



On 20 March 2021, the CPME Board adopted the 'CPME Position on the Commission's Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control' (CPME 2021/025 FINAL).

**CPME Position on the Commission's
Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a
European Centre for disease prevention and control**

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.¹

CPME welcomes the opportunity to comment on the European Commission's Proposal for a Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control. We wish to highlight the following key aspects:

One Health (Recital 6)

- The Commission plans to enhance the role of the European Centre for Disease Prevention and Control (ECDC) in pandemic preparedness and management by increasing capacities and infrastructures for cooperation.
- CPME welcomes the focus on the One-Health approach in recognition of the interlinks between human health, animal health and the environment as well as the high percentage of communicable diseases which are zoonotic.

Collection and analysis of data (Article 11)

- CPME welcomes the proposal to improve the capacity of the ECDC to improve data collection and sharing related to infectious diseases. Member States need to align their data collection and reporting to improve data quality and comparability in the EU and EEA countries.

¹ CPME is registered in the Transparency Register with the ID number 9276943405-41.

- CPME supports the development of the category of ‘EU public health data’ and define relevant data to be collected at national level which should be shared. This data on health systems can support the development of further policy recommendations e.g. ratios for resources per population unit for Member States to use as a benchmark for preparedness.
- CPME believes that the precise health data that the ECDC requires to perform its tasks needs to be mapped and accounted for in a separate Annex in order to be compliant with EU data protection laws.

General

- CPME would like to highlight the need to ensure the division of tasks between the different agencies (European Medicines Agency, European Centre for Disease Prevention and Control, and the future Health Emergency Response Authority) is coordinated to avoid competing competences and overlap.

Proposed amendments

Proposal for a Regulation Article 1 – point 13 – point b

Regulation (EC) No 851/2004 Article 11 – paragraph 1a (e)

<i>Commission proposal</i>	<i>CPME amendments</i>
(b)1a. The Centre shall collect data and information, and will ensure links to relevant research data and outputs on: [...] (e) health systems data required for managing cross-border health threats.	(b)1a. The Centre shall collect data and information, and will ensure links to relevant research data and outputs on: [...] (e) health systems data required for managing cross-border health threats. <i>This includes but is not limited to data on the stock of health professionals, stock of medicines, medical devices and personal protection equipment, intensive care and acute care bed capacity and beds in use, ventilators and ventilators in use, testing capacity and tests performed, and data on the resourcing of public health departments, in particular per capita staffing levels for community medicine.</i>
<i>Justification</i>	
The lack of robust comparable data on health systems’ resources and capacities was a major barrier to better pandemic management, therefore it is necessary to ensure that plans are grounded in up-to-date evidence. The reference to community medicine refers to the medical specialty as described in Directive 2005/36/EC, Annex V, 1.3 , covering titles in public health medicine, social medicine, epidemiology.	

Proposal for a regulation – Article 1 – point 13 – point c

Regulation (EC) No 851/2004 Article 11 – paragraph 2 (d)

<i>Commission proposal</i>	<i>CPME amendments</i>
<p>2. For the purposes of paragraph 1, the Centre shall: [...] d) develop solutions to access relevant health data made available or exchange through digital infrastructures, in accordance with data protection rules, allowing for health data to be used for healthcare, research, policy making and regulatory purposes; and provide and facilitate controlled access to health data to support public health research.</p>	<p>2. For the purposes of paragraph 1, the Centre shall: [...] d) develop solutions to access relevant health data made available or exchange through digital infrastructures, in accordance with data protection rules, allowing for health data to be used for healthcare, research, policy making and regulatory purposes; and provide and facilitate controlled access to health data to support public health research. <i>The relevant health data shall be identified in Annex I.</i></p>
<p><i>Justification</i></p>	
<p>Processing of health data can only be required for specific and concrete purposes. The ECDC's use of relevant health data with possible transfer to third entities requires that such data is identified and mapped in a separate Annex.</p>	

Proposal for a regulation - Annex I (new)

Regulation (EC) No 851/2004 – Annex I

<i>Commission proposal</i>	<i>CPME amendments</i>
	<p><i>Annex I</i></p> <p><i>Health Data referred to in Article 11 (2) (d)</i></p> <ul style="list-style-type: none"> • <i>(to be defined and consented to by the patient)</i>
<p><i>Justification</i></p>	
<p>To comply with personal data protection principles of purpose limitation and data minimisation, avoiding broad access by ECDC to patient data, a precise list of health data should be developed in a separate Annex.</p>	