



Workshop EU4Health

Programme 2021 -
potential solutions for a healthier European
Union

24/03/2021

Overview

- Decision 1082/2013/EU on Serious cross-border threats to health
 - Crisis preparedness
- European Health Union proposal
- Health Emergency Response Authority (HERA)



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Decision 1082/2013 on Serious cross border to health

- This decision lays down the rules on **epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning** related to those activities, in order to **coordinate and complement national policies.**
- Aim to **support cooperation and coordination between the Member States in order to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the Union.**



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Serious cross-border threat to health definition - article 3 (g)

1. Life-threatening or otherwise **serious hazard to health** of biological, chemical, environmental or unknown origin
2. spreads or entails a significant risk of **spreading across the national borders of Member States,**
3. **may necessitate coordination at Union level** in order to ensure a **high level of human health protection**



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Article 4 of Decision 1082 aims at ensuring adequate coordination between the Member States to achieve a consistent level of preparedness and interoperability between the existing and future national preparedness plans

Preparedness and response planning is an essential element for effective monitoring, early warning of and combating serious cross-border threats to health. Such planning should include in particular:

IHR core capacities



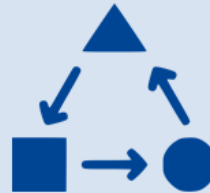
Supporting **implementation of core-capacity requirements** for surveillance and response (as per Art. 5 and 13 of the IHR)

Intersectorality



Addressing **intersectoral dimension** of preparedness and response planning at Union level

Interoperability



Promoting **interoperability** of national preparedness plans

EU-wide collaboration



Sharing **best practice** and experience in preparedness and response planning



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Early Warning and Response System (EWRS)

EWRS is a rapid alert system to notify alerts at Union level in relation to serious cross-border threats to health (**Article 8 of Decision 1082/2013/EU**).

The system enables the EC and the National Competent Authorities in **EU/EEA countries** to be in **permanent communication to alert, assess public health risks and determine the measures that may be required to protect public health.**

The system is **owned** by the EC, DG SANTE, and the IT application has been **operated** by the European Centre for Disease Prevention and Control (ECDC) since 2005.

Health



Biological¹



Chemical



Environmental



Unknown

Origins of threats



Health Security Committee (HSC)

The HSC is composed of representatives of the Member States (**art. 17 of Decision 1082/2013/EU**) having the following tasks:

- a.** support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Decision;
- b.** coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 4;
- c.** coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 11.



European Health Union proposal

**Stronger crisis preparedness and
response for Europe**



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Tackling health crises

Early lessons learnt from the COVID-19 pandemic show that the EU needs:

- more coordination
- more resilient health systems, and
- to be better prepared for future crises



Coronavirus impact



8.2 million

infected people in the EU
since January 2020



€2.7 billion

EU emergency support for coronavirus
health response, e.g. medicines, vaccines
and protective equipment



66% of citizens

want more EU responsibility
in health crises

European Health Union proposal -

11 November 2020

First steps towards European Health Union, as announced in State of the European Union, a set of proposals to:

1. strengthen the EU's health security framework,
2. reinforce the crisis preparedness and response, including the new mandate of key EU agencies



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1. A stronger EU health security framework

The EC proposes a **new Regulation on serious cross-border threats to health** to:

- **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

2. Stronger and more operational EU Agencies



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

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

2. Stronger and more operational EU Agencies

European Medicines Agency (EMA)

Evaluating and monitoring the safety of medicines



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 on 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



Health Emergency Preparedness and Response Authority HERA

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

11 Nov 2020 – Building a European Health Union

- strengthen the EU’s health security framework
- 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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HERA Inception Impact Assessment (27 Jan 2021)

- **Mission:** Enable the EU and its MS to rapidly deploy the most advanced medical countermeasures 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**
 - **Knowledge generation:** threat assessment, market intelligence, foresight
 - **Development:** late stage research, innovation and development
 - **Production:** flexible and scalable manufacturing capacities
 - **Deployment:** EU level stockpiling and distribution
 - **Training**



*Flexible and
resourced
financing &
procurement
capacities*



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HERA Incubator - 17 Feb 2021

– Commission Communication

Key action areas:

- rapid detection of variants;
- adaptation of vaccines;
- EU clinical trial network –
- VACCELERATE; regulatory approval procedure; upscaling vaccine production and delivery
- The HERA Incubator will also serve as a blueprint for the EU's upcoming HERA

Overview

Although rates of infectious diseases in the EU have fallen or remained stable in recent years, threats are still recurrent. The pandemic influenza (H1N1) in 2009, the E. Coli outbreak in Germany in 2011, the Ebola virus threat in Western Africa in 2014, Zika in 2016 and COVID-19 in 2020 show that international threats through new infections can emerge at any time.

The COVID-19 pandemic brought an unprecedented challenge to public health and life as we know it. Combatting cross-border health threats requires good preparedness and coordinated action before, during and after a crisis.

As part of [building a European Health Union](#), the European Commission proposed a new health security framework fit for the health challenges of tomorrow on 11 November. Based on [lessons learnt from combatting the coronavirus](#), the new framework will extend the role of EU agencies in the coordination of preparedness and response measures.

🔗 Dealing with health threats

Responding to a health threat involves a number of elements:

- detect and identify a threat, outbreak or crisis through surveillance and monitoring
- have early warning and notification channels through trusted procedures and other tools that health authorities can use to exchange information rapidly and in a targeted manner

A competent **risk assessment** is a key element in deciding whether and how to respond to a threat. This is particularly important in an international context.

Increasing preparedness is crucial to have the right capacities, processes and measures in place when needed. Preparedness is fundamental in making sure that procedures and mechanisms are set in place in advance and can be quickly mobilised in times of a health threat to protect the citizens. Lessons learnt from real events and regular simulation exercises to test existing procedures provide valuable input to improving and adapting preparedness activities.

Some threats are long term and require specific targeted action. [Antimicrobial resistance](#) is a very important growing public health problem that requires an adequate level of preparedness and response. Epidemics such as those of HIV/AIDS, viral hepatitis and tuberculosis also require special, coordinated and long-term attention. The same is true for terror attacks preparedness, hybrid threats and all forms of man-made threats to the public.

🔗 EU cross-border action


EUROPE'S BEATING CANCER PLAN
LET'S STRIVE FOR MORE

#EUCancerPlan

CORONAVIRUS
COVID-19

e-newsletter

Mon, 03/15/2021

th: The backing for a strong European h 

Latest updates

Call for expression of interest – Members representing non-governmental organisations in the Advisory Forum of the European Centre for Disease Prevention and Control (ECDC)

Released 15 March 2021

Coronavirus: EU Health Security Committee agrees on a common list of COVID-19 rapid antigen tests

Released 18 February 2021

Any questions?

Thank you

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