Serious cross-border threats to health

2020/0322(COD) - 04/10/2022 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 544 votes to 50, with 10 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission proposal as follows:

Subject matter and scope

The proposed Regulation aims to enable the EU to **better anticipate and respond to serious cross-border health threats**. The new rules provide for improved prevention, preparedness and response planning at EU and Member State levels.

The Regulation will apply to the epidemiological surveillance of communicable diseases, **including those of zoonotic origin**. As human, animal and environmental health are inextricably linked, the Regulation will have to follow the ‘One Health’ approach to address current and emerging crises.

Health Security Committee (HSC)

The HSC - composed of representatives of the Member States, divided into two working levels - will be given additional responsibilities for the adoption of guidelines and opinions to better support Member States in the prevention and control of serious cross-border health threats, and to promote better coordination between Member States in dealing with such threats. Representatives of relevant EU agencies and bodies may participate in the meetings of the HSC as observers. A representative appointed by the European Parliament should also be able to participate in the HSC as an observer.

EU prevention, preparedness and response plan

This plan should be drawn up by the Commission, in cooperation with the Member States and the relevant EU agencies and taking into account the WHO framework. It will complement national prevention, preparedness and response plans and promote effective synergies between Member States, the Commission, the European Centre for Disease Prevention and Control (ECDC) and other relevant EU agencies or bodies.

It should include joint governance, capacity and resource arrangements for:

- timely cooperation between the Commission, the Council, the Member States, the HSC and relevant EU agencies or bodies;

- secure exchange of information between the Commission, the Member States, in particular the competent authorities or designated bodies at national level, the HSC and the relevant EU agencies or bodies;

- epidemiological surveillance and monitoring;

- early warning and risk assessment, in particular regarding cross-border and interregional preparedness and response;

- risk and crisis communication, including for health professionals and citizens;

- health-related preparedness and response and multi-sectoral collaboration, such as the identification of risk factors for disease transmission and the associated disease burden, including social, economic and environmental factors;

- the drawing up of an EU-wide capacity map for the production of relevant critical medical countermeasures to address serious cross-border health threats

- emergency research and innovation;

- support to Member States in monitoring the impact of a serious cross-border health threat on the provision and continuity of health care services.

National prevention, preparedness and response plans

National prevention, preparedness and response plans may include elements relating to governance, capacity and resources laid down in the EU prevention, preparedness and response plan. Member States should consult within the HSC and agree with the Commission to ensure consistency with the EU Prevention, Preparedness and Response Plan to the greatest extent possible.

No later than 12 months from the date of entry into force of the Regulation, and every three years thereafter, Member States will be required to 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.

Every three years, ECDC will assess the status of implementation of national prevention, preparedness and response plans by Member States. The ECDC will make recommendations to the Member States and the Commission based on the assessments to the Member States. If a Member State decides not to follow a recommendation, it should explain the reasons for its decision.

Public health emergencies at EU level

For serious cross-border health threats, the Commission may, after considering any expert opinion issued by the ECDC, or any other relevant EU agency or body, or the Advisory Committee for Public Health Emergencies, formally **recognise a public health emergency at EU level**, including pandemic situations where the serious cross-border health threat in question endangers public health at EU level

Joint procurement

The regulation strengthens and extends the framework for **joint procurement of medical countermeasures** for different categories of cross-border health threats, including vaccines, antiviral drugs and other treatments.

The Commission should support and facilitate joint procurement of medical countermeasures by providing all relevant information for the negotiation of such joint procurement, such as information on envisaged prices, manufacturers, delivery times and joint procurement modalities.

Before launching a joint procurement procedure, the Commission will have to prepare an assessment indicating the general envisaged conditions of the procedure with regard to **possible restrictions on parallel procurement** and negotiation activities by the participating countries for the countermeasure in question during the procedure. This assessment will take into account the need to ensure the security of supply of medical countermeasures concerned to the participating countries.