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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**Review of the implementation of the operations of the Health Emergency Preparedness
and Response Authority (HERA)**

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1. INTRODUCTION

The COVID-19 pandemic brought huge challenges for the EU. It soon became clear that the scale of the EU could make a major contribution to tackling the pandemic, and common action could also ensure better mitigation of the threat. From the first lessons drawn from the COVID-19 pandemic¹, it became clear that more structural solutions were needed, to address the COVID-19 pandemic itself but also to prepare for future health crises. Recent crises reinforce the conclusions of Special Advisor Niinistö's report,² underlining the need for a strong health crisis preparedness and response framework.

The Health Emergency Preparedness and Response Authority (HERA) was set up in a time of urgency, in the midst of the COVID-19 pandemic, and with an acute awareness of the EU's vulnerabilities in preparedness and response to health emergencies. It was recognised from the start that it would be important to review the situation at an early stage³. This report presents a review of the work and functioning of HERA since its establishment and draws first lessons on its achievements.

2. HERA'S SET UP AND ROLE

In the 2020 State of the Union address, President von der Leyen called to build a European Health Union where Member States prepare for, prevent and protect their population against health crises, by acting together where joint European action is necessary. A year later, the State of the Union address set out the establishment of HERA, citing global examples where a dedicated health security structure was in place. HERA was swiftly set up by a Commission Decision⁴ and was able to start its work in 2021.

HERA was tasked with anticipating health threats and potential health crises through intelligence gathering, and with putting in place the necessary response capacities. To allow for a swift operationalisation and to give access to the Commission's existing powers, tools and programmes, HERA was established within the Commission. Given the national competences in the area of health, strong cooperation with Member States was established. HERA is assisted and advised by the HERA Board, with high-level representation from each Member State⁵.

¹ Communication 'Drawing the early lessons from the COVID-19 pandemic', COM(2021) 380, 15.6.2021.

² Report by Sauli Niinistö, former President of the Republic of Finland, in his capacity as Special Adviser to the President of the European Commission: Safer Together: Strengthening Europe's Civilian and Military Preparedness and Readiness (26 November 2024).

³ This was recognised in the Commission Decision establishing the Health Emergency Preparedness and Response Authority, C(2021) 6712, 16.9.2021 (hereafter "HERA Decision").

⁴ HERA Decision, C(2021) 6712, 16.9.2021. See also Communication introducing HERA, COM(2021) 576, 16.9.2021. Preparatory work had started earlier in 2021 following the Communication on HERA Incubator: Anticipating together the threat of COVID-19 variants, COM(2021) 78, 17.02.2021.

⁵ The HERA Board was set up under the HERA Decision. Its role was defined as assisting and advising the Commission in the formulation of strategic decisions concerning HERA, given the need to develop close

When an emergency hits – and to the extent possible, already before – HERA helps to ensure the development, production and distribution of medical countermeasures. Its core mission is set out in the HERA Decision: to improve preparedness and response to serious cross-border threats in the area of medical countermeasures, in particular by:

- strengthening health security coordination during preparedness and crisis response times, and bringing together the Member States, industry and stakeholders in a common effort;
- addressing vulnerabilities and strategic dependencies related to the development, production, procurement, stockpiling and distribution of medical countermeasures;
- contributing to the reinforcement of the global health emergency preparedness and response architecture.

Medical countermeasures⁶ include vaccines, therapeutics (medicines), medical equipment, chemical antidotes, diagnostic tests, and personal protective equipment such as surgical gloves and masks. They can also include services required to prepare and respond to serious cross-border threats to health.

Within this initial mission, HERA is responsible for working on medical countermeasures in terms of assessment of health threats and intelligence gathering; promoting advanced research and development; addressing market challenges and boosting the Union's open strategic autonomy in production; swift procurement and distribution; increasing stockpiling capacity; and strengthening knowledge and skills in preparedness and response.

The creation of HERA was one of a number of steps taken by the Commission to enable the EU and Member States to be better prepared for and better manage health crises, based on the lessons learned from the COVID-19 pandemic. In November 2020, the Commission proposed a “Health union package”. Its adoption led to Regulation 2022/2371⁷ (“Regulation on serious cross-border health threats”), providing a mandate to the Commission for coordination and cooperation for a more effective response to serious cross-border health threats; and to strengthened mandates for both the European Centre for Disease Control (ECDC) and of the European Medicines Agency (EMA). All these steps play a part in helping the EU to anticipate, prepare for, and respond to major health threats – not only infectious diseases but also, for instance, environmental, climate-related and chemical threats, reflecting the evolving threat landscape. This new landscape already put an onus on the importance of coordination and

cooperation between HERA and Member States, ensuring that Member States' resources and capacities are leveraged as much as possible towards HERA's joint goals. Key areas identified for the HERA Board's assistance and advice were: the functions of HERA within the Union's crisis preparedness and response management, research and innovation as well as industrial strategy in the area of medical countermeasures; the scientific/technical management of HERA; and the performance of the tasks entrusted to HERA.

⁶ Medical countermeasures are defined in the Regulation on serious cross-border health threats and include (i) medicinal products for human use, (ii) medical, and (iii) other goods or services necessary for the purpose of preparedness for and response to serious cross-border threats to health.

⁷ Regulation (EU) 2022/2371 on serious cross-border threats to health, OJ L 314, 6.12.2022, p. 26; Regulation (EU) 2022/2370 establishing a European Centre for disease prevention and control, OJ L 314, 6.12.2022, p. 1; and Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ L 20, 31.1.2022, p. 1.

cooperation between HERA and the ECDC and EMA, as well as between structures such as the Health Security Committee (HSC)⁸ and the HERA Board.

In 2023, persistent shortages of critical medicines resulted in calls to step up action at EU level⁹. The Commission responded with a coordinated strategy, building on existing work¹⁰. HERA had already developed experience in addressing market challenges and boosting coordinated EU action in respect of medical countermeasures. HERA therefore was well placed to start to take forward several actions in the area of critical medicines, including helping to launch the Critical Medicines Alliance and a preparatory study on a potential Critical Medicines Act.

3. THE HERA REVIEW

HERA was designed to be a flexible structure that would be adapted as required, and the Commission already committed to a review. The HERA Decision provides for, by 2025, “*an in-depth review of the implementation of the operations of HERA, including its structure and governance. The review shall address in particular any need to modify the mandate of HERA and the financial implications of any such modification*”. This report contains the findings of the Commission’s in-depth review in accordance with that requirement.

Elements relevant to the review were also included in other legal acts. The regulation on serious cross-border health threats¹¹ and Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (the “Emergency Framework Regulation”)¹² both provide for an evaluation of their implementation by HERA, as well as an assessment of the need to establish HERA as a distinct entity (i.e. separate from the Commission). The Emergency Framework Regulation covers response actions only and it has not so far been activated, so there is formally no action to assess. This report follows the logic of the HERA Decision, also addressing the issue of assessing HERA as a distinct entity in accordance with the different review provisions.

HERA was set up in a landscape of existing legal and funding tools. It benefited from being established under a dedicated Commission Decision, reflecting HERA’s particular nature and the circumstances in which it was established. Setting up a service inside the Commission

⁸ The role and composition of the Health Security Committee is set out in the Regulation on serious cross-border health threats. It is composed of representatives of Member States, with EU agencies as observers. Its tasks are to: (a) support coordinated action by the Commission and the Member States; (b) liaison with the work of the Commission on prevention, preparedness and response planning; (c) coordinate, in liaison with the Commission, the risk and crisis communication and responses of the Member States; (d) adopt opinions and guidance for Member States, including on specific response measures; and (e) an annual work programme.

⁹ The June 2023 European Council conclusions invited the Commission to “propose an initiative for urgent measures to ensure sufficient production and availability of the most critical medicines and components in Europe and to diversify international supply chains”.

¹⁰ See Communication Addressing Medicine Shortages in the EU, COM(2023) 672, 24.10.2023.

¹¹ Article 33, second subparagraph, of the regulation on serious cross-border health threats : “*The evaluation ...shall also include an evaluation of the Commission's work in preparedness and response activities provided for in this Regulation including, where relevant, a review of the implementation of this Regulation by [HERA], as well as an assessment of the need to establish HERA as a distinct entity, considering relevant agencies or authorities active in the field of health preparedness and response*”.

¹² Article 16 of the Emergency Framework Regulation: “*That review shall include an evaluation of the work of [HERA] under the emergency framework established by this Regulation, and its relation to the preparedness activities of HERA. That review shall also include an assessment as regards the need to establish HERA as a distinct entity considering relevant agencies or authorities active in the field of health crisis.*”

through an establishing Decision is not common, but was not unprecedented¹³. The HERA Decision does not impinge on the prerogative of the President to assign additional tasks¹⁴ – as illustrated when HERA was tasked with launching work on critical medicines.

The Commission has organised the review in separate workstreams. An external study¹⁵ drew on stakeholder consultation, including public consultation, a call for evidence, targeted surveys and interviews, as well as an extensive literature review. A separate workstream looked into the internal dimension within the Commission and the interaction with the ECDC and EMA.

The consultation exercise encompassed a public consultation¹⁶, call for evidence feedback¹⁷, targeted surveys¹⁸ and interviews¹⁹. The consultation covered the general public, Member State national authorities (covering health, civil protection, industry and research), the European Parliament, EU agencies, international organisations and partners, as well as concerned stakeholders (civil society, healthcare professionals, patients, industry, researchers etc.). It also drew on the reports of internal and external audit services.

The review has also drawn on positions from both the European Parliament and the Council. The European Parliament's July 2023 resolution on lessons to be learned from COVID-19²⁰ saw HERA as a "much-needed body to improve the EU's preparedness for health emergencies". It also argued for HERA as an "independent EU agency with sufficient funding" and called for a greater degree of parliamentary scrutiny. This was echoed in April 2024 when the European Parliament agreed its position on the pharmaceutical reform, proposing to make HERA a separate entity under the ECDC. As for the Council, the most recent conclusions came in June 2024, with the Council Conclusions on the Future of the European Health Union²¹. These included a call for a thorough evaluation of the post-pandemic EU health emergency governance framework, and to clarify the relations between relevant entities involved in crisis preparedness and management. This debate has continued: On 4 February 2025, 12 Member States submitted a non-paper to the Commission on HERA's missions and governance, calling on the Commission to preserve HERA's structure. This argued that HERA's "missions are an

¹³ The European Anti-Fraud Office OLAF was also set up by a Commission Decision of 28 April 1999.

¹⁴ Article 17(6) (b) TEU provides that the President of the Commission shall "decide on the internal organisation of the Commission".

¹⁵ <https://data.europa.eu/doi/10.2929/322979> (Study) and <https://data.europa.eu/doi/10.2929/939775> (Executive summary).

¹⁶ The Public Consultation questionnaire published on the Commission's central webpage *Have your say* was launched on 27th November 2023 and ran until 19th February 2024. A total of 44 submissions to the questionnaire were received, and 19 documents were uploaded by respondents.

¹⁷ The Call for Evidence was launched on 28th November 2023 and closed on 19th February 2024. The total number of replies received was 47, including 15 attached documents. The feedback to the call for evidence is available on the *Have your say* portal.

¹⁸ Three sets of targeted surveys were sent to identified stakeholders on 28th November 2023. The surveys yielded a total of 210 responses. Six duplicated responses (same author, same reply) were deleted. Out of the remaining 204 responses, only those that replied to at least 30% of the questions were considered in the analysis. Overall, 117 valid responses across the three stakeholder groups were considered.

¹⁹ Nine targeted interviews were conducted, comprised of six MEPs, two representatives of ECDC and EMA and one advisor to the Commission.

²⁰ [Texts adopted - COVID-19 pandemic: lessons learned and recommendations for the future - Wednesday, 12 July 2023 \(europa.eu\)](https://data.europa.eu/doi/10.2929/322979)

²¹ Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects, see <https://data.consilium.europa.eu/doc/document/ST-9900-2024-INIT/en/pdf>

essential element of the EU's sovereignty and strategic autonomy that must be dealt with centrally and specifically without losing the health perspective.”

Although this review of HERA is a *sui generis* exercise, the process has sought to follow the principles of the Better Regulation Guidelines to the extent possible. It assesses the implementation of HERA's operations, including its structure, governance and mandate, compared with the situation before its establishment²².

4. HERA'S WORK AND INTERACTIONS WITH OTHER SERVICES AND STAKEHOLDERS

The ecosystem for health crisis preparedness or crisis response is complex: an effective response needs to engage a wide variety of stakeholders, at national, EU and global level. HERA's goal to reinforce the existing health security framework implies close cooperation and coordination with other services of the Commission, EU agencies, and other structures. Key areas of cooperation include Commission services responsible for health²³, research and innovation, civil protection and international partnerships; the EU agencies EMA and ECDC, as well as the European Health and Digital Executive Agency (HaDEA)²⁴ on implementation; and with Member States, industry and civil society. In addition, there has been significant cooperation with international organisations and third countries.

This interconnection of different dimensions of health preparedness and response requires a constant flow of information, common prioritisation, and operational cooperation and coordination.

4.1. Work with Member States and other stakeholders

One of the defining features of HERA is cooperation and coordination with national efforts. The HERA Board brings together senior Member States representatives to assist and advise the Commission on strategic decisions concerning HERA activities. The work of the HERA Board can also help decision-making at the national level, because it informs Member States of the broader European context. Representatives of the ECDC and the EMA, the Emergency Response Coordination Centre, as well as a representative of the European Parliament, may participate as observers in the meetings of the HERA Board, and other Commission services have also been regularly invited to attend. To strengthen information exchange and knowledge generation more broadly, the HERA Board is also supported by the HERA Advisory Forum, consisting of Member State experts from the area of health, research and industrial policy. As a subgroup of this Forum, a Joint Industrial Cooperation Forum has been set up to link Member States and industry representatives. The Civil Society Forum ensures exchanges with academia and civil society.

In the area of critical medicines, the Commission set up the Critical Medicines Alliance (involving Member States, industry and civil society), with HERA as secretariat, and EMA and

²² This review assesses the operations of HERA until the end of November 2024.

²³ In addition to the usual processes to align within the Commission, the HERA Decision points explicitly to a close collaboration with the Directorate-General for Health and Food Safety.

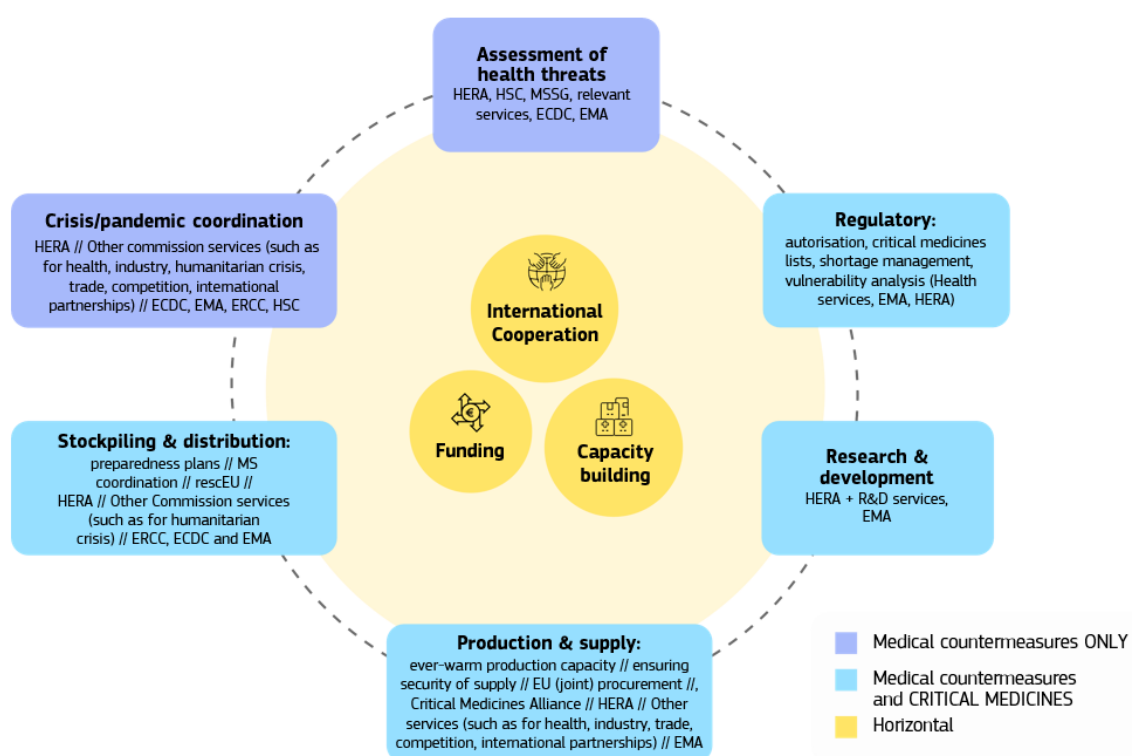
²⁴ As an executive agency, the European Health and Digital Executive Agency supports EU policies through operational support to the work of the Commission.

its Medicines Shortages Steering Group (MSSG²⁵). Other Commission services with responsibilities linked to critical medicines are involved in the work of the Alliance and able to link into their own stakeholder networks.

To improve the coordination of clinical research in response to public health emergencies, a dedicated sub-group of the HERA Board was established in June 2024 to advise on the prioritisation of clinical trials and their funding for public health emergencies (the Clinical Trials Coordination Mechanism) and involves several Commission services, Member States, and the EMA.

4.2. HERA's contribution to health security preparedness and response

Actors and tools in delivery on medical countermeasures (MCMs) and critical medicines (CMs)



Assessment of health threats to ensure the availability of medical countermeasures

Several actors have responsibilities for the assessment of health threats. ECDC²⁶ monitors communicable diseases, including identification and assessment of the threats to human health from communicable diseases. It also provides science-based recommendations and support to the coordination of the EU response. The Health Security Committee (HSC)²⁷ brings together Member States representatives with the Commission services dealing with prevention of cross-border health threats, health security preparedness and response, as well as health crisis

²⁵ The role of the MSSG, is to ensure a robust response to medicine supply issues caused by major events or public-health emergencies. It coordinates urgent actions within the EU to manage medicine supply issues and issues related to the quality, safety and efficacy of medicines.

²⁶ Article 3 of Regulation (EU) 2022/2370.

²⁷ Article 4 of Regulation (EU) 2022/2371.

response and coordination. A key role of the HSC is to ensure coordinated action by the Commission and Member States, including on prevention, preparedness and response planning. It provides opinions and guidance on preparedness, planning, risk and crisis communication and response – drawing on the expertise of EU agencies (for example, EMA's input on the effectiveness of different medicines, ECDC's rapid risk assessments, or the European Chemicals Agency's risk assessment of a threat of chemical origin).

In addition to advice received from the HERA Board, HERA draws on the work and on expertise from across the Commission and EU agencies. Delivering results action in the area of medical countermeasures involves different actors at different stages. Early analysis, the definition of gaps and the prioritisation of needs feeds action, to target the problems identified by deploying steps such as fostering research and development, boosting production capacity or joint procurement. This requires close cooperation – between Member States, ECDC, EMA and the Commission, as well as inside the Commission.

After broad consultation²⁸, in June 2022, HERA put forward the first list of high-impact health threats to ensure preparedness and response, in particular by addressing possible gaps in the availability and accessibility of medical countermeasures. This list guides EU-level medical preparedness interventions, also tied into global alignment and close collaboration on global health security. The list of priority threats identified by HERA, as updated in 2024, includes anti-microbial resistance (AMR), pathogens with pandemic potential and CBRN (Chemical, Biological, Radiological and Nuclear) threats originating from accidental or deliberate release, and threats associated with emerging technologies. Climate change is increasingly seen as a growing threat²⁹. HERA, in consultation with Member States and its Joint Industrial Cooperation and Civil Society Forum, also established a catalogue of medical countermeasures relevant for preparedness and response to these threats. This prioritisation then informs actions in terms of research and development, industrial policy measures such as manufacturing capacity, and procurement or stockpiling actions.

Research and innovation

Research and innovation are critical to the delivery of medical countermeasures now and into the future. This is carried out by the public or private sector, using private or public, national or EU funds. When HERA was established, it was recognised that this work should draw on two main sources of funding: Horizon Europe, the EU Framework Programme for Research and Innovation, in particular its cluster on Health, and the EU4Health programme.

HERA, taking into account the advice of the HERA Board and together with other Commission services responsible for research and innovation, assesses the need and priority for novel medical countermeasures with a view to providing effective, safe and affordable products. Depending on the assessment, EU funds can be directed either to the earlier stages of research

²⁸ HERA consulted Member States, Union and national agencies, Chief Medical Officers, international actors and experts on the threat prioritisation exercise. At the international level, HERA has notably exchanged with specific departments of government in the United States, CEPI, and the WHO Hub for Pandemic and Epidemic intelligence. The first ever list of top-3 health threats was presented in July 2022. HERA's work on threat assessment and prioritisation will continue to be regularly updated.

²⁹ Climate change impacts health in many different ways, including death and illness caused by increasingly frequent extreme weather events; the disruption of food systems; increases in zoonoses and food-, water- and vector-borne diseases; and mental health issues. It also undermines many of the social determinants for good health, such as livelihoods, equality and access to health care and social support structures.

(for example, to innovative anti-microbials), or to boost development of products that are closer to approval. The EMA also has a key role in terms of expertise on the effectiveness and efficacy of different products, as well as when these products reach the approval stage.

This work has supported research and innovation within the Horizon Europe programme to develop medical countermeasures for pathogens with high pandemic potential. This includes the development of next-generation vaccines, in vitro diagnostics, and broad-spectrum antivirals. A notable achievement was the Commission's support for the first-ever vaccine protecting against Chikungunya virus, a mosquito-borne virus that poses a growing threat to the EU due to climate change³⁰. The vaccine was authorised by the Commission in June 2024.

The ability of the EU to respond to patients' future needs for medical countermeasures will depend heavily not only on research results, but on ensuring the development and scaling up of successful research projects. HERA supports this effort, including through innovative financing tools to help offset potential underinvestment by the private sector. In 2023, EUR 100 million from EU4Health were directed to Invest EU programme³¹, to facilitate the development and production of innovative medical countermeasures. "HERA INVEST" provides financial support to innovative European small and medium-sized enterprises working on medical countermeasures against high-impact health threats. The first transactions support measures on CBRN countermeasures and new antimicrobials.

EU research funding has well-established ways of working determined by its legislative framework, often with a focus on basic research and the pre-clinical phase, whereas HERA's work tends more naturally towards research closer to market deployment.

Critical medicines, vulnerability analysis, management of shortages

For critical medicines, HERA has started to build up a monitoring capacity through interaction with the EMA³² and the MSSG, which fed the discussions in the Critical Medicines Alliance.

Following the Commission Communication on medicines shortages³³, HERA and the Commission service dealing with the Internal Market jointly led a pilot project on vulnerability analysis, in order to help develop a methodology for critical medicines in the Union list³⁴. 11 critical medicines were selected, to cover a broad set of supply chain specificities. This analysis has been the basis of the work of Critical Medicines Alliance and contributed to reinforcing expertise in market and supply chain intelligence. While the responsibilities for Critical Medicines Act have now been entrusted to the Commission service dealing with health, HERA will continue to provide support on collaborative procurements, given its experience in this area and the overlaps between critical medicines and medical countermeasures.

³⁰ An EU Horizon partnership with the Coalition for Epidemic Preparedness Innovations (CEPI) has been ongoing already since 2019.

³¹ The Research, Innovation, and Digitalisation Policy Window Thematic Innovation financial product.

³² In crisis times, EMA, under its renewed mandate, monitors the shortages of medicines and medical devices. See Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ L 20, 31.1.2022, p.1

³³ "Addressing medicine shortages in the EU" COM(2023)672, 27.10.2023.

³⁴ Article 131 of the proposed revision of the pharmaceuticals legislation COM(2023) 193, 26.4.2023. A first version of the Union Critical Medicines ([First Union Critical Medicines list \(europa.eu\)](https://european-council.europa.eu/media/en/press-communications/infographic/infographic-union-critical-medicines-list)) list was published on 12 December 2023 by the Commission, the EMA and Member States' Heads of Medicines Agencies.

Encouraging supply and production

The COVID-19 pandemic demonstrated that industrial readiness and security of supply chains are key for emergency preparedness and response. Monitoring of supplies, addressing market failures and a targeted industrial policy are necessary to ensure access to medical countermeasures and critical medicines, to meet the needs of patients and citizens and promote the EU's open strategic autonomy.

Recognising that crises can bring surges in demand, ever-warm production capacities and support given to develop innovative medicine production technologies and processes were recognised as a key element of preparedness. In 2022, the Commission set up the EU FAB programme³⁵, the EU's first ever-warm network of manufacturing facilities for vaccines. Annually, EUR 160 million is devoted to ensuring sufficient and agile manufacturing capacities for three different vaccine platforms in six production facilities located across Europe. This network is ready to be activated swiftly in the event of a public health emergency and to deliver up to 325 million doses annually.

Tackling the risks of anti-microbial resistance is an EU priority³⁶. HERA is working to coordinate measures at EU level to ensure access to the relevant antimicrobials, but also to diagnostics, other treatments and vaccines preventing the unnecessary use of antimicrobials. In addition, to improve access to antimicrobials that are by their nature very rarely used and not widely available across the EU, HERA is working with 23 Member States to develop a financial pull incentive, in the form of a revenue guarantee. This revenue guarantee scheme would offer an annual revenue guarantee to producers, in return for launching and maintaining production on the market and deliver the ordered products in participating countries within 24 hours. Unfortunately, so far none of the pilots have led to an agreement with a producer.

Collaborative procurement, in its various forms, can be a powerful tool, giving assurances of scale to manufacturers and suppliers and assurances of delivery to Member States. Based on contracts initially negotiated by the Commission service dealing with health, joint procurement has been used by HERA to secure the products needed to address COVID-19. HERA secured medical countermeasures to address mpox, or zoonotic avian flu³⁷. This included vaccines, but has also been used for other key products such as personal protective equipment. Lessons learned include the need to ensure that purchase agreements promote post-authorisation and comparative research. This makes an important contribution to the securing reliable supply of medical countermeasures.

³⁵ Framework contract signed under EU4Health to guarantee a fast response to future health crises - European Commission (europa.eu).

³⁶ Antimicrobial resistance is considered a serious cross-border health threat under the Regulation on serious cross-border threats to health. It is estimated that more than 35 000 people die each year in the EU/EEA as a direct consequence of an infection due to bacteria resistant to antibiotics, with the situation deteriorating. For more details on state of play and EU measures, see Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (2023/C 220/01), OJ C 220, 22.6.2023, p. 1.

³⁷ Making use of 'Purchase Agreements,' Joint Procurement, Emergency procurement under EU4Health and through stockpiling under rescEU.

This industrial action experience on medical countermeasures was the basis for HERA taking responsibility for supporting similar activities in the area of critical medicines. The work on critical medicines has been crystallised in the Critical Medicine Alliance, and led to a first set of recommendations in a strategic report in February 2025³⁸, identifying priority challenges and recommending possible steps at EU level to tackle the vulnerability of supply chains for critical medicines. The Commission has followed up with a proposal to enable structural cooperation and industrial measures in the form of a Critical Medicines Act³⁹. The task-force approach with the Commission service dealing with health will continue on critical medicines, with HERA focusing on collaborative procurements.

HERA's work necessarily involved coordination at EU level, between Member States and with a wide variety of EU policies, in the broader setting of EU public health, industrial policy, strategic autonomy and economic security, with major efforts under way to ensure EU supply in areas such as critical raw materials. It also needs to work with broader policy goals in health, the global dimension, competition, and trade. The expertise of other Commission services, the EMA and Member States is essential to ensure effective targeting and delivery. It is increasingly important that information is available on existing capacity to meet future needs. HERA brings together industry, Member States and other stakeholders, fostering collaboration to identifying actions and instruments to address vulnerabilities in the supply chains of critical medicines and of medical countermeasures at large. The working relations developed by HERA with third country equivalent organisations also help in addressing these issues with like-minded partners.

Stockpiling and distribution

The Commission has a well-developed crisis response policy and coordination mechanism in civil protection⁴⁰. Medical needs are at the forefront of EU response capabilities, and when HERA was established, the provision of medical countermeasures at times of crisis was recognised as a key part of this work. In the EU, stockpiling and distribution of medical countermeasures remain a primary competence of Member States, supported by EU-level initiatives such as rescEU. Nevertheless, the added value of coordination and complementary action at EU level is recognised as an essential element of preparedness, so HERA works to this end.

The legal framework of the rescEU programme governs how this work is taken forward. Since its creation in 2022, HERA has stepped up, in coordination with the Commission service responsible for civil protection, the work with Member States to identify where stockpiles are required to be ready in case of needs which can follow pandemics, but also security threats such as CBRN attacks. By the end of 2024, a total of thirteen grant agreements were put in place, with stockpiles so far focused on CBRN, containing antidotes, antibiotics, and vaccines,

³⁸ https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en?filename=hera_cma_strat-report_en.pdf

³⁹ COM(2025) 102, 11.03.2025.

⁴⁰ Civil protection assistance consists of governmental aid delivered in preparation for or immediately after a disaster strikes in Europe and worldwide. When an emergency strikes, the EU Civil Protection Mechanism can be activated by national authorities to enable a coordinated assistance. The Emergency Response Coordination Centre (ERCC) is the heart of the EU Civil Protection Mechanism. It coordinates the delivery of assistance to disaster-stricken countries, such as relief items, expertise, civil protection teams and specialised equipment. The ERCC operates 24/7. It can help any country inside or outside the EU affected by a major disaster upon request from the national authorities or a UN body.

as well as specific CBRN response equipment such as detection, decontamination, and personal protective equipment.

These rescEU stockpiles are designed to be used as a last resort, complementing national stockpiles and only activated when national capacity is exhausted. They provide an extra layer of preparedness and can be accessed by Member States and rescEU partner countries. However, stockpiling is a complex exercise, with many different factors to consider (including shelf-life, regulatory requirements, environment and security requirements, and transport), requiring strong coordination with EU and national authorities and experts. Under the mandate of the new Commission, HERA is developing a Strategy on medical countermeasures, alongside a wider reflection on stockpiling, as part of the Preparedness Union Strategy.

Contribution to coordination and response to public health emergencies

Health crisis coordination and crisis response in the EU is governed by different legislation. The Regulation on serious cross-border threats to health is the main legal act, setting out the EU health security architecture, including mechanisms such as for EU agencies to provide risk assessments, for the coordination of response within the Health Security Committee, for ensuring public health preparedness, including of relevant national capacities of Member States, and also the procedure for recognising a public health emergency at Union level⁴¹. HERA contributes to its implementation, notably on the provisions of joint procurement.

In the event of a public health emergency, the Emergency Framework Regulation allows the Commission to propose to Council to activate emergency measures to ensure the supply of crisis-relevant medical countermeasures, as well as setting up a Health Crisis Board⁴². If emergency measures are activated (“crisis response mode”), the state of play for crisis-relevant medical countermeasures and raw materials is to be monitored, including production capacity, stockpiles, and the risk of disruption in supply chains – this would be a key role for HERA and preparation for this eventuality is an important part of HERA’s work.

This preparedness for crises ensures that it can effectively and efficiently operate in the EU crisis response architecture, requiring strong coordination and collaboration with other Commission services, Member States and stakeholders. HERA organises regular simulation exercises to assess coordination and interoperability between all EU institutions involved in the current health crisis architecture and to ensure better preparedness of all actors. Procedures to optimise HERA’s response, by developing an emergency protocol, and threat-specific response blueprints, have also been developed.

Capacity building for Member States

HERA’s role includes work with Member States which have identified gaps, sharing best practices learnt from previous health crises and strengthening skills and knowledge on the full cycle of management of medical countermeasures through tailored trainings and exercise programmes. Since 2023, training offered by HERA has included four dedicated workshops,

⁴¹ By the Commission, after considering any expert opinion issued by the ECDC, with provision for independent advice to be provided to the Commission and the Health Security Committee by an Advisory Committee, amongst others on whether a threat constitutes a public health emergency at Union level and on response measures (see Article 23 of Regulation 2022/2371).

⁴² EMA, ECDC, the Advisory Committee under Regulation (EU) 2022/2371 on serious cross-border threats to health, and the Health Security Committee, as well as the European Parliament.

on the scope and operational management of stockpiles of medical countermeasures, and on public procurement. This work complements ECDC training to build capacity in areas such as epidemic intelligence and risk assessment. A Pact for Skills in the pharmaceutical sector also supports the development of skills to help production in this area.

HERA also organises tabletop exercises to assess coordination and interoperability between HERA and Member States. This work requires a strong coordination with Member States and other Commission services. It also requires strong coordination within the EU in relation to global outreach to link into the work of the World Health Organization Academy.

International coordination

HERA's work has an important international dimension. Supporting the availability of medical countermeasures depends on global supply chains, while new medical countermeasures are developed in the context of a global research community. With the aim to provide early information regarding possible needs for medical countermeasures, HERA also supports work to reinforce global surveillance and intelligence gathering, in coordination with ECDC.

HERA collaborates at global level with the World Health Organization Hub for pandemic and epidemic intelligence and the African Centre for Disease and Control, and bilaterally with similar organisations in countries such as the United States, Japan, South Korea and Canada. Working arrangements have been put in place or are being developed to frame these collaborations. On more sectoral issues, HERA is also supporting the Global Antibiotic Research and Development Partnership, the Coalition for Epidemics Preparedness Initiative and the work of the European and Developing Countries Clinical Trials Partnership⁴³. This work needs to be taken forward in close synergy with the wide range of ties developed in other areas of health and international partnerships policy and programmes by the Commission services and the EEAS, EU agencies, and Member States. HERA's work on the production and supply of medical countermeasures also feeds into the Commission's work to deepen the global framework for health, including negotiations on a potential new WHO Pandemic Agreement.

4.3. Funding

The EU budget allocated to health, and to protecting citizens from cross-border health threats in particular, saw a steep rise with the COVID-19 crisis. In the period 2014-2020, only EUR 5.4 million was allocated for crisis preparedness, out of a total of around EUR 500 million for health policies in total. This amount has risen significantly under the EU4Health Programme for the 2021-2027 period, which had an overall budget of EUR 5.4 billion.

When HERA was created, it was recognised that substantial funding would be required at EU level, to complement the investment by Member States in their own preparedness. With the 2020-2027 Multiannual Financial Framework already under way, funds were identified to be devoted to HERA's activities from existing programmes: EU4Health, Horizon Europe and rescEU. This amounted to some EUR 6 billion.⁴⁴ However, a targeted revision of the

⁴³ <https://www.global-health-edctp3.europa.eu/>

⁴⁴ Other EU programmes also make an important contribution to the resilience of health systems (and therefore to preparedness for crisis), such as the Recovery and Resilience Facility, REACT-EU, STEP44, Cohesion Funds and the InvestEU Programme, as well as the Neighbourhood, Development and International

Multiannual Financial Framework⁴⁵ led to a reduction of several programmes, including EU4Health and Horizon Europe. To mitigate the reduction, the largest part of this cut would be in 2027, when the budget will be at its peak.

HERA manages funds mainly devoted to promoting advanced research and innovation of medical countermeasures, production capacity, and joint procurement, as well as stockpiling and health crisis coordination, in cooperation with other Commission services. It also supports threat assessment capacities and surveillance systems. Private funding has also been mobilised under InvestEU through HERA Invest leveraging cooperation with the European Investment Bank Group and other financial actors. Both national support for actions related to preparedness and response to health threats, and multi-country projects, can also contribute to the mission of HERA⁴⁶. This diversity of funding sources allows HERA to use different types of award procedures and financial instruments under direct and indirect management, varying from grants, procurements, and financial instruments/loans under the Financial Regulation⁴⁷.

The fact that HERA's activities draw on existing funding programmes also means that these activities are governed by the legal frameworks already in place, implying different governance structures, and different stakeholders, with a broader range of concerns than the specific goals of HERA. This means not only that the different services responsible inside the Commission need to be well coordinated, but it also calls for close cooperation at national level between the HERA stakeholders and the Member States representatives in the governance bodies/programme committees of the respective funding programmes.

HERA's activities, whether innovative steps such as maintaining ever-warm production facilities, or pull incentives for antibiotics, meet very targeted needs. For example, it is often only late in the product development cycle that the specific medical countermeasures required can be defined. This is not always easy to reconcile with the existing programmes on which it draws for funding.

5. FINDINGS OF THE REVIEW

The review has sought to assess HERA's relevance, effectiveness, efficiency, coherence and EU added value.

The relatively recent establishment of HERA means that any assessment of its delivery must recognise that much of its work is still being developed and consolidated. The fact that HERA took on new tasks related to critical medicines also underlines that its tasks as set out in the HERA Decision are evolving with changing needs. Nevertheless, all its key work strands are being implemented, and a wide variety of stakeholders have been able to comment on how they see the effectiveness of its work so far.

Cooperation Instrument (NDICI) outside the EU. During the COVID-19 pandemic, the EU also drew on the possibilities offered by the Emergency Support Instrument (ESI), demonstrated to be both flexible and fast.

⁴⁵ This aimed at providing urgent financial support to Ukraine, supporting EU action on migration, investing in strategic industries and covering higher NextGenerationEU funding costs.

⁴⁶ For example, Important Project of Common European Interest (IPCEI) define actions to promote the execution of an important project of common European interest.

⁴⁷ Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 and the financial rules applicable to the general budget of the Union (recast).

The quantitative evidence base of this review is necessarily limited, given its timeframe, so the emphasis has been on qualitative evidence and analysis.

As HERA's "crisis response mode" has never been activated by the Commission, there are no points of comparison against which HERA's performance during a recognised public health emergency can be assessed. Nevertheless, HERA's role in the response to the mpox outbreaks in Europe in 2022 and in Africa in 2024 help to assess HERA's performance in emergency response⁴⁸. As HERA works at EU level, and that combined efforts are central to its way of working, it cannot be compared quantitatively with institutions performing similar functions at the national level.

In reviewing HERA's actions, it is important to note that it is closely integrated and builds on the work of other entities, in particular of other services inside the Commission, EU agencies, or Member States. The ability of HERA to help galvanise a collective impact within the EU, as well as cooperating with partners globally, should be seen as an important part of the work to be analysed.

5.1. Key points from the review exercise

The different workstreams of the review, and including the study carried out by the external contractor, have resulted in a comprehensive picture of HERA's work. The study sets out findings relating to effectiveness, efficiency, relevance, coherence and EU added value. A summary of the consultation exercise undertaken as part of the external study has also been published⁴⁹.

The consultation exercise reported a consensus among the general public, stakeholders and experts that HERA's mission remains *relevant* and in line with the EU policy goals and priorities⁵⁰. As new threats emerge or gain in importance – whether climate change, accidental or deliberate health threats – actions to reinforce preparedness and response at EU level will continue to be required. The role of the EU in working to reduce the risks of not being sufficiently prepared, and to help in response, now seems well established.

Member States as well as international stakeholders recognised the importance that the Commission could play in that field, and the additional role played by HERA since its creation has been welcomed by several stakeholders from Member States, industry and civil society. In less than three years, and in the wake of an unprecedented health crisis, HERA is seen to have brought concrete and new deliverables. The added value of EU action also helped to contribute

⁴⁸ WHO Director-General Dr Tedros Adhanom Ghebreyesus determined on 14 August 2024 that the upsurge of mpox in the Democratic Republic of the Congo and a growing number of countries in Africa constituted a public health emergency of international concern (PHEIC) under the International Health Regulations (2005).

⁴⁹ Factual Summary Report of the Contributions to the Public Consultation and Stakeholders Consultation on HERA Review - Synopsis Report, available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14035-Review-of-the-Health-Emergency-Preparedness-and-Response-Authority-HERA-public-consultation_en

⁵⁰ In both the Public Consultation and in the targeted surveys there is above 80% agreement that HERA's mission and activities are still relevant, that the needs addressed require action at EU level, and that HERA's activities correspond to wide EU policy goals and priorities. This clearly converges with opinions expressed in scientific articles and policy reports, as well as with the views stakeholders expressed in free-text replies to open questions, in documents attached to the Public Consultation and to the Call for Evidence, and in targeted interviews. <https://data.europa.eu/doi/10.2929/322979>, pages 20-23.

to the visibility of EU leadership in health security. The role demonstrated by HERA was also reflected when it was called upon to stimulate the active participation of key stakeholders in the Critical Medicines Alliance and the role it will continue to play in supporting collaborative procurements of critical medicines and of other medicinal products of common interest.

From the perspective of *effectiveness* of its actions, the consultation and the analysis⁵¹ of the 77 activities launched and implemented by HERA in its first three years of activity⁵² show the different ways in which HERA has worked on its specific objectives. HERA has positively contributed to strengthening the health security architecture in the EU, through coordination and centralisation of activities, strengthening threat assessment capabilities, improving intelligence on market and supply chain intelligence, and contributing to research on, as well as production and deployment of, new medical countermeasures to be deployed in times of crisis. When Europe was faced with the mpox outbreak in 2022, HERA responded immediately by purchasing and donating medical countermeasures to affected countries, drawing on the EU budget for the first time for this purpose.

The joint procurement instrument in particular has proven very valuable, with medical counter measures being secured for better preparedness against zoonotic avian influenza, COVID-19 or diphtheria. HERA's work contributed to the overall stockpiling already under way under rescEU. The stockpile of medical and CBRN countermeasures are seen to have offered an effective contingency for preparedness: the experience will help to inform the stockpiling strategy foreseen to be adopted soon.

HERA cooperated effectively with other Commission services, including the Emergency Response Cooperation Centre, to manage rescEU grants and ensure the distribution of vaccine donations via ReliefEU.

As regards the international dimension, HERA has developed into a credible and recognised player valued by international partners, as for example illustrated by the rapid response to the mpox outbreak in Africa during the summer of 2024, where the Commission purchased, donated and coordinated Team Europe donations of vaccines. Synergies were developed with the EU's humanitarian response capacity (ReliefEU) managed by the ERCC to ensure the effective delivery of the donations of Member States to the different affected countries, as well as with research projects on global health.

The ability of HERA to respond to challenges beyond the tasks set out in the HERA Decision, by mobilising resources and offering innovative solutions to new emerging issues, such as the shortages of critical medicines, also demonstrates its effectiveness, as well as its flexibility and readiness to respond intrinsic to its mission.

This effectiveness also needs to be seen in the broader context of the Commission's approach to build a European Health Union with a strong health security pillar in response to COVID-19 pandemic, that will continue to be developed as part of a wider EU Preparedness Union Strategy. The broader efforts of the Commission and EU agencies, as well as the impulse given

⁵¹ Detailed analysis per specific objectives on pages 25-40 of the final study, <https://data.europa.eu/doi/10.2929/322979>

⁵² The study sets out HERA's activities under the 2022, 2023 and 2024 Work Programmes. See <https://data.europa.eu/doi/10.2929/322979>, study table 3 (p. 32).

to cooperation with Member States in the wake of the pandemic, have all been key to the ability of HERA to deliver.

In terms of resource *efficiency*, the external study⁵³ showed that, based on the budget spent so far, HERA produced most of the planned outputs within the costs initially foreseen. HERA has a very important role in the design of the work programmes and of different calls, but this can vary between funding programmes. As HERA relies on different funding programmes, strong coordination and cooperation between services is needed to avoid overlaps and inefficiencies in the management of funds. For the implementation of its tasks, HERA also uses innovative funding mechanisms.

A majority of consulted stakeholders consider that the potential benefits from HERA's activities largely outweigh its cost. This seems to be in line with analysis concluding that investment in preparedness is generally cost-effective, given the risk of much higher costs in the event of a crisis and given the evidence that EU-level action can provide real added value.

HERA contributed to *coherence* by giving a new focus to pandemic preparedness in the work of the EU. Coordination during preparedness and crisis response times is a key mission of HERA, with the establishing decision specifying that HERA should bring together Member States, industry and stakeholders. The HERA Board has played a key role in this regard. HERA coordinates and collaborates with other entities at five levels: first, with other Commission services, and with agencies; second, with Member States⁵⁴, both bilaterally and collectively; third, with countries included in the WHO's European Regions that are not part of EU27 or EEA³⁰; fourth, at global level with the WHO and with other key groupings such as the G20 and G7, to promote collective agreements on sustainability and resilience; and finally, in bilateral collaborations, both on an intergovernmental basis and with private companies, especially in countries with strong research infrastructure.

This complex environment requires HERA and its partners to pay particular attention to collaboration and coordination. The Commission has well-established procedures for internal coordination, and a dedicated Coordination Committee was set up at political level to provide strategic oversight⁵⁵. Strategic coherence entails that HERA draws on the work of EU agencies, including in terms of threat intelligence (primarily from ECDC) and medical countermeasures intelligence (with a strong role by EMA), as well as on the guidance and advice provided by the HERA Board and the Health Security Committee.

HERA also helped in ensuring coherence and coordination with national and international activities, considering the limited resources available globally for the area. It also offers a more coherent and strategic approach between different EU instruments.

HERA delivers *EU added value* by filling the gap at EU level identified at the time of the pandemic, drawing on the scale and versatility possible at EU level to effectively complement Member State efforts on medical countermeasures. For example, the organisation of cost-effective procurement offered an outcome that was both more certain in terms of delivery and

⁵³ <https://data.europa.eu/doi/10.2929/322979>, pages 51-59.

⁵⁴ And, on some issues, with the 30 members of the European Economic Area.

⁵⁵ The Coordination Committee provides political steering on the planning and implementation of HERA's tasks and is composed of the Vice-President of the Commission in charge of Health, the Member of the Commission in charge of Health and the Members of the Commission in charge of the Internal Market, Innovation and Research and Crisis Management.

more equitable in terms of access. Further stockpiling of medical countermeasures under rescEU was also cited by a number of stakeholders as bringing added value, drawing on effective cooperation within the Commission.

The HERA Decision explicitly defines HERA's activities, and the focus on improving preparedness and response to cross-border threats in the area of medical countermeasures. But HERA's added value has also been shown in developing skills and experience which can be drawn on in other areas. When HERA was called upon to act in the area of critical medicine shortages, it reflected an understanding that HERA was best placed to take the lead, given its experience on industrial measures and collaborative procurements of medicines, even if some stakeholders queried the extension of HERA's activities beyond the areas identified in the HERA Decision. This experience will continue to be further used in this area, notably to support collaborative procurements.

HERA's collaboration with global actors in the area of medical countermeasures, whether bilateral or with bodies such as the World Health Organization and the Africa Centre for Disease Control and Prevention (AfCDC), also adds a necessary additional dimension to the EU's work to build a robust global health security framework.

The results achieved from having a structure dedicated to pandemic preparedness and response, with a tailor-made governance, have demonstrated the added value of working together in an area where the EU's competence is otherwise limited.

5.2. Areas for improvement

The risks of duplication

HERA was created during a time of crisis and in a landscape where many actors were already working. EU health security policy was expanding at the same time, through the European Health Union. HERA's need to be up and running quickly has paid dividends in the results achieved, but has faced the challenge of finding the best ways of working hand in hand with the structures and instruments already in place. Overlaps in responsibilities or actions can create confusion and dilute the impact and added value of EU policies and actions, and a conscious effort is needed to resolve the difficulties. These overlaps can also bring inefficiencies, like the parallel collection of data. Such overlaps can have a negative impact on the EU's preparedness for future crisis.

A consistent theme of the public consultation was the importance of addressing the risk that preparedness and emergency response can be undermined by shortcomings in coordination and a lack of clarity in the division of tasks, risking duplication of effort and resources. Some of the contributions to the consultation called for additional clarification of HERA's mandate, also highlighting the difference between the tasks identified in the HERA Decision, and those which have subsequently emerged in the area of critical medicines. Several stakeholders consider that new problems have emerged, identified in the tasks covered under the HERA Decision⁵⁶.

⁵⁶ See p. 55 of final report: "In the Public consultation respondents were presented with the following statement "Industrial policy actions to support the availability of critical medicines should be taken at EU level to address current challenges, including those outlined in the recent Communication on addressing medicine

Both in the external and internal consultations, concerns were raised about the risk of duplication and a lack of clarity in the role of HERA in public health, civil protection and research funding, including in the interaction with the ECDC, with the Health Security Committee and the newly established Advisory Committee on Public Health Emergencies, as well as with the EMA (both on medical countermeasures and critical medicines)⁵⁷. The profile and branding of HERA has been seen to create some confusion amongst outside stakeholders as to who is speaking for the Commission.

Tangible efforts have already been made to streamline the collaboration within the Commission and with agencies, for instance through working arrangements⁵⁸. A good example came with the Commission proposal for a Critical Medicines Act where HERA's expertise in joint procurement and extensive contacts with the pharmaceutical industry were drawn upon. The Commission set out that HERA will also organise collaborative procurements for critical medicines and other medicinal products of common interest and will continue to provide secretariat services to the Critical Medicines Alliance, an essential consultative and cooperation mechanism aiming to reinforce the EU pharmaceutical supply chain.

But more can be done to increase effective interaction and bring synergies. President Niinistö's report underlines that effective preparedness requires a comprehensive and integrated approach. The EU health security framework could benefit from further consolidation to maximise EU preparedness and coordination for future health threats.

Similarly, close cooperation with the Union Civil Protection Mechanism, in particular the Emergency Response Coordination Centre, would be mutually beneficial, and would build on existing synergies.

Cooperation

An important lesson learned during the COVID-19 crisis was the need for a strong cooperation and coordination, between the different structures in charge of health security, all the more so given that implementation of health measures remains the responsibility of Member States. As pointed out in the Preparedness Union Strategy adopted on 26 March 2025⁵⁹, the effectiveness of the EU response will be compromised without comprehensive, cross-sectoral cooperation. HERA's work on production and supply of medical countermeasures downstream can be most

shortages". About 66% agreed with this statement. In the targeted surveys, respondents were asked to state their agreement with the statement "Since HERA's establishment, health challenges and/or problems (e.g. shortages of medicines) emerged or became more salient that are not (entirely) addressed by HERA's mandate as currently defined". The agreement with the statement was at 50%, and a similar proportion called for more flexibility in HERA's work than implied from the HERA Decision alone.

⁵⁷ The external study reports stakeholder concerns about overlaps between HERA and other bodies (p. 66), data and information gathering and are aware that HERA results cannot be achieved without a strong cooperation with other Commission services and agencies (p. 10), as well as with Member States (p. 67), <https://data.europa.eu/doi/10.2929/322979>

⁵⁸ [HERA signs agreement with ECDC and with EMA to strengthen cooperation on health emergency preparedness and response - European Commission \(europa.eu\)](#); [Working arrangements between HERA and ECDC](#); [Working arrangements between HERA and EMA](#)

⁵⁹ Preparedness Union Strategy, available at <https://webgate.ec.europa.eu/circabc-ewpp/ui/group/2868c14b-717d-4a95-93bd-57e5c4dafdae/library/b81316ab-a513-49a1-b520-b6a6e0de6986/details>
Annex to the Preparedness Union Strategy, available at <https://webgate.ec.europa.eu/circabc-ewpp/ui/group/2868c14b-717d-4a95-93bd-57e5c4dafdae/library/18537b82-f73b-46ff-b1bb-4c7e02d4404a/details>

effective when it can benefit from a strong HERA involvement upstream, in the assessment of health threats and in research and development, as well as being coordinated with broader stockpiling and overall crisis coordination.

Funding optimisation

HERA was created after the adoption of the current multiannual financial framework and its programmes. This meant that HERA had to draw on existing funds to fulfil its objectives, with access to funding on a substantial scale and of a nature which could reflect the diversity of HERA's activities, but also the need to respect the parameters of those programmes and the rules governing their operations.

These considerations lie behind stakeholder calls seen in the study⁶⁰ for HERA's activities to have access to more tailor-made funding. The calls for a more tailor-made or even dedicated funding instrument will need to be assessed as part of considerations in preparation of the next Multi-annual Financial Framework.

HERA's activities often require an innovative approach, as they focus on preparedness for uncertain events that could nevertheless have dramatic consequences in terms of public health and even loss of lives. Therefore, the nature of the actions also means that they might need to be designed as an insurance, and assessed not for their immediate result, but from the perspective of the opportunity costs of having no measures in place should these events occur (e.g. saving lives, reducing the impact on health, on economic activity).

HERA Board

One of the specificities of HERA is the HERA Board, set up to assist and advise the Commission on strategic decisions concerning HERA, and to develop close cooperation between HERA and Member States, ensuring that Member States' resources and capacities are leveraged as much as possible. The HERA Board allows EU level decision-making to take full account of the national context.

However, the consultations have shown that there is concern about the coordination with other bodies and structures such as the Health Security Committee, and the high number of (sometimes overlapping) activities from different EU organisations requiring Member State participation. Similar concerns could emerge as to a certain duplication between the HERA Board and the new Advisory Committee for Public Health Emergencies. All this points to the need for streamlining and better coordinating work and to ensure a clearer framing of the role of the HERA Board in its advisory role as an expert group of the Commission.

Transparency

One of the calls made in the European Parliament has been for more transparency on HERA's activities and governance, echoed by some other stakeholders. Others considered that HERA's dedicated governance structure provides such transparency, and bodies such as the HERA Board and the Critical Medicines Alliance add variety of views to HERA's work.

As a service of the Commission, HERA has the established structures and rules for transparency and accountability, for which it is subject to the same mechanisms that apply to other

⁶⁰ <https://data.europa.eu/doi/10.2929/322979>

Commission services (e.g. adherence to ethical standards, involvement of stakeholders, internal audits and evaluation, access to documents, reporting obligations etc.). The European Parliament can raise questions or ensure accountability in the same way as in other areas of the Commission's activities— as happened in the case of several in-camera meetings with Members of Parliament on the negotiations for the COVID-19 vaccines⁶¹. The European Parliament also has the opportunity to participate in all meetings of the HERA Board as an observer.

HERA has already initiated several actions to strengthen a more proactive communication towards external stakeholders and improve transparency even further. Since February 2024, it has issued bi-monthly newsletters and factsheets explaining its work. It is also organising HERA Info days across Member States and launched the HERA Stakeholders Hub. The communication activities also extend to outreach towards the general public, through the HERA website and social media.

5.3. Status

HERA was established as a Commission service to allow it to start work fast and to work flexibly between preparedness and crisis mode. Despite its positive record to date, some discussion persists regarding its institutional status (i.e. whether it should be an EU agency / authority). Issues raised since HERA's establishment as a Commission service include a lack of independence from the Commission, the European Parliament's position regarding specific scrutiny of HERA, the absence of a Scientific Advisory Committee, perception of unbalanced stakeholder representation, transparency issues and funding vulnerabilities.

As a Commission service, HERA can work more effectively with EMA, ECDC, and the executive agency HaDEA⁶² and can draw on the Commission's resources, and expertise in other policy areas (health, industry, research and innovation, competition, civil protection, humanitarian aid, external relations, international partnerships, etc). This helps enhance synergies between policies and supports a closer involvement in the Commission's decision making process. Having HERA as part of the Commission allows also to better position HERA's needs in proposals made from different policy perspectives across the Commission.

A need for flexibility is inherent in HERA's work in case of crisis, a Commission service can benefit from the fast mobilisation of human resources, by setting up ad-hoc task forces, while the human resources in an agency are pre-determined by an establishment plan. Most importantly, at times of crisis, swift decision-making is indispensable – it is difficult to see how it would be possible for a body to be engaged in this process if not inside the EU's institutional core.

There are a number of additional technical advantages in HERA's position inside the Commission. For example, an agency cannot use the services of another agency for executing

⁶¹ E.g. <https://www.europarl.europa.eu/committees/en/covi-hearing-with-ecdc-hera-and-chief-ep/product-details/20221111CHE10923>

⁶² The European Health and Digital Executive Agency (HaDEA) was established on 16 February 2021 with the purpose of delegating certain tasks relating to the management of Union programmes, including budget implementation. Its tasks are linked to the implementation of Union programmes in the field of EU4Health, Single Market, Research and Innovation, Digital Europe, Connecting Europe Facility – Digital, and comprise in particular the implementation of appropriations entered in the general budget of the Union.

the budget, which would entail at least duplicating the HaDEA staff implementing EU4Health and Horizon Europe budget and diverting resources to financial management.

Any assessment of HERA's set-up also has to take into account the EU's overall policy objectives and budgetary context. Any change would need to establish that HERA's ability to deliver would be enhanced, and not diminished, by the change.

6. CONCLUSION

This review has explored the work of HERA so far, how it is viewed by outside stakeholders and the results it has achieved. In almost three years of operations, HERA has made a significant contribution to reinforcing EU preparedness and response capabilities for medical countermeasures, but also as regards threat prioritisation and preparedness, and showed its agility in adapting to new tasks. As explained in the Niinistö report, preparedness investments can contribute to the resilience of the EU, as well as to the competitiveness of strategic sectors, bringing benefits to patients in “peace times” through the strengthening of supply chains. As the climate, geopolitical and security landscape changes, the risk of health emergencies increases, and the EU must further strengthen and consolidate its preparedness and response capabilities on health security. HERA's work can make an important contribution to a more secure and better-prepared EU.

Pandemics and other cross-border health threats can no longer be assumed to be rare events. In the past they were a “once-in-a-century” occurrence, but developments like globalisation and climate change have increased their probability and frequency. Building on the lessons from the COVID-19 pandemic, the Commission has taken major steps to bolster health security preparedness and has expanded the EU's response to health emergencies within the EU and globally.

The experience since the COVID-19 crisis has reinforced the lessons learned during the pandemic: that crisis coordination requires agile governance structures. A high level of coordination is of critical importance, given the different responsibilities of the Commission, the Member States and EU agencies; and also given the many policies which need to be taken into account in delivering effectively, whether health, civil protection, research and innovation, industry, trade, competition, transport, border management and overall crisis response coordination.

This review sets out how HERA has found a place to provide added value in this complex setting, and also identifies a number of areas where further work and clarity is needed to make the most of the combined potential to better protect the health of citizens. This review also highlights areas where improved coherence between the Commission's work on medical countermeasures and broader health security could help streamline efforts and enhance overall coherence.

Since HERA was established, a series of tools have been put in place by the Commission and EU agencies to ensure that emerging health security threats can be more rapidly detected, better understood, and better combatted in a one health approach. All this helps the EU to anticipate, prepare for, and respond to major health threats – not only infectious diseases but also environmental, climate-related, or chemical and nuclear risks, shifting the EU's approach from reaction to proactive readiness.