

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

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About the Federation of European Academies of Medicine (FEAM)

FEAM is the European umbrella group of national Academies of Medicine, Pharmacy and Veterinary Science, or national Academies via their medical division. It brings together under one umbrella 23 National Academies representing thousands among the best scientists in Europe. The mission of the Federation is to promote cooperation between national Academies of Medicine, Pharmacy and Veterinary Science, or national Academies via their medical division, in the WHO European region; to provide a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community. The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information or becoming a partner, please contact elisa.corritore@feam.eu.

About the Wellcome Trust

The Wellcome Trust is a politically and financially independent foundation, with offices in London and Berlin. Our vision is to support science in tackling the major health challenges facing everyone; alongside a broad programme of discovery research, we have a new ambition to focus on mental health, global heating and infectious disease. Our work includes grant funding, supporting researchers, campaigning to improve science, and investing in partnerships to tackle global health issues.

Appendix 1 – List of Participants

- *Annabel Seeböhm*, Standing Committee of European Doctors (CPME)
- *Anna Sandström*, AstraZeneca
- *Antonella Cardone*, European Cancer Patient Coalition (ECPC)
- *Bianca Ferraiolo*, Active Citizenship Network (ACN)
- *Despoina Iatridou*, Federation of Veterinarians of Europe (FVE)
- *Florence Baron-Papillon*, Sanofi, Vaccines Europe/EFPIA
- *François Meunier*, Federation of European Academies of Medicines (FEAM)
- *George Griffin*, Federation of European Academies of Medicines (FEAM)
- *Ilse Bosch*, NHS Confederation
- *Jens Jäger*, Helmholtz Association of German Research Centres
- *Juan Fernandez*, European Patients' Forum (EPF)
- *Michael Zaiac*, Novartis Oncology Region Europe
- *Michele Calabro*, European Patients' Forum (EPF)
- *Pascal Garel*, European Hospital and Healthcare Federation (HOPE)
- *Piotr Kolczynski*, Standing Committee of European Doctors (CPME)
- *Richard Price*, European Cancer Organisation (ECCO)
- *Rosie Richards*, NHS Confederation
- *Viviana Galli*, European Alliance for Responsible R&D and Affordable Medicines
- *Yannis Natsis*, European Public Health Alliance (EPHA)

Staff from Wellcome & FEAM

- *Amelia Dearman*, Wellcome Trust
- *Catherine Guinard*, Wellcome Trust
- *Elisa Corritore*, Federation of European Academies of Medicines (FEAM)
- *Erika Loggin*, Wellcome Trust
- *Laure Guillevic*, Federation of European Academies of Medicines (FEAM)
- *Laurence Legros*, Federation of European Academies of Medicines (FEAM)
- *Rosa Castro*, Federation of European Academies of Medicines (FEAM)