e-FabRIC Consortium Event Report: Upscaling EU Healthcare Systems: Promises and Challenges of Innovative Therapeutics for Pandemic Preparedness

WP8 – Task 8.3

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Summary

This report forms part of the WP8 objective to communicate and disseminate the findings generated by the Consortium's research and investigations. Its main purpose is to summarise the outcomes of the discussions and highlight key lessons learned regarding the European Union's pandemic preparedness and response.

On 14 October 2025, the e-FabRIC Consortium hosted a policy dialogue in the European Parliament to discuss how innovative therapeutics can strengthen Europe's pandemic preparedness and strategic autonomy. Policymakers and experts stressed the need for increased EU investment, streamlined regulation, and stronger support for SMEs to ensure Europe can innovate, manufacture, and rapidly deploy medical countermeasures locally. Presentations from EU-funded projects highlighted efforts to develop next-generation antiviral technologies and build a coordinated, long-term preparedness strategy across the EU.

Keywords

Pandemic Preparedness, Medical Countermeasures, Multiannual Financial Framework, Small and Medium-sized Enterprises, Health Emergency Preparedness and Response Authority, Therapeutics, Clinical trials, Stockpiling, European Production

Acronyms

Acronym	Description
WP	Work Package
D	Deliverable Event Report
MEP	Member of the European Parliament
S&D	Socialists and Democrats
SMEs	Small and Medium-sized Enterprises

IPOPI	International Patient Organisation for Primary Immunodeficiencies
HERA	Health Emergency Preparedness and Response Authority
CEPI	Coalition for Epidemic Preparedness Innovations
EMA	European Medicines Agency
MFF	Multiannual Financial Framework
BARDA	Biomedical Advanced Research and Development Authority
MCM	Medical Countermeasures
UCPM	Union Civil Protection Mechanism
EIB	European Investment Bank
ID Cluster	Infectious Disease Cluster
EU4Health	European Union for Health Programme
SRIA	Strategic Research and Innovation Agenda

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1 Introduction

On the 14th of October, the e-FabRIC Consortium convened policymakers, industry representatives, regulators and patient communities' representatives in the European Parliament for a policy dialogue on the role of innovative therapeutics in strengthening pandemic preparedness in Europe. This event was held under the patronage of MEP Pierre Jouvet. The session focused on the critical measures that Europe needs to take to ensure its preparedness for health crises and future pandemics.

The event welcomed speakers representing a wide range of stakeholders, including:

- MEP Pierre Jouvet, S&D, France
- Laurent Muschel, Deputy Head, DG HERA
- Anaïs Belledant, Head of Innovation, Fabentech / Coordinator, e-FabRIC Consortium
- Diana Lousa, Co-Coordinator, EvaMobs Consortium
- Hervé Raoul, Coordinator, BE READY European Partnership for Pandemic Preparedness
- Willo Brock, EU representative, CEPI
- Marco Cavaleri, Head of Biological Health Threats and Vaccines Strategy, EMA
- Cornelius Schmaltz, Head of Unit, DG HERA
- Sébastien Iva, Chief Executive Officer, Fabentech
- Johan Prevot, Executive Director, IPOPI
- Bruno Lina, President, IDCluster
- Lucile de Traversay, Deputy Coordinator, French Health Innovation Agency

2 Welcoming Remarks

MEP Pierre Jouvet, S&D, France

MEP Jouvet opened the discussion emphasizing that the COVID-19 pandemic reminded the EU—at a profound cost—that health security and pandemic preparedness are essential to safeguard the bloc's resilience and to protect our citizens from a wide spectrum of health threats. The crisis exposed Europe's vulnerabilities, particularly its heavy dependence on Asia for medical countermeasures. In the current geopolitical context, he argued, Europe must urgently reinforce its capacity to innovate, produce, stockpile, and rapidly deploy essential medical resources.

He called for Europe to become a continent of producers again by mobilising science and industry locally, strengthening industrial sovereignty, and advancing strategic autonomy—principles long championed by France. This includes supporting SMEs and maintaining key pharmaceutical assets in Europe.

MEP Jouvet also warned that science is increasingly under attack by populist movements, threatening future crisis responses. He emphasised that Europe must be prepared for the next health emergency and set an example for the rest of world.

He highlighted the crucial role of SMEs in biomedical innovation, noting their agility and willingness to take risks. However, he pointed out the considerable barriers they face—from limited financing to costly clinical trials and complex regulations.

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Without addressing these challenges, MEP Jouvet noted that Europe risks losing cutting-edge innovators not due to weak science, but because the system remains too burdensome for them to succeed.

3 The role of innovation in the EU's pandemic preparedness and response

Laurent Muschel, Deputy Head, DG HERA

Mr Muschel recalled the publication of the EU's MCM Strategy and stressed the importance of ensuring strong support for health from the co-legislators in the next MFF 2028–2035. He underlined the need for dedicated funding for health programmes to reinforce Europe's resilience and health security. Funding for preparedness will be channelled through Horizon Europe, the EU Competitiveness Fund, and the UCPM/RescEU mechanism for stockpiling.

Mr Muschel underlined that HERA's mission is to guide research, support manufacturing capacity, and ensure market access for key health-security actors. He highlighted an end-to-end preparedness approach covering research, development, manufacturing, and stockpiling. Mr Muschel warned that Europe must not repeat the missed opportunities seen in the biotechnology sector and should continue learning from the US model – notably the work done by BARDA.

He added that Europe's weaknesses in clinical trial capacities, stemming from a combination of European and national regulations, must be addressed. Mr Muschel also emphasised the critical need to expand venture-capital support for health innovation; in this context, DG HERA is working with the EIB to develop innovative funding mechanisms. Upcoming infrastructure hubs and stockpiling initiatives aim to secure the EU's supply of pandemic-response tools.

Finally, he pointed to recent examples, such as the Mpox response and the development of an antidote to counter a ricin-attack threat—as proof that strategic investment can save lives.

4 Project Presentation

E-FabRIC's first event was meant to bring together partners in the field of innovative healthcare systems. The project was therefore joined by several other initiatives involved in pandemic preparedness, including EvaMobs — a sister project under Horizon Europe — and the BE READY European Partnership for Pandemic Preparedness – both closely aligned with e-FabRIC in their shared ambition to drive forward innovative practices in Europe.

4.1 e-FabRIC

Anaïs Belledant, Head of Innovation Fabentech / Coordinator e-FabRIC Consortium

Ms Belledant presented the project, which aims to develop a broad-spectrum antiviral effective against multiple Sarbecoviruses. She explained that the e-FabRIC approach is based on a novel immunization strategy designed to generate polyclonal antibodies capable of neutralizing several virus of Sarbecovirus family.

Ms Belledant highlighted that the project's main challenge is keeping the development of the biological product aligned with the Horizon Europe project timeline, given the gap between

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theoretical planning and the realities of biological treatment development. A second challenge is ensuring that such innovative treatments can ultimately reach patients. Since these threats have not yet emerged in humans, regulatory and clinical development aspects are particularly important.

Ms Belledant also underlined that an innovative broad-spectrum therapy—capable of addressing several threats simultaneously—could influence the future deployment of medical stockpiles.

In conclusion, the key challenge for the project is ensuring that the e-FabRIC Consortium can move from innovation to a concrete, effective solution that contributes to future pandemic preparedness and response.

4.2 EVAMOBs

Diana Lousa, Co-Coordinator EvaMobs

Ms Lousa presented the EvaMobs project, which focuses on developing evolvable and rapidly adaptable monobodies through a platform designed for the discovery and validation of adaptable antivirals. She stressed that the project addresses a critical challenge in global health: the inability to accurately predict which viruses will cause future pandemics. Considering this uncertainty, Ms Lousa emphasised that it is essential to create new solutions capable of targeting a broad range of viruses through discovery, development, production, and validation processes that are both efficient and cost-effective.

The main objective of the project is to develop an innovative computational framework for the discovery of antiviral biologics based on the monobody scaffold (Mobs). This will involve implementing a robust pipeline for the production, stabilization, and screening of antiviral Mobs, followed by their preclinical validation. Furthermore, a selected Mob will be validated in a phase I clinical trial to ensure the clinical translation of the project's results. Ms Lousa added that to demonstrate the concept's applicability, four viruses will be used as proof of concept: Influenza, SARS-CoV-2, Zika, and RSV. She highlighted that the project's core innovation lies in the use of monobodies—adaptable protein scaffolds capable of being engineered to target diverse viral threats, offering a promising pathway toward the rapid development of broad-spectrum antiviral therapeutics.

Finally, Ms Lousa noted that main challenges that the EvaMobs is facing involve regulatory and manufacturing expertise gaps that limit the transition from research to market and high GMP production costs as well as a lack of complementary funding to advance promising candidates to deployment.

4.3 BE READY European Partnership for Pandemic Preparedness

Hervé Raoul, Coordinator BE READY European Partnership for Pandemic Preparedness

Mr Raoul presented the objectives and key features of the BE READY European partnership, an initiative designed to establish a sustainable and long-term framework for anticipating, preventing, and responding to emerging health threats. He explained that the partnership is an EU co-funded project combining both in-house activities and open joint transnational calls, with a total budget of €240 million and a duration of six years, running from 2026 to 2032.

Mr Raoul highlighted that the project is structured around four main pillars: SRIA research alignment, joint transnational calls, research and ecosystem readiness, and transversal activities. Within this framework, the Strategic Research and Innovation Agenda (SRIA) is organised around three principal axes. The first axis, *Understand and prepare*, focuses on enhancing scientific knowledge on pandemic-relevant issues and strengthening the European research ecosystem's preparedness. The second, *Prevent and anticipate*, seeks to improve infrastructures, processes, and workflows to ensure a permanently active and coordinated research system capable of responding effectively to health threats. The third axis, *Respond and control*, aims to guide the optimal use of research resources during crises to accelerate the development of countermeasures and to ensure efficient monitoring and surveillance mechanisms.

Mr Raoul concluded that these research areas encompass all key domains essential for effective responses to pandemics and epidemics — from basic and pre-clinical research to clinical, public health, and implementation research — and also integrate social sciences through a comprehensive One Health approach.

5 Panel Discussion

After the presentation of the various projects, the session transitioned to a panel discussion, during which speakers from different sectors shared insights on how EU healthcare systems can integrate innovative technologies to enhance pandemic preparedness and overcome implementation challenges.

Willo Brock, EU representative, CEPI

Mr Brock was asked whether, in the context of developing a vaccine using the same mosaic antigen technology as the one currently being explored for therapeutic treatment (e.g., e-FabRIC), it would be relevant to build a combined arsenal of vaccines and treatments for pandemic preparedness. He underscored the importance of balancing funding and development between vaccines and therapeutics, noting that therapeutics will increasingly be used preventively. Europe's challenge is to convert innovation into global leadership. Mr Brock highlighted that technology transfer and international collaboration—rather than competition with the US—were prerequisites for global impact. He added that ensuring equitable access to European-developed technologies remains a key principle.

Marco Cavaleri, Head of Biological Health Threats and Vaccines Strategy, EMA

Mr Cavaleri was asked about the EMA's efforts to adapt regulatory pathways to accelerate the approval of innovative therapeutics targeting multiple viral families, including those without prior human cases — while maintaining high standards of safety and efficacy. He recalled the Ebola vaccine as a regulatory success enabled by innovative non-human models. Mr Cavaleri emphasised the need for sufficient data, platform-based approaches with defined safety profiles, and continued global regulatory coordination on MCMs. He announced that an EMA workshop examining non-clinical models for therapeutic agents will be held at the end of November. Finally, Mr Cavaleri stressed the EMA's continuous work on post-approval monitoring and adaptive regulatory mechanisms.

Cornelius Schmaltz, Head of Unit, DG HERA

Mr Schmaltz responded to a question on HERA's efforts to ensure that the monitoring of innovation translates into the availability of effective treatments, and how these risks are converted

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into concrete stockpiling needs. He outlined funding pathways including EU4Health for procurement and HERA Invest to support SMEs. Mr Schmaltz emphasised that HERA is part of a broader ecosystem and its ability to scale support depends on available funding. He added that strategic stockpiling with Member States remains a priority.

Sébastien IVA, CEO, Fabentech

Mr Iva was invited to comment on the key enablers that would allow innovators like Fabentech to take risks sustainably in an environment where regulatory pathways are not yet fully mature and market visibility is limited. He answered that funding remains the core challenge. Mr Iva stressed that while manufacturing readiness in Europe is improving, more work is required to accelerate market access and maintain European leadership. He added that support for European manufacturing and procurement policies favouring EU-produced medical tools will be crucial.

Johan Prevot, Executive Director, IPOPI

Mr Prevot offered insights on the biggest concerns for people living with primary immunodeficiencies in a future pandemic. He stressed that from a patient organisation perspective the biggest concern in a future pandemic is access to innovative therapies. This is a major concern, as these patients are particularly vulnerable. Mr Prevot described the inequities observed during the previous pandemic between different Member States: high-income countries were better off, and Europe's fragmented response led to poor patient outcomes. He added that for some people living with immunodeficiencies the pandemic is not over yet.

Bruno Lina, President, IDCluster

Mr Lina was asked about the key challenges clinicians face in navigating regulatory pathways for broad-spectrum products, and how infectious disease specialists can contribute to accelerating safe and effective approvals. He stressed that market failures hinder the development of essential medical products, highlighting the need for sustained public funding. Mr Lina added that strengthening biobanking capacity and adopting adaptive clinical trial models across Europe are crucial to improving preparedness and enabling the adjustment of drug indications during emerging outbreaks. He concluded that clinicians must play a central role in evaluating new tools and defining predetermined response frameworks.

Lucile de Traversay, Deputy Coordinator, French Health Innovation Agency

Finally, Ms Traversay discussed the main opportunities and challenges in aligning national innovation efforts with EU-wide strategies such as HERA and the EMA's preparedness plans. She emphasized the need to coordinate national and European investment strategies to ensure continuity and prevent fragmentation. France, she noted, is investing €7.5 billion in health innovation, focusing on reducing external dependencies, strengthening hospital and laboratory capacity, and supporting SMEs. Ms Traversay also highlighted the importance of dual-use technologies, the integration of behavioural and social sciences to foster acceptance of MCMs, and cross-sector governance to enhance Europe's crisis-response capability. A partnership with the ID Cluster was cited as an example of effective coordination in innovation efforts.

6 Conclusion

In conclusion, across all interventions, a common message emerged from the panellists: **Europe must accelerate investment, coordination, and industrial capabilities to ensure readiness for the next crisis**. Research excellence alone will not be sufficient without the ability to manufacture, stockpile, and deploy medical countermeasures rapidly across all member states. Speakers and attendees agreed that Europe should also better leverage small consortia like e-FabRIC and EvaMobs, which aim to strengthen health preparedness through innovative therapeutics. Greater funding harmonised clinical trial structures, stronger SME support, and a strategic commitment to European production are essential to ensure that Europe not only responds effectively to future health threats but sets a global standard in innovation, resilience, and health security.

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