EU HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

How should the EU prepare and respond to future cross border health threats?

FEAM
Federation of European Academies of Medicine

wellcome

CONTENTS:

EXECUTIVE SUMMARY:

In 2020, the European Commission announced the EU "Health Emergency and Preparedness Response Authority" (HERA) as part of a broader set of proposals for an EU Health Union. In response to Covid-19, the proposals aim to build a Europe that is better prepared for the next cross-border health threat. With EUR 5.1 billion over a seven-year period (2021-2027), the Health Union's budget is ten times larger than the last health budget.

This report sets out the role that the EU HERA could fill in the evolving European Health landscape. It is informed by interviews with over 40 experts from research organisations, civil society, think tanks and industry, based in Brussels, EU Member States and beyond. Although consultation was a crucial element of the project, the report recommendations are independent and reflect the opinions of the Federation of European Academies of Medicine (FEAM) and Wellcome Trust.

KEY RECOMMENDATIONS

HERA must be focused, yet flexible to deliver results, build credibility, efficacy, and consider the long-term.

- In the short-term, HERA should seek to understand in detail and remedy the gaps at a European level on medical countermeasures for pandemic preparedness and response. HERA must ensure these are accessible to low- and middle-income countries. At the same time, it should be realistic about what it can achieve with the funding available.
- HERA's structure, remit and funding must be ambitious and flexible to react in scenarios different from the Covid-19 context.
- In the mid- to long-term, the Commission should analyse all cross-border health threats facing European citizens and propose a larger ambition for HERA. Activities HERA pursues in the future should be defined after an in-depth gap analysis.
- The creation of HERA is an opportunity to harmonise the European research and development biomedical landscape for pandemic preparedness and rapid response capacity.
- HERA should formalise and coordinate end-to-end oversight for R&D efforts across the EU during health emergencies.
- HERA must maintain expertise and resources between crises.
- HERA should embed a One Health approach.

HERA must be independent in its activities, opinions and governance, and guided by the principles of transparency, autonomy, accountability and integrity.

- A clear mandate is needed for HERA to respond effectively in a crisis.
- Transparency in HERA's decision making is critical for accountability and integrity and to build trust in its public actions.
- HERA must be an independent public Authority.
- HERA should use its independence to take strategic and evidence-based risks.

HERA must be collaborative to build on strengths in the EU health and research system.

- HERA must work closely with other EU institutions (including European health related agencies), initiatives and programmes to enable and amplify, rather than detract from, existing activities.
- HERA must work closely with Member States to build legitimacy and trust, incorporating and sharing national expertise.
- HERA must build and maintain relationships between crises so that in emergencies it can respond quickly in collaboration with trusted partners.
- HERA must prioritise building strong relationships with industry.
- HERA must build a broad base of support to be effective and to gain trust.

HERA must be global in its approach to health threats to reflect European values, by embedding collaboration and access in its work.

- HERA must take a global approach to emergency preparedness and rapid response capacity.
- HERA should prioritise equitable access in its funding and operations.

INTRODUCTION:

Towards better EU pandemic preparedness and response

The COVID-19 pandemic has created the impetus for a European strategy to better prepare for, and respond to, health emergencies. To quote European Commission President von der Leyen, when Covid-19 hit Europe in March 2020, "too many [EU Member states] initially looked out for themselves [...], too many initially gave an 'only for me' response."[1] To be better prepared in the future, the European Commission has put forward ambitious plans for a European Health Union, to protect the health of EU citizens and respond to cross-border health threats.

The Health Union will be funded with a sizable EUR 5.1 billion over a seven-year period (2021-2027), a total which is ten times larger than the previous health budget. The proposals include extending the mandates of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) and revising the Regulation on serious cross-border health threats. The EU Health Emergency Preparedness and Response Authority (HERA) was also announced as part of this package – framed by President Ursula von der Leyen as an Authority to be modelled on the US Biomedical Advanced Research and Development Authority, BARDA (see Case Study).[2] The Authority's mission, outlined in a communication in November 2020,[3] "will be to enable the EU and its Member States to rapidly deploy the most advanced medical measures in the event of a health emergency, by covering the whole value chain from conception to distribution and use." In doing so, HERA will address structural gaps in the EU's health preparedness and response capacities.

The European Commission will present a legislative proposal in September 2021 with the new agency becoming operational in 2023. President von der Leyen launched a 'pilot' project, the HERA Incubator, to tackle new variants of Covid-19 in February 2021.[4]

At the same time, global efforts to fight cross-border health threats are increasing. The President of the European Council Charles Michel, alongside global Heads of State, has called for an international treaty on pandemic prevention and preparedness, supported by the World Health Organisation (WHO).[5] The Global Health Summit on May 21, 2021 will focus on this issue, galvanising participants around principles of preparedness.

This report sets out a series of recommendations on the EU HERA at this critical moment in its development and in emergency preparedness and response globally. To inform the report, a consultation was held with over 40 experts from research organisations, civil society, think tanks, and industry, from across Brussels, EU Member States and beyond. Through one-to-one interviews and a FEAM European Biomedical Policy Forum roundtable (summary in Annex 3), the consultation explored HERA's scope, how it could sit alongside existing EU and global institutions, and what could be learned from these institutions to ensure HERA's success. This report draws extensively on interviewees' expertise, but its recommendations are independent.

BOX 1:

Why is a new authority needed?

- **What is the existing gap?** The COVID-19 pandemic has shown the potential of action at the EU level to address health emergencies, while also highlighting current weaknesses in the system.[i] The resultant proposal from the European Commission for the European Health Union aims to address these.[ii] Europe has particularly faced hurdles in developing medical countermeasures, a critical part of responding to a new health threat.[iii]

- **Why is a formal mechanism needed?** Many interviewees agreed that a clear mechanism is needed for rapid collaboration between the EU Commission, Member States and EU Agencies – as set out by the Commission's HERA proposals. To respond in a crisis, legal and financial capacities are also needed. An informal network without a clear mandate and role, on the other hand, would not ensure the flexibility, reliability and agility needed to respond quickly, in the way a standalone authority would.

- **Why can't an existing agency cover this work?** This report explores this question in some detail (see Chapter 1: HERA must be flexible, yet focused). Existing European agencies have defined roles that would have to undergo a radical shift to assume a role similar to the United States' BARDA. While some European agencies are reevaluating their activities through the European Health Union proposals, the development of medical countermeasures is a very broad activity to add to any organisation's current mandate. Developing medical countermeasures will require an extensive set of interactions with organisations and institutions working on R&D and stakeholders including industry and academia (see Chapter 3: HERA must be collaborative). It will also require the ability to make decisions while remaining accountable and transparent (see Chapter 2: HERA must be independent).

- An important foundation for HERA will be to assess and understand in a granular way the weak spots of the EU response to Covid-19. A deep understanding of the challenges faced will be important for setting HERA's immediate priorities.

CASE STUDY:

US Biomedical Advance Research and Development Authority (BARDA)

The European Commission announced that HERA should be modelled on the US Biomedical Advanced Research and Development Authority (BARDA).[i] **Though established in 2006 to counter bioterrorism threats, BARDA has been a critical part of America's response to the Covid-19 pandemic as well as work on other health emergencies.**

BARDA's mandate is to anticipate and prepare for chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza and emerging infectious diseases. BARDA's budget reflects its ambition: for 2021 it was granted a budget of USD 1.4 billion.[ii]

During Covid-19, BARDA played an important role in **Operation Warp Speed (OWS)**, incentivising pharmaceutical companies to develop medical countermeasures against the coronavirus through the rapid deployment USD 11 billion in funding.[iii]

Despite BARDA's successes, it cannot simply be transferred to a European context. There are several things HERA could adopt from BARDA, and several that cannot be replicated (for further detail see Annex 1):

ELEMENTS OF US BARDA THAT EU HERA SHOULD ADOPT:

- BARDA's large budget allows it to **take risks.** The US invested USD 11 billion through OWS while EU spending remained comparatively low at EUR 1.8 billion.
- BARDA is **adaptable.** Though created in response to anthrax attacks, it has shifted to work on antimicrobial resistance (AMR) and more recently pandemics.
- Between pandemics, the authority **maintains expertise** through continuous training and work on specific research areas, like AMR through the CARB-X programme.
- BARDA invests in **long-standing relationships** with industry that allows the authority to quickly mobilise in a crisis.
- As an office of the US Department of Health and Human Services, BARDA is a **public organization** whose funding and objectives are not influenced by politics.

> **"The reason the US could act as fast as they did in the current pandemic was because they had ongoing relationships with pharma organisations; they had contracts in place and could pivot their scope."**
>
> ***– Katrine Thor Andersen,*** *Deputy Director, Alliance Management, Global Health, Bill and Melinda Gates Foundation*

ELEMENTS OF US BARDA THAT CANNOT BE REPLICATED IN THE EU CONTEXT:

- BARDA has strong ties to national security and the US **military.** While HERA may have future links to the European Defence Agency and the North Atlantic Treaty Organisation (NATO), defence is not an exclusive EU competency.
- BARDA's purpose is to serve American interests. While HERA will be dedicated to safeguarding European citizens' health, it should avoid BARDA's **nationalistic focus** and pursue a global approach.
- BARDA's funding agreements with pharmaceutical companies **lack provisions for access, pricing, intellectual property and licensing.** HERA should prioritise these to reflect EU values and public interest.

> **"Operation Warp Speed accelerated the development process for Covid-19 vaccines, but on the downside, the Covid-19 agreements signed by the US Government with pharmaceutical companies do not contain provisions that address all of the issues necessary to ensure affordable access, nor which would enable the US to share the resulting vaccine doses with other countries in need."**
>
> ***– Julia Barnes-Weise,*** *Executive Director, GHIAA*

Above all, HERA must reflect the **European context and values.** The EU and US have very different healthcare systems and funding landscapes, and the type of support HERA provides should be relevant for all 27 Member states.

> **"There will always be fundamental differences between BARDA and HERA because the EU's not one country, so it's a completely different equation."**
>
> ***– Margriet den Boer,*** *NTD Advisor, Médecins sans Frontières UK and Ireland*

For further information on US BARDA, please see Annex 1.

1. HERA must be focused, yet flexible

RECOMMENDATIONS:

- In the short-term, HERA should seek to understand in detail and remedy the gaps at a European level on medical countermeasures for pandemic preparedness. HERA must ensure these are accessible to low- and middle-income countries. At the same time, it should be realistic about what it can achieve with the funding available.
- The structure, remit and funding of HERA must be ambitious and flexible to react in scenarios different to the Covid-19 context.
- In the mid- to long-term, the European Commission should analyse all cross-border health threats facing European citizens and propose a larger ambition for HERA. Activities HERA pursues should be defined after an in-depth gap analysis.
- HERA could formalise and coordinate end-to-end oversight for R&D efforts across the EU during health emergencies.
- The creation of HERA is an opportunity to harmonise the European biomedical research and development landscape for pandemic preparedness and rapid response capacity.
- HERA must maintain expertise and resources between crises.
- HERA should embed a "One Health" approach.

This chapter sets outs out recommendations on HERA's approach in the short- to long-term, and how this approach could differ when a health emergency is declared (Box 2). It does not detail exactly what activities HERA should pursue, as a full gap analysis is required to work out what HERA's added value could be.

BOX 2:

Overview of recommendations for HERA's approach

	DURING A PUBLIC HEALTH CRISIS	BETWEEN PUBLIC HEALTH CRISES
SHORT-TERM	• Focus on understanding and filling the gap at a European level on medical countermeasures for pandemic preparedness and response, and ensure they are accessible to low- and middle-income countries. • Build on the HERA Incubator actions.	• Analyse all cross-border health threats facing European citizens and propose a larger ambition for HERA. • Conduct an in-depth gap analysis to define which activities HERA pursues long-term.
LONG-TERM	• Formalise and coordinate end-to-end oversight for R&D efforts across the EC during public health emergencies. • Assume specific and extraordinary powers to coordinate activity until the end of the emergency.	• Harmonise the European biomedical research and development landscape for pandemic preparedness and response capacity. • Maintain relationships, expertise and resources.

In the short-term, HERA should focus on understanding and filling the gap at a European level on medical countermeasures for pandemic preparedness and response. HERA must ensure these are accessible to low- and middle-income countries. It should be realistic about what it can achieve with the funding available.

Covid-19 has demonstrated that the EU must be better prepared for, and able to respond quickly to future serious cross-border health threats. Yet HERA can't – and shouldn't try to – do everything. Many interviewees discussed the need to be realistic and define HERA's role and remit.

The Authority will need to begin with a narrow scope, commensurate with its budget (Box 3).

As a logical first step, the new Authority should build on recent work to tackle Covid-19, including the HERA Incubator actions (Box 4), and have an initial focus on pandemic threats. Demonstrating early success and relevance will be crucial for building trust in HERA – among citizens, EU member states and other agencies. Trust brings with it legitimacy, and in turn a mandate to operate on a broader scale.

> **"If you try to do too much, you'll do nothing."**
> ***– Dr Marie-Paule Kieny,*** *Director of Research, Inserm*

BOX 3: *HERA's funding*

HERA will be funded from the EU Health Union budget; there is EUR 5.1 billion available for all EU4Health activities from 2021-27.[i]

With the aim to establish HERA by 2023, the European Commission will need to consider how much funding it requires for the first four years and how this interacts with other ongoing activities in the Health Union. Following this assessment, the Commission can build a longer-term ambition for HERA in the next Multiannual Financial Framework.

BOX 4: *HERA Incubator*

The HERA Incubator, a series of initiatives to anticipate and respond to new Covid-19 variants, was announced by President von der Leyen and Commissioners Kyriakides and Breton in February 2021.[i] **The Incubator covers five key actions:**

1. Detection and analysis of new variants – develop specialized RT-PCR tests for new variants and support whole genomic sequencing in Member States, with EUR 75 million.
2. Research and swift adaptation of vaccines – boost research and data exchange on variants with EUR 150 million funding (through Horizon 2020/Europe).
3. Establish a European Covid-19 clinical trials network – a new 'VACCELERATE' trials network will bring together 16 Member States, plus five associated countries, to exchange data.
4. Fast-tracking regulatory approval of adapted vaccines – based on the annual influenza vaccine model, the EU will provide accelerated approval for adapted Covid-19 vaccines.
5. Enable upscaling of production of new and existing vaccines – address bottlenecks in production and supply of raw materials; develop a dedicated voluntary licensing mechanism to facilitate technology transfer; and, build up emergency response production capacity.

The Incubator actions are funded by Horizon 2020, InvestEU and a topped-up Emergency Support Instrument.[ii]

A narrow scope should not be interpreted as a lack of ambition. Indeed, clearly articulating HERA's role demonstrates a strategic self-awareness of where HERA sits in the broader preparedness ecosystem and how it can add value. While some stakeholders argued that HERA should cover all cross-border threats and capitalise on the current political will around preparedness, our conclusion is that too broad an approach could be less effective.

While HERA should start its operations with a focus on pandemic threats, it should build in clear mechanisms to learn from, and collaborate with, other organisations to provide medical countermeasures (and eventually address critical drug supply) in the event of non-pandemic threats.[6] This will mitigate the risk of an initially narrow focus.

The structure, remit and funding of HERA must be ambitious and flexible to react in scenarios that are different to Covid-19.

While the European Commission should consider what it can realistically achieve for HERA in the short-term and build from there, many interviewees stressed that, notwithstanding the helpful lessons the European Commission can learn from Covid-19, HERA must not 'over-learn' from the current pandemic. It is impossible to fully predict what a future health threat will be and when it might occur – and HERA must have the flexibility to adapt to this.

> **"The legislation for HERA must be written so that it's flexible enough to respond to any health threat. No one was thinking about pandemics when the legislation for BARDA was written, like how now nobody's thinking about bioterrorism."**
>
> *– **Terri Stewart,** VP, Head of Global Innovative Medicines Franchise Policy, EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany*

> **"It's valuable to have flexible institutions. For example, specific institutions created for developing HIV therapeutics were later adapted to include hepatitis C. There was some discussion at the time about whether this was appropriate. When institutional frameworks can be used for more than one thing, it saves cost, time and attention."**
>
> *– **James Love,** Director, Knowledge Ecology International*

In the mid- to long-term, the European Commission should analyse all cross-border health threats facing European citizens and propose a larger ambition for HERA. Activities HERA pursues in the future should be defined after an in-depth gap analysis.

In the mid- to long-term, the European Commission should carry out a full gap analysis to determine the Authority's future remit and focus, matched to the funding available. This gap analysis should identify cross-border health threats that HERA can make a meaningful contribution towards addressing. For example, it could analyse the:

- **Urgency and potential burden of the threat:** what are the direct and indirect rewards for European citizens in tackling health threats in Europe and beyond?
- **High risk approach required:** when is HERA's approach to risk most needed, and most likely to work?
- **Complementarity with other European initiatives:** is the threat being tackled by other initiatives? This criterion will be important to avoid duplication; a good example here is antimicrobial resistance (AMR) which is a known, critical health threat to European citizens. While HERA could play an important role in creating medical countermeasures for AMR, there are significant ongoing efforts at the EU level, so HERA must consider where it is most efficient to contribute.[7]
- **Breadth of activity needed to address the threat:** is the threat something HERA can address alone, or does it require support from other actors? Many interviewees brought up Chemical, Biological, Radiological and Nuclear (CBRN) threats. When approaching the full breadth of CBRN threats, HERA must consider the many existing initiatives at the European and global level as significant responsibilities sit with organisations like NATO, and military involvement is embedded.[8]
- **Level of funding needed to address the threat:** what proportion of any future European Health Union funding package should HERA be allocated?
- **Leadership potential for Europe:** does the threat require intervention from Europe, or is it being addressed by other global actors? For example, in response to the Ebola virus outbreak in West Africa, the European Commission supported vaccine development through the Innovative Medicines Initiative (IMI) and the Horizon Programme, filling an important gap on the world stage to tackle an outbreak with pandemic potential.[9]

With pandemic threats as a starting point for HERA, part of a gap analysis should look at current initiatives to provide a full picture of existing European activities. This mapping exercise should identify gaps and key areas where HERA can add value. At a minimum, it should compare alternative options regarding the type of health threats, medical countermeasures, and activities at different stages of the value chain for medical countermeasures that HERA could develop or contribute to. In its impact assessment,

BOX 5:

Essential Medicines Shortages

While shortages of critical medical countermeasures are critical for pandemic preparedness, this is being tackled with other initiatives at a European level, so HERA will need to determine its unique contribution to this area.

- The European Health Union proposals envisage a more active role for the European Medicines Agency (EMA) to deal with this.[i]
- Shortages of medicines are currently being addressed by the EU Commission in parallel to its proposal for HERA.[ii]
- If HERA covers shortages of essential medicines, it must collaborate with the EMA and the European Directorate for the Quality of Medicines & HealthCare (EDQM), Directorate of the Council of Europe.

the European Commission should better define what areas HERA could realistically develop in the short term to maximise its impact considering many factors, including parallel developments within the European Health Union. An example of a complex and multi-factorial problem is essential medicines shortages in the EU – HERA will need to consider how it can best approach issues like this (Box 5).

The creation of HERA is an opportunity to harmonise the European research and development landscape for pandemic preparedness and rapid response capacity.

The creation of HERA, and the broader European Health Union, provides a timely opportunity to improve coordination of the European landscape and oversight of the Health Union.

From the outset, HERA and key agencies should detail how they will work together and their respective roles and responsibilities. The ECDC and EMA will closely align with HERA's work, so articulating the relationship between these institutions and where HERA, as a new agency, could add value will be particularly important – ideally within their respective legislation or via a Memorandum of Understanding (MoU). An oversight committee or similar structure should be in place to enable coordination between these three agencies. While such a committee could coordinate the work of the agencies between emergencies, HERA should assume a leadership and coordination role once a health emergency is declared (see Chapter 2: HERA must be independent).

> **"Setting up a new agency is a good opportunity to harmonise the whole landscape, and perhaps to solve political problems on defining these competencies between EU agencies."**
>
> ***– Annika Thies,*** *Director, Brussels Office, Helmholtz Association of German Research Centres*

> **"HERA should form part of a triad with the ECDC and EMA [...] the relationship between existing agencies and others needs to be taken into account."**
>
> ***– Professor Ilona Kickbusch,*** *Chair, Global Health Centre, The Graduate Institute Geneva*

BOX 6:

Collaboration between HERA and the ECDC

The ECDC is an EU agency aimed at strengthening Europe's defences against infectious diseases. Over the years, it has built expertise in managing surveillance and early warning systems by harnessing data from Member States. The Covid-19 crisis highlighted areas in which the ECDC's work could be improved. Its revised mandate (within the European Health Union proposals) aims to develop its competencies in risk assessment as well as its ability to provide scientific and technical advice.[i]

HERA's work will rely on fast and accurate information about potential health emergencies. By working closely with the ECDC, HERA might build upon its work while concentrating on its own core competency.

Likewise, horizon-scanning and foresight activities are crucial for HERA to be well prepared for health emergencies and are also part of the ECDC's proposed new mandate. HERA's contribution to these activities must be clearly defined to avoid duplication.

One particular area where strong collaboration will be required is foresight and anticipation of health threats. HERA should work in particular with the ECDC (foresight and anticipation is foreseen in its current 2021-2027 Strategy)[10] and others, such as the WHO Global Observatory on Health R&D and the WHO R&D blueprint.[11] The ongoing extensions of the ECDC and EMA's mandates must be considered when designing how these agencies will collaborate.

To succeed in this, the new agency will need to build strong collaborations with EU Commission services and agencies working on public health including the Directorate-General for Health and Food Safety, the ECDC and the EMA (as above). Building trust will be crucial for the triad relationship between the ECDC, EMA and HERA. Between crises, HERA should work alongside the ECDC, EMA and EU Commission Services to establish its legitimacy and expertise.

> **"HERA's needs assessment should consult all concerned organizations such as WHO, GAVI, to produce a systemic and transparent evaluation, to ensure additionally and avoid duplication. Parallel efforts will undermine public trust in EU institutions and compromise global network relations."**
>
> – ***Professor Debby Guha-Sapir,*** *Director, Centre for Research on the Epidemiology of Disasters, Université Catholique de Louvain*

HERA should formalise and coordinate end-to-end oversight for R&D efforts across the EC during health emergencies.

> **"To work effectively in a pandemic, the agency should act as a one stop shop, on all topics from R&D, to manufacturing, to procurement, as it is starting to act with the [HERA] Incubator."**
>
> – ***Dr Florence Baron Papillon,*** *Head of Corporate Public Affairs Europe Sanofi, Vice-President Vaccines Europe, EFPIA*

A lack of coordination at the European level during a crisis, highlighted during Covid-19,[12] can be addressed by HERA. When a health emergency is declared, HERA should assume specific and extraordinary powers to coordinate critical stages of R&D activity until the end of the emergency – interviewees emphasized the need for a clear point of contact during crises.

Collaborations with those working on research and development will also be critical, including the Directorate-General for Research and Innovation and existing public-private partnerships such as: the Innovative Health Initiative (IHI); the European and Developing Countries Clinical Trials Partnership (EDCTP); the Horizon Europe Programme; and, the European Innovation Council. Funding streams across Europe – including Horizon, the European Innovation Council, EDCTP, IMI/IHI, and upstream clinical work – need to be streamlined (see Chapter 3: HERA must be collaborative).

HERA must maintain expertise and resources between health crises.

> **"Hiatuses between programmes present areas of weakness. When you're dealing with epidemics, you can never predict when the next one is going to be. If it happens during a time of a hiatus, all your prior investments may be wasted or not put to optimal use."**
>
> ***– Dr Michael Makanga,*** *Executive Director, EDCTP*

To ensure Europe is prepared for the next pandemic, HERA must be a long-term endeavour with sufficient resources to operate and maintain expertise between crises. While public interest in HERA's activities may wane, the authority must be proactive and ready to respond to unpredictable threats.

The European Commission should consider what activities HERA will pursue between health crises to remain relevant and active. For example, BARDA was established in response to bioterrorism threats, but has diversified its activities over time and between health emergencies, including investing in the development of new antibiotics and other life-saving products to counter antimicrobial resistance.[13]

> **"HERA must not sleep in between problems. Prevention and health promotion are important for HERA to work on between crises - this will help to keep authority alive and the interest of people too. To be effective this has to be kept ongoing."**
>
> ***– Professor Henrique Barros,*** *President, Institute of Public Health, Porto University, and President, National Council of Health, Portugal*

Some interviewees reflected that between crises HERA could work to ensure EU Member States health infrastructure is strengthened and better coordinated for preparedness. As the Commission's new Regulation on serious cross-border health threats[14] plans to use stress tests to strengthen preparedness and response plans at national level, HERA could collaborate with national authorities to ensure that plans include key elements to facilitate the development and scale up of medical countermeasures. Another important activity between health crises is building relationships with stakeholders which can then be easily activated in an emergency (see Chapter 3: HERA must be collaborative).

HERA should embed a "One Health" approach.

A One Health approach which recognises the health of people is closely connected to the health of animals and our shared environment will be important for HERA's future work. 61% of all existing human pathogens are zoonotic, while 75% of pathogens which have emerged in the past decade are zoonotic.[15] The Commission is already taking this approach in its One Health Action Plan against Antimicrobial Resistance.[16]

Implementing a "One Health" approach would require HERA to champion deep collaborations, for instance, between researchers and laboratories working on human and animal health. There are important crossovers and potential added value for responding fast to emergencies, when both sectors work together.[17] For this to happen, however, existing barriers to collaboration would need to be overcome.[18] A good example of success here has been support received from veterinary laboratories to develop tests for COVID-19.[19]

2. HERA must be independent

RECOMMENDATIONS:

- A clear mandate is needed for HERA to respond effectively in a crisis.
- Transparency in HERA's decision making is critical for accountability and integrity and to build trust in its public actions.
- HERA must be an independent public Authority.
- HERA should use its independence to take risks.

To succeed, HERA will need to be independent – to take risks and have clear mandate for decision making, safeguarded from political or commercial interests. This chapter explains how this independence can enable HERA to prepare for, and respond to, a health crisis effectively.

> **"If you're at risk of a pandemic, a key aspect for a good response is speed. Acting at speed means you understand risk. This was not understood at a European level [for Covid-19] – and Europe waited for a clear sign there was a pandemic. If you understand risk, you act quickly, but you need to have clear decision-making structure to enable that."**
>
> ***– Professor Ilona Kickbusch,*** *Chair, Global Health Centre, The Graduate Institute Geneva*

> **"US BARDA has several branches and its objectives are organized quite simply; this clear definition helps when crises emerge. HERA needs to agree upon a command structure and mandate. What guidance HERA is allowed to give to Member States and other partners like academia and industry also needs to be clear."**
>
> ***– Pierre Neirinckx,*** *MD, Surgeon General of the Belgian Defense, Associated Member of the Belgian Royal Academy of Medicine*

A clear mandate is needed for HERA to respond effectively in a crisis.

Interviewees reflected on how better coordination at the start of the Covid-19 outbreak may have quickened Europe's response. To address this gap in future, HERA must be empowered to make decisions quickly. For this to happen, Member States will need to support HERA's mandate and its independent action. Agreeing in advance the context in which HERA can act will be critical for political buy-in. For example, HERA could be activated on specific issues if a Public Health Emergency of International Concern (PHEIC) is declared (see Chapter 3: HERA must be collaborative). A PHEIC can be declared globally by the WHO and under the Commission's new serious cross-border health threat regulation proposal (article 23) it could in future be declared at the EU level by the Commission, based on the expert opinion of an advisory committee.[20]

> **"[HERA] should have some independence with regards to the Member States. The appointed Director should be free to make technical decisions, including what and where to support."**
>
> ***– Dr Marie-Paule Kieny,*** *Director of Research, Inserm*

Transparency in HERA's decision making is critical for accountability and to build trust and integrity in its public actions.

To build confidence in HERA's ability to lead on preparedness and response, it will need to be transparent in its decision-making. Having a clear decision-making structure will also help to build trust and help stakeholders to understand how to interact with HERA and the boundaries under which it operates. Funding decisions must be based on the best evidence available, overseen by technical experts, and endeavour to be separate from political objectives.

A HERA Director, sitting outside of the Commission and endorsed by Member States, should be responsible for decision-making and be a step removed from political structures.

In a similar mechanism to the ECDC, HERA could have a Board to hold the Director accountable for HERA's work.[21] Members of this board could be nominated by Member States, the European Parliament and the European Commission. In addition, yearly progress reports could be presented to the European Parliament to ensure that HERA remains fully accountable. Transparency, accountability and integrity should not be seen in contradiction to agility or capacity to respond during emergencies. A proper mechanism could be that once a PHEIC is declared, the European Parliament and Member States would agree to emergency mandate powers of HERA, enabling it to act without undue burden such as reporting obligations. This would allow HERA to remain fully accountable and transparent but also able to react quickly during emergencies.

HERA must be an independent public Authority.

> **“The public should act as a wise investor in HERA’s activities. Industry will need to be involved for HERA to deliver, and this involvement must be open and inclusive.”**
>
> ***– Yannis Natsis,*** *Policy Manager Universal Access and Affordable Medicines, European Public Health Alliance*

HERA should be a fully public Authority, with industry as a key partner (see Chapter 3: HERA must be collaborative) and significant effort should be invested in these relationships. While industry should not be included in governance, as it would likely be a direct beneficiary of HERA’s public funding, the Commission should carefully consider the potential advantages and disadvantages of industry playing a decision-making role during a crisis. This participation in decision-making should be transparent, with an assurance that industry will not have a privileged role compared to other actors.

The use of public money must be reflected in HERA’s operations – HERA’s relationship with industry must be open and financial rewards or public investment must be shared. For example, pricing or other conditionalities could be embedded in any formal agreements.

HERA should use its independence to take strategic and evidence-based risks.

> **“HERA needs a clear dedicated budget that allows for risk-taking. This has been the big difference between EU and the US – the US has been able to put significant money on the table quickly.”**
>
> ***– Bernard Grimm,*** *Healthcare Biotechnology Director, EuropaBio*

Being independent will also allow HERA to take evidence-based risks that make the best use of public funds. The Authority must be able to fund innovative biomedical research and development that may not have a guaranteed outcome and manage this portfolio or risk. For example, the success of vaccine candidates in development for Covid-19 was unpredictable and would not have been possible without the global drive for vaccine development, something which HERA will play a role in in the future.

HERA’s ability to balance strategic risk-taking and the responsible use of funds will depend on its independence, use of internal and external expertise and its ability to make fast, informed decisions both during and between crises. Its budget and accountability structures will also shape the risks it can take.

3. HERA must be collaborative

RECOMMENDATIONS:

- **HERA must work closely with other EU institutions (including EMA and ECDC), initiatives and programmes to enable and amplify, rather than detract from, existing activities.**
- **HERA must work closely with Member States to build legitimacy and trust, incorporating and sharing national expertise.**
- **HERA must build and maintain relationships between health crises so that in emergency it can respond quickly in collaboration with trusted partners.**
- **HERA must prioritise building strong relationships with industry.**
- **HERA needs a broad base of support to be effective.**

HERA will need to collaborate and interact with actors at all levels (e.g. global, national and EU) and sectors. This section illustrates how HERA should collaborate with actors at the EU and national level while global collaborations are addressed in Chapter 4: HERA must be global.

HERA must work closely with other EU institutions (including EMA and ECDC), initiatives and programmes to enable and amplify, rather than detract from, existing activities.

HERA must work closely with other EU institutions, initiatives (e.g. the pharmaceutical strategy) and programmes (e.g. Horizon Europe) to enable and amplify, rather than detract from, existing activities (See Chapter 1: HERA must be focused, yet flexible). This is crucial for avoiding duplication and ensuring effectiveness.

HERA should look to the US BARDA for lessons on inter-agency collaboration – one of BARDA's strengths has been its ability to interact with a wide range of related US agencies, including on research and public health. BARDA is included in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), an effort led by the US Department of Health and Human Services to coordinate US Federal efforts. PHEMCE coordinates BARDA, the US CDC (via the Strategic National Stockpile), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Homeland Security (DHS). BARDA's links to these agencies help it to enable collaborations and avoid wasteful duplications (for more detail, see Annex 1).

> **"We need to understand what are the gaps that must be filled and try to fill them in a coordinated way."**
>
> ***– Dr Stéphan Zientara,*** *Director, ANSES/INRAE/INRA Joint Research Unit in Virology, Alfort National Veterinary School*

HERA must work closely with Member States to build legitimacy and trust, incorporating and sharing national expertise.

> **“When you compare across the 27 countries, the strength of their agencies is very diverse, and a critical part of biodefence is that everyone needs to be on the same level. The EMA took the best [from national agencies] and helped countries to move forward – this becomes a virtuous cycle where you take the best practice from Member States, digest it and reshare it across Europe.”**
>
> ***– Professor Henrique Barros,*** *President, Institute of Public Health, Porto University, and President, National Council of Health, Portugal*

HERA must also interact and collaborate with national authorities, playing a key role in preparedness and response across EU Member States, and sharing best practice from national agencies.

HERA must strike the right balance between acting quickly in an emergency and ensuring national opinion – and expertise – is taken into account (see Chapter 1: HERA must be independent). A solution to this could be that, in a similar way to the EMA, HERA delegates specific activities to Member States to build expertise between emergencies. A more directional, coordinating role could then be assumed by HERA during emergencies. This co-creation approach could help the agency build legitimacy and trust. The Covid-19 crisis has highlighted the needed for collective efforts to be improved during emergencies, however any such authority must recognise national expertise when advising Member States.

HERA must build and maintain relationships between health crises so that in emergency it can respond quickly, in collaboration with trusted partners.

> **“The reason why the US could act as fast as they did in the current pandemic was because they had ongoing relationships in place with industry; they had contracts in place and could pivot the scope.”**
>
> ***– Katrine Thor Andersen,*** *Deputy Director, Alliance Management, Global Health, Bill and Melinda Gates Foundation*

HERA must engage many different stakeholders. When building relationships HERA will need to balance inclusivity and transparency, and the need to respond quickly to health emergencies. This will require additional effort to build trusted relationships between crises, so that HERA is prepared to rapidly respond in time of emergency.

HERA must prioritise building strong relationships with industry.

To succeed, HERA must prioritise its engagement with industry. A close relationship with industry needs to build upon an open and constant dialogue, as well as deep understanding of how the sector operates. For these reasons, it is advisable that HERA staff should have experience working or collaborating with industry.

BOX 7:

Learning from other organisations' approaches to industry partnerships

- **The Innovative Medicines Initiative (IMI):** IMI has built positive and productive collaborations with industry through public-private partnerships. However, as a standalone Authority with an ambition to fund beyond IMI's scope into late-stage clinical trials, HERA will need to handle industry collaboration differently. HERA should therefore have the right financing for agility while protecting the interests of stakeholders.
- **US BARDA:** Early collaboration with manufacturing companies to scale up production was a key success factor during the Covid-19 crisis. On the other hand, a lack of clear global vision stopped BARDA from addressing equitable access when developing agreements with industry. HERA should differentiate itself by providing balanced solutions that are mindful of incentives for industry while addressing the important ongoing issues of accessibility and affordability of medical countermeasures in Europe and worldwide (see Chapter 4: HERA must be global).

HERA should act as an honest broker to represent public interest but recognise industry expertise and proactively involve the sector in HERA (see Chapter 2: HERA must be independent).

> **"EU HERA should foster public-private partnerships and act as an honest broker to facilitate industry-academia agreements."**
>
> ***– Dr Michel Goldman,*** *MD, President, Institute for Interdisciplinary Innovation in healthcare, Université libre de Bruxelles. Former Executive Director, Innovative Medicines Initiative*

Articulating how Small and Medium Enterprises (SMEs) engage with HERA, also in light of the Pharmaceutical Strategy,[22] will be crucial. During the Covid-19 crisis, there was no structure in place for the Commission to engage SMEs and biotechnology companies, meaning their innovations were missed. HERA could provide a simple, clear and direct channel for SMEs to partner with the Commission, to ensure innovation originating in small companies is supported.

HERA needs to build a broad base of support to be effective and gain trust.

> **"When preparing for the long-term it's important to involve stakeholders. In order to act quickly – you should explain what you are doing and be clear. Good communication will be based on prior stakeholder relationships."**
>
> ***– Bernard Grimm,*** *Healthcare Biotechnology Director, EuropaBio*

To build legitimacy and ensure accountability, HERA must generate support for its activities from a range of stakeholders including civil society, academia and industry. Part of this will be through regular, transparent dialogue with stakeholders. HERA could also incorporate formal mechanisms for collaboration, like an advisory group to provide expertise on different parts of HERA's operations, for example distribution or access (See Chapter 4: HERA must be global). HERA should also communicate its work clearly and in an accessible way.

The type of consultation HERA conducts should be different during a crisis and between crises. During the Covid-19 crisis, the European Commission set up an ad hoc advisory panel chaired by Peter Piot, special advisor to President Von der Leyen.[23] Bearing in mind that open consultation will likely not be possible when HERA will need to make decisions quickly during a crisis, a consensual, collaborative approach between crises will enable HERA to be more directive when necessary.

4. HERA must be global

RECOMMENDATIONS:

- → **HERA must take a global approach to emergency preparedness and response.**
- → **HERA should prioritise equitable access in its funding and operations.**

> **"A strong EU should embrace the rest of the world. It needs to look out for and help everyone."**
>
> ***– Dr Dorit Nitzan,*** *Regional Emergency Director, WHO Regional Office for Europe*

HERA will be a crucial mechanism for helping deliver the European Commission's vision for global health.[24] HERA should enable the EU to assume a leading role globally, not only by committing part of its resources towards equitable access to medical countermeasures for low- and middle-income countries, but also by encouraging key partners to do the same.

This chapter demonstrates why taking a global approach will allow HERA to protect citizens in Europe and in low- and middle-income countries, while upholding EU values and avoiding duplication, especially as it establishes itself.

HERA must take a global approach to emergency preparedness and response.

Covid-19 has demonstrated that, in the case of health emergencies, no one is safe until everyone is safe. While created to improve coordination in Europe, HERA must collaborate with global organisations to be effective. There is no European solution to infectious disease.

HERA should work closely with global organisations and networks when deciding what research to fund, and on the production and distribution of medical countermeasures. Doing this will ensure both a coordinated response and that the work of HERA fills genuine gaps in the existing emergency response landscape. The "Team Europe" funding package to support partner countries against the Covid-19 pandemic is a strong example of the multilateral coordination that HERA should embed in its work.[25]

> **"If we emerge out of the Covid-19 with more competition rather than cooperation, this would be very detrimental."**
>
> ***– Dr Dorit Nitzan,*** *Regional Emergency Director, WHO Regional Office for Europe*

BOX 8:

Team Europe

To improve cross-border coordination, the EU launched its "Team Europe" initiative in April 2020.[i] This funding package, totalling over EUR 40 billion, will fund vaccines and support partner countries' health systems and economic recovery.

Team Europe funding includes support for the Access to Covid-19 Tools (ACT) Accelerator to ensure equitable access to Covid-19 tests, treatments and vaccines. Team Europe Initiatives are informed by the Neighbourhood, Development and International Cooperation Instrument (NDICI) programming guidelines.[ii]

HERA will also require strong ties to international clinical trials networks. As part of the Incubator actions, VACCELERATE[26] is taking steps to coordinate Covid-19 trials across Europe. The European and Developing Countries Clinical Trials Partnership (EDCTP) is an example of a European partnership between countries in Europe and sub-Saharan Africa to accelerate the development of medical interventions for poverty-related infectious disease. It will be important as part of the initial assessment of existing gaps at EU level, to consider why existing European clinical trials networks like EDCTP, but also PREPARE and COMBAT, were insufficient to respond to Covid-19 and the Commission should take these lessons forward when building HERA's activities.[27]

These relationships can be developed during 'peace time' and will enable HERA to maintain expertise and establish its role between crises (see Chapter 1: HERA must be focused yet flexible).

HERA should prioritise equitable access in its funding and operations.

Part of HERA's global approach must be a commitment to equitable access for the medical countermeasures it funds. Throughout the Covid-19 pandemic, we have seen new variants emerge in different countries and spread worldwide. HERA's ability to protect Europeans from emerging and residual health threats will be predicated on its actions beyond Europe.

HERA should embed global access requirements into its funding agreements, based on the principles of equality and solidarity that inform all EU external action[28] and the EU's commitment to Sustainable Development Goal 3, to help ensure medical countermeasures are available, affordable and appropriate for use in LMICs.[29] Leading by example, the EU should encourage other nations and regions to behave in the same way – as it did in its early support for the ACT Accelerator, by investing and hosting pledging events.[30]

> **"HERA needs to have a holistic view; as long as there are countries that don't have access to treatments and preventions, we will have reservoirs of disease that can come back."**
>
> ***– Katrine Thor Andersen**, Deputy Director, Alliance Management, Global Health, Bill and Melinda Gates Foundation*

> **"Affordability and accessibility should be non-negotiables. They should be mandated and built into the agreements of all activities funded by the agency."**
>
> ***– Dr Michael Makanga,** Executive Director, EDCTP*

When accelerating and upscaling the production of medical countermeasures, HERA should ensure that this contributes to global efforts to meet demand for products and tackle health emergencies. This should include identifying long-term actions that can be undertaken ahead of time to scale supply capacity for health emergencies and help meet global demand. Collective action to increase production capacity will help reduce supply constraints and inequitable distribution in the current pandemic.[31] This advance commitment and increased production will help mitigate the scarcity conditions that have prompted nationalistic responses to the current pandemic. HERA should also invest in delivery systems so that medical countermeasures like vaccines remain safe and effective when they reach third countries.

Access to medical countermeasures is also supported by access to know-how. HERA should build on existing networks to facilitate technology transfer and scientific cooperation, in line with the new EU-African Strategy's[32] emphasis on research and innovation capacities, and the EU's Open Science policy.[33]

> **"In terms of self-interest and global solidarity, the Health Union cannot be thought about without a global dimension."**
>
> ***– Professor Ilona Kickbusch,*** *Chair, Global Health Centre, The Graduate Institute Geneva*

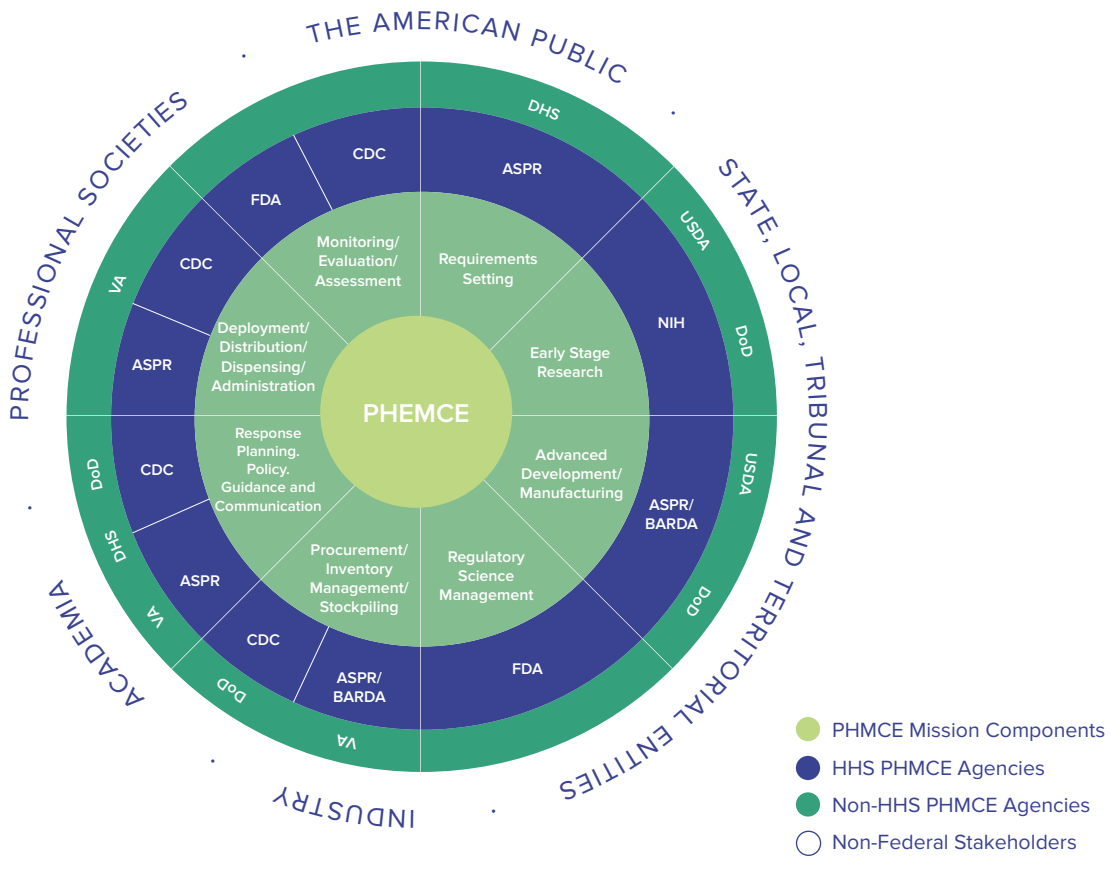
ANNEX 1:

Further detail on BARDA

In addition to the case study on page 7, there are other important elements of the US Biomedical Advanced Research and Development to consider when using it as a model.

The United States emergency preparedness and response landscape is coordinated by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). One of BARDA's strengths is that it is part of this network – of which core components are the U.S. Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes for Health (NIH), the Department of Defense (DoD), the Department of Veterans Affairs (VA), the Department of Agriculture (USDA), and the Department of Homeland Security (DHS) (see image, right).

Another important element of BARDA's activity is that it takes a proactive approach to address medicine supply issues – an area the European Commission is addressing through its pharmaceutical strategy.[34] An example of this is a contract with Phlow, a little-known US-based company, that BARDA proactively awarded a contract to, to secure a domestic supply of essential medicines during Covid-19. The initial USD 354 million four-year contract will on-shore the manufacture of critical active ingredients to guarantee a supply of essential medicines.[35]



PHMCE mission components.

Image from: https://www.phe.gov/Preparedness/mcm/phemce/Pages/mission.aspx

ANNEX 2:

Contributors to this report

ACKNOWLEDGMENTS

This report has been informed by over 40 individuals from across research organisations, civil society, think tanks, and industry, from across Brussels, EU Member States and beyond. We are very grateful to everyone who took part in our interviews and the policy roundtable.

This report is not a synthesis of their views but is independent. The recommendations are a collaboration between Wellcome Trust and the Federation of European Academies of Medicine.

We are also grateful to FEAM's Member Academies, for reviewing and providing comments to earlier drafts, to Wellcome and FEAM staff for their work, and in particular to Catherine Guinard and Amelia Dearman (Wellcome) for designing the methodology for this report, and to Amelia Dearman, Catherine Guinard, Erika Loggin (Wellcome), Laure Guillevic, and Rosa Castro (FEAM), for carrying out the interviews with experts and stakeholders and drafting the report.

DISCLAIMER

The Austrian Academy of Sciences, which is a member of FEAM, requires additional data to formulate its opinion and, as a result, reserves its position.

PROJECT PARTICIPANTS *(interview and roundtable)*

Dr Anna Sandstrom, *Science Policy and Relations Director Europe, AstraZeneca*

Annabel Seebohm, *Secretary General, Standing Committee of European Doctors (CPME)*

Annika Thies, *Director, Brussels Office, Helmholtz Association of German Research Centres*

Antonella Cardone, *Director, European Cancer Patient Coalition (ECPC)*

Bernard Grimm, *Healthcare Biotechnology Director, EuropaBio*

Bianca Ferraiolo, *Head of the Representative Office to the EU, Active Citizenship Network (ACN)*

Professor Debby Guha-Sapir, *Director, Centre for Research on the Epidemiology of Disasters, Université Catholique de Louvain*

Dr Despoina Iatridou, *Senior Policy Officer, Federation of Veterinarians of Europe (FVE)*

Dr Dorit Nitzan, *Regional Emergency Director, World Health Organization (WHO) Regional Office for Europe*

Dr Pierre Neirinckx, *MD, Surgeon General of the Belgian Defense, Associated Member of the Belgian Royal Academy of Medicine*

Dr Florence Baron-Papillon, *Head of Corporate Public Affairs Europe Sanofi, Vice-President Vaccines Europe, European Federation of Pharmaceutical Industries and Associations*

Francoise Meunier, *MD, Director General, European Organisation for the Research and Treatment of Cancer (EORTC) and Board Member, Federation of European Academies of Medicine (FEAM)*

Professor George Griffin, *President, Federation of European Academies of Medicine (FEAM)*

Georgina Wright, *Head of Europe Programme, Institut Montaigne*

Dr Gundo Aurel Weiler, *Director, Country Support and Emergengies (CSE), WHO Regional Office for Europe*

Professor Henrique Barros, *President, Institute of Public Health, Porto University, and President, National Council of Health, Portugal*

Professor Ilona Kickbusch, *Chair, Global Health Centre, The Graduate Institute Geneva*

Ilse Bosch, *International Policy Consultant, NHS Confederation*

James Love, *Director, Knowledge Ecology International*

Dr Jens Jäger, *Delegate for the Research Field Health, Helmholtz Association of German Research Centres*

Jeremy Knox, *Policy and Advocacy lead Drug-resistant Infectious Programme, Wellcome Trust*

Juan Fernandez, *Policy Assistant, European Patients' Forum (EPF)*

Julia Barnes-Weise, *Executive Director, Global Healthcare Innovation Alliance Accelerator (GHIAA)*

Katrine Thor Andersen, *Deputy Director, Alliance Management, Global Health, Bill and Melinda Gates Foundation*

Magali Poinot, *Advisor to IMI Executive Director, Innovative Medicines Initiative (IMI)*

Magda Chelbus, *Executive Director Science Policy and Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA)*

Margriet den Boer, *NTD Advisor, Médecins sans Frontières UK and Ireland*

Marieke Meijer, *Communication & Policy Coordinator, BioMed Alliance*

Dr Marie-Paule Kieny, *Director of Research, Inserm*

Melanie Saville, *Director, Vaccine Development, Coalition for Epidemic Preparedness (CEPI)*

Professor Mical Paul, *Head Division of infectious diseases, Rambam Health Care Campus*

Dr Michael Makanga, *Executive Director, European & Developing Countries Clinical Trials Partnership (EDCTP)*

Michael Zaiac, *MD, Head of Medical Affairs, Oncology Region Europe, Novartis*

Dr Michel Goldman, *MD, President, Institute for Interdisciplinary Innovation in Healthcare (I3h), Université libre de Bruxelles, Former Executive Director of the Innovative Medicines Initiative (IMI)*

Michele Calabro, *Policy Advisor, European Patients' Forum (EPF)*

Pascal Garel, *Chief Executive, European Hospital and Healthcare Federation (HOPE)*

Piotr Kolczynski, *Legal Advisor, Standing Committee of European Doctors (CPME)*

Richard Price, *EU Affairs Policy Manager, European Cancer Organisation (ECCO)*

Rosie Richards, *Senior International Policy Manager, NHS Confederation*

Samia Saad, *Director of Resource Mobilisation & Investor Relations, Coalition for Epidemic Preparedness (CEPI)*

Dr Stéphan Zientara, *Director, ANSES/INRAE/INRA Joint Research Unit in Virology, Alfort National Veterinary School*

Terri Stewart, *VP, Head of Global Innovative Medicines Franchise Policy, EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany*

Dr Timothy Jinks, *Head of Drug-resistant Infectious Programme, Wellcome Trust*

Viviana Galli, *Coordinator, European Alliance for Responsible R&D and Affordable Medicines*

Yannis Natsis, *Policy Manager Universal Access and Affordable Medicines, EPHA*

ANNEX 3:

FEAM Forum Summary

15 March 2021

The FEAM European Biomedical Policy Forum in partnership with the Wellcome Trust

A stronger crisis preparedness: The European Health Emergency Response Authority (HERA)

Forum roundtable discussion - Meeting Summary

The Federation of European Academies of Medicine (FEAM) and Wellcome are consulting with a range of stakeholders to produce recommendations for the European Commission's proposal for an EU Health Emergency Preparedness and Response Authority (HERA). As part of this consultation, FEAM European Biomedical Policy Forum members and other interested parties came together to discuss the EU HERA proposals. Attendees included industry, civil society, and patient groups (full attendee list – appendix 1). The following questions were discussed by the group:

What gap could HERA fill and what needs to be in place for it to succeed?

There was some debate on **HERA's ambition**, and what is achievable given the scale of funding available. Some attendees suggested HERA should take a broad approach to preparedness and response, where others thought it was more feasible to start with a more limited scope in terms of health threats, particularly as political support may change. There was agreement that for HERA to succeed, it needed **significant and sustained funding** and it would need to weather political cycles. The future relationship between EU Member States and HERA was seen to be critical to ensure **national commitment** and adherence to HERA policy recommendations.

Attendees noted that for HERA to succeed, it must have a **mandate for decision-making** to ensure it can respond quickly in a crisis. HERA would also require technical expertise, a focus on being proactive rather than reactive, and strong stakeholder relationships to succeed. Some attendees believe HERA would be most beneficial as a **single point of contact** for EU funding preparedness and response – from research and development, to manufacturing, to purchasing and delivery. Supply chains were also mentioned as important to invest in, to be able to rapidly mobilise medical countermeasures across different geographies.

Some attendees see HERA as an opportunity for a joined-up **horizon scanning** function across the EU to identify future health threats, including improved coordination across European health data systems, in the context of the planned European Health Data Space. Others raised the importance of HERA taking a **One Health** approach, to consider humans, animals and their environment together, particularly in the context of emerging zoonotic diseases.

Monitoring **healthcare workforce capacity** and **shortages in medical counter-measures** across the EU was also considered an important function for response.

What could we learn from other organisations and previous health crises?

Attendees recognised that while there was much to learn from US Biomedical Advanced Research and Development Authority (**BARDA**), the European context must be taken into consideration. The budget for HERA is much smaller than BARDA and the European innovation landscape is different. Stakeholders reflected that BARDA could be more transparent, and this was something that could be an added advantage for HERA. On transparency, there was also a suggestion that HERA could adopt open science principles – for rapid information sharing during a crisis and to publish public/private contracts.

From the **COVID-19 pandemic**, attendees noted that a key gap in the European response has been the issue of affordability and access to medicines and this must be a key consideration for HERA. COVID-19 has also demonstrated the need for solidarity and coordination across the EU bloc; nationalistic approaches have sometimes contradicted efforts at the pan-EU level. It was also noted that the **HERA Incubator** has begun to set the direction of the broader HERA proposals and there will be important lessons to learn from its implementation.

Some stakeholders said that while there are many lessons to be learned from the **Innovative Medicines Initiative (IMI)**, this public private partnership has also highlighted issues of mistrust towards the private sector and that HERA could help to rebuild this relationship. Also, while IMI's investment focuses on pre-clinical stage research, HERA could take a more end-to-end approach to developing medical counter-measures, to ensure product development.

How could HERA work in practice?

There was a lot of discussion about the role of **public private partnerships** (PPPs) in HERA. Some reflected that HERA could provide a new model for European PPPs – including more of a focus on product development and deployment, rather than precompetitive research. Others noted industry could move away from the IMI model (where industry mainly provides in-kind contributions) to increase risk-sharing. An example of an activity HERA could pursue to share risk and investments was the use of Advanced Purchase Agreements, which have been used to collectively procure COVID-19 vaccines and ramp-up industrial capacities in Europe. It was recognised that while HERA will need to remain attractive to industry partners, its creation could be a good opportunity to establish a new social contract between pharmaceutical and lifescience industries and society and patients.

There was also a recognition that the **public element** of HERA is critical and could be core to ensure its independence and transparency. Participants also recognised a need for public interest safeguards in agreements with industry, including the need to ensure that public funding is reflected in the final procurement and pricing of products receiving HERA funding. Having political independence was considered important to ensure accountability and to establish distance when setting objectives not liable to change with political cycles. Some attendees reflected that HERA will need to navigate political and market tensions while maintaining its **autonomy**.

Attendees agreed that HERA should position itself within the **European and international ecosystem**; it should not be isolated, and any medical countermeasures created through HERA should be globally accessible.

Acknowledgments

FEAM warmly thanks the participants for their contribution to the discussion, the Wellcome Trust for its support, in particular Catherine Guinard for moderating the event, Amelia Dearman and Erika Loggin for drafting its summary report.

REFERENCES:

1. President von der Leyen on the COVID-19 outbreak (europa.eu)
2. State of the Union Address by President von der Leyen (europa.eu)
3. https://ec.europa.eu/info/sites/info/files/communication-european-health-union-resilience_en.pdf
4. communication-hera-incubator-anticipating-threat-covid-19-variants_en.pdf (europa.eu)
5. Global leaders unite in urgent call for international pandemic treaty (who.int)
6. Given the absence of a formal definition for pandemic, the European Commission should also carefully consider whether to rely on the definition of a Public Health Emergency of International Concern (as per the International Health Regulation of the WHO), or on a broader definition of cross-border epidemic. Clearly agreeing on a definition will facilitate earlier action by HERA.
7. Pharma strat and EU AMR action plan
8. https://www.nato.int/cps/en/natolive/topics_49156.htm
9. https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/ebola/ebola-research-and-innovation-strategy_en
10. https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-Strategy-2021-2027.pdf
11. https://www.who.int/research-observatory/analyses/rd_blueprint/en/
12. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31411-2/fulltext#%20
13. https://carb-x.org/
14. https://ec.europa.eu/info/sites/info/files/proposal-regulation-cross-border-threats-health_en.pdf
15. https://www.who.int/neglected_diseases/diseases/zoonoses/en/
16. https://ec.europa.eu/health/antimicrobial-resistance/eu-action-on-antimicrobial-resistance_en
17. https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/COV-19/A_Guidance_for_animal_health_laboratories_1April2020.pdf
18. https://theconversation.com/lutte-contre-le-coronavirus-mais-ou-sont-passes-les-veterinaires-137279
19. https://academie-veterinaire-defrance.org/communiques-de-presse/realisation-des-tests-covid-19-par-les-structures-veterinaires
20. https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/646123/EPRS_BRI%282020%29646123_EN.pdf
21. https://www.ecdc.europa.eu/en/about-us/how-we-are-governed/management-board
22. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761
23. https://ec.europa.eu/health/advisorypanel_covid19_en https://www.lshtm.ac.uk/newsevents/news/2021/professor-peter-piot-appointed-special-advisor-president-european-commission
24. https://ec.europa.eu/health/international_cooperation/overview_en
25. “Team Europe” - Global EU Response to Covid-19 supporting partner countries and fragile populations - European External Action Service (europa.eu)
26. https://vaccelerate.eu/
27. https://www.prepare-europe.eu/
28. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016ME/TXT&-from=EN#d1e826-13-1
29. https://ec.europa.eu/international-partnerships/sdg/good-health-and-well-being_en
30. https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-on-line-pledging-event-hosted-by-the-european-commission
31. https://wellcome.org/reports/equitable-access-health-technologies-lessons-covid-19
32. communication-eu-africa-strategy-join-2020-4-final_en.pdf (europa.eu)
33. https://ec.europa.eu/info/research-and-innovation/strategy/goals-research-and-innovation-policy/open-science_en
34. https://ec.europa.eu/health/human-use/strategy_en
35. Little-known drug manufacturer gets big contract for COVID-19 response

BOX 1:

I. https://www.sciencedirect.com/science/article/pii/S016885102030107X; https://www.bmj.com/content/368/bmj.m1075.full
II. https://link.springer.com/chapter/10.1007/978-3-030-51791-5_44
III. https://voxeu.org/article/how-strengthen-european-industries-leadership-vaccine-research-and-innovation

CASE STUDY: US Biomedical Advance Research and Development Authority (BARDA):

I. https://www.phe.gov/about/barda/Pages/default.aspx
II. https://www.phe.gov/about/aspr/Pages/aspr-fy2021-bib.aspx
III. https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

BOX 3:

I. https://ec.europa.eu/health/funding/eu4health_en

BOX 4:

I. https://ec.europa.eu/commission/presscorner/detail/en/ip_21_641
II. https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_642

BOX 5:

I. https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-medicines-agency_en.pdf
II. ii https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761#footnote44

BOX 6:

I. https://ec.europa.eu/info/files/proposal-extend-mandate-european-centre-disease-prevention-and-control_en

BOX 8:

I. https://ec.europa.eu/international-partnerships/topics/eu-global-response-covid-19_en
II. WBT Team Europe | Capacity4dev (europa.eu)


FEAM
Federation of European
Academies of Medicine


wellcome