



REFLECTION PAPER

THE FIRST YEAR OF THE EUROPEAN HEALTH EMERGENCY PREPAREDNESS AND RESPONSE (HERA)

2022 DECEMBER

About this paper

The reflection paper was drafted by Dr Samantha Field, a public health registrar hosted by EPHA. It was reviewed by Dr Rosa Castro, Senior Policy Manager at EPHA and EPHA members in the Healthcare Delivery cluster.

This paper draws extensively on Wouters et al. The launch of the EU Health Emergency Preparedness and Response Authority (HERA): Improving global pandemic preparedness? *Health Policy* 2023; 133: 104844.

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About EPHA

EPHA is a change agent – Europe’s leading NGO alliance advocating for better health. We are a dynamic member-led organisation, made up of public health civil society, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe.



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SUMMARY AND RECOMMENDATIONS

One year after its creation, this paper reflects on HERA's contribution from the perspective of the public health community represented at the European Public Health Alliance (EPHA). The paper takes stock of HERA's work during multiple crises, key documents (e.g., the 2022 State of Preparedness Report and the EU Global Health Strategy), and the work of the HERA's Civil Society Advisory Forum where EPHA participates as a member, to reflect and provide the following recommendations for HERA as well as for the European Commission:

GOVERNANCE

- ✓ Provide greater clarity around its remit, scope, and mandate.
- ✓ Set up transparent priority setting procedures and accountable R&D and budget decision-making processes.
- ✓ Ensure sufficient and sustainable funding to allow balanced, long-term R&D investments.
- ✓ Set up feedback mechanisms for stakeholders to ensure good communication on priorities and coordination.
- ✓ Consider setting it up as an independent and autonomous public authority in future revisions.

JOINT PROCUREMENT

- ✓ Consolidate learnings from COVID-19 procurement.
- ✓ Publish guidance on how it will align with EU, global, national, and regional procurement mechanisms.

RESEARCH AND DEVELOPMENT

- ✓ Identify the most effective subsidies and incentives for new medical countermeasures.
- ✓ Determine financing mechanisms that guarantee equitable access to and affordability of new and existing medical countermeasures.
- ✓ Address fragmentation of EU R&D funding for pandemic preparedness and response.
- ✓ Consider the creation of a public sector, end-to-end research infrastructure leading to better EU and global R&D coordination.

GLOBAL HEALTH

- ✓ Explore effective ways of working with other organisations on pandemic preparedness and response to avoid duplication and coordination gaps.
- ✓ Clarify its position in the global health ecosystem in line with the recent EU Global Health Strategy.

INTRODUCTION

The COVID-19 pandemic highlighted weaknesses in the EU's preparedness and response for major global health threats. In response to this, the Health Emergency Preparedness and Response Authority (HERA) was established as a new European Commission Directorate-General on 16 September 2021. Much like the US Government's Biomedical Advanced Research and Development Authority (BARDA), the organisation is taking responsibility for horizon scanning; research and development, manufacturing capacity and procuring and stockpiling of essential medicines, vaccines, diagnostics, and equipment. It is a key pillar of the European Health Union and aims to strengthen the EU's health emergency preparedness and response by replacing *ad hoc* approaches with a permanent structure.

This paper outlines the current pressing issues that HERA is placed to address and makes recommendations for how HERA could use its position to ensure equitable and appropriate steps towards improving EU pandemic preparedness and response.

With a budget of EUR 6 billion for the next six years and the potential to manage larger budgets during health emergencies,¹ the European Public Health Alliance (EPHA) calls for HERA to provide transparency and accountability on how these funds will be spent.

1 <https://www.politico.eu/article/hera-eu-commission-health-emergency-preparedness-response-authority/>



GOVERNANCE

INTERACTION WITH CIVIL SOCIETY AND OTHER STAKEHOLDERS

HERA was initially proposed as a standalone agency, but later introduced as a Directorate-General (DG) within the European Commission. It is run by a board with representatives from each EU country, similar to the EU's vaccination steering committee and based on the sense of urgency during the COVID-19 pandemic. The process conducting to its set up did not have to go to the European Parliament for approval. In February 2022, the HERA board published its first work plan and in July 2022, it highlighted the top three health threats that will require EU coordination: pathogens with high pandemic potential; chemical, biological, radiological, and nuclear threats; and threats resulting from antimicrobial resistance (AMR).² As per the 2022 State of Health Preparedness Report, there will be an annual assessment of these three prioritised threat categories to guide the development of novel medical countermeasures, among other activities.³ HERA should transparently communicate how these assessments will be conducted.

Set up in 2022, the HERA Civil Society Advisory Forum is a mechanism to facilitate exchanges between HERA and civil society, patients, consumers, and healthcare professionals. The group met twice during 2022 (last time in November 2022). Alongside this, and as a subgroup of the HERA Advisory Forum, the Commission set 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. However, as per the 2022 Work Plan, the HERA Advisory Forum will engage with stakeholders as needed, rather than formalising any continuous dialogue or establishing communication channels.

Currently, there is uncertainty about what the HERA's governance mechanisms will be, with the Commission outlining that these will change when in preparedness phase and when in crisis phase. A transparent and balanced governance structure should be a priority for HERA, ensuring that it represents patient and public health organisations, representatives of public research bodies and healthcare professionals. HERA can only succeed if it is part of a coherent EU health ecosystem including stakeholders from the European Commission, Member States, the ECDC, the EMA, among others, and should take a convening role in advocacy for health within the EU. For instance, in the US, BARDA coordinates widely in the US health ecosystem, including with the National Institutes of Health, and the biotechnology and pharmaceutical industry. HERA could learn from this to break down silos within the EU and contribute to a functioning health research and development ecosystem. Finally, while industry are clearly important stakeholders for HERA, and collaboration as well as exchanges with industry are essential, it is important that industry is kept outside of the governance structures to ensure the focus remains on the public interest.

PRIORITIES AND BUDGET

Outlining its priorities within the allocated budget will be crucial for HERA. Although at over EUR 1 billion a year HERA represents a huge financial player in the international pandemic preparedness ecosystem, its remit is vast. It is debatable whether its funding will be sufficient to meet all HERA's objectives in terms of procurement of medical countermeasures, scaling up manufacturing capacity and subsidising or incentivising R&D for novel countermeasures. In particular, there needs to be clarity on how HERA will meet the challenge of ensuring sufficient, sustainable financing of R&D whilst having sufficient funds to rapidly meet the procurement challenges of any new

2 https://ec.europa.eu/commission/presscorner/detail/en/IP_22_4474

3 https://health.ec.europa.eu/publications/state-health-preparedness-report_en

pandemic threat. As competing priorities emerge, the sustainability of HERA's funding will take increasing importance.

In terms of R&D there also needs to be clarity in how HERA will set its priorities. For developing antibiotics, it is worth clarifying for instance, whether the WHO priority list will be used when determining which pathogens are of greatest threat, or whether specific priorities will be set for the EU. Either way, a transparent and accountable decision-making process should be used. Aside from defining which vaccines and antibiotics should be prioritised, decisions will also need to be taken about which other medical countermeasures HERA should focus on.

Other decisions will also need a clear governance to ensure they are made with the public in mind and independently of politics or industry, including the definition of HERA's remit and scope. Additionally, there may be calls for HERA to broaden its remit beyond emergencies and use its expertise in procurement to tackle other crises that meet the 'serious' and 'cross-border' criteria— for example, some Member State having surplus medications and others having shortages. In terms of global health security, the origin of pathogens of pandemic-potential often extends far beyond the borders of Europe, and it is currently unclear the role that HERA will play in funding R&D for these pathogens. At a minimum, there needs to be greater clarity on how HERA will engage the public health sector in informing these decisions.

Finally, there needs to be clarity on HERA's position in coordinating EU collective pandemic action. HERA was recently criticised for failing to provide direction for a collective response for EU countries to take on China's opening of borders.⁴ While it is unclear whether this type of coordination falls within HERA's remit, some potential opportunities for HERA to coordinate more powerful actions to counter novel

threats could be missed without proper reflection on this. More clarity on what HERA will and will not advise on in advance of future threats will help the EU and member states prepare for pandemics.

RECOMMENDATIONS

- *The European Commission and HERA should provide greater clarity around HERA's remit, scope, and mandate.*
- *HERA should establish transparency procedures around priority setting and an accountable decision-making process in terms of budget and R&D, ensuring these are in line with public health objectives, needs-driven, evidence-based and aligned to European values and needs.*
- *The European Commission should ensure sufficient and sustainable funding to allow balanced, long-term R&D investments alongside other HERA commitments, either from the EU budget or from co-funding from Member States.*
- *HERA should establish feedback mechanisms from industry, academia, civil society, and other stakeholders to ensure good communication on preparedness and response priorities and coordination.*
- *Future revisions of HERA should consider outlining its governance mechanisms as an independent public authority with autonomy from the EU, national governments and the private sector and with a clear mandate driven by the public interest.*

4 <https://www.politico.eu/article/europes-mess-china-covid-surge/>

(JOINT) PROCUREMENT AND HERA

Improving procurement procedures is one of the primary objectives of HERA, which was set up partly in response to the difficulties related to procurement that the European Commission experienced over the course of the COVID-19 pandemic. In situations where there are limited suppliers and worldwide competition for resources, joint procurement (or direct procurement by the EU) aims to make use of the EU's negotiating power to benefit member states, as well as protect the internal market from the potentially disruptive effects of member states brokering individual deals. Through joint procurement, EU countries may opt in and specify the quantity of the medicine/vaccine in question they want. HERA then negotiates a contract for all participating countries. With HERA acting as a broker, there is back and forth between Member States, HERA and the companies, and agreements negotiated by HERA need to be approved by each participating country. This process requires time and can lead to lengthy negotiations.

After success in securing 4.6 billion COVID-19 vaccine doses on behalf of Member States, the EU's procurement mechanisms during the COVID-19 pandemic are currently under scrutiny. The European Public Prosecutor's Office is currently investigating the acquisition of COVID-19 vaccines⁵ after watchdog agencies raised concerns about the process. The European Court of Auditors found that COVID-19 vaccine contracts signed by the European Commission lacked specific provisions to address supply disruptions and felt procurement processes lacked scrutiny.⁶ It is also expected that the procurement approach will be reviewed during the European Parliament Special COVI-Committee hearings.

HERA's procurement arrangements were put to the test shortly after the COVID-19 pandemic, when MPOX emerged as the next global outbreak. However, HERA was initially criticised for being slow to purchase vaccines for the 450 million people that it serves. An initial order of only 163,000 doses, was seen as falling short of the 250,000 doses already bought by France and the 130,000 purchased by the U.K.⁷ As the EU doses were bought directly with EU funds there was less need for the back-and-forth which in the past has delayed negotiations, and it was thought that the limited manufacturer supplies dictated the amount delivered. However, episodes such as this bring the challenges that HERA faces into sharp relief. As of the time of writing, HERA has directly purchased 334,540 doses of vaccine, which were then made the available to EU Member States, Norway, and Iceland,⁸ with a joint procurement agreement with Bavarian Nordic to supply up to 2m doses of the MPOX vaccine over 2023-24 and 14 countries participating in the joint procurement.⁹ Alongside this, they recently signed a purchase agreement for 3 million doses of Paxlovid which shows ongoing focus on COVID-19.¹⁰

The EU is aware that the process could benefit from improvement. Joint procurement agreements were transformed on 4th October 2022 with the passing of the new law on serious cross-border threats to health and an assessment of the joint procurement mechanism, to identify and analyse possible opportunities for improvement is currently ongoing.¹¹ One of the priorities of this review should be assessing how to streamline the negotiation process and shorten the overall timelines.

5 <https://www.eppo.europa.eu/en/news/ongoing-eppo-investigation-acquisition-covid-19-vaccines-eu>

6 <https://www.euractiv.com/section/coronavirus/news/eu-auditors-urge-commission-to-draw-lessons-from-covid-vaccine-procurement/>

7 <https://www.politico.eu/article/monkeypox-covid-19-eu-to-review-how-to-speed-up-vaccine-drug-deals-in-health-emergencies/>

8 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5362

9 <https://www.biopharma-reporter.com/Article/2022/11/18/europe-locks-in-monkeypox-vaccine-supply-up-to-2024-with-bavarian-nordic-contract>

10 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_6491

11 <https://www.politico.eu/article/monkeypox-covid-19-eu-to-review-how-to-speed-up-vaccine-drug-deals-in-health-emergencies/>

It currently remains unclear where HERA will fit within existing procurement spaces and therefore, a priority should be to define how it will interact with existing organisations and different procurement procedures. As HERA assumes responsibility for EU procurement, it will need to ensure it is aligned with procurement systems at European and global levels, as well as sharing good practices and data. This includes organisations such as the WHO and Specific Procurement Procedure Steering Committees which exist for specific vaccines, therapeutics, and equipment such as ventilators. HERA will also need to support existing procurement efforts, such as those in place under the Emergency Support Instrument and consider existing legal agreements such as Joint Procurement Agreements for purchasing medical countermeasures for cross-border health threats. It will also have to think beyond procurement to ensure resilience of the supply chain, put in place mechanisms to reduce competition between Member States in the European medicine market and facilitate the sharing of products. There must be a focus on fair distribution between Member States at a time of crisis. Bringing together industry and Member States will be necessary to ensure sustainability of supply chains.

RECOMMENDATIONS

- *HERA should consolidate learnings from COVID-19 procurement procedures along with the upcoming review of joint procurement process to improve mechanisms, in particular regarding supply chain issues and manufacturing bottlenecks in relation to contracts.*
- *HERA should publish clear guidance on how it will align with existing EU and global procurement mechanisms as well as national and regional procurement mechanisms. The sharing of good practices and data about procurement should be facilitated.*



RESEARCH AND DEVELOPMENT

FINANCING

There are many ways to finance R&D, including direct grants or subsidies to the pharmaceutical industry, risk sharing with pharma, or novel mechanisms which are taxpayer funded. Each mechanism comes with its own risks and benefits.

During the COVID-19 pandemic the European Commission, allocated over EUR 2.7 billion to support R&D and secure priority access to COVID-vaccines, with preference given to vaccines manufactured in EU countries.¹² The European Commission made advance purchases of several hundred million doses of COVID-19 vaccines from AstraZeneca/Oxford, BioNTech/Pfizer, and Moderna. However, little oversight was given to vaccine manufacturers that received substantial public funding, which could have been asked to commit to engage with the WHO's COVID-19 Technology Access Pool or the Medicines Patent Pool to share knowledge, data, and intellectual property related to these products.¹³

HERA recently set out its plans for 'HERA INVEST', a stand-alone funding instrument with a EUR 100 million budget which, supported by the EIB, will invest in the end-to-end R&D and production of medical countermeasures. This investment will be on top of Invest EU efforts to de-risk private investment and stimulate innovation for medical countermeasures that do not have sufficient market incentives.¹⁴ More clarity needs to be provided on how this instrument will combine public and private investment to incentivise innovation in medical countermeasures. There also needs to be greater clarity on who and what HERA will fund including decisions on whether and how funding will go to big pharmaceutical companies or SMEs, or to either early phase research or late-stage clinical trials, which are inherently more expensive.

Regardless of these decisions, lessons from the COVID-19 pandemic point towards the need to consider the multi-layered public investment through funding of early-stage research. In order to serve its public health mission, HERA needs to go beyond offering advance payments to companies which could be seen as subsidising the pharmaceutical sector. To address existing gaps in areas of low commercial profitability that are critical to prepare and respond to health emergencies, not-for-profit EU infrastructure should also be considered and even prioritised.¹⁵ Doing so will boost many non-commercial research institutions across the Union by offering them new possibilities of cooperation and by bringing them closer to the EU medicine regulatory system.

It is important that HERA channels public funds to investments into public health-driven innovations and is resistant to influence from industry and political pressures. Whilst being a responsible investor, HERA should accept the financial risk associated with the possibility of failure inherent in R&D funding,¹⁶ cooperate with other non-commercial research institutions and support both the pre-clinical development and the clinical trials phase. This would ensure much-needed transparency of clinical trials data and research and development costs. If HERA is to fund private sector activities, including late-stage development and manufacturing, the Commission needs to define the limits of what companies will be able to do with public money. De-risking of investments can be brokered through advance purchasing agreements (APAs). There also needs to be a clear plan for how risks and rewards will be shared, and how the Commission will win the public's confidence.

12 European Commission. Communication from the Commission to the European Parliament, the European Council, the Council, and the European Investment Bank. EU Strategy for COVID-19 vaccines. 2021.

13 Wouters OJ, Shadlen KC, Salcher-Konrad M, Pollard AJ, Larson HJ, Teerawattananon Y, Jit M. Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment. *The Lancet* 2021; 397:1023-34.

14 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7154

15 [https://www.europarl.europa.eu/stoa/en/document/EPRS_STU\(2021\)697197](https://www.europarl.europa.eu/stoa/en/document/EPRS_STU(2021)697197)

16 <https://epha.org/hera-should-be-independent-and-autonomous-with-a-clear-public-health-mission-epha-says/>

ACCESS TO MEDICAL COUNTERMEASURES

Given the use of public R&D investments into the development of medical countermeasures (including vaccines), access to these tools should be carefully addressed. To avoid repeating the mistakes of the COVID-19 pandemic, HERA should treat the products of its funding as global public goods and funding should be conditional on data sharing, fair pricing, and equitable distribution.¹⁷ This will require (early) consideration of affordability, availability, and accessibility and can be operationalised by:

- ✓ selecting when possible open access and open data requirements, with prioritisation of public ownership, control, and management of resulting intellectual property rights.
- ✓ using clauses guaranteeing downstream access and affordability and addressing the transfer of manufacturing knowledge to third parties to achieve greater scale and faster delivery of products developed with public funds.
- ✓ attaching socially responsible licensing and transparency conditions to the end products, including reasonable pricing clauses.¹⁸

When considering how best to ensure a focus on access in contracts, HERA could look at other organisations developing equitable access policies, including the Advancing Equitable Access partnership agreement provisions used by CEPI,¹⁹ DNDi's Pro-Access Policy and contractual access clauses used by CARB-X.²⁰ As well as the focus on R&D, HERA (and the European Commission) should consider funding manufacturing infrastructure at EU level to facilitate the production of medicines and vaccines as a non-profit public activity.²¹

COORDINATION WITH EU R&D FUNDING LANDSCAPE

There is a need for permanent, coordinated R&D infrastructure in the EU to underpin health emergency preparedness and response. However, it is still unclear how HERA will operate within EU's complex health research landscape.

HERA joins a fragmented and complicated EU funding landscape, with sources such as the Recovery and Resilience Facility, REACT-EU, Cohesion Funds and InvestEU all already providing funding for health emergency preparedness and potentially contributing to HERA's activities. HERA already works closely and strategically with Horizon Europe, which contributes EUR 35 million to its EUR 1 billion budget, and reports to have taken into account lessons learned from other programmes from the European Innovation Council, European Institute of Innovation and Technology and Innovative Medicines Initiatives.²² However, to ensure the full research cycle is funded whilst avoiding duplication, sustained efforts will be needed to build synergies between different funding mechanisms, each of which has a different focus and strategic advantage.²³ EU pharmaceutical companies and academic organisations are world leading and HERA could be a locus of cooperation and synergy across Europe and internationally by using its powers to convene and lead coalitions of the willing.

HERA should therefore ensure it co-ordinates health research priorities and targets related to pandemic preparedness and response closely with the European Medicines Agency, the European Centre for Disease Prevention and Control, the European Commission's Directorate General for Research and Innovation and others, such as the Innovative Health Initiative. Other streams include the EIB programmes that incentivise pharmaceuticals through grants and other EU programmes that directly or indirectly fund similar

17 <https://epha.org/hera-will-the-eu-lead-global-action-against-pandemics/>

18 <https://epha.org/hera-should-be-independent-and-autonomous-with-a-clear-public-health-mission-epha-says/>

19 https://cepi.net/wp-content/uploads/2019/03/Advancing-Equitable-Access_CEPI_29032019.pdf

20 <https://carb-x.org/about/stewardship-and-access/>

21 <https://epha.org/position-paper-the-european-pharmaceutical-strategy-one-year-post-launch/>

22 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7154

23 [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31411-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31411-2/fulltext)

efforts. Alongside EU-level R&D funding, national programmes, and agencies of Member States, in particularly in France and Scandinavia, may have their own funding priorities within their national life science programmes. Whilst developing a strategic research and innovation agenda, careful collaboration with other funding streams should ensure that HERA's investments leverage its strategic advantage as a funder whilst addressing major research gaps in a coordinated way.

As well as coordinating with other EU research funding instruments to deliver R&D that is committed to principles of public return on public investment, HERA needs to work with other organisations within the EU and internationally to ensure a coordinated approach to the use of advance market commitments (or similar payments, for instance, those potentially used to spur antibiotic development). It should be mindful of the potential lack of coherence between EU and national funding schemes and aim to bridge that gap, so that EU-funded discoveries are translated into large scale industrial development across the EU while ensuring an optimal use of public funds. This will include integrating and streamlining efforts throughout the value chain from basic research to large-scale manufacturing and distribution, across public and private sectors.²⁴

It has been argued that major funders can use their leverage and purchasing power to get companies to license more widely.²⁵ As outlined above, HERA should make use of its purchasing power and take a lifecycle approach where companies that receive public funding are obliged to engage in technology transfer to share the intellectual property rights around these technologies and any technical knowledge necessary to boost production and facilitate manufacturing.

COORDINATION WITH THE INTERNATIONAL FUNDING LANDSCAPE

HERA is also entering a complex global pandemic preparedness ecosystem. It should coordinate with other global players to avoid duplicating the efforts of existing governmental and non-governmental bodies in funding and supporting research and development. Beyond the EU, HERA should ensure it is coordinating with, among others, BARDA, CARB-X and the UK's Advanced Research and Invention Agency.

HERA and the Coalition for Epidemic Preparedness Innovations (CEPI) have recently signed a letter of intent to facilitate cooperation on developing next generation vaccines, including for COVID-19, as part of the EU's Vaccines 2.0 Strategy. Alongside seeking out similar bilateral agreements with the major players in the global R&D landscape, HERA could establish a joint committee or working group with major publicly-funded research partners to define priorities and avoid duplication. It should take a proactive approach to liaising with other organisations to ensure coordination in use of tools such as advance market commitments or other similar means to incentivise R&D in line with public health priorities.

ANTIMICROBIAL RESISTANCE

AMR is recognised as a serious cross-border threat to health that requires concerted EU action, and there are also clear EU competences in terms of veterinary issues, food safety and research actions. AMR has been identified as a clear priority in the current HERA workplan, with activities such as gap analysis planned, and HERA's 2023 workplan sets out how it intends to work with DG SANTE and DG RTD to support funding for AMR medical countermeasures R&D. Given existing work in this space, HERA needs

24 <https://epha.org/hera-should-be-independent-and-autonomous-with-a-clear-public-health-mission-epha-says/>

25 <https://www.politico.com/news/agenda/2021/03/02/us-coronavirus-variants-471981>

to assess what advantage it holds tackling AMR in relation to existing efforts at EU level.²⁶ AMR is a complex and cross-sectoral issue and unclear mandates run the risk of diluting responsibility and policy initiatives. However, it is likely that the remit of HERA as a coordinating and centralising body make it well positioned to take a leading role for the EU in AMR, in particular within the remit of developing innovative medical countermeasures to address AMR as well as contributing to better access to existing tools (e.g., old antibiotics). Given this, HERA's position in this area should be made explicit.

Therefore, the current focus should be on understanding what other activities are ongoing in this area on an EU-European and international basis and using its strategic advantage to encourage progress. This should include both broad spectrum and narrow spectrum countermeasures, and HERA should remain flexible on the types of products, including biological, chemical and phage countermeasures, as well as the modalities of tackling antimicrobial resistance including prevention, cure, and diagnostics. As there will be similar mechanisms to incentivise development of medical countermeasures for both pathogens of pandemic potential and AMR, HERA is well placed to be a leader in this field. Recent EU-funded projects have identified the use of milestone prizes as a potential incentive to shape and accelerate the development of new antibiotics, with HERA taking on the role as a “pipeline coordinator”.²⁷

RECOMMENDATIONS

- *HERA should systematically explore how subsidies and incentives for development of new medical countermeasures can transform the current landscape to determine which mechanisms will be the most effective in stimulating the pipeline to address priority pathogens.*
- *HERA should determine which financing mechanisms will guarantee access to and affordability of new and existing medical countermeasures equitably across the EU, with a focus on the most vulnerable and disadvantaged populations (e.g., obstetrics, children, migrants, homeless).*
- *The European Commission and HERA should contribute to address fragmentation of existing EU R&D funding for pandemic preparedness by mapping and coordinating different EU funding streams and ensuring coherence.*
- *The European Commission and HERA should consider the creation of a public sector, end-to-end research infrastructure and guarantee better coordination amongst existing R&D efforts both at EU and global level.*

26 <https://epha.org/wp-content/uploads/2021/11/position-paper-on-pharma-strategy-23-nov-19.pdf>

27 https://eu-jamrai.eu/wp-content/uploads/2021/07/1.3.1_Policy_brief_Improving_access_to_essential_antibiotic.pdf

HERA IN THE GLOBAL HEALTH LANDSCAPE

Alongside a complex R&D ecosystem HERA joins a complex global health architecture, with the World Health Organization (WHO), World Bank, UNAIDS, Global Fund, GAVI, the Gates Foundation as well as numerous national governments funding many of the same pandemic-preparedness activities as HERA such as horizon scanning. Within the EU, HERA joins organisations such as the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the European Environment Agency, and the European Food Safety Authority (EFSA) with involvement in health issues. In particular, the ECDC and EMA now have extended mandates under the EU Health Union programme, many of which (such as surveillance, clinical trials coordination and production capacities) overlap with HERA's proposed actions. Additionally, many non-health organisations such as the G20 and OECD are now taking an active interest in health matters following the far-reaching impacts of the COVID-19 pandemic. The new EU Global Health Strategy reasserts global health as an essential component of EU external policy, and health security as a priority for 'Team Europe.'²⁸ Despite evidence that it plans to coordinate and collaborate with international pandemic preparedness bodies, HERA's contribution to the EU's role in global health security governance is still unclear.

As pandemics do not respect borders, HERA needs to consider how it will interact with countries neighbouring the EEA, including WHO European region countries that are not within the EU. This can be managed by agreements with the WHO's Regional Office for Europe and ensuring the Medical Countermeasures Intelligence Platform that is in development prioritises secure information exchange with relevant global stakeholders to maximise its utility.²⁹ Additionally, HERA should consider its relationships with other international organisations with interests in health security such as NATO. To this end, HERA needs to establish what global health security system strengthening activities are within its remit, acknowledging there are benefits from

both an ethical perspective and direct benefits to the EU. For example, the European Commission and ECDC are investing almost EUR 40 million into helping EU member states reinforce genomic sequencing capacity. However, improving global health infrastructure in terms of developing lab capacity for genomics internationally would also greatly help the EU in surveillance. The recent State of Health Preparedness Report states a commitment to developing a network of laboratories and research institutes with global reach.³⁰ Although there is no doubt that the EU plays an important role in global pandemic preparedness, given the limited funding and wide aims for HERA, whether this is a priority or could be better addressed by other organisations in line with the EU Global Health Strategy should be carefully examined.

There are some aspects of the EU Global Health strategy that HERA will be uniquely positioned to enact. For example, when considering access clauses for Member States, HERA should ensure that consideration is given to global distribution of vaccines and medical countermeasures in order to effectively combat future pandemics on a global level and prevent the inequities in global vaccine rollout seen during the COVID-19 pandemic. Similarly, commitment to strengthening EU production capacity of medical countermeasures should be done with global equity of access to these countermeasures in mind.

There are some HERA activities, such as horizon scanning and surveillance, which will require strong relationships with other EU and global bodies. Similarly, monitoring activities will require close collaboration with EMA and other agencies to assess medical countermeasures, devices, and technologies that are under development worldwide in a timely fashion. These activities will require strong political commitment and engagement with other EU agencies

28 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153

29 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7154

30 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7154

like ECDC and EMA, as well as global agencies involved in pandemic preparedness such as the WHO.

In order to foster the communication and coordinate the containment measures necessary to adequately perform its role as the EU's pandemic preparedness agency, HERA will need to consider how to form international partnerships with non-EU countries, including low-income and middle-income countries, and global organisations. HERA will have to establish new ways of brokering bilateral and multilateral cooperation outside the borders of the EU and will need to engage the WHO closely.³¹

HERA has already signed, or plans to, memoranda of understanding with the WHO Hub for Pandemic and Epidemic Intelligence, the ECDC and the EMA, BARDA, the UK's Advanced Research and Invention Agency, the Coalition for Epidemic Preparedness Innovations, and the Africa Center for Disease Control and Prevention. This should help establish structured collaborations. However, despite outlining ambitious international activities, HERA only assigned EUR 2 million to them in its 2022 workplan. More recently, HERA's EUR 15 million partnership with the WHO to improve global pandemic preparedness signals its willingness to act as an important player in the global health field.³² HERA's 2023 Work Plan outlines further ambitions in the international health space, including providing support to LMICs in terms of surveillance, R&D and manufacturing potential and supporting the Commission in negotiating international pandemic preparedness treaties and agreements.

At the moment it is unclear whether HERA has a mandate to represent the EU internationally, but given its scope and remit, HERA would be well positioned to set the direction for EU member states, bringing them together to support homogenous and coordinated pandemic response policy formulation and implementation at national and sub-national level whilst acting as a bridge between other EU (e.g., ECDC and EMA) and non-EU entities (WHO, Africa Centres for Disease Control and Prevention and US CDC). These harmonised activities should include coordinated stockpiling rules, development of joint operational procedures, and essential item lists for an effective EU and global response.

RECOMMENDATIONS:

- *The European Commission and HERA should explore effective ways of working with other international organisations occupying the global health security and pandemic preparedness space to avoid duplication and gaps with coordination to establish clear division of tasks between agencies.*
- *The European Commission should clarify HERA's position in the global health ecosystem in line with the recent EU Global Health Strategy, and an adequate budget allocated to fund HERA's role in this space should be ensured.*

31 [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)01107-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01107-7/fulltext)

32 <https://www.who.int/news/item/08-12-2022-the-european-union-and-who-further-enhance-their-partnership-for-stronger-pandemic-preparedness-and-response>



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