PANDEMIC AND OTHER HEALTH CRISSES
Lessons learned and future scenarios

MPCMU/STOA Workshop

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“For me, it is crystal clear – we need to build a stronger European Health Union…we need to **strengthen our crisis preparedness and management** of cross-border health threats

As a first step, we will propose to reinforce and empower the EMA and ECDC

As a second step, **we will build a European BARDA** – an agency for biomedical advanced research and development.”
Building a stronger European Health Union and transitioning out of the emergency

- Regulation (EU) 2022/123 on the extended mandate of the European Medicines Agency (EMA) entered into force on 1 February 2022

- On 20 December 2021, the Council also reached a political agreement on the Emergency Framework Regulation allowing for the activation of urgent and targeted medical countermeasures by the European Health Emergency Preparedness and Response Authority (HERA) during public health emergencies in the EU

- Political agreement on the extended mandate of the European Centre for Disease Prevention and Control (ECDC) was reached on 29 November 2021

- Serious cross-border threats to health Regulation – a political agreement reached on 23 June 2022

- European Health Data Space
Regulation on serious cross-border threats to health

Negotiators from the Council and the European Parliament reached agreement on the draft regulation on 23/06/2022.

KEY OBJECTIVES:

➢ **Strengthen preparedness:**
  - Adoption of plans at national levels
  - Comprehensive and transparent frameworks for reporting and auditing

➢ **Reinforce surveillance:**
  - Surveillance system at EU level,
  - Using artificial intelligence (AI) & other advanced technological means

➢ **Improve data reporting:**
  - Reporting of health systems indicators

→ A declaration of an EU emergency situation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis relevant products
Stronger and more operational EU Agencies

European Centre for Disease Prevention and Control (ECDC)
Defending Europe against infectious diseases

European Medicines Agency (EMA)
Evaluating and monitoring the safety of medicines

CURRENT MANDATE
- Networking and information exchange
- Monitoring based on diverse data sets
- Non-binding guidance and risk assessments
- Early warning and response mechanism for exchange of information
- Cooperation with Member States’ experts

FUTURE MANDATE
- Recommend measures for outbreak control
- State-of-the-art epidemiological surveillance to monitor infectious disease outbreaks based on common standards and definitions
- Concrete recommendations for response
- Early warning and response mechanism for
  - Alertness
  - Information exchange
  - Preparedness planning
- Network of reference laboratories for crisis-relevant advice on new pathogens and network on substances of human origin, e.g. tissues, cells and blood

CURRENT MANDATE
- Monitoring the safety of medicines
- Evaluating the safety of medicines

FUTURE MANDATE
- Monitoring and mitigating shortages of medicines and medical devices caused by major events
- Offering advice on medical devices and medicines which may treat, prevent or diagnose a disease causing an outbreak
- Coordinating studies to monitor the effectiveness and safety of vaccines
- Coordinating and advising on clinical trials of medicines
The future of health preparedness in the EU

- **EU VACCINES & COVID-19 THERAPEUTICS STRATEGIES**
  - To effectively tackle the current COVID-19 pandemic in a coordinated manner

- **EXTENDED EMA MANDATE**
  - To provide stronger surveillance, scientific analysis and guidance before and during a crisis

- **Health Emergency Preparedness and Response Authority (HERA)**
  - To strengthen coordination at EU-level when facing cross-border health threats

- **EXTENDED ECDC MANDATE**

- **UPDATED REGULATION ON SERIOUS CROSS-BORDER THREATS TO HEALTH**

- **PHARMACEUTICAL STRATEGY FOR EUROPE**
  - To modernise the regulatory framework and support research and technologies that reach patients
Sustaining EU preparedness and response and strengthening health system resilience

KEY STRATEGIES AND CHALLENGES:

- Step up actions to increase COVID-19 vaccination uptake
- Intensify the fight against mis- and disinformation
- Development of second generation COVID-19 vaccines, therapeutics and clinical trials
- Adapt surveillance and intelligence gathering strategies
- Continue targeted testing and sequencing of sufficient samples
- Invest in the recovery and resilience of healthcare systems
- Assess the wider health impacts of the pandemic (e.g. mental health, ‘long COVID’)
- Coordination of COVID-19 travel measures
- Digitalisation in health matters
- Global dimension: solidarity and governance

Measures in long and medium term

Tackling wider health impacts of the pandemic, including “long COVID” and mental health through further data collection and analysis in the coming years.

Increased focus on healthcare system resilience.

Speeding up digitalisation in health through a European Health Data Space.
Thank you.