Health Emergency Preparedness and Response:

Introducing European Health Union package and HERA

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European Commission
DG SANTE

25 March 2021

AMR One Health Network Virtual Meeting

European Health Union package

SOTEU 2020 – President von der Leyen

- We need to build **a stronger European Health Union**
- Opportunities for **strengthening EU preparedness and response** to serious cross-border health threats
- Set up a "**European BARDA**" – an agency for biomedical advanced R&D to support capacities and readiness for response

https://www.eppgroup.eu/newsroom/publications/a-european-solidarity-pact-against-the-coronavirus-pandemic

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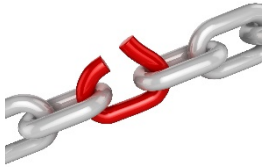
Building a European Health Union



Early lessons learned from COVID-19

- Weak or suboptimal preparedness plans and modelling
- Fragmentation of efforts in the EU
- Market failures and lack of medical countermeasures
- Vulnerabilities in global supply chains
- Insufficient oversight of manufacturing capacities and research priorities

Building blocks of the European Health Union (11 Nov 2020), set of proposals to:

- strengthen the EU's health security framework, **including AMR under Decision 1082**
- reinforce the crisis preparedness and response role of key EU agencies – ECDC and EMA
- **outline for the Health Emergency Preparedness and Response Authority (HERA)**

25 Nov 2020 – EU Pharmaceutical Strategy

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Communication: Building a European Health Union

- **Present key lessons** learned with health preparedness and response to the COVID-19 pandemic
  - capacities for surveillance, preparedness, early warning, risk assessment and response
  - operation of the key EU structures and mechanisms, including epidemiological surveillance, Early Warning and Response System, Health Security Committee, joint procurement
  - health response of EU agencies, and international cooperation
- **Propose a stronger** and more comprehensive health security **framework** for the Union to prepare and respond to health crises
- Set out the main elements of the future Health Emergency Preparedness and Response Authority (HERA)

Proposal for a Regulation on serious cross-border threats to health

Preparedness and response planning *(Articles 5-12)*

- EU health crisis and pandemic preparedness plan including interregional elements, and coordination for the adoption of plans at national levels
- Comprehensive and transparent framework for reporting and auditing on preparedness
- Regular public health and cross sector stress tests and exercises carried out with Member States including corrective measures
- Targeted training and knowledge exchange activities for healthcare and public health staff
- A reinforced joint procurement agreement beyond the EU

Proposal for a Regulation on serious cross-border threats to health

Epidemiological surveillance, new networks *(Articles 13-16)*

- A new high performing epidemiological surveillance system at the EU level, using artificial intelligence, harmonised datasets and digital tools for accurate modelling, risk assessment and response for the surveillance of novel pathogens based on common EU case definitions
- Strengthened access of ECDC to health data for research and epidemiological aspects, in the context of the European Health Data Space
- Reporting requirements on health system capacity; surveillance linked to other available information sources and data
- Creation of an EU reference laboratories network that would allow alignment on diagnostics, serological testing, testing methods, use of certain tests
- Creation of a network including Member State services supporting transfusion, transplantation and medically assisted reproduction

Proposal for a Regulation on serious cross-border threats to health

Early warning and risk assessment *(Articles 18-20)*

- Notifications including on urgent need or shortage of medical countermeasures; requests and offers for cross-border emergency assistance
- A new risk assessment framework for all hazards, including rapid and appropriate recommendation for response measures that Member States should implement
    - Agencies involved, including: ECDC, EFSA, ECHA, EEA, EMCDDA, Europol, EMA

Proposal for a Regulation on serious cross-border threats to health

Coordinated response at EU level *(Articles 21-25)*

- Recommendations on response measures by ECDC as part of rapid risk assessments
- Adoption of opinions and guidance, including on specific response measures by the Health Security Committee, Commission Recommendation on response measures
- EU recognition of an emergency situation and advice on response measures, supported by an independent Advisory Committee
    - EU emergency situation triggering increased coordination and allow for the development, stockpiling and procurement of crisis relevant products

Stronger and more operational EU agencies - ECDC

European Centre for Disease Prevention and Control (ECDC)

Defending Europe against infectious diseases

CURRENT MANDATE	FUTURE MANDATE
Networking and information exchange	• Recommend measures for outbreak control
Monitoring based on diverse data sets	• State-of-the-art **epidemiological surveillance** to monitor infectious disease outbreaks based on common standards and definitions
Non-binding guidance and risk assessments	• Concrete recommendations for response
Early warning and response mechanism for exchange of information	• **Early warning and response mechanism** for - Alertness - Information exchange - Preparedness planning
Cooperation with Member States' experts	• **Network of reference laboratories** for crisis-relevant advice on new pathogens and network on substances of human origin, e.g. tissues, cells and blood

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Proposal to extend the mandate of the ECDC

Reinforced mandate to support the Commission and Member States in the following areas:

- **prevention of communicable diseases** and specific health issues, e.g., antimicrobial resistance, vaccination and biosecurity
- **preparedness** and response planning, reporting and auditing
- **epidemiological surveillance** via integrated, digital systems enabling real-time surveillance
- provision of **non-binding recommendations** for risk management
- a **robust system for automated contact tracing**, using modern technologies, building on contact tracing and warning applications
- **coordination of new networks** including EU reference laboratories

Proposal to extend the mandate of the ECDC

Support to filed response – international cooperation

- Establishment of the **EU Health Task Force** within ECDC to mobilise and deploy to assist local response to outbreaks of communicable diseases in Member States and third countries
- **Framework for the mobilisation** of the Task Force to contribute to international response teams mobilised by the WHO Health Emergencies Programme mechanism, the Global Outbreak Alert and Response Network and the Union Civil Protection Mechanism
- Development of **field response capabilities and crisis management expertise** among ECDC's staff and experts from EU/EEA and other countries

Health Emergency Preparedness and Response Authority

HERA

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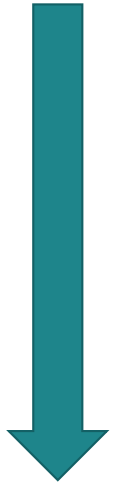
HERA

- **Mission**: Enable the EU and its MS to rapidly deploy the most advanced medical and other counter measures in the event of a health emergency
- Assembly of **ecosystems of public and private capabilities**
- This will be done by covering the **whole value chain** and by providing **end-to-end solutions**

Flexible and resourced financing & procurement capacities



Knowledge generation: horizon scanning, market intelligence, foresight

Development: late stage research, innovation and development

Production: flexible and scalable manufacturing capacities

Deployment: EU level stockpiling and distribution

Use: training programmes

- **Preparatory actions in 2021:** consideration of action on AMR

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Setting up HERA – timeline and steps

- **Inception Impact Assessment:** Jan – Feb 2021
  - Presentation of several policy options
- **Further stakeholder consultations:** March – June 2021
- **Legislative proposal:** second half 2021
- **Preparatory actions**: launch in 2021
  - Piloting HERA
  - HERA Incubator and consideration of action on **AMR** & horizontal threats
- **HERA to be operational**: latest 2023

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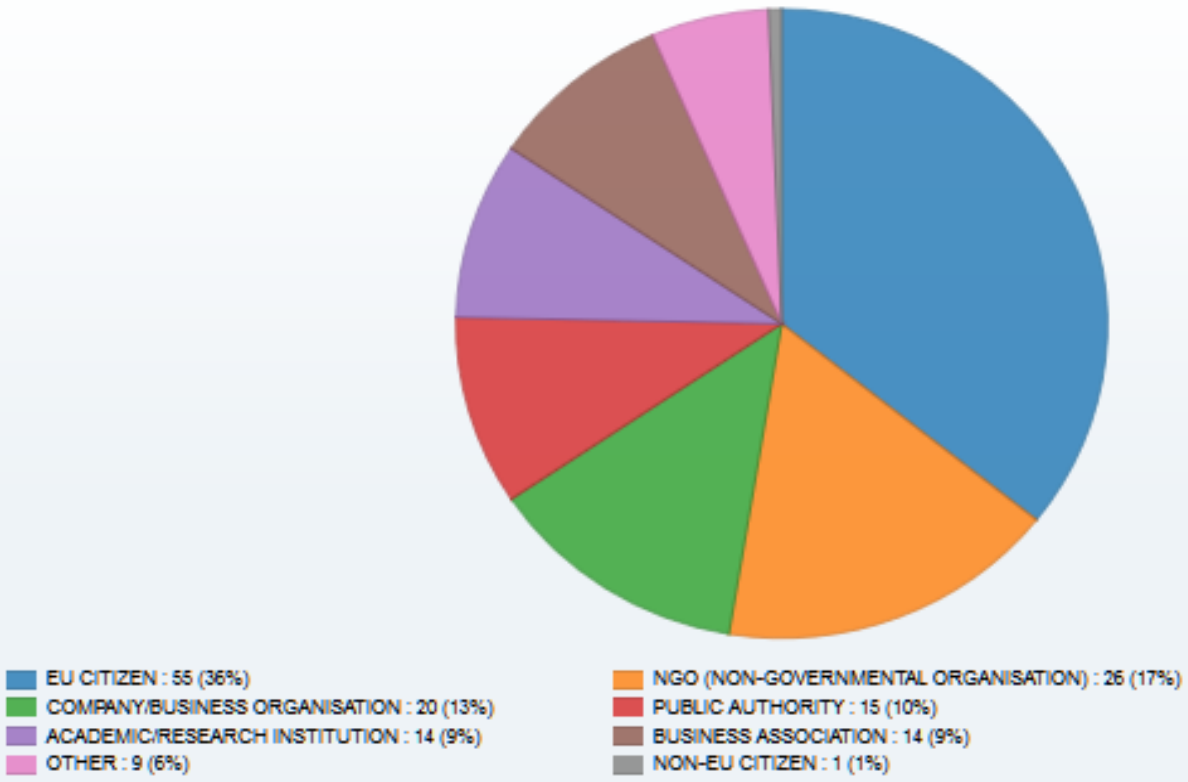
Inception Impact Assessment – Responses

- > 150 responses
- EU citizens (36%), NGOs (17%), companies (13%)



- Overall, **public authorities welcomed** HERA and are **looking forward to involvement** of MS in the work of HERA.
- Overall, **companies and business associations welcomed HERA** and **favored option 3.**
- Overall, **research institutions** were **positive** and welcomed creation of HERA and signaled towards the **involvement of research institutes, global partnerships,** and setting strong modelling and data collection structures.
- Overall, **NGOs show support for creation of HERA** but would like to see **a clear public-private distinction** and **a clear governance structure** to make sure there are **no duplications with work of other EU Agencies.**
- Overall, **citizens were not supportive** of the initiative (concerns over how democratic HERA will be, questions on accountability and involvement of Big Pharma) and a few comments were not about HERA but about the overall management of the pandemic.
- Overall, **'other' were positive** and welcome the creation of HERA but **concerns still remain over governance.**

Consultation strategy & Outreach

- **Public consultation:** will be open for 6 weeks
- **Targeted consultations** with Member States and with other stakeholders (e.g. industry, NGOs, international organisations, third countries)
- **Stakeholder mapping**
- **Outreach activities**

  Member States: political and technical level
  - **High-level group meetings** with DGs of relevant ministries
    - Regular meetings to specifically discuss scope, funding, governance and legal options
    - Letters were sent on 5 March asking for nominations (7 so far received).
  - **Bilateral meetings** with Member States a strong industrial/biopharmaceutical base

Continuous exchanges

- European Parliament, Council (relevant Council working groups(s)
- Agencies EMA/ ECDC/ EFSA/ EEA/ ECHA/ Europol/ EMCDDA/ EU OSHA

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HERA Incubator

HERA Incubator

- 17 Feb – Commission Communication
- Launch of a **EU bio-defence preparedness plan against COVID-19 variants**
- Key actions to boost preparedness, develop vaccines for the variants and increase industrial production
- The HERA Incubator will also serve as a blueprint for the EU's long-term preparedness for health emergencies

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Focus on 5 key action areas

Rapid detection of new variants

- Sequencing capacities
- Exploring use of detection assays
- Data sharing and exchange
- Wastewater monitoring
- Support to low income countries

Swift adaptation of vaccines

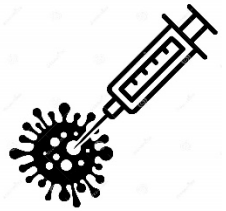
- Bringing together research and evidence on VOC
- Aligning research with existing/new vaccines and their technologies
- Vaccine development for children and adolescents

Setting up a EU Clinical Trials network

- Launch of VACCELERATE
- Ensure MS involvement
- Streamline the process between clinical trials and the regulatory approval process

Fast tracking of regulatory vaccine approval process

- Amending the regulatory procedure to accelerate vaccine approval
- Amending EU pharmaceuticals legislation
- Ensuring support to manufacturers



Upscaling of vaccine production and swift delivery

- Creating the “EU-FAB” project
- Mapping of potential bottlenecks of vaccine production
- Exploring use of flexible production models
- Providing capacity support
- Facilitate technology transfer
- APAs

1. Rapid detection of new variants (I)

EUCO Meeting – 25 February 2021

"It is our task to detect and tackle as soon as possible, as fast as possible ***COVID-19 variants****. That is the reason why we launched last week the HERA Incubator to build up our response to variants to stay ahead of the curve.*

What we need to do is to ***support the rapid detection*** *of new variants through cooperation with Member States, notably by* ***increasing the sequencing.***

For that, the European Commission is providing ***EUR 200 million*** *because we have to detect on a regular basis how the virus is spreading and whether the variants are spreading and how they are developing."*

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Rapid detection of new variants (II)

1. **Whole genome sequencing**
   - Increase MS sequencing capacities (ECDC FWC), transport of vials
   - Strengthen national infrastructures and support to labs
   - Capacity building and training
2. **Specialised RT-PCR**
   - Validation and deployment in case of demand
3. **Wastewater monitoring**
   - Development of a web-based platform
   - Support MS capacities and infrastructures

2. R&D: adaptation of vaccines

1. **Boost research & development on variants**
   - Additional € 30 million to projects running under Horizon 2020
   - Additional €120 million for actions under the new Horizon Europe programme
2. **Focus: COVID-19 vaccine development for children and adolescents**
3. **Horizon Europe Partnership on pandemic preparedness**
   - Being set up by DG RTD with a core group of 16 Member States + UK and CH
   - Scope: epidemics and pandemics
   - A first meeting with Member States took place on 24 Feb, next scheduled for 30 March

3. VACCELERATE

Launched in February 2021 (duration: 36 months)

- VACCELERATE will connect EU stakeholders involved in vaccine development to provide a **pan-European platform for clinical trial design and conduct**, with a particular focus on COVID-19.
- VACCELERATE will establish a virtual infrastructure that will enable and accelerate **phase 2 and 3 clinical trials** for vaccines.
- VACCELERATE involves **26 partners** in 16 Member States and 5 associated countries, led by University-Hospital Köln (DE). More countries have expressed interest to participate in a later stage.

First outcomes

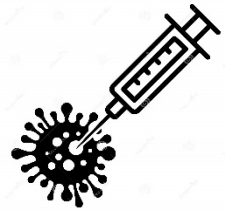
- **Mapping of vaccine trial sites**: more than 220 vaccine trial sites in 30 European countries were identified and 76 sites have expressed interest.

4. Fast-tracking of regulatory process

12 March: Delegated Regulation amending Commission Regulation (EC) 1234/2008 (Variation Regulation)

- Adaptations to active substances of an authorised COVID-19 vaccine may be required to ensure the vaccine's effectiveness against variants
- This amendment enables the approval of an adapted vaccine with a smaller set of additional data to be submitted to the EMA.
- It builds on the approach taken for adaptations of human influenza (flu) vaccines.

5. Upscaling of vaccine production



Mapping of production sites

- In-depth mapping of the available and potential production capacity of the EU's supply chain – this is continuously being updated

TFIS (Task Force for Industrial Scale-up)

- One-stop-shop contact point for industry
- Structural dialogues with EU industry to identify current or potential bottlenecks in production and supply + Identify producers that can help address these bottlenecks

EU Fab project

- A network of a number of 'ever-warm', single and/or multi-user technology production capacities for vaccine and medicine manufacturing in the EU.

Thank you