



# Manufacturing capacities for pandemic preparedness

*Isabel Holmquist, Policy Officer,  
HERA.3 – Medical counter-measures*

# HERA mission

Addressing vulnerabilities and strategic dependencies within the EU related to the development, production, procurement, stockpiling and distribution of **medical countermeasures**

## Manufacturing and Procurement

- Implement flexible EU manufacturing and capacity for medical countermeasures
- Promote wider use of procurement and reservation contracts

# Ongoing study on flexible manufacturing

Assessing the scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation of medical countermeasures for serious cross-border threats to health



Outcome:  
Allow surge and scalable manufacturing of needed medical countermeasures in the case of a health emergency  
Covers both vaccines and therapeutics

Commissioned by HERA under the EU4Health program. Contract managed by the **European Health and Digital Executive Agency (HaDEA)**

# Flexible manufacturing – key considerations

## Flexible manufacturing options

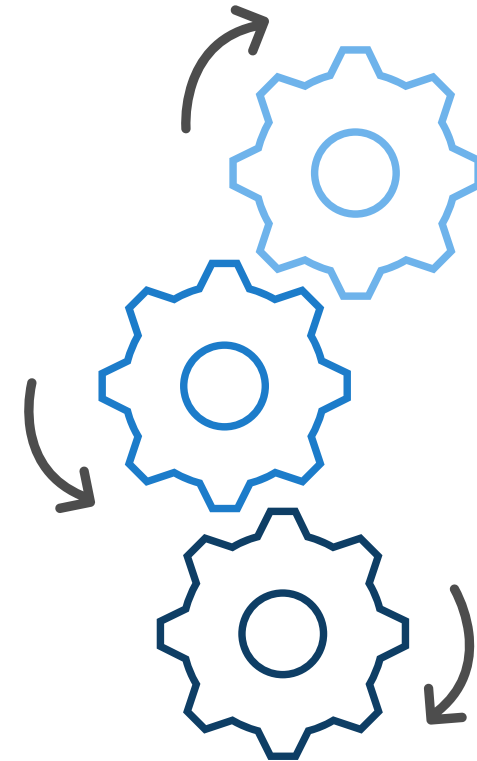
- What options are there for flexible manufacturing? What are their pros and cons?
- Which are most appropriate for consideration by HERA?

## Needs and technical requirements

- For what threats and corresponding MCMs does the EU need to ensure additional capacity?
- What may the volume and financing needs look like?
- What are the most appropriate technology platforms (vaccines) and modalities (therapeutics)?

## Recommendations

- What **operating model** should be chosen?
- How can **innovation** be incorporated in the model?
- What steps/considerations are needed for **HERA to implement it?**





# EU FAB – reserving manufacturing capacity

- Network of vaccine manufacturing facilities in the EU and EEA
- Secure early availability of manufacturing capacities
- The Commission will:
  - **reserve capacities** for the manufacturing of **vaccines** (preparedness phase)
  - have **priority right for the manufacturing of vaccines** (crisis phase)
  - Facilities remain property of companies, to be kept operational during the preparedness phase

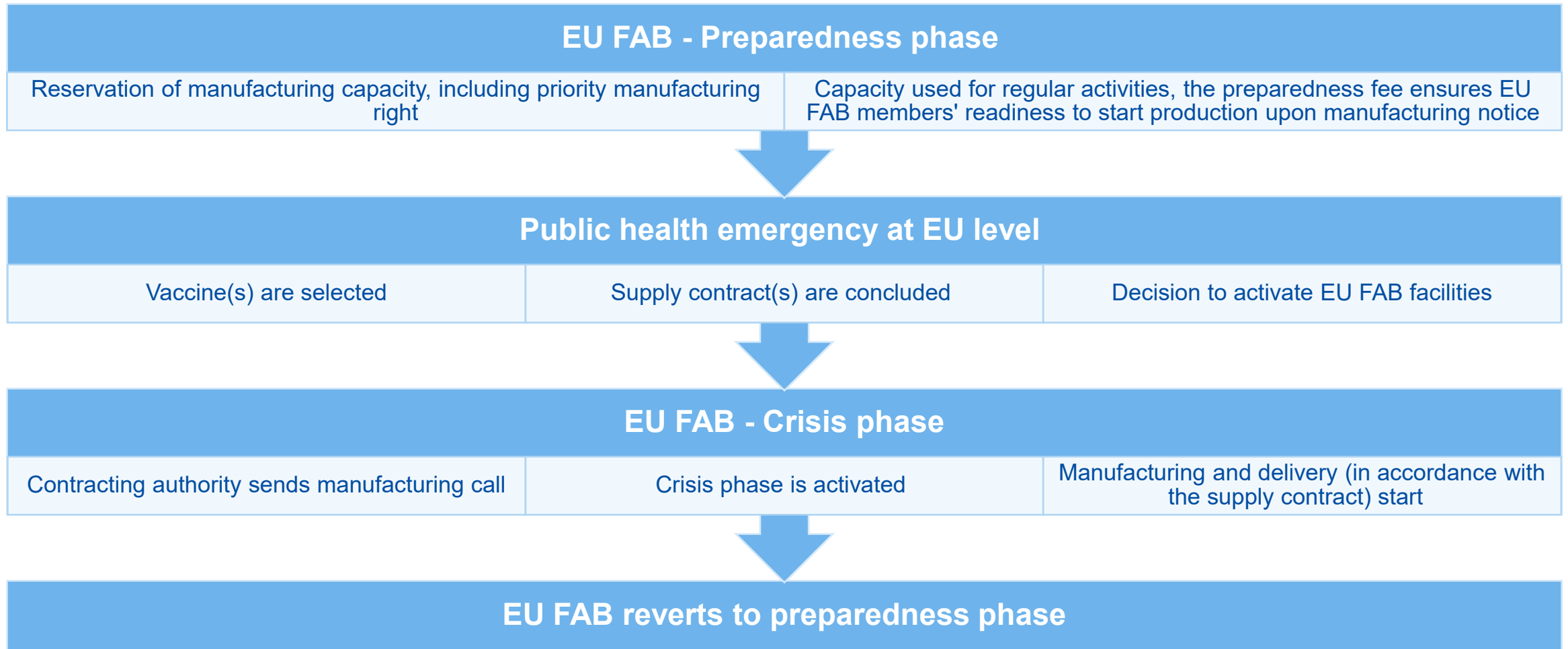
€ EUR 160 million/year

 To be signed in 2023

 Contract duration max 8 years

 mRNA, vector, and protein-based vaccines

# EU FAB – how will it work?



# Purchase Agreements

- Launch of the EU Vaccines Strategy in June 2020 to accelerate the development, manufacturing and deployment of vaccines against COVID-19
- A common EU approach to securing supplies and facilitating distribution
- (Advance) Purchase Agreements with individual vaccine producers securing the right to buy a specified number of vaccine doses in a given timeframe and at a given price
- Council Regulation 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369 - in force until 31 January 2022



10 (Advance) purchase agreements with 7 vaccines producers



mRNA, inactivated vector-, and protein-based vaccines



Contracts run until 2024



EUR 2.7 billion financed upfront

# Joint Procurement

- *Joint Procurement Agreement for Medical Countermeasures* signed by 36 EU, EEA and EU candidate countries
- Vaccines, antivirals, and other medical countermeasures for serious cross-border threats to health
- Complements procurement at national level
- More equitable access to MCMs, improved security of supply, fairer pricing, and transparency
- HERA and participating countries work together to identify and implement priorities, such as vaccines or therapeutics, for joint procurement



Six contracts for COVID-19 MCMs  
Two contracts for monkeypox MCMs  
Two reservation contracts for pandemic influenza vaccines



Antivirals, monoclonal antibodies, vaccines and PPE



MS place orders based on FWCs



# Thank you



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