The EU response to serious cross-border public health threats

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Outline of the presentation

- The European governance of cross-border public health risks under the EU legal framework
- The global governance of PHEIC under the international legal framework
- Integration and coordination between the two systems
- Strength and weaknesses of the EU system
The European framework

- European Health Security Initiative and EU Strategic Framework on Health Security

- Health Security Committee
  - chaired by the Commission and composed of national authorities, DG SANTE and relevant agencies (e.g. (ECDC, EMA, etc.)

- European Centre for Disease Control (Regulation 851/2004)
  - An independent agency whose mission is to identify, assess and communicate current and emerging threats from communicable diseases – it is responsible for the operation of the European EWRS
The EU legal framework

- Art. 168 TFEU: Union action has to cover monitoring, early warning of, and combating serious cross-border threats to health

- Decision No. 2119/98/EC of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

- Commission Implementing decision of 22 December 1999 on the EWRS for the prevention and control of communicable diseases under Decision No. 2119/98/EC

- Decision No. 1082/2013/EU of 22 October 2013 on serious cross-border threats to health and repealing Decision No. 2119/98/EC
Decision No. 1082/2013

- Overall modernization of the general system
- Formal establishment of the Health Security Committee
- Adoption of the “all-hazards approach” -> threats of biological (communicable diseases, AMR, biotoxins), chemical, environmental and unknown origin)
- Risk assessment by EFSA, ECDC, other agencies
- Recognition of PH emergency situations independently of WHO
- Concern for possible duplication of efforts and enhancement of synergies and coordination
- Call for international cooperation and coordination
Obligations under Decision No. 1082/2013

- Obligation to consult other Member States and the Commission within the Health Security Committee (art. 4)
- Obligation to communicate information for epidemiological surveillance – including events occurring in third countries (art. 6)
- Obligation to inform other Member States and the Commission through the EWRS (art. 7)
- Obligation to notify an alert in the EWRS if there is an unusual and unexpected event affecting more than one member State and requiring a coordinated response (art. 9)
Multiple reporting and early warning systems (each one with its own portal for notification)

- **EWRS** – Early Warning and Response System originally for communicable diseases, later extended to public health risks of biological, chemical, environmental and unknown origin
- **RASFF** – Rapid Alert System for Food and Feed for foodborne diseases
- **ADNS** – Animal Disease Notification System for zoonoses (e.g. swine fever, avian influenza, bluetongue, BSE)
Complexities of the EU system

- Information exchange networks
  - **RAS BICHAT** – Biological and Chemical Attacks and Threats, for the deliberate release of chemical, biological and radio-nuclear agents
    - (since 2001: Health Security Programme)
  - **RAS CHEM** – deliberate release of chemical agents
    - (since 2014)

In 2005 the Commission established a general European rapid alert system called **ARGUS**, an internal network aimed to assure a coordinated and effective management of major multi-sectoral crises requiring a reaction at the European Union level. Member States and external bodies are connected through sector-specific rapid alert systems.
Complexities of the EU system

- Asymmetrical participation (also in terms of competent national authorities)
  - **EWRS** → EU Member States, Commission, ECDC, EEA Countries (Iceland, Liechtenstein and Norway)
  - **RASFF** → EU Member States, Commission, EFSA, Norway, Liechtenstein, Iceland and Switzerland
  - **ADNS** → EU Member States and Andorra, Faroe Islands, Norway and Switzerland
The global framework: WHO IHR (2005)

- Pursuant to an all-hazards approach, the IHR apply to any ‘illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans’

- Public health emergencies of international concern (PHEIC)

- Integrated global alert and response system (GAR)
  - Global Outbreak Alert and Response Network (GOARN), a global network launched in 2000 to combat the international spread of disease
  - International Food Safety Authorities Network (INFOSAN), a joint WHO-FAO global network launched in 2004 to promote the exchange of food safety information
  - Global Early Warning System for Major Animal Diseases, including Zoonoses (GLEWS), a WHO-FAO-OIE joint early warning system launched in 2006
Obligations under the IHR 2005

- Obligation to develop, strengthen and maintain core capacities to detect, assess, notify and report events (art. 5)

- Obligation to notify through National IHR Focal Points events occurring within a State’s territory which may constitute a PHEIC and the public health measures adopted (art. 6)

- Obligation to share information during unexpected or unusual public health events (art. 7)

- Obligation to consult the WHO on appropriate health measures for public health events not subject to notification (art. 8)
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Intersections between Decision 1082/2013 and IHR

- **Article 2** -> the Decision applies to measures adopted in case of a PHEIC, provided that it falls under one of the indicated categories of serious cross-border threats.

- **Article 4** -> consultation between member States, the Commission and the HSC aimed, inter alia, at supporting implementation of core capacities required by the IHR.

- **Article 9.2** -> simultaneous notification to EWRS of events notified to WHO as possible PHEIC.

- **Article 10** -> risk assessment by the EU shall «take into account» relevant information provided by the WHO in case of PHEIC.

- **Article 12** -> the Commission may recognise a PHE before a PHEIC is declared by the WHO DG if there is a specific danger at Union level.
Strength and weaknesses

Strength

- Improved integration and stronger coordination among EU actors (Commission-HSC-EFSA-ECDC) and reporting systems (EWRS-ADSN-RASFF)
- Possibility to adopt immediately applicable acts
- Possibility to intervene before WHO action
- Enforcement mechanisms for non-compliance with EU obligations

Weaknesses

- Possible overlapping of obligations and duplication of efforts
- Weak or incomplete coordination with other international organisations
- Imperfect integration with the WHO system and the IHR 2005
- No human rights concerns
Possible solutions?

Ad hoc cooperation agreement EU – WHO

- Exchange of information from monitoring and alert systems
- Integration among the several existing RAS or direct access of the WHO to European RAS (and vice versa)
- Participation of third countries to the surveillance network
- Mandatory simultaneous notification to both systems
- Consultation on the identification of emerging threats and the declaration of public health emergencies
- Appointment of the same health authorities as IHR National Focal Points and EWRS competent authorities for notification
Thank you!

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