CPME/AD/Board/20032021/010_Final/EN

On 20 March 2021, the CPME Board adopted the 'CPME Position on the Commission's Proposal for a Regulation on serious cross-border threats to health' (CPME 2021/010 FINAL).

CPME Position on the Commission's Proposal for a Regulation on serious cross-border threats to health

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 on serious cross-border threats to health. We wish to highlight the following key aspects:

Cooperation with third countries (Recital 21)

- The proposal acknowledges that cooperation with third countries and international organisations in the field of public health should be fostered. It also highlights the importance of ensuring the exchange of information with the WHO on the measures taken pursuant to the Regulation.
- CPME supports fostering cooperation with third countries and international organisations, as well as expanding the geographical scope of the European Centre for Disease Prevention and Control (ECDC) to cover also other than EU and EEA countries. This would allow better collaboration with the WHO European Region and avoid duplication of work.

General Provisions - Scope (Article 1)

- The implementation of this Regulation must be carried out in full respect for the dignity and fundamental rights and freedoms of persons.

General Provisions - Health Security Committee (HSC) (Article 4)

- Legally binding measures at EU level should be discussed and decided in one body, not in several parallel or even competing bodies as has been the case to date. In our view, this should be the Health Security Committee (HSC). The proposal aims at giving additional responsibilities to Health Security Committee

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41. More information about CPME's activities can be found under www.cpme.eu.

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(HSC) with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.

- CPME supports the strengthening of the HSC which should be able to formally adopt guidance and opinions. The ongoing COVID-19 pandemic has shown the limited ability of the HSC to enforce and coordinate the national responses around control measures or to implement the agreed common approaches.

Chapter II: Preparedness and Response Planning (Articles 5-12)

- CPME strongly believes that cross-border threats from within the EU need to be prevented where possible, so the planning in Chapter II and throughout should be called ''Prevention, Preparedness and Response Planning". ''Preparedness and Response" planning is too reactive and not sufficiently proactive.
- Moreover, where it is read 'preparedness and response planning' it should be read 'prevention, preparedness and planning'.

Union Preparedness and Response Planning (Article 5)

- The proposal aims at developing an EU health crisis and pandemic preparedness plan and requirements for the plans at national level.
- CPME welcomes the proposal to establish a new Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level. It is important that the preparation of national plans will be supported by the European Centre for Disease Prevention and Control (ECDC) and other EU agencies.
- Prevention, preparedness and response planning should be strengthened by scoping a set of EU public health data and define relevant data to be collected at national level which should be shared (e.g. stock of health professionals including shortages, 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). Identifying the data to be shared in advance offers procedure transparency, increases trust on the adopted countermeasures by Member States and facilitates the coordination of patients in border regions, in particular by understanding a Member State capacity to treat patients from nearby Member States.
- Community medicine needs to be resourced and strengthened at all levels relevant to each Member State including national, regional and community level in order to ensure that the expertise and capacity is available to prevent and minimise threats from developing and spreading. 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.

Commission report on preparedness planning (Article 9)

- On the basis of the health systems data collected, the European Commission should develop concrete recommendations for ratios for resources per population unit for Member States to use as a benchmark for preparedness. 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'[2] (please see 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).

Training for health care staff and public health staff (Article 11)

- The proposal aims at enabling the Commission, in cooperation with the Member States, to organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.
- CPME believes that training of doctors and other healthcare professionals is essential. They must have knowledge and skills to develop and implement the national preparedness plans, implement activities to strengthen crisis preparedness and surveillance capacities.
- Therefore, CPME welcomes the commitment of European Commission organising training activities for healthcare staff and public health staff in the EU Member States, including preparedness capacities under the International Health Regulations.
- CPME wishes to highlight the importance of ensuring training activities also to cover 'One-Health' both in terms of content and format of training, 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.
- Moreover, CPME supports that the training activities may be open to staff of the competent authorities of third countries and may be organised outside the Union.
- Where Member States share a land border, 'Prevention, Preparedness and Response Planning' should include familiarity with public health structures and staff in the adjoining State and should involve conducting joint cross-border exercises.
- To reduce barriers to access, training should be provided during working time and at no expense to participating healthcare professionals.

Epidemiological surveillance (Article 13)

- The proposal aims at ensuring a permanent communication between the European Commission, the ECDC, and the competent authorities responsible at national level by a network for the epidemiological surveillance of the communicable diseases.
- CPME believes that monitoring trends in communicable diseases in the wider European region is essential to assess the situation and respond to threats with evidence-based action. Therefore, CPME finds the communication between EU institutions, EU agencies and the national level crucial.

Platform for surveillance (Article 14)

- The proposal aims at building an epidemiological surveillance system at EU level which will be managed by ECDC and the data fed by Member States.
- CPME believes that human oversight is required at strategic moments of the process when implementing automated real-time surveillance for the purpose of supporting communicable disease prevention and control.

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[2] 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.

- CPME further believes that the wording proposed in Article 14(2)(a) of the Regulation in relation to electronic health records is too wide and could become an open door to disproportionate access to patient data. The precise relevant health data to be processed must be listed in a separate Annex in order to be compliant with EU data protection laws.
- Processing patient data can only be required for specific and concrete purposes. The proposal does not offer a definition of what implies processing patient data for 'epidemiological purposes'. This open concept can also lead to disproportionate use. CPME advocates to relate the purpose to the surveillance objective.
- Moreover, the list of the precise health data that the ECDC needs to have access to perform its tasks needs to be mapped and accounted for in the above-mentioned Annex.

EU reference laboratories (Article 15)

- The proposal aims at designating EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by EU Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by member states.
- CPME welcomes the proposal as the COVID-19 pandemic has shown a lack of comparable data and understanding of the situation on which to base decision-making.

Recognition of emergency situations (Article 23)

- CPME supports the improved coordination of clear division of competences between Member States, WHO and WHO-Europe, the EU and its agencies, and OECD as to the declarations of pandemics, subsequent containment or treatment measures, effective data collection and sharing and horizonal coordination on recommendations.

Proposed amendments

Proposal for a regulation – Recital 7

Commission proposal	*CPME amendments*
(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.	(7) ***Prevention,*** preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' ***prevention,*** preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. ***This training should be consistent with the One-Health approach in recognition of the interlinks between human health, animal health and the environment.*** To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. ***Specific considerations should be given to border regions, where joint cross-border exercises should be promoted and familiarity with the public health system structures encouraged.*** Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.
Justification	
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, it is vital to explicitly include One-Health as an area of training.	

Proposal for a regulation – Article 1 – paragraph 4 (new)

Commission proposal	*CPME amendments*
(…)	***(4) The implementation of this Regulation shall be with full respect for the dignity and fundamental rights and freedoms of persons.***
Justification It is important to ensure that sanitary regulations are not misused to restrict fundamental rights and freedoms of individuals.	

Proposal for a regulation – Chapter II – Title

Commission proposal	*CPME amendments*
Preparedness and Response Planning	***Prevention,*** Preparedness and Response Planning
Justification Cross-border threats from within the EU need to be prevented where possible. ''Preparedness and Response" planning is too reactive and not sufficiently proactive.	

Proposal for a regulation – Articles 5-12

Commission proposal	*CPME amendments*
Preparedness and Response Planning	***Prevention,*** Preparedness and Response Planning
Justification In line with the previous amendment, where it is read 'preparedness and response planning' it should be read ***'prevention***, preparedness and planning'.	

Proposal for a regulation – Article 5 – paragraph 5

Commission proposal	*CPME amendments*
(5) In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.	(5) In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary. ***The prevention, preparedness and response plan will take into account health systems data and relevant data to be collected at national level. Based on EU health systems data, the European Commission should issue recommendations as to ratios of resources in relation to population unit for baseline universal health coverage and emergencies, including the option of pooling resources at Union level.***

Justification
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. Additionally, ratios for resources per population unit are guidance to identify under resourced areas. 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'. 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 9 – paragraph 2

Commission proposal	*CPME amendments*
(2) The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.	(2) The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1. ***These recommendations shall include ratios for resources per population unit, developed on the basis of good practice and policy assessments.***
Justification	
The pandemic showed that health systems in several Member States were not sufficiently resourced, e.g. in terms of intensive care unit capacity or healthcare professionals to staff the units. It is therefore necessary to make explicit recommendations of ratios for resources per population unit as a benchmark for Member State action.	

Proposal for a regulation – Article 11 – paragraph 1

Commission proposal	***CPME amendments***
(1) The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations. The Commission shall organise those activities in cooperation with the Member States concerned.	(1) The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations. The Commission shall organise those activities in cooperation with the Member States concerned. ***At border regions, joint cross-border exercises***

	should be promoted and familiarity with public health systems encouraged.

Justification
Due to patient mobility in border regions there is a need to ensure that the healthcare staff and public health staff understand the public health system of the adjoining Member State and are able to trust each other by conducting joint exercises.

<u>Proposal for a regulation – Article 11 – paragraph 2</u>

Commission proposal	*CPME amendments*
(2) The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.	(2) The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools ***and consistent with the One-Health approach.***

Justification
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, it is vital to explicitly include One-Health as an area of training.

<u>Proposal for a regulation – Article 14 – paragraph 1</u>

Commission proposal	*CPME amendments*
(1) The ECDC shall ensure the further development of the digital platform through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control.	(1) The ECDC shall ensure the further development of the digital platform through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control. ***Human oversight should be ensured.***

Justification
There needs to be assurances that a human is in the loop at some point during the process of automated exchange and analysis.

<u>Proposal for a regulation – Article 14 – paragraph 2</u>

<table>
<tr><th>Commission proposal</th><th>CPME amendments</th></tr>
<tr><td>(2) The digital platform shall
(a) enable the automated collection of surveillance and laboratory data, make use of information from electronic health records, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;
(b) allow for the computerised handling and exchange of information, data and documents.</td><td>(2) The digital platform shall
(a) enable the automated collection of surveillance and laboratory data, make use of relevant health data identified in Annex I ~~information from electronic health records~~, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;
(b) allow for the computerised handling and exchange of information, data and documents.</td></tr>
<tr><td colspan="2">Justification
Processing of health data can only be required for specific and concrete purposes. Making use of electronic health records (EHR) by ECDC implies an open door to disproportionate access. It is not proportional to the purposes of epidemiological surveillance.</td></tr>
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<u>Proposal for a regulation – Article 14 – paragraph 5</u>

<table>
<tr><th>Commission proposal</th><th>CPME amendments</th></tr>
<tr><td>(5) For epidemiological purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.</td><td>(5) For epidemiological surveillance purposes, ECDC shall also have access to relevant health data identified in Annex I accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.</td></tr>
<tr><td colspan="2">Justification
'Epidemiological purposes' are an open concept which can lead to disproportionate use. It is necessary to relate the use to <u>surveillance</u> objective. Moreover, the list of the precise health data that the ECDC needs to have access to perform its tasks needs to be mapped and accounted for in a separate Annex.</td></tr>
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<u>Proposal for a regulation - Annex I (new)</u>

<table>
<tr><th>Commission proposal</th><th>CPME amendments</th></tr>
<tr><td></td><td>Annex I
Health Data referred to in Article 14 (2) (a)
• (to be defined and consented to by the patient)</td></tr>
<tr><td colspan="2">Justification
To comply with the GDPR principles of purpose limitation and data minimisation, avoiding disproportionate access by ECDC to patient data, a precise list of health data should be developed.</td></tr>
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