

# European Health Emergency Preparedness and Response Authority Public Consultation

Fields marked with \* are mandatory.

## Introduction

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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

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\* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

\* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority

- Trade union
- Other

\* First name

Giovanni

\* Surname

Dalle Nogare

\* Email (this won't be published)

g.dallenogare@medtecheurope.org

\* Organisation name

*255 character(s) maximum*

MedTech Europe

\* Organisation size

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

Transparency register number

*255 character(s) maximum*

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

433743725252-26

\* Country of origin

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

- |                                     |  |                                     |  |
|-------------------------------------|--|-------------------------------------|--|
| <input type="radio"/> Afghanistan   | <input type="radio"/> Djibouti           | <input type="radio"/> Libya         | <input type="radio"/> Saint Martin                     |
| <input type="radio"/> Åland Islands | <input type="radio"/> Dominica           | <input type="radio"/> Liechtenstein | <input type="radio"/> Saint Pierre and Miquelon        |
| <input type="radio"/> Albania       | <input type="radio"/> Dominican Republic | <input type="radio"/> Lithuania     | <input type="radio"/> Saint Vincent and the Grenadines |

- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Samoa
- 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
- Central African Republic
- 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
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- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- 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
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

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.

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## EU framework to develop, manufacture and deploy medical countermeasures

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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 ( E M A ) .

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:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
1.2 The EU capability to manufacture (production) medical countermeasures is:	<input type="radio"/>	<input type="radio"/>	<input checked="" 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 EU response to the COVID-19 pandemic has been disrupted by national requisition orders and the shutting down of internal borders. The EU has been the only trading block in the world which has failed to put in place emergency approvals for medical technologies. This has disrupted an EU wide response. EU wide procurement instruments have been hampered by a failure to assess demand and an unpredictable procurement process. E.g in a JPA 10,000 ventilators requested, 50 procured.

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*

As experience with US-BARDA, HERA will bring an additional leverage to develop medical countermeasures that are almost market ready, which is not feasible with programmes like Horizon Europe. Taking inspiration from the US BARDA, the inclusion of the industry and civil society makes the work of the agency more relevant and efficient. One way of doing this would be to include industry representatives as part of an advisory committee to the Agency which can play a crucial role in reducing fragmentation and better coordination of measures.

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

Real-time, reliable and comparable information/data on global and national shortages of medical countermeasures is available at EU level.	<input checked="" type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input 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 checked="" type="radio"/>	<input 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 type="radio"/>	<input checked="" 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?

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree	Don't know
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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 checked="" type="radio"/>	<input 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 <a href="#">EU Joint Procurement Agreement</a>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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*

Procurement showed itself to be key in an effective response to a public health emergency. Centralisation will not solve all issues. What is needed is:

- Clear assessment of demand
- Commitment by both suppliers and purchasers to use centralised procurement.
- Transparency in tendering process – in particular use of the EU TED platform.
- Including procurement options for additional purchases over time or stockpiling.
- Ensuring the technologies available meet the different demands acr

[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

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

If relevant, please provide further comments

500 character(s) maximum

Current risk assessment focuses on information useful in a public health response. There is a dearth of information to ensure that production and supply of medical countermeasures is available – of all the metrics by the ECDC modelling the pandemic use of ICU capacity which correlates well with the medical technologies used in an ICU setting has been the most useful. An equivalent metric is needed to provide forecasting for the demand, in particular diagnostic systems and protective equipment.

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 <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

EU instruments for research, innovation and development of medical countermeasures should have the right to bypass the usual rules for topic selection, project evaluation and project selection which are time and resource consuming, generally lengthy and not fit-for-purpose. HERA could also keep the capacity to support individual companies if necessary, instead of the usual requirement of a minimum of three partners. HERA should complement collaboration between the authorities.

[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

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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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU level knowledge of exports of medical countermeasures from EU Member States to third countries	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU level knowledge of suppliers and supply chain of medical countermeasures into EU Member States	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU level knowledge of supply deliveries of medical countermeasures into EU Member States	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Market intelligence to anticipate possible interruptions in the demand and supply of medical countermeasure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
EU level knowledge on logistical distribution of medical countermeasures to Member States	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU level knowledge on manufacturing capacities within the EU for medical countermeasures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU level knowledge on identification and support to repurposing/reconversion activities of manufacturing capacities for medical countermeasures within the EU	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sustainability of EU supply chains of medical countermeasures and flexible supply of key inputs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU level knowledge on supply dependency from third country	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
stockpiling capacity (e.g. virtual or physical or otherwise) at EU level	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Market intelligence for new countermeasures or innovative technologies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

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

If relevant, please provide further comments

*500 character(s) maximum*

Actions should be sustainable – supply cannot be increased without demand unless there is a long-term financial commitment ensuring excess supply which may not be sustainable long term.  
 Increasing demand, results in increasing supply of the finished medical countermeasures and of key components of the supply chain will be a successful approach.  
 Demand can be increased by stockpiling medical countermeasures or developing new uses for them or their components leading to resilience.

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*

Market forces have consolidated the manufacturing of key medical countermeasures in global hubs. This has been driven by market efficiencies. Strategic autonomy in the EU for key medical countermeasures will require taking action to counteract the efficiencies of global manufacturing hubs – though this is possible on a small scale, attempting to do so on a large scale (either in volume or over time) is more challenging than the alternative – to build up a globally resilient supply chain.

## Development and financing of new countermeasures in times of crisis

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

If relevant, please provide further comments

*500 character(s) maximum*

EU intervention could be beneficial for the following:

- Keep borders open to allow supply chain to function any time and to stay diversified
- Logistic support (ensuring capacity, financial support for freight)
- Stockpiling is essential to ensure that workers and especially healthcare workers are protected. Resilient and efficient stockpiling at EU level should include rotation of stock and inventory management to guarantee turnover and prevent products deterioration.

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

If relevant, please provide further comments

*500 character(s) maximum*

The COVID crisis has demonstrated the EU capacity to react fast in developing countermeasures with its Public Private Partnership.

HERA should also:

- award contracts with a competitive application process, awarding contracts to single entities, over consortia, for better accountability and faster execution;
- provide financial incentives to companies: eg when conducting clinical trials;
- complement funding for research & development, especially later-stage, in times of health crisis

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 experience of US BARDA shows that the optimal stage is the beginning of product development and very precise up-front specifications to ensure that the product produced meets the needs, for example for a stockpile. Only after the build and release process will the Strategic National Stockpile step in and discuss procurement.

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

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

### If relevant, please provide further comments

*500 character(s) maximum*

The following is needed:

- Keeping internal and external borders open and providing efficient support to the transportation of medical technologies – including the components and materials needed to manufacture those technologies – into and within the EU territory,
- Securing the ongoing openness of global supply chains, and
- Coordinating the various procurement actions to anticipate actual demand and better adapt supply chain, production, and logistics requirements

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

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

Please provide further explanations:

*500 character(s) maximum*

- Clear roles and responsibilities between agencies and levels to avoid overlap and unpredictability, esp. in normal times vs in crisis mode;
- Good knowledge and insight into the scientific and technical requirements;
- Transparency and true industry involvement in creation of measures, plans, roles to ensure feasibility and effectiveness of roles, responsibilities and measures.

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

*500 character(s) maximum*

Health threats of microbial origin with an increasing anti-microbial resistance may generate biological crossborder health threats. HERA should focus on areas where the EU provides added value to all Member States to existing and emerging risks: The threat of AMR is growing and surpasses EU States individual capacity. Focus on AMR mitigation, prevention and best cases is therefore highly recommended. Infectious diseases public health policies, research and capacity building should be prioritised

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 has to be designed to cover all potential risk situations, not just a COVID-like health crisis. Two areas of focus can be considered:

- the key first line of defense is early detection and deployment of diagnostics targeting the emerging threat;
- personal protective equipment (PPE) are essential countermeasures to health threats: PPE availability, accessibility, affordability and effectiveness should be ensured

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 following interplay should be considered:

- overlap and duplication of work should be avoided;
- transparency and predictability of processes and responsibilities must be ensured for those who need to interact with the system, include feedback loops;

- tasks and responsibilities and shifts of those in non-crisis time and crisis time must be clearly defined;
- HERA shall be involved in EU and national actions in identifying suspicious certificates for MD and PPE and protect the value of CE marking. To be safe, it is important MD and PPE are correctly tested and certified.

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

If relevant, please provide further comments:

*500 character(s) maximum*

Real coordination between EC programmes and/or agencies is critical to prevent duplication or holes in the EC action towards preparedness and reaction to health threats. The specificities of the interventions of each EC agency and/or programme should be explicit to prevent loss of time especially in health crisis times



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*

Unlike the US, the EU lacks institutional public health laboratory capacity at the ECDC. For (re)emerging viral diseases, the ECDC supports a network of laboratories; the EVD-LabNet is a European Network of Expert Laboratories supporting ECDC for early detection and surveillance of (re)emerging viral diseases in the EU/EEA, and for providing scientific advice. This network lacks the capacity to develop and rapidly deploy diagnostics if there is emergence of a new pandemic threat.

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

## Business and their associations

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

*1000 character(s) maximum*

As the industry association representing the medical technology industry MTE is uniquely placed to cooperate with HERA to prepare for and react to public health emergencies. Cooperation during the preparation for an emergency can include dialogue in preparatory activities where MTE acts as a liaison between the Medtech industry and HERA, mobilizing experts from relevant sectors to ensure that from both a strategic and operational perspective preparations for future emergencies are optimal. During an actual public health emergency much more frequent contact would be needed – during this crisis weekly calls have been setup between MTE and the clearing house on medical devices to help address shortages, bottlenecks and other supply issues. A similar continuous engagement would be a minimum to ensure supply of critical technologies and rapid resolution of emerging problems. At MTE we remain committed to supporting initiatives to better prepare and react to any public health crisis.

## Other

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

If so, please specify:

*500 character(s) maximum*

Compiling timely and reliable data is crucial to prepare for and to manage health crises. It is therefore of utmost importance to scale up cross-border exchange of health data. HERA should benefit from the future European Health Data Space to further contribute to unlocking the potential of data for the benefit of the EU and its people. HERA should also leverage initiatives such as GAIA-X, which is the leading example of a federated, open data infrastructure based on European values.

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

## **Contact**

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