

**EUROPEAN
HEALTH PARLIAMENT**

EUROPE'S NEXT GENERATION OF HEALTH

COMMITTEE ON INNOVATION & VALUE

LEADING HEALTH INNOVATION
TOWARDS VALUE IN EUROPE

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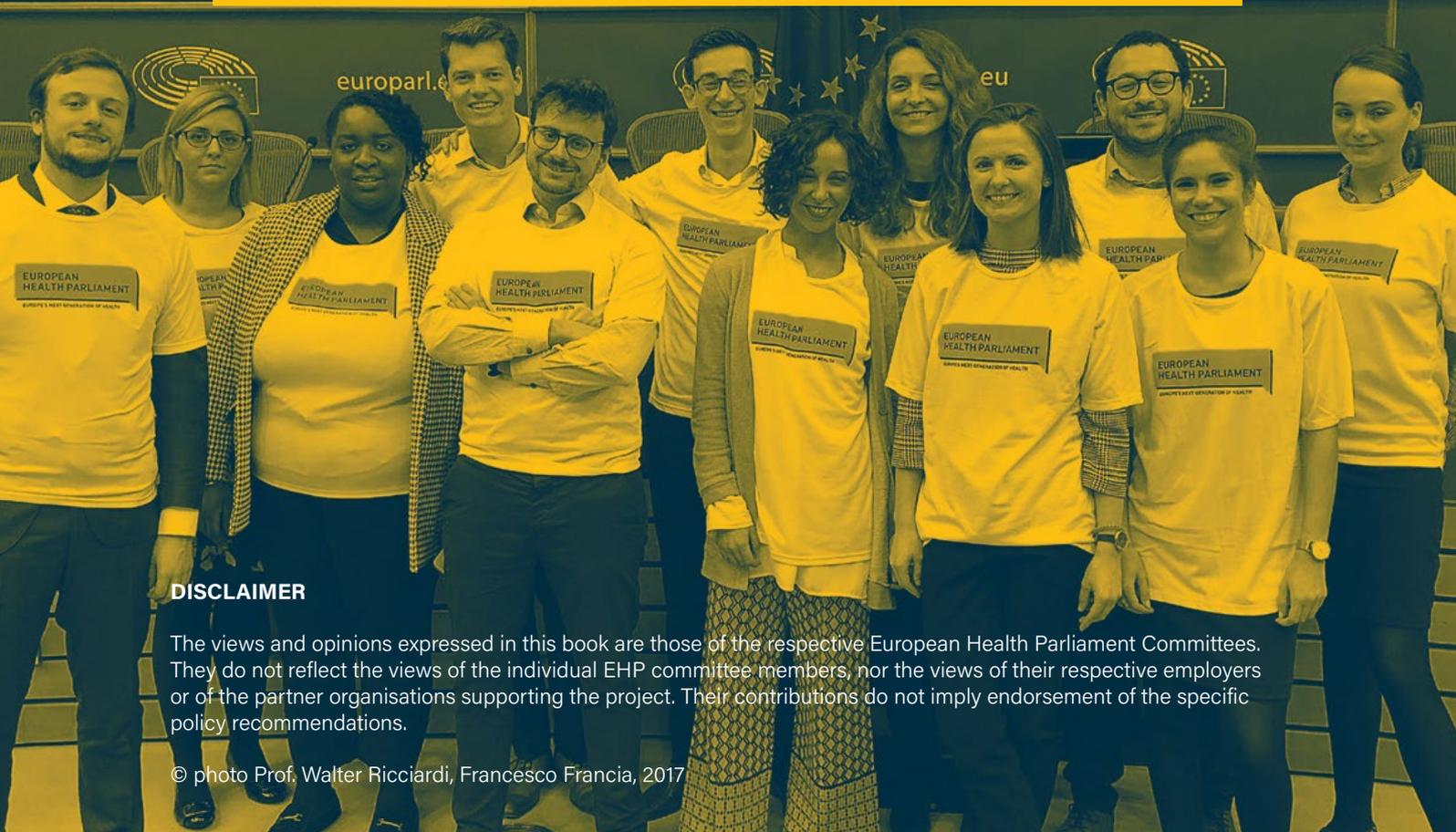
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The views and opinions expressed in this book are those of the respective European Health Parliament Committees. They do not reflect the views of the individual EHP committee members, nor the views of their respective employers or of the partner organisations supporting the project. Their contributions do not imply endorsement of the specific policy recommendations.

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- › **European Cancer Patient Coalition (ECPC)**

José Inácio Faria

Member of the European Parliament (EPP, Portugal)



"Innovation in healthcare is only true when it undoubtedly responds to both the needs of individuals and of health systems as a whole. I believe that a wider concept of innovation is flourishing in these recommendations of the Health Parliament. The value of innovation needs to encompass patients' quality of life, accessibility to and affordability of healthcare systems, as well as to cover the preparation of the societal network where it will land. Innovative technologies for prevention, diagnosis and treatment are only beneficial when all know how to put them to good use."

Prof. Walter Ricciardi

Professor of Hygiene and Public Health at the Università Cattolica del Sacro Cuore, Member of the Executive Board of the WHO, Member of the Expert Panel on Effective Ways of Investing in Health (European Commission, DG SANTE)



"I congratulate this Committee of EHP4 for addressing the difficult but pressing topic of steering innovation towards value to preserve the sustainability of our health systems. Health systems are increasingly faced with multiple socio-economic challenges. All these processes must be governed, or the result will be more differences across and between countries and additional shocks to our healthcare systems. Proposals such as the European Health Innovation Day and preparing health workforce to share and deliver innovations within healthcare systems are pivotal to promote a common understanding of value in our healthcare systems. The challenges and solutions identified in this brief provide critical insights for decision-making, which inevitably needs to be made by political and health system managers."

EXECUTIVE SUMMARY

European Member States are increasingly faced with multiple socio-economic issues that challenge the sustainability of their healthcare systems. Aware of such challenges, young Europeans are eager to harness and protect the potential of health innovation, which could bring sustainable solutions to some of today's most pressing issues.

Health innovation should bring added value to people's health and wellbeing through increased efficiency, effectiveness, safety, quality, affordability and sustainability. It can take multiple forms, such as breakthrough treatments, novel technologies and improved processes and services that empower citizens and patients.

We want the European Union to be a global leader in the development and implementation of health innovation. We want Europe to be conducive to innovation and to place patients and citizens at the centre when shaping the future of health – if not for the seven in ten Europeans who believe that the EU should do more in terms of health, then for future generations.

To stimulate health innovation and its value for the next generations, we recommend to:

1. Set up a "European Health Innovation Day" to promote a common understanding on the value of health innovation and engage European citizens in setting health priorities.
2. Develop an EU framework for patient involvement in the full life-cycle of health innovation development.
3. Facilitate the objective assessment of all factors important to patients and caregivers in healthcare resource decisions.
4. Establish a permanent EU body to prepare for the regulatory and ethical challenges of disruptive technologies.
5. Prepare the health workforce to deliver innovation within health systems.
6. Broaden and facilitate the appraisal and decision-making on health innovations within the European market to benefit decision makers, patients and innovators.



INTRODUCTION

European healthcare systems are increasingly faced with multiple socio-economic challenges, including a rise in non-communicable diseases, multimorbidity, antibiotic resistance, healthcare costs and funding deficiencies, and an ageing population.¹ Within this context, health systems and policies struggle to anticipate, manage and understand the implications of innovation.

Aware of such challenges, young Europeans also recognise the potential of innovation in providing sustainable solutions to preserve our healthcare systems. Health innovation can and indeed should bring added value to people's health and wellbeing through increased efficiency, effectiveness, quality, sustainability, safety and affordability.² It can take the form of breakthrough treatments and novel technologies, but can also entail new or improved processes and services that change the way in which healthcare is delivered and empowers citizens.³ Innovation is not just about technology, it also encompasses cultural, organisational and conceptual aspects in the way our health systems are designed. Regulation should not hamper innovation in the health sector but should support and push for it to be valuable both to patients and society at large.

In its effort to support Member States' healthcare systems, the European Union (EU) can play an important role in enabling the scaling of benefits for producers and the alignment of priorities between Member States. We want the EU to be a global leader in the development and implementation of health innovations. We want Europe to be conducive to innovation and to place patients and citizens at the centre of shaping the future of health. This policy brief therefore provides six recommendations on how the EU and Member States may generate novel policies which would foster valuable health innovation and place patients and society at the centre of the healthcare innovation ecosystem.

"Innovation is not just about technology, it also encompasses cultural, organisational and conceptual aspects in the way our health systems are designed."



OUR APPROACH



For the development of this policy brief, members of the Committee on Innovation and Value conducted 22 interviews with experts and representatives from across the entire healthcare ecosystem, including industry (7), patients (4), policymakers (8) and academia (3). The outcomes of these interviews were supplemented with desk research focusing on setting priorities for innovation, assessing innovations and the patient access pathway, as well as ensuring the swift and safe implementation of innovations. All the research was horizontally informed by the ambition to better serve European patients and citizens.

The authors of this report decided to focus on key ideas rather than on the political implications of the recommendations. As such, the policy recommendations are aimed at the EU as a whole, including its institutions and its Member States. As it tackles only some of the many issues encountered when bringing valuable innovations to patients, we strongly encourage the next European Parliament and Commission to continue exploring how they can contribute to an innovative and healthy future for Europe.

RECOMMENDATIONS

Set up a “European Health Innovation Day” to promote a common understanding on the value of health innovation and engage European citizens in setting health priorities

Even if innovation has significantly contributed to a rising life expectancy⁴, citizens do not necessarily fully understand the associated socio-economic benefits. The EU should proclaim a **“European Health Innovation Day” as a platform for dialogue** between citizens and governments to establish **a common understanding of health innovation, of its societal cost, and also of the role and value it brings to European society.** This would help citizens to elect representatives that champion their views on the future of health, and further support governments in making complex trade-offs when allocating budgets on treatments, health systems, disease prevention and research into unmet medical needs.

During the European Health Innovation Day, the EU should support Member States to:

- › Launch **national public surveys on health priorities** tailored to regional contexts;
- › Conduct **educational programmes in schools**, for instance by bringing students to hospitals, laboratories or innovative companies, educating them on the latest technologies, and promoting career paths to actively shape the future of our innovation and healthcare systems;
- › **Break the silos in the decision-making processes** which define health investment by fostering a dialogue between health, finance, social and environmental decision makers;
- › Extensively **leverage new social media** and other means to gain wide visibility and continuous engagement.



“Break the silos in the decision-making processes which define health investment by fostering a dialogue between health, finance, social and environmental decision makers.”

Develop an EU framework on patient involvement in the full life-cycle of health innovation development

Existing codes of practice for patient involvement do not comprehensively cover the life-cycle of innovation. Indeed, meaningful patient involvement across all phases can bring multiple benefits to researchers, patients, clinicians and society.⁵ The EU should build on the work of the ongoing PARADIGM and EUPATI projects to develop **a clear framework for patient involvement in health innovation and ensure an EU-wide, sector-wide, comprehensive uptake.**

The framework for patient involvement in health innovation should:

- › Cover all health innovations and enable meaningful patient engagement **in the entire life-cycle of**

innovation, from setting research priorities and participating in research design, to research operations and dissemination;

- › Facilitate **a continued and transparent interaction** between the pharmaceutical industry and patients, following clear regulation put in place to this end;
- › Include **clear standards on how to frame and accurately report** the results of meaningful patient involvement.

Trade and research associations should play an important role in the wide roll-out of the framework through its inclusion into their internal regulations (e.g. EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations⁶).

Facilitate the objective assessment of all factors important to patients and caregivers in healthcare resource decisions

Health innovation is often solely viewed as the development of ground-breaking new curative treatments. However, there is also great societal value in **innovations that incrementally improve the everyday lives of patients and their caregivers**.⁷ This could be the new formulation of an existing molecule which may reduce the intake frequency or mitigate side effects⁸, or a mobile app which can answer medical questions on demand.⁹

To adequately assess the value of such innovations, and to incentivise innovators to consider both clinical and non-clinical outcomes of their products, thereby reflecting more patient value, the EU should:

- › Further **facilitate research in advancing meaningful quality of life outcome measures**¹⁰, especially patient and caregiver reported treatment outcome measures (PROMs & CROMs), and patient reported experience measures (PREMs);
- › **Boost research on factors important to patients and their caregivers** and how to measure them¹¹;
- › Facilitate the **adoption of value assessment frameworks** at national level. This would open doors to capture and measure factors relevant for patients in a more accountable, objective and transparent way across the EU.

Establish an EU permanent body to prepare for regulatory and ethical challenges of disruptive technologies

Innovations in healthcare are often held back by lack of regulatory guidance or framework.¹² At the same time, patients and citizens increasingly seek access to new technologies independently of whether these are regulated or not.¹³ This can be exacerbated by the speed at which especially digital innovation continues to rise. Soon enough, citizens could be able to 3D print their own biomaterials and medicines, rely on artificial intelligence instead of doctors, or even ensure their "digital immortality"¹⁴

The EU should establish a permanent body specialising in long-term disruptive health innovation horizon scanning.

This body could be a standalone EU agency, a new unit within the European Commission or a committee of the European Medicines Agency. By dealing with digital and disruptive care with a long-term perspective, the EU can support Member States in preparing their healthcare systems, regulatory frameworks and access pathways, prompting global EU leadership in the field of health innovation. This permanent EU-level body – that we call the Health Innovation Centre – should:

- › **Analyse novel and anticipated technologies** and issue guidance on their potential impact from technological, health systems, ethical, political and economic angles.
- › **Ensure the system readiness for innovations** by working closely with the Member States and key stakeholders, through e.g. the eHealth Network and the European Commission's eHealth Stakeholder Group¹⁵, whilst ensuring **the right level of citizen protection**.
- › Operate as **an embedded body within an existing EU institution** to inform the work of adjacent policy units and ensure horizontal integration of emerging future health solutions in all policies. It should further identify knowledge gaps and pilot opportunities for research programmes.

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Prepare the health workforce to deliver innovation within health systems

Although the number of physicians and nurses in Europe has increased by approximately 10% over the last ten years¹⁶, there are still worrying shortages of health professionals and this gap is set to rise as the health needs of our societies continue to grow.¹⁷ Under these strains, an additional effort is needed to **ensure that our health workforce is trained and fully equipped to bring innovations to patients.**

At the same time, innovation could **contribute to relieving health workforce imbalances** as it boosts efficiency of care.¹⁸ For example, the deployment of AI could help doctors review mammograms 30 times faster and 99% more accurately than before, which would lead to much earlier detection of breast cancer.¹⁹

To harness such potential from innovation in practice, we call on the EU to:

- › Provide **guidance for medical education facilities** on how to best prepare future health professionals to **disruptive innovation** in their practice;
- › Co-create **interactive e-learning tools** with and for health workers on the use and adoption of new technologies in healthcare. This way, health professionals can become **champions for change in health and care delivery** and impact the uptake of new technologies in healthcare systems²⁰;
- › Increase the number of **cross-country educational and training projects** accessible to all professionals of health and care delivery;
- › Identify and spread **local best practices and key learning experiences** of health workforce training, with view to incorporating innovations into daily use. To this end, the EU should incentivise individuals and institutions to use a centralised platform where health providers and institutions can access and submit case-based reports of real-life best practices and key learning experiences.

Broaden and facilitate the appraisal and decision making on health innovations within the European market to benefit decision makers, patients and innovators.

Health Technology Assessment (HTA) plays a vital role in getting innovations into reimbursed healthcare and to patients.²¹ So far, it is mainly used for new medicines across EU Member States²², with only 58% of national HTA institutions assessing technologies such as IT, e-health and m-health technologies, population level interventions and service delivery systems.²³ To be ready for the next generation of health innovations, the EU should set **ambitious goals to achieve common HTA frameworks for health innovations**, including specific medical devices, services and processes. The EU should support Member States to:

- › Perform **HTA on health innovations**, including technologies and processes to ensure that health resource allocation decisions are value-based;
- › Establish a **single point of contact** responsible for **defining clear patient-access pathways** for all innovations in healthcare, making sure that the process is both transparent for citizens and clear for companies;
- › Build on the European Commission proposal for a joint-EU HTA to **further harmonise HTA processes and methodologies** throughout the EU.

While we fully acknowledge that convergence and centralisation of HTA systems remains a contentious and controversial political topic, we believe it is important to further suggest that the EU and Member states should **gradually work towards coordination and possibly centralisation of HTA expertise on relative clinical benefits.** Scaling benefits and pooling expertise in the HTA process will be a key element in addressing the resource challenges that come with evaluating a whole new class of health innovations.



CONCLUSIONS



The main aim of our policy brief has been to present various suggestions on how the EU can be a proactive agent which enables valuable and innovative change in European healthcare systems. Indeed, as we have discussed, there are still strides to be made in order to develop novel sustainable policies capable of fostering valuable health innovation and placing patients and society at the centre of healthcare systems. This is why we firmly believe that the EU is, more than ever, needed to support regulatory systems, healthcare workforce, and most of all citizens to make the most out of current and future opportunities.

However, with health innovation having such powerful potential, the difficulty lies in defining and prioritising the exact roles, out of many, that the EU can play to facilitate such processes. Moving beyond the EU's community acquis, notably the many benefits reaped from the Single Market in enabling innovation across EU countries, our aim has been to demonstrate that the EU has the potential and the capacity to be the key actor that guides innovation in the direction of where it should be most valuable.

Innovation is, by nature, unpredictable and the speed with which it is taking over our daily lives is nearly surpassing our ability to harness it. Let's once and for all embrace this unique opportunity by empowering the EU and its Member States to make positive disruption and valuable innovation the cornerstone of European healthcare.

REFERENCES

1. Expert Panel on Effective Ways of Investing in Health, "Innovative Payment Models for High-Cost Innovative Medicines", European Commission, 2018.
2. World Health Organization, "Health Topics: Innovation", 2019.
3. Eurostat, "Glossary: Innovation", 2019, <https://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Innovation>, last consulted on 02.03.2019.
4. F.R. Lichtenberg, "Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-Income Countries, 2000-2009", *Health Policy and Technology*, no. 3: 36, 2014.
5. J. Geissler *et al.*, "Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap", *Therapeutic Innovation & Regulatory Science*, no. 5: 612, 2017.
6. European Federation of Pharmaceutical Industries and Associations, "Code of Practice on Relationships between the Pharmaceutical Industry and Patients Organisations", 2011
7. B. Addario *et al.*, "Patient Value: Perspectives from the Advocacy Community", *Health Expectations*, no. 21: 57, 2018.
8. M. Toumi & C. Rémuzat, "Value added medicines: what value repurposed medicines might bring to society?", *Journal of Market Access & Health Policy*, no. 5: 1264717, 2017.
9. N. Lineaweaver, "Chatbot Patient Engagement Platform raises \$6 million — Telehealth Saves Insurers \$1.5 million — UK Bets on AI for Chronic Disease Treatment", *Business Insider*, 23 May 2018.
10. The Economist Intelligence Unit, "Creating Healthy Partnerships: The Role of Patient Value and Patient-Centred Care in Health Systems", Patient Centred Care, 2019.
11. Avalere Health, "Patient-Perspective Value Framework" Faster Cures, 2017, <https://www.fastercures.org/assets/Uploads/PPVF-Version-1.0-Methodology-Report-Final.pdf>, last consulted 02.03.2019.
12. European Commission, "Innovation in Healthcare From Research to Market to Health-systems to Patient, Main conclusions from 2010, 2011, 2012 conferences", Brussels, 2013.
13. B. Meskó *et al.*, "Digital Health is a Cultural Transformation of Traditional Healthcare", *Mhealth*, no. 3: 38, 2017.
14. R. Kurzweil, "The Singularity is Near: When Humans Transcend Biology", New York: Viking Press, 2005.
15. <https://ec.europa.eu/digital-single-market/en/ehealth-experts>, last consulted on 02.03.2019.
16. World Health Organization, "Core Health Indicators in the WHO European Region", Copenhagen, 2015.
17. European Commission, "Commission staff working document on an Action Plan for the EU Health Workforce", Strasbourg, pp.5-6, 2012.
18. World Health Organization, "Global Strategy on Human Resources for Health: Workforce 2030", Switzerland, 2016.
19. S. Griffiths, "This AI software can tell if you're at risk from cancer before symptoms appear", *Wired*, 26 August 2016.
20. N. Sarkis & L. Mwanri, "The Role of Information Technology in Strengthening Human Resources for Health", *Health Education*, no. 114: 67, 2013.
21. European Commission, "Proposal for a Regulation of the European Parliament and of the Council of 31 January 2018 on health technology assessment and amending Directive 2011/24/EU", Brussels, pp.16-18, 2018.
22. S. Fuchs *et al.*, "Health Technology Assessment of Medical Devices in Europe: Processes, Practices, and Methods", *International Journal of Technology Assessment in Health Care*, no. 32: 246, 2016.
23. European Commission, "Mapping of HTA methodologies in EU and Norway", Luxembourg, 2017.

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