Proposals for regulation on serious cross-border threats to health and stronger mandate for ECDC and EMA

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European Health Union proposals
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First building blocks of the European Health Union, as announced in SOTEU; a set of proposals to:

- strengthen the **EU's health security framework**, and
- **reinforce** the crisis preparedness and response **role of key EU agencies**

- Communication: Building a European Health Union – Reinforcing the EU's resilience for cross-border health threats
- Proposal for a Regulation on serious cross-border threats to health
- Proposal to extend the mandate of the European Centre for Disease Prevention and Control
- Proposal to extend the mandate of the European Medicines Agency

European Commission

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

European Commission

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

Stronger and more operational European Medicines Agency

Shortages of medicines and crisis management

Preparatory

- Establish **Medicines Steering Group** – high-level MS representation (HMA) + COM + (Industry on an invitational basis)
- **Monitoring and reporting** procedures – MS and industry data submission; aggregation
- Develop **IT tools**
- **Escalate** when major event

Legal Basis: Art 114 / 168(4)(c) TFEU

Shortages of medicines and crisis management

MAJOR EVENT/ PHE

Operational shortages

- Establish **list of 'critical' medicines**
- **Monitor** supply and demand - MS and industry
- **Reporting** mechanisms
- Provide **recommendation**
- Consider need for **action** for mitigation/countermeasures – link to Cross Border Health Threats

Legal Basis: Art 114 / 168(4)(c) TFEU

Shortages of medicines and crisis management

MAJOR EVENT/ PHE

Operational – quality, safety, efficacy

- **Build on IRN structure**: IRN will continue dealing with incidents and routine measures and the steering group with major event/crises
- Assist in management of major events
- **Urgent and coordinated action** with regard to Quality / Safety /Efficacy

Legal Basis: Art 114 / 168(4)(c) TFEU

Shortages of medical devices and expert panels

Similar to medicinal product approach, while **safeguarding** the specific characteristics of the medical device sector and its regulatory approach, with some variations possible e.g. more **sector-specific** mitigation measures

Shortages of medical devices

Expert panels objective:

Provide a permanent home for the **panels** and maximise how they are used, incl. during crisis

EMA to provide **secretariat** and host meetings

Additional tasks on behalf of the Commission to support work of the panels

Emergency Task Force

Scientific response

PREPARATORY

- Establish **Emergency Task Force**
  - Membership to include various Agency committees and working groups, the Co-ordination Group for Mutual Recognition And Decentralised Procedures (CMD(h)) and the Clinical Trials Coordination and Advisory Group (CTAG))
- Specific composition and external input can be **adapted** to event
- **Develop working procedures** – submission of data, provision of Member State expertise
- **Develop IT tools** for data submission, effectiveness and safety monitoring for vaccines
- Tasks shall be performed separate from and *without prejudice to scientific committees*

Emergency Task Force

Scientific response

OPERATIONAL (during a public health crisis)

- **Accelerated scientific advice** on draft clinical trial protocols for candidate medicines
- **Review** at the request of a developer – endorsement of the advice by CHMP
- **Involvement** of representatives of Member States where the Clinical Trial Application is or will be submitted
- Member States need to take the advice duly into account when authorising the clinical trial
- **Scientific support to facilitate clinical trials** in the EU, including advice on the possibilities to set up larger multinational trials by defining responsibilities of (co-)sponsors Rolling review' of incoming evidence
- ETF assists CHMP
- ETF may **request data** from developers and use observational data
- **Recommendations** of the use of candidate medicines in national compassionate use programmes and on 'repurposed' medicines based on request of MS or Commission
- **CHMP remains responsible for scientific opinions** – no change to current distribution of tasks – however, clarifications with regard to possibility to provide compassionate use opinions on nationally authorised products
- **Communication** activities