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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 (https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041) of November 2020. It aims to equip the Union with a new Authority, similar to the US BARDA, which addresses all future serious cross-border threats to health. The new Authority, which will be called the “European Health Emergency Preparedness and Response Authority” (HERA), will take into account the EU institutional setting and provide for a coordinated approach to health preparedness for the full array of serious cross-border threats to health that takes into account competences of the Member States in this area. HERA will complement and create synergies with the work of existing national and EU Agencies, in particular the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). Further background information (https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_1655%20&https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0724&from=EN&https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Response-Authority) on the creation of the legislative proposal for HERA may be found in the hyperlinks.

Please note that this consultation relates specifically to the European Health Emergency Preparedness and Response Authority. The Commission Communication ‘Hera Incubator: Anticipating together the threat of COVID-19 variants’ (https://ec.europa.eu/info/sites/info/files/communication-hera-incubator-anticipating-threat-covid-19-variants_en.pdf) of February 2021 is not a legislative proposal. Therefore, this consultation does not serve to provide feedback on the work being undertaken by the Commission on mitigating, preventing and preparing for COVID-19 variants described in that Communication.

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

About you

Language of my contribution

English

I am giving my contribution as

Non-governmental organisation (NGO)

First name

Paul

Surname

DE RAEVE

Email (this won't be published)

efn@efn.be

Organisation name

255 character(s) maximum

European Federation of Nurses Associations (EFN)

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.

87872442953-08

Country of origin

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

Belgium

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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

Medical countermeasures refer to medicines, medical devices and other goods or services that are aimed at combating serious cross-border threats to health[1], a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin, which spreads or entails a significant risk of spreading across countries. These medical countermeasures may necessitate coordination at Union level in order to ensure a high level of human health protection. Examples consist of infectious diseases such as COVID-19, a pandemic influenza, or other events caused by biological or unknown agents, accidents caused by chemical agents, natural events of environmental origin or deliberate acts.

The EU framework for cross-border threats to health is based on Decision 1082/2013/EU, which sets out how the EU coordinates preparedness and response to serious cross-border threats to health. In light of COVID-19, the Commission put forward a proposal to revise this framework and proposed a Regulation for serious cross border threats to health, as well as reinforcements to the mandates of the key EU Agencies: The European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

In addition to Decision 1082/2013/EU, under which the Early Warning and Response System, the Health Security Committee and the Joint Procurement Agreement is established, the Commission has additional instruments that are active in the area of development, manufacturing and deployment of medical

countermeasures.

These will be mentioned in below, but comprise for example: EU4Health (https://ec.europa.eu/health/funding/eu4health_en), Horizon Europe (https://ec.europa.eu/info/horizon-europe_en), European Innovation Council (https://eic.ec.europa.eu/index_en), European Regional Development Fund (https://ec.europa.eu/regional_policy/en/funding/erdf/), Emergency Support Instrument (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en), the European Defence Fund (https://ec.europa.eu/defence-industry-space/index_en); Advanced Purchase Agreements under the EU Vaccines Strategy (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en), Emergency Response Coordination Centre (https://ec.europa.eu/echo/what/civil-protection/emergency-response-coordination-centre-ercc_en), Innovation Partnership, and external action support under EU programmes supporting our partners across the world (https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1267).

[1] Decision 1082/2013/EU on serious cross-border threats to health

1. What is your view on the existing EU capability to develop, manufacture and deploy medical countermeasures (e.g. vaccines, antitoxins, antibiotics, chemical antidotes, antiviral drugs, personal protective equipment, medical devices, etc.) aimed at combating serious cross-border threats to health?

	Fragm ented	Sub- optimal	Adeq uate	Go od	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 checked="" type="radio"/>	<input 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 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

Based on COVID-19 lessons learned, the EU capability to develop, manufacture and deploy medical countermeasures have been overall fragmented and sub-optimal in all Health Security domains. Multi-country research, production and distribution of protective equipment, medical devices or vaccines have shown very challenging to organise at the EU level with only few initiatives of coalition of states succeeding. Huge gaps in European health workforce such as nurses is of extremely high concern.

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

EFN considers that the Policy Option 3 would be the best to improve EU capacities. To combat serious cross-border threats to health, HERA plan relies a lot on technological & commercial solutions but does not cover workforce development. WHO Benchmarks for International Health Regulations Capacities lists "human resources" as one of its 18 technical areas and "required human resources" are presented as a key component to achieve the highest capacity level of preparedness in many technical areas. Tackling the issue of human resources is key in the creation of HERA. EFN recommends that the EC consider the addition of legally binding standards of number of healthcare professionals per habitants/patients & the establishment of a highly educated & trained public health workforce at local level, according to the relevant EU policy mechanisms. When crisis emerges, ALL EU MS lack nurses to support other MS (see North Italy difficulty with COVID-19 - impossible to send nurses from other MS).

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 type="radio"/>	<input type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" 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 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 available supplies (including global value chains and national stocks) is available at EU level.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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 checked="" type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input 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 type="radio"/>	<input checked="" 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
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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Strengthening the EU Joint Procurement Agreement (https://ec.europa.eu/health/security/preparedness_response_en)	<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 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
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If relevant, please provide further comments:

500 character(s) maximum

EFN thinks the measures can overcome these challenges provided the healthcare system is strengthened to ensure the measures can impact the frontline level. In the problem definition, nothing is said on vulnerabilities about healthcare and public health workforce. Increasing the coordination and improving the logistics without having enough professionals to face the problem on the ground is likely to have a limited impact on serious cross-border threats to health.

[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:

	Frag ment ed	Sub- Optim al	Ade quat e	Go od	Very Goo d	Ot her	Don't know
Capacity for anticipatory public health threat and risk assessments at EU level (including global threats)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>				

Capacity for modelling and foresight of serious cross-border threats to health at EU level (including global threats)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU instruments for research, innovation and development of medical countermeasures[1]	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>				
EU instruments for access and deployment of medical countermeasures[2]	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>				

If relevant, please provide further comments

500 character(s) maximum

COVID-19 crises impact on the EU shows that none of these capacities/instruments can be rated as adequate. The coordinated approach of COVID-19 vaccine production & supply has demonstrated that EU can implement effective instruments that must be institutionalised. Again, the improvement of these capacities & instruments would be highly potentialised by ambitious EU actions to improve the availability of sufficient & well-educated and trained nursing workforce to face health emergencies.

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:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
6.2 EU capacity for modelling and foresight 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 research, innovation and development [3] of medical countermeasures:	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
6.4 EU instruments for access and deployment [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

EFN recommends that the European Commission consider the addition of legally binding standards of number of healthcare professionals per habitants or patients and the establishment of a highly educated and trained public health workforce (Directive 2013/55/EU) at local level (doing prevention in normal time and doing public health emergency management when needed), according to the relevant European policy mechanisms such as the European Council and Parliament.

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

[2] e.g. Joint Procurements, Advanced Purchase Agreements under the EU Vaccines Strategy (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), Emergency Support Instrument the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en) and Emergency Response Coordination Centre, Innovation Partnership, external action support under EU programmes supporting our partners across the world

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

[4] e.g. Joint Procurements, Advanced Purchase Agreements under the EU Vaccines Strategy (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), Emergency Support Instrument the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en) and Emergency Response Coordination Centre, Innovation Partnership, external action support under EU programmes supporting our partners across the world

Market dynamics and supply chain intelligence

The market (e.g. demand and supply) of medical countermeasures is constantly evolving and faces a variety of changing challenges. As such, knowledge and awareness of novel technologies, as well as pressures that can affect demand and supply - that can impact the availability of medical countermeasures - is important to monitor. Such pressures include, for example, incentives of key stakeholders (such as investors, industry and innovators), return on investment, uncertainty of demand, and impacts of future risks and needs. The supply chains of medical countermeasures extends to overall awareness of the supply into the EU and countries of specific medical countermeasures, as well as manufacturing capacities within the EU (including reconversion/repurposing possibilities) and the EU's position in global supply chains for critical raw materials needed to produce the final product.

7. To what extent is there a need for EU level action to strengthen the following elements for ensuring sufficient demand and supply of medical countermeasures in the EU?

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree	Don't know
Real-time analysis at EU level of the demand for medical countermeasures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" 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 type="radio"/>	<input type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
EU level knowledge on supply dependency from third country	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" 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 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

Medical countermeasures aimed at combating serious cross-border threats to health, including global threats, can save many lives so can be considered as a public good. Therefore, the market is prone to fail in their effective production and supply. If the regulation happens at country level, EU countries could be very likely to compete, the medical countermeasures resulting in being inequitably allocated. Intervention of the EU in this domain is key for solidarity and equity against crises.

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

In line with the previous comment, strategic autonomy in medical countermeasures to respond to health emergencies considering actions at regional or national level is likely to result in inequitable allocation, people in poorer regions or nations being disadvantaged. Only strategic autonomy at EU level can allocate countermeasures adequately and equitably and would allow to negotiate effectively the cooperation with other world powers.

Development and financing of new countermeasures in times of crisis

Upfront investment and parallel development processes pertain 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

"We are not prepared, unless we are all prepared!" - Dr Paul De Raeve (EFN Report on Ebola and COVID-19 - June 2019 - <https://anyflip.com/eumpx/ounw/>)

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

If relevant, please provide further comments

500 character(s) maximum

It could also be through Direct contracts. Because some key medical countermeasures might not create enough private profit, the private sector is likely to fail to invest in them. Therefore, the use of public procurement is necessary to ensure the highest level of health emergency preparedness at EU level and protect its citizens.

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 optimal stage of product development upon which financial or procurement intervention could have the highest impact is research and development of medical countermeasures based on anticipatory public health threat and risk assessments. Other relevant stages are the production of contingency stocks of these medical countermeasures and the preparedness of industries to scale-up rapidly when health emergencies occur.

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

If relevant, please provide further comments

500 character(s) maximum

Medical countermeasures aimed at combating serious cross-border threats to health, including global threats, can save many lives so can be considered as a public good. Therefore, the EU should ensure the highest level of control possible on their production and supply so that they are allocated timely and equitably.

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 type="radio"/>	<input checked="" 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 type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
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Please provide further explanations:

500 character(s) maximum

This would be optimal if the Policy Option 3 is chosen. The health, economic and social impacts would be highly potentialized by ambitious actions of the EU to improve the availability of sufficient and well-educated and trained nursing workforce to face health emergencies in addition to these coordinated market interventions.

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

500 character(s) maximum

Environmental threats and pandemic risk. The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services has demonstrated that man-made global ecological disruption is one of the main causes of the COVID-19. As we are failing to mitigate the biodiversity collapse and climate, the environmental threat, including emergence of new pathogens, is getting disproportionately bigger than any other ones.

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

This prioritisation should be based on the results of the risk assessments and research on the best solutions rather than the opinion of the public.

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

1,000 character(s) maximum

HERA could be the coordinating authority during crises (model of Health Emergency Operation Centre, might host or overlap with the Emergency Response Coordination Centre), deciding all strategic emergency actions to be implemented by the other EU agencies. In normal time, HERA could have the authority to enforce necessary preparedness measures concerning the different agencies, e.g. ask for regular risk assessment and modelling and needs monitoring (ECDC, EFSA, EEA, ECA) and coordinate the development of preparedness plans (EMA for emergency protocols, Europol for measures linking public health and security authorities). EFN is interested to contribute to HERA's impact assessment where these interplays could be analysed and different scenarios proposed.

18. What should be the interaction of HERA with other EU instruments contributing to the development, manufacturing and deployment of medical countermeasures (e.g. EU4Health (https://ec.europa.eu/health/funding/eu4health_en), Horizon Europe (https://ec.europa.eu/info/horizon-europe_en), European Innovation Council (https://eic.ec.europa.eu/index_en), European Regional Development Fund (https://ec.europa.eu/regional_policy/en/funding/erdf/), Emergency Support Instrument (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en), the European Defence Fund (https://ec.europa.eu/defence-industry-space/index_en); Advanced Purchase Agreements under the EU Vaccines Strategy (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en), the Union Civil Protection Mechanism and its rescEU (https://ec.europa.eu/echo/what/civil-protection/resceu_en), Emergency Response Coordination Centre (https://ec.europa.eu/echo/what/civil-protection/emergency-response-coordination-centre-ercc_en), Innovation Partnership, and external action support under EU programmes supporting our partners across the world.)? Should they be:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
Coordinated like they are now, ensuring synergies with HERA when created	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input 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 type="radio"/>	<input checked="" 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 type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

If relevant, please provide further comments:

500 character(s) maximum

The number 1 problem the HERA initiative aims to tackle is the fragmentation of efforts in the EU. The European Commission must take advantage of the opening of the COVID-19 recovery window of opportunity to reform extensively the existed fragmented system that have failed to deliver a coordinated response in the EU. A single body to ensure a multisectoral and integrated action is the only way forward. When problems are global, the mechanism to solve them should be too.

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 could represent the EU in terms of health emergency preparedness and response in the interactions with the World Health Emergency Program of the World Health Organization and the Global Preparedness Monitoring Board. HERA could coordinate the intercontinental measures with agencies such as the US or the African CDC.

[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

As a European NGO, EFN would like to be integrated as an advisory member of the board management of HERA to represent the views and interests of European nurses in the policy orientation and decision. EFN could advise on and facilitate any action related to the education and training of nurses in health emergency preparedness. During crises, EFN could disseminate emergency decisions to its members and ensure their feedback is considered in decisions.

Regarding next steps of the HERA's inception impact assessment, the impact assessment should cover the component of nursing workforce and number HCP per country and sub-geographical areas (ILO is reviewing the categories). EFN recommends that the views of frontline nurses (Directive 2013/55/EU) on HERA options are collected as part of the impact assessment. EFN would also like to be part of study steering (cf. Evidence base and data collection in HERA's inception impact assessment) as an advisory stakeholder.

Other

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

If so, please specify:

500 character(s) maximum

As mentioned earlier, the increase of the quantity and quality of nursing workforce for better preparedness to health security threats is a key missing angle of HERA's inception impact assessment. This is also the case for funding of training and organisation of regular simulation exercises at all EU levels and involving healthcare professionals. EFN would like to understand why this point is not covered and how the European Commission is planning to address it if not in HERA.

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.

**EFN_Policy_Statement_on_Consequences_Nurses__Shortages_in_Public_Health_-
_Final_Nov_2020.pdf**

Lessons_learned_from_Ebola___COVID19_-_June_2020-compressed.pdf

Contact

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