FEAM
Federation of European Academies of Medicine

FEAM Position Statement on the new Pharmaceutical Strategy for Europe

Timely patient access to affordable medicines

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FEAM welcomes the opportunity to respond to the open consultation on the Pharmaceutical Strategy for Europe. The COVID-19 pandemic has illustrated the importance of strengthening the EU's health research and biomedical R&D landscape. While biomedical innovation has now received an additional boost in the EU's pandemic recovery strategy,[1] carrying the European health research enterprise forward will require addressing challenges across the life cycle of health technologies - from basic research to commercialization[2] and eventually to access for patients. As we have learned during the past few months, an important degree of flexibility to define and update priorities, and a sound regulatory system for approval of medicines, including a rapid and robust mechanism to approve drugs in emergency situations -for example in pandemics- will be essential to address future crises.

The EU Pharmaceutical Strategy Roadmap's focus on a wide range of issues is commendable. This includes strengthening Europe's biomedical R&D capabilities, redirecting health research towards unmet medical needs, addressing shortages of medicines and vaccines as well as the EU's increasing dependence on medicines and active pharmaceutical ingredients manufactured in non-EU countries, and enhancing timely and equal access to affordable medicines for patients. Many of these challenges, including the increasing dependence on non-EU countries and shortages of critical medicines, have been particularly emphasised during the COVID-19 crisis. FEAM also welcomes the emphasis on enabling EU cooperation on these and other related areas, such as health technology assessment (HTA), for the benefit of patients and citizens.

Ideally, EU innovation should address the needs of the public by developing a comprehensive health research strategy. While all the areas mentioned above deserve careful consideration, in this short statement, FEAM outlines its vision for the improvement of Europe's biomedical R&D ecosystem and includes the following recommendations for strategic priority-setting in health research, public investment in underserved disease areas, and capacity building for health research across EU Member States:

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[1] *The Role of Research and Innovation in Europe's Recovery.* European Commission. (2020). https://ec.europa.eu/info/sites/info/files/research_and_innovation/strategy_on_research_and_innovation/documents/ec_rtd_covid19-recovery-factsheet.pdf

[2] *Workshop Summary Report: Working Together for the Future of European Health Research.* Federation of European Academies of Medicines and Biomedical Alliance in Europe. EU Parliament, Brussels. (2020). https://www.feam.eu/wp-content/uploads/Working-together-for-the-Future-of-European-Health-Research-summary-report.pdf#page=6

1. Set up a European Health Research Council to coordinate and steer the European health research agenda;
2. Break silos and foster trans-disciplinary and cross-border collaboration (including with the UK post-Brexit), as well as collaboration between the public and private sectors;
3. Engage with all stakeholders and particularly with patients to improve the priority setting process and ensure that research matches societal needs;
4. Identify areas lacking sufficient industry-driven innovation to respond to public health needs, provide public funding for research in these areas, and foster publicly-funded clinical trials;
5. Address inequalities in health research capacity, which often translate into health inequalities;
6. Foster the synergistic use of public funds such as European Structural Funds and Horizon Europe to address inequalities in health research in a sustainable way that reflects the spirit of the EU Green Deal;
7. Improve access to novel medicines based on molecular targets and immunotherapy and to the required molecular testing for these treatments throughout EU;
8. Streamline data sharing capabilities while safeguarding privacy and security, including through the development of a sound framework for the proposed European Health Data Space.

Across the EU, funding and capacity for health research remain fragmented, potentially leaving key disease areas unaddressed.[3] It is imperative that the EU research community strive to ensure that future innovation can both advance Europe's contribution to biomedical science, and improve the value of healthcare for citizens. Addressing these topics in the new Pharmaceutical Strategy for Europe – and its subsequent implementation— would greatly support the EU's leadership in biomedical innovation, and would also be in the interest of its strategic autonomy in the global value chain for health technologies.

A. Channelling research towards priority disease areas and unmet medical needs.

EU innovation must be tailored to the public's needs to ensure that forthcoming biomedical R&D is truly in the public interest.[4] As we have learned from the COVID-19 crisis, establishing a more targeted approach to biomedical research will require time and investment across the

[3] Sipido, Karin R., et al. *Overcoming fragmentation of health research in Europe: lessons from COVID-19*. THE LANCET. (2020). https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31411-2.pdf

[4] *FEAM position on the European Commission proposals on Horizon Europe*, FEDERATION OF EUROPEAN ACADEMIES OF MEDICINE. (2018). https://www.feam.eu/wp-content/uploads/FEAM-position-on-Horizon-Europe_Final.pdf#page=2;

life cycle of new health technologies.[5] In this respect, the EU should consider how priority research areas could be identified, prioritized, and governed under a comprehensive health research strategy.[6]

Steering the research agenda: FEAM, along with other stakeholders, continues to endorse the establishment of a **European Health Research Council –** a long-standing proposal initiated by the Scientific Panel for Health**,** which would coordinate and steer the European R&D pipeline towards disease areas in need of more attention.**[7]** A European Health Research Council would also foster **stronger internal collaboration across EU institutions involved in health research,** which is instrumental in ensuring that the EU Pharmaceutical Strategy is compatible with the European R&D framework.[8]

Breaking silos through collaboration. **Trans-disciplinarity and collaboration** are crucial in biomedical research.[9] Therefore, cross-border collaboration in clinical trials – specifically for complex conditions like cancer, neurological disorders or sepsis disease, and for complex approaches, such as personalised medicine, which require holistic and long-term investigation— as well as support for pan-EU clinical trial networks and data repositories— should be promoted.**[10]** Ensuring continued cooperation with the UK on biomedical research and innovation post-Brexit[11] and encouraging collaborations between the public and private sectors –including through **public-private partnerships—** is also essential to promote the discovery and development of new drugs, vaccines, and diagnostics.[12]

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[5] *Joint Statement by FEAM and the Alliance for Biomedical Research in Europe: Strengthening biomedical research for the benefit of European citizens.* Federation of European Academies of Medicine and Alliance for Biomedical Research in Europe. (2017). https://www.feam.eu/wp-content/uploads/JointStatement_StrengtheningBiomedicalResearchInEurope_September2017.pdf ; *Biomedical and health research: developing a vision for Europe, summary report of an annual lecture.* Federation of European Academies of Medicines Biomedical Policy Forum. (2018). https://www.feam.eu/wp-content/uploads/FEAM-Forum_Annual-lecture-2018_Report_Final.pdf

[6] Bouillon, Roger *supra* note 3; *Letter to President Von der Leyen, Commissioner Gabriel, and Commissioner Kyriakides: Europe should fill the gap and exercise leadership in health research.* Federation of European Academies of Medicine, Biomedical Alliance in Europe, European Academy of Paediatrics, and EU Health Coalition. (2020). *https://www.feam.eu/europe-should-fill-the-gap-and-exercise-leadership-in-health-research/*

[7] *Proposal for a European Council for Health Research: A consensus document of the H2020 Scientific Panel for Health*. European Commission. (2018). https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/building_the_future_of_health_research_sph_22052018_final.pdf *; EU health cooperation.* Federation of European Academies of Medicine. (2020). https://www.feam.eu/wp-content/uploads/FEAM-Board-Statement-EU-cooperation-110620.pdf. Sipido, Karin R., et al.. *Overcoming fragmentation of health research in Europe: lessons from COVID-19.* The Lancet 395.10242 (2020): 1970-1971.

[8] *EU health cooperation.* Federation of European Academies of Medicine. (2020). https://www.feam.eu/wp-content/uploads/FEAM-Board-Statement-EU-cooperation-110620.pdf*h*

[9] *Supra* note 4.

[10] *Supra* note 4; See also *Vaccination in Europe, An EASAC and FEAM commentary on the EC Roadmap 'Strengthened cooperation against vaccine preventable diseases'.* Federation of European Academies of Medicine and The European Academies Science Advisory Council. (2018). https://www.feam.eu/wp-content/uploads/EASAC-FEAM-Statement-on-vaccines-April-2018-FINAL.pdf

[11] *Safeguarding European Medical Research Post Brexit.* Federation of European Academies of Medicine. (2020). https://www.feam.eu/wp-content/uploads/FEAM-statement-Brexit-reprinted-2020.pdf

[12] *FEAM position on the European Commission proposals on Horizon Europe.* Federation of European Academies of Medicine. (2018). https://www.feam.eu/wp-content/uploads/FEAM-position-on-Horizon-Europe_Final.pdf

Engaging multiple stakeholder perspectives. FEAM is a strong supporter of cross-sectorial collaboration and has set up a European Biomedical Policy Forum to facilitate discussions among diverse stakeholders. FEAM has especially underlined the importance of **patient engagement** to ensure that health research matches societal needs.[13] Therefore, we welcome the **expansive stakeholder engagement** within the EU Mission on Cancer, which explicitly seeks input from patients, researchers, and public health experts at the level of each Member State through public consultations.[14] Engaging relevant stakeholders would greatly refine this priority-setting process[15] and particularly contribute to **define priority disease areas** and delineate public's health priorities more accurately –including the interpretation of the term "unmet medical need".[16]

B. Addressing market gaps and improving clinical research quality

FEAM recognizes the crucial role of private investment in biomedicine. Along with this, it is important to highlight that certain public health areas might not provide enough incentives for industry-driven R&D (for instance, certain fields of research target extremely small patient groups, or require extensive research with disproportionately small returns on investment). Accordingly, where industry-driven innovation is not enough to adequately respond to public health needs, innovation must be supported by publicly funded research or incentive policies to trigger public research and industry to collaborate in filling those gaps.[17]

Identifying disease areas that require public investment. Market gaps have been especially prominent in the field of **antimicrobial resistance (AMR)** where no new classes of antibiotics have been brought to market in decades.[18] Similarly, public funding for research on antiviral therapies, vaccines and virology has been insufficient. FEAM, along with other stakeholders, has also identified under-funded disease areas to include complex medical issues such as

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[13] *Supra* note 2.

[14] *Horizon Europe Mission Area: Cancer.* European Commission. (2020). https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/mission-area-cancer_en

[15] *The European medicines agencies draft network strategy to 2025: Protecting public health at a time of rapid change.* EMA/321483/2020. European Medicines Agencies. (2020). https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

[16] Commission Regulation (EC) No. 507/2006: "Unmet medical needs means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment in the Union or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected". https://www.ema.europa.eu/en/documents/presentation/presentation-defining-unmet-medical-need-jstokx_en.pdf.

[17] *Supra* note 2 ; *Biomedical and health research: developing a vision for Europe, summary report of an annual lecture.* Federation of European Academies of Medicines Biomedical Policy Forum. (2018). https://www.feam.eu/wp-content/uploads/FEAM-Forum_Annual-lecture-2018_Report_Final.pdf ; *Health research and innovation: Why the EU supports health research and innovation.* European Commission. (Last visited 6 August 2020). https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation_en

[18] Joint statement on Antimicrobial Resistance by the Presidents of EASAC and FEAM. Federation of European Academies of Medicine and European Academies' Science Advisory Council. (2016). https://www.feam.eu/wp-content/uploads/EASAC_and_FEAM_Joint_Statement_from_the_Presidents.pdf

sepsis disease, certain neurological disorders, rare and paediatric diseases, and novel treatment approaches such as personalized medicine.[19] Furthermore, treatments for neurodegenerative illnesses like dementia and Alzheimer's disease continue to fail in clinical trials at a disproportionately high rate, emphasizing the need for further fundamental research -including on the implied pathophysiological mechanisms- and support as highlighted by the Science Advice for Policy by European Academies' (SAPEA) research.[20]

Expanding publicly funded clinical trials. The development of **publicly funded clinical trials is crucial** for areas which have been rarely covered by healthcare and wellness or pharmaceutical industry-driven research and could thus benefit from public support.[21] These include surgical techniques, screening programmes, or lifestyle interventions, as well as efforts on improving the quality of existing vaccines or developing new ones.[22] As addressed in the Roadmap, industry stakeholders are typically reluctant to conduct **comparative effectiveness analysis,** or research ways of repurposing off-patent health technologies - both of which are crucial for improving the cost-effectiveness of health interventions.[23] Publicly funded clinical trials might also afford opportunities for more robust Health Technology Assessments on the therapeutic value of health technologies.

C. Building capacity in health research infrastructure.

While the Roadmap addresses the need to strengthen EU health research infrastructure, more elaboration would be desirable to address persistent gaps and barriers. Along with other stakeholders, FEAM has highlighted that unequal research capacity constitutes a significant roadblock for the advancement of EU biomedical innovation; inequalities in health research capacity "often translate into health inequalities".[24] As such, public investment at EU level should also aim to enhance health research capabilities across EU Member States.[25]

Sustainably eliminating structural barriers. The EU must more clearly address structural barriers such as **inequalities in research equipment, staff, and infrastructure, as well as in access to novel therapies and molecular tests required for such therapies**. There is still room to expand on and improve synergies between Horizon 2020's proposed mechanisms to

[19] *Supra* note 2.
[20] *Transforming the future of ageing.* SCIENCE ADVICE FOR POLICY BY EUROPEAN ACADEMIES. (2019). https://www.sapea.info/wp-content/uploads/tfa-report.pdf
[21] *Supra* note 2.
[22] *Vaccination in Europe, An EASAC and FEAM commentary on the EC Roadmap 'Strengthened cooperation against vaccine preventable diseases'.* FEDERATION OF EUROPEAN ACADEMIES OF MEDICINE AND EUROPEAN ACADEMIES SCIENCE ADVISORY COUNCIL. (2018). https://www.feam.eu/wp-content/uploads/EASAC-FEAM-Statement-on-vaccines-April-2018-FINAL.pdf
[23] *Supra* note 2 ; Neyt, M., Christiaens,T., Demotes, J. & Hulstaert, F. *Publicly-funded practice-oriented clinical trials - KCE Report.* BELGIAN HEALTH CARE KNOWLEDGE CENTER. (2015)
[24] de Graca Carvalho, Maria *supra* note 2.
[25] *See generally, EU Budget for the Future: Research and Innovation.* EUROPEAN COMMISSION. (2018). https://ec.europa.eu/commission/sites/beta-political/files/budget-proposals-research-innovation-may2018_en.pdf

address infrastructure gaps, and the administration of **structural funds** under the EU Cohesion Policy.[26] On the other hand, such capacity-building must also remain universally sustainable. FEAM is a strong supporter of the One Health Concept, which strives to address human, animal, and environmental health in a coordinated manner.[27] Thus, as discussed within the FEAM Biomedical Policy Forum, it is critical to ensure that any scale-up in infrastructure is in line with the EU Green Deal and cognizant of the environmental impact of pharmaceutical products.[28]

Streamlining data capabilities. FEAM supports the notion that sound data exchange can advance health research, as efforts around COVID-19 have demonstrated.[29] This notion is compatible with the creation of a **European Health Data Space**[30] which would allow researchers across Europe to exchange health-related data more easily to advance research interests, while also safeguarding privacy and security measures enshrined in the General Data Protection Regulation.[31] Sound data exchange is especially critical for R&D for rare diseases, and as acknowledged by FEAM, the European Reference Network constitutes an excellent example.[32] In line with the EU Pharmaceutical Strategy's vision, establishing a European Health Data Space would be an excellent opportunity to leverage **AI and other novel data capabilities** in health interventions.[33]

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[26] *Europe's moment : Repair and Prepare for the Next Generation, Communication from the Commission To The European Parliament, The European Council, The Council, The European Economic And Social Committee And The Committee Of The Regions*. EUROPEAN COMMISSION. (2020). https://ec.europa.eu/info/sites/info/files/communication-europe-moment-repair-prepare-next-generation.pdf

[27] Bucharest Declaration On The 'One Health' Concept. FEDERATION OF EUROPEAN ACADEMIES OF MEDICINE. (2014). https://www.feam.eu/wp-content/uploads/OneHealthDeclarationBucharestMay2014Online20May2014.pdf

[28] *Summary Report: One Health in action: Pharmaceuticals including antimicrobials and their environmental impact Policy session, 2nd European One Health Conference*. Bucharest, Romania. (2019). https://www.feam.eu/wp-content/uploads/ONE-Health-Policy-Session-Report-2-Oct-2019.pdf

[29] *Recommendations and joint statement supporting citizens' interests in the benefits of data driven healthcare in a secure environment*, HEALTHCARE COALITION ON DATA PROTECTION – INCLUDES FEAM. (2014) https://www.feam.eu/wp-content/uploads/HealthcareCoalitionOnDataProtection_2014_jointstatementPUBLISHED-2.pdf

[30] https://ec.europa.eu/digital-single-market/en/policies/building-european-data-economy

[31] *Supra* note 2 ; *See generally,* von der Leyen, Ursula. *President-elect of the European Commission's Mission Letter to Stella Kyriakides, Commissioner-designate for Health*. (2019). https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

[32] *See generally, supra* note 8.

[33] *Use of data in cross-border biomedical research: what are the challenges ahead for Europe? .Summary report of a workshop held on 20 November 2017*. FEAM EUROPEAN BIOMEDICAL POLICY FORUM. (2017). https://www.feam.eu/wp-content/uploads/FEAM-Forum_Data-workshop-report_Final.pdf; *Annual lecture - Summary report: Artificial Intelligence in healthcare: is Europe ready?* Palais des Academies, Brussels. FEAM EUROPEAN BIOMEDICAL POLICY FORUM. (2019). https://www.feam.eu/wp-content/uploads/AI-Summary-report-15-Apr-2019-FV.pdf

About The Federation of European Academies of Medicine (FEAM)

FEAM is the European platform of national Academies of Medicine, Medical Sections of Academies of Sciences, Academies of Veterinary Sciences and of Pharmacy in Europe. It brings together 22 national Academies representing over 5000 among the best biomedical scientists in Europe. FEAM's mission is to promote cooperation among them; to provide them with 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.

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