

HOPE Position Paper

on the Proposal for a regulation on serious cross-border threats to health on the Proposal for a regulation to extend the mandate of the ECDC

On 11 November 2020 the European Commission proposed three regulations: the proposal for a Regulation on serious cross-border health threats repealing Decision 1082/2013/EU (COM(2020) 727), the proposal for a Regulation to extend the mandate of the European Centre for Disease Prevention and Control (COM(2020)0726), and the proposal for a Regulation to extend the mandate of the European Medicines Agency (COM(2020)0725). A Communication “Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats” (COM/2020/724 final) was also published the same day.

HOPE considers that Member States are and should remain responsible for the organisation of their social protection and healthcare systems. The EU health policy should remain supplementing and supporting Member States in a meaningful way.

In addition, it is essential that administrative and financial repercussions on hospitals and healthcare services resulting from new EU legislation are thoroughly scrutinised, evaluated and made transparent by the European legislator in terms of their added value.

Implementation of a coordinated response at EU level

Proposed regulation

In order to improve the coordination and communication between EU level and Member States the European Commission proposes to strengthen the EU Health Security Committee, in particular by giving it a power to adopt guidelines and positions. The EU Health Security Committee would determine its rules of procedure by a majority of two-thirds, including the modalities for the participation of experts (*article 4, paragraph 6, proposal for a Regulation on serious cross-border threats to health*).

Position

HOPE welcomes the proposal of an improved systematic structure for the exchange of information between Member States and the European Commission for the coordination in health crisis.

This should respect the responsibilities of the Member States for the financing and organisation of their healthcare systems, even in crisis times.

HOPE is in favour of experts being involved but this means health scientists, health professionals but also representatives of healthcare services.

EU preparedness and response plan and regular exercises

Proposed regulation

The European Commission proposes to develop an EU preparedness and response plan for health crises that also includes interregional preparedness and response elements to create cross-border means (*article 5, paragraph 4, proposal for a Regulation on serious cross-border threats to health*).

The European Commission proposes that the Member States should issue similar, interoperable plans on a national and local level (*article 5 and article 6, proposal for a Regulation on serious cross-border threats to health*). It is recommended in the *Communication "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats"* that regular exercises would be organised.

Position

Disaster preparedness and response are organised in different ways in EU countries. In some countries civil protection is the responsibility of the federal states/regions, whereby the federal/central government provides assistance in situations in which the damage is of national concern. It may happen that in the case of hospital policies, the federal states/regions are exclusively responsible for hospital planning. This should be given more consideration in the proposal.

In any case, the reimbursement of the costs incurred by the hospitals for such large-scale projects must be planned and covered.

In the case of cross-border plans such exercises should be funded within the scope of EU4Health programme. If weaknesses are identified in the reporting and auditing processes, measures to remedy to those weaknesses should also be funded by the EU4Health programme.

All EU funding programmes should undergo a radical change to simplify them in the next funding period. Experiences with EU projects show that it is difficult for small operators to follow the current implementation procedure.

Epidemiological surveillance and communication of healthcare system data to assess healthcare system capacities

Proposed regulation

The COVID-19 pandemic has revealed that there is a lack of comparable data to support political decision-making. Consequently, the European Commission proposes the introduction of an integrated epidemiological surveillance and monitoring system at EU level, also in respect of research data and healthcare system capacities in the areas of diagnosis, prevention and treatment of specific communicable diseases (*article 13, paragraph 2, proposal for a Regulation on serious cross-border threats to health; article 1, paragraph 4, proposal for a Regulation to extend the mandate of the European Centre for Disease Prevention and Control*). The ECDC would assume a central role in setting up and managing the system.

In terms of practical implementation, the Member States, European Commission and ECDC would agree on case definitions, indicators, standards, protocols and procedures for data transmission (*article 1, paragraph 3, proposal for a regulation to extend the mandate of the European Centre for Disease Prevention and Control; article 13, paragraph 4 and 5, proposal for a Regulation on serious cross-border threats to health*). On this basis the Member States would report in a timely manner to the ECDC the complete and comparable data and feed it into the system (*article 1, paragraph 3, proposal for a regulation to extend the mandate of the European Centre for Disease Prevention and Control; article 14, paragraph 3, proposal for a regulation on serious cross-border threats to health*).

On the other hand, the system would be capable of automatically collecting information and data from existing digital information systems and using information from electronic health records (*article 14, paragraph 2, proposal for a regulation on serious cross-border threats to health*).

As the ECDC is to be given the task of surveying and assessing the capacity of the national healthcare systems to diagnose, prevent and treat communicable diseases (*article 1, paragraph 4, proposal for a regulation to extend the mandate of the European Centre for Disease Prevention and Control*), the Commission also provides for the communication and transmission by the Member States of all data and information necessary for this to the ECDC. The European Commission also includes as indicators in the *Communication "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats"* the availability of hospital beds, specialised treatment and intensive care capacities, and the number of medically trained staff.

Position

The communication of epidemiological data and information that supports the assessment of the situation and political decision-making in an economic area strongly shaped by mobility is clearly aimed at guaranteeing the health security of the EU population (e.g., infection rates, test numbers). Concerning the automated collection of information and data from existing digital information systems, there should be no direct access to electronic patient records nor can new interfaces to electronic patient records be created.

The responsibilities for the organisation and capacities of the healthcare system lie with the Member States and in some country, in respect of hospital capacities, with the federal states/regions. There is then no legal basis for mandatory communication and transmission of planning relevant healthcare system data – i.e., the availability of hospital beds, specialised treatment and intensive care capacities, number of medically trained staff – to institutions, agencies and bodies of the European Union to enable it to monitor and assess the national healthcare systems.

HOPE reject mandatory communication and transmission of monitoring and planning relevant healthcare system data to/at the EU level. The use of existing freely accessible data might be possible.

However, there are serious doubts that, considering the diversity of the national healthcare systems in the European Union, it will be possible to establish communication standards that make sense for every healthcare system. Past experiences have shown that often crucial national system subtleties need to be levelled off in order to be able to create a sufficient degree of abstraction for transnational comparisons. In the past, this abstraction resulted in there being little resemblance to the reality of the healthcare systems in the Member States. It should be noted that, even if there were monitoring and planning relevant healthcare system data available at EU level, they could not be used to manage capacities, as the EU has no competence. This raises the question of the added value of the collection of such data at EU level. The fact that hospitals in Europe are prepared to help each other in times of crisis has been proven by the acts of solidarity in this COVID-19 crisis. The EU can provide further support in bilateral cooperation and should also adapt rules within the regulation of coordination of social security systems to fit for special crisis situations.

Training of healthcare staff and public health staff

Proposed regulation

The Commission proposes to organise training for healthcare staff, to be organised and financed in collaboration with the Member States (*article 11, proposal for a Regulation on serious cross-border threats to health*).

Position

There have been for many years a variety of voluntary projects in existence in the area of cross-border cooperation and training of specialist healthcare staff co-financed by the European Union. It has been possible to gain further experience through funding projects run by the European Commission for further intensive care training in hospitals, especially in 2020 and 2021. In the process, it has become clear that it is essential in EU projects to also involve the management of these institutions.

HOPE welcomes the fact that the European Commission is trying out options for funding procedures that require little administration. This path should be pursued further. However, simplified procedures, deadlines, and selection and funding criteria should always be communicated with the utmost transparency. Moreover, in light of the continuing staff shortage in the healthcare system, it is crucial for the success of the training that funding is available for the staff costs incurred through the EU project.

Early warning and response system and EU-wide declaration of state of emergency: options to support cooperation between Member States

Proposed regulations

The early warning and response system would enable the European Commission and the competent authorities of the Member States to be in permanent communication (*article 18, proposal for a regulation on serious cross-border threats to health*). This includes alerts, risk assessments and the coordination of responses. The ECDC should support the European Commission in operating the system (*article 1, paragraph 9, proposal for a regulation to extend the mandate of the European Centre for Disease Prevention and Control*). The system should be used to record requests and/or offers in the area of cross-border emergency aid (*Communication “Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats”, p. 21*). Based on the alert and risk assessment the European Commission would, on submission by an independent advisory committee to be established, be able to recognise a “public health emergency at Union level” (*article 23, proposal for a regulation on serious cross-border threats to health*).

Position

In the COVID-19 pandemic hospitals have shown that they are prepared on a voluntary basis to support their neighbours in times of crisis with capacities wherever possible. This cooperation is based on bilateral agreements. HOPE agrees that the European Union can provide further support for this voluntary bilateral cooperation in times of crisis. It would be conceivable to install a reporting platform as part of the early warning and response system, to which the planning-relevant authorities have access, which they can activate for the hospitals if a state of emergency is declared in order for them to record requests and/or offers in the area of cross-border emergency aid. The COVID-19 pandemic has brought to light regulatory gaps in the coordination of social security systems in the case of health crises and major incidents. In some countries the legislator has been able to close the EU regulatory gap in the short term by introducing its own special regulation. However, the gap will have to be closed at EU level in the long term in order to be prepared, also from a regulatory perspective, for treatment solidarity in crisis situations.

HOPE, the European Hospital and Healthcare Federation, is a European non-profit organisation, created in 1966. HOPE represents national public and private hospitals associations and hospitals owners either federations of local and regional authorities or national health services. Today, HOPE is made up of 36 organisations coming from the 27 Member States of the European Union, as well as from the United Kingdom, Switzerland and Serbia as observer members. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.