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THE FUTURE HERA:


WHAT IS AT STAKE?

PARTLY IN RESPONSE TO THE PANDEMIC,
THE EUROPEAN COMMISSION HAS PROPOSED
CREATING A NEW AGENCY — THE HEALTH EMERGENCY
PREPAREDNESS AND RESPONSE AUTHORITY (HERA).
WHAT SHOULD IT DO? WHO WILL FUND IT?

THESE ARE AMONG THE QUESTIONS DEBATED AT AN
ONLINE SCIENCE|BUSINESS WORKSHOP IN JANUARY 2021.

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This report is based on an online workshop organised by Science|Business. The views expressed are those of the individuals quoted, and do not necessarily represent those of Sanofi or other organisations with participating representatives. None of the workshop participants received any financial incentives from Sanofi or Science|Business, and Science|Business wishes to thank the participants for their time and insights.

The rapporteur was Nicholas Wallace, correspondent at Science|Business.

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AVENUE DES NERVIENS 79
1040 BRUSSELS, BELGIUM
info@sciencebusiness.net**

SUMMARY: DEBATING THE FUTURE OF THE NEXT EU HEALTH AGENCY

In the midst of the pandemic in September 2020, European Commission president Ursula von der Leyen announced the creation of a new organisation to help deal with such disastrous health issues: the Health Emergency Preparedness and Response Authority (HERA). Exactly what it will do, how and with what money, remain open questions as we enter 2021; member states are still discussing the plans. But it is clear to all that such an authority would be a major, and important, departure in EU efforts to promote its citizens' health.

To help elucidate some of the open questions, Science|Business on 14 January 2021 organised an online conference about HERA. In an effort to widen that debate on a matter of vital public interest, this impartial document reports on the questions raised – with a call for policy makers to consider their answers carefully before acting.

Experts discussed the extent to which HERA should emulate the US Biomedical Advanced Research Authority (BARDA), which since 2006 has been stockpiling and funding the development and manufacture of a variety of medical countermeasures, including for influenza-like epidemics. HERA's funding is unlikely to be of the order of BARDA's \$1.6 billion per year, so participants agreed that its scope must be limited to goals that can be agreed within the budget available. For example, participants said, the European Commission should define clearly what HERA will or will not fund, such as whether it will bankroll manufacturing directly or coordinate financing from the European Investment Bank or other sources.

The next key question under debate is how HERA itself will be funded. The EU budget for the next seven years is settled and contains no provisions for anything like HERA. For example, the BARDA-coordinated public-private partnership (PPP) for SARS-CoV2 Vaccines, Operation Warp Speed, invested some \$12 billion, whereas the EU's PPPs for vaccine R&D are worth a fraction of that. Taking money from existing programmes could prove controversial, experts warned. EU member states could be asked to contribute directly, but they would likely ask for a direct role in HERA's governance in return.

HERA's governance needs to be designed carefully because healthcare is a national competence in the EU treaties. Other EU agencies focused on health or medicines are intergovernmental—they answer to member states—and are independent of the European Commission. That raises a series of questions about HERA's structure and governance—will it take a similar form? Will it be a concrete entity, or a policy of coordination among existing bodies? Will the authority be a full-blown EU agency, and will it answer directly to the Commission, to the member states, or an independent board? Meanwhile, the EU's Innovative Medicines Initiative (IMI), which funds early-stage medicines research, is not an agency at all but a public-private partnership. So will HERA be an exclusively public body, or a partnership that gives the private sector a seat at the table? And how will its activities remain focused on science and epidemiological insights, while keeping political interference at bay?

Whatever form it takes, HERA is likely to fund private sector activities, including late-stage development and manufacturing—so the Commission needs to define the limits of what companies will be able to do with public money. 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. Pharmaceutical companies sink huge amounts of money and time into medicines and vaccines that never take off, and make up for that with large profits from those that do. So how much public money will be put at risk in this way, and how will the public's fair share of the rewards be guaranteed?

Finally: the EU is a union of high-income countries, and COVID-19 shows that pandemics can come to the EU from far beyond its borders. Participants asked what HERA's global role will be: for example, will it help address breakouts around the world before they spread, and will it help guarantee medical supplies for underserved regions?



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INTRODUCTION

PREPARING EUROPE FOR

THE NEXT HEALTH EMERGENCY

The COVID-19 pandemic caught governments everywhere off guard. Here in Europe, startled leaders, struggling to contain the rapidly-spreading new coronavirus, followed China by imposing harsh “lockdown” policies never before seen in liberal democracies. The European Commission soon came under criticism for its failure to match US support for vaccine development, and for its sluggish attempts at joint vaccine procurement, which saw Germany, the EU’s largest and wealthiest member state, lose patience and buy its own supply. The SARS-Cov-2 vaccine rollout in the EU has been much slower than in the United Kingdom, the United States, and several other countries.

The question now is what must be done to ensure the EU does better next time. The Commission, for its part, wants to establish a new EU body responsible for ensuring rapid and secure access to vaccines, therapies and medical equipment when the next emergency arrives. The Health Emergency Preparedness and Response Authority (HERA) is tipped as Europe’s answer to the \$1.6 billion per year US Biomedical Advanced Research and Development Authority (BARDA). Since 2006, BARDA has worked with the pharmaceutical industry and US public health and defence agencies to procure and stockpile medical countermeasures against pandemics; emerging diseases; and chemical, biological, radiological and nuclear threats [CBRN].

The Commission says a full legislative proposal for HERA is in the works and should surface towards the end of 2021. But for

now, the authority has no budget, no mandate, no governance and no form—it remains little more than a partially-defined ambition for medical preparedness in the EU, where health policy is legally the responsibility of national governments.

However, on 17 February, the Commission did launch the preliminary ‘HERA incubator’ to mobilise resources to respond to new COVID-19 variants. The initiative includes a €150 million fund to boost research into new variants of COVID-19, paid for out of the Horizon 2020 & Horizon Europe research programmes. The incubator will pay labs to identify and analyse new variants of the virus. It will also support companies to develop vaccines and improve Europe’s manufacturing capacity. Additionally, the incubator will help organise pan-European clinical trials under a new scheme called ‘VACCELERATE.’ This work will lay some of the foundations for HERA proper, the permanent structure of which is still to be decided.

So how will HERA work? What will it do? Who will run it? Who will pay for it? Whom will it have to work with—and how—to have an impact on Europe’s ability to handle large-scale medical emergencies well? On 14 January 2021, Science|Business, supported by Sanofi, convened a two-hour online meeting to discuss possible answers to these questions. In attendance were representatives of the European Commission and experts from the public, private, nonprofit and academic sectors in Europe and beyond. This report is a summary of their discussion, focusing on the key questions participants raised and tried to address.

01

WHAT
SHOULD
HERA DO?

In Brussels, the need for action is well understood. “The responses to the COVID-19 pandemic were not coordinated to the extent needed,” said Pierre Delsaux, deputy director-general of DG SANTE, the European Commission’s health policy department. In future, “we need to have a much more coordinated response, as outlined in the Commission’s Communication of November 2020 on strengthening the EU Health Union” he said. “We believe by working together in the future we will be better prepared as the EU for the next health crisis.”

Enter HERA: a combined EU-level authority responsible for identifying threats and securing the means to address them. “Trying to anticipate the threat, and which kind of medical countermeasures we need to address it, is certainly part of the job description of HERA,” said Delsaux. That means HERA will have to take a close look at commercial supply chains for various countermeasures to ensure they can be made ready when they’re needed, “monitoring the situation in the market and looking at possible deficiencies,” and also “addressing the issue of shortages of supplies,” said Delsaux.

Health is a national matter under the EU treaties, yet HERA would not be the first EU body with a role in health policy. It would share the field with others—including the European Centre for Disease Prevention and Control (ECDC), the Innovative Medicines Initiative (IMI) and the European Medicines Agency (EMA)—so its role needs to be defined clearly to avoid pointless duplication, and to justify its own existence.



PIERRE DELSAUX,
Deputy Director-General, DG SANTE,
European Commission



ROBIN ROBINSON,
Chief Scientific Officer, Renovacare;
Former Director, BARDA



JEAN LANG,
Associate Vice President, R&D Global Health,
Partnerships & Funding, Sanofi

The EMA is an independent authority for drug supervision; though it is constituted through EU legislation, its board represents neither the Commission nor the member states. The ECDC, meanwhile—a none-too-subtle nod to the US Centers for Disease Control and Prevention [CDC]—is an intergovernmental agency, independent of the Commission. It monitors diseases and problems like antimicrobial resistance, publishes data and guidance, and provides a vehicle for policy coordination among member states. Whereas the ECDC mostly deals in information, HERA would handle money, though exactly how—or how much—isn't clear yet. Likewise, its governance is undecided. The Commission has published what's known as an "inception impact assessment" laying out the options, as Brussels sees them. They include everything from a coordination mechanism among structures that already exist, to a fully centralised EU agency—but the document is vague about whether any of HERA's proposed incarnations would be creatures of the Commission, the member states, or something in between.

While stressing that HERA's functions remain undecided, Delsaux suggested the authority could get involved in co-financing the manufacture of pharmaceuticals by private companies, which is something BARDA does. He said that where a lack of commercial opportunity is preventing companies from investing the substantial resources needed for development and manufacture of necessary drugs, some kind of intervention may be necessary to address the market failure. The final proposal is due later in 2021.

A key difference between HERA and BARDA is that the latter, though part of the US Department of Health and Human Services, has both public health and national defence aspects to its mandate in protecting the US population from CBRN threats. Robin Robinson, BARDA's former director, said BARDA officials worked closely with Pentagon colleagues. Delsaux emphasised that HERA's role is serious cross-border threats to health, not defence per se, though he pointed to EU defence cooperation as an example of how member states can work together on a matter the treaties reserve for the member states.

Robinson also stressed the importance of the agency's focus on late-stage development and manufacturing, and warned that HERA would also need to be vigilant in avoiding mission

creep. "Many of the people at BARDA had to be warned that if they wanted to work on discovery and early development of products, they needed to go to the NIH [National Institutes of Health], because BARDA's mission was advanced development," said Robinson.

Similarly, in Europe, some of that early-stage work is already being funded by IMI, a large public-private partnership [PPP] for pre-competitive research. It will soon morph into the broader Innovative Health Initiative under Horizon Europe, the EU's new research funding programme.

Unlike IMI and NIH, HERA "should really support advanced product development, in order to get urgently needed products into the market and to the people as quickly as possible," said Stefan Jungbluth, head of business development at the European Vaccine Initiative, a nonprofit partnership for vaccine development. Isabelle Bekeredjian-Ding, head of microbiology at the Paul Ehrlich Institute, a German institution that specialises in research and regulation for vaccines and biomedicines, said "we do have very good funding of basic research [in Europe], but we need to have second stage funding, as we see with BARDA."

Public intervention in late-stage development and manufacturing of new pharmaceuticals is necessary because it comes at a "huge cost" that often can't be justified by market forces, said Jean Lang, associate vice president for global health R&D at Sanofi. He said firms are often reluctant to spend that money if they're not confident of a return. For example, Lang worked on development of vaccines for the SARS virus and the West Nile virus. Both got as far as phase two trials, but neither was ever used. "It was not a win-win solution," he said.



ISABELLE BEKEREDJIAN-DING,
Head of Division of Microbiology,
Paul Ehrlich Institute

02

HOW SHOULD HERA BE FUNDED?

Given the colossal sums of money needed to fund late-stage development, how much of its own money will HERA have at its disposal, and to what extent will it be able to marshal resources from elsewhere? The EU's budget for 2021-2027 has already been decided, and HERA isn't in there. That means not only is HERA's budget undecided, its funding sources are still unknown as well.

Delsaux hinted that at least some of HERA's resources could come from the EU's EU4Health funding programme, which has a seven-year budget of €5.1 billion, and pandemic preparedness is part of its brief. This money "will not be completely dedicated to HERA—far from it—but at least part of this money certainly could be helpful," he said. The EU's research and innovation programme, Horizon Europe, is another potential source of funding, he said. Again, however, the final proposal, which will also consider funding options, will be put forward later in 2021.

But BARDA's budget is about twice that allocated to the entire EU4Health programme. There is a danger that HERA's funding will fall short of requirements, warned Jungbluth. "This happens so often in Europe," he said. "There are wide dreams about agencies [and] what they could do, and then they fall embarrassingly short of resources." The ECDC is an example of this problem; "they have a theoretical mandate which they are magnitudes away from, budget-wise," said Jungbluth.

Others agree. "It has to be well financed. If you under-finance the effort, you're going to get under-performance," said David Robinson, deputy director of vaccines development at the Bill and Melinda Gates Foundation, which funds access to vaccines in low-and middle income countries.



MARIE-PAULE KIÉNY,
Director of Research,
Inserm



RIFAT ATUN,
Professor of Global Health Systems,
Harvard University



VICTOR DZAU,
President, US National Academy of Medicine



DAVID ROBINSON,
Deputy Director, CMC Vaccines Development
and Surveillance, Bill & Melinda Gates Foundation

Marie-Paule Kieny, director of research at Inserm, the French government's national health research institute, said that given the inevitable budget constraints, HERA's mandate should be realistic. "BARDA is a good model" for HERA, but "it would be counterproductive to do exactly the same as BARDA because it will never have as much money," she said.

If the Commission does intend for HERA to draw money from EU4Health and Horizon Europe, it can only do so within the legal scope of those funding programmes' functions. The Commission can't lawfully divert money from the agreed budget because of a new policy idea. But after the law comes politics: in last year's budget compromises, both programmes saw their planned funding cut substantially from the original plans. Those disappointed by the outcome will be anxious to see the money spent as intended.

Rifat Atun, professor of global health systems at Harvard University, said it is "very important that the European HERA has its own dedicated funding," and that the money doesn't come from the "already constrained budgets" of Horizon Europe and EU4Health.

Kieny said it's important that HERA's funding be secure, which is hard to guarantee for novel agencies that depend on the EU budget. She said, "HERA should be funded by the member states and the Commission. It should be a long-term funding and not like a short term funding."

Atun added that BARDA in the US operates in an environment with considerably more private investment in new pharmaceuticals than is available in Europe—meaning HERA faces a bigger challenge with an almost certainly smaller budget. "There are very large amounts of angel investment, venture capital financing and private equity that encourage funding of innovations in the U.S.," he said. "That innovation ecosystem does not really exist in the European context, or when it does, it is actually fairly small." He argued that HERA could play a coordinating role in directing money from different sources to new pharmaceuticals.

Similarly, Victor Dzau, president of the US National Academy of Medicine, indicated that the European Investment Bank (EIB) could be an important source of investment for pharmaceutical development and manufacturing, working in cooperation with HERA. The EIB is an independent bank which has the EU's 27 member states as its shareholders. It cooperates with the Commission through joint efforts such as the European Fund for Strategic Investments (EFSI)—better known as the Juncker Plan—which sees the Commission provide guarantees for high-risk EIB loans. The EIB often acts as a lead investor, making the first move as an equity investor in the expectation that private capital will follow. The new European Innovation Council, which is controlled by the Commission, aims to play a similar role in financing tech startups—such as biotech firms, for example.

However, Europe should not expect much additional funding from nonprofit foundations that concentrate on poorer countries, said David Robinson. Even the Gates Foundation's large endowment "pales in comparison to government spending," he said.

03

HOW SHOULD HERA BE GOVERNED?

If HERA draws money from anywhere other than the EU's main budget, that could have knock-on effects for its governance structure, which is a delicate matter in itself. Firstly, HERA's governance needs to account for the fact that health policy is a national matter in the EU treaties—the ECDC, for example, answers to the member states—though this limitation does not mean the Commission itself cannot put money into health R&D, as it does with Horizon Europe. Secondly, given the likely constraints on public funding for HERA, a formal partnership with the private sector, like IMI, would give it direct access to additional funding—but it would also mean private companies get a seat at the top table.

Delsaux stressed that with HERA, the goal is to improve coordination without having to revisit the treaties. "Health remains a competence for the member states and of course we don't want to change this; we don't want a treaty change," he said. "But still having more coordination at EU level will help, as seen with COVID-19." He said that "we don't want this to be a bureaucratic exercise" and "our idea is really to bring on board member states, all stakeholders and to make sure that we listen to everybody and build on lessons learned in a practical and tangible manner."

Kieny of Inserm argued that HERA, like the ECDC, should be an "independent EU agency" that "doesn't belong to the Commission" and "reports to a management board whose members are nominated by member states, the European Parliament and the European Commission." She said that management board should appoint a director who takes responsibility for its results, and has the authority to decide what organisations get funded and when that funding should be cut off.

She added that HERA should be a wholly public organisation, like BARDA. "I don't think that it should be a public-private partnership. It should work with the private sector, of course, but I don't think that the private sector should be part of the governance," Kieny said.

Jean Lang said an alternative model could be found in the Coalition for Epidemic Preparedness (CEPI), a global partnership for pandemic preparedness and response for low and middle-income countries. In CEPI, developers from the private sector sit as observers on the board and contribute to the partnership's advisory committees.

It's also important that HERA's governance be free of political interference, said Robinson. He said that although political pressure had had "very untoward effects on BARDA" in the last couple of years, this was not a problem for most of the agency's lifespan. A key part of BARDA's independence was having leadership that spanned the changeover of different political administrations.

04

WHAT SHOULD HERA SUPPORT FOR INDUSTRY LOOK LIKE?

Even if the pharmaceutical industry isn't seated at the board, the pitch for HERA is that it will put money into pharmaceutical development, and possibly manufacturing. But whether it's allowed to do that depends on how the Commission's proposal is received, since it has to pass muster with national politicians and—depending on what form it takes—the European Parliament.

IMI already funds pre-competitive pharma research, meaning the research results won't become the property of one firm. Competing businesses are happy with that for early-stage research because it gives them access to knowledge they can turn into competitive products later, knowledge that might have been unattainable or more costly to attain on their own. But for later-stage product development, companies need a commercial reason to put their own resources into the work alongside the public money.

That means there need to be commercial compromises by firms benefiting from publicly subsidised costs, and political compromises by policymakers trying to maximise the public's return on investment.

Tom Inglesby, director of the Center for Health Security at the Johns Hopkins Bloomberg School of Public Health, said it took time for BARDA to find the right funding model. He said a key factor wasn't just reimbursement of costs, but procurement of the finished product: companies were keen to participate because "in the end the government might actually want to buy some of the things that they were developing."



HANNA NOHYNEK,
Chief Physician & Deputy Head of Unit, Infectious Diseases Control and Vaccines, Department of Health Security, Finnish Institute for Health and Welfare (THL)



TOM INGLESBY,
Director, Center for Health Security, Johns Hopkins Bloomberg School of Public Health



MICHEL GOLDMAN,
Co-Director, I3h Institute; Professor of Medical Immunology, Université libre de Bruxelles

But governments wanted to see their support reflected in the purchase price, said Robin Robinson. “The money that we had put into supporting the development of the product did weigh into the procurement of the product and the price that we paid,” he said. Not only did the U.S. government often pay well below the retail price, but often the retail price itself was cut as a condition of BARDA funding. In addition, private sector partners of BARDA were expected to shoulder their fair share of the financial risk: “up to 50% of the entire cost of the project to develop the products was shared by the company,” said Robinson.

Sanofi’s Lang said public-private partnerships should have clear, transparent and binding commitments that demonstrate the purpose of their collaboration is not to “throw money” at the private sector. “This is not a grant, this is not a subsidy, this is a contract,” he said. “Transparency is essential.”

But in Europe, getting support for any collaboration with the pharmaceutical industry can be difficult even if it is done transparently, said Hanna Nohynek, chief physician at the Finnish Institute for Health and Welfare’s Department of Health Security. She said there was a “PPP hesitancy” among public health institutes, and that despite prominent examples of PPP transparency—such as an IMI-funded vaccine effectiveness project called DRIVE— “that has not been sufficient to bring on board public health institutes.” She said she felt “pessimistic” about getting public health institutes on board. “If we cannot, let’s face that and think of other ways we can bring the different players together.”

“I think there is a certain level of *défi*ance [mistrust] regarding the fact that in Europe you have the public sector, which is dealing with public health, and you have the private sector which is dealing with business interests,” said Lang.

Michel Goldman, former executive director of IMI, said he shared some of Nohynek’s pessimism. “The question is whether we are ready in Europe indeed to directly fund companies’ manufactures,” he said. “I think that to have the member states and the European Parliament endorsing the project will be rather difficult.” But the current crisis provides “a window of opportunity, because the difference today is that everyone realises that the pharmaceutical companies are critical in overcoming the pandemic,” Goldman said. He added that to win political support, HERA will need to be able to establish clear contractual guarantees for the public interest.

Inglisby of Johns Hopkins said the pandemic changes things when it comes to winning public support, and that if the purpose and benefits of the collaboration are well-communicated, there shouldn’t be controversy. “It’s the policymaker, the political leader, that has to make the value proposition to the public,” he said. “The public already accepts research as a fundamental benefit for society, and in this case, we’re actually talking about translating research into products that will go to the public.”



05

WILL HERA HAVE A ROLE BEYOND EUROPE?

HERA will be a European body, but COVID-19 demonstrates that a faraway epidemic can quickly land in Europe, and vaccines or other countermeasures may similarly be more readily available from abroad. That raises the question of how HERA will act globally: the extent to which it will partner with similar agencies in other countries, and even whether European money could directly or indirectly benefit non-Europeans. “We don’t live in isolation,” said Jungbluth of the European Vaccines Initiative. He argued that HERA needed a “global dimension.”

“Any initiative that is dealing with infectious diseases of epidemic potential needs to recognise that these do not respect borders, and for this reason I emphatically advocate for special attention to international partnerships,” said Michael Makanga, executive director of the European and Developing Countries Clinical Trials Partnership, which received funding from Horizon 2020, the predecessor to Horizon Europe. Similarly, Inglesby said “medical countermeasures, therapeutics, [and] diagnostics for diseases that occur in countries outside of Europe” should be “an explicit part of the mission” of HERA.

Makanga argued that HERA should build partnerships around the world and set up “flexible mechanisms” to drive a mix of public and private finance into pandemic preparedness and response capabilities, which are costly and require long-term funding to be effective.

Besides the fact diseases can spread from other parts of the world, guaranteeing the pharmaceutical supply also requires a global perspective, argued David Robinson. He suggested that HERA could work with similar agencies elsewhere in the world—such as BARDA—to “help support a coordinated response around the globe, particularly for manufacturing.”

International coordination is also necessary to avoid “vaccine nationalism” and competition among authorities like HERA and BARDA, argued Dzau. “We have to think about the global

architecture where everyone can participate,” so that all regions can “climb together,” he said.

Similarly, Jayasree Iyer, executive director of the Access to Medicine Foundation, said there are smaller regions both inside and outside the EU that are often “overlooked” in the medical supply chain, “because they are smaller markets or their ability to pay for access is actually reduced.” She said HERA should look closely at how products are registered and brought into different markets.

Martin McKee, research director at the European Observatory on Health Systems and Policies, added that between HERA’s EU focus and its global perspective, policymakers also need to consider the “wider European neighbourhood.” He said that brings in a mix of very different countries, including the UK, Switzerland, the western Balkans, Ukraine, Turkey and Israel, which are all at the EU’s doorstep.



JAYASREE K. IYER,
Executive Director,
Access to Medicine Foundation



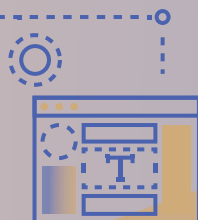
MICHAEL MAKANGA,
Director, Center for Health Security,
Johns Hopkins Bloomberg School
of Public Health

KEY POINTS TO CONSIDER WHEN DESIGNING HERA

Partly in response to the pandemic, EU officials have proposed a creation of a new health organisation, the Health Emergency Preparedness and Response Authority. It is, at present, just an idea, without budget or legal definition – in short, while HERA has caught a lot of attention, we have at present more questions than answers about what it would do. That demonstrates the need for careful design that keeps all the relevant people in the loop.

At the Science|Business workshop, experts discussed the issues to be resolved if HERA is to be a success.

WHAT SHOULD HERA DO?



- Define and pursue goals that can be achieved within the available budget. Too little money for too big an ambition will not work.
- Distinguish between what activities HERA will fund—or co-fund—and what it will not.
- Develop a plan for collaboration with EU and international agencies to avoid duplication.

HOW SHOULD HERA BE FUNDED?



- Define HERA's budget and funding sources. Will it be funded entirely from the EU budget, or will member states contribute? Will it be "new money", or taken from existing programmes?
- Can HERA's budget be secured for the long-term?
- Draw up a clear plan for encouraging investment by third parties, including governments, the European Investment Bank, and possibly the private sector.

HOW SHOULD HERA BE GOVERNED?

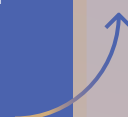
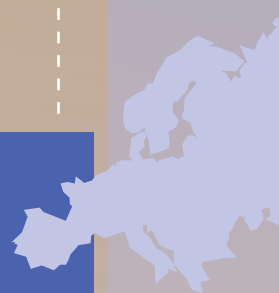
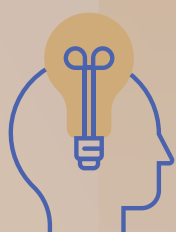
- Will HERA be an instrument of the European Commission, or an independent agency that answers to EU member states?
- Will the private sector form part of HERA's governance, or will it be wholly public?
- How can HERA be protected from political interference?

WHAT SHOULD HERA SUPPORT FOR INDUSTRY LOOK LIKE?

- Will HERA fund manufacturing, or only development?
- How will HERA ensure risks and rewards are shared fairly?
- How will the Commission win support of the public and policymakers sceptical of public-private partnerships in pharmaceuticals?

WILL HERA HAVE A ROLE BEYOND EUROPE?

- How will HERA protect the interests of European taxpayers while recognising that pandemics and countermeasures often originate from outside Europe?
- How will HERA's efforts to promote capabilities avoid "vaccine nationalism" and counter-productive competition with similar agencies elsewhere in the world?
- How will HERA address the problem of underserved regions?





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