



HERA – MCM preparedness and response

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IANPHI, Oslo, 8.10.25

Past PHEICS / Epidemics / Pandemics

..... SARS 2003

MERS 2008

Swine Flu 2010

Ebola 2014/15/18

Zika 2016

Covid -19

mpox 2022/24

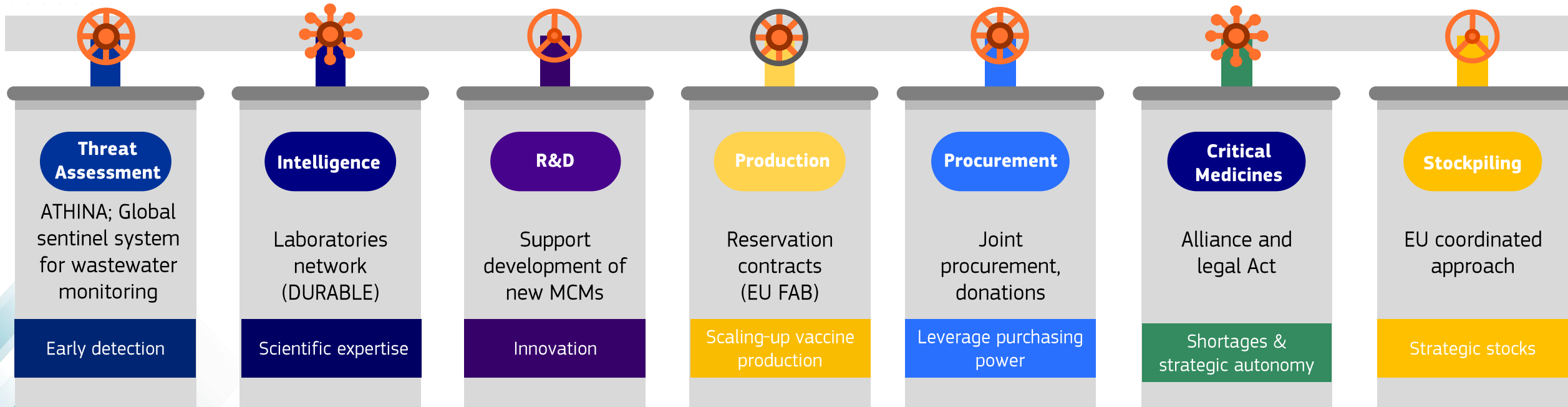
disease X

.....



- **Based on initial response shortcomings for C-19, the EU health security framework was strengthened in 2020 and 2021**
 - Establishment of HERA
 - Serious cross-border threats to health Regulation ('SCBTHR')
 - Strengthened mandates of EMA and ECDC
 - Emergency Framework Regulation ('EFR')
- **HERA's tasks in responding to health crises in the area of MCMs**
 - Ensuring swift access and availability of relevant MCMs to respond to health threats
 - Strengthening Health Security coordination in the area of MCMs
- **Emergency Framework Regulation**
 - Laying down a set of measures to be implemented by Commission upon activation by the Council

End-to-end approach for MCMs from R&D to stockpiling



- research through Horizon Europe (1.7B €) and late-stage innovation through EU4Health (2.1B €)
- Partnerships with third countries and organisations, e.g. CEPI, EIB (HERA Invest), US BARDA, GARDP,...



HERA R&D funding

2023 – 24 R&D spending: ca. EUR 1bn

Early-stage research (Horizon Europe)

- ❖ **Basic MCM research:** EUR 120M
 - ❖ Immunogenicity
 - ❖ Host-pathogen interactions
 - ❖ Vaccine-induced immunity
- ❖ Broad spectrum **antivirals:** EUR 50 m
- ❖ **Innovative diagnostics:** EUR 40 m

Innovation support to external organisations

- ❖ **CEPI:** EUR 70m on vaccines
- ❖ **EDCTP3:** LMIC clinical trials for e.g. Ebola
- ❖ **GARDP:** EUR 20m on antibiotics development
- ❖ **FIND:** EUR 11.6m on diagnostic development

Late-stage development

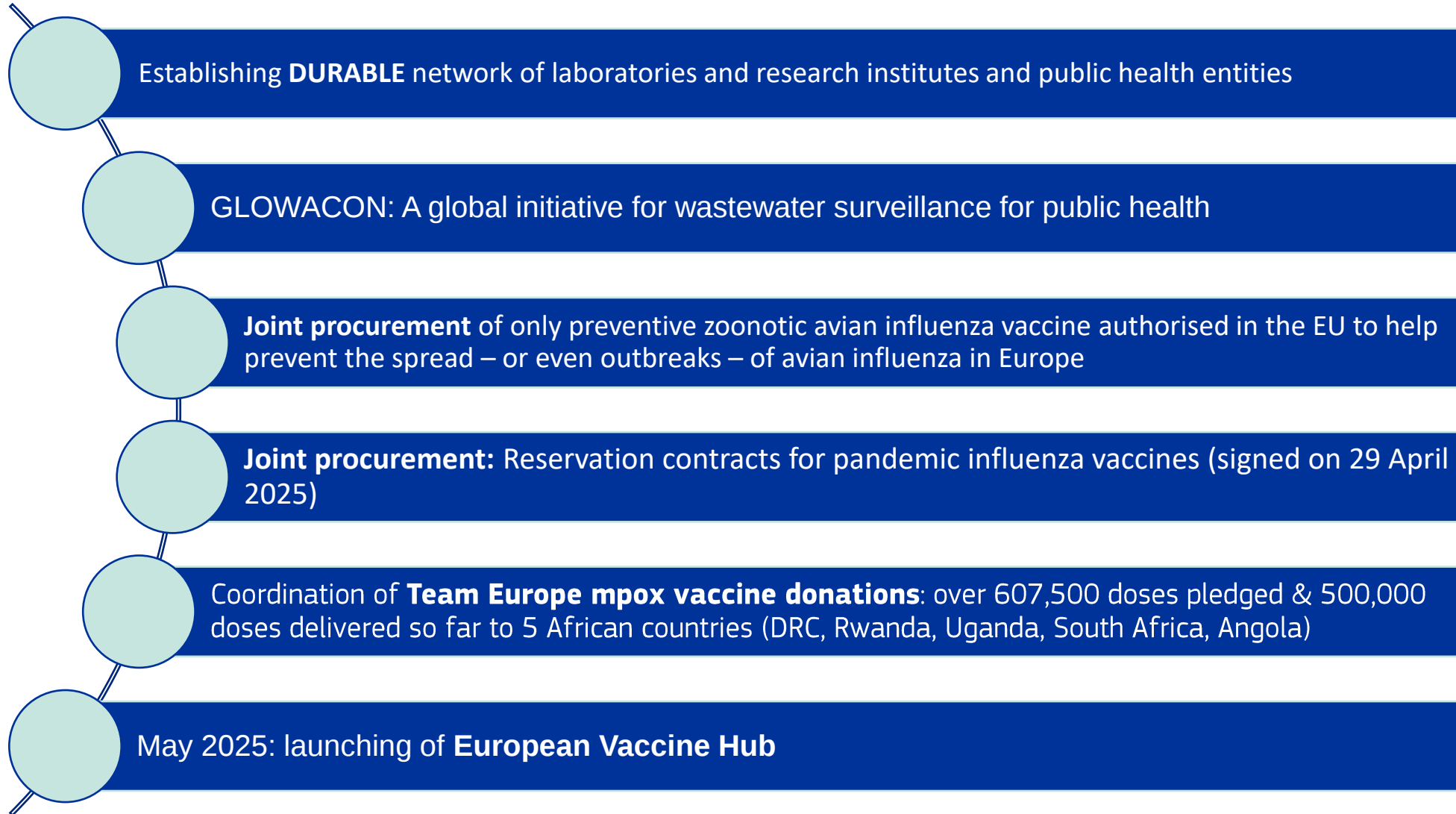
- ❖ Speeding up development of MCMs: EUR 120m
 - ❖ Phase II clinical trials for antivirals, vaccines
 - ❖ BARDA-collaboration for diagnostics
- ❖ EIC Accelerator Challenges: EUR 130m
 - ❖ 2023: **Tech to avoid social distancing**
 - ❖ 2024: **Monoclonal antibodies**
- ❖ Next-generation **face masks:** EUR 20m

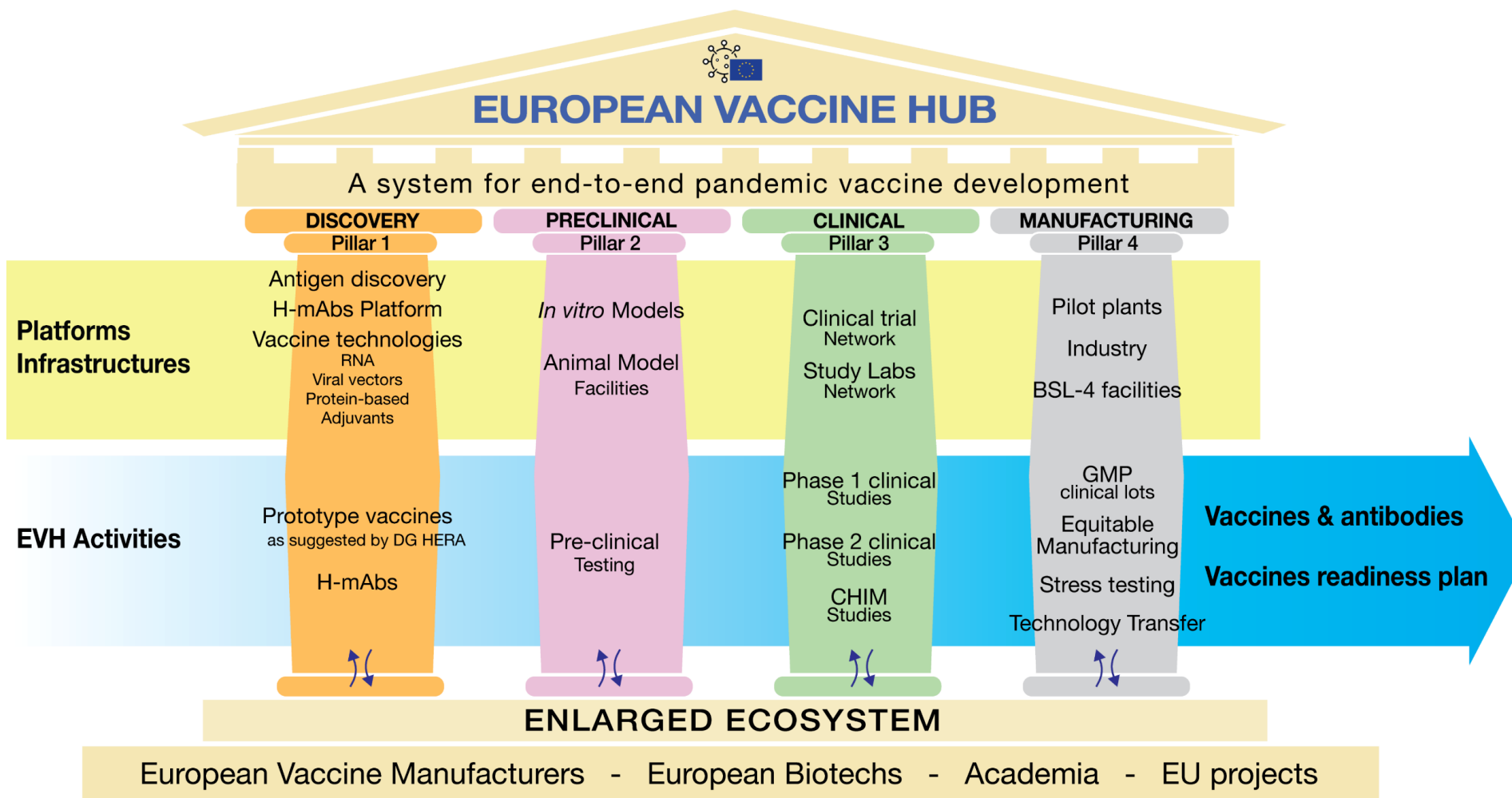
European Vaccine Development Hub: EUR 102m

HERA Invest: EUR 100m



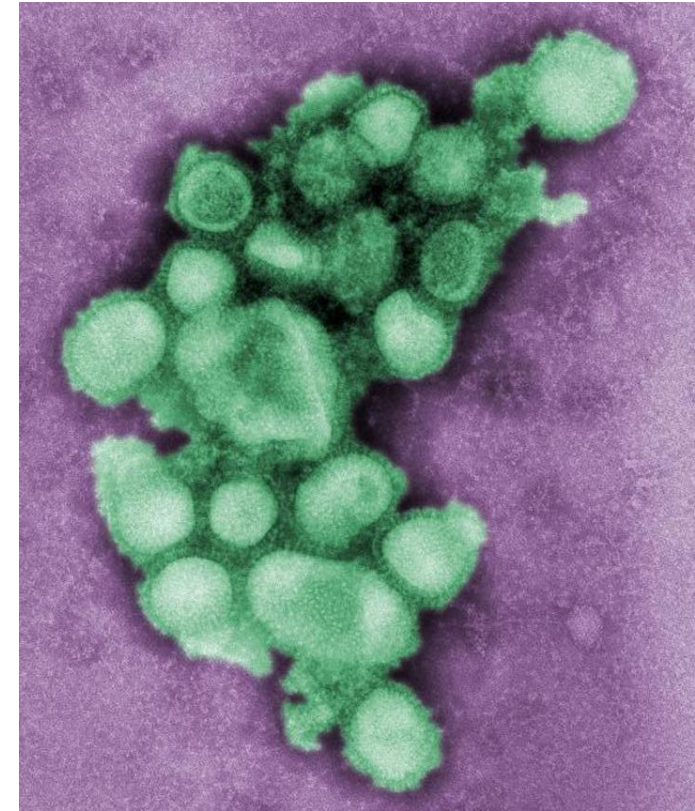
Recent achievements





Next Generation Influenza Vaccines (tender)

- Goal: translate gains in vaccine R&D into innovative products made in Europe for priority threat – **Influenza**
- HERA to fund clinical development of next generation vaccines **from phase I to phase III** across approx. 8 yrs (total budget: ca. **EUR 208 Mio**)
- Main elements:
 - Scalability of manufacturing
 - New administration routes
 - Improved immunogenicity
 - Broader protection



Joint procurement and EU FAB

Joint purchases at EU level

- To ensure equitable access to MCMs to 38 participating countries
- To improve preparedness of Member States against health crises

Examples of JP contracts

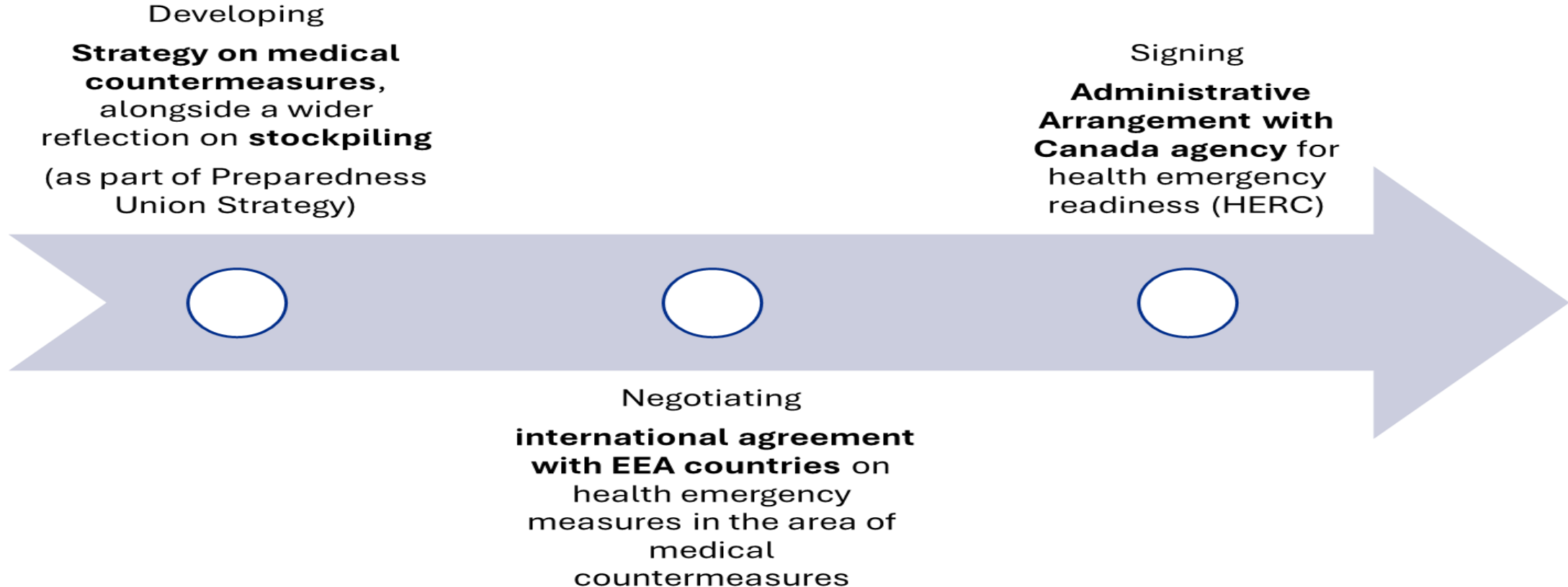
- A contract for **pre-pandemic zoonotic influenza vaccines** giving access to more than 40 million doses to 15 countries.
- A contract for **mpox vaccines** (outbreak mpox in DRC - summer 2024)
- Renewal of COVID-19 vaccines contract to ensure security of supply

EU FAB

- To guarantee the capacity to produce required vaccines in case of a new crisis => HERA established EU FAB network of ever-warm vaccine production in the EU
- Through this action => capacities to quickly manufacture vaccines up to 325 million doses

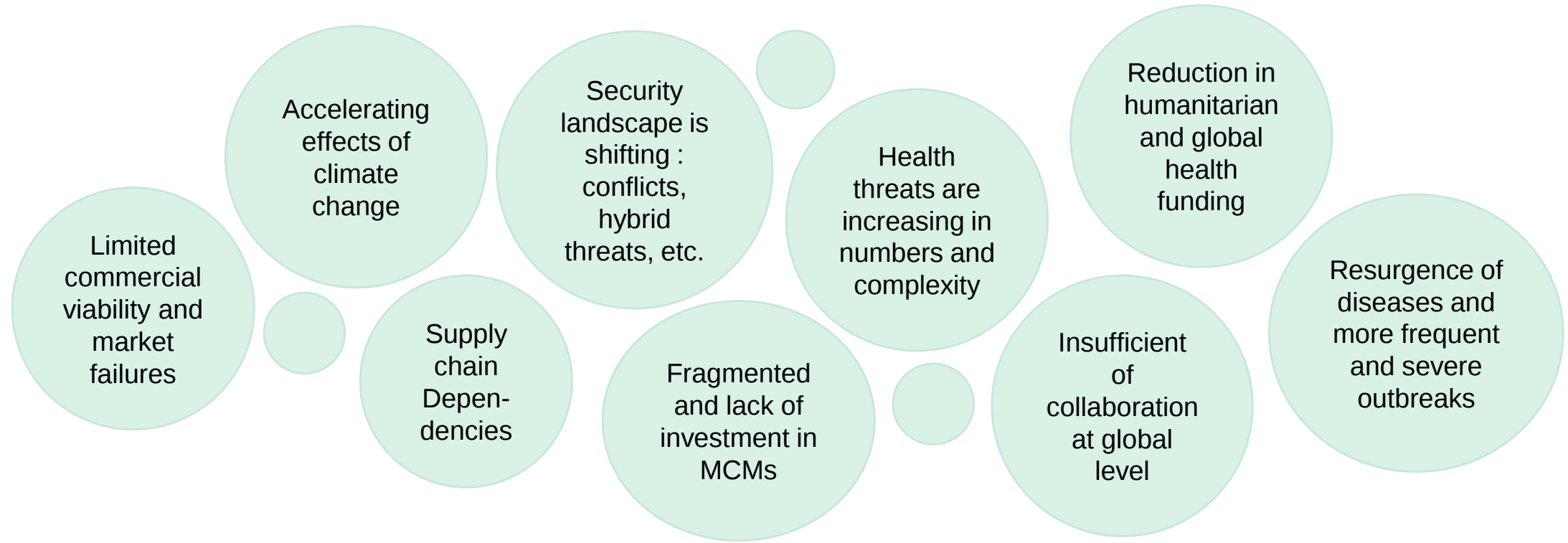


MCM policy and cooperation 2025



A pressing need more medical countermeasures

Medical countermeasures: Vaccines, therapeutics, diagnostics, other medical devices, personnel protective equipment (PPE). They are **strategic assets** to protect citizens, keep our societies and economies safe.



Medical countermeasures remain unavailable for most priority health threats.



EU Strategy on medical countermeasures

- MCM Strategy at interface EU preparedness and competitiveness agendas
- 2 Annexes: threat prioritisation report and stockpiling strategy
- referencing
 - Preparedness Union Strategy – adopted on 25 March
 - ProtectEU – European Internal Security Strategy – adopted on 1 April



A strategy at the interface of the Niinistö and Draghi reports

The Medical Countermeasures Strategy is one of the first deliverables of the **Preparedness Union Strategy**. With this strategy, the EU aims to **reinforce its preparedness for the next health emergency**, irrespective of its origin, from pandemics to human-made biosecurity threats or conflicts, by ensuring that medical countermeasures are rapidly, sufficiently and equitably available to **protect citizens at all times**.

Stimulating MCM innovation, production and availability in end-to-end approach.

Driving EU-level cooperation with Member States and collaboration with global partners.

Scaling-up public and private partnerships and cross-sectoral collaboration including civil-military.

A threat-based strategy – 4 categories of priority health threats requiring medical countermeasures



Respiratory and contact-based viruses with pandemic potential – i.e. coronaviruses, Ebola, influenza, Disease X.



Vector-borne or animal-reservoir viruses with epidemic potential – i.e. dengue, West Nile virus, chikungunya.



Antimicrobial resistance (AMR)– the emergence and spread of resistant pathogens is intensified by overuse of antibiotics, climate change, conflicts.



Armed conflict related threats and Chemical, Biological, Radiological and Nuclear (CBRN) threats – both accidental or intentional.

17 Key Actions to ensure access and availability of MCMs, taking a comprehensive end-to-end approach



Threat intelligence and detection

- Create an **EU list of Medical Countermeasures** for priority threats. (2026)
- Develop **Medical Countermeasures Preparedness Roadmaps** for specific health threats. (2026)
- Together with ECDC, operationalise and expand an **EU Wastewater Sentinel System** and expand it globally. (2026)
- Develop **next generation mobile labs** (2026)



Accelerating innovation and R&D

- Launch a **Medical Countermeasures Accelerator**. (2025)
- Enhance risk capital for start-ups and SMEs by increasing with the EIB the size of **HERA Invest** (2027).
- Set up **hubs for the development of therapeutics and diagnostics** to accelerate the development of next-generation diagnostics and broad-spectrum therapeutics. (2026 & 2027)



Manufacturing Capacity

- Create a **Rapid and Agile Manufacturing Partnerships** to ensure rapidly scalable EU-based manufacturing capacity in case of crisis. (2026)
- Explore expanding the scope of **EU FAB** to other type of medical countermeasures such as PPEs. (2026)
- Continue supply chains vulnerability assessments of medical countermeasures that are not on the Union list of Critical Medicines (PPE, diagnostics devices, or MCMs for CBRN threats).



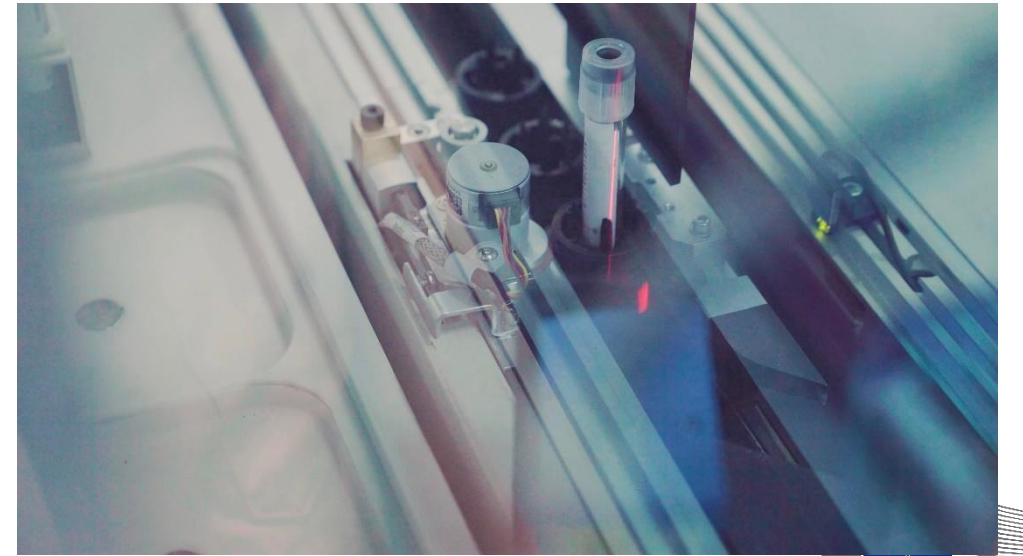
Availability, equitable access and distribution

- Establish **crisis procurement guidelines**. (2026)
- Consider and if appropriate **propose the revision of the Joint Procurement Agreement** to make it better fit to today's needs (2026).
- Enhance coordination of **EU stockpiling of MCMs**: propose a compendium of MCMs suitable for EU stockpiling, shelf-life extension programme, explore how purchase of unauthorised or investigational products can be facilitated at EU-level, etc.

Ongoing and next ...

- **EU Vaccines HUB** – level of preparedness up
- **Stockpiling: JA, management**
- **International partnerships**
- **Drugs, diagnostics + vaccines development**
- AI? Global Health Security? ... BeReady?
- Pull incentives for **AMR**, R+D, CARB-X, GARD-P
- Clinical Trials coordination mechanism for PHE
- **Early detection and monitoring**
- A Global Consortium for Wastewater Surveillance –global roll-out

- **Strategies 2025:**
 - **Preparedness Union**
 - **MCM**
 - **Stockpiling**



Thank you!

