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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN
ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE
REGIONS**

**Introducing HERA, the European Health Emergency preparedness and Response
Authority, the next step towards completing the European Health Union**

1. INTRODUCTION

Over the last decade, the world has experienced some of the most devastating outbreaks of infectious diseases ever, including Influenza, Ebola and the Zika epidemics. Global population growth, climate change and the consequential pressure on land use, food production and animal health are driving the rise and increasing the frequency of emerging pathogens. Modern travel allows viruses and other pathogens to spread across the world in a matter of hours. These factors made a major health crisis almost inevitable. Nonetheless, nations across the globe were under-prepared for a pandemic when COVID-19 struck and brought the world to a near halt in 2020.

Over the course of the COVID-19 crisis, significant lessons have been learnt. The COVID-19 pandemic showed the wide variety of policies and programmes which have to be harnessed for an effective response. It showed that by acting together, we are stronger in the face of crisis, working together to access the supplies needed for the health response, and above all to scale up and procure vaccines. It showed how this cooperation is still more potent when working on an international scale. And it showed that every minute counts: for all the energy and determination of the EU response, the need to build crisis response from scratch inevitably came with a human and economic cost.

COVID-19 will not be the world's last public health emergency, Europe needs to be better prepared to anticipate and address jointly the ongoing and increasing risks, not only of pandemics but also of man-made threats such as bioterrorism. This Communication sets out a key step to make the EU better prepared and more able to respond, as a way to ensure that the EU and Member States can work together to bring a major step forward in the health security of citizens.

2. HERA: THE NEW HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

The best way to master future health crises is to anticipate and prepare before they materialise. The Communication on the early lessons of the COVID-19 pandemic¹ set out in detail the imperative need to further invest money and efforts in pandemic preparedness and response, in particular via a broader toolbox for crisis situations. It also demonstrated that we need a radically reinforced and joined-up approach to health security governance, to transform the lessons learnt from the COVID-19 pandemic into structural and systematic change.

The new **Health Emergency preparedness and Response Authority (HERA)** is set up to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures.

Medical countermeasures are products that can be used to diagnose, prevent, protect from or treat conditions associated with any kind of serious health threat. Examples are vaccines, antibiotics, medical equipment, chemical antidotes, therapeutics, diagnostic tests and personal protective equipment (PPE), such as gloves and masks.

¹ COM(2021) 380 final, 15 June 2021.

The core mission of HERA will be:

- To strengthen health security coordination within the Union during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort;
- To address vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures;
- To contribute to reinforcing the global health emergency preparedness and response architecture.

HERA will be established within the Commission as a shared resource for Member States and EU alike. Establishing HERA within the Commission will allow for a swift operationalisation by early 2022, flexibility in its organisation and the mobilisation of the Commission's existing powers, tools and programmes.

To achieve its goals, HERA will need a special working relationship with Member States. Close partnerships are needed to ensure that development work, manufacturing, and supply chains are directed to the strategic objectives of the EU and the Member States in normal times, and ramped up as soon as a crisis arrives. HERA should mean that the EU and Member States work together to analyse and define threats and strategic approaches, coordinating priorities so that the resources devoted to preparedness and response are as effective as possible.

HERA will have different modes of operation during preparedness and crisis times. In the “preparedness phase”, it will steer investments and actions in strengthening prevention, preparedness and readiness for new public health emergencies. In the “crisis phase”, HERA will be able to draw on stronger powers for swift decision-making and implementation of emergency measures. Its actions in both phases will be aimed at ensuring swift access to safe and effective medical countermeasures and at the scale needed. In both phases, HERA will integrate its operations with existing crisis management mechanisms².

It will build upon the work launched by the biodefence preparedness plan set up in February 2021 as the HERA Incubator³, which brought together researchers, biotech companies, manufacturers, regulators and public authorities to rapidly detect and characterise new variants, adapt vaccines as necessary and scale up existing production capacities.

HERA will have at its disposal €6 billion from the EU budget over a 6 year time period. As seen with COVID-19, investments in preparedness rapidly pay off when weighed against the actual costs – human and economic – of responding to a crisis. The case for making significant investments in prevention and preparedness is compelling. This has already been recognised by the EU through the increases in financial investments in health security in 2020, in particular with the new EU4Health programme, a large share of Horizon Europe, and the reinforced Union Civil Protection Mechanism (UCPM), as well as health being a major pillar of the Recovery and Resilience Facility and a main focus of investments under cohesion policy's Coronavirus Response Investment Initiatives (CRII) and REACT-EU.

² Notably the Union Civil Protection Mechanism (UCPM) and the Emergency Response Coordination Centre (ERCC).

³ COM(2021) 78 final, 12 February 2021.

The work of HERA will start as of today, with a transitional phase to make HERA fully operational by early 2022. HERA will bring together expertise from different fields and look beyond the current pandemic. The result will be a structure which can swiftly harness the full range of EU powers, tools and programmes for the most effective use of limited resources; which can draw on new investment possibilities and new powers in times of crisis; and which will work in continuous coordination with Member States in full respect of their competences in the area of health to ensure that citizens benefit from a health response which is better prepared, more coordinated and more effective.

HERA and EU Agencies

Whilst the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) have been at the forefront of the EU's response to the COVID-19 crisis, their mandates and tools limit their ability to protect EU citizens from cross-border health threats.

ECDC has a well-established specific mandate in the area of communicable disease threats⁴. However, it has no mandate in the area of other health threats, nor on the procurement, development or production of medical countermeasures.

EMA is the regulatory body responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU⁵. Throughout the crisis, EMA's regulatory capacity to support the development of safe and effective vaccines, therapeutics, and diagnostics has been constantly demonstrated. However, it has currently no mandate in the area of medical countermeasures other than medicines, and does not carry out procurement, stockpiling and distribution of capacities in the EU⁶.

The EU has already undertaken key initiatives to build a European Health Union by reinforcing our collective health security framework. In November 2020, the Commission tabled proposals to reinforce the mandates of the ECDC and EMA and to strengthen the EU health security framework with a new regulation on cross-border health threats.

HERA will complement and bring added value to the work conducted by ECDC and EMA in both preparedness and crisis times, thus becoming a crucial pillar of the European Health Union. Compared to the ECDC, HERA will have a stronger anticipatory, forward-looking and response-focused dimension in terms of threat assessments and foresight. EMA's scientific advice on the safety, effectiveness and high-quality of medical products will be a key input to the work of HERA's much broader work on development and production capacities, stockpiling and deployment mechanisms for vaccines, therapeutics and diagnostics.

Further details are provided in Annex I.

⁴ <https://www.ecdc.europa.eu/en/about-ecdc>

⁵ <https://www.ema.europa.eu/en/about-us/what-we-do>

⁶ As part of building a European Health Union, the Commission proposed on 11 November 2020 to reinforce the mandate of the European Medicines Agency. The new Steering Groups set-up under the extended mandate will provide important data to support actions on procurement, stockpiling and distribution."

3. HERA OPERATIONS DURING THE PREPAREDNESS PHASE

HERA will work closely with Member States to analyse, identify, and priorities possible health threats. This will be the basis for strategic coordination for the development of medical countermeasures, and the industrial capacity to produce and supply those countermeasures.

(Task 1) Threat assessments and intelligence gathering

Objective: To detect biological and other health threats soon after they emerge, evaluate their impacts and identify potential counter measures.

Globalisation, climate change, natural and man-made disasters, biodiversity loss, habitat encroachment as well as armed conflicts and terrorism drive the emergence and escalation of health emergencies, which can emerge anywhere on the globe and rapidly spread across continents. The timely availability of effective countermeasures depends on high quality data sourcing and the evaluation of potential threats, their impacts, and the identification of innovative solutions. Europe must be ahead of the curve, having relevant structures in place to identify and react to the next health crisis as early and effectively as possible.

HERA will focus on anticipatory threat assessments, foresight, market intelligence and horizon scanning of emerging pathogens as well as of developing technologies. Threats caused by biological, chemical, or environmental agents, as well as unknown threats – whether of natural⁷ or deliberate origin – will also be a focus, working in close coordination with the chemical, biological, radiological and nuclear (CBRN) response capacity and expertise available under the Union Civil Protection Mechanism.

HERA will have dedicated capacities for horizon scanning, foresight, data analysis and market intelligence, as well as building a continuous exchange with national expertise to build a common analysis. It will strengthen genome sequencing and environmental monitoring including wastewater-based surveillance and establish efficient data-sharing mechanisms, building on the planned European Health Data Space⁸ and the European Open Science Cloud⁹. The results will feed directly into HERA's work on research and innovation and the boosting of EU's industrial resilience. HERA will swiftly establish operational ties with global networks to ensure timely and relevant intelligence gathering.

Key actions:

- ❖ Threat detection: Establish state of the art, real-time data and intelligence on threats, relevant countermeasures, and enabling technologies, through a full partnership with Member State expertise and enhanced collaboration with industry, international actors and institutions, as well as with EU agencies.
- ❖ Threat modelling: Strengthen real-time analytics and develop accurate models to forecast the course of an outbreak.

⁷ For example, with regard to permafrost, it will assess the biological threats related to bacteria and viruses, which have been held within permafrost and risk release due to climate change. For example, in 2016, an anthrax outbreak occurred in Russia, which is believed to have emanated from the melting of permafrost.

⁸ https://ec.europa.eu/health/ehealth/dataspace_en

⁹ <https://digital-strategy.ec.europa.eu/en/policies/open-science-cloud>

- ❖ Threat prioritisation: By early 2022, identify and act on at least 3 specific high impact threats and address the possible gaps in terms of the availability and accessibility of related medical countermeasures.
- ❖ Threat awareness: Produce an annual State of Preparedness report to be discussed among EU leaders to ensure that preparedness remains on top of the political agenda.
- ❖ Epidemic surveillance: Extend support programmes set up under HERA Incubator to strengthen the detection and identification of variants in the EU¹⁰.

(Task 2) Promoting advanced R&D of medical countermeasures and related technologies

Objective: Promote research and innovation to develop effective, safe and affordable medical countermeasures

Promoting research on key and emerging pathogens as well as incentivising advanced research, innovation and development of relevant technologies and countermeasures – including diagnostics, therapeutics, and vaccines – will be an important aspect of work during the preparedness phase. Key to this will be open and FAIR¹¹ data sharing arrangements, which can lead to breakthrough discoveries and accelerate the development of health solutions.

European clinical trial networks for vaccines and therapeutics, as well as platforms, are the pan-European backbone to accelerate trials and connect all development stakeholders for designing and conducting trials. These platforms should be easily adjustable to respond to a broad range of potential threats and reduce current lead times. A first basis for cooperation will be VACCELERATE¹² – the first EU-wide network for COVID-19 vaccine trials, launched as part of the HERA Incubator. A close collaboration with EMA will be ensured to guarantee that these clinical trials provide timely and relevant evidence for the assessment of medicines for marketing authorisation procedures for medicines. These networks will be brought together during the preparedness phase into a large-scale EU platform for multi-centre clinical trials to avoid fragmentation and to ensure that they are swiftly operational in the event of a future public health emergency.

For these activities, HERA will rely on the health cluster of Horizon Europe, the EU's research and innovation programme. Synergies will also be sought with the European Institute for Innovation and Technology (EIT), the European Innovation Council (EIC), the European Research Council (ERC) and InvestEU actions to overcome innovation and investment gaps in this area.

Key actions:

- ❖ Create a common strategic EU research and innovation agenda for pandemic preparedness to help guide both EU and national funding and link with the planned Important Project of Common European Interest (IPCEI) Health.

¹⁰ The support programmes that were set as part of HERA Incubator include, for a total budget of €135m, a whole genome sequencing support framework contract, a national infrastructure support programme and a capacity building support programme, as well as a support programme and data network related to detection of SARS-CoV-2 variants in wastewater.

¹¹ Findable, Accessible, Interoperable, Reusable.

¹² <https://vaccelerate.eu/>

- ❖ Build on the EU Pandemic Preparedness Partnership to pool fragmented pandemic preparedness research capacities across the EU and ensure shared responsibility and funding between the Commission, Member States and countries associated.
- ❖ Further develop the European COVID-19 Data Platform to encourage breakthrough discoveries and accelerate the development of health solutions.
- ❖ Work with EMA to create a long-term and large-scale EU platform for multi-centre clinical trials and corresponding data platforms.

(Task 3) Addressing market challenges and failures and boosting the Union's open strategic autonomy

Objective: Identify and ensure the availability of critical technologies and production sites for medical countermeasures in the EU capable of increasing their production in times of need, including through support of breakthrough innovation.

As shown by the COVID-19 pandemic, a lack of industrial reserve manufacturing and supply capacities, complex global value chains for production and distribution of pharmaceuticals, and lack of diversification of sources of dependencies from third countries can quickly result in shortages of essential medical countermeasures. This must be addressed through enhancing the EU's industrial resilience. Longer-term investments, strategic planning and strategic alliances with industry are required to make the Union more resilient to external shocks and maintain an adequate supply base in the EU. By coordinating EU and Member State efforts to reduce supply risks, secure resilient supply chains and excessive external dependency, and to increase potential production capacity, Member States and their citizens will get access to vaccines, therapeutics and diagnostics earlier and at a greater scale.

The market for medical countermeasures has significantly expanded due to investments and technological advances driven by the COVID-19 pandemic¹³. Within Member States, a number of initiatives related to boosting access to and availability of medical countermeasures were launched or are under preparation. These new initiatives are encouraging and should be continued. These are complemented by the work under way through the Commission's Task Force for Industrial Scale-up of COVID-19 to foster business cooperation between developers, producers and suppliers. To have a clear and dynamic view of which critical production facilities in the EU are capable of upscaling their production, with the support of Member States HERA will systematically map EU and international market and supply chains, and monitor current and potential manufacturing capabilities. HERA will also act to address the identified bottlenecks and supply chain dependencies of medical countermeasures.

HERA will then build on several planned or ongoing initiatives to help it achieve its goal. The Pharmaceutical Strategy for Europe and its structured dialogue on security of medicines' supply and actions aim to address systemic shortages¹⁴. The updated EU Industrial Strategy¹⁵ will pay particular attention to small and medium-size enterprises that contribute to the development of ground-breaking solutions addressing public health needs¹⁶. Furthermore, there is a need to combine public and private efforts to incentivize breakthrough research and

¹³ https://ec.europa.eu/growth/coronavirus-response/task-force-for-industrial-scale-up-of-covid-19-vaccines_en

¹⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761>

¹⁵ COM(2021) 350, 5 May 2021

¹⁶ <https://www.smeunited.eu/news/a-view-on-the-covid-impact-on-and-support-measures-for-smes>

innovation in the health ecosystem, making it more resilient. Member States and industry are in the process of designing a future IPCEI Health¹⁷, which can include developing new generations of medical countermeasures or breakthrough manufacturing technologies, such as for flexible and modular production and supporting their first industrial deployment. The Commission stands ready to support Member State and industry plans and coordinate where necessary.

Finally, to support large-scale production of medical countermeasures, maintain and quickly guarantee access to sufficient production capacity, the Commission is setting up the EU FAB flexible manufacturing project, a network of ever-warm single and/or multi-technology production capacities for vaccine and therapeutics manufacturing in the EU. The goal is to greatly reduce the time needed between development and industrial scale-up.

Key actions:

- ❖ Identify critical production facilities by systematically mapping and monitoring supply chains, manufacturing capacities and ever-warm production sites.
- ❖ Identify bottlenecks within and outside the EU and market failures that could limit production capacity of medical countermeasures and raw materials during a health crisis, including through collecting feedback from industry via the Joint Industrial Cooperation Forum.
- ❖ Work with industry to address bottlenecks and supply chain dependencies within and outside the EU.
- ❖ Set up new industrial partnerships and organise pan-European matchmaking events across the EU.
- ❖ Establish close linkages with and build on the outcomes of relevant programmes and initiatives such as IPCEI Health and EU FAB. A first step will be to devote some €120 million to a call for EU FAB in early 2022.

(Task 4) Ensuring the provision of medical countermeasures

Objective: Use stockpiling and EU procurement to ensure provision of countermeasures

The EU Vaccines Strategy is a case in point of how public procurement can ensure rapid access to strategic medical countermeasures, diversify and strengthen supply chains, stimulate the market and thus contribute to the acceleration of the economic recovery. Developed as an ad-hoc tool between the European Commission, and Member States, the EU Vaccines Strategy can become a model for future public procurements in response to health emergencies.

The current EU legal framework for public procurement offers an effective range of tools. In particular, the innovation partnership procedure promotes agile cooperation between public buyers and economic partners. It combines co-development and procurement in a single tender procedure. Its objective is to jointly develop a new solution and subsequently for the

public buyer (e.g. Member States) to purchase the new solution without having to launch another competitive procedure.

The EU experienced major public concern when disruptions to the global supply of PPE experienced at the beginning of the pandemic put lives at risk, especially those of healthcare workers. This is an example of why HERA will reinforce stockpiling capacity in the EU and work with EU agencies, national authorities, and external stakeholders to coordinate¹⁸ coverage and deployment across the EU. The Union Civil Protection Mechanism has already shown the potential for EU action to bring major benefits. This work should also be taken forward in close coordination with EMA, whose extended mandate foresees the monitoring of critical medical products and medical devices.

Key actions:

- ❖ Identify specific opportunities and promote wider use of joint EU-level procurement to achieve health security policy objectives during the preparedness phase.
- ❖ Identify requirements and tackle possible challenges related to the transportation, storage and distribution of medical countermeasures across the EU.
- ❖ Assess existing stockpiling capacity in the EU and develop a strategy to ensure effective geographical coverage and timely deployment across the EU.
- ❖ Provide operational recommendations to the Union Civil Protection Mechanism with regard to medical countermeasures and their stockpiling and deployment.

(Task 5) Strengthening knowledge and skills

Objective: Improve Member States' capacities in preparedness and response related to medical countermeasures

HERA will draw on best practices and the expertise of Member States in particular to design and deliver training programmes to strengthen capacities across all Member States. It will look for synergies with training programmes planned under initiatives including the Pharmaceutical Strategy for Europe, the planned European Health Data Space and European Reference Networks. HERA will also assess the potential of the European Universities Alliances under ERASMUS+ Programme¹⁹ and the Pact for Skills²⁰ to support training opportunities in the health security area. The training programmes will also assist public buyers in using the flexibility of the EU public procurement rules and help them to achieve supply chain security in the mid and longer term. It will also draw from the expertise of the European Agency for Safety and Health at Work (EU-OSHA) to design and deliver guidance specifically for work environments.

Key action:

- ❖ Organise training programmes to improve knowledge and skills related to all aspects of access to medical countermeasures.

¹⁸ In terms of logistic transport, HERA will cooperate with EU transport agencies such as the European Union Aviation Safety Agency (EASA), the European Maritime Safety Agency (EMSA) and the European Union Agency for Railways (ERA). The competence of the EU transport agencies on transports measures and protocols remains ultimately in their remit.

¹⁹ [European Universities Alliances: Who are they? | Education and Training \(europa.eu\)](https://ec.europa.eu/social/main.jsp?catId=1517&langId=en)

²⁰ <https://ec.europa.eu/social/main.jsp?catId=1517&langId=en>

4. THE CRISIS PHASE

The crisis stimulated public authorities at EU, national and local level to take an unprecedented series of measures to react to the crisis, in health as in other policy areas. However, measures were often taken on an *ad hoc* basis, were reactive to the circumstances and lacked an anticipatory overall management system. HERA's task will be to ensure that the EU and Member States are much more ready to act in the face of a cross-border crisis. Preparedness means that when crisis comes, key medical countermeasures will have been developed and clear plans will be in place for their production and deployment; essential materials and components required for manufacturing will be available; operational steps will have been defined and made ready; and the monitoring tools will be in place to track a crisis and define the right policies in response. A key part of HERA's role in the crisis phase will be to ensure the effective deployment of all the preparations taken in advance.

In the crisis phase, HERA would shift into a different operational mode. To be able to work effectively, this must include swift decision-making and emergency measures. As announced in the Communication on the early lessons from the COVID-19 pandemic of 15 June 2021²¹, the proposal for a Council Regulation accompanying this Communication lays down a framework of emergency measures. If a public health emergency is recognised at EU level, the Council, upon the proposal of the Commission, may adopt a regulation activating the emergency framework where that is appropriate to the economic situation.

The Council activation of the emergency framework will also specify which of the following emergency measures, appropriate to the economic situation, should be implemented:

- The establishment of a **Health Crisis Board** to coordinate urgent action in response to the crisis. The Health Crisis Board will be composed of the Commission and one representative from each Member State; other institutions and agencies should also be closely involved;
- A **mechanism for monitoring crisis-relevant countermeasures**;
- The **procurement, purchase and manufacturing of crisis-relevant medical countermeasures** and raw materials;
- The **activation of EU FAB facilities** to make available reserved surge manufacturing capacities;
- The **activation of emergency research and innovation plans** and the use of Union wide clinical trial networks and data sharing platforms;
- The **establishment of an inventory of crisis-relevant medical countermeasures production facilities** and measures to ensure their aiming at increasing their production availability and supply in the EU;
- The activation of **emergency funding**.

5. THE INTERNATIONAL DIMENSION

COVID-19 has clearly demonstrated that unilateral responses to health emergencies are limited in reach and results. Coordination and cooperation within and beyond Europe are necessary to build up resilience and to provide timely and appropriate responses to potential health crises in the future. In line with the principles that the European Union has committed

²¹ COM(2021) 380 final, 15 June 2021.

to through the Rome Declaration²², the setting up of HERA will contribute, in coordination with the European External Action Service, to strengthening the global health security architecture for preparedness, prevention, detection of, and response and recovery to health emergencies.

EU and international engagement and cooperation are crucial in the context of the global nature of health threats and the global dynamics of the market for medical countermeasures. Pharmaceutical supply chains are increasingly interconnected and multinational. Disruptions caused by the COVID-19 crisis made evident the need to promote open, diversified and reliable global supply chains related to health emergencies, from raw materials to finished products. HERA will contribute to ensuring close collaboration with global partners to address international supply chain bottlenecks, remove unnecessary restrictions and expand global production capacity. Given interlocked supply chains, there is also a particular role to be played with the EU's neighbours.

In the event of a health emergency, HERA will facilitate cooperation with global actors to ensure availability and access of needed medical countermeasures both for the Union and for third countries. Furthermore, building on the current experience in Africa under the Team Europe Initiative for manufacturing of vaccines, medicines and health technologies, HERA's work will contribute to supporting low- and middle-income countries to build response capacity and expertise in preparedness and response as well as develop local manufacturing and distribution capacities. This will be done in close cooperation with key partner institutions and initiatives.²³ Based on exchange of evidence and experience from across the globe (e.g. training programmes, twinning partnerships, and expert exchanges), HERA will be able to provide targeted recommendations and funding to Member States, EU agencies and relevant stakeholders, to help addressing identified capacity gaps.

By facilitating information, knowledge and data sharing, reducing duplication and capitalising on existing structures and efforts, HERA will contribute to reinforcing global surveillance and maximising access to relevant medical countermeasures. HERA will develop inclusive collaborations with comparable national structures and leverage synergies with international actors, as well as with security actors and other relevant sectors.²⁴ It will also ensure coherence with other EU policies in areas like international trade of essential medical goods, notably the "Trade and Health Initiative" promoted by the EU in the World Trade Organisation.

Finally, HERA will support access to EU-funded or EU-procured medical countermeasures and regional and local manufacturing capacities in third countries. This work will account for existing EU mechanisms for the distribution of medical countermeasures, including PPE and vaccines, through the Union Civil Protection Mechanism. HERA will, within its remit, develop proposals for funding agreements aiming to support third countries to strengthen their preparedness and response capacity, for example, to reinforce their surveillance capacities or their skilled workforce needed in times of a health crisis.

²² https://global-health-summit.europa.eu/rome-declaration_en

²³ As well as the World Health Organisation, this includes the Africa Centres for Disease Control and Prevention (Africa CDC), the Partnership for African Vaccine Manufacturing (PAVM), the future African Medicines Agency (AMA) and the Pan-American Health Organisation (PAHO)

²⁴ As well as the World Health Organisation, this includes the World Organization for Animal Health (OIE), the Global Health Security Initiative (GHSI) and the Coalition for Epidemic Preparedness Innovations (CEPI),

Key actions:

- ❖ Ensure close collaboration with global partners to address international supply chain bottlenecks, removing unnecessarily restrictions, and expanding global production capacity.
- ❖ Reinforce global surveillance.
- ❖ Facilitate reinforced international cooperation and support for crisis-relevant medical countermeasures with global actors in case of health emergency to ensure their availability and accessibility both for the Union and for third countries.
- ❖ Provide support to low- and middle-income countries to build expertise as well as develop local manufacturing and distribution capacities of relevant medical countermeasures.
- ❖ Support access to EU-funded or EU-procured medical countermeasures and regional and local manufacturing capacities in third countries.

6. THE STRUCTURE AND GOVERNANCE OF HERA

Establishing HERA as a structure within the European Commission will allow it to benefit from the full range of financial, regulatory, technical and organisational tools and expertise available to the Commission, from the outset.

Strengthening the EU's overall health security capacities will require both EU and national efforts, and achieving our common goals require these to be coordinated. This means that the EU and its Member States will need to develop a new way of working, in full respect of institutional competences. This should lead to a shared analysis of threats and needs, jointly-agreed priorities for action, and joined-up EU and national activities to best address these priorities. HERA will build a close and constant relationship with national authorities and national structures set up to address health emergency preparedness and response. Building on a dedicated governance structure, all parties will need to be committed to open dialogue and cooperation in pursuit of a shared goal.

Considering the importance of industry in medical counter measures development and production at scale, regular and systematic exchanges will be held between HERA and industry, via the joint Industrial Cooperation Forum based on experience gained through the Task Force for Industrial Scale-up of COVID-19 vaccines and therapeutics.

HERA is designed to be a flexible structure and will be adapted as required. In 2025, the Commission will conduct an in-depth review on the implementation of the operations of HERA, including on its structure and governance, and issue a report to the European Parliament and the Council.

6.1 HERA Board

While respecting the institutional competences of the Commission and of the Member States and without prejudice to the institutional prerogative of the Commission, HERA will be assisted by the "HERA Board". The Board will bring together Commission expertise and senior Member States representatives and contribute to the preparation of multiannual strategic planning, which will help to set HERA objectives and shape the strategic direction of both EU and national health preparedness and response. In this way, HERA will further strengthen the close relationship between Member States and the Commission. The Board will also play a key role in outreach beyond the Member States, including with the health, research and industry communities.

Observers

Representatives of EU agencies and bodies will be invited to participate as observers. The Board will also make sure to avoid overlaps with other key structures, such as the Health Security Committee, the Vaccine Steering Board and relevant committees involved in the management of EU programmes, with close contacts needed.

The European Parliament will also be invited to designate an observer in the HERA Board. The Commission will also ensure a regular exchange with the European Parliament about the work of HERA.

6.2 HERA networks

Of critical importance will be HERA's work with national authorities. A network will be set up of existing and developing national or regional agencies in EU Member States responsible for carrying out tasks related to the availability and accessibility of relevant medical countermeasures in case of a health emergency. The network will provide for close day-by-day exchange, building common analysis and understanding, reinforcing joint priorities and feeding into the work of the HERA Board. This should be fully in place in the course of 2022.

A HERA Advisory Forum will ensure increasingly close cooperation between HERA and competent bodies in Member States on the planning and implementation of scientific, health and industrial activities of HERA. There will be a strong dimension of cooperation with external stakeholders such as industry, academia and civil society representatives to ensure constant exchanges on coordination and convergence of preparedness priorities. As sub group of the Advisory Forum, a Joint Industrial Cooperation Forum will be setup, including industry representatives.

To ground its work on scientific evidence and translate into coherent communication, HERA will establish a set of close working arrangements with the future European Chief Epidemiologist and the future group of leading national epidemiologists²⁵.

6.3 Resources

HERA operations require a significant and sustainable budget. Investing in prevention and preparedness now will result in a significantly lower human and economic cost later and will have a large return on investment – not only for the economy, but also for society and the health of European citizens²⁶.

During the preparedness phase, HERA will draw on existing structures, programmes and activities at EU and at national level. HERA activities will rely on an indicative budget (2022-2027) of €6 billion from the current Multiannual Financial Framework, part of which will come from the NextGenerationEU top-up. Several programmes already have objectives and a scope which corresponds to the tasks of HERA. EU4Health allows for major support to health security preparedness. Research and innovation in health is a key work stream of Horizon Europe. The Union Civil Protection Mechanism has important experience in areas such as building stockpiles. The legal instruments governing these programmes allow for such

²⁵ COM(2021) 380 final

²⁶ Studies have estimated that it would take 500 years to spend as much on investing in preparedness as the world is currently losing due to COVID-19:

https://apps.who.int/gpmb/assets/annual_report/2020/GPMB_2020_AR_EN_WEB.pdf

expenditure, in accordance with their respective rules and implementing structures. There may also be directly relevant spending in other programmes, such as the European Defence Fund.

Other EU programmes could also contribute directly and indirectly to health emergency preparedness inside and outside the EU. Investment foreseen to build strong health systems through the Recovery and Resilience Facility and REACT-EU inside the EU, and the work of the Neighbourhood, Development and International Cooperation Instrument outside the EU, will have a major impact on the resilience of health systems. Together with the €6 billion foreseen for HERA activities directly, this will amount to almost €30 billion under the next financing period. To this could be added of the support from the Cohesion Funds for improving health systems' resilience, accessibility and effectiveness. In addition, Member States devote large-scale resources from their own budgets to health preparedness and countermeasures, which will contribute to meeting common strategic goals.

HERA should also benefit from the mobilisation of private funding (in the form of loans, guarantees, equity or quasi-equity), supported by budgetary guarantees under InvestEU and possibly the European Fund for Sustainable Development for external actions, in cooperation with the European Investment Bank Group and other financial actors.

HERA operations will also rely on national budgets allocated to activities aimed at supporting national plans for preparedness and response to health threats. Multi-country projects, such as the planned IPCEI Health, will also contribute to the mission of HERA. Only with a strong commitment from the Member States will HERA be able to fully fulfil its mission and thus enable an adequate level of preparedness for future health crises in all EU countries. At the same time, Member States are invited to make their preparedness and pandemic programmes fit by using the abovementioned programmes and instruments to build more resilient health systems.

HERA will also benefit from reinforced flexibility for the recruitment of relevant experts including through the secondment of national experts, and adjusted in size and composition to specific crisis situations or to normal, preparedness mode.

Funding during the crisis phase

In the event of a public health emergency at Union level, in order to ensure the necessary flexibility and rapidity in implementation, the Council could also trigger financing through the Emergency Support Instrument (ESI), demonstrated in the past to be both flexible and fast. During the COVID-19 crisis, the ESI²⁷ proved efficient and effective in ensuring rapid and flexible funding, essential in times of urgency²⁸. As ESI does not have an annual dedicated budget²⁹, when it is activated, the Commission will analyse the necessity of transferring funding from existing programmes or resort to Special Instruments. As foreseen by the founding regulation of ESI, contributions could also be made by Member States (and by other public or private donors as external assigned revenue) in accordance with the Financial Regulation.

²⁷ Regulation (EU) 2016/369, 15 March 2016.

²⁸ The Emergency Support Instrument made available nearly €100 million for the procurement of personal protective equipment and medicines. It also mobilised €100 million to directly purchase more than 20 million rapid antigen tests to complement national testing strategies.

²⁹ Regulation (EU) 2016/369

7. CONCLUSION

Health security in the EU must become a collective endeavour. The COVID-19 pandemic made evident that no country can address all the challenges associated with serious health emergencies alone. It has also shown that there is a strong will and ambition to improve EU's capacity to respond to health emergencies, and initiatives such as the EU Vaccines Strategy demonstrated how much the EU can achieve when it acts with coordination, solidarity and unity of purpose. They have also shown, however, that the EU needs to move swiftly from ad hoc solutions to structural ones.

Structural anticipation, preparedness and joint response capabilities are needed at EU level to ensure that sufficient safe, effective and affordable medical countermeasures are available as quickly as possible in a public health crisis.

With the new HERA, embedded in a stronger EU health security framework, the EU and its Member States will take a major step forward in building a strong European Health Union that meets citizens' expectations.

The European Parliament and Council are invited to endorse and support this approach, in order to make HERA an operational reality in the EU in the shortest possible timeframe. There is no time to waste.



Brussels, 16.9.2021
COM(2021) 576 final

ANNEX

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


Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions




Introducing HERA, the European Health Emergency Preparedness and Response Authority, the next step towards completing the European Health Union




ANNEX

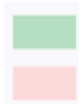
Comparative overview of competences – HERA, ECDC and EMA

The below provides a comparative overview of the roles and functions that are envisaged for HERA, ECDC and EMA during the preparedness and crisis phase, covering different aspects of work related to preventing and addressing health emergencies. It takes into account existing roles and functions as well as future ones based on the EU Health Union proposals.

| | | HERA | ECDC | EMA |
|--|---|--|---|--|
|  PREPAREDNESS PHASE | | <ul style="list-style-type: none"> • Threat anticipation and prioritisation • Horizon scanning • Consequence management • Identifying MCM requirements • Mapping of capacities • In-house expertise on medicines and medical devices | <ul style="list-style-type: none"> • Epidemiological intelligence and analysis • Epidemiological surveillance system • Harmonised health data sets and tools | <ul style="list-style-type: none"> • Monitoring/mitigating the risk of shortages of critical medicines and medical devices • Scientific advice on clinical trials design and product development as well as the ‘rolling’ review of emerging evidence on MCMs • Medical device expert panels |
|  CRISIS PHASE |  INTELLIGENCE GATHERING & ANALYSIS | <ul style="list-style-type: none"> • Inventory of crisis-relevant MCMs production • Production facilities • Crisis-relevant raw materials, consumables, equipment and infrastructure • Monitoring of crisis-relevant MCMs • Provision of non-binding recommendations on MCMs • Emergency research and innovation plans | <ul style="list-style-type: none"> • Epidemiological intelligence and analysis • Provision of non-binding recommendations and options for risk management (advice on application of health measures, e.g. masks, social distancing, testing strategies, etc.) | <ul style="list-style-type: none"> • Update list of critical medicines and medical devices • Monitoring supply and demand of those products • Scientific advice on new/repurposed MCMs • Coordination clinical trials • Studies assessing vaccine safety and effectiveness • recommendations on most advanced MCMs |


| | HERA | ECDC | EMA |
|---|--|--|---|
|  <p>PANDEMIC PREPAREDNESS & RESPONSE PLANNING</p> | <ul style="list-style-type: none"> • Pandemic preparedness and response planning with a focus on MCMs in close coordination with the pandemic preparedness research and innovation partnership • Annual State of Preparedness report | <ul style="list-style-type: none"> • EU pandemic preparedness and response plan • Stress tests • Audits • EU reference laboratories network • EU network for substances of human origin • Automated contact tracing system | N/A |
|  <p>DEVELOPMENT CAPACITIES</p> | <ul style="list-style-type: none"> • IT platforms for MCMs • End-stage research and clinical trials as part of the pandemic preparedness research and innovation partnership • Intellectual property access | N/A | N/A |
| | <ul style="list-style-type: none"> • Emergency funding instruments and requirements | | <ul style="list-style-type: none"> • Emergency Task Force • Regulatory support for marketing authorisations • Acceleration of regulatory processes |
|  <p>PRODUCTION CAPACITIES</p> | <ul style="list-style-type: none"> • EU FAB • Cooperation mechanism with EU industry • Contributing to ensure sufficient EU manufacturing capacities | N/A | N/A |
| | <ul style="list-style-type: none"> • Emergency funding instruments and requirements | | <ul style="list-style-type: none"> • Sub-networks of single points of contact from marketing authorisation holders, medical device manufacturers and notified bodies based on the products included on the critical medicines and medical device lists |

| | HERA | ECDC | EMA |
|---|---|--|---|
| | | | |
|  PROCUREMENT CAPACITIES | <ul style="list-style-type: none"> • Management of a portfolio of EU procurement tools | N/A | N/A |
| | <ul style="list-style-type: none"> • Emergency funding • Central purchasing body | | |
|  STOCKPILING AND DISTRIBUTION CAPACITIES | <ul style="list-style-type: none"> • IT platforms for EU/national MCM stockpiles and supplies • EU level stockpiling or supply network of critical raw materials • Logistical infrastructures • MCMs management/ deployment | N/A | N/A |
| | <ul style="list-style-type: none"> • Efficient re-organisation of supply chains and production lines | | |
|  TRAINING AND CAPACITY BUILDING | <ul style="list-style-type: none"> • Twinning partnerships • Expert exchanges and centres of excellence • Capacity-building forum • Skills in biopharmaceutical science and bio-manufacturing | <ul style="list-style-type: none"> • Training for healthcare staff on pandemic preparedness and response planning | <ul style="list-style-type: none"> • Training on innovative medical technologies • Training on regulatory aspects |



PREPAREDNESS PHASE

CRISIS PHASE

| | HERA | ECDC | EMA |
|--|--|--|---|
|  <p>INTERNATIONAL ENGAGEMENT AND REINFORCEMENT</p> | <ul style="list-style-type: none"> • Global needs assessment for MCMs • Global surveillance capacities gaps assessment • Technical assistance for global capacity building • Global alliances with HERA like structures • Distribution of HERA procured/financed MCMs at international level • International twinning partnerships, expert exchanges and centres of excellence | <ul style="list-style-type: none"> • Engagement with other Centres for Disease Control and capacities • Deployment of experts in international response teams • Deployment EU Health Task Force to support local responses in Member States and third countries | N/A |
| | <ul style="list-style-type: none"> • Trigger activation of the necessary preparedness plan/cooperation with identified third countries as source countries • Cooperation on availability and deployment of crisis-relevant MCMs and raw materials | <ul style="list-style-type: none"> • Engagement with other CDCs and capacities | <ul style="list-style-type: none"> • Liaise with counterparts regarding authorised medicines or products under development • Liaise with counterparts to mitigate shortages of critical medicines or their active pharmaceutical ingredients • Liaise with counterparts to mitigate shortages of critical medical devices or their component parts |