

# 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](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](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](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

Non-governmental organisation (NGO)

\*First name

Linda

\*Surname

Abdelall

\*Email (this won't be published)

linda@europeancancerleagues.org

\*Organisation name

*255 character(s) maximum*

Association of European Cancer Leagues (ECL)

\*Organisation size

Micro (1 to 9 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.

19265592757-25

\*Country of origin

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

Belgium

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association', 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

\*Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

**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.

**Public**

Organisation details and respondent 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. Your name will also be published.

I agree with the personal data protection provisions (<https://ec.europa.eu/info/law/better-regulation/specific-privacy-statement>)

---

## 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<sup>[1]</sup>, 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](https://ec.europa.eu/health/funding/eu4health_en)), Horizon Europe ([https://ec.europa.eu/info/horizon-europe\\_en](https://ec.europa.eu/info/horizon-europe_en)), European Innovation Council ([https://eic.ec.europa.eu/index\\_en](https://eic.ec.europa.eu/index_en)), European Regional Development Fund ([https://ec.europa.eu/regional\\_policy/en/funding/erdf/](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](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](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](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](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](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](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:	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1.2 The EU capability to manufacture (production) medical countermeasures is:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1.3 The EU capability to deploy (distribution) medical countermeasures is:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If relevant, please provide further comments:

*500 character(s) maximum*

The COVID-19 pandemic has shown that the European Institutions, EU Agencies, and national Member States do not have a clear overview of the pharmaceutical supply chain, from production to delivery. More transparency and centralised communication channels, also making use of digital tools, should be enhanced.

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 is a great opportunity to build on the excellent EU research centers and academia sites, to learn the lessons from the ongoing crisis, and ensure that investments address patients' needs and steer public health needs-driven innovation. The development of the European Health Data Space will be critical to ensure that research will not be stopped by the various interpretations of the GDPR. To combat cross-border threats to health, it is important to support the flow of data across EU countries, ensure interoperability of the systems, whilst protecting patients' privacy to avoid any abuse of health data.

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.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sufficient capacities are in place at national level to ensure demand analysis of healthcare delivery ahead of a health emergency.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sufficient capacities are in place at national level to ensure planning of healthcare delivery ahead of a health emergency.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There is a risk of low-quality, non-compliant medical countermeasures entering the EU market.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Real-time, reliable and comparable information/data on global and national shortages of medical countermeasures is available at EU level.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Real-time, reliable and comparable information/data on available supplies (including global value chains and national stocks) is available at EU level.	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Third country trade restrictions on medical countermeasures and/or inputs critical to their development/ production impact Member States.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
EU Member States have unequal access to medical countermeasures.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
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).	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of coordination at EU level of manufacturing capacity for medical countermeasures (leading to under- or overcapacity).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

Do you think the following measures can overcome these challenges?

	Stro ngly disa gree	Di s a gr ee	N e u t r a l	A g r ee	St ro n g l y A g r ee	D o n' t k n o w
Putting in place real-time monitoring of preparedness regarding the demand and supply of critical medical countermeasures in the EU	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Ensuring increased coordination of efforts at EU level (e.g. avoid competition - e.g. research and development and procurement - between Member States).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Joint procurement by central purchasing bodies buying on behalf of other public buyers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strengthening the EU Joint Procurement Agreement ( <a href="https://ec.europa.eu/health/security/preparedness_response_en">https://ec.europa.eu/health/security/preparedness_response_en</a> )	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Creation of a tailored EU procurement instrument for health emergency response and management.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU approach to address the whole life cycle of medical countermeasures capacity building (including tailored research and development, testing, certification, production and delivery logistics).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

If relevant, please provide further comments:

*500 character(s) maximum*

Despite some bottlenecks, joint negotiations with vaccine suppliers turned out to be successful from both an economic and political perspective. The European Commission should explore similar approaches for (cancer) medicines characterised by high prices and limited patient population. Due to the challenging nature of rare and paediatric cancers, an EU approach should be promoted, especially when Member States face similar barriers.

[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:

	Fra gme nted	Sub - Opti mal	Ad eq uat e	G o o d	Ver y Go od	O th er	D o ' t kn o w
<b>Capacity for anticipatory</b> public health threat and risk assessments at EU level (including global threats)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Capacity for modelling and foresight</b> of serious cross-border threats to health at EU level (including global threats)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU instruments for <b>research, innovation and development</b> of medical countermeasures[1]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU instruments for <b>access and deployment</b> of medical countermeasures[2]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If relevant, please provide further comments

*500 character(s) maximum*

The pharmaceutical supply chain needs to be strengthened as the pandemic demonstrated. The objective should be to establish an open strategic autonomy to avoid protectionist measures and unfair competition. The EU should be capable of guaranteeing protection to its citizens and patients by fostering prevention plans against medicine shortages, enhancing transparency, communication channels, and foreseeing a system of obligations and sanctions for the pharmaceutical industry.

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	D o ' t kn o w
--	--	--	---	----------------------------------

6.1 EU capacity for <b>anticipatory public health threat and risk assessments</b> at EU level and including global threats:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
6.2 EU capacity for <b>modelling and foresight</b> of serious cross-border threats to health at EU level and including global threats:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
6.3 EU instruments for <b>research, innovation and development</b> [3] of medical countermeasures:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
6.4 EU instruments for <b>access and deployment</b> [4] of medical countermeasures:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

If relevant, please provide further comments

*500 character(s) maximum*

The provision and shortage of medicines and health technologies are not a cross-border health threat but a cross-border threat to health given the global dimension of the pharmaceutical markets. The current innovation and research landscape in Europe is quite fragmented. HERA offers the opportunity to guarantee better oversight and accountability, enhance coordination and increase efficiencies, monitor implementation and review performance.

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





EU level knowledge on national public sector investment into research and development of medical countermeasures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
EU level knowledge on private sector investment into research and development of medical countermeasures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

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?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

If relevant, please provide further comments

*500 character(s) maximum*

Transparency on the supply chain for health technologies should be fostered to promptly identify bottlenecks. Also, diversification of the supply chain could tackle shortages and reduce the dependency on a few providers. The EU should continue the process towards an EU Health Union by preventing, monitoring, and tackling medicine shortage as a single market. Impact assessments should precede any incentives or flexibilities granted to manufacturers.

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*

Strategic autonomy encompasses repurposing and the off-label use of medicines. This needs to be monitored with digital tools to ensure that, in case of an unexpected increase of demands for specific medicines and medical devices, patients treated with on-label medicines have their treatment guaranteed. Strategic autonomy is as important as supply diversification to guarantee the continuity of patients' treatment.

## 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.

	V e r y U n d e s i r a b l e	U n d e s i r a b l e	N e u t r a l	D e s i r a b l e	V e r y D e s i r a b l e	D o n' t 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?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

If relevant, please provide further comments

*500 character(s) maximum*

Upfront investment should be linked to specific milestones, target goals, conditions attached to end products (affordability, availability provisions, socially responsible licensing etc.) , clear oversight and governance structures that hold industries that benefit from public support accountable.

11.

	Public- private partnerships	Dire ct contr acts	Disburs ement scheme s	F e e s	Combined EU and national financing
What kind of tailored financial instruments would be needed in your view to facilitate upfront EU investment?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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?**

	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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pre-arranged emergency contract network for EU surge manufacturing capacities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Maintaining flexible and "ready to use" EU manufacturing capacities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Streamlined EU level initiatives relating to medical countermeasures under a 'one-stop shop'	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

If relevant, please provide further comments

*500 character(s) maximum*

The EU Health Union should be foreseen both in case of emergency and during "normal" times. Hence, the EU should intervene whenever its citizens and patients are treated differently based on the country they live. Large inequalities in access, availability, and affordability of medicines may be tackled with the revision of key articles of the TFEU. The EU needs to use its leverage to set the rules of engaging with private actors and drive innovation where needed the most.

## 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Economic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Social	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Environmental	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer protection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Administrative burden	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide further explanations:

*500 character(s) maximum*

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

*500 character(s) maximum*

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*

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](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*

HERA may play a major role in the research, development, manufacturing, and deployment of medical countermeasures in case of cross-border health threats. Its mandate for these purposes should be strongly intertwined with the role played by ECDC and EMA. It is important to avoid confusion and bottlenecks in particular in situations when smooth functioning of the EU is much needed, namely public health emergencies. The EMA should continue to be the EU Agency responsible for the management of the entire pharmaceutical supply chain in Europe. The EMA should maintain the leading role of preventing, monitoring, and tackling medicine shortages liaising with the national competent authorities and stakeholders. ECL calls for a new Agency that can mirror the US BARDA and its activities in medical countermeasures without diminishing the well-established Agencies.

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](https://ec.europa.eu/health/funding/eu4health_en)), Horizon Europe ([https://ec.europa.eu/info/horizon-europe\\_en](https://ec.europa.eu/info/horizon-europe_en)), European Innovation Council ([https://eic.ec.europa.eu/index\\_en](https://eic.ec.europa.eu/index_en)), European Regional Development Fund ([https://ec.europa.eu/regional\\_policy/en/funding/erdf/](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](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](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](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](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](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:

	Str on gly dis ag ree	D is a g r e e	N e u t r a l	A g r e e	S t r o n g l y a g r e e	D o n' t k n o w
Coordinated like they are now, ensuring synergies with HERA when created	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coordinated by HERA when created in close collaboration with the European Commission, Member States and other relevant agencies	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If relevant, please provide further comments:

*500 character(s) maximum*

HERA needs to be independent, sustainable, and protected from political pressure and evolving political priorities. It should ensure that discoveries made with the support of EU funds will be translated into large-scale industrial development across the EU. Its governance structure should be transparent, accountable, and balanced, including patient, public health organisations, and representatives of the research community.

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 has to be in close contact and coordinate (where necessary) actions with international bodies/agencies mentioned above. It can mirror the US BARDA but it can also take stock of its weaknesses: HERA should be more transparent and accountable than BARDA. A skilled workforce, experts in industrial processes, will be essential.

[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?

*1,000 character(s) maximum*

---

## 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.

## Contact

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

---