

HERA Work Plan 2022

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 to exchange scientific knowledge and best practices. 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, including chemical, biological, radiological and nuclear (CBRN) threats. This document sets out key activities 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.

The best way to master future health crises is to anticipate and prepare before they materialise. 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.

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 is established as a shared resource for Member States and EU alike. 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. It means that the EU and Member States, meeting in the **HERA Board**, with representatives of the European Parliament and of ECDC and EMA, 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 at its disposal and manage the network of ever-warm manufacturing facilities for vaccines and therapeutic (EU FAB), an important element to be better prepared in case of future public health crises.

This work plan presents all HERA activities foreseen throughout the year 2022. This work plan is a living document, and will remain agile to timely address urgent needs, including emerging supply chain bottlenecks. It is structured around five tasks and includes a number of deliverables. Some of these actions imply the mobilisation of EU money through procurement or grant.

Main financing in times of crises would come from the Emergency Support Instrument (ESI) and would follow financial rules foreseen for ESI.

HERA will have at its disposal EUR 6 billion from the EU budget over a 6 year time period, primarily building on the activities of EU4Health, Horizon Europe and Union Civil Protection Mechanism (UCPM).

A total contribution of EUR 1.3 billion from the EU budget is allocated to HERA in 2022 for preparedness activities. The budget of HERA for 2022 foresees contributions from EU4Health (EUR 275 million), Horizon Europe (EUR 395 million) and UCPM/rescEU EUR 630 million). The work plan considers ongoing or planned calls under Horizon Europe and rescEU in 2022, the exact final allocations depend on the projects that will be selected in the open calls.

Task 1. Threat assessments and intelligence gathering	EUR 139.5 million
Task 2. Promoting advanced R&D of medical countermeasures and related technologies	EUR 306.08 million
Task 3. Addressing market challenges and failures and boosting the Union’s open strategic autonomy	EUR 165.3 million
Task 4. Ensuring the provision of medical countermeasures	EUR 666.5 million
Task 5. Strengthening knowledge and skills	EUR 5 million
Task 6. International dimension	EUR 2 million (+101 million under Task 2)
Total for preparedness phase in 2022	EUR 1 284.38 million

With the COVID-19 pandemic still on-going, some of the actions described in this work plan are linked to the “**crisis mode**” of HERA.

In this regard, vaccines have been playing a central role fighting the COVID-19 pandemic. To implement the EU **Vaccines Strategy** in collaboration with Member States in the Vaccines Steering Board, ten contracts have been signed to date: 7 advance purchase agreements and 3 purchase agreements. The European Commission has approved its eighth advance purchase agreement for COVID-19 vaccines and HERA continues to observe the market for further developments. Work continues in the Vaccines Steering Board with Member States.

Actions under the **HERA Incubator** continue to rapidly detect and characterise new variants, adapt vaccines as necessary and scale up existing production capacities.

This includes the work of the European Expert Group on SARS-CoV-2 variants on the categorisation of SARS-CoV-2 variants and the need to develop or adapt the vaccines against those variants, as well as on the COVID-19 therapeutics portfolio.

In the context of the Joint Procurement Agreement, the European Commission recently concluded two framework contracts for the acquisition of monoclonal antibodies with Hoffmann-La Roche for Ronapreve (combination of casirivimab and imdevimab) and with GSK for Xevudy (sotrovimab). Discussions with other companies are ongoing for other promising COVID-19 therapeutics, such as oral antivirals from MSD and Pfizer.

Concerning the HERA's structure and governance mechanism, the **HERA Advisory Forum** is being set up involving members from technically competent bodies designated by each Member States. As a subgroup of the HERA Advisory Forum, the Commission is setting up a Joint Industrial Cooperation Forum for regular and systematic exchanges with the industry, based on experience gained through the Task Force for Industrial Scale-up of COVID-19 vaccines and therapeutics. Feedback from industry via this Forum, could help to identify bottlenecks within and outside of the EU and market failures that could limit production capacity of medical countermeasures and raw materials. HERA further aims to establish and maintain close **cooperation with external stakeholders such as civil society, academia and industry** representatives to ensure constant exchanges on preparedness priorities and coordination. In addition, a **network** will be set up of 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.

Close collaboration with international networks for increasing production capacity will be pursued, together with DG INTPA as well as the Task Force for Industrial Scale-up of COVID-19 vaccines and therapeutics in DG GROW, including the joint EU-US taskforce and with the Partnerships for African Vaccine Manufacturing (PAVM) of the African Union.

Task 1. Threat assessments and intelligence gathering (EUR 139.5 million, 2022)

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

Action	Deliverables		Timeline (Due date/Status as applicable)	Budget (EUR million; 2022 budget in bold)
<p>Threat detection: Establish state of the art, real-time data and intelligence on threats with regard to the availability of 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.</p> <p>Threat modelling: Strengthen real-time analytics and develop accurate models to forecast the types and amount of medical countermeasures needed in the course of an outbreak).</p>	1.1	<p>Proposal for a prototype EU interactive mapping platform on availability and supply chains production capacity including raw materials, and analysis of products under development (methodology for data collection and analysis, identification of existing tools/systems and legal assessment of data protection and confidentiality aspects).</p> <p><i>HERA Preparatory Action: a feasibility study, design and prototype development for a mapping platform on COVID-19 therapeutics in the EU</i></p>	<p>Q3 2022</p> <p>(Call under evaluation, contract – if signed – lasts 9 months)</p>	<p>5 (EU4Health)</p>
	1.2	<p>Development of HERA IT platform for intelligence gathering, with regard to the production and availability of medical countermeasures, threat assessment and mapping medical countermeasures based on the prototype developed under deliverable 1.</p> <p>Stockpiling management system (including procurement on therapeutics and vaccines) linked to IT platform (tbc).</p>	<p>Q4 2023</p>	<p>24.5 (EU4Health)</p> <p>49.4 (UCPM/rescEU)</p>
	1.3	<p>Establishing a structured collaboration with WHO Hub for Pandemic and Epidemic Intelligence¹ through a Memorandum of Understanding.</p>	<p>Q2 2022</p>	
	1.4	<p>Establishing working arrangements with ECDC and EMA through Memorandum of Understanding.</p>	<p>Q1 2022</p>	

¹ https://cdn.who.int/media/docs/default-source/2021-dha-docs/who_hub.pdf?sfvrsn=8dc28ab6_5

	1.5	HORIZON-CL3-2022-DRS-01-02: Enhanced preparedness and management of High Impact Low-Probability or unexpected events	Calls published, work starts in 2022, deliverables expected from 2023	5 (Horizon Europe)
	1.6	HORIZON-CL3-2022-DRS-01-03: Improved quality assurance / quality control of data used in decision-making related to risk management of natural hazards, accidents and CBRN events	Calls published, work starts in 2022, deliverables expected from 2023	5 (Horizon Europe)
	1.7	HORIZON-CL3-2022-DRS-01-07: Improved international cooperation addressing first responder capability gaps	Calls published, work starts in 2022, deliverables expected from 2023	2 (Horizon Europe)
	1.8	HORIZON-CL4-2022-RESILIENCE-01-19: Advanced materials modelling and characterisation (RIA)	Calls published, work starts in 2022, deliverables expected from 2023	14.4 (Horizon Europe)
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.	1.9	Establishing a regular prioritisation exercise (e.g., risk ranking) based on analysis of scientific evidence to be carried out in consultation with relevant EU agencies (e.g. ECDC, EMA, ECHA, etc.), public health departments/agencies at national level, the HSC and other relevant international organisations.	Q1 2022	
	1.10	As a final step of the prioritisation exercise, selection of three high-impact threats by the Commission in consultation with the HERA Board/HERA Advisory Forum. <i>(Preliminary list: SARS-CoV2, pandemic influenza, AMR, emerging infectious diseases such as certain viral haemorrhagic fevers, vector borne diseases, agents for intentional release, chemical and biological threats, Orthoparamyxoviruses (Henda, Nipah virus), Ricin (bioterrorism))</i>	Q1/2 2022	
	1.11	List of critical medical countermeasures (incl. vaccines, therapeutics and diagnostics, protective and decontamination equipment) based on selection of 3 specific high impact threats.	Q2 2022	

		<p>List of COTS and desirable products to be developed drafted by the Commission in consultation with agencies, international organizations (WHO, NATO) and experts as well as HSC.</p> <p>Discussion with the HERA Board.</p> <p>The list will be gradually extended to cover all threats areas and medical countermeasures.</p>	2022	
	1.12	Study on market research and mapping of innovative diagnostic testing solutions.	Q2 2022	0.2
Threat awareness: Produce an annual State of Preparedness report to be discussed among EU leaders to ensure that medical countermeasures preparedness remains on top of the political agenda.	1.13	Annual State of Preparedness report.	November 2022	
	1.14	Transmission of the report to the European Parliament and to the Council.	December 2022	
	1.15	Dialogue with relevant stakeholders, including civil society, patients, consumers, healthcare workers and researchers on the priorities of HERA and their implementation, based on the analysis of ongoing activities.	December 2022	
Epidemic surveillance: Extend support programmes set up under HERA Incubator to strengthen the detection and identification of variants in the EU as well as for intelligence gathering and surveillance following a One Health approach.	1.16	Expand capacity for genomic sequencing: enhancing whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic.	Ongoing under HERA Incubator	39
	1.17	European expert group on SARS-CoV-2 variants.	Ongoing	

Task 2. Promoting advanced R&D of medical countermeasures and related technologies (EUR 306.08 million, 2022)

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

Action	Deliverables		Timeline (Due date/Status as applicable)	Budget (EUR million; 2022 budget in bold)
Fund research projects on a variety of medical countermeasures and other related health technologies via Horizon Europe	2.1	Calls under Horizon Europe	Calls published, work starts in 2022, deliverables expected from 2023	306.08²
	2.1.1	Cluster 1 – Health		235.08 (Horizon Europe)
		HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next generation of immunotherapies for diseases or disorders with unmet medical needs		30
		HORIZON-HLTH-2022-DISEASE-06-03-two-stage: Vaccines 2.0 - developing the next generation of vaccines		40
		HORIZON-HLTH-2022-DISEASE-07-02: Pandemic preparedness (pathogen X)		10
		HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment		35
		HORIZON-HLTH-2022-IND-13-02: Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation		30

² *The present estimation represents an approximation of the possible contribution of Horizon Europe-funded projects.*

		HORIZON-HLTH-2022-IND-13-04: Setting up a European Smart Health Innovation Hub		2
		CEPI 3 - Contribution to the Coalition for Epidemics Preparedness Initiative		35
		HORIZON-HLTH-2022-CARE-10-01: European partnership on transforming health and care systems		10
		European & Developing Countries Clinical Trials Partnership (EDCTP3) Joint Undertaking		20.44
		Innovative Health Initiative (IHI)		22.64
	2.1.2	Horizon Europe Cluster 4 - Digital, Industry and Space		26 (Horizon Europe)
		HORIZON-CL4-2022-RESILIENCE-01-13: Smart and multifunctional biomaterials for health innovations (RIA)		20
		HORIZON-CL4-2022-DIGITAL-EMERGING-02-19: 2D materials-based devices and systems for biomedical applications (RIA)		6
	2.1.3	Horizon Europe Cluster 6 - Food, Bioeconomy, Natural Resources, Agriculture & Environment		10 (Horizon Europe)
		HORIZON-CL6-2022-GOVERNANCE-01-09: Environmental observations solutions contributing to meeting “One Health” challenges		10
	2.1.4	European Innovation Council (EIC)		35 (Horizon Europe)
		IV.2.1 EIC Accelerator Challenge: Technologies for Open Strategic Autonomy		35

	2.1.5	European Research Council (ERC)		
		Ex ante analysis of past/ongoing projects in scope with HERA		
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	2.2	Ongoing action under Horizon Europe WP 2021.	The evaluation of the proposal will be done in December 2021 and the work will be carried out in 2022	
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	2.3	Action under preparation under Horizon Europe Work Programme 2023-2024.	In preparation	
Work with EMA to create a long-term and large-scale EU platform for multi-centre clinical trials and corresponding data platforms	2.4	Ongoing action under Horizon Work Programme 2020 and Horizon Europe Work Programme 2021.	Work is ongoing to continue to support and coordinate the large-scale EU platform for multi-centre clinical trials and data platforms	
Further develop the European COVID-19 Data Platform ³ to encourage breakthrough discoveries and accelerate the	2.5	Ongoing action under Horizon Work Programme 2020 and Horizon Europe Work Programme 2021.	Call for evaluation	

³ <https://www.covid19dataportal.org/>

development of health solutions				
Other actions for advanced research of medical countermeasures	2.6	Identify products for a joint call for proposal in 2023 for phase 3 clinical trials for certain vaccines/therapeutics.	Q1 2022	EU4Health
	2.7	AMR Technology review, methodological refinement and gap analysis on AMR medical countermeasures brought to market, new technologies with breakthrough potential and including evidence on repurposed medicines; gap analysis and needs assessment in the Member States and amongst stakeholders. Cost estimations and options for action; methodology to assess and propose legal options and prioritised purchase models. <i>HERA Preparatory Action: Feasibility Study on Stockpiling of Medical Countermeasures in the Area of AMR</i>	Q3 2022 (Evaluation process – if signed – lasts 9 months)	1 (EU4Health)

Task 3. Addressing market challenges and failures and boosting the Union’s open strategic autonomy (EUR 165.3 million, 2022)

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.

Action	Deliverables		Timeline (Due date/Status as applicable)	Budget (EUR million; 2022 budget in bold)
<p>Identify critical production facilities by systematically mapping and monitoring supply chains, manufacturing capacities and ever-warm production sites</p> <p>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</p>	3.1	<p>Collection and analysis of comprehensive data on supply chains production capacity inside and outside the EU and availability of COVID-19 therapeutics in the EU market, including key raw materials.</p> <p>The deliverable will allow to identify specific actions to be launched as of 2023 addressing needs identified as part of a broader supply chain monitoring for medical countermeasures.</p> <p><i>HERA Preparatory Action: a feasibility study, design and prototype development for a mapping platform on COVID-19 therapeutics in the EU</i></p>	<p>Q2 2022</p> <p>(Call under evaluation, contract – if signed – lasts 9 months)</p>	<p>5 (EU4Health)</p>
	3.2	<p>Analysis of three options for implementing a flexible (multi technology) EU manufacturing and innovation capacity for vaccines and therapeutics.</p> <p><i>HERA Preparatory Action: a study assessing scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation of medical countermeasures for serious cross border threats to health</i></p>	<p>Q2 2022</p> <p>(Call under evaluation, contract – if signed – lasts 8 months (3 for vaccines))</p>	<p>3 (EU4Health)</p>
	3.3	<p>HORIZON-CL4-2022-TWIN-TRANSITION-01-01: Rapid reconfigurable production process chains (Made in Europe Partnership) (IA)</p>		<p>5 (Horizon Europe)</p>

Set up new industrial partnerships and organise pan-European matchmaking events across the EU Set up of structures for cooperation with Member States, research and civil society stakeholders	3.4	Exploratory meetings with companies and trade associations to develop structured partnerships.	Early January – end of March 2022	
	3.5	Set up of HERA Advisory Forum, in engagement with civil society stakeholders.	Q1 2022	
	3.6	Set up of the Joint Industrial Cooperation Forum.	Q2 2022	0.1
	3.7	Set up of network of national or regional BARDA like agencies or entities.	Q2 2022	
	3.8	HERA Industry Day for Preparedness 2022 – matchmaking event at EU level focused on critical medical countermeasures (in collaboration with DG GROW). Series of matchmaking events with survey on results to inform HERA actions.	September 2022	0.2
	3.9	Set up HERA website and include a section on ‘Doing Business with HERA’ ⁴ .	March 2022	
Work with industry to address bottlenecks and supply chain dependencies within and outside the EU for medical countermeasures	3.10	Meeting of the Joint Industrial Cooperation Forum dedicated to give the group the mandate to identify bottlenecks (incl. on logistical aspects) and supply chain dependencies within and outside the EU.	May 2022	
	3.11	Identification and discussion of bottlenecks and supply chain dependencies in the Joint Industrial Cooperation Forum, formalising a regular and permanent basis a two ways dialogue with industry also in view of the Structured Dialogue process.	September – December 2022	
	3.12	Meeting of Joint Industrial Cooperation Forum-HERA Board towards continued identification of solutions.	December 2022	

⁴ Modelled on BARDA’s website: <https://aspr.hhs.gov/Pages/About-Us/BARDA/Doing-Business-with-BARDA.aspx>

	3.13	Exchanges between the Joint Industrial Cooperation Forum and relevant global actors.	May-onwards 2022	
Establish close linkages with and build on the outcomes of relevant programmes and initiatives such as IPCEI Health and EU FAB.	3.14	Identify and engage with potential ever-warm facilities for vaccines and therapeutics production through EU FAB.		160
	3.15	Engage with Member States on IPCEI Health plans and build coordination mechanisms to ensure IPCEI and HERA can reinforce each other.		

Task 4. Ensuring the provision of medical countermeasures (EUR 666.5 million, 2022)

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

Action	Deliverables		Timeline (Due date/Status as applicable)	Budget (EUR million; 2022 budget in bold)
Identify specific opportunities and promote wider use of joint EU-level procurement to achieve health security policy objectives during the preparedness phase.	4.1	Procurement of vaccines against infectious disease threats such as pandemic influenza vaccines.	Q3 2022	46
	4.2	Procurement and reservation contracts. Calls on medical stockpiles and CBRN (<i>preliminary priorities: COVID-19 vaccines / combined vaccines, other vaccines against priority pathogens, antivirals, antibiotics, antitoxins, antidotes, PPE, rapid diagnostics, ICU / isolation equipment, emergency beds for transport/triage/treatment</i>)	2022-2023	580.5 (rescEU/UCPM)
	4.3	Joint procurement of COVID-19 therapeutics.	Ongoing discussion for new therapeutics with MSD and Pfizer.	
	4.4	Advance Purchase Agreements of COVID-19 vaccines.	Ongoing	
	4.5	HORIZON-HLTH-2022-CARE-08-02: Pre-commercial research and innovation procurement (PCP) for building the resilience of health care systems in the context of recovery		25 (Horizon Europe)
	4.6	HORIZON-HLTH-2022-CARE-08-03: Public procurement of innovative solutions (PPI) for building the resilience of health care systems in the context of recovery		15 (Horizon Europe)
Assess existing stockpiling capacity in the EU and develop a strategy to ensure effective geographical coverage and timely deployment across the EU	4.7	Methodology to map the antimicrobials and APIs most needed within the EU, assess the gaps in access and vulnerabilities in the EU.	Q2 2022 TBC (closed on 12/11 and starting evaluation)	1 (EU4Health)

		<p>Mapping of established or planned physical stockpiles/ procurement and/or pre-arranged reserve/access agreements at national and EU level, and operated by third parties (e.g. WHO, UNICEF; GAVI or other).</p> <p><i>HERA Preparatory Action: Feasibility Study on Stockpiling of Medical Countermeasures in the Area of AMR</i></p>	process– if signed – lasts 6 months)	
	4.8	Stockpiling management system linked to IT platform (including procurement for vaccines and therapeutics) (tbc)		<i>Listed under Task 1</i>
Provide operational recommendations to the Union Civil Protection Mechanism with regard to medical and CBRN countermeasures and their stockpiling and deployment. Identify requirements and tackle possible challenges related to the transportation, storage and distribution of medical and CBRN countermeasures across the EU.	4.9	List of medical and CBRN countermeasures for stockpiling and deployment under rescEU/UCPM and HERA coordination (with involvement of the HERA Board)	Ongoing	rescEU/UCPM

Task 5. Strengthening knowledge and skills (EUR 5 million, 2022)

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

Action	Deliverables		Timeline (Due date/Status as applicable)	Budget (EUR million; 2022 budget in bold)
Organise training programmes to improve knowledge and skills related to all aspects of access to medical countermeasures.	5.1	Compiling and assessing lessons learnt from the current pandemic at EU and national level (best practices, major problems, critical questions, etc.).		
	5.2	Identify major knowledge gaps and areas where specific knowledge needs to be improved; agree on a comprehensive training schedule to reduce overlap and duplication; identify clear targets for the trainings. Discussion in the HERA Board.	Q3 2022 Follow-up by training activities planned in 2023	
	5.3	Assist all Member States in organising a national/regional assessment process of public procurement practices in the health sector with all relevant stakeholders, including some decision makers. Implementation of these recommendations will make public procurement more efficient and resilient for the future. The first wave of the assessment process will cover 10 Member States, which will be extended to all Member States in 2023.	Q3 2022 – duration of 6 months/per Member State	5
	5.4	Trainings on medical countermeasure management, e.g. for personnel managing the stockpiling of medical countermeasures and interconnection of IT systems between HERA and national counterparts.		

Task 6. International Dimension (EUR 2 million, 2022 + 101.08 million listed under Horizon Europe and EU4Health, and INTPA-managed NDICI resources)

Objective: 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.

Action	Deliverables		Timeline (Due date/Status as applicable)	Budget (EUR million; 2022 budget in bold)
Ensure close collaboration with global partners to address international supply chain bottlenecks, removing unnecessarily restrictions, and expanding global production capacity	6.1	Establish linkages with the Joint EU-US COVID Manufacturing and Supply Chain Taskforce.	Ongoing	
	6.2	Establishing a structured collaboration with US (HHS, BARDA, CDC, etc.) through a Memorandum of Understanding. Establishing a structured collaboration with potential third countries (BARDA-like agencies).	Q1 2022	
	6.3	Establishing a structured collaboration with WHO through a Memorandum of Understanding HERA-WHO.	Q1 2022	
	6.4	CEPI 3 - Contribution to the Coalition for Epidemics Preparedness Initiative. Establishing a structured collaboration with CEPI through a Memorandum of Understanding HERA-CEPI.	Ongoing	35 <i>Listed under Task 2</i>
	6.5	Establishing cooperation mechanism with CEPI, Bill and Melinda Gates Foundation and other relevant organisations. Work with philanthropic foundations.	Q1 2022	
	6.6	Establishing collaboration with the Africa CDC (Jointly with the ECDC) – building on ongoing programme ECDC for AfCDC.	Q1 2022	

		Establishing collaboration with the nascent Africa Medicines Agency in close coordination with the European Medicines Agency. ⁵		
Reinforce global surveillance	6.7	Work with African CDC and the new African Medicine Agency to strengthen global surveillance (also in view of the EDCTP3 Joint Undertaking) and provide regulatory support to African Union.		
	6.8	Work with WHO Berlin Hub (focuses on data, analytics and decision making for detection and response to health emergencies).	Ongoing discussion	
	6.9	Collaboration with WHO global infectious hazard preparedness on data sharing, vaccine composition and virus evolution.	Ongoing discussion	
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	6.10	HORIZON-HLTH-2022-DISEASE-07-01: Support for the functioning of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)		2
	6.11	HORIZON-HLTH-2022-CARE-10-01: European partnership on transforming health and care systems		10 <i>Listed under Task 2</i>
	6.12	European & Developing Countries Clinical Trials Partnership (EDCTP3) Joint Undertaking		20.44 <i>Listed under Task 2</i>
	6.13	Innovative Health Initiative (IHI)		22.64 <i>Listed under Task 2</i>
Provide support to low- and middle-income countries to build expertise as well as develop local manufacturing and distribution	6.14	Support to manufacturing capacity for LMIC countries - assessing the possibility to use EU FAB production capacities in peace times.		

⁵ INTPA's budget: 10 million for AfCDC and ECDC4AfCDC; 20 million for EMA/AMA collaboration.

capacities of relevant medical countermeasures		Support the INTPA-led TEI MAV+: Support to the Partnerships for African Vaccine Manufacturing (PAVM) and support to local production capacity in Africa.		
Support access to EU-funded or EU-procured medical countermeasures and regional and local manufacturing capacities in third countries.	6.15	COVAX and other relevant organisations for donations of medical countermeasures for LMIC countries. ⁶	Ongoing	

⁶ INTA's budget: 100-150 million for distribution of 200 million vaccine doses procured by EU budget.

Crisis relevant actions for COVID-19 response – summary of actions also included under Tasks 1-6.

Action	Deliverables		Timeline (Due date/Status as applicable)	Budget (EUR million; 2022 budget in bold)
Coordination of EU response to COVID-19	1	Management of the Vaccine Steering Board.	Ongoing	
	2	Implementation of the EU Vaccines Strategy, esp. management of the APA implementation.	Ongoing	
	3	Implementation of the EU Strategy of COVID-19 therapeutics, incl. Therapeutics Innovation Booster.	Ongoing	
	4	Establishment of clinical research network for the coordination and conduct of COVID-19 vaccine trials under VACCELERATE (HERA Incubator).	Ongoing	
Procurement and purchase of medical countermeasures	1	Advance Purchase Agreements of COVID-19 vaccines.	Ongoing	
	2	Joint procurement of COVID-19 therapeutics.	Ongoing discussion for new therapeutics with MSD and Pfizer.	
	3	COVAX and other relevant organizations for donations of medical countermeasures for LMIC countries.	Ongoing	
	4	Support to DG INTPA and DG ECHO ongoing initiatives for production and deployment of medical countermeasures beyond Europe (e.g. ongoing DG ECHO support for vaccine deployment in Africa; ongoing discussions on a support package for vaccine deployment). ⁷	Ongoing DG ECHO support for vaccine deployment in Africa	100 (INTPA)

⁷ INPTA's budget: 100 m.

Tackling COVID-19 variants	1	WGS services under the HERA Incubator to rapidly detect COVID-19 variants.	Ongoing	
	2	Expert group on SARS-CoV-2 variants to advise the Commission on (i) the categorization of variants; (ii) the need to develop new or adapted vaccines to the variants; (iii) the criteria and the categories to select the most promising therapeutics for COVID-19; (iv) the need to develop additional public health measures at EU level depending on the variants.	Ongoing	
	3	Cover the information gaps on the risks posed by the appearance of new variants of concern in collaboration with ECDC.		
	4	Set up the HERA Labs network, which supports the Commission by conducting research on variants.	Ongoing	
Improved data collection and sharing on COVID-19	1	European COVID-19 Data Platform	Ongoing	