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European Health Emergency Preparedness and Response Authority 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.

This questionnaire will be available in all EU-languages in the coming weeks. It includes several thematic sections. The specific terminology is explained at the beginning of the relevant sections.

About you

* Language of my contribution

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- ○ Croatian
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- ◉ Non-governmental organisation (NGO)
- ○ Public authority

- Trade union
- Other

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Piotr

* Surname

Kolczyński

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piotr.kolczynski@cpme.eu

* Organisation name

255 character(s) maximum

Standing Committee of European Doctors (CPME)

* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

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- Algeria
- American Samoa
- Andorra
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- Aruba
- Australia
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- Azerbaijan
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- Saudi Arabia
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- Serbia
- Seychelles
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- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden

- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
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- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
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- Nigeria
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- Switzerland
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- Taiwan
- Tajikistan
- Tanzania
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- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
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- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom

- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
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- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
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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] Decision 1082/2013/EU on serious cross-border threats to health

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:	◉	○	○	○	○	○
1.2 The EU capability to manufacture (production) medical countermeasures is:	○	◉	○	○	○	○
1.3 The EU capability to deploy (distribution) medical countermeasures is:	◉	○	○	○	○	○

If relevant, please provide further comments:

500 character(s) maximum

The capacity of the EU pharmaceutical sector to combat cross-border health threats has been neglected by the public sector. Underfunding biomedical innovation and entrusting R&D necessary to meet public health needs to private companies operating for the purpose of making profit leave Europe unprepared. Globalised and opaque supply chains, lack of sufficient and coordinated stockpiles and unsuitable joint procurement mechanisms result in the EU being unable to respond quickly to health crises.

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?

1000 character(s) maximum

Through HERA, the EU should take responsibility for investing in and shaping biomedical innovation.

The new system offers the opportunity to establish a new public-driven model of R&D that ensures health innovations respond to real public health needs and are equally accessible. The EU can benefit from a fully publicly governed mechanism with a substantial, sustainable and flexible budget that is based on transparency and accountability, and that from the outset fairly defines the sharing of risks and rewards of future technologies between the public and private sectors.

Thus designed, HERA, whose primary objective should always be to improve public health and health security, would be well positioned to guarantee the pharmaceutical sector's readiness and enable the EU to make decisions on how, when and where future medical countermeasures are researched, developed, manufactured and distributed.

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.	○	◉	○	○	○	○
Sufficient capacities are in place at national level to ensure demand analysis of healthcare delivery ahead of a health emergency.	○	◉	○	○	○	○
Sufficient capacities are in place at national level to ensure planning of healthcare delivery ahead of a health emergency.	○	◉	○	○	○	○

There is a risk of low-quality, non-compliant medical countermeasures entering the EU market.	○	○	○	○	◉	○
Real-time, reliable and comparable information/data on global and national shortages of medical countermeasures is available at EU level.	○	◉	○	○	○	○
Real-time, reliable and comparable information/data on available supplies (including global value chains and national stocks) is available at EU level.	○	◉	○	○	○	○
Third country trade restrictions on medical countermeasures and/or inputs critical to their development/ production impact Member States.	○	○	○	○	◉	○
EU Member States have unequal access to medical countermeasures.	○	○	○	◉	○	○
EU Member States have to compete against each other for the research and development of medical countermeasures (e. g. higher prices, distorted access and lower EU wide utility).	○	○	○	◉	○	○
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).	○	○	○	◉	○	○
Lack of coordination at EU level of manufacturing capacity for medical countermeasures (leading to under- or overcapacity).	○	○	○	◉	○	○

4. The Commission’s preliminary assessment identified various challenges[1]

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	○	○	○	○	◉	○
Ensuring increased coordination of efforts at EU level (e.g. avoid competition - e.g. research and development and procurement - between Member States).	○	○	○	○	◉	○
Joint procurement by central purchasing bodies buying on behalf of other public buyers	○	○	○	◉	○	○
Strengthening the EU Joint Procurement Agreement	○	○	○	◉	○	○
Creation of a tailored EU 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.	○	○	○	○	◉	○
EU approach to address the whole life cycle of medical countermeasures capacity building (including tailored research and development, testing, certification, production and delivery logistics).	○	○	○	○	◉	○

If relevant, please provide further comments:

500 character(s) maximum

In addition:

Identifying criteria for assessing the criticality of medical countermeasures is a precondition for monitoring their demand and supply.

The EU needs to develop its capacity to implement large trials by improving its infrastructure, governance, and funding.

The EU and Member States need to ensure that their laws allow for the effective use of intellectual property-related instruments to improve access during health emergencies and encourage the sharing and pooling of IP.

[1] 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.)

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	Other	Don't know
Capacity for anticipatory public health threat and 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)	○	◉	○	○	○	○	○
EU instruments for **research, innovation and development** of medical countermeasures[1]	○	◉	○	○	○	○	○
EU instruments for **access and deployment** of medical countermeasures[2]	◉	○	○	○	○	○	○

If relevant, please provide further comments

500 character(s) maximum

The COVID-19 pandemic has shown that it is essential for the EU to have better rapid response capacity to enable it to react to major public health threats in a more coordinated manner.

EU instruments for public health-related R&D in the form of public-private partnerships (PPPs), such as the IMI, led to negligence of pandemic preparedness. Crucially, EU instruments must go beyond PPPs and create strong public leadership in biomedical R&D and distribution.

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:	○	○	◉	○
6.2 EU capacity for **modelling and foresigh**t of serious cross-border threats to health at EU level and including global threats:	○	○	◉	○
6.3 EU instruments for **research, innovation and development**[3] of medical countermeasures:	○	○	◉	○
6.4 EU instruments for **access and deployment**[4] of medical countermeasures:	○	○	◉	○

If relevant, please provide further comments

500 character(s) maximum

The shortcoming identified in the question above related to the lack of sufficient EU capacity and coherence of national instruments clearly point to the need to improve the current system. While enhanced coordination in terms of threat assessment and modelling based on joint mechanisms is essential, it needs to be balanced with the importance of individual EU Member States maintaining their capabilities to act at national and regional level to prepare and respond to emergencies.

[1] e.g. Horizon Europe, European Innovation Council, European Regional Development Fund, the European Defence Fund
[2] 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

[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

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	○	○	○	○	◉	○
EU level knowledge of exports of medical countermeasures from EU Member States to third countries	○	○	○	◉	○	○
EU level knowledge of suppliers and supply chain of medical countermeasures into EU Member States	○	○	○	○	◉	○
EU level knowledge of supply deliveries of medical countermeasures into EU Member States	○	○	○	○	◉	○
Market intelligence to anticipate possible interruptions in the demand and supply of medical countermeasure	○	○	○	○	◉	○
EU level knowledge on logistical distribution of medical countermeasures to Member States	○	○	○	○	◉	○
EU level knowledge on manufacturing capacities within the EU for medical countermeasures	○	○	○	○	◉	○
EU level knowledge on identification and support to 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	○	○	○	○	◉	○
EU level knowledge on supply dependency from third country	○	○	○	○	◉	○
stockpiling capacity (e.g. virtual or physical or otherwise) at EU level	○	○	○	○	◉	○
Market intelligence for new countermeasures or innovative technologies	○	○	○	○	◉	○

EU level knowledge on national public sector investment into research and development of medical countermeasures	○	○	○	○	◉	○
EU level knowledge on private sector investment into research and development of medical countermeasures	○	○	○	○	◉	○

8.

	Undesirable	Neutral	Desirable	Don't know
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?	○	○	◉	○

If relevant, please provide further comments

500 character(s) maximum

EU level action is indispensable to ensure the resilience of supply chains and equitable access to medical countermeasures. By pooling resources, strengthening the regulatory framework (e.g., requiring contingency plans for suppliers to the EU market) and reinforcing joint mechanisms (e.g., EU level stockpiling), Member States significantly increase their capacity. Having all Member States speaking with one voice strengthens the EU's bargaining power and improves its negotiating position.

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?

500 character(s) maximum

Overreliance on manufacturing sites located in third countries exposes Europe to supply risks. Improving the EU domestic capacities should therefore be one of the measures taken to improve the response to health emergencies. However, diversification of supply sources, identification of supply chains' vulnerabilities and development of mitigation measures are equally important.

Strategic autonomy should also refer to improving the power balance between the EU and pharmaceutical companies.

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.

	Very Undesirable	Undesirable	Neutral	Desirable	Very Desirable	Don't know
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?	○	○	○	○	◉	○

If relevant, please provide further comments

500 character(s) maximum

EU intervention in the form described is of key importance. However, it cannot be limited to de-risking industry R&D and providing AMCs without strings attached. Public investment is indispensable, but must be subject to concrete commitments on e.g., pricing, transparency, participation in comparative joint clinical trials, meeting desired product characteristics or, when possible, sharing of data and knowledge obtained through public funding. The EU should actively shape biomedical innovation

11.

	Public-private partnerships	Direct contracts	Disbursement schemes	Fees	Combined EU and national financing
What kind of tailored financial instruments would be needed in your view to facilitate upfront EU investment?	○	○	○	○	◉

If relevant, please provide further comments

500 character(s) maximum

-

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

500 character(s) maximum

-

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

	Strong 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	◉	○	○	○	○	○
Pre-arranged emergency contract network for EU surge manufacturing capacities	○	○	○	○	○	◉

Maintaining flexible and “ready to use” EU manufacturing capacities	○	○	○	◉	○	○
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	○	○	◉	○	○	○
Streamlined EU level initiatives relating to medical countermeasures under a ‘one-stop shop’	○	○	○	○	○	◉

If relevant, please provide further comments

500 character(s) maximum

HERA should map existing production facilities capable of being mobilized during emergencies and implement a mechanism to enable scalable and flexible manufacturing and distribution of medical countermeasures.

Reliance on voluntary licensing alone is not desirable as it leaves it to the private sector to decide when and how medical countermeasures become universally available and affordable. In response to the COVID-19, its use was very limited, and the WHO C-TAP has not been used to date.

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[1] would trigger (primarily from an EU perspective but also from a global perspective)?

	Negative impact	Neutral impact	Positive impact	Don’t know
Health	○	○	◉	○
Economic	○	○	◉	○
Social	○	○	◉	○
Environmental	○	○	○	◉
Consumer protection	○	○	◉	○
Administrative burden	○	○	○	◉

Please provide further explanations:

500 character(s) maximum

Improving public health and health security should always be the primary objective of HERA. The Authority's potential to have positive economic impacts should also be exploited, but on no account must economic objectives take precedence over health interests. HERA must be judged on the benefits it brings to public health not to business The creation of HERA and its interplay with other EU Agencies should not lead to duplication of tasks and increased administrative burden at EU or national level

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

500 character(s) maximum

The new mechanism could initially focus on biological threats, including infectious diseases and antimicrobial resistance. The scope of HERA should be further gradually expanded to include all health emergencies Europe could be confronted with, as they are numerous and not always foreseeable.

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

500 character(s) maximum

At its initial stage, HERA should offer an alternative approach to funding and cooperating with the private sector for R&D on antibiotics that is aligned with the WHO Priority Pathogen List, and the development of vaccines and treatments for infectious diseases. However, as the Authority's scope is progressively extended, the mechanism should assume responsibility for R&D on other types of medical countermeasures to ensure adequate preparedness and response to prioritized health threats.

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)?

1000 character(s) maximum

The interplay between the mandate of HERA and the competencies of other EU Agencies and existing instruments should be a primary issue to be explored by the Commission.

The establishment of HERA could foster the EU's preparedness and response capacities and ensure adequate coordination of the current fragmented initiatives. Its added value in areas such as manufacturing capacity, shaping and funding public health R&D, joint public procurement, stockpiling or distribution could address many of the current shortcomings.

However, given the experience and expertise of the EMA and ECDC, the planned extension of their mandates and the introduction of a new regulation on cross border health threats, it requires an in-depth examination on how the new agency should be positioned within the EU institutional framework or even whether the new mechanisms would not be more efficient if implemented within the existing structure.

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	○	◉	○	○	○	○
Coordinated by HERA when created in close collaboration with the European Commission, Member States and other relevant agencies	○	○	○	○	○	◉
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?	○	○	○	○	○	◉

If relevant, please provide further comments:

500 character(s) maximum

While the Authority with a broad end-to-end mandate seems likely to ensure preparedness and response capacity most efficiently, a throughout study and impact assessment are needed to determine what form would be best for HERA and, consequently, how the interaction between the Authority and other EU instruments would look like.

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.)

500 character(s) maximum

The HERA approach should reflect the global dimension of health threats and maximize its global health outcomes. The Authority should align its priorities with international partners and collaborate with them as to e.g. defining target product profiles for med. counter. or designing clinical trials. Through HERA the EU should have a strong voice at the international level in setting a high standard of governance in the public interest and advocate an adequate level of return on public investment

[1] This pertains to policy options 2-3, as set out in the Inception Impact Assessment

Environmental organisations, international organisations, researchers, academia

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

1000 character(s) maximum

Health professionals such as medical doctors or pharmacists should be closely involved in different areas of the proposed HERA framework, such as identifying critical countermeasures, prioritizing public health R&D or monitoring supply and demand.

Medical doctors have direct experience with the use of different medicines and medical devices in the context of health emergencies and can provide valuable input to planning and response activities.

Due to their close and regular contact with patients, medical doctors play a key role in communicating, raising awareness and providing advice on the use of medical countermeasures. Importantly, for doctors to fulfil their mission, they need to have up-to-date and detailed data on them.

Healthcare professionals can also provide information on any potential changes in demand for medicines.

Other

22. Would you like to raise other issues that need to be address?
If so, please specify:

500 character(s) maximum

While developing a new mechanism for biomedical R&D, the Commission should not overlook other issues necessary to ensure health emergency preparedness and response capacity ranging from the organization and capacity of health care systems to logistical vulnerabilities.

Recognising HERA's potential to improve cooperation and coordination at EU level, the Authority must also ensure public health preparedness at national, regional and local level, close to the population.

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

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