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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 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

- ○ Bulgarian
- ○ Croatian
- ○ Czech
- ○ Danish
- ○ Dutch
- ◉ English
- ○ Estonian
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- ○ Academic/research institution
- ○ Business association
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- ○ Consumer organisation
- ○ EU citizen
- ○ Environmental organisation
- ○ Non-EU citizen
- ◉ Non-governmental organisation (NGO)
- ○ Public authority

- Trade union
- Other

* First name

Catherine

* Surname

Hartmann

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c.hartmann@europeanbloodalliance.eu

* Organisation name

255 character(s) maximum

European Blood Alliance (EBA)

* Organisation size

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

Transparency register number

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Check if your organisation is on the transparency register. 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.

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- Åland Islands
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- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines

- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
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- French Southern and Antarctic Lands
- Gabon
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- Germany
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- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- 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
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
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- Chad
- Chile
- China
- Christmas Island
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
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- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom

- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
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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, 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 current pandemic has clearly shown serious deficiencies with the current arrangements. Things have improved however they need to be permanent and clearly communicated with all EU Member States (MS).

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

We favor the creation of the stand alone authority (HERA). The EBA reasserts the importance of individual EU MS maintaining the right (legislation) to act at a regional, and national level to respond to such crisis on an individual basis if necessary. Contingency planning and crisis preparedness is already successfully performed by many EU MS. The scope, role and responsibilities of HERA should be well defined especially when it comes to its interaction with other EU agencies for example the ECDC and EMA. HERA should have the legitimacy, financial capacity and know how to ensure the EU is self sufficient in matters of swift development, manufacturing, procurement of key medical countermeasures such as PPE, medical devices and in vitro diagnostic medical devices (including tests and testing materials), available therapies, vaccines and essential medicines and ensure their equitable distribution across the EU. It is not only a matter of procurement. Digital solutions are key.

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

The EBA believes that a better coordinated EU plan led by HERA will undoubtedly enable the EU to be much better prepared and positioned to deal with other unplanned emergencies such as another pandemic but it is only one of many other actions required. In parallel Individual MS must also take the necessary steps to improve their own country's preparedness and ability to respond to such crisis.

[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

These are very difficult questions to answer on a European basis as who has access to each member's current status / capabilities in all of the above areas under investigation? Many of the EBA answers are based on recent observed evidence on how individual member states have re-acted to the pandemic and observation of other none EU Countries such as the UK, USA , Russia, India etc

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

It is clear to the EBA that a significant amount of work, investment and development is required by the EU (and each individual MS) to improve in all of these critical areas. HERA should re-enforce the EU level of co-operation and support mechanisms for the engagement of authorities and professionals. The lessons learned from the COVID pandemic should provide insight into the specific areas that need to be strengthened

[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

Stockpiling of medical products and PPE, the development of joint public procurement and research and innovation policies must be a high priority to ensure our preparedness for future pandemics. However, *smart* stockpiling is key as there are complexities of stockpiling specialist products involving: different quality standards / specifications, expiry dates, first in first out, product recall, narrowing – interfering with the free market. Complicated logistical requirements must be identified

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

The EBA believes that strategic autonomy is a key factor in dealing with future crisis such as a pandemic. The EU must learn and act on what has happened during this Covid -19 pandemic however all Member States must also review and improve their own preparedness and resilience. Both steps combined will allow the EU and MS to be in a much stronger place re. preparedness and the ability to react better in the future.

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

By positioning itself with a global perspective, the EU will ensure that crisis that start in another part of the World may be addressed through EU preparedness and its agility to help eradicate whatever problem occurs before it might become a global issue. This is turn will help the EU reduce the risk that the crisis may spill over into its Member States.

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

Combined EU and national financing will ensure the EU will start sooner to address the inadequacies of the current situation. Actions are needed immediately. Obviously other financial instruments should be included (in particular Public / Private partnerships) but theses types of partnerships take time and are prone to last minute complications hence further delays. EU and national commitment means that actions will be taken faster especially if legislation accompanies decisions & commitments

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

500 character(s) maximum

The EBA feels that the financial commitment should be given at as early a stage as possible, perhaps rewarded in predefined stages of development and testing. Without a 'seed' capital approach delays and financial restraints will stifle new product development unnecessarily

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

The EBA believes that a one stop shop approach is not the right step to take in this particular development. The EBA believes that individual Member States must also look at and develop their own individual solutions to all of these identified challenges. There must be however an overall holistic overview of all of these developments and it is HERA working with the other identified agencies which must co-ordinate this.

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

By taking this pro-active approach and establishing and appropriately resourcing HERA , the EU can only improve all of the above headings. Preventative actions can help both negate the risk of another pandemic occurring but perhaps more importantly reduce the potential devastating effects it could have. The economic impact of a pandemic has now been clearly witnessed and taking action now can reduce such a catastrophic occurrence from hopefully happening again.

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

500 character(s) maximum

HERA should have access to, or develop a risk assessment tool which would prioritise which health threats to begin with and which areas to focus on initially. There are many common areas of action that can be taken to respond to each of them should they occur and it is that foundation ‘core base’ of response that should be prioritorised and put in place quickly and decisively. The specific details of each individual health threat can then be reviewed with a specific "specialist" plan

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

Prioritization of medical countermeasures should rely on careful and repeated risk assessments for shortage and criticality of shortage

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 scope, role and tasks of HERA should be well defined, especially when it comes to its interaction with other EU agencies e.g. ECDC and EMA and national agencies of EU countries. The interplay needs to be highly visible and non competing. Open and frequent communication is key to these developments happening quickly and successfully.The mission definition is a key priority for HERA. The vision and values will greatly help on how HERA will co-ordinate with other EU organisations and countries.

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

The EBA believes that HERA's authority and relationship with other bodies both internally within the EU and globally, is critical for HERA to be truly effective as the EU wants it to be. Clarification of roles and responsibilities must be clear and unambiguous. Their legal status must be clearly defined to allow them to play their role.

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 would be the main body meeting with all of the bodies and entities mentioned above representing the EU's position on all relevant issues. The EBA believes that individual EU Member States still have their own National right to meet and discuss these bodies individually if they so wish. Communication though between Member States and HERA is an absolute given and transparency is key.

[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

EU Blood Establishments' representatives must be part of contingency planning discussions and decisions taken at national level, to include their role and services in the plan. Likewise, their EU representations, through Competent Authorities and associations such as EBA, must be key stakeholders in the HERA. Cooperation would be based on having a seat in the governance structure of HERA so that EU and national authorities dealing with blood are systematically involved and the potential impact on blood and blood components provisions of measures put in place assessed - so as to maintain a safe and adequate level of supply of blood and blood components, for transfusion and medicines including in times of crisis

Other

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

500 character(s) maximum

The transfusion act is likely the most frequent therapeutic option in both private and public hospitals; blood establishments, by making transfusions possible hold a critical and unique position in the EU healthcare systems, providing a public service, even through times of crisis. Preparedness is essential to ensure continuity of service.
Transfusion and transplantation activities are performed throughout the EU allowing the gift of life for an increasing number of patients

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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