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COMMISSION DELEGATED REGULATION (EU) 2024/1232

of 5 March 2024

supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU ([1]), and in particular Article 8(4) thereof,

Whereas:

(1) Regulation (EU) 2022/2371 lays down mechanisms and structures for coordinating preparedness for and response to serious cross-border threats to health, including reporting on prevention, preparedness and response planning.

(2) Pursuant to Article 7(1) of Regulation (EU) 2022/2371, Member States are to provide the Commission and relevant Union agencies and bodies with an updated report on prevention, preparedness, and response planning and implementation at national level, and where appropriate, cross-border interregional levels by 27 December 2023 and every 3 years thereafter. The information in that report is to be collected through responses provided using the template for the provision of information on prevention, preparedness and response planning set out in Commission Implementing Regulation (EU) 2023/1808 ([2]) and the European Centre for Disease Prevention and Control (ECDC) is to take account of that information when assessing the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan in accordance with Article 8(1) of Regulation (EU) 2022/2371. Such assessments are to be based on a set of agreed indicators and carried out in cooperation with the relevant Union agencies or bodies and aim to assess prevention, preparedness and response planning at national level regarding the information referred to in Article 7(1) of Regulation (EU) 2022/2371.

(3) The ECDC assessment procedure should be organised in phases, which should include a desk review and a country visit, followed by an ECDC assessment report. In so far as the assessments cover areas within the remit of the Commission or of other Union agencies or bodies, the ECDC should closely cooperate with the Commission or those Union agencies or bodies. The ECDC may seek support of the Office for the European Region of the World Health Organization and experts from other Member States upon agreement with the assessed Member State.

(4) The standards and criteria to be used for the ECDC's assessments should be based on the capacities referred to in the template for the provision of information on prevention, preparedness and response planning as set out in Implementing Regulation (EU) 2023/1808. Those capacities are needed to ensure adequate prevention, preparedness and response planning.

([1]) OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj.

([2]) Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023 setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council (OJ L 234, 22.9.2023, p. 105, ELI: http://data.europa.eu/eli/reg_impl/2023/1808/oj).

(5) In carrying out its assessments, the ECDC should use the criteria with associated indicator levels and responses to the open questions provided in the template for the provision of information on prevention, preparedness and response planning as set out in Implementing Regulation (EU) 2023/1808.

(6) The ECDC assessments should have a qualitative approach to the state of implementation of Member States' national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan.

(7) In accordance with Article 8(2) of Regulation (EU) 2022/2371, the ECDC is to present to the Member States and to the Commission recommendations based on its assessments of the standards and criteria, addressed to Member States taking into account national respective circumstances. Those recommendations may contain recommended follow-up actions by the Member State. Those recommendations are to be addressed by the Member States in an action plan in accordance with Article 8(3) of that Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down procedures, standards and criteria for the assessments, in accordance with Article 8(1) of Regulation (EU) 2022/2371, of the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan.

Article 2

Procedures

The procedures for the assessments by ECDC of Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan are set out in Annex I.

Article 3

Standards and criteria

The ECDC shall assess the Member States' state of implementation of their prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan against the standards and on the basis of the criteria set out in Annex II.

Article 4

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Procedures to assess the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan

The ECDC shall start assessment procedures with a general preliminary discussion with each Member State. The assessment procedure shall be organised in phases, which shall include a desk review and a country visit, followed by an ECDC assessment report, which may include recommendations. In so far as the assessments cover areas within the remit of the Commission or of other Union agencies or bodies, the ECDC shall closely cooperate with the Commission or those Union agencies or bodies. The ECDC may seek support of the Office for the European Region of the World Health Organization and experts from other Member States upon agreement with the assessed Member State.

The desk review shall encompass gathering and analysis of relevant documents prior to the experts' discussion.

The country visit shall include discussions with experts and relevant stakeholders of the assessed Member State to investigate the state of implementation of national prevention, preparedness and response plans on the basis of reports provided pursuant to Article 7 of Regulation (EU) 2022/2371 and the desk review. The Member States may provide additional information during the assessment.

The country visit shall be structured in two parts:

(a) an initial discussion covering all the capacities as referred to in the template for the provision of information on prevention, preparedness, and response planning as set out in Implementing Regulation (EU) 2023/1808;

(b) a second part focusing on specific capacities, which may be different in every cycle, considering national respective circumstances.

The ECDC assessment report shall provide results of the assessments with an overview of each Member State's prevention, preparedness and response planning at national level based on the outcome of the desk review process, the country visit and other information provided by the Member States during the assessment process, thereby applying the standards and criteria set out in Annex II.

The ECDC shall share a preliminary assessment report with the assessed Member State and consider the Member State's comments when preparing the final assessment report. The decision to publicly disclose fully or partially ECDC's assessment report shall be left to the discretion of the assessed Member State.

ANNEX II

Standards and criteria to assess the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan

The standards and criteria for assessing Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan are listed in the table below. The ECDC assessments shall have a qualitative approach to the state of implementation of Member States' national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan.

The standards and criteria are based on capacities set out in the International Health Regulations (2005) and additional capacities referred to in Article 7(1) of Regulation (EU) 2022/2371, including the information submitted as part of the State Party Self-Assessment Annual Reporting Tool (SPAR). The SPAR is used by Member States to report on core capacities for surveillance and response on the implementation of Article 54 of the International Health Regulations (2005). The standards are grouped by reference to the capacities set out in Sections A and B of the Annex to Implementing Regulation (EU) 2023/1808. The ECDC shall assess to which extent the criteria have been implemented in the prevention, preparedness and response planning of Member States and their relation to the reporting under Article 7 of Regulation (EU) 2022/2371 by using the associated indicator levels and responses to the open questions provided in the template.

Table

Standards and criteria for assessing Member States' state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan

Capacity	Standard	Criteria
A. INTERNATIONAL HEALTH REGULATIONS (IHR) 2005 CAPACITIES		
1a. Policy, legal and normative instruments to implement the International Health Regulations (IHR) 2005	1a.1 Policy, legal and normative instruments for preparedness and response planning	1a.1.1 Conduct legal analysis of legal and normative instruments and policies for IHR implementation 1a.1.2 Incorporate coordination across national, regional and local levels 1a.1.3 Include in the legal instruments coordination with sectors responsible for critical infrastructure 1a.1.4 Incorporate coordination and cooperation at national-Union interface 1a.1.5 Include a clear decision-making process during public health emergencies 1a.1.6 Evaluate and test operational readiness of legal and normative instruments and policies including identification of gaps 1a.1.7 Include a mechanism for revising legal instruments which includes all government levels
	1a.2 Gender equality in health emergency	1a.2.1 Assess systematically gender equality 1a.2.2 Include an action plan to address gender gaps and inequalities, which is funded and with mechanisms in place for monitoring, evaluation and reporting
1b. IHR coordination, national IHR focal point functions and advocacy	1b.1 Mechanisms for IHR implementation	1b.1.1 Have IHR national focal point functions appropriately resourced, positioned, regularly tested and updated 1b.1.2 Include multisectoral coordination mechanisms across administrative levels, which are regularly tested and updated 1b.1.3 Include advocacy mechanisms in place across all administrative levels, regularly tested and updated

Capacity	Standard	Criteria
2. Financing	2.1. Financing for IHR implementation	2.1.1. Include a financial planning across all administrative levels involving all relevant sectors 2.1.2 Have the ability to provide financial support to other countries 2.1.3 Incorporate a monitoring and accountability mechanisms
	2.2. Financial resources to respond to a public health emergency	2.2.1 Incorporate financial planning across all administrative levels 2.2.2 Conduct regular tests of financial resources for contingency funding and implement recommendations for improvement 2.2.3 Have the ability to offer financial support to other countries
	2.3. Coordination of policies and activities in the case of a public health emergency	2.3.1 Have procedures involving Ministry of Health and Ministry of Finance
3. Laboratory	3.1 Specimen referral and transport system	3.1 Have a referral and transport system for all specimen types across all administrative levels 3.2 Test and update the transport system
	3.2 Biosafety and biosecurity	3.2.1 Include guidelines in all laboratories across all administrative levels 3.2.2 Test and update the procedures regularly 3.2.3 Have access to high-containment laboratories
	3.3 Quality system	3.3.1 Implement national quality standards across all administrative levels 3.3.2 Test and update the procedures regularly 3.3.3 Have a facility dedicated to validating new devices for novel pathogen diagnosis
	3.4 Testing capacity	3.4.1 Have a laboratory system that can perform in all capacities, including characterisation of a novel pathogen by Next Generation Sequencing 3.4.2 Include a plan to scale-up testing capacities in case of a public health emergency, which is regularly tested and updated 3.4.3 Have appropriate time for implementation of new nucleic acid amplification-based tests (NAATs) with scale-up capacity of diagnostic NAAT testing services and adapt associated laboratory systems 3.4.4 Have access to additional sources of laboratory capacity 3.4.5 Configure a laboratory network to support the testing needs, which is regularly tested and updated
	3.5 Diagnostic network	3.5.1 Implement testing strategies across all administrative levels, which are regularly tested and updated
	3.6 Laboratory testing result reporting system	3.6.1 Include an electronic reporting system 3.6.2 Have capacity to scale-up the reporting system 3.6.3 Integrate different sources of laboratory capacities

Capacity	Standard	Criteria
4. Surveillance	4.1 Early warning, surveillance functions and surveillance system	4.1.1 Cover all healthcare levels for acute respiratory infections 4.1.2 Have automated surveillance system for acute respiratory infection, influenza-like illness and severe acute respiratory infections 4.1.3 Provide immediate and weekly reporting of events and/or data 4.1.4 Have ability to scale-up during a public health emergency for respiratory infections 4.1.5 Include guidelines and/or standard operating procedures for surveillance across all administrative levels 4.1.6 Have ability to monitor relevant indicators during a public health emergency for the whole territory 4.1.7 Test and update surveillance system across all administrative levels 4.1.8 Have a wastewater monitoring system
	4.2 Assessment of pandemic threats and event management	4.2.1 Have assessment methodology which consider information on transmissibility, severity, immunological information, vaccine effectiveness and impact 4.2.2 Implement event management mechanism across all administrative levels, which is regularly tested and updated
5. Human resources	5.1 Human resources for implementation of the IHR	5.1.1 Have appropriate human resources in all relevant sectors across all administrative levels according to IHR provisions 5.1.2 Have documented policies and procedures for sustainable appropriate human resources in relevant sectors, which are regularly tested and updated 5.1.3 Include mechanisms to support other countries in planning and developing human resources capacities
	5.2 Surge capacity in human resources in the event of a public health emergency	5.2.1 Include mechanisms to ensure a surge in human resources, such as a national multisectoral workforce surge strategic plan, including an operational instrument considering different services and administrative levels 5.2.2 Include agreement to receive and exchange human resources support in the health sector considering the government and non-governmental partners, different administrative levels and other countries 5.2.3 Test and update the mechanism regularly 5.2.4 Ensure training of participants

Capacity	Standard	Criteria
6a. Health emergency management – Management of health emergency response	6a.1 Prevention, preparedness, and response planning for public health emergencies	6a.1.1 Have an all-hazard risk informed health emergency plan and/or prevention, preparedness, and response plan for public health emergencies in use across all sectors and at all administrative levels, which is regularly tested and updated 6a.1.2 Include provisions for medical transfer of patients and/or mobile medical teams to other countries 6a.1.3 Seek coherence with the Union prevention, preparedness and response plan and include cross-border interregional preparedness elements 6a.1.4 Include a strategy for emergency research and innovation 6a.1.5 Include a One Health approach, which is regularly tested and updated 6a.1.6 Ensure a coordination mechanism in case of intentional release scenario with specific national coordination mechanisms 6a.1.7 Consider support roles, functions and instruments of the Commission and relevant Union agencies and bodies 6a.1.8 Include provisions for cross-border mutual aid which have been regularly tested and shared with the Health Security Committee.
	6a.2 Management of specific health threats – epidemic response plans	6a.2.1 Conduct routine health emergency risk profiling for serious cross-border threats to health 6a.2.2 Develop specific health emergency risk profiling and epidemic response plans, which are regularly tested and updated 6a.2.3 Have a plan to address availability and use of threat specific medical countermeasures used for specific threats
	6a.3 Incident Management System (IMS)	6a.3.1 Have an IMS or equivalent system linking the public health sector with sectors involved in health preparedness and response planning, which is regularly tested 6a.3.2 Integrate an incident management system with a national public health emergency operations centre with the ability to support across all administrative levels 6a.3.3 Adapt the command and control structure/hierarchy composition of the IMS 6a.3.4 Include interoperability with Early Warning and Response System module for incident and/or crisis management
	6a.4 Public Health and Social Measures (PHSM)	6a.4.1 Provide for a multi-disciplinary and cross-sectoral mechanism for the implementation of PHSMs during a public health emergency, which is regularly evaluated and tested 6a.4.2 Have capacity of evaluating the timeliness and effectiveness of PHSM 6a.4.3 Conduct testing of the mechanism
6.b Health Emergency Management – Emergency logistic and supply chain management	6b.1 Demand and supply of critical medical countermeasures (MCMs)	6b.1.1 Identify critical MCMs for preparedness and response to serious cross-border threats to health 6b.1.2 Include emergency logistics and supply chain management system across all administrative levels, which is regularly evaluated and updated 6b.1.3 Have national policies or plans for monitoring of the supply and estimating demand of critical MCMs, which are regularly tested and updated 6b.1.4 Implement provisions in the preparedness and response plan to mitigate supply chain vulnerabilities of critical MCMs

Capacity	Standard	Criteria
	6b.2 Production of MCMs	6b.2.1 Identify the current production of critical MCMs (full or partial) at national level 6b.2.2 Have existing or planned arrangements to timely scale-up manufacturing of crisis-relevant MCMs
	6b.3 Strategic stockpiles	6b.3.1 Have national strategic stockpiles of MCMs 6b.3.2 Incorporate clear requirements for the deployment of the MCMs held within the stockpile
7. Health Service Provision	7.1 Continuity of healthcare service	7.1.1 Provide for foresight assessment of the potential impact of a health emergency on continuity of health services in the prevention, preparedness and response plan or equivalent document 7.1.2 Have a dedicated operational plan for continuity of healthcare services, which is regularly tested and updated 7.1.3 Have a mechanism for monitoring service continuity across all administrative levels, which is regularly tested and updated 7.1.4 Include a mechanism for prioritisation/flexibility of health service provision in the operational plan, which is regularly tested 7.1.5 Ensure interdisciplinary crisis management coordination between all actors of the healthcare system 7.1.6 Implement national clinical case management guidelines for priority health events across all administrative levels, which are regularly tested and updated
	7.2 Business continuity for healthcare providers	7.2.1 Have a national guidance/recommendations for business continuity plans using a multi-sectorial approach, which are regularly tested and updated 7.2.2 Have strong levels of service utilisation at all health care facilities and administrative levels, and allow revision and update of information on service utilisation 7.2.3 Require the hospitals to have a hospital alert and response plan, which is regularly tested 7.2.4 Have capacity to map available health services in the case of a public health emergency
8. Risk communication and community engagement (RCCE)	8.1 RCCE coordination	8.1.1 Implement mechanisms for coordination of RCCE functions and resources, including infodemics management, across all administrative levels, which are regularly tested and updated 8.1.2 Provide for coordination with the Health Security Committee on the risk and crisis communication in the communication plan
	8.2 Risk communication	8.2.1 Have national risk communication plan across all administrative levels, which is regularly tested and updated 8.2.2 Conduct analysis of target audiences and preferred communication channels to inform risk communication interventions 8.2.3 Include proactive outreach and media monitoring to adjust and improve risk communication strategies

Capacity	Standard	Criteria
	8.3 Community engagement	8.3.1 Have mechanisms for systematic community engagement and implement activities across all administrative levels 8.3.2 Test and update the community engagement mechanisms 8.3.3 Conduct socio-behavioural research
9. Points of entry (PoE) and border health	9.1 Core capacities and contingency plan	9.1.1 Implement, test, and update routine core capacities in all PoE with an approach that encompasses all hazards and is multi-sectoral 9.1.2 Integrate routine core capacities with national surveillance system 9.1.3 Implement, test, and update PoE all-hazard public health emergency contingency plans 9.1.4 Implement and test instruments regularly for sharing and reporting of travel related health information
	9.2 International travel-related measures	9.2.1 Implement, test and update international travel-related measures adoption mechanism across all administrative levels 9.2.2 Include communication with the Health Security Committee prior to implementation of measures
10. Zoonotic diseases and threats of environmental origin, including those due to the climate	10.1 One Health approach	10.1.1 Have One Health multisectoral capacities to prevent, detect, assess and respond to zoonotic events, which are regularly tested and updated 10.1.2 Implement training programmes for One Health professionals on zoonoses 10.1.3 Have information for the public available on the personal protective measures to follow when finding sick/dead wild animals 10.1.4 Conduct surveillance of agreed prioritised zoonotic diseases in coordination between animal health, public health, and environmental sectors
	10.2 Environmental threats	10.2.1 Include provisions about the effects of climate change on zoonotic diseases 10.2.2 Include provisions about the impacts of extreme weather events on public health
11. Chemical events	11.1 Preparedness and response for chemical events	11.1.1 Implement a chemical preparedness and response plan, which is regularly tested and updated 11.1.2 Include procedures for a health risk assessment a case of a health threat from chemical origin 11.1.3 Conduct surveillance, assessment and management of chemical events and poisoning/intoxication 11.1.4 Have an integrated system of public health surveillance linked with environmental monitoring, that captures and assesses data on chemical exposures from multiple sources

Capacity	Standard	Criteria
B. ADDITIONAL CAPACITIES AS PER REGULATION (EU) 2022/2371		
12. Antimicrobial resistance and healthcare-associated infections	12.1 Antimicrobial resistance (AMR)	12.1.1 Have a national action plan on AMR, appropriately costed and funded, including a One Health multi-sectoral governance or coordination mechanism on AMR 12.1.2 Have appropriate monitoring and evaluation arrangements for national action plans on AMR, including all/the relevant targets agreed at EU level 12.1.3 Have in place functional systems for the rapid detection, confirmation and notification of novel or priority multidrug-resistant organisms (MDROs) 12.1.4 Have national procedures for screening and reporting MDRO carriage at hospital admission 12.1.5 Have antimicrobial stewardship guidelines implemented at healthcare facilities 12.1.6 Have a national surveillance system on AMR that also includes reporting on antimicrobial consumption and designated (a) national reference laboratory/ies for AMR 12.1.7 Identify challenges in addressing AMR
	12.2 Healthcare-associated infections (HAIs)	12.2.1 Implement national strategic plan for HAI surveillance, which is regularly tested and updated 12.2.2 Implement infection prevention and control programmes, which are regularly tested and updated 12.2.3 Implement national standards and resources to ensure safe environment in health facilities across all administrative levels, which are regularly tested and updated 12.2.4 Identify challenges in addressing HAIs
13. Union level coordination and support functions	13.1 Coordination with the Health Security Committee and involvement in support functions	13.1.1 Incorporate the Health Security Committee representative into national level coordination structures and support the flow of information between the Member State and the Health Security Committee 13.1.2 Incorporate and/or factor in Union level support functions: opinions and guidance from the Health Security Committee for the prevention and control of serious cross-border threats to health; Commission's recommendations on common temporary public health measures; recommendations from the ECDC on response to health threats
14. Research development and evaluations to inform and accelerate emergency preparedness	14.1 Research in prevention preparedness and response plans	14.1.1 Include a strategy for emergency research and innovation, allocating and mobilising funds and strengthening capacity 14.1.2 Have a process in place to link public health needs with research priorities and needs 14.1.3 Strengthen research, innovation and capacities

Capacity	Standard	Criteria
	14.2 Research procedures in public health emergencies	14.2.1 Participate in networks of clinical trial sites or cohorts 14.2.2 Have processes in place to establish protocols and data collection during public health emergencies 14.2.3 Have procedures in place for rapid site accreditation and for expedited coordination 14.2.4 Have an approach to operational (e.g. in action) research in place
15. Recovery elements	15.1 Recovery plan	15.1.1 Have a recovery plan including capturing lessons learnt and embedding them in a national action plan 15.1.2 Implement and monitor the recovery process across all administrative levels
16. Actions taken to improve gaps found in the implementation of prevention, preparedness, and response plans	16.1 National action plan and strategy for prevention, preparedness, and response improvement	16.1.1 Use complementary mechanisms to assess the implementation of IHR capacities and prevention, preparedness, and response planning 16.1.2 Develop a national action plan aligned with whole of government and One Health for all hazards approach 16.1.3 Conduct a cost estimation of the national action planning for health security or equivalent system and implement it