/ro/stamina-proiect-h2020/stamina-heraEuropean Health Emergency Preparedness and Response Authority (HERA) Public Consultation

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Introduction

The outbreak of the COVID-19 pandemic revealed vulnerabilities in European health preparedness and crisis response for serious cross-border threats to health. Member States encountered difficulties in ensuring monitoring on needs, swift development, manufacturing, procurement, and equitable distribution of key medical countermeasures such as personal protective equipment, medical devices and in vitro diagnostic medical devices (including tests and testing materials), available therapies, vaccines and essential medicines. Some of these (e.g. protective equipment, such as masks or gloves, swabs, reagents, ventilators and some other medical devices and medicines used in intensive care units) ran short, whilst much-needed vaccines and therapies were not at authorisation or even at late stage development. Overall, the pandemic revealed vulnerabilities in global supply chains and insufficient oversight of manufacturing capacities and research priorities in the EU.

This new initiative is an integral part of the European Health Union proposal of November 2020. It aims to equip the Union with a new Authority, similar to the US BARDA, which addresses all future serious cross-border threats to health. The new Authority, which will be called the "European Health Emergency Preparedness and Response Authority" (HERA), will take into account the EU institutional setting and provide for a coordinated approach to health preparedness for the full array of serious cross-border threats to health that takes into account competences of the Member States in this area. HERA will complement and create synergies with the work of existing national and EU Agencies, in particular the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). Further background information on the creation of the legislative proposal for HERA may be found in the hyperlinks.

Please note that this consultation relates specifically to the European Health Emergency Preparedness and Response Authority. The Commission Communication 'Hera Incubator: Anticipating together the threat of COVID-19 variants' of February 2021 is not a legislative proposal. Therefore, this consultation does not serve to provide feedback on the work being undertaken by the Commission on mitigating, preventing and preparing for COVID-19 variants described in that Communication.

EU framework to develop, manufacture and deploy medical Countermeasures

Medical countermeasures refer to medicines, medical devices and other goods or services that are aimed at combating serious cross-border threats to health[1], a life- threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin, which spreads or entails a significant risk of spreading across countries. These medical countermeasures may necessitate coordination at Union level in order to ensure a high level of human health protection. Examples consist

of infectious diseases such as COVID-19, a pandemic influenza, or other events caused by biological or unknown agents, accidents caused by chemical agents, natural events of environmental origin or deliberate acts.

The EU framework for cross-border threats to health is based on Decision 1082/2013/EU, which sets out how the EU coordinates preparedness and response to serious cross-border threats to health. In light of COVID-19, the Commission put forward a proposal to revise this framework and proposed a Regulation for serious cross border threats to health, as well as reinforcements to the mandates of the key EU Agencies: The European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) .

In addition to Decision 1082/2013/EU, under which the Early Warning and Response System, the Health Security Committee and the Joint Procurement Agreement is established, the Commission has additional instruments that are active in the area of development, manufacturing and deployment of medical Countermeasures.

These will be mentioned in below, but comprise for example: EU4Health, Horizon Europe, European Innovation Council, European Regional Development Fund, Emergency Support Instrument, the European Defence Fund; Advanced Purchase Agreements under the EU Vaccines Strategy, the Union Civil Protection Mechanism and its rescEU, Emergency Response Coordination Centre, Innovation Partnership, and external action support under EU programmes supporting our partners across the world.

1. **What is your view on the existing EU capability to develop, manufacture and deploy medical countermeasures (e.g. vaccines, antitoxins, antibiotics, chemical antidotes, antiviral drugs, personal protective equipment, medical devices, etc.) aimed at combating serious cross-border threats to health?**

	Fragmented	Sub-optimal	Adequate	Good	Very good	Don't know
1.1 The EU capability to develop (including research) medical countermeasures is:					CNZ-IVN	
1.2 The EU capability to manufacture (production) medical countermeasures is:			CNZ-IVN			
1.3 The EU capability to deploy (distribution) medical countermeasures is:				CNZ-IVN		

If relevant, please provide further comments:

CNZ-IVN: These questions are very relevant for the existing capabilities of EU in order to solve a huge trans-border health emergency until now, for the future we all hope that HERA could solve and help EU member states to solve any trans-border threat or emergency. While medical research and deployment means are well organised and financed, the production, per-se, could be better, such as EU wouldn't be dependent on some vaccine and equipment imports (for instance, PCR reactive).

2. **What is your view on the EU added value of HERA in light of the existing EU capacities in place to develop, manufacture and deploy medical countermeasures aimed at combating serious cross-border threats to health?**

CNZ-IVN: If it is involved in resolving medical crisis situations in the EU Member State, a body carrying out surveillance activities (HERA) would be needed for the appropriate future. COVID-19 pandemic has demonstrated, the existing differences between national organizations. We presume that a unitary response will adjust the best reaction to imminent dangers, if it adjusts and correlates measures between states, which would allow citizens to adapt more to use of the rules when traveling through the EU. In our view, the future HERA will replace some existing committees like the Health Security Committee which with minimum replacements would play its role in HERA, the same for MIC and probable for the Civil Protection Committee in the same time there is a need for EU to take example from the NATO in creation of system for crisis management through establishing an national expert's system in order to provide the necessary consultation in crisis management.

3. **What do you believe are the key challenges that should be tackled to ensure effective EU-wide access to the most developed medical countermeasures aimed at combating serious cross-border threats to health, including global threats?**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
Sufficient capacities are in place at national level to ensure foresight of healthcare delivery ahead of a health emergency.			CNZ-IVN			
Sufficient capacities are in place at national level to ensure demand analysis of healthcare delivery ahead of a health emergency.				CNZ-IVN		
Sufficient capacities are in place at national level to ensure planning of healthcare delivery ahead of a health emergency.				CNZ-IVN		
There is a risk of low-quality, non-compliant medical countermeasures entering the EU market.				CNZ-IVN		
Real-time, reliable and Comparable information/data on global and national shortages of medical countermeasures is available at EU level.			CNZ-IVN			
Real-time, reliable and Comparable information/data on available supplies (including global value chains and national				CNZ-IVN		

stocks) is available at EU level.						
Third country trade restrictions on medical countermeasures and/or inputs critical to their development/ production impact Member States.				CNZ-IVN		
EU Member States have unequal access to medical countermeasures.					CNZ-IVN	
EU Member States have to compete against each other for procurement of medical countermeasures (e.g. higher prices, distorted access and lower EU wide utility).				CNZ-IVN		
Lack of coordination at EU level of manufacturing capacity for medical countermeasures (leading to under- or overcapacity).				CNZ-IVN		

4. The Commission's preliminary assessment identified various challenges[2] Do you think the following measures can overcome these challenges?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
Putting in place real-time monitoring of preparedness regarding the demand and supply of critical medical countermeasures in the EU					CNZ-IVN	
Ensuring increased coordination of efforts at EU level (e.g. avoid competition - e.g. research and development and procurement - between Member States).					CNZ-IVN	
Joint procurement by central purchasing bodies buying on behalf of other public buyers					CNZ-IVN	
Strengthening the EU Joint Procurement Agreement					CNZ-IVN	
Creation of a tailored EU					CNZ-IVN	

procurement instrument for health emergency response and management.						
An EU network of relevant enterprises in the supply chain of which production capacity can be immediately mobilised or repurposed without cross-border delivery constraints.					CNZ-IVN	
EU approach to address the whole life cycle of medical countermeasures capacity building (including tailored research and development, testing, certification, production and delivery logistics).					CNZ-IVN	

If relevant, please provide further comments:

CNZ-IVN: The creation of HERA would be strengthening the capacity of EU to solve an important part of preparedness of a concentrated response in case of a pandemic or another trans-border emergency with a huge number of human beings affected. It would be useful for HERA to draft general Action Plans (a general Agenda) for emergency situations (including medical ones), defining procedures, tax and custom facilities, network of important production facilities etc. All competent authorities from each member state have duties to fulfil in connection with the above-mentioned Agenda.

Threat and risk assessments & EU instruments

Public health modelling is an essential element for anticipatory threat and risk assessments. Modelling should be considered as the simulation of scenarios based on mathematical techniques and all available data (e.g. indicator- and event based data). In this context, it may extend to modelling of health risks and impacts of health interventions using medical countermeasures.

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.

5. **How would you qualify**:

	Fragmented	Sub-optimal	Adequate	Good	Very good	Don't know
Capacity for anticipatory public health threat and			CNZ-IVN			

risk assessments at EU level (including global threats)						
Capacity for modelling and foresight of serious cross-border threats to health at EU level (including global threats)		CNZ-IVN				
EU instruments for research, innovation and development of medical countermeasures[3]				CNZ-IVN		
EU instruments for access and deployment of medical countermeasures[4]				CNZ-IVN		

6. **What are your views on the following?**

	This should be addressed at a national level and not by the EU	There is no need to change. The current EU system should be maintained	The EU should further strengthen coordination and capacities in this area	Don't know
6.1 EU capacity for anticipatory public health threat and risk assessments at EU level and including global threats:			CNZ-IVN	
6.2 EU capacity for modelling and foresight of serious crossborder threats to health at EU level and including global threats:			CNZ-IVN	
6.3 EU instruments for research, innovation and development[5] of medical countermeasures:			CNZ-IVN	
6.4 EU instruments for access and deployment[6] of medical countermeasures:		CNZ-IVN		

If relevant, please provide further comments

CNZ-IVN: Any EU organization, in their supervisory role, should offer as much information and advice to the member states as possible, maybe even offer medical supplies, if possible. Ultimately, however, each country should perform their own individual risks assessment of any public health threat and also the risk/benefit assessment of any public health measure. As the recent pandemic has shown, modelling isn't always reliable, so each country performing their own modelling of the threat and possible solutions and then making it available for comparison to other countries would encourage open scientific debate and the determining of the best plan of action for each country.

Market dynamics and supply chain intelligence

The market (e.g. demand and supply) of medical countermeasures is constantly evolving and faces a variety of changing challenges. As such, knowledge and awareness of novel technologies, as well as pressures that can affect demand and supply - that can impact the availability of medical countermeasures
– is important to monitor. Such pressures include, for example, incentives of key stakeholders (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 critical raw materials needed to produce the final product.

7. To what extent is there a need for EU level action to strengthen the following elements for ensuring sufficient demand and supply of medical countermeasures in the EU?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
Real-time analysis at EU level of the demand for medical countermeasures				CNZ-IVN		
EU level knowledge of exports of medical countermeasures from EU Member States to third countries				CNZ-IVN		
EU level knowledge of suppliers and supply chain of medical countermeasures into EU Member States				CNZ-IVN		
EU level knowledge of supply deliveries of medical countermeasures into EU Member States					CNZ-IVN	
Market intelligence to anticipate possible interruptions in the demand and supply of medical countermeasure				CNZ-IVN		
EU level knowledge on logistical distribution of medical countermeasures to MemberStates				CNZ-IVN		
EU level knowledge on manufacturing capacities within the EU for medical countermeasures					CNZ-IVN	
EU level knowledge on identification and support to				CNZ-IVN		

repurposing/reconversion activities of manufacturing capacities for medical countermeasures within the EU						
Sustainability of EU supply chains of medical countermeasures and flexible supply of key inputs				CNZ-IVN		
EU level knowledge on supply dependency from third country stockpiling capacity (e.g. virtual or physical or otherwise) at EU level				CNZ-IVN		
Market intelligence for new countermeasures or innovative technologies					CNZ-IVN	
EU level knowledge on national public sector investment into research and development of medical countermeasures					CNZ-IVN	
EU level knowledge on private sector investment into research and development of medical countermeasures					CNZ-IVN	

8. What is your view on increasing EU level action in the market dynamics (e.g. demand and supply, as well as supply chains) of medical countermeasures?

- Undesirable
- Neutral
- Desirable CNZ-IVN
- Don't know

If relevant, please provide further comments

CNZ-IVN: The support provided to EU member states through contracting, paying and distribution of vaccines was very important, especially for the countries with reduced negotiation capacity, on an extremely crowded market, if this support would be completed with other items (like masks, gloves, Personal Protection Equipment and so on) it would be much better, because in our experience there exist a range of wrong acquisitions. This activity should be focused on the following long-time results: a better and time-optimal distribution of all resources within EU, avoidance of price agreements between the main suppliers, getting a better centralized situation of medical supplies dynamics and EU medical supplies availability and lacks.

9. What is your view on strategic autonomy in the area of medical countermeasures to respond to health emergencies considering actions at EU, regional or national level?

CNZ-IVN: As the European Council has repeatedly emphasized, ensuring the strategic autonomy of the European Union is a goal that justifies the identification and taking of measures to eliminate any dependency in sensitive areas, such as public health. Strategic autonomy of the member states is not only an ethical

necessity, but a reality. Each country needs to be prepared with their own stockpiles of medical supply, their own guidelines and risk assessment measurements. The EU may provide additional guidance and even supplies, if needed, but ideally, each country would be prepared to handle its own crises and only in unexpected situations request help from the EU. Additionally, each member country having its medical strategic autonomy, with its own set of guidelines and responses, only strengthens the whole of the EU, as different responses can be observed and member states learn from each other.

Development and financing of new countermeasures in times of crisis

Upfront investment and parallel development processes pertains to undertaking financial investments for the development and access to medical countermeasures prior to a final product being available, approved or produced. Parallel development processes of medical countermeasures refers to when product development occurs prior or whilst the product is undertaking trials, approvals, market demand, etc. The contrary is sequential development process, which is approached in a step-by-step fashion.

Flexible and "ready to use" EU manufacturing capacities would entail the management of manufacturing infrastructure at the EU level, that remains ready to be activated for the production of a given medical countermeasure for the EU. It should optimally be 'flexible' in order to be able to manufacture key medical countermeasures that may require different technological/engineering requirements.
'One-stop shop', refers to an entity that manages and controls all instruments related to a product or service – in this case medical countermeasures for the EU.

10. **What is your opinion on further EU intervention in upfront investment and parallel development processes to ensure rapid manufacturing of needed medical countermeasures in a health emergency, primarily within Europe but also from a global perspective?**

- Very undesirable
- Undesirable
- Neutral
- Desirable - CNZ-IVN
- Very desirable
- Don't know

If relevant, please provide further comments

CNZ-IVN: Time is of the essence when Pandemics occurs, therefore, a prompt, well-tailored intervention in prior investment and parallel development processes chould have as result, saving of the innocent people etc.

11. What kind of tailored financial instruments would be needed in your view to facilitate upfront EU investment?

- Public-private partnerships - CNZ-IVN
- Direct contracts - CNZ-IVN

- Disbursement schemes - CNZ-IVN
- Fees - CNZ-IVN
- Combined EU and national financing CNZ-IVN

If relevant, please provide further comments

CNZ-IVN: A better outcome than the current one may be attained by: a) diversification of funding sources (through the interest of private investors), so as to reduce the burden borne by EU budget and to attract resources to ensure results in a shorter time; b) accelerating the public procurement processes related to this field.

12. Is there an optimal stage of product development upon which financial or procurement intervention could have the highest impact?

CNZ-IVN: The above mentioned solutions will have positive results in connection with all stages of design and testing, authorization and mass production of health products. Yet, the optimal stage for the highest impact is the initiation of product development especially research and implementation.

13. What is needed in your view to ensure rapid EU manufacturing capacities during a health emergency?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
There is no need for EU intervention in this area/this should be addressed at a national level		CNZ-IVN				
Pre-arranged emergency contract network for EU surge manufacturing capacities				CNZ-IVN		
Maintaining flexible and "ready to use" EU manufacturing capacities					CNZ-IVN	
Voluntary licensing mechanisms facilitating an effective and rapid sharing of technology, know-how and data with other manufacturers, but also ensuring technology owners' control over their rights					CNZ-IVN	
Streamlined EU level initiatives relating to medical countermeasures under a 'onestop shop'				CNZ-IVN		

If relevant, please provide further comments

CNZ-IVN: The European medical equipment industry is very well developed and can provide a good response in case of high demand. HERA could intervene in the distribution of equipment according to territorial needs and for greater promptness in managing the problems of production and delivery of medical equipment.

Impacts, role, scope and coordination

14. How would you rate the expected health, economic, social and environmental impacts, as well as the impact on consumer protection and administrative burden (adverse or positive), which the creation of HERA[7] would trigger (primarily from an EU perspective but also from a global perspective)?

	Negative impact	Neutral impact	Positive impact	Don't know
Health			CNZ-IVN	
Economic		CNZ-IVN		
Social			CNZ-IVN	
Environmental		CNZ-IVN		
Consumer protection		CNZ-IVN		
Administrative burden		CNZ-IVN		

Please provide further explanations:

CNZ-IVN: The benefits of setting up HERA certainly outweigh the associated costs, leading to a streamlining of the administrative process, as it outlines material competences in the field. The impact of such a decision-making body would have several benefits: • Health: a better organization of national medical systems by homogenizing the response to pandemics or disaster medicine. A common decision, mediated by HERA would lead to a united and more prompt response of the member states and a unitary legislation much easier to assimilate and implicitly to respect by the citizens. • Economic: many savings in the management area, larger stocks of medical equipment, medication that would be automatically purchased at better prices and a mediation of trade activities that would help even the poorest EU countries to have access to the latest medical equipment generation. • Social: A unitary decision in the EU would help citizens understand the situation and accept it more easily, without protest organizations because other states have better managed the critical medical situation and can facilitate the rules of free movement taking into account medical constraints.

15. What types of health threats should the HERA prioritize (e.g. chemical, biological, radiological and nuclear, environmental)?

CNZ-IVN: In our view, HERA should consider the full range of threats to human health, but should focus primarily on biological or environmental threats. Never the less, HERA should have the means to adapt to any

health dangers according to their imminence and focus on ongoing medical situations. Any of the threats may be present at one time, one or more, and decisions must focus on the threat and overcoming the crisis situation at that time. In other words, HERA must be a flexible body in everyday situations.

16. What types of medical countermeasures should the HERA prioritize (e.g. vaccines, antibiotics, antitoxins, chemical antidotes, therapeutics, diagnostics and medical equipment and supplies)?

CNZ-IVN: We believe that the most important medical countermeasures at the moment, are: a) ensuring sufficient reserves of medical equipment and consumables; b) research and implementation of new types of antibiotics, in the context of proven diminution of the efficiency of the already existing ones; c) last but not least, the patenting, testing and production of vaccines to reduce the risks associated with communicable diseases.

17. What should be the interplay of HERA with other EU Agencies (e.g. European Medicines Agency, European Centre for Disease Control and Prevention, European Food Safety Authority, European Monitoring Centre for Drugs and Drug Addiction, European Environment Agency, European Chemicals Agency, Europol)?

CNZ-IVN: HERA should have a strong bound and communication system with other EU Agencies in order to succeed for what was developed. Probably, the most important interplay should be with *European Medicines Agency* and with *European Centre for Disease Control and Prevention* .With the information coming from these two sources , HERA will be able to develop new medicines, in order to reconvert the EU focus on research into production. Until now, *EMA* was involved into monitories and evaluate the safety of medicine, but now will be more involved in pharmaceutical industry. HERA and *EMA* will make sure there are always medicines and medical display available in stock, and will coordinate studies with vaccines. It's also important that HERA collaborate with *EUROPOL* and *European Monitoring Centre for Drugs and Drug addiction* in order to prevent terrorist acts like turning medicine or vaccine into biological weapon. The other EU institutions should organize their activities and agenda, for coping with the general Action Plan (set of procedures) that HERA shall issue for setting of a unitary policy regarding the preparedness and action against infectious diseases. As an example, the European Medicines Agency should, as a matter of priority, deal with applications for authorization of medicinal products / vaccines provided for in the necessary procedures and stocks, as provided for by HERA.

18. What should be the interaction of HERA with other EU instruments contributing to the development, manufacturing and deployment of medical countermeasures (e.g. EU4Health, Horizon Europe, European Innovation Council, European Regional Development Fund, Emergency Support Instrument, the European Defence Fund; Advanced Purchase Agreements under the EU Vaccines Strategy, the Union Civil Protection Mechanism and

its rescEU, Emergency Response Coordination Centre, Innovation Partnership, and external action support under EU programmes supporting our partners across the world.)? Should they be:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
Coordinated like they are now, ensuring synergies with HERA when created				CNZ-IVN		
Coordinated by HERA when created in close collaboration with the European Commission, Member States and other relevant agencies				CNZ-IVN		
Brought under the control of HERA when created by streamlining them into one full end-to end (e.g. from conception to distribution and use of medical countermeasures, incorporating all existing financial and operational instruments at EU level) Authority?					CNZ-IVN	

If relevant, please provide further comments:

CNZ-IVN: In most hypothesis, those bodies are independent and have they their own attributions, clearly defined by the European legislation. Since each of those entities have their own attributions, clearly defined by the European legislation, the only interference permitted for HERA should concern the application of the Public Health Policy and the preparedness and response plan to situations that threaten the health of European citizens. This kind of coordination also includes the situations mentioned at the last question above ("Brought under the control of HERA when created by streamlining them into one full end-to end").

19. What would be in your view the role and interplay of HERA with key international bodies/agencies (e.g. World Health Organization, Global Preparedness Monitoring Board, U.S. Biomedical Advanced Research and Development and U.S. Centres for Disease Control and Prevention, etc.)

CNZ-IVN: The role entails: a) communication, collective planning and cooperation for unitary preparedness policies and measures, b) sharing of medical data and statistics, c) organizing of international scientific events (conferences), for monitoring, evaluating of current situation and possible threats and about preparedness procedures and means. The communication with key international bodies/agencies aims to identify and analyze variants of virus as soon as possible, to support the adaptation of current vaccines, if necessary and to develop new ones, to launch a global network of clinical trials, for the rapid approval of updated vaccines, to increase the mass production of new and updated vaccines.

Environmental organisations, international organisations, researchers, Academia

20. What would be the best cooperation model and contribution between your entities and HERA?

CNZ-IVN: HERA was designed to be a supranational (central EU authority) for the Health Preparedness Field. Therefore, their role would be to develop and supervise implementation of unitary European Health Procedures for preparedness, organizing and sustaining EU research and production process for medical devices/means. Institutional cooperation includes collaboration and joint work within and between organizations. Such cooperation requires the sharing of objectives, knowledge, resources, responsibilities or consent between several actors. Between the state institutions in Romania (Ministry of Health, Public Health Directorate) and HERA, the cooperation relationship is beneficial to help the country in terms of budget contribution, exchange of specialists and provision of services, especially in the current situation of infection with SARS-COV-2 virus. The Romanian Virology Institute can participate with fundamental research in the medical field (virology) and consultations regarding the drafting and structuring of preparedness procedures.

Business and their associations

21. What would be the best cooperation model and contribution between your entities and HERA?

CNZ-IVN: Through the relevant government agencies that would communicate with the European agencies, HERA could make decisions with an impact on the Romanian institutions. HERA could also provide government support at some point.

Other

22. Would you like to raise other issues that need to be address?

If so, please specify:

CNZ-IVN: First of all, a general legislative framework should be created on the basis of which the activity of HERA should be established. Then, each Member State has the responsibility to align its legislation with European decisions. A good start would be to initiate a working group to determine how to organize and how European agencies can come under the influence of HERA.

23. If you wish to provide additional information (for example a position paper) or raise specific points not covered by this questionnaire, you can upload your additional document here.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

CNZ-IVN: How soon should be HERA operative, regarding the fact that we are still in a pandemic outbreak? ; How exactly would HERA maintain an equilibrium between countries with different economic development? ; Where would the financial resources come from?

[1] Decision 1082/2013/EU on serious cross-border threats to health

[2] See question 3 for challenges (e.g. foresight, demand analysis and planning of healthcare delivery ahead of a health emergency; low-quality, non-compliant medical countermeasures entering the EU market; real-time, reliable and comparable information/data on national shortages and available supplies
(including stocks) of medical countermeasures is available at EU level; Member States can have unequal access to medical countermeasures; EU Member States have to compete against each other for the development and procurement of medical countermeasures; lack of coordination of manufacturing capacity
for medical countermeasures.)

[3] e.g. Horizon Europe, European Innovation Council, European Regional Development Fund, the European Defence Fund

[4] e.g. Joint Procurements, Advanced Purchase Agreements under the EU Vaccines Strategy, Emergency Support Instrument the Union Civil Protection Mechanism and its rescEU and Emergency Response Coordination Centre, Innovation Partnership, external action support under
EU programmes supporting our
partners across the world

[5] e.g. Horizon Europe, European Innovation Council, European Regional Development Fund, the European Defence Fund

[6] e.g. Joint Procurements, Advanced Purchase Agreements under the EU Vaccines Strategy, Emergency Support Instrument the Union Civil Protection Mechanism and its rescEU and Emergency Response Coordination Centre, Innovation Partnership, external action support under
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[7] This pertains to policy options 2-3, as set out in the Inception Impact Assessment