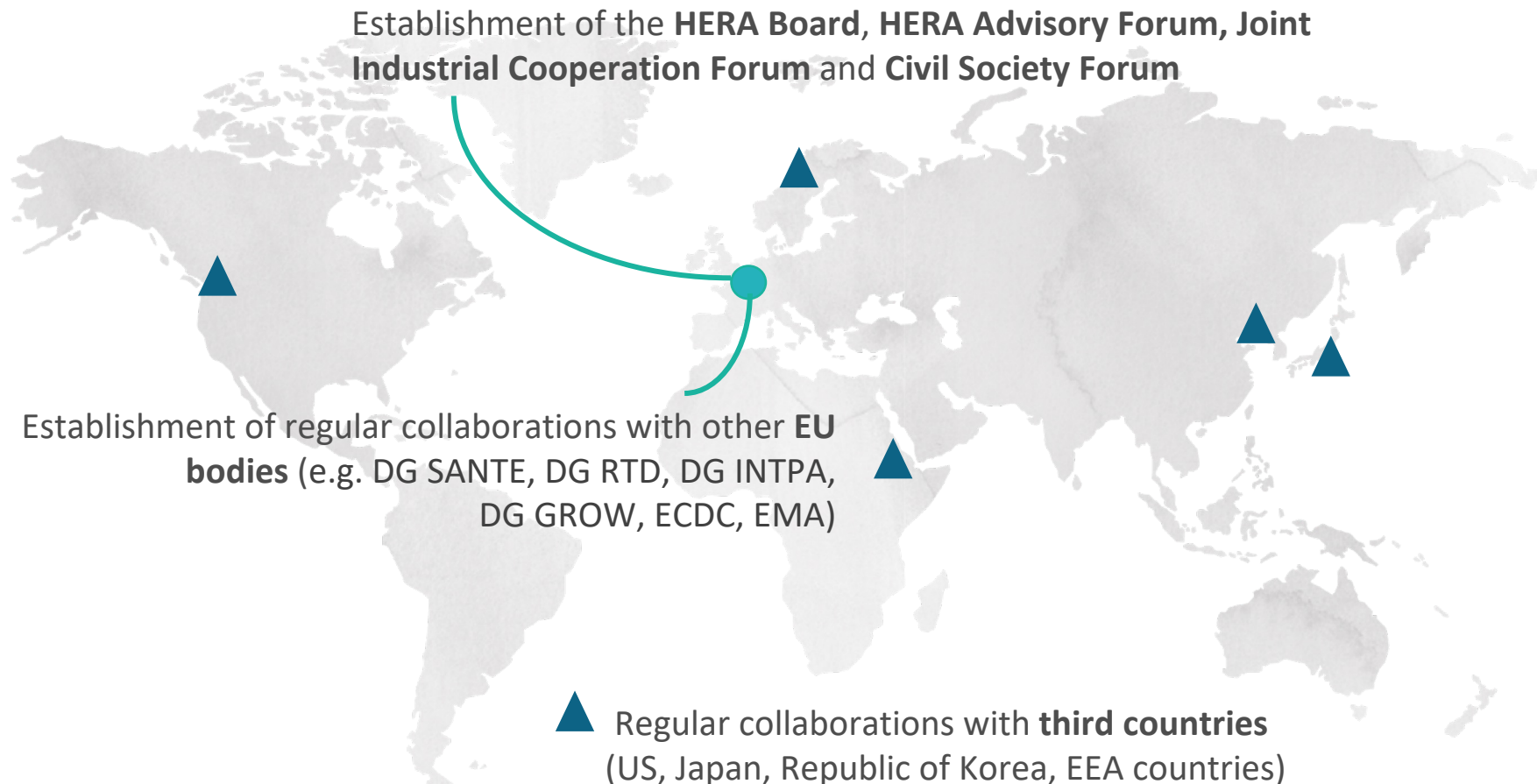
Regular collaboration with international partners:

BARDA, Gates Foundation, WHO Hub, CEPI, Africa CDC

Planned support to WHO:

intelligence gathering, sequencing capacities, AMR, manufacturing scale-up

Engagement in multilateral fora such as **G7** and **G20**



Thank you