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

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 7(3) 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), first subparagraph, of Regulation (EU) 2022/2371, Member States are to provide the Commission and relevant Union agencies and bodies 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.

(3) Article 7(1), second and third subparagraphs, of Regulation (EU) 2022/2371 lay down the information on prevention, preparedness and response planning which Member States are to provide to the Commission and relevant Union agencies and bodies.

(4) Pursuant to Article 7(2)), first subparagraph, of Regulation (EU) 2022/2371, every 3 years the Commission is to make the information received available to the Health Security Committee (HSC) in a report prepared in collaboration with the European Centre for Disease Prevention and Control (ECDC) and other relevant Union agencies and bodies. That report is to include country profiles for monitoring progress and developing action plans to address gaps identified at national level for which the Commission may issue general recommendations considering the outcomes of the assessment of Article 8 of that Regulation.

(5) Pursuant to Article 7(2), second and third subparagraphs, of Regulation (EU) 2022/2371, based on that report, the Commission is to initiate discussion in the HSC on the progress and gaps in preparedness. An overview of recommendations of the report is to be published on the websites of the Commission and the ECDC.

(6) The template of the questionnaire to be used by Member States when providing the information referred to in Article 7(1) of that Regulation should ensure its relevance to the objectives identified in that paragraph and its comparability, while avoiding any duplication of information requested and submitted. The template was elaborated in close collaboration with the Working Group on Preparedness of the HSC with active participation of majority of Member States, the relevant Commission Directorates-General, the ECDC, and the World Health Organisation (WHO). The template was aligned, where possible, with the International Health Regulations (2005) State Party Self-Assessment Report (SPAR).

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on serious cross-border threats to health,

[1] OJ L 314, 6.12.2022, p. 26.

HAS ADOPTED THIS REGULATION:

Article 1

The template to be used by Member States when providing information on their prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Article 7(1) of Regulation (EU) 2022/2371, as is set out in the Annex to this Regulation, is adopted.

Article 2

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, 21 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

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A. INTERNATIONAL HEALTH REGULATIONS (IHR) 2005 CAPACITIES

1. **Policy, legal and normative Instruments to implement the International Health Regulations (IHR) 2005**

	Question		Indicator
A.1.1	Regarding your Member State's legal instruments for preparedness and response planning, please indicate your Member State's corresponding level:		Indicator 1-5
		level	
	Legal instruments do not incorporate coordination across national, regional, and local levels of government during a public health emergency	1	
	Legal instruments incorporate coordination across national, regional, and local levels of government during a public health emergency	2	
	Legal instruments incorporate coordination across national, regional, and local levels of government during a public health emergency. In addition, legal instruments also incorporate coordination with sectors responsible for critical infrastructure during a public health emergency	3	
	Legal instruments incorporate coordination across national, regional, and local levels of government during a public health emergency. In addition, legal instruments also incorporate coordination with sectors responsible for critical infrastructure during a public health emergency. Moreover, the operational readiness of these legal instruments has been tested in the last 3 years	4	
	As per level 4 and, in addition, there is a mechanism for reviewing and revising legal instruments (if needed based on recommendations from testing)	5	
	— If level 5: has your country revised the legal instruments in the last 3 years? (yes/no) — If yes, please upload relevant links (optional for Member States): — Additional comments:		
A.1.2	In the event of a public health emergency, do your country's legal instruments for IHR 2005 implementation assign a clear decision-making process, which may comprise one or more authorities? (yes/no/other) — If other, please describe:		Not applicable (N/A)

2. **Financing**

	Question		Indicator
A.2.1	Regarding Member States's planning to test the financial resources for contingency funding to respond to health threats, please indicate your Member State's corresponding level:		Indicator 1-5 or N/A
		level	
	Member State cannot answer the question [at central state level]	N/A	
	There are no plans to conduct tests of financial resources for contingency funding for response to health threats in the next 3 years	1	
	There are plans to conduct tests of financial resources for contingency funding for response to health threats in the next 3 years but this is on an ad hoc basis	2	
	There are plans to conduct tests of financial resources for contingency funding for response to health threats and this is to be conducted on a regular basis	3	
	Tests of financial resources for contingency funding for response to health threats have been and continue to be conducted on a regular basis	4	
	As per level 4, and, in addition, recommendations from the tests have been implemented and corresponding plans have been reviewed and revised	5	
	— Additional comments: *Your Member State cannot answer this question at the central state level, due to governance and legislative frameworks? (yes)* *In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)* *If yes, please advise if at central level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges* *If not, please explain:*		
A.2.2	Does the Ministry of Health and Ministry of Finance of your Member State have dedicated procedures for the coordination of policies and activities in the case of a public health emergency? (yes/no/other) — If yes, please elaborate: (e.g., regular meetings, joint task force orworking group, guidelines, and regulatory measures, etc.) — If other, please describe:		N/A

3. **Laboratory**

	Question		Indicator
A.3.1	Please indicate your Member State's corresponding level in relation to the scaling up the laboratory testing capacity in the event of a public health emergency:		Indicator 1-5
		Level	
	There is no plan and organisation ([1]) for scaling up the laboratory testing capacity in the event of a public health emergency	1	
	A plan and organisation for scaling up the laboratory testing capacity in the event of a public health emergency is being developed	2	
	There is a plan and organisation for scaling up the laboratory testing capacity in the event of a public health emergency, but the plan has not been tested in the last 3 years	3	
	There is a plan and organisation for scaling up the laboratory testing capacity in the event of a public health emergency and this plan has been tested in a stress test in the last 3 years	4	
	As per level 4 and, in addition, the system has been revised accordingly	5	
	— Additional comments:		
A.3.2	Please indicate your Member State's corresponding level regarding implementation of new nucleic acid amplification-based tests (NAATs) and adapted associated laboratory systems in the event of a novel pathogen emergence with pandemic potential:		Indicator 1-5
		Level	
	In the context of my Member State, it would not be possible to implement new NAATs and adapt associated laboratory systems within 6 months.	1	
	> 3 – 6 months	2	
	> 1 – 3 months	3	
	2 – 4 weeks	4	
	< 2 weeks	5	
	— Additional comments:		

([1]) Here, in this question an organisation refers to an officially mandated group responsible for implementing the emergency plan

A.3.3	Please indicate you Member State's corresponding level, in an event of a public health emergency with pandemic potential requiring large-scale testing	Indicator 1-5 or N/A

	Level
Your Member State cannot answer due to difficulties to quantify NAAT capacity according to these levels	N/A
In an event of a public health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to up to 0,01 % of the population in my Member State	1
In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to 0,01-0,1 % of the population in my Member State	2
In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to 0,1-1 % of the population in my Member State	3
In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to 1-2 % of the population in my Member State	4
In an event of a health emergency and where a validated NAAT is available, it would be possible to scale up diagnostic NAAT testing services to a weekly sample testing capacity corresponding to > 2 % of the population in my Member State	5
— If N/A, please quantify NAAT capacity according to your own proposal: — Additional comments:	

A.3.4	Does your Member State have access to additional sources of laboratory capacity for diagnostic services in an event where an increased capacity is needed (e.g. research or veterinary laboratories, etc.)? (yes/no/other) — If yes, please advise if this is by formal agreement or on an *ad hoc* basis. — If other, please describe:	N/A

A.3.5	Does your Member State have the capacity for reporting laboratory testing results for national surveillance via an electronic reporting system? (yes/no/other) — If yes, is this reporting system capable of managing scaled up testing information? (yes/no) — If yes, is this reporting system capable of integrating input from different sources of laboratory capacities (e.g., research, hospitals, commercial or veterinary laboratories, etc.)? (yes/no) — If other, please describe:	N/A
A.3.6	Please indicate if your Member State has access to high-containment laboratories i.e. biosafety level 3 or 4 laboratories: Does your Member State have access to a biosafety level 3 laboratory? (yes/no/other) — If no, does your Member State have a formal agreement with another EU/EEA country for this service? (yes/no) — If other, please describe: Does your Member State have access to a biosafety level 4 laboratory (yes/no/other) — If no, does your country have a formal agreement with another EU/EEA Member State for this service? (yes/no) — If other, please describe: *In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*	N/A
A.3.7	Does your Member State have the capacity for characterization of a novel pathogen by Next Generation Sequencing (NGS)? (yes/no/other) — If yes, are NGS data for national surveillance reported via an electronic reporting system? (yes/no) — If no, does your country have an arrangement with another Member State? (yes/no). — If yes, please indicate the Member State: — If other, please describe:	N/A
A.3.8	Does your Member State have a facility dedicated to validating newly introduced devices for the diagnosis of the novel pathogen? (yes/no/other) — If other, please describe:	N/A

4. **Surveillance**

	Question		Indicator
A.4.1	Does your Member State's surveillance system for acute respiratory infections cover all healthcare levels? (yes/no/other) — If other, please describe:		N/A
A.4.2	Are the surveillance systems for Acute Respiratory Infection (ARI), Influenza -Like Illness (ILI) and Severe Acute Respiratory Infections (SARI) automated ([2]) in your Member State? (yes/no/other) — If other, please describe:		N/A
A.4.3	Would your Member State's surveillance system for respiratory infections be able to scale up during a pandemic (i.e., to increase the number of reporting sites, the breath of data collected, the timeliness of reporting, etc.)? (yes/no/other) — If other, please describe:		N/A
A.4.4	Is your Member State able to monitor the following indicators on an ongoing basis and for the whole country's territory, during a public health emergency (i.e. taking into account expanded capacities and/or new settings)?		N/A
		yes/no	
	Hospital bed capacity		
	Hospital intensive care units' capacity		
	Hospital emergency rooms capacity		
	Hospital utilisation		
	Testing capacity		
	Contact tracing capacity		
	Other, please describe		
	— Additional comments:		
A.4.5	Does your country have a wastewater monitoring system in place for respiratory pathogens? (yes/no/other) — If other, please describe:		N/A
A.4.6	Does your country have plans and infrastructures for timely and ongoing assessment of a pandemic threat, i.e., for assessing:		N/A
		yes/no	
	Transmissibility, route of transmission, effective reproduction number		
	Severity		

([2]) Automation refers to the surveillance process being embedded in the healthcare provision system with automatic extraction and sharing of relevant information, or other type of automation that reduces the dependency on human resources.

	Immunologic correlates of protection		
	Vaccine effectiveness		
	Epidemic trajectories and impact through mathematical modelling		
	Other, please specify:		
	— Additional comments:		

5. **Human resources**

	Question						Indicator
A.5.1	In the event of a public health emergency regarding a potential surge in demand of human resources, please indicate your Member State's level:						Indicator 1-5 or N/A
			Hospital services	Outpatient primary care services	Laboratory services (outside of hospitals)	Other public health services	
	N/A	Member State cannot answer the question at central state level					
	Level 1	There is no mechanism to ensure a surge in human resources in the event of a public health emergency					
	Level 2	There is no mechanism to ensure a surge in human resources in the event of a public health emergency but there is a plan to work on a strategy to have it in the coming 3 years					
	Level 3	There is a mechanism to ensure a surge in human resource in the event of a public health emergency, but it is not a structured operational instrument nor is it routinely updated					
	Level 4	There is a mechanism to ensure a surge in human resource in the event of a public health emergency which comprises a structured operational instrument that is routinely updated and participants are periodically trained					
	Level 5	As per level 4 and, in addition, this mechanism is tested to ensure its functioning					

	— Additional comments: *Your country cannot answer this question at the central state level due to governance and legislative frameworks? (yes)* *— In this case, please indicate whether national level recommendations/guidelines are sent to regional authorities (yes/no)* *— If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:* *— If not, please, explain*	
A.5.2	Please advise if regions within your Member State have agreements to receive/exchange human resource support in the health sector in case of need? (yes/no/other) — If other, please describe:	N/A

6. **Health emergency management**

Management of health emergency response

	Question		Indicator
A.6.1	Regarding your Member State's prevention, preparedness, and response planning for public health emergencies, please indicate if your country uses: — A generic [prevention, preparedness and response plan? (yes/no) — Equivalent documents? (yes/no) — If yes, please describe: — Other, please describe:		N/A
A.6.2	Regarding health emergency risk profiling and specific epidemic response plans, please indicate your Member State's level:		Indicator 1-5
		Level	
	There is no routine health emergency risk profiling for serious cross-border threats to health	1	
	There is routine health emergency risk profiling for serious cross-border threats to health	2	
	There is routine health emergency risk profiling for serious cross-border threats to health and this is undertaken at least once every 3 years	3	
	There is routine health emergency risk profiling for serious cross-border threats to health, this is undertaken at least once every 3 years and specific plan(s) to these threats have been developed	4	
	As per level 4 and, in addition, these plan(s) have been tested and revised as needed	5	

<table>
<tr><td></td><td colspan="7">— Additional comments:
— If level 2 or above, please advise if your Member State has a plan in place which addresses the availability and use (i.e. development, manufacturing, procurement, stockpiling, and distribution) of threat-specific medical countermeasures (MCMs) in relation to:</td><td></td></tr>
<tr><td></td><td></td><td>Development (yes/no)</td><td>Manufacturing (yes/no)</td><td>Procurement (yes/no)</td><td>Stockpiling (yes/no)</td><td>Distribution (yes/no)</td><td>Other:</td><td></td></tr>
<tr><td></td><td>Communicable diseases with epidemic or pandemic potential</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Chemical and biological-related threats</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Multi-drug resistant agents in a crisis situation</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="7">— If yes to any of the above, please specify the agents of concern and related MCMs:
In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security</td><td></td></tr>
<tr><td>A.6.3</td><td colspan="7">Regarding your Member State's specific epidemic response plan(s), please indicate which plan(s) have been developed and, where possible, provide link to the specific epidemic response plan(s):</td><td>N/A</td></tr>
<tr><td>A.6.4</td><td colspan="7">Regarding the national level Incident Management System (IMS) or equivalent structure, please indicate your Member State's corresponding level:</td><td>Indicator 1-5</td></tr>
<tr><td></td><td colspan="6"></td><td>Level</td><td></td></tr>
<tr><td></td><td colspan="6">There is no IMS – or equivalent system – linking the public health sector with sectors involved in health preparedness and response planning</td><td>1</td><td></td></tr>
<tr><td></td><td colspan="6">There is no IMS or equivalent system linking the public health sector with sectors involved in health preparedness and response planning there is a plan to create one in the next 3 years</td><td>2</td><td></td></tr>
<tr><td></td><td colspan="6">There is an IMS or equivalent system linking the public health sector with sectors involved in health preparedness and response planning but this has not been tested or it has been tested more than 3 years ago</td><td>3</td><td></td></tr>
<tr><td></td><td colspan="6">There is an IMS or equivalent system linking the public health sector with sectors involved in health preparedness and response planning and this has been tested in the last 3 years</td><td>4</td><td></td></tr>
<tr><td></td><td colspan="6">As per level 4 and, in addition, the IMS has the capacity to adapt its command and control structure/hierarchy (e.g. its composition, depending on the nature of a potential event)</td><td>5</td><td></td></tr>
<tr><td></td><td colspan="7">— Additional comments:</td><td></td></tr>
</table>

A.6.5	Regarding the implementation and evaluation of public health and social measures (PHSMs) and in the case of a public health emergency, please indicate your Member State's corresponding level:		Indicator 1-5
		Level	
	There is no mechanism for decision-making for the implementation of PHSMs during a public health emergency	1	
	There is a mechanism in place to support decision-making for the implementation of PHSMs during a public health emergency, but the multi-disciplinary and cross-sectoral nature is not fully defined	2	
	There is a mechanism for the implementation of PHSMs during a public health emergency and the multi-disciplinary and cross-sectoral nature is fully defined	3	
	There is a mechanism for the implementation of PHSMs during a public health emergency, which is multi-disciplinary and cross-sectoral and includes provisions for evaluating the timeliness and effectiveness of Non Pharmaceutical Interventions (NPIs)	4	
	As per level 4 and, in addition, this mechanism has been tested in the last 3 years	5	
	— Additional comments:		
A.6.6	Regarding provisions for cross-border mutual aid in the preparedness and response plan or equivalent document(s), please indicate your Member State's corresponding level:		Indicator 1-5 or N/A
		Level	
	Cannot answer question as Member State does not have a preparedness and response plan or equivalent document(s)	N/A	
	The preparedness and response plan or equivalent document(s) does not include cross-border mutual aid	1	
	The preparedness and response plan or equivalent document(s) includes cross-border mutual aid	2	
	The preparedness and response plan or equivalent document(s) includes cross-border mutual aid, and this has been tested with at least one Member State	3	
	The preparedness and response plan or equivalent document(s) includes cross-border mutual aid, and this has been tested with at least one Member State and updated where relevant	4	
	As per level 4 and, in addition, information related to the cross-border mutual aid as well as results of the testing have been shared within the Health Security Committee (HSC)	5	
	— Additional comments: — If level 2 or higher, please list the type of cross-border mutual aid included and with which Member State:		
	Country/Grouping of Member State (please specify):	Type of cross-border mutual aid (please specify):	
	— If level 3 or higher, please list the Member States and type of cross-border mutual aid that has been tested:		
	Country/Grouping of countries (please specify):	Type of cross-border mutual aid (please specify):	

	Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes) — *In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)* — *If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:* — *If not, please explain:*	
A.6.7	Does your Member State's preparedness and response plan or equivalent document(s) ensure specific national coordination mechanisms ([3]) for preparedness and response in case of an intentional release scenario? (yes/no/other) — If yes, is the governance structure for response – between the health sector and other critical sectors for the management of the response – clear and defined? (yes/no) — If yes, please advise which sector leads the response: — If other, please describe: *In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*	N/A

Emergency logistic and supply chain management

	Question		Indicator
Critical MCMs demand and supply			
A.6.8	Has your Member State identified critical MCMs for preparedness and response to serious cross-border threats to health? (yes/no/other) — If yes, is there a list? (yes/no) — If yes, please provide a hyperlink or the list itself. *(Please include a hyperlink of these MCMs categorized by specific threats, if applicable.)* — If other, please describe: *In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*		N/A
A.6.9	Regarding national policies or plans for the monitoring of supply and estimating demand of critical MCMs, please indicate your Member State's corresponding level:		Indicator 1-5
		Level	
	There are no foreseen national policies or plans for the monitoring of supply and estimating demand of critical MCMs	1	

([3]) Here this refers to coordination between sectors such as security, justice, defence and civil protection that allows a specific mechanism for preparing and responding to an intentional release.

	National policies or plans for the monitoring of supply and estimating demand of critical MCMs are under consideration	2	
	There are national policies or plans for the monitoring of supply and estimating demand of critical MCMs	3	
	There are national policies or plans for the monitoring the supply and estimate demand of critical MCMS, which are reviewed, evaluated and updated on a regular basis	4	
	There are national policies or plans for the monitoring the supply and estimate demand of critical MCMs, which are reviewed, evaluated and updated on a regular basis including a gap analysis of supply and demand	5	
	— If yes, provide details of how the national policies and plans monitor supply and estimate demand: — Additional comments:		
A.6.10	Regarding the inclusion of provisions in the preparedness and response plan or equivalent document(s) or mechanisms to mitigate supply chain vulnerabilities of critical MCMs, please indicate your Member State's corresponding level:		Indicator 1-5
		Level	
	There are no foreseen provisions in the preparedness and response plan or equivalent document(s) or mechanisms to mitigate supply chain vulnerabilities of critical MCMs	1	
	Provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs are under consideration	2	
	There are provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs. However, these provisions are not yet implemented	3	
	There are provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs. However, only some of them are implemented or under implementation	4	
	There are provisions in the preparedness and response plan or equivalent document(s) or mechanism to mitigate supply chain vulnerabilities of critical MCMs. These provisions are all implemented	5	
	— If yes, please provide details of the national policies: — Additional comments:		

Production of MCMs

A.6.11	Please indicate the critical MCMs referred in question A.6.8 that are currently produced in your Member State as follows:			N/A
	Type of production	Product information (if raw materials or components please also add information on the MCMs for which the products are needed)	Economic operator information including address	
	Full production including raw materials/components/ active pharmaceutical ingredients (APIs)			
	Finished products, please identify the MCM, the producer of the finished product and critical suppliers (including location) on which the production relies on			
	Production of critical raw materials/components/APIs of MCMs: please identify the producer and relevant MCMs that need these materials for its manufacturing process.			
	— Additional comments: *In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*			
A.6.12	Does your Member State have existing or planned arrangements to ensure that manufacturing of crisis-relevant MCMs can be scaled-up in a timely manner in times of crisis, for example through product or capacity reservation contracts or other mechanism.? (yes/no/other) — If yes, provide a list of specific MCMs and of type of arrangement: — If other, please describe: *In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*			N/A

Strategic stockpiles [4]

A.6.13	Does your Member State have national strategic stockpiles of MCMs? (yes/no/other) — If yes, please advise: — which MCMs are covered by this stockpile: — type of stockpile (virtual/physical): — size of the stock — If yes, please indicate how you manage your stockpile and if there are requirements for the deployment of the MCMs held within the stockpile: — If other, please describe: *In accordance with Article 346(1) of the Treaty, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security*	N/A

[4] Stock of pharmaceuticals and medical equipment held by Member States to save lives in crisis.

7. **Health services provision**

<table>
<tr><th></th><th colspan="7">Question</th><th>Indicator</th></tr>
<tr><td>A.7.1</td><td colspan="7">Does your Member State's prevention, preparedness and response plan or equivalent document(s) provide for foresight assessment of the potential impact of a health emergency on continuity of healthcare services? (yes/no/other)
— If other, please describe:</td><td>N/A</td></tr>
<tr><td>A.7.2</td><td colspan="7">In the case of a public health emergency where there is an increase in demand for healthcare provision and potential decrease in healthcare staff, please indicate your Member State's corresponding level:</td><td>Indicator
1-5 or N/A</td></tr>
<tr><td></td><td></td><td></td><td>Hospital services</td><td>Outpatient primary care services</td><td>Laboratory services (outside of hospitals)</td><td>Other public health services</td><td></td></tr>
<tr><td></td><td>N/A</td><td>Member State cannot answer the question at central state level</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Level 1</td><td>Your Member State does not have a dedicated operational plan for continuity of healthcare service</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Level 2</td><td>Your Member State has a dedicated operational plan for continuity of healthcare service</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Level 3</td><td>Your Member State has a dedicated operational plan for continuity of healthcare service, but it has not been tested in the last 3 years</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Level 4</td><td>Your Member State has a dedicated operational plan for continuity of healthcare service, and it has been tested in the last 3 years</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td>Level 5</td><td>As per level 4 and, in addition, recommendations from the testing have been implemented and the operational plan has been reviewed and revised</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="6">— If level 2 or above, please advise if this includes a mechanism for prioritisation/flexibility of health service provision to ensure sufficient continuity of care? (yes/no/other)
— If yes, is this a permanent or an ad hoc mechanism?
— If yes, has the mechanism been tested in the last 3 years and is there a provision for regular testing?
— If no, please describe why:
— If other, please describe:</td><td></td></tr>
</table>

	— Additional comments: *Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)* — *In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)* — *If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:* — *If not please explain*		
A.7.3	Please advise if your Member State ensures interdisciplinary crisis management coordination between all actors of the health care system (e.g., hospital services, rescue services, other public health services, outpatient primary care services, pharmacies, laboratory services, nursing/rehabilitation services)? (yes/no/other) — If other, please describe:		N/A
A.7.4	Regarding your Member State's business continuity plans for healthcare providers in case of a disruptive event, please indicate your country's corresponding level:		Indicator 1-5 or N/A
		Level	
	Member State cannot answer the question [at central state level	N/A	
	There is/are no national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services	1	
	There is/are national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services	2	
	There is/are national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services and guidance/recommendations have been reviewed and revised in the past 3 years	3	
	There is/are national guidance/recommendations for business continuity plans (or equivalents such as contingency plans) to ensure the continuity of healthcare services and guidance/recommendations have been reviewed and revised in the past 3 years using a multi-sectoral approach	4	
	As per level 4 and, in addition, all healthcare services implement the national guidance/recommendations for business continuity plans	5	
	— Additional comments: *Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)* — *In this case, please indicate if national level recommendations/guidelines are sent to regional authorities (yes/no)* — *If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:* — *If no, please explain*		

A.7.5	Please advise if your Member State requires hospitals to have a hospital alert and response plan or equivalent document(s) ([5]) in order to be prepared for public health emergencies that may affect a hospital's capacity and function? (yes/no/other) — If yes, please advise if the plans include instructions on how to sustain patient care in the event of a shortage (medical personnel, medical stockpile, treatment facilities) or a technical breakdown (e.g., energy, water, IT): — If yes, please advise if these plans or equivalent document(s) are tested on a regular basis: — If other, please describe: *Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)* — *In this case, please advise if national level recommendations/guidelines are sent to regional authorities (yes/no)* — *If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:* — *If not, please explain:*	N/A
A.7.6	Does your Member State have the capacity to map immediately available health services in the case of a public health emergency? (yes/no/other) — If other, please describe:	N/A
A.7.7	Does your Member State's prevention, preparedness and response plan or equivalent document(s) include agreements and/or provisions for the medical transfer of patients and/or mobile medical teams with other countries? (yes/no/other) — If yes, please list countries involved: — If other, please describe:	N/A

([5]) Such as the hospital response and operational plan

8. **Risk communication**

	Question		Indicator
A.8.1	Regarding risk communication, please indicate your country's corresponding level:		Indicator 1-5 or N/A
		level	
	Member State cannot answer the question at central state level	N/A	
	There is no separate national risk communication plan or risk communication section as part of a preparedness and response plan or equivalent document(s) is not in place and mechanisms for public communication are on an ad-hoc basis and only includes conventional media focus	1	
	A separate national risk communication plan or section in a preparedness and response plan or equivalent document(s) is being developed and mechanisms for public communication are on an ad-hoc basis and includes conventional media with minimal online and social media focus	2	
	National risk communication is in place as a defined section within a preparedness and response plan or equivalent document(s) and includes conventional media and online and social media focus. In addition, there is analysis of target audiences and preferred communication channels to inform risk communication interventions	3	
	A separate, dedicated national risk communication plan is in place and includes conventional media and online and social media focus. In addition, there is analysis of target audiences and preferred communication channels to inform risk communication interventions. Moreover, there is proactive outreach through a variety of channels (e.g. hotline, complaint systems, social listening), online and offline media are monitored daily for feedback and insights and data are used to adjust and improve risk communication strategies	4	
	As per level 4 and, in addition, the national risk communication plan has been tested in the last 3 years	5	
	— Additional comments: *Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)* — *In this case, please advise if national level recommendations/guidelines are sent to regional authorities (yes/no)* — *If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:* — *If not, please explain:*		
A.8.2	Does your Member State's risk communication plan include a dedicated step to coordinate in liaison with the HSC the risk and crisis communication related to a serious cross-border threat to health? (yes/no/other) — If other, please describe:		N/A

9. **Points of entry (PoEs) and border health**

	Question					Indicator
A.9.1	Regarding your Member State's nationally designated POEs public health emergency contingency plans, please indicate your Member State's corresponding level:					Indicator 1-5
			Ports	Airports	Ground Crossings	
	Level 1	The nationally designated POEs' public health emergency contingency plan has no operational instruments to facilitate sharing of travel related health data/information and reporting to the national level				
	Level 2	The nationally designated POEs' public health emergency contingency plan has operational instruments to facilitate sharing of travel related health data/information and reporting to the national level				
	Level 3	The nationally designated POEs' public health emergency contingency plan has operational instruments to facilitate sharing of travel related health data/information and reporting to the national level and this has been tested in the last 3 years				
	Level 4	The nationally designated POEs' public health emergency contingency plan has operational instruments to facilitate sharing of travel related health data/information and reporting to the national level and this has been tested in the last 3 years. In addition, the national level also has operational instruments to then facilitate the sharing of this information to other national sectors ([6]) and third parties e.g. WHO and Early Warning Response System (EWRS)				
	Level 5	As per level 4 and, in addition, this has been tested in the last 3 years				
	— Additional comments:					

([6]) This may include the health, civil protection and border control sectors for implementation, if needed, of dedicated measures such as quarantine, screening, NPIs, etc.

A.9.2	Regarding the implementation and evaluation of international travel-related measures please advise: — If the implementation of international-travel related measures has been tested in at least one nationally designated POE in the last 3 years (yes/no/other) — If other, please describe: — If there is a dedicated step to discuss with the HSC prior to implementation of international travel related measures? (yes/no/other) — If other, please describe:	N/A

10. **Zoonotic diseases and threats of environmental origin, including those due to the climate**

	Question		Indicator
A.10.1	Regarding your country's implementation of One Health as referred to in Article 3(7) of the Regulation (EU) 2022/2371, please indicate your Member State' s corresponding level:		Indicator 1-5 or N/A
		Level	
	Member State cannot answer question as Member State does not have a prevention, preparedness and response plan or equivalent document(s)	N/A	
	There is no One Health approach in the preparedness and response plan or equivalent document(s)	1	
	A One Health approach in the preparedness and response plan or equivalent document(s) is being developed but coordination of surveillance between animal health, public health, and environmental sectors and mechanisms for information sharing have not been established	2	
	A One Health approach in the preparedness and response plan or equivalent document(s) is in place and coordination of surveillance between animal health, public health, and environmental sectors and mechanisms for information sharing has been established	3	
	A One Health approach in the preparedness and response plan or equivalent document(s) is in place and coordination of surveillance between animal health, public health, and environmental sectors and mechanisms for information sharing has been established. In addition, this has been tested in the last 3 years	4	
	As per level 4 and, in addition, its implementation is monitored and revised on a regular basis	5	
	— Additional comments: — If at level 2 or above: — please advise if there is in the preparedness and response plan or equivalent document(s), coordination of surveillance between two out of the three sectors (animal health, public health, and environmental) and mechanisms for information sharing? (yes/no/other) — If yes, please indicate the sectors involved: — If other, please describe:		

	— please indicate if you have developed any joint training programmes for One Health professionals (animal health, public health and environmental sectors) on zoonoses prevention, detection, and response? (yes/no/other) — If other, please describe: — please indicate if you have developed a guideline on the procedures to follow for the public on finding sick and/or dead wild birds and other animals? (yes/no/other) — If other, please describe: — please advise if there is a list of prioritised zoonotic diseases for surveillance purposes? (yes/no/other) — If yes, please list the prioritised zoonotic disease: — If other, please describe:	
A.10.2	— Does your Member States integrate provisions about the actual or projected effects of climate change on zoonotic diseases (yes/no/other) If yes, please elaborate on the potential effects and any dedicated provisions for health preparedness and response If other, please describe:	N/A
A.10.3	— Does your Member State integrate provisions about the actual or projected impacts of extreme weather events (like heatwaves, floods or – indirectly – wildfires) on public health (yes/no/other) If yes, please elaborate on the potential impacts and any dedicated provisions for health preparedness and response: If other, please describe:	

11. **Chemical events**

	Question		Indicator
A.11.1	Regarding the management of a health threat from chemical origin, please indicate your country's corresponding level:		Indicator 1-5 or N/A
		Level	
	Member State cannot answer the question at central state level	N/A	
	There is no separate chemical preparedness and response plan or equivalent document(s), nor is it included in the preparedness and response plan or equivalent document(s)	1	
	There is a chemical preparedness and response plan or equivalent document(s) and/or it is included in the preparedness and response plan or equivalent document(s)	2	
	The chemical preparedness and response plan or equivalent document(s) is in place and roles and responsibilities as well as major hazard sites are considered and identified	3	

	The chemical preparedness and response plan or equivalent document(s) is in place and roles and responsibilities as well as major hazard sites are considered and identified. In addition, the chemical response plan or chapter in the preparedness and response plan or equivalent document(s) has been tested through a simulation exercise in the last 3 years	4	
	As per level 4 and, in addition, recommendations from the test(s) have been implemented and corresponding plans reviewed and revised	5	
	— Additional comments: *Your Member State cannot answer this question at the central state level due to governance and legislative frameworks? (yes)* — *In this case, please advise if national level recommendations/guidelines are sent to regional authorities (yes/no)* — *If yes, please advise if at national level you know if these recommendations/guidelines are implemented at regional level and whether there are gaps or challenges identified:* — *If not, please explain*		
A.11.2	Does your Member State have procedures for a health risk assessment in case of a health threat from chemical origin? (yes/no/other) — If yes, please describe: — If no, please describe: — If other, please describe:		N/A
A.11.3	Does your Member State have available guidelines on: — Surveillance of chemical events and poisoning/intoxication? (yes/no/other) — If yes, please describe: — If no, please describe: — If other, please describe: — Assessment of chemical events and poisoning/intoxication? (yes/no/other) — If yes, please describe: — If no, please describe: — If other, please describe: — Management of chemical events and poisoning/intoxication? (yes/no/other) — If yes, please describe: — If no, please describe: — If other, please describe:		N/A

B. ADDITIONAL CAPACITIES AS PER REGULATION (EU) 2022/2371

12. **Antimicrobial resistance (AMR) and Healthcare associated infections (HAIs)**

AMR

<table>
<tr><th></th><th colspan="2">Question</th><th>Indicator</th></tr>
<tr><td>B.12.1</td><td colspan="2">National One Health Action Plans on AMR
In order to avoid duplication of efforts, the Commission and the European Center For Disease Prevention and Control (ECDC) will be relying on inputs made to WHO Tracking Antimicrobial Resistance Country Self- Assessment Survey (TrACSS) (7). Thus, national reporting to TrACSS will be considered as part of the assessment under Article 8 of Regulation (EU) 2022/2371
Please upload in pdf format your Member State's most recent TrACSS submission to WHO.
Regarding the national action plan (NAP) on AMR, have there been any updates since your country's last reporting to TrACSS?
— No
— Yes (please detail in the open text)</td><td>N/A</td></tr>
<tr><td>B.12.2</td><td colspan="2">Resources
What resources are allocated to the implementation of the NAP on AMR?</td><td>N/A</td></tr>
<tr><td></td><td>Level</td><td></td></tr>
<tr><td></td><td>No or very few resources (budget and human resources) are available for the implementation of the NAP.</td><td>1</td></tr>
<tr><td></td><td>No specific resources are available, and implementation is entrusted to the resources (budget and human resources) of national/regional stakeholders (e.g. relevant competent authorities responsible for health, agriculture, environment, etc.) involved in the implementation of the NAP</td><td>2</td></tr>
<tr><td></td><td>Non-earmarked funding can be accessed for AMR activities from national/regional funds and can be used for implementation of the NAP</td><td>3</td></tr>
<tr><td></td><td>Specific earmarked funding for AMR activities is available from national/regional funds and is used for implementation of the NAP</td><td>4</td></tr>
<tr><td></td><td>Implementation of the NAP is fully costed and funded through dedicated budget lines from national/regional funds.</td><td>5</td></tr>
<tr><td></td><td colspan="2">— Additional comments:</td></tr>
</table>

(7) https://www.who.int/publications/m/item/tripartite-amr-country-self-assessment-survey—tracss-(6.0)-2022

B.12.3	**Monitoring and evaluation of progress** Does your Member State have national indicators or targets to measure national progress on AMR (including antimicrobial consumption/use) and/or HAIs? Please, provide a description of the indicators/targets or a hyperlink to where they can be found in the comments section.	Indicator 1-5
		Level
	No, there are neither national indicators, nor national targets to measure progress on AMR (including antimicrobial consumption/use) and/or HAIs in the country	1
	There are plans to set up national indicators and/or national targets, and these will be in place in the near future	2
	There are national indicators, similar to the globally available indicators (e.g. Sustainable Development Goals and WHO, etc.), but without targets	3
	Yes, there are national indicators that cover AMR (including antimicrobial consumption/use) and/or HAIs with concrete national targets to be reached by a certain timeframe, and progress is reviewed regularly but this is not linked to the objectives of the NAP on AMR	4
	Yes, there are national indicators and national targets that cover both AMR (including antimicrobial consumption/use) and HAIs, which are linked to the NAP on AMR, and progress is reviewed regularly	5
	— Additional comments:	
B.12.4	**Main challenges** Currently, what are the biggest challenges that your Member State faces in addressing AMR? Please choose three challenges, then rank them from 3 – the most important to 1 – the least important):	N/A
	Implementation of prevention and control measures in routine practice	
	Budget limitations	
	Ensuring One-health coordination across the different sectors	
	Absence of or insufficient legal framework	
	Lack of human resources	
	Infrastructure limitations (e.g. lack of single rooms, old hospital buildings, etc.)	
	Insufficient awareness among stakeholders such as healthcare professionals, e.g. doctors, nurses, pharmacists, etc., animal keepers and farmers and the general public	
	Limited access to certain antimicrobials, e.g. narrow-spectrum antibiotics and novel antimicrobials	
	— Additional comments:	

B.12.5	**Prevention of priority multidrug-resistant organisms (MDROs)** Regarding the prevention of multidrug resistant organism, please indicate your Member State's level below. Note: the below levels have been adapted based on the wording of the Joint External Evaluation (JEE) ([8]), question P4.3 referring to the prevention of multidrug resistant organism. The MDROs considered under this indicator are listed below, as they are considered critical at Union level. If a Member State considers that its replies cannot cover all MDROs, this can be specified in the comments section below.	Indicator 1-5
		Level
	These MDROs (phenotypes and genotypes) have not been identified as priority by national authorities, and they are not detected	1
	National strategy or guidance for MDRO containment exists and includes colonization screening for priority MDROs (phenotypes and genotypes) that have been identified by national authorities. Some health facilities can detect priority MDROs based on laboratory data.	2
	Selected health facilities have access to MDRO phenotype confirmation. Facilities notify national levels when priority MDROs are detected	3
	All health facilities have access to MDRO phenotype confirmation. Facilities notify national levels when priority MDROs are detected in a timely manner. Responses are tracked and supported at the national level	4
	Functional system is in place to rapidly communicate and track the detection, confirmation and notification of novel or priority MDROs within hospitals and to national levels. All hospitals are able to launch response activities to priority MDROs in a timely manner. Facilities regularly communicate pertinent MDRO data to local referral networks to inform prevention/containment efforts	5
	— Additional comments:	
B.12.6	**Priority MDROs in hospitals and cross-border patient transfers** Regarding national activities related to screening patients for MDRO carriage at hospital admission, as a means to reduce the spread of priority MDROs among hospitals, please indicate your Member States' s corresponding level below. Note: the MDROs considered under the indicator are listed below, as they are considered critical at Union level. If a Member State considers that its replies cannot cover all MDROs, this can be specified in the comments section below.	Indicator 1-5
		Level
	There are no national procedures and protocols in place for screening patients for MDRO carriage at hospital admission	1
	There are national procedures and protocols in place for screening for MDRO carriage only for patients being directly transferred from a hospital in another country	2

([8]) Joint External Evaluation tool developed by the World Health Organization third edition, 2022

	There are national procedures and protocols in place for screening for MDRO carriage only for patients being directly transferred from a hospital in another country or who have recently been hospitalised in another country	3	
	There are national procedures and protocols in place for screening for MDRO carriage only for patients being directly transferred from a hospital in another country or who have recently been hospitalised in another country, as well as for patients admitted to special wards, such as intensive care units	4	
	There are national procedures and protocols in place for screening for MDRO carriage for all patients, at hospital admission	5	
	— Additional comments: Do you have national requirements to communicate on the infection status of a patient (i.e. information on infection by/carriage of a communicable microorganism, in particular priority MDROs, when referred from one hospital (or healthcare facility) to another? (yes/no/other) — Yes, in case of cross-border transfer as well as transfer to a hospital (or healthcare facility) within the country — Yes, only in case of cross-border transfer — No (please explain why) — If other, please describe:		
B.12.7	**Antimicrobial stewardship/prudent use of antimicrobials** in primary and secondary care: Regarding the optimal use of antimicrobial medicines in human health, please indicate your Member State's corresponding level below. Note: the below indicator levels have been adapted based on the wording of the Joint External Evaluation (JEE) ([9]), question P4.4 referring to the optimal use of antimicrobial medicines in human health		Indicator 1-5
		Level	
	No or weak national policy and/or regulations on appropriate use, availability, quality and use of antimicrobials in human health	1	
	National policy and regulations promoting appropriate antimicrobial use/antimicrobial stewardship activities are developed for the community and health care settings	2	
	Guidelines for appropriate use of antimicrobials are available and antimicrobial stewardship programmes are established in some health care facilities. The latest WHO "Access, Watch and Reserve" (AWaRe) classification of antibiotics is adopted in the national essential medicines list	3	
	Guidelines and practices to enable appropriate use of antimicrobials are implemented in health care facilities nationwide. Functioning AMR stewardship programs in all major health care facilities. Monitoring of antibiotic consumption is being performed and based on the latest AWaRe classification of antibiotics	4	
	Guidelines on optimizing antibiotic use are implemented for all major syndromes and data on use is systematically fed back to prescribers. The AWaRe classification of antibiotics is incorporated into antimicrobial stewardship strategies. Robust national monitoring of antibiotic consumption is being performed	5	
	— Additional comments:		

([9]) Ibid

B.12.8	**AMR surveillance** Regarding the surveillance of AMR, please indicate your Member State's corresponding level below. Note: the below indicator levels have been adapted based on the wording of the Joint External Evaluation (JEE) ([10]), question P4.2 referring to the surveillance of AMR	Indicator 1-5

	Level
No or limited capacity for generating, collating, and reporting data (antibiotic susceptibility testing and accompanying clinical and epidemiological data)	1
AMR data are collated locally for common pathogens in hospitalized and community patients, but data collection may not use a standard approach and lacks national coordination and/or quality management	2
AMR data are collated nationally for common pathogens, but national coordination and standardization are lacking	3
There is a standardized national AMR surveillance system collecting data on common pathogens in hospitalized and community patients, with an established network of surveillance sites, designated national reference laboratory for AMR and a national coordinating centre producing reports on AMR	4
In addition to the above, the national AMR surveillance system's data is analysed, interpreted and reported together with antimicrobial consumption and/or use data for human health, and analysis of similar data across sectors (human and animal health and agriculture) is attempted	5
— Additional comments:	

([10]) Ibid

Healthcare associated infections (HAIs)

	Question		Indicator
B.12.9	**Main challenges** Currently, what are the biggest challenges that your country faces in addressing healthcare associated infections (HAIs)? Please choose three challenges, then rank them from 3 – the most important to 1- the least important):		N/A
	Implementation of prevention and control measures in routine practice		
	Budget limitations		
	Absence of or insufficient legal framework		
	Lack of human resources		
	Infrastructure limitations (e.g. lack of single rooms, old hospital buildings, etc.)		
	Insufficient awareness among healthcare professionals, e.g. doctors, nurses, pharmacists, etc. and the general public		
	Limited access to certain antimicrobials, e.g. narrow-spectrum antibiotics and novel antimicrobials		
	— Additional comments:		
B.12.10	**HAI surveillance** Regarding the surveillance of HAI, please indicate your Member State's corresponding level below. Note: the below indicator levels have been adapted based on the wording of the Joint External Evaluation (JEE) ([11]), question R4.2 referring to the surveillance of HAI		Indicator 1-5
		Level	
	No national HAI surveillance programme or national strategic plan for HAI surveillance, including pathogens that are antimicrobial resistant and/or prone to outbreaks is available or under development	1	
	A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) is available but not implemented	2	
	A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) is available and implemented through a national programme and system for data collection, analysis, and feedback. Selected secondary and tertiary health care facilities are conducting HAI surveillance (as specified above) and provide timely and regular feedback to senior management and health workers	3	

([11]) Ibid

	A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) is available and implemented nationwide in all secondary and tertiary health care facilities through a national system according to the WHO recommendations on Infection Prevention and Control (IPC) core components. Regular reports are available for providing feedback	4	
	A national strategic plan for HAI surveillance (including pathogens that are antimicrobial resistant and/or prone to outbreaks) are available and implemented nationwide in all secondary and tertiary health care facilities through a national programme and system according to the WHO recommendations on IPC core components. Data are shared and being used continuously and in a timely manner to inform prevention efforts. The quality and impact of the system are regularly evaluated, and improvement actions are taken accordingly	5	
	— Additional comments:		

13. **Union level coordination and support functions**

	Question	Indicator
B.13.1	Do your Member State's legal instruments for health response to a public health emergency incorporate coordination and cooperation at national-Union interface during a public health emergency? (yes/no/other) — If other, please describe:	N/A
B.13.2	During a health emergency, is your Member State's HSC representative incorporated into national level coordination structures, notably to support the flow of information between your Member State and the HSC? (yes/no/other) — If no, what is the role of the HSC representative in the national emergency response and if they do not act as the liaison with the HSC during public health emergencies, who does? — If other, please describe:	N/A
B.13.3	Is your Member State's Public Health Emergency Operation Center or IMS interoperable with the Early Warning and Response System module for incident and/or crisis management? (yes/no/other) — If other, please describe:	N/A
B.13.4	Over the last 3 years, has your Member State incorporated or factored in opinions and guidance from HSC for the prevention and control of serious cross-border threats to health? (yes/no/other/partial) — If yes, please describe how — If no, why — If other, please describe: — If partial, please describe:	N/A
B.13.5	Over the last 3 years, has your Member State incorporated or factored in Commission's recommendations on common temporary public health measures? (yes/no/other/partial) — If yes, please describe how — If no, why — If other, please describe: — If partial, please describe:	N/A

B.13.6	Over the last 3 years, has your Member State incorporated or factored in recommendations from the ECDC on response to health threats? (yes/no/other/partial) — If yes, please describe how — If no, why — If other, please describe: — If partial, please describe:	N/A
B.13.7	Please indicate if the following support roles, functions and instruments of the Commission and relevant Union agencies and bodies are considered in your Member State's preparedness and response planning process:	N/A

	yes/no
Medical Evacuation Support via EWRS	
European External Action Service (EEAS) for consular and repatriation support	
Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO) and its support capacities, including those in the ResEU reserve as well as the union Civil Protection Mechanism Prevention and Preparedness Projects (e.g. tenders and grants on developing cross-border health projects)	
Directorate-General for Health Emergency and Response to support to medical countermeasures research and development, manufacturing, production, stockpiling and deployment (DG HERA)	
DG HERA's Emergency Office	
Instruments for the mobilisation of EU funding for rapid research	
Risk Assessment of the ECDC	
Risk Assessment of the European Medicines Agency (EMA)	
Risk Assessment of the European Food Safety Authority (EFSA)	
Risk Assessment of the European Chemicals Agency (ECHA)	
Risk Assessment of the European Environment Agency (EEA)	
Risk Assessment of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)	
Risk assessments carried out in cooperation with the European Union Agency for Law Enforcement Cooperation (Europol) where the threat is emanating from terrorist or criminal activity	
Technical reports and guidance of the ECDC	
Risk Assessment of the European Agency for occupational safety and health	
ECDC's ad-hoc support in preparedness and outbreak response (e.g. EU Health Task Force)	
EU reference laboratories	
Other, please specify:	
— Additional comments:	

B.13.8	— Does your Member State take into account the Union prevention, preparedness and response plan established in accordance with Article 5 () of Regulation (EU) 2022/2371, by including also cross-border interregional preparedness elements into your Member's State preparedness and response plan or equivalent document(s)? If yes, please describe how — If no, why — If other, please describe:	N/A

14. **Research development and evaluations to inform and accelerate emergency preparedness**

	Question		Indicator
B.14.1	Regarding the role of research in the preparedness and response plan or equivalent document(s), please indicate your Member State's corresponding level:		Indicator 1-5 or N/A
		Level	
	Member State cannot answer question as the Member State does not have preparedness and response plan or equivalent document(s)	N/A	
	A preparedness and response plan or equivalent document(s) is in place, but it does not include a strategy for emergency research and innovation	1	
	A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, but no funding has been set aside for conducting research during health emergencies	2	
	A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, and funding has been set aside for conducting research during health emergencies	3	
	A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, funds have been set aside for conducting research during health emergencies and a process is in place for their swift mobilisation	4	
	A preparedness and response plan or equivalent document(s) that includes a strategy for emergency research and innovation is in place, funds have been set aside for health emergencies, a process is in place for their swift mobilisation and research and innovation capacities have been strengthened	5	
	— If level 2 or above: does the strategy for emergency research and innovation (in the preparedness and response plan or equivalent document(s)) include a process to link public health needs with research priorities and needs? (yes/no/other) — If yes, please describe this process — If other, please describe: — Additional comments:		

B.14.2	Is your Member State part of a i) national, ii) Union-wide or iii) international network of clinical trial sites or cohorts to promote the participation in large-scale trials that have more chance to reach meaningful results in limited timeframes? (yes/no/other) — If yes, please specify (name and level)				N/A
		National	Union-wide	International	
	Clinical Trial sites				
	International network of cohorts				
	— If other, please describe:				
B.14.3	Does your Member State have processes in place for the establishment of harmonised protocols and data collection within these networks? (yes/no/other) — If yes, please specify which ones: — If other, please describe:				N/A
B.14.4	Does your Member State have procedures in place for rapid site accreditation and for expedited coordinated (between the national competent authorities and ethics committees) clinical trial assessment and authorisation in the case of a public health emergency? (yes/no/other) — If yes, please specify, including cooperation with ethics committees: — If other, please describe:				N/A
B.14.5	Please advise if your Member State has an approach to operational (e.g. in action) research which includes:				N/A
			Yes	No	
	Research preparedness, including predesigned protocols, partnerships, roles, and responsibilities in place in advance of a health emergency				
	In case of a public health emergency, operational instruments in place so needed resources are available with means for rapid funding				
	In case of a public health emergency, operational instruments in place for rapid ethical clearance and data sharing				
	— Additional comments:				

15. **Recovery elements**

	Question		Indicator
B.15.1	Regarding your Member State's recovery plan or the recovery section in your prevention preparedness and response plan or equivalent document(s), please indicate your Member State's level:		Indicator 1-5
		Level	
	No recovery plan or recovery section in the preparedness and response plan or equivalent document(s) available	1	
	Recovery plan or section available	2	
	Recovery plan or section includes or links to a process of capturing lessons using After Actions Reviews (AARs) or Inter Action Reviews (IARs), and embedding them in practice through an action plan	3	
	Recovery plan includes or links to a process of capturing lessons using AARs or IARS and embedding them in practice under an overarching framework such as the National Action Planning for Health Security (NAPHS) or equivalent. This process is implemented and regularly monitored at national level	4	
	Recovery includes or links to a process of capturing lessons using AARs or IARS and embedding them in practice through NAPHS or equivalent. This process is implemented and regularly monitored at national and regional (sub-national) level	5	
	— Additional comments:		

16. **Actions taken to improve gaps found in the implementation of prevention, preparedness and response plans**

	Question		Indicator
B.16.1	Please upload your Member State's most recent IHR State Party Annual Report as submitted by the National IHR Focal Point to WHO in pdf format		Indicators IHR
B.16.2	Please indicate whether your Member State has used any of the following complementary mechanisms to assess the implementation of IHR capacities and prevention, preparedness, and response planning in the last 3 years: *Tick where appropriate:*		N/A
		Completed in the last 3 years? (Yes/No) (If published, please provide link)	
	Joint External Evaluation		
	In-action reviews		

	After action reviews		
	SimEx		
	Joint Assessment and Detection of Events		
	Other: please specify		
B.16.3	Please indicate your Member State's corresponding level regarding the NAPHS proposed by WHO or equivalent system:		Indicator 1-5
		level	
	NAPHS or equivalent system is not developed or under development	1	
	NAPHS or equivalent system developed but not yet whole of government and one health for all hazards approach aligned	2	
	NAPHS or equivalent system is developed and aligned with whole of government and one health for all hazards approach including defined roles, responsibilities, and collaborative mechanism	3	
	NAPHS or equivalent system is developed and aligned with whole of government and one health for all hazards approach including definitions of roles, responsibilities, and collaborative mechanisms. In addition, the National Action Planning for Health Security or equivalent system has been costed	4	
	As per level 4 and, in addition, at least one activity planned is being implemented	5	
	— Additional comments: — If level 1: please advise if your Member State is planning to start a National Action Plan for Health Security or equivalent system: — All levels: if your Member State does not use the National Action Planning for Health Security, please describe the equivalent system:		

C. **OTHER**

C.1	Please describe your ideas on what further actions the Commission could undertake to support the implementation of prevention, preparedness, response, and recovery planning to serious cross-border threats to health:
C.2	Please provide any comments or clarifications in relation to the questions above and, if considered necessary, list any relevant activities that your country has conducted or provide additional information which is relevant to the topic of this questionnaire: