Contribution ID: bcd8fdbb-4347-41cd-bd7a-1495556c5f25
Date: 12/05/2021 01:30:21

# European Health Emergency Preparedness and Response Authority Public Consultation

Fields marked with * are mandatory.

## 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 (https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041) 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 (https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_1655%20&https:/eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0724&from=EN&https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Response-Authority) 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’ (https://ec.europa.eu/info/sites/info/files/communication-hera-incubator-anticipating-threat-covid-19-variants_en.pdf) 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

English

*I am giving my contribution as

Business association

*First name

Magda

*Surname

CHLEBUS

*Email (this won't be published)

magda.chlebus@efpia.eu

*Organisation name

*255 character(s) maximum*

European Federation of Pharmaceutical Industries and Associations (EFPIA)

*Organisation size

Small (10 to 49 employees)

Transparency register number

*255 character(s) maximum*

Check if your organisation is on the transparency register (http://ec.europa.eu/transparencyregister/public/homePage.do?redir=false&locale=en). It's a voluntary database for organisations seeking to influence EU decision-making.

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*Country of origin

Please add your country of origin, or that of your organisation.

Belgium

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- **Anonymous**
  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.
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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 (https://ec.europa.eu/health/funding/eu4health_en), Horizon Europe (https://ec.europa.eu/info/horizon-europe_en), European Innovation Council (https://eic.ec.europa.eu/index_en), European Regional Development Fund (https://ec.europa.eu/regional_policy/en/funding/erdf/), Emergency Support Instrument (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en), the European Defence Fund (https://ec.europa.eu/defence-industry-space/index_en); Advanced Purchase Agreements under the EU Vaccines Strategy (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en), Emergency Response Coordination Centre (https://ec.europa.eu/echo/what/civil-protection/emergency-response-coordination-centre-ercc_en), Innovation Partnership, and external action support under EU programmes supporting our partners across the world (https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1267).

[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*

While early R&D receives limited support, late-stage funding is even more scarce, meaning that the EU is unable to advance products that lack market incentives. Figure 1 in the attachment outline the gaps in the current EU ecosystem, which HERA should address by enhancing the EU's capability to develop, manufacture, and deploy medical countermeasures. HERA can build on existing private sector capabilities through better coordination and tackling the current fragmentation in the landscape.

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?

*1,000 character(s) maximum*

HERA should be solution-oriented, focusing on advanced stage research and clinical development through to product manufacturing and procurement. It should have a defined role: undertaking a monitoring and principal coordination role in risk assessment and early development, a leading role in late-stage development funding and ensuring, manufacturing capabilities including for clinical trials materials, as well as supporting with regulatory pathways, overseeing purchasing and stockpiling. In essence, this would equate to a 2.2+ option as laid out by the Commission in the IIA. Such set-up would provide end-to-end coordination and certainty for industry partners. Additionally, HERA would help to tackle fragmentation and duplication, minimise bureaucracy, and speed up decision-making processes. That said, HERA should not replace existing EU programmes for early R&D, instead enhancing the ability to pool resources and fund at scale that no Member State is able to achieve alone.

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 | Neutra | Agree | Strongly A | Don't kn |
|---|---|---|---|---|---|---|

| | | e | l | | gr e e | o w |
|---|---|---|---|---|---|---|
| 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?

| | Stro | D is | N | A | S tr o n | D o n' |
|---|---|---|---|---|---|---|

| | ngly disagree | agree | eutral | gree | gly Agree | tknow |
|---|---|---|---|---|---|---|
| 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 (https://ec.europa.eu/health/security/preparedness_response_en) | ○ | ○ | ○ | ◉ | ○ | ○ |
| 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*

Due to the complexity of the joint procurement mechanism, it should only be used for procurement of medical countermeasures when it can improve access to products and should be limited to situations where purchase and supply of medicinal products cannot be ensured by other means. Such measures should be also proportionate to the situation and limited in time. Additionally, any procurement practices, including joint procurement, should foster fair competition, timely access, and reliable supply.

[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*

To maximise its potential, HERA should establish strong ties and operate in close collaboration with the European Centre for Disease Control (ECDC) and international counterparts such as the World Health Organisation (WHO). This will help to identify potential health threats early-on and update its priority areas accordingly. It is essential that once a priority has been established, this prioritisation is clearly communicated to all stakeholders in a transparent and timely manner.

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*

HERA should rely on existing EU structures and not duplicate already ongoing work. Thus, HERA should operate in close collaboration with the ECDC, depending on the final shape of its mandate, to identify threats and set its priority areas accordingly. Priorities should be identified through a multi-stage approach. HERA should also operate in collaboration with programmes funding early development research to ensure a smooth transition from promising early R&D to late-stage development.

[1] e.g. Horizon Europe (https://ec.europa.eu/info/horizon-europe_en), European Innovation Council (https://eic.ec.europa.eu/index_en), European Regional Development Fund (https://ec.europa.eu/regional_policy/en/funding/erdf/), the European Defence Fund (https://ec.europa.eu/defence-industry-space/index_en)

[2] e.g. Joint Procurements, Advanced Purchase Agreements under the EU Vaccines Strategy (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), Emergency Support Instrument the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en) 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 (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), Emergency Support Instrument the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en) 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*

Setting up clear structures to address the existing gaps in supporting late-stage development and manufacturing of medical countermeasures could bring more certainty, limit complexities, end redundancies, and allow the pooling of resources to fund at the magnitude needed to make a difference. That said, not every area that needs improvements would de-facto need HERA's involvement

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*

To adequately respond to pandemics and health emergencies, global cooperation is key. While strategic autonomy is important, it is crucial to ensure that it does not impede or restrict EU capacity to address cross-border health threats in a timely and efficient manner nor weaken global supply chains that are important in global health. Enhancing EU strategic autonomy should imply investing in disruptive technologies and the ability to produce them in cutting-edge flexible bioproduction plants

## 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 Und | Unde | Neut | Desi | Very De | Don't |
|---|---|---|---|---|---|---|

| | es ir a bl e | si ra bl e | ra l | ra bl e | si ra bl e | k n o w |
|---|---|---|---|---|---|---|
| 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*

To stimulate innovation, HERA should have a flexible, collaborative, and agile setup and support all stages of medical countermeasures development. Thus, to enhance Europe’s manufacturing capabilities HERA should facilitate the creation of networks of the existing manufacturers with innovative infrastructure, which can be mobilised quickly in times of crisis and enable production of medical countermeasures using multiple technology platforms. For more details please refer to the attachment

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*

HERA should use contracts with single entities over grants or loans. Unlike traditional EU-level contracts, which are very rigid, having flexibility will be crucial to adapt to the industry’s requirements, the type of projects, and their risk level. Since industry may be simultaneously contracting with the BARDA and HERA, both agencies should ensure that there are no exclusion criteria that would impede industry’s ability to pursue different projects simultaneously

12. Is there an optimal stage of product development upon which financial or procurement intervention

could have the highest impact?

*500 character(s) maximum*

Funding at all levels of development starting from pre-clinical, clinical,development and supply of raw materials and components, finish products is critical. Level of investment also depends on the stage of epidemic, the type of intervention/product, and the maturity of the science.

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 | ◉ | ○ | ○ | ○ | ○ | ○ |
| 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*

To stimulate innovation in areas of health security, HERA should have a flexible, collaborative, and agile setup. It will be key to guarantee a new, fit-for-purpose framework together with tools to eliminate overly bureaucratic procedures and guarantee the necessary flexibility and speed for the EU and industry partners to act in times of emergencies. HERA should facilitate networks of partners in manufacturing (see attachment) avoiding direct investments in expensive to maintain plants

## 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*

For HERA to stimulate innovation in areas of health security threats and ensure effective emergency preparedness and response, HERA needs to be responsive and collaborative. This means that the level of administrative burden cannot be excessive. HERA's success will depend on the ability to develop a flexible, collaborative, and agile setup, building on the contributions and needs of existing actors

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

*500 character(s) maximum*

In addition to responding to ongoing pandemics, HERA should also focus on preparedness and continuous investment beyond times of crisis. EFPIA and VE support aligning HERA's focus with the scope outlined in article 2.1. of the European Commission's proposal for serious cross-border health threats regulation. In line with its budget, HERA should focus first on the most pressing cross-border health threats and gradually expand its scope in line with the One Health approach

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*

HERA should support all types of countermeasures to address cross-border health threats, including primary and secondary prevention (including vaccines, testing), diagnostics, and therapeutics in the specific disease areas that are identified as a priority. Such a multi-pronged approach is crucial for guaranteeing adequate pandemic preparedness in Europe

17. What should be the interplay of HERA with other EU Agencies (e.g. European Medicines Agency (https://www.ema.europa.eu/en), European Centre for Disease Control and Prevention (https://www.ecdc.europa.eu/en), European Food Safety Authority (https://www.efsa.europa.eu/en), European Monitoring Centre for Drugs and Drug Addiction (https://www.emcdda.europa.eu/emcdda-home-page_en), European Environment Agency (https://www.eea.europa.eu/), European Chemicals Agency (https://echa.europa.eu/), Europol (https://www.europol.europa.eu/))?

*1,000 character(s) maximum*

To maximise its potential, HERA should have a clearly defined relationship with national and EU agencies (EMA, ECDC), BARDA, CEPI, WHO, CDC and other global actors. This would allow effective coordination and avoid duplicating efforts. Managing these relationships will be key to preparing and responding to cross-border health threats. Roles and responsibilities of each player need to be clarified upfront with transparent, lean and agile processes, communication and arbitration in case of divergent positions

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 (https://ec.europa.eu/health/funding/eu4health_en), Horizon Europe (https://ec.europa.eu/info/horizon-europe_en), European Innovation Council (https://eic.ec.europa.eu/index_en), European Regional Development Fund (https://ec.europa.eu/regional_policy/en/funding/erdf/), Emergency Support Instrument (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en), the European Defence Fund (https://ec.europa.eu/defence-industry-space/index_en); Advanced Purchase Agreements under the EU Vaccines Strategy (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en), Emergency

Response Coordination Centre (https://ec.europa.eu/echo/what/civil-protection/emergency-response-coordination-centre-ercc_en), 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*

Some of the already existing early stage pre-competitive R&D projects should not be the in scope for funding, including Horizon Europe and its health PPPs as well as pre-competitive/consortium projects, which are already adequately covered within the EU environment. Nonetheless, HERA should actively collaborate and monitor early development projects to identify promising candidates that should be supported in later stages of its development through manufacturing and deployment

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*

HERA should become a strong player and contribute to strengthening the global network of agencies in charge of preparedness and response. A collaborative relationship with national agencies across the EEA, BARDA, the UK Vaccination Task Force, and CEPI are important to optimise exchange of knowledge and increase the impact of actions. HERA's relationship with global institutions and initiatives will be critical for the EU to position as a global leader in addressing common health threats

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

## Business and their associations

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

*1,000 character(s) maximum*

EFPIA and VE welcome the creation of HERA and are committed to supporting the European Commission in its next steps to help ensure that HERA will be fully operational and successful. Overall, the success of HERA will depend on several factors which are detailed in the joint EFPIA and VE White Paper attached to this consultation. The paper spells out the directions that we believe the new authority should take in order to be successful. We believe that to ensure HERA's success the following will be key: leadership and political independence, lean processes, capability and skills, partnership with industry, fit-for-purpose instruments for contracting and intellectual property, appropriate level of financing, clarity of scope and integration in the global network of preparedness and response mechanisms.
!! Please note that responses to question 3 relate to the statements in the table, not the main question which is ambiguous.!!

## Other

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

*500 character(s) maximum*

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.

**HERA_White_Paper_EFPIA_and_VE_final.pdf**

## Contact

Contact Form (/eusurvey/runner/contactform/HERAPC2021)