



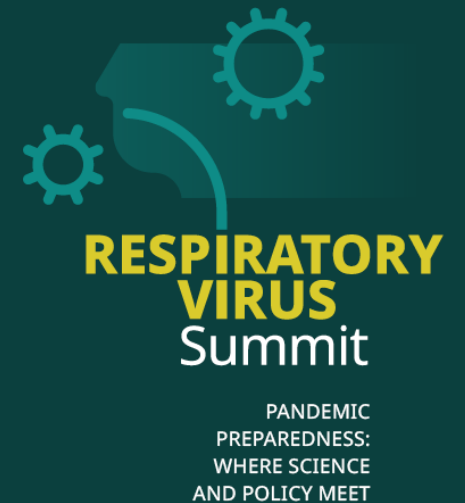
RESPIRATORY VIRUS Summit

organised by **ESWI**

PANDEMIC
PREPAREDNESS:
WHERE SCIENCE
AND POLICY MEET

HERA: what's new in pandemic preparedness?

Dr. Wolfgang Philipp, *HERA, Belgium*





HERA – what's new for the next pandemic

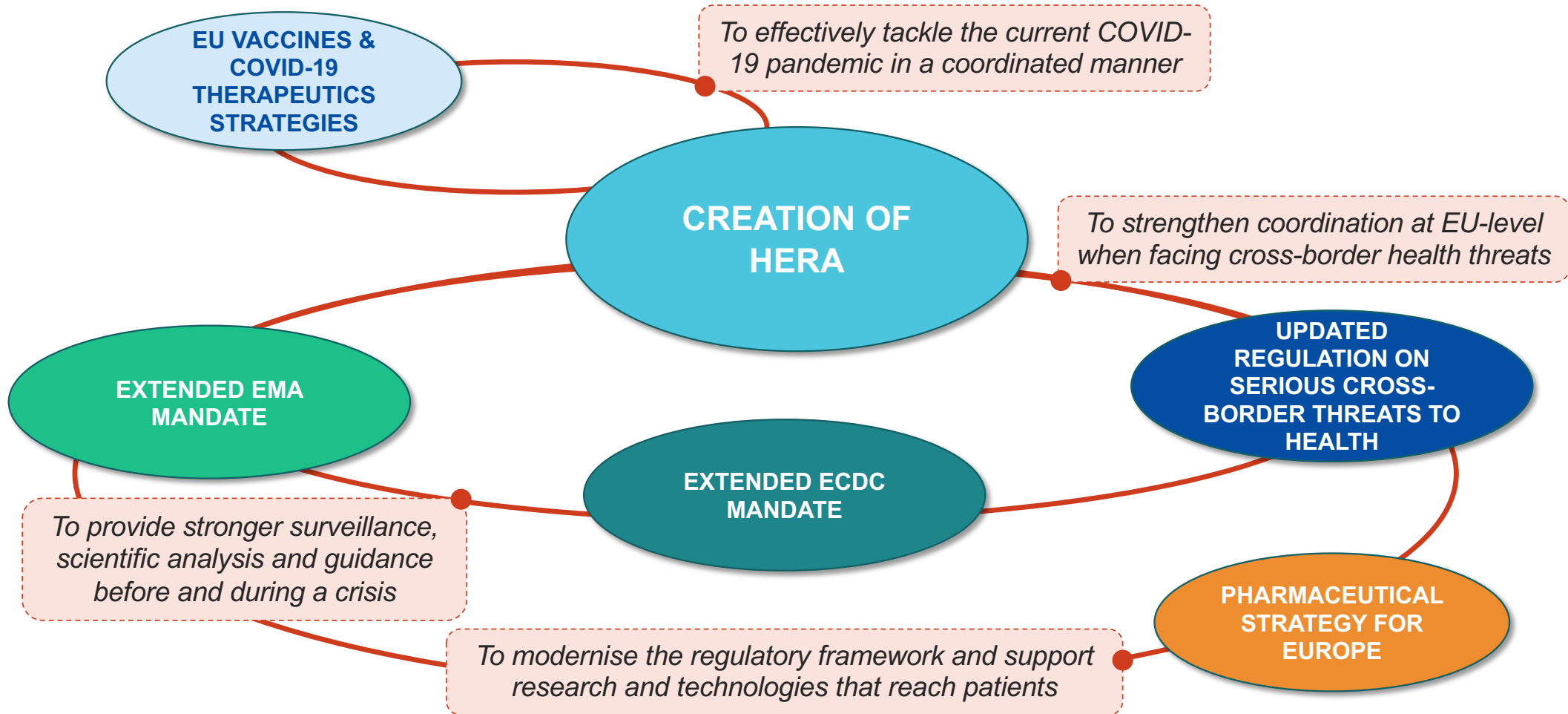
Wolfgang Philipp

Deputy Head HERA

The aim remains in place

- need to further invest in our EU-wide and global coordination for health preparedness and response
- protecting public health while keeping society and economy open and resilient

Better health preparedness for the EU



Mission

- ❖ Addressing **serious cross-border health threats** in an all-threat approach (e.g. biological, chemical, environmental threats of natural, accidental or intentional origin)
- ❖ Addressing vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of **medical countermeasures**



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

- ❖ Contributing to reinforcing the **global health emergency preparedness and response** architecture

Budget and staff

Operational budget: EUR 6bn from MFF 2021-2027

EU4Health, Horizon Europe, UCPM/rescEU

2022 Total budget: EUR 1.3 billion

Staff: up to **120 FTEs**

Crisis operations: **Emergency Support Instrument**

Some lessons learned and translation into action

1. **Contribute to better surveillance and epidemic intelligence**
2. **Ensure better coordination on EU level**
3. **Ensure better coordination internationally**
4. **Reinforce resilient supply chains for critical equipment and medicines**
5. **Ensure that sufficient and agile manufacturing capacities for vaccines are kept operational**
6. **Speed up significantly the approval of clinical trials of vaccines and therapeutics**
7. **Establish flexible financing facilities to boost pertinent research projects and enable swift and targeted procurement**
8. **Invest in health care systems, public health functions and capacities by providing key funding opportunities**
9. **Invest in health security preparedness and resilient health and social protection systems**

HERA main tasks

❖ Preparedness mode:



Threat assessments and intelligence gathering



Advanced research and development capacities for medical countermeasures



Production capacities for medical countermeasures



Procurement, stockpiling, and distribution capacities for medical countermeasures



Knowledge and skills capacity building



International engagement to ensure **availability and access of critical medical countermeasures** both for the Union and for third countries

❖ Crisis mode:



Monitoring of crisis-relevant countermeasures



Procurement, purchase and manufacturing of crisis-relevant medical countermeasures



Activation of **EU FAB facilities**



Activation of **emergency research and innovation plans**



Establishment of an **inventory** of crisis-relevant medical countermeasures production facilities



Activation of **emergency funding**



Threat assessments and intelligence gathering

- ❖ Develop **methodologies and IT platforms** for:
 - ❖ **intelligence gathering and analysis**
 - ❖ **anticipatory threat assessment**
 - ❖ **mapping medical countermeasures and raw material availability (incl. stockpiling) and production capacity**
- ❖ Regular prioritisation exercise to identify **three high-impact threats** to be addressed in the course of 2022 and relative **list of MCM**
- ❖ Extend **epidemic surveillance** support programmes
- ❖ Draft and present the **EU's State of Preparedness Report**



Promoting advanced R&D of medical countermeasures and related technologies

- ❖ Support the development of **next generation vaccines** and the pre-clinical development of the next generation of **immunotherapies**
- ❖ **Horizon scanning** for potential medical countermeasures and innovative technologies against emerging pathogens
- ❖ Gap analysis and needs assessment for **AMR medical countermeasures**
- ❖ Contribution to **CEPI** and **EDCTP3** (clinical trials)
- ❖ Create a **common strategic EU research and innovation agenda for pandemic preparedness**



International dimension

- ❖ Close collaboration with global partners to **address international supply chain bottlenecks and expanding global production capacity**
- ❖ Conduct a **gap analysis and develop methodologies for data collection** to reinforce global surveillance
- ❖ Support the functioning of the **Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)**
- ❖ Support **manufacturing capacity for LMIC countries**



Addressing market challenges and failures and boosting the Union's open strategic autonomy

- ❖ Facilitate the development of a prototype for a **mapping platform on COVID-19 therapeutics (and key raw materials)**
- ❖ Implement a **flexible (multi technology) EU manufacturing and innovation capacity (EU FAB)** for medical countermeasures
- ❖ Rapidly **reorganise production process chains** in case of need
- ❖ Close interplay with **IPCEI Health** (esp. on AMR and emerging health threats)
- ❖ Series of **matchmaking events** for medical countermeasure manufacturers
- ❖ Close cooperation with **civil society stakeholders** (Civil Society Cooperation Forum) and with **industry** (Joint Industrial Cooperation Forum)



Ensuring medical countermeasures provision

- ❖ Promote wider use of **procurement and reservation contracts**, for instance for vaccines against infectious disease threats such as pandemic influenza vaccines and COVID-19 vaccines and therapeutics
- ❖ Develop a **methodology to map antimicrobials and APIs** most needed within the EU and assess the gaps in access
- ❖ Develop an **IT platform for stockpiling management**
- ❖ Establish a **list of medical and CBRN countermeasures** for stockpiling and deployment



Clinical trials

- ❖ **EU-wide networks for clinical trials**
 - ❖ Work with EMA to create a long-term and large-scale EU platform for multi-centre clinical trials and corresponding data platforms
 - ❖ On COVID-19: EU-wide networks for vaccines (VACCELERATE) and for therapeutics
- ❖ **Third programme of the European & Developing Countries Clinical Trials Partnership (EDCTP3)**
 - ❖ The EU–Africa Global Health Partnership will support international research partnerships accelerating the clinical evaluation of drugs, vaccines and diagnostics for key infectious diseases affecting sub-Saharan Africa, as well as novel approaches for surveillance and control of emerging/re-emerging infections



Strengthening knowledge and skills

- ❖ Identify **major knowledge gaps** in the field of medical countermeasures and provide **trainings** accordingly
- ❖ Assist all Member States in organising a **national/regional assessment process of public procurement practices** in the health sector with all relevant stakeholders

Conclusion: HERA

a streamlined, sustainable, institutional approach to

- conduct health threat assessments and intelligence gathering
- promote advanced R&D of medical countermeasures and related technologies
- address market challenges and failures and boost the Union's open strategic autonomy
- ensure the provision of medical countermeasures
- and strengthen knowledge and skills

→ Better prepared for next pandemic?