

KEY ISSUES

Background: The COVID-19 pandemic has revealed shortcomings in the management of health threats at EU level. Based on this experience, the EU wants to strengthen the coordination of preparedness and response in handling serious cross-border health threats, with the European Centre for Disease Prevention and Control (ECDC) playing a key role.

Objective of the Regulation: Both the mandate and capacity of the ECDC is to be reinforced in order to strengthen prevention, preparedness and response planning for future serious cross-border health threats in the EU.

Affected parties: EU citizens, all stakeholders of EU and national disease control.



Pro: (1) The ability of the ECDC to provide non-binding recommendations can support Member States in countering communicable disease outbreaks. It does not interfere with their health policy competence.

(2) The development of digital platforms for epidemiological surveillance and their interoperability facilitates the availability and efficient exchange of information, which is necessary in such crisis situations.

(3) The EU Health Task Force will help Member States to respond to communicable disease outbreaks through increased capacity and crisis management expertise.

Contra: (–)

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Proposal COM(2020) 726 of 11 November 2020 for **amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control**

Brief Summary

Note: Unless otherwise indicated: (1) article numbers refer to Regulation [(EC) 851/2004] as amended by the present proposal; (2) recitals and page numbers refer to the proposal [COM(2020) 726].

► Background and Context of the Proposal

- According to the Commission, the COVID-19 pandemic has revealed shortcomings in the EU’s ability to manage health threats [p. 1].
- That includes the surveillance system of the European Centre for Disease Prevention and Control (ECDC). The ECDC currently has a limited mandate and capacity for analysing and providing data that support early evidence-based decision making and real-time situational awareness [COM(2020) 724, p. 4].
- In order to tackle the shortcomings, the Commission’s vision of a European Health Union encompasses three regulation proposals concerning
 - the European Medicines Agency (EMA) [COM(2020) 725; see cepPolicyBrief No. 12/2021],
 - the European Centre for Disease Prevention and Control (ECDC) [this cepPolicyBrief],
 - serious cross-border threats to health [COM(2020) 727; cepPolicyBrief to follow].

► Aim of the Proposal

- The Commission wants to reinforce the role of the ECDC to support preparedness, surveillance, risk assessment, early warning and response to future health crises [p. 1 and p. 4].
- The mission of the European Centre for Disease Prevention and Control (ECDC) is to identify, assess and communicate current and emerging threats to human health from communicable diseases [Art. 3 (1)].
- “Communicable diseases” are infectious diseases caused by a contagious agent transmitted from one person to another person [COM (2020) 727, Art. 3 (2)].
- The current mandate of the ECDC is to be extended to the provision of (non-binding) recommendations for response at EU, national and regional levels [Art. 3 (1)].
- The proposal especially aims to expand the tasks of the ECDC to [p. 4 et seq.]:
 - monitoring the capacity of national health systems;
 - reinforcing epidemiological surveillance;

- ensuring better prevention and preparedness in Member States;
- establishing an “EU Health Task Force”.

► **Monitoring the Capacity of National Health Systems**

- The ECDC will monitor the capacity of national health systems to respond to communicable disease threats and other special health issues [Recital 6 and Art. 3 (2) (e)]. “Special health issues” are antimicrobial resistance and healthcare-associated infections related to communicable diseases [Art. 3 (1) in conjunction with [COM\(2020\) 727](#), Art. 2 (1) (a) (ii)].
- This task includes monitoring and assessing the
 - capacity for diagnosis, prevention and treatment of communicable diseases and patient safety [Art. 5 (4) (d)];
 - possible shortcomings in the planning of preparedness and response [Art. 5b (1) (d)];
 - capacity to detect, prevent and recover from outbreaks of communicable diseases [Art. 5b (1) (i)].
- Member States must inform the ECDC about their preparedness and about health systems capacities to deal with outbreaks of communicable diseases and about response measures taken to tackle serious cross-border health threats [Recital 7 and Art. 4 (a) and (b)].

► **Reinforcing Epidemiological Surveillance**

- “Epidemiological surveillance” is the systematic collection, recording, analysis, interpretation and distribution of data and analysis on communicable diseases and related special health issues [Art. 2 (6) in conjunction with [COM\(2020\) 727](#), Art. 3 (4)].
- The ECDC will ensure [Recital 9 and Art. 5 (2) (a) and (g)]
 - further development of digital platforms for epidemiological surveillance at EU level and
 - interoperability of these platforms especially with the future EU Health Data Space so that health data can be used for healthcare, research, policy making and regulatory purposes.
- The existing network for the epidemiological surveillance of communicable diseases and of related special health issues (“epidemiological surveillance network”) will continue to ensure permanent communication between the Commission, Member States and the ECDC [[COM\(2020\) 727](#), Art. 13 (1)].
- Through the epidemiological surveillance network, the ECDC is to detect, monitor and report on communicable disease trends across Member States and in third countries [Art. 5 (4) (a)].
- The Member States will provide national surveillance data to the ECDC [Art. 5 (5)].
- The ECDC will
 - broaden the collection and analysis of data on epidemiological surveillance [Recital 14 and Art. 11 (1a) (a)],
 - develop solutions to access relevant health data made available or exchanged through digital infrastructures, allowing the use for healthcare, research, policy making and regulatory purposes [Art. 11 (2) (d)].

► **Ensuring better Prevention and Preparedness in Member States**

- The ECDC will support the Member States in strengthening their communicable disease prevention and control systems [Art. 5a (1)] especially by
 - evaluating and monitoring corresponding programmes in order to provide evidence for recommendations to improve them at national and EU level [Art. 5a (3)]; and
 - providing recommendations for actions to prevent and control communicable disease threats and other special health issues [Art. 3 (2) (b)].
- The ECDC will provide scientific and technical expertise to the Member States and the Commission [Art. 5b (1)] and especially
 - monitor shortcomings in preparedness and provide targeted support to Member States [Art. 5b (1) (d)];
 - develop specific preparedness activities addressing vaccine preventable diseases, antimicrobial resistance, laboratory capacity and biosecurity [Art. 5b (1) (f)];
 - provide recommendations to strengthen the health systems of the Member States [Art. 5b (1) (i)].
- The ECDC will ensure the operation of the network of EU reference laboratories [[COM\(2020\) 727](#), Art. 15] for the diagnosis, detection, identification and characterisation of infectious agents that may present a threat to public health [Art. 5 (6)].
- EU reference laboratories
 - promote good practice and alignment by Member States on a voluntary basis especially on testing methods as well as notification and reporting of diseases [Recital 11 and [COM\(2020\) 727](#), Art. 15 (1)];
 - will strengthen the capacity in the EU to diagnose and identify infectious agents causing a public health threat [Recital 11 and Art. 5 (7)].
- The ECDC already provides independent scientific opinions, expert advice, data and information [(EC) 851/2004, Art. 6 (1)]. For this, the ECDC will have access to health data made available or exchanged through digital infrastructures, allowing the use for healthcare, research, policy making, and regulatory purposes [Art. 6 (3)].

► **Establishing an “EU Health Task Force”**

- The ECDC will mobilise and deploy outbreak assistance teams (“EU Health Task Force”) that quickly intervene in a healthcare crisis when a “public health emergency at Union level” [COM(2020) 727, Art. 23 (1)] has been recognised [Recital 16; COM(2020) 727, Art. 25 (1) (c)].
- Consequently, the ECDC will
 - maintain capacity for missions to Member States to provide recommendations on response to threats to health within its mandate upon request of the Commission and Member States [Art. 11a (6)];
 - establish capacity to mobilise and deploy the EU Health Task Force to assist the local response to outbreaks of communicable diseases in Member States and third countries [Recital 16 and Art. 11a (1)];
 - develop a framework and procedures for mobilisation in collaboration with the Commission [Art. 11a (2)].

Statement on Subsidiarity by the Commission

Serious cross-border health threats have transnational implications. Public health measures at national level need to be consistent with each other and coordinated to minimise the consequences of these threats. [p. 2]

Legislative Procedure

11 November 2020	Adoption by the Commission
14 December 2020	Committee referral announced in Parliament
23 July 2021	Agreement in the Council on the general approach
Open	Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

Options for Influencing the Political Process

Directorates General:	DG SANTE (Health and Food Safety)
Committees of the European Parliament:	Environment, Public Health and Food Safety (leading), Rapporteur: Joanna Kopcińska (European Conservatives and Reformists Group, Poland)
Federal Germany Ministries:	Federal Ministry of Health
Committees of the German Bundestag:	Committee on Health
Decision-making Mode in the Council:	Qualified majority (55% of Member States & 65% of the EU population)

Formalities

Competence:	Art. 168 (5) TFEU (protection and improvement of human health)
Type of Legislative Competence:	Support, Coordinate, Supplement (Art. 6 (a) TFEU)
Procedure:	Art. 294 TFEU (ordinary legislative procedure)

ASSESSMENT

Economic Impact Assessment

The ECDC’s new ability to provide non-binding recommendations at regional, national and EU level **can support the Member States in countering communicable disease outbreaks**. Through such guidance, Member States can benefit from the expertise of the ECDC which may lead to a more efficient use of resources by Member States. In parallel, more consistency regarding national health measures across the EU may help to alleviate negative consequences of serious cross-border threats to health, which by their very nature are transnational issues.

Data communicated to the ECDC on the preparedness and capacity of the national health systems, is necessary for managing cross-border health threats, for example providing recommendations on responses to outbreaks. However, this should not lead to an unnecessary administrative burden. A clear definition of “national health systems capacity” and corresponding indicators could help to safeguard both effective monitoring by the ECDC as well as a proportionate obligation for Member States to continuously provide corresponding data. This would also help Member States to determine whether data on their health system capacities can already be provided through existing national structures.

The development of digital platforms for epidemiological surveillance and their interoperability facilitates the availability and efficient exchange of information and reduces administrative burdens. As was apparent at the start of the COVID-19 pandemic, even a comparison of the situations in the Member States was difficult. This was primarily due to the differing approaches to data collection and data reporting. Thus a reliable picture of the spread of the virus at any one time has not always been possible [see also cep [Input Three Steps Towards a European Health Union](#), p. 9].

The planned integration of these platforms in the EU Health Data Space will enable Member States to exchange health data and have better access to it. This will support the Member States in defining their health policies more accurately.

Health data is a special category of personal data. Processing this type of data is prohibited unless a legal exception is applicable, such as public health reasons. Therefore, the access to and the processing of health data must accord with the principles of the General Data Protection Regulation (GDPR), especially data minimisation, purpose limitation and storage limitation.

The network of EU reference laboratories will have a positive impact on disease response as diverse testing strategies have hampered the EU's efforts to coordinate its response to the disease. **Greater alignment between Member States** in terms of how they operate, e.g. regarding testing strategies and reporting, **will allow disease threats to be identified sooner and contained more effectively**. The network of EU reference laboratories will facilitate a more common approach to work and enhanced exchange of information between Member States.

The EU Health Task Force will help Member States to respond to communicable disease outbreaks through increased capacity and crisis management expertise. Furthermore, expertise can be developed and shared between ECDC staff and other experts, leading to increased knowledge and consequently better response to outbreaks. Support from the EU Health Task Force in third countries may help to stop the spread of communicable diseases to the EU.

The EU Health Task Force may be deployed to Member States upon recognition of a "public health emergency at Union level". However, it is unclear whether it can also be deployed without recognition of that event at the request of a Member State. This should be possible because it may help prevent an EU-wide public health emergency at an early stage.

Legal Assessment

Legislative Competence of the EU

The Member States are responsible for the definition of their health policy and for the organisation and delivery of health services and medical care [Art. 168 (7) TFEU]. The EU though may adopt (1) measures designed to protect and improve human health and in particular to combat the major cross-border health scourges and (2) measures concerning monitoring, early warning of and combating serious cross-border threats to health [Art. 168 (5) TFEU]. **The ability of the ECDC to give non-binding recommendations on the prevention and control of, as well as the response to, communicable diseases does not breach the general competence of the Member States in the field of health policy** [Art. 168 (7) TFEU].

Subsidiarity

Unproblematic. To support preparedness, the surveillance, risk assessment and early warning of and response to serious cross-border health threats can better be dealt with at EU level.

Proportionality with Respect to Member States

Unproblematic.

Summary of the Assessment

The ECDC's new ability to provide non-binding recommendations can support the Member States in countering communicable disease outbreaks. The development of digital platforms for epidemiological surveillance, and their interoperability, facilitates the availability and efficient exchange of information. The network of EU reference laboratories will have a positive impact on disease response. Greater alignment between Member States will allow disease threats to be identified sooner and contained more effectively. The EU Health Task Force will help Member States to respond to communicable disease outbreaks through increased capacity and crisis management expertise. The ability of the ECDC to give non-binding recommendations on the prevention and control of, as well as the response to, communicable diseases does not breach the general competence of the Member States in the field of health policy.