Serious cross-border threats to health

2020/0322(COD) - 11/11/2021 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted **amendments** by the European Parliament to the proposal for a regulation of the European Parliament and of the Council on serious cross-border health threats and repealing Decision No 1082/2013/EU.

The matter was referred back to the committee responsible for inter-institutional negotiations. The main amendments adopted in plenary are the following:

Subject matter and scope

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

As the health provisions of the Treaties remain largely underused, Members believe that the regulation should aim to make the best use of these provisions to demonstrate the strength of the EU's health policy.

Members proposed that the regulation should also establish rules on **emergency research and innovation plans**, including clinical trial networks and innovation platforms as well as a network of **national strategic stockpiles** and available medical countermeasures.

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 concerning and treatment of other serious diseases are not halted.

The strengthened EU health framework should work in synergy with other EU policies and funds. It should be implemented with full respect for the dignity and fundamental rights and freedoms of persons.

The Regulation should apply to the epidemiological surveillance of communicable diseases as well as to the surveillance of the impact of communicable diseases on **major non-communicable diseases** and on specific related health issues, 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)

In liaison with the Commission **and the relevant EU agencies**, including the European Health Emergency Preparedness and Response Authority (HERA), the HSC should coordinate Member States' prevention, preparedness and response planning. It should adopt an annual action programme with clear priorities and objectives. Representatives of the relevant EU agencies, as well as a representative appointed by the European Parliament, should be able to participate in the HSC as observers.

Members of the Committee should have no financial or other interests that could affect their impartiality. The list of members of the HSC should be made public.

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 risk and crisis communication, aimed at health professionals and at citizens;

- 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 without disruption during health emergencies;

- the implementation of the provisions of the plan relating to emergency research and innovation aspects and ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;

- an adequate and needs-oriented staffing level;

- 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 **single market functions** normally in the event serious cross-border threats to health arise.

National prevention, preparedness and response plans

Patients' organisations, health professionals' organisations, industry and supply chain stakeholders and national social partners should be consulted 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. The plan should include information on the '**strategic reserve**', i.e. the number and availability of medical countermeasures and other essential medicinal products and critical medical devices for the control of the threats as well as the capacity for their safekeeping and storage.

Every two years, the ECDC should conduct **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 public contracts or concluding procurement contracts. The procurement process should require all parties to deliver and respect clear commitments, including that manufacturers deliver the agreed production quantities and that authorities buy the agreed set-aside volumes.

The precise quantities ordered by and provided to each participating country and the details of their liabilities should be made public. In the case of joint procurement, the award criteria should also take into account, for example, the manufacturer's ability to ensure security of supply during a health crisis.

The **European Parliament** should be informed of the negotiations and should reserve the right, at all times, to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings.

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.