

Serious cross-border threats to health

2020/0322(COD) - 06/12/2022 - Final act

PURPOSE: to improve the EU's capacity to respond to future pandemics and other cross-border health crises.

LEGISLATIVE ACT: Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

CONTENT: the Regulation on **serious cross-border health threats** aims to create a stronger mandate for coordination at EU level, update reporting requirements for health system indicators and streamline cooperation between EU countries, the European Commission and EU agencies. The revised legislation on cross-border health threats is part of the broader package on a European Health Union.

Scope

This Regulation applies to public health measures in relation to the following categories of serious cross-border threats to health:

- threats of biological origin, consisting of: (i) communicable diseases, including those of zoonotic origin; (ii) antimicrobial resistance; (iii) biotoxins or other harmful biological agents not related to communicable diseases;
- threats of chemical origin;
- threats of environmental origin, including those due to the climate;
- threats of unknown origin.

Health Security Committee (HSC)

The Regulation establishes a Health Security Committee (HSC) composed of representatives of the Member States. The HSC will support **coordinated actions by the Commission and the Member States** for the implementation of the Regulation. It will coordinate, in liaison with the Commission, (i) prevention, preparedness and response planning, (ii) risk and crisis communication, and (iii) Member States' responses to serious transboundary health threats. The Committee may adopt opinions and provide guidance on response measures in relation to the prevention and control of serious cross-border health threats.

Union prevention, preparedness and response plan

The Commission, in cooperation with the Member States and the relevant EU agencies and bodies, will establish an EU health crisis and pandemic plan to support an effective and coordinated response to cross-border health threats at EU level.

The Union plan will include cross-border and inter-regional preparedness elements to support aligned multi-sectoral cross-border public health measures, in particular with regard to surveillance, screening, contact tracing, laboratory capacity, training of health personnel and specialised treatment or intensive care in neighbouring regions.

To ensure the implementation of the EU plan, the Commission will need to facilitate the organisation of **stress tests**, simulation exercises and in-action and after-action reviews with Member States.

National prevention, preparedness and response plans

When developing their national plans, Member States will consult with each other and with the Commission to ensure consistency with the EU prevention, preparedness and response plan.

By 27 December 2023, and every three years thereafter, Member States will provide the Commission and the relevant EU agencies and bodies with an **updated report** on the planning and implementation of prevention, preparedness and response at national level and, where appropriate, at interregional cross-border levels.

The report will include country profiles to monitor progress and develop action plans to address identified gaps at national level, taking into account respective national circumstances. To this end, the Commission may issue general recommendations. An overview of the recommendations contained in the reports will be made public.

Evaluation

The European Centre for Disease Prevention and Control (ECDC) will evaluate the status of implementation of the national plans. Where appropriate, it will make recommendations to the Member States and the Commission based on the evaluations.

On the basis of the information provided by the Member States and the results of the evaluation, the Commission will report to the European Parliament and the Council every three years on the **status and progress of prevention, preparedness and response planning** at EU level.

Data sharing and reporting

A strengthened and integrated monitoring system is created at EU level to improve data sharing. EU countries are invited to intensify reporting on health system indicators.

Public health emergencies at EU level

The Commission will **declare an EU public health emergency** on the basis of expert advice such as that provided by the Advisory Committee on Public Health Emergencies. The declaration of an EU emergency may lead to: (i) the joint stockpiling and procurement of medical products or devices needed in the event of a crisis; (ii) the activation of ECDC support to mobilise and deploy the EU Health Task Force.

The **Advisory Committee** on Public Health Emergencies, composed of relevant independent experts, including representatives of health professionals, social workers and representatives of civil society, will contribute to the formulation of response measures.

Procurement

The Commission and Member States will be able to initiate **joint procurement procedures** for the purchase of medical countermeasures.

Before launching a joint procurement procedure, the Commission will prepare a joint procurement assessment indicating the envisaged general conditions of the joint procurement procedure, including possible restrictions on parallel procurement and negotiation activities by participating countries for the countermeasure in question during the specific joint procurement procedure. This assessment will take

into account the need to ensure the security of supply of the participating countries with the medical countermeasures concerned.

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