



Summary report

31 January 2022, Paris

The response to COVID-19 required rapid and coordinated assessment and action across Europe. The pandemic crisis highlighted some broader weaknesses in research, production of, and access to, healthcare products (diagnostics, vaccines, therapeutics and PPE). Although there were early problems in mounting the response in the EU (and elsewhere), lessons were rapidly learnt: the successful, collective, production and distribution of vaccines, including sharing EU supplies worldwide, demonstrated adaptability and commitment to equity. Lessons must now be implemented further to be better prepared for future health threats.

Required attributes for HERA

- There will be future epidemics and pandemics because infectious disease knows no borders. The inception of HERA (Health Emergency Preparedness and Responsiveness Authority) is an important part of future European preparedness.
- HERA must be focused yet flexible, independent with a clear mandate and transparent decision-making; collaborative, building on particular strengths of EU health and research systems; and global in orientation, with equitable access in its funding and operations. One core activity is the investment in research for vaccines and provision of other countermeasures.
- Because of the dominant focus recently on COVID-19, other major health threats - e.g. AMR and HIV - have been relatively neglected, but they must now be re-prioritised.

ECDC

- HERA must also be well integrated with other EU bodies, in particular ECDC (European Centre for Disease prevention and Control) and EMA (European Medicines Agency). ECDC was designed to assess, prepare for, and respond to communicable disease health threats, working closely with Member States. Post-COVID-19, in extending its mandate, ECDC will have an enhanced role to adapt to changing circumstances; facilitate knowledge exchange and learning, including issuing non-binding recommendations on risk-management; reinforce its role in monitoring and surveillance of infectious diseases EU-wide and globally, and monitoring of Member States health system capacity. Strengthening the ECDC mandate will also include network coordination of reference testing laboratories; with EMA, a new vaccine effectiveness and safety monitoring platform; and an initiative on surveillance digitalisation in collaboration with Member States.
- Clearly, to ensure complementary activities and avoid duplication, ECDC must engage closely with HERA, with roles defined in a Memorandum of Understanding.

HERA and governance issues

- Initially, HERA was envisaged as an Agency but creation would take significant time; expeditious action required placing HERA within the European Commission, and this also enables interaction with other Commission services, rapid access to finance and other resources, and direct contact via the Commission President with Heads of countries. This governance structure is novel (and experimental) but inclusive: the solidarity emerging during the pandemic, if sustained, is anticipated to encourage collective working with Member States.
- The European Parliament and Member States must be involved in democratic and effective governance of HERA, linking with strategic European Parliament roles to enable coordination of actions, collaboration between Member States, and promotion of solidarity.
- HERA governance must avoid complicated interactions with the Agencies and other actors, and lead the way to simplifying governance at national level: lessening the bureaucracy that has slowed innovation. For example, Member States should each identify a unified national contact point for connecting with HERA.
- HERA developments must also be considered in the context of wider debates about the relative responsibilities of Member States and EU Institutions on health matters. While Member States may show solidarity in a crisis, it is less certain that, for example, they would accept collective procurement for other health products such as expensive cancer drugs. Member States may be far from convinced of the need for shared mechanisms of procurement, price negotiation and access, but the EU does need a strategy for health equity, given the observable disparities in COVID-19 mortality between Member States. It remains to be resolved whether joint procurement is consistent with the principle of subsidiarity but the EU should replace Member States' responsibility if national policy cannot solve supply and accessibility problems.

HERA and funding issues

- The annual budget is €1 billion per year for 6 years, directly managed, but HERA can influence and rapidly mobilise other Commission budgets, up to €4 billion per year. For example, investment might come from Regional Funds to strengthen hospital capacity.
- There has been significant concern expressed that the HERA €1 billion per year is taken from existing budgets (e.g. EU4Health, Horizon Europe) because the current overall multiyear budget has already been set. It is important that HERA accounts for its use of these funds to the research community.
- There is also concern about the long-term sustainability of HERA funding. A new income would need to be negotiated within the next multiyear funding settlement.
- One of the lessons learnt during COVID-19 is that the EU is less agile in making funding decisions than, for example the USA, and better choices may need to be made when selecting company candidates to fund. The complexity of EU-Member States systems risks inertia in innovation and EMA, although it does well, does not have all the means to deploy its desired initiatives. New funding mechanisms must enable sharing of product development risks and facilitate access. And there is scope for the EU to do more in attracting private sector funding in public-private partnerships to increase returns on investment by the public sector.

HERA cooperation

- HERA is designed to be operationally effective, based on practical cooperation with Member States and the rest of the world.
- It is anticipated that HERA EU operations will involve civil society and researchers, and internationally with the World Health Organisation, BARDA (Biomedical Advanced Research and Development Authority) and other US institutions, and equivalent bodies e.g. in Japan, Korea and Canada, to build networks to detect threats. There is much also to be done with low and middle income countries: ECDC already has important contact with the African CDC and HERA is managing COVID-19 vaccination donations in Africa. Global ambition is a crucial part of HERA building its own resilience for the EU: HERA could regard itself as a regional hub in the global architecture for health preparedness, e.g. coordinating with CEPI (Coalition for Epidemic Preparedness Innovations) and driving consistency with G7 and G20 objectives.
- One particular issue for HERA, drawing on the BARDA analogy, is the role to assess and counter health threats arising from deliberate misuse of pathogens (e.g. in terrorism). How will HERA gain access to the requisite information from biodefence intelligence sources?

HERA and European academies

- FEAM has been active in examining strategic issues for HERA and ECDC, convening different expertises and perspectives as part of broader considerations for the European Health Union. Academies also represent an unparalleled critical mass of practical expertise and can mobilise researchers to advise HERA and other Commission activities.
- In One Health (e.g. zoonotic threats), it is agreed that the veterinary sector must be part of risk analysis. However, it is vital for the veterinary sector not just to sound the alarm on the potential for threats to human health, but also to ensure that the animal health priorities, e.g. for animal vaccines and research in emergency situations, are taken into account by HERA.
- Efforts to improve human and animal health must also encompass environmental health issues, e.g. AMR concerns about antibiotic use in agriculture; direct and indirect effects of climate change; and importation of pathogens and vectors from outside the EU.
- Another issue emphasised by academies is the priority to tackle medicines' shortages and the analogy with US BARDA indicates possible additional future roles for HERA. HERA will have an advisory role with Member States on stockpiling of essential supplies and sustaining EU supply chains for countermeasures during a crisis. Currently, there are multiple problems arising from fragmentation in production, reimbursement and access. The pandemic highlighted the problem of EU dependency on PPE supplies from elsewhere.
- Rapid new research during a crisis must be able to build on strong, established research infrastructure. One option is for multi-country research networks covering different areas of expertise relevant to communicable disease, integrated into an EU platform coordinated by ECDC, HERA and others. The ESFRI (European Strategic Forum on Research Infrastructures) Roadmap 2021 provides valuable impetus but it will be necessary again to attract private as well as public funding to establish comprehensive research infrastructures. The recent model of IHI (Innovative Health Initiative) replacing IMI (Innovative Medicines Initiative) is instructive in this respect.
- HERA can also play a critical role in assessing and deploying new technologies, particularly in the era of digital health. For examples, there may be potential value in using Artificial Intelligence to monitor social networks for early detection of health threats and their trends.

Conclusions

Health issues have become much more visible at the political level in consequence of COVID-19. This health crisis leaves a legacy of interest to tackle health priorities more generally. Moreover, the levels of diagnosis and health care delivery in COVID-19 between Member States were much more homogenous than has been the case for other diseases. This concerted response to the pandemic provides the basis for a new EU improved approach by HERA together with ECDC, EMA and EDQM (European Directorate for the Quality of Medicines) for tackling other diseases (communicable and non-communicable).

Better preparedness for cross-border health threats is crucial for all of Europe, not just EU, and this must be financial and political as well as scientific preparedness. Member State- and EU-level actions must be better coordinated, perhaps unified: cooperation not competition. Simplifying bureaucracy, involving experts to advise on decision-making, clarifying responsibilities and capitalising on what is already functioning well (ECDC and EMA) as well as increasing commitment to invest in fundamental research, are important parts of optimising the robust HERA operational response and global collaboration.

February 2022

Acknowledgment: FEAM is grateful to the French Academies of Medicine, of Pharmacy, of Veterinary Sciences and of Agriculture for their collaboration in organising this event and to the French Academy of Medicine for hosting it. FEAM and the French Academies warmly thank speakers and panel discussants for their insightful contribution to the webinar; Dr. Olivier Mariotte for moderating discussions; and Dr. Robin Fears for preparing the summary report of the workshop.

Disclaimer: Opinions expressed in this document do not necessarily represent the views of all participants at the event, FEAM and its Member Academies and the French Academy of Agriculture.

How should Europe prepare and respond to cross-border health threats: HERA?

WORKSHOP

31 JANUARY 2022 | 1 PM - 4 PM (CET) | HYBRID EVENT

Register at www.feam.eu

Logos: FRANCE22 FRENCH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION, FEAM, ACADÉMIE NATIONALE DE MÉDECINE, Académie Vétérinaire de France, Académie nationale de Pharmacie, AAF ACADÉMIE et AGRICULTURE de FRANCE AGRICULTURE • ALIMENTATION • ENVIRONNEMENT

Agenda of the Workshop

21 January 2022, French Academy of Medicine and virtually

Moderator: Dr. Olivier Mariotte, Journalist

13:00 Opening and welcome

Prof. Bernard Charpentier

President of the French Academy of Medicine; former President of FEAM; Honorary Dean and Emeritus Professor at the Faculty of Medicine Paris-Sud; former Head of the Department of Nephrology, Dialysis and Transplantation at the Bicêtre University Hospital

13:05 A European Health Union: the strengths of FEAM and its Academies in informing its development

Prof. Stefan Constantinescu

FEAM President, President elect of the Belgian Royal Academy of Medicine (ARMB), Member of the Romanian Academy of Medicine; Head of the Cell Signalling Pole, de Duve Institute, Catholic University of Louvain, Brussel; Director of Research (Honorary), Fonds National de la Recherche Scientifique, Belgium; Member, Ludwig Institute for Cancer Research, Brussels, Belgium

13:15 The enhanced role of the European Center for Disease Prevention and Control

Dr. Andrea Ammon

Director of the European Centre for Disease Prevention and Control (ECDC)

13:30 Added value of the Health Emergency Preparedness and Responses Authority

Pierre Delsaux

Director-General of HERA, European Commission

14:00 Pandemic preparedness and response: a French perspective

Prof. Jean-Louis Touraine

Member of the French National Assembly and Member of the French Commission of Social Affairs

14:10 The role of the European Parliament in pandemic preparedness and response

Prof. Véronique Trillet-Lenoir

Member of the European Parliament; Professor of Oncology, University Hospital

14:30 Panel discussion

- Prof. **Jean-Louis Touraine**, *French National Assembly*
- Prof. **Véronique Trillet-Lenoir**, *European Parliament*
- Prof. **Stefan Constantinescu**, *FEAM*
- Prof. **Didier Houssin**, *Member of the French Academy of Medicine; former French Director General for Health; President of the COVID-19 Emergency Committee of WHO*
- Dr. **Andrea Ammon**, *European Centre for Disease Prevention and Control*
- Dr. **Bruno Bonnemain**, *Vice-President of the French Academy of Pharmacy and President of the Academy's Committee on Shortages of Medicines*
- Prof. **Stephan Zientara**, *Member of the French Academies of Veterinary Sciences and of Medicine; Director UMR Virology at Alfort National Veterinary School*
- Prof. **Arlette Laval**, *Honorary Member of the French Academy of Agriculture; Veterinary Doctor, Associate Professor of Medicine of livestock*
- Prof. **Emília Monteiro**, *Board Member of the Portuguese Academy of Medical Sciences; Professor of Pharmacology, CEDOC-Chronic Diseases Research Centre, NOVA Medical School, Universidade Nova de Lisboa*
- Prof. **Michal Andel**, *President of the Czech Medical Academy; Head of Center for Research of Diabetes, Metabolism and Nutrition, Third Faculty of Medicine, Charles University in Prague*
- Dr. **Catherine Guinard**, *Head of EU Affairs, Wellcome Trust*

15:45 Key conclusions and next steps

Prof. George Griffin

Chair of the FEAM One Health Committee; Immediate Past President of FEAM; Member of the UK Academy of Medical Sciences; Emeritus Professor of Infectious Diseases at St. George's University of London

Prof. Stefan Constantinescu

FEAM President

15:55 Closing remarks

Prof. Bernard Charpentier

President of the French Academy of Medicine

16:00 Meeting closed

Federation of European Academies of Medicine (FEAM)

FEAM is the European platform of National Academies of Medicine, Pharmacy and Veterinary Sciences, or National Academies via their medical section. It represents 23 national academies within the WHO European region. FEAM's mission is to promote cooperation between them; offer them a platform to formulate and express their common position on European issues concerning human and animal medicine, biomedical research, education and health; and to extend to European authorities the advisory role they play in their own countries on these issues.

FEAM | 13 rue d'Egmont B-1000 Brussels | www.feam.eu

French Academy of Medicine

The mission of the National Academy of Medicine is to respond to government requests on any question concerning public health and to take care of all research objects that can contribute to the progress of the art of healing.

French Academy of Medicine | 16 rue Bonaparte F-75006 Paris | www.academie-medecine.fr

French Academy of Pharmacy

The National Academy of Pharmacy is interested in all areas of medicine, health products, biology, public health and environmental health: teaching, research, chemistry, pharmacology, toxicology, biology, industry, hospital pharmacy, pharmacy, administration, army, but also hygiene, environment, health security, public health, in all their scientific, technical, legal, societal and ethical aspects. It elaborates reports and issues opinions and recommendations intended primarily for public authorities and health professionals.

French Academy of Pharmacy | 4 avenue de l'Observatoire F-75006 Paris | www.acadpharm.org

French Veterinary Academy

The mission of the French Veterinary Academy is to study all subjects relating to the scientific, technical, legal, historical and ethical fields in which the skills of the veterinarian are exercised, in particular those relating to animals, their diseases, their relations with man and the environment, animal production and veterinary public health; to contribute to the dissemination of scientific progress and the improvement of techniques relating to veterinary activities; to advise the public authorities and enlighten public opinion in the aforementioned areas; and to develop technical and scientific relations, national or international, between veterinarians and other players in life sciences and health.

French Veterinary Academy | 34 rue Bréguet F-75011 Paris | www.academie-veterinaire-defrance.org

French Academy of Agriculture

The French Academy of Agriculture, a "learned society" in the fields of agriculture, food and the environment, has the mission of reflecting on progress; explaining the technical, economic, social and environmental issues; and enlightening society and decision-makers.

French Academy of Agriculture | 18 rue de Bellechasse F-75007 Paris | www.academie-agriculture.fr