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PHARM  
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COVID-19  
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WORKING PAPER

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From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (General)
Subject:	Informal videoconference of the members of the Working Party on Pharmaceuticals and Medical devices on 23 March 2021 - Presentation by the Commission

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Delegations will find enclosed the presentation made by the Commission on Chapter II of the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross border threats to health and repealing Decision No 1082/2013/EU



Proposal for a  
REGULATION OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL  
on serious cross-border threats to health  
and repealing Decision No 1082/2013/EU

*Art 5-10*

## Chapter II

- Preparedness and response planning
  - Article 5 – Union preparedness and response plan
  - Article 6 – National preparedness and response plans
  - Article 7 – Reporting on preparedness and response plans
  - Article 8 – Auditing by the Commission
  - Article 9 – Commission report on preparedness
  - Article 10 – Coordination of preparedness and response planning in the HSC

## Background

- COVID-19: national-level preparedness and response capacities were sub-optimal – e.g. export restrictions of PPE in spring 2020
- COVID-19: clear lack of overall vision on the operationalisation of MS preparedness and response plans & incoherence with regards compatibility – lack of baseline standards and indicators
- No pan-EU preparedness plan
- Proposal:
  - Strengthen coordination mechanism for pandemic preparedness – EU-level plan
  - National preparedness plans - interoperable
  - Audit process to strengthen operationalization of the plans – by ECDC
  - Address gaps with funding support from EU4Health, structural funds etc.



# Article by Article

## ARTICLE 5

### Union preparedness and response plan

1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a 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.
2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

## ARTICLE 5

### Union preparedness and response plan

3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

- (a) the timely cooperation between the Commission, the MS and the Union agencies;
- (b) the secure exchange of information between the Commission, Union agencies and the MS;
- (c) the epidemiological surveillance and monitoring;
- (d) the early warning and risk assessment;
- (e) the risk and crisis communication;
- (f) the health preparedness and response and intersectoral collaboration;
- (g) the management of the plan.

## ARTICLE 5

### Union preparedness and response plan

4. The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.

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.

## ARTICLE 6

### National preparedness and response plans

1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission

in order to reach consistency with the Union preparedness and response plan,

also inform without delay the Commission and the HSC of any substantial revision of the national plan.

## ARTICLE 7

# Reporting on response and response planning

1. Member States shall by the end of November 2021 and every 2 years thereafter provide the Commission with a report on their preparedness and response planning and implementation at national level. That report shall cover the following:

(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;

## ARTICLE 7

### Reporting on response and response planning

That report shall cover the following:

- (b) elements of emergency preparedness, in particular:
- (i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery; coordination mechanisms;
- (ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;
- (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies;

# ARTICLE 7

## Reporting on response and response planning

- That report shall cover the following:
- (c) implementation of national response plans, including where relevant implementation at the regional and local levels, covering epidemic response; antimicrobial resistance, health care associated infection, and other specific issues. The report shall include, whenever relevant, interregional preparedness and response elements in line with the Union and national plans, covering in particular the exist.
- The report shall include, whenever relevant, interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions.

## ARTICLE 7

# Reporting on response and response planning

2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years. The report shall include country profiles for monitoring progress and developing action plans to address identified gaps at national level. Based on the report, the Commission shall, in a timely manner, initiate discussion in the HSC to discuss progress and gaps in preparedness. The recommendations of the report shall be published on at the website of the Commission.

## ARTICLE 7

# Reporting on response and response planning

3. The Commission shall, by means of implementing acts, adopt templates to be used by the Member States when providing the information referred to in paragraph 1, in order to ensure its relevance to the objectives identified in that paragraph, and its comparability. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

4. When receiving classified information transmitted pursuant to paragraph 1, the Commission and the HSC shall apply the rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/44325 and 2015/44426.

## ARTICLE 27(2) – examination procedure

- Article 27(2) “Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. “
- Regulation No 182/2011 – Article 5
- (1) [...] the committee shall deliver its opinion by the majority laid down in Article 16(4) and (5) of the Treaty on European Union and, where applicable, Article 238(3) TFEU, for acts to be adopted on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in those Articles.
- Positive opinion: EC to adopted the implementing act
- Negative opinion: amendment / appeal committee
- No opinion: adopt draft IA / amendment

## ARTICLE 7 Reporting on response and response planning

5. Each Member State shall ensure that its national security regulations apply to all natural persons resident on its territory and all legal persons established on its territory that handle the information referred to in paragraphs 1 and 2, where it is classified as EU classified information. Those national security regulations shall offer a degree of protection of classified information at least equivalent to that provided by the rules on security as set out in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom<sup>27</sup> and by Council Decision 2011/292/EU<sup>28</sup> .

## ARTICLE 8 Auditing by the Commission

1. Every 3 years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred in Article 7(1).
2. Member States shall present an action plan addressing the proposed recommendations of the audit and the corresponding corrective actions and milestones. These actions may, in particular, include: (a) review/adjustment of the legislation, if necessary; (b) training initiatives; (c) overview reports of audits series, which present cases of good practice.
3. The Commission shall adopt delegated acts in accordance with Article 28 concerning procedures, standards and criteria for the audits referred to in paragraph 1.

## ARTICLE 28 (2) – Exercise of delegation

- The power to adopt delegated acts referred to in Article 8(3) shall be conferred on the Commission for an indeterminate period of time from [date].
- The delegation of power referred to in Article 8(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. [...] It shall not affect the validity of any delegated acts already in force.
- Before adopting a delegated act, the Commission shall consult experts designated by each Member State
- As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the EP and to the Council.
- A delegated act adopted pursuant to Article 8(3) shall enter into force only if no objection has been expressed either by the EP or by the Council within a period of two months of notification

## ARTICLE 9 Commission report on preparedness

1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.
2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.

## ARTICLE 10 Coordination of preparedness and response planning in the HSC

1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health. The coordination shall, in particular, be aimed at:

- (a) sharing best practice and experience in preparedness and response planning;
- (b) promoting the interoperability of national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level;
- (c) supporting the implementation of capacity requirements for surveillance and response as referred to in the IHR;

## ARTICLE 10 Coordination of preparedness and response planning in the HSC

(d) developing the preparedness plans referred to in Articles 5 and 6;

(e) monitoring progress, identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels.

# Thank you



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