



Introducing HERA – a new actor in European health security



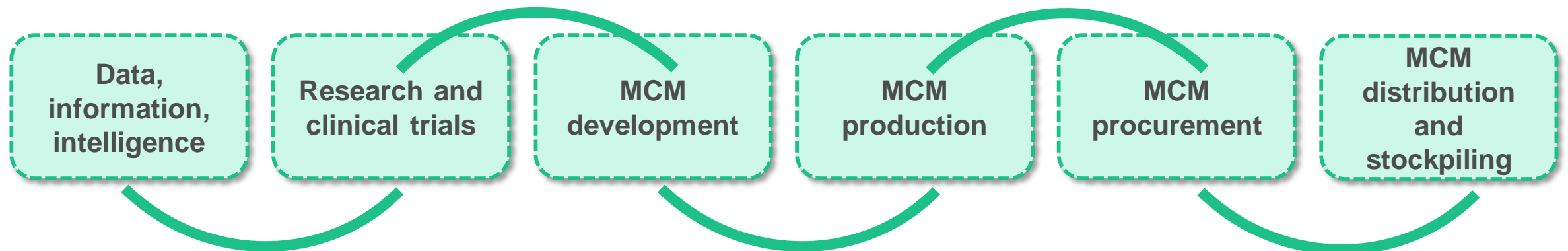
Charlotte Renckens, Emergency Office, HERA

HERA'S mission and mandate

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**

= 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



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



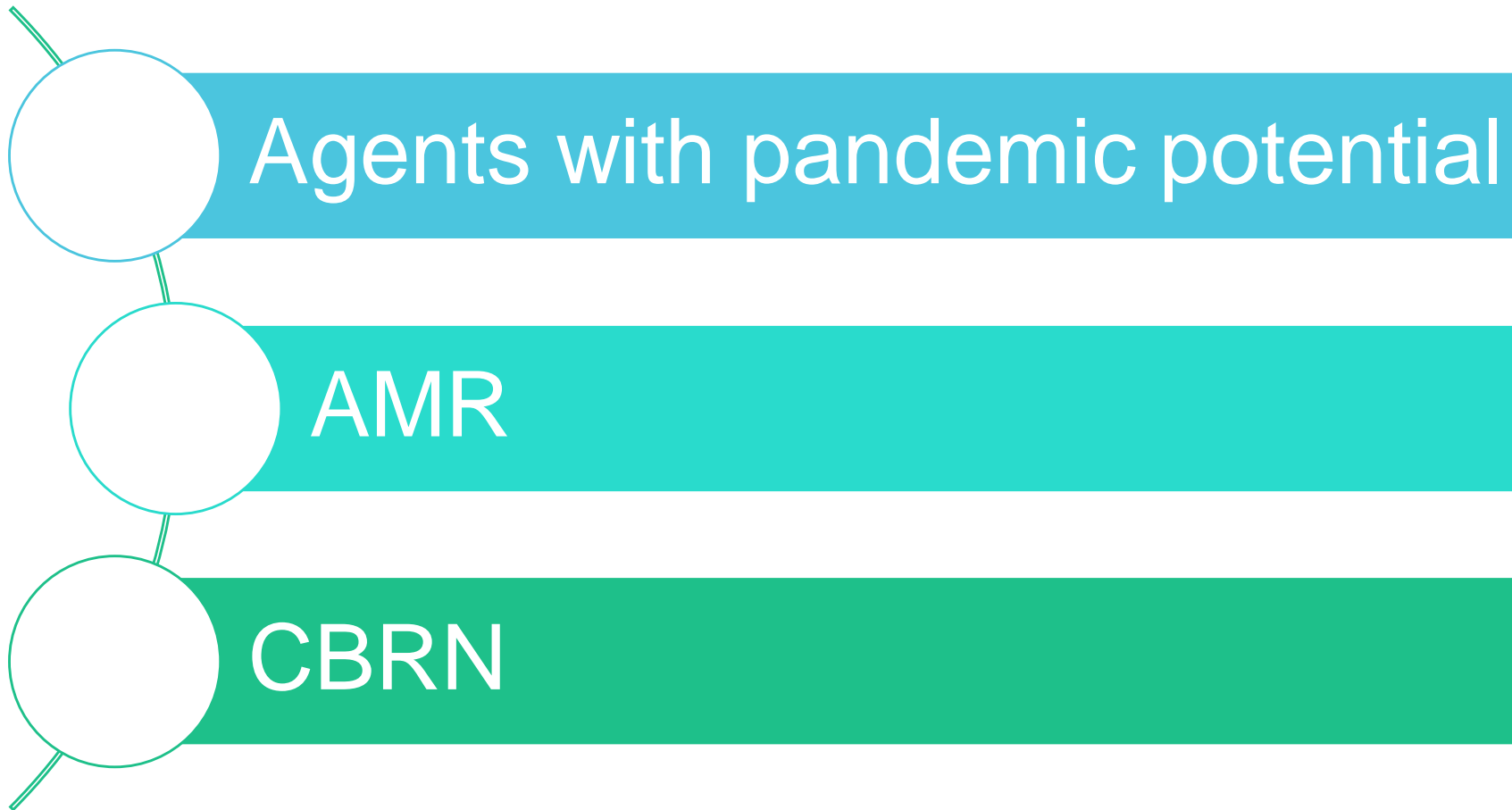
Establishment of an inventory of crisis-relevant MCM production facilities



Activation of emergency funding

International collaboration

HERA's priority threats



EU FAB: a network of production capacities for vaccines

- **Secure early availability of manufacturing capacities**
- **Reserve capacities** for the manufacturing of mRNA, protein-based and viral-vector **vaccines** (preparedness phase)
- Have **priority right for the manufacturing of vaccines** (crisis phase)
- Budget: **160 mio € /year**

Activation principles:

- Recognition of a public health emergency at EU level
- Selection of vaccine and conclusion of purchasing contracts
- Activation of EU FAB facilities after decision by the Commission
- EU FAB starts manufacturing within agreed timeline
Manufacturing to start as soon as possible, with at least 50% of the doses to be manufactured in the first 6 months and 100% by 12 months
- Supply of vaccines once marketing authorisation available

HERA Invest

- Aim: to financially support the development of medical countermeasures tackling HERA priority health threats (pathogens, AMR and CBRN)
- European Investment Bank will cover a maximum of 50% of investment costs



Joint procurement

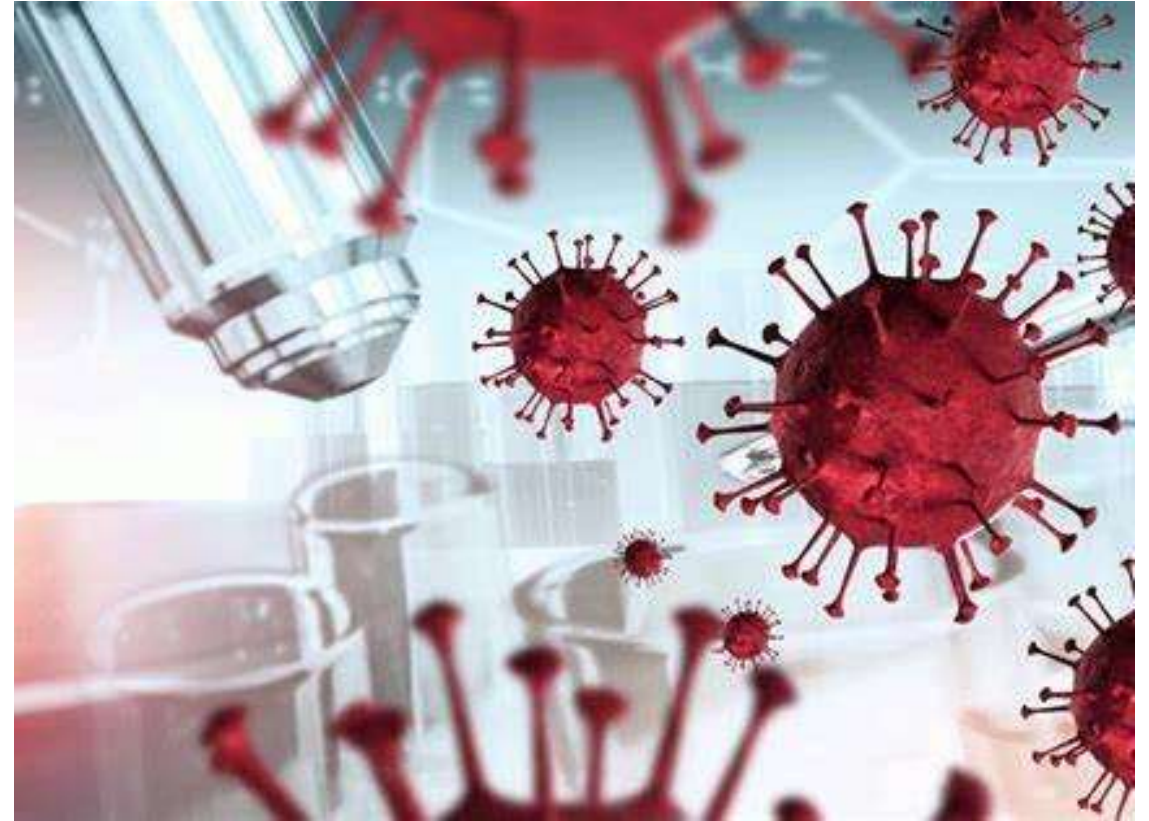
Joint Procurement Agreement (JPA)

- The JPA was signed to improve *Security of supply and equitable access to MCM, better preparedness for health crises, balanced prices, and flexibility for the countries*
- Meets the mid and long-term MCM needs of countries
- To initiate a JP at least five Contracting Parties, including the Commission, must show willingness to take part
- Different types of procedures & contracts



Mpox vaccines: wholesale procurement

- May 2022: mpox outbreak declared in the Member States
- HERA purchased Jynneos vaccines (non-EU authorised):
 - Donation to EU Member States (including non EU countries participating in EU4Health programme).
- Tecovirimat in rescEU stockpile





Stockpiling medical countermeasures

- ❖ HERA budget: 1.2bn EUR under rescEU → last resort stockpiles
- ❖ Specific focus on pathogens with high pandemic potential, antimicrobial resistance and **CBRN countermeasures**
- ❖ Four countries procuring, hosting and managing the stock in 2022: **Croatia, Finland, France and Poland**

Stockpiling



- ❖ Strategy to be published in 2023, focusing on:
 - ❖ Defining the stockpiles (items, quantities)
 - ❖ Establishment (procurement, predictability, funding mechanisms, geographical spread)
 - ❖ Management (Governance, database, waste, shelf life, interoperability)
 - ❖ Deployment & distribution
 - ❖ Use and replenishment

HERA and its international dimension

❖ **Aim:** reinforcing **global health security** while ensuring availability and access to relevant MCMs

Reinforce **global surveillance and intelligence gathering**

Address **international supply chain bottlenecks**

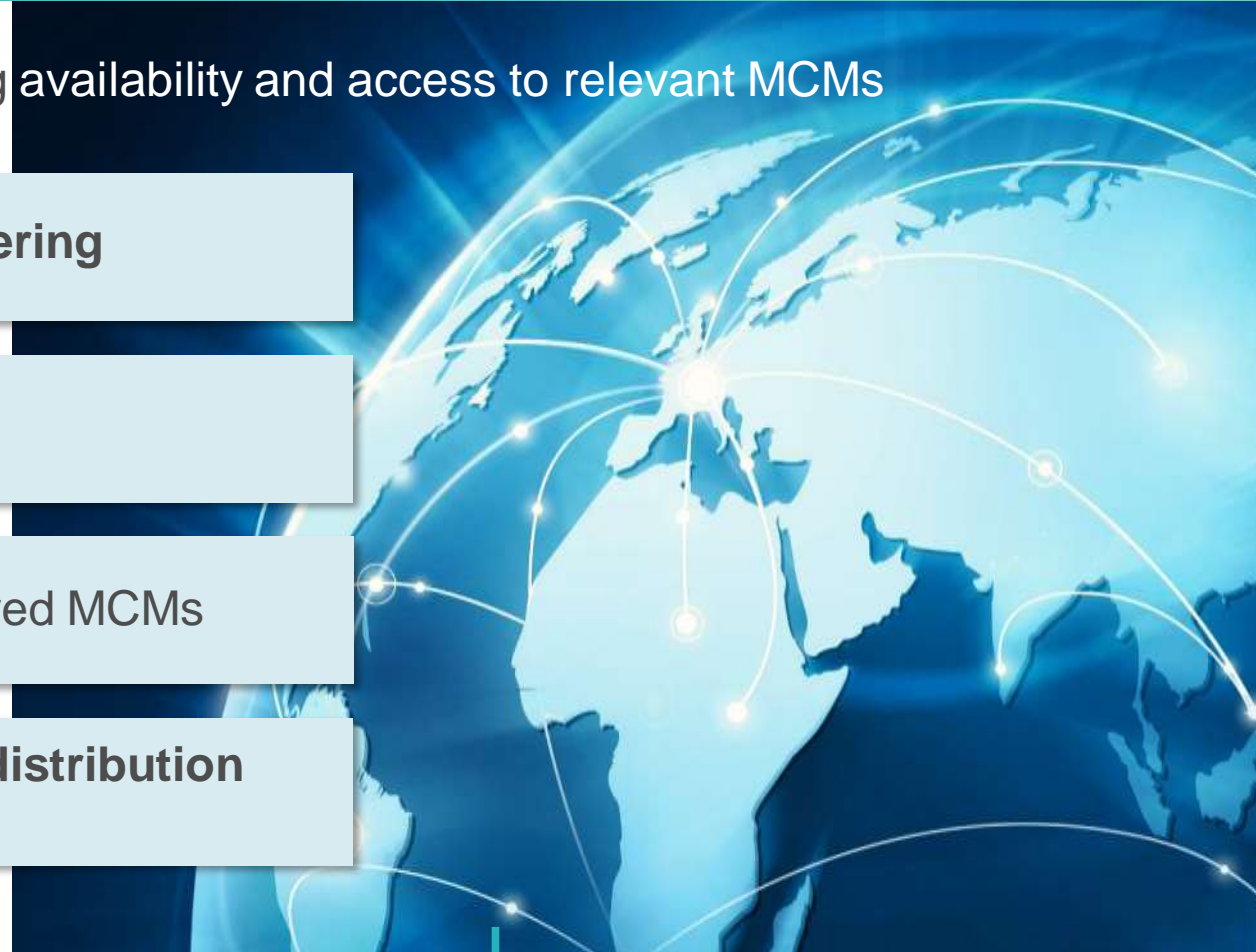
Provide **access for LMICs** to EU-funded or EU-procured MCMs

Build expertise, develop **local manufacturing and distribution capacities** in LMICs for relevant medical cooperation

bilateral cooperation
with **third countries**

bilateral cooperation with relevant
international organisations

engagement in
multilateral fora



Thank you

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