

HERA
Public Consultation Questionnaire

Public Consultation Questionnaire – Health Emergency Preparedness and Response Authority

The below outlines the questions proposed for the public consultation of the HERA. Sections A to F will be open to all stakeholders. The following sections are additional questions for specific stakeholders, as described below.

A. Fragmentation of efforts in the EU

1	What is your view on the existing EU and national public actors' capacities in the field of preparedness and crisis management regarding medical countermeasures?						
	Don't know	Fragmented	Dispersed	Sub -optimal	Adequate		
2	Do you consider that the following elements constitute challenges to effective cooperation between national and EU authorities on coordination and access to the most developed medical countermeasures within the EU						
		Don't know	Strong disagree	Disagree	Neutral	Agree	Strongly Agree
	No one country can adequately address all challenges associated with medical countermeasures in a pandemic						
	EU Member States are vulnerable to the risk of unequal access to medical countermeasures due to differing purchasing power						
	EU Member States are vulnerable to competing against each other for the development and purchase of medical countermeasures (e.g. higher prices, distorted access and lower EU wide utility)						
The Joint Procurement Agreement is an inadequate tool for health emergency response and							

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	management					
3	What would be in your view the solutions to overcome these challenges? Would mutualising efforts at the EU level for medical countermeasures to overcome these challenges be a viable solution moving forward					
	Increased coordination efforts at EU level (e.g. avoid inter MS competition)	EU level action to represent all MS equally	Tailored EU procurement instrument adequate for health emergency response and management	Member State implementation of equivalent capacities to prepare, respond and manage medical countermeasures in health emergencies	Other	
%						
If relevant, please provide further comments:						

B. Weak anticipatory threat and risk assessments, modelling and needs monitoring, suboptimal intervention instruments & public-private ecosystems

4	How would you qualify:							
		Don't know	Very poor	Poor	Fair	Good	Very Good	Excellent
	the existing EU level anticipatory public health threat and risk assessments, modelling and needs monitoring							
	the existing EU intervention instruments for development and access to medical countermeasures							
	the existing EU public-private ecosystems for development and access to medical countermeasures							
5	What is your opinion about maintaining the current EU system for threat and risk assessments, modelling, needs monitoring, intervention instruments and public-private ecosystems							
		There is no need to	The EU should	The EU	This should be	Other		

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	change and the current EU system should be maintained	strengthen coordination and capacities for threat assessment and knowledge generation	should also create tailored intervention instruments and bolster EU public-private ecosystems	addressed at a national level and not the EU	
%					
If relevant, please provide further comments:					

C. Market and supply chain intelligence/market failures in specific contexts

6	Do you consider the following elements challenges for managing market and supply chains of medical countermeasures						
		Don't know	Strong disagree	Disagree	Neutral	Agree	Strongly Agree
	Knowledge of supply/arrivals of medical countermeasures into countries						
	Logistical distribution of medical countermeasures to Member States						
	Manufacturing capacities within the EU for medical countermeasures						
	Identification and overview of repurposing/reconversion of manufacturing capacities for medical countermeasures within the EU						
	Supply chains of key raw materials for medical countermeasures						
	EU dependency from third country imports						
	Market intelligence to react to failures when supply of medical countermeasure is too limited or not achieved (e.g. lack of private incentive as a result of concerns on return of investment or unknown nature of future risks and needs)						

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	Limited EU stockpiling capacities						
	Market intelligence for new countermeasures or novel technologies						
	Reluctant public sector investment due to unpredictable nature of health threats and success risks in R&D						
7	What is your view on increased EU action in the fields identified in the previous questions?						

D. Development, financing and deployment of new countermeasures in times of crisis

8	What is your opinion on the EU intervention in upfront investment and parallel development processes to ensure rapid manufacturing of needed medical countermeasures in a health emergency						
	Don't know	Very undesirable	Undesirable	Neutral	Desirable	Very desirable	
%							
	What kind of decision-making process/governance structure should be in place to accompany upfront EU investments? If relevant, please provide further comments						
9	What kind of tailored financial instruments would be needed to facilitate upfront EU investment? Is there an optimal stage of product development that intervention could have the highest impact?						
10	What would be needed to ensure EU rapid manufacturing capacities in case of a health emergency?						
	There is no need for intervention in this area	Maintaining flexible EU manufacturing capacities	Emergency contract network for EU surge manufacturing capacities	Streamlined EU level initiatives relating to medical countermeasures	This should be addressed at a national level and not the EU	Other	
%							
	If relevant, please provide further comments:						

E. General

11	Please indicate adverse or positive economic, social and environmental impacts from the creation of HERA
12	What would be in your view the role of HERA and other EU Agencies (e.g. EMA, ECDC) and instruments (e.g. HORIZON, IMI, Union Civil Protection Mechanism, RescEU, Joint Procurement)? Is there any benefit in streamlining all EU level initiatives of medical

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	countermeasures into one full end-to end Authority?
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F. Public Authorities

13	What governance approaches between Member States, Public Authorities and HERA could bring the most value?
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G. Business and their Associations, International organisations, Researchers, academia and learned societies

14	Please indicate models or approaches for cooperation or ecosystems that would be best suited under HERA with your entities?
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Glossary

Term	Definition
Medical Countermeasure	Any medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health
Modelling	Modelling should be considered as the simulation of scenarios based on mathematical techniques. In this context, it may extend to modelling of health risks and impacts of health interventions using medical countermeasures.
Needs monitoring	Needs monitoring in this context extends to the monitoring of the quantity and the specific type of medical countermeasure(s) that a Member State requires in terms of its preparedness and response to a serious cross-border threat to health.
EU intervention instruments for development and access to medical countermeasures	EU intervention instruments for development and access to medical countermeasures pertains to financial instruments for development (e.g. HORIZON, IMI) and procurement instruments (e.g. Emergency Support Instrument, Joint Procurement and the Advanced Procurement Agreements, rescEU) of medical countermeasures.
Market and supply chains of medical countermeasures	The market of medical countermeasures pertains to knowledge and awareness of novel technologies, as well as market dynamics that can impact the availability of medical countermeasures (e.g. incentives of key stakeholder, such as investors, industry and innovators, return on investment, uncertainty of demand, and impacts of future risks and needs. The supply chains of medical countermeasures extends to overall awareness of the supply into the EU and countries of specific medical countermeasures as well as manufacturing capacities within the EU (including reconversion/repurposing possibilities) and the EU's position in global supply chains for key raw materials needed to produce the final product.