Serious cross-border threats to health

2020/0322(COD) - 14/09/2021 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 594 votes to 85, with 16 abstentions, **amendments** to 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 matter was referred back to the committee responsible for interinstitutional negotiations.

The main amendments adopted in plenary concern the following points:

Purpose and scope

The proposal provides for a stronger and more comprehensive legal framework enabling the EU to react rapidly and to trigger preparedness and response measures to cross-border health threats throughout the EU.

According to Members, the COVID-19 crisis has shown that **more action is needed at EU level** to support cooperation between Member States, in particular between border regions. The regulation should respect the 'One Health' and 'Health in All Policies' approaches and ensure that in future health emergencies, the detection of, health interventions and treatment of other serious diseases, are not halted.

The regulation should apply to threats of biological origin including communicable diseases, including those of zoonotic origin, and to epidemiological surveillance of communicable diseases and monitoring of the impact of these diseases on **major non-communicable diseases** and health problems such as mental health.

Members proposed that the EU call for the development of a **WHO Framework Convention on Pandemic Preparedness and Response**. This convention should facilitate the implementation of the International Health Regulations (2005) and address the shortcomings of these regulations identified during the COVID-19 crisis.

Coordination of preparedness and response planning in the Health Security Committee (HSC)

Representatives of relevant EU agencies, including the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), should participate in HSC meetings as observers. The European Parliament should nominate representatives to participate in the HSC as observers. In liaison with the Commission and the relevant EU agencies, the HSC should coordinate Member States' prevention, preparedness and response planning.

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 should include:

- the mapping of the production capacities of medical products in the Union as a whole;

- the establishment of a Union stock of critical medicinal products, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;

- ensuring that healthcare services, including the screening, diagnosis, monitoring, treatment and care for other diseases and conditions, are provided without disruption during health emergencies;

- ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;

- monitoring whether adequate risk assessments, preparedness plans and training courses are foreseen for health and social care professionals.

The EU plan should also include measures to ensure that the EU preparedness and response plan should also provide for measures to ensure that the single market functions normally in the event serious cross-border threats to health arise.

National prevention, preparedness and response plans

Members proposed that each Member State should consult patients' organisations, health professionals' organisations, industry and supply chain stakeholders and national social partners when drawing up national plans.

Member States should provide the Commission with an **updated report** on their national and, where appropriate, regional and cross-border prevention, preparedness and response planning and implementation within 6 months of the entry into force of the Regulation and every two years thereafter. Every two years, the ECDC should carry out **audits** in Member States to verify the state of implementation of national plans and their consistency with the EU plan. These audits would be based on a set of indicators and would be carried out in cooperation with the relevant EU agencies.

Joint procurement

Members also want the EU to be more **transparent** when awarding contracts or making purchases. The precise quantities ordered by and supplied to each participating country and the details of their commitments should be made public.

The joint procurement process should be conducted in such a way as to strengthen the purchasing power of participating countries, improve security of supply and ensure equitable access to medical countermeasures in the event of serious cross-border health threats. If joint procurement is deployed, qualitative criteria should be considered in the award process, in addition to cost. Such criteria should also take into consideration, for example, the ability of the manufacturer to ensure security of supply during a health crisis.

The European Parliament reserves at all times the right to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings referred to in this Regulation.

Early warning and response system

The ECDC should broaden its communication activities to European citizens by setting up a portal for sharing verified information. In addition, Members proposed to update the Early Warning and Response System (EWRS), an instrument managed by the ECDC, with modern technology to ensure its interoperability with international, European, national and regional alert systems.