

Our Manifesto for the European Health Union:

Empowering innovation in healthcare and life sciences
for patients and society

Johnson&Johnson



At Johnson & Johnson, we believe health is everything. It is the foundation of vibrant lives, thriving communities and forward progress.

Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. We invest billions in R&D to improve human health through sustainable, inclusive, and innovative solutions.

We strive to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. We aim to improve access and affordability, create a healthier global community, and put a healthy mind, body, and environment within reach of everyone, everywhere.

The European Union's (EU) recent communication on "the long-term competitiveness of the EU: looking beyond 2030" highlights the importance of growth and innovation, as well as the need for coordinated action to bridge the European competitiveness gap in an increasingly complex geopolitical context.¹

The healthcare industry is a key pillar of the European economy, playing a vital role all along the value chain in job creation and community growth. It is essential, therefore, that Europe strengthens its leadership position in biopharmaceuticals, medical technologies, health, and digital innovation, and we need a strategic and proactive approach to achieve this.

As a global company with a strong footprint in Europe, we are certain our industry will play a critical role in addressing patients' needs and achieving the EU ambition in the areas of Health Union, Competitiveness, Digital Transformation and Environmental Sustainability.



¹ European Commission, 2023, available at https://commission.europa.eu/system/files/2023-03/Communication_Long-term-competitiveness.pdf



Our manifesto presents recommendations in key areas we consider essential to empowering innovation and growth in healthcare and life sciences in Europe and its Member States, placing patients and citizens at the core:



Supporting a review of the EU's pharmaceutical framework that facilitates innovation and unlocks tomorrow's cures for patients



Evolving healthcare systems to be more patient-centric



Securing a reliable and flexible Medical Device Regulation (MDR) fit for the digital age



Supporting healthy people and a healthy planet through our approach to environmental sustainability



Empowering healthcare through data, Artificial Intelligence (AI) and digitalisation: policies for trust, innovation, and access



Ensuring secure, resilient and diverse supply chains

Supporting a review of the EU's pharmaceutical framework that facilitates innovation and unlocks tomorrow's cures for patients

The review of the pharmaceutical¹ and IP² packages provides us with a 'once-in-a-generation' opportunity to ensure that Europe remains at the forefront of biomedical innovation³.

We believe that the proposals adopted by the European Commission must lead to a more resilient system, where regulations keep pace with scientific progress and facilitate innovations that address unmet needs, are accessible across the EU, and improve patient outcomes.

The pharmaceutical package: we welcome the upgrade of our regulatory system to an agile, fit-for-purpose and future-proofed framework. We believe that stronger EU coordination fully involving the industry, alongside proportionate requirements that take into account the global nature of our supply chains, would enhance resilience and flexibility to tackle shortages. The review is also an opportunity to address the environmental challenges we all face, without compromising on patient access to medicines.



We welcome the goal of establishing a harmonised approach to Supplementary Protection Certificates (SPC). It will lead to more clarity and efficiency in the EU IP framework. However, procedural guidelines are needed to ensure that pre-grant opposition proceedings are not misused to delay the SPC grant until the basic patents expire. We are concerned though about the proposal to add an EU-wide Compulsory License on top of existing, well functioning national frameworks. The proposal lacks robust guardrails to ensure it would only be exercised within the right policy and judicial framework and in compliance with all international obligations.



1. Reform of the EU Pharmaceutical Legislation, available at: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en. Last accessed October 2023.

2. Intellectual property: harmonised EU patent rules boost innovation, investment and competitiveness in the Single Market. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_2454. Last accessed October 2023.



Securing a reliable and flexible Medical Device Regulation (MDR) fit for the digital age

Evolving healthcare systems to be more patient-centric

The last few years highlighted many structural challenges facing healthcare systems, created by years of underfunding and systemic inefficiencies, such as delayed diagnosis and access to treatment, healthcare professional (HCP) shortages, and an aging healthcare workforce.⁴

Despite these challenges, we have an unprecedented opportunity to design healthcare systems fit for the future, where the unmet medical needs of both patients and society are at the centre of decision-making. The policies and funding dedicated by the EU to overcoming healthcare disparities have played, and should continue to play, an important role in healthcare systems' evolution.

We believe the way forward requires a holistic approach including increased public investment in disease prevention, early detection, timely access to the best treatment options (better uptake of procedures and medicines), transformation of patient pathways, better working conditions and continuous learning for HCPs, and incentives that reward and facilitate health innovation and attract top talent to the sector in Europe.

We also encourage better utilisation of public private partnerships to enable best use of available expertise and resources and to address the most burning needs of the healthcare systems.

We welcome the adoption in March 2023 of the regulation to amend MDR and urge stakeholders to continue to investigate how the outstanding shortcomings of the MDR system can be addressed, including:

- Designing a dedicated pathway for innovative technologies, and improving current pathways for legacy devices: by driving efficiency and predictability of timelines and cost, allowing leveraging of clinical evidence, and removing the recertification requirement every five years.
- Decision-makers should strengthen global regulatory alignment to avoid duplicative requirements and ensure that the products and solutions reach patients and healthcare systems as quickly as possible. MDR should recognise the increasing presence of new types of medical technologies, such as software that requires a more agile framework for short and frequent improvement loops; regulatory frameworks should also embrace solutions such as digital labelling and electronic Instructions for Use (e-IFU) for all devices. Much can be done to introduce greater agility, efficiency and flexibility right now. One example is the implementation of early dialogue between manufacturers and Notified Bodies to make sure final submissions meet expectations.
- Moreover, we encourage the collection of Real-World Data (RWD) and Real-World Evidence (RWE) to enhance healthcare decision-making by demonstrating outcomes and value for patients, healthcare professionals, regulatory bodies and payers.

3. Life Sciences Investment Attractiveness Report, available at <https://www.janssen.com/emea/life-sciences-investment-attractiveness-report-0> Last accessed October 2023

4. OECD, Health at a Glance 2021: OECD Indicators. Available at: <https://www.oecd-ilibrary.org/docserver/ae3016b9-en.pdf?expires=1699370990&id=id&accname=guest&checksum=FAEDA953DD8F663168C9AEC79BCCAE5>. Last accessed October 2023.

Supporting healthy people and a healthy planet through our approach to environmental sustainability

We encourage the advancement of a broad set of policy solutions, including public private partnerships, to promote and drive innovation and the scale-up of renewable and low-carbon technologies. This would support our commitment to improving the environmental footprint of our operations, our products, and our value chain.

We advocate for environmental sustainability policies to be consistent with sector-specific regulatory requirements to support the availability of safe medical products for patients and users.

We encourage the adoption of evidence-based and proportionate policies considering the relative footprint and influence of the medical products industries on environmental outcomes and fully considering the impact of any measure on patient access to medicines and medical technologies.

We call on regulators to foresee appropriate timelines for any potential changes to healthcare products or packaging, to allow the highly regulated healthcare sector the time to implement any necessary testing and recertification.



Empowering healthcare through data, Artificial Intelligence (AI) and digitalisation: policies for trust, innovation, and access

We are committed to contributing to the digital transformation in healthcare through collaboration and partnership with all stakeholders.⁵ Implementing digital health requires a multi-faceted policy approach, where patients, citizens, policymakers, researchers, HCPs and industry work together to build a trustworthy and robust framework that keeps patients at the forefront and facilitates the development of digital solutions for better outcomes for patients.

Data is at the heart of what we do – from understanding the burden of disease and unmet needs, to delivering new treatments and quality healthcare services for patients and supporting value-based and sustainable healthcare systems. That is why we advocate for strong policies that support the use, access to and sharing of health data to build public trust, drive innovation, and foster sustainable health data ecosystems.

Our call includes:

- Building a European Health Data Space (EHDS) where all actors work together to improve patient outcomes, unlock the power of data science and foster innovation. EHDS should underpin a patient-centric health data ecosystem based on the full respect of ethics, privacy and security. To unleash the potential of data in delivery of care, electronic health records, and research and innovation, we need to ensure the EHDS provides access to correct data types for appropriate purposes. We need cost-effective conditions for industry, while fully protecting data holders' IP/trade secrets rights, and we advocate for a harmonised implementation across Member States.

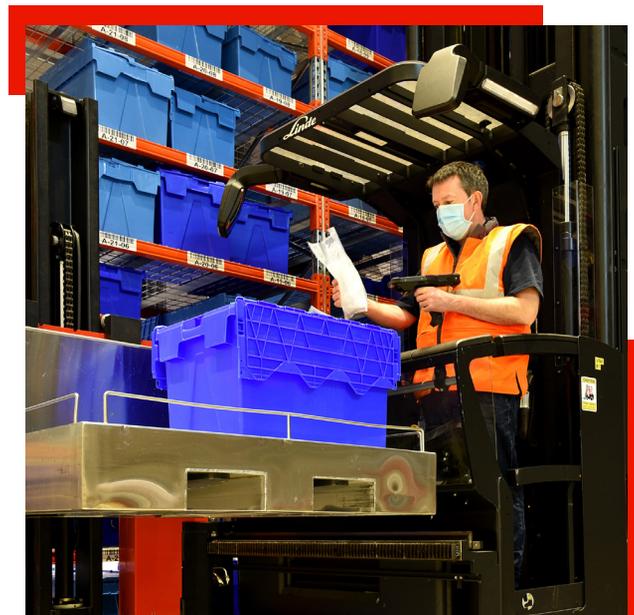
5. Pharma AI Readiness Index: Who's best-positioned for the AI boom? Available at: <https://www.cbinsights.com/research/ai-readiness-index-pharma/>. Last accessed October 2023.

- Developing policies which unlock the power of AI in healthcare based on ethics, trust and excellence. AI can impact the entire healthcare value chain, from R&D to supply chain, treatment and recovery. Therefore, it is critical to have a holistic view where policies support skills, testing and development capabilities and sustainable integration of AI solutions into the healthcare system.
- Addressing the current fragmentation of data protection and localisation practices by establishing clear and harmonised rules for national and international data access, sharing, and use. These rules should protect patient privacy and involve stakeholders through public consultation, applicable in healthcare delivery, research, and innovation. This approach may involve a thoughtful reconsideration of the implementation of existing regulations, all while actively engaging stakeholders through a consultative process.
- Establishing standardised data security measures, including obligations for critical infrastructure and minimum-security standards in the healthcare sector. Global cooperation is essential to harmonise standards and enhance data control, promoting innovation in healthcare.
- Promoting digital access and literacy in the utilisation and governance of digital health technologies to enhance equitable access to these technologies and build a trustworthy data ecosystem.

Ensuring secure, resilient and diverse supply chains

We believe that resilient medical supply chains can benefit from a combination of regional and global policies that focus on:

- Maintaining global, diversified supply chains, enabling a consistent response to external stressors, and improving global regulatory harmonisation to allow for more resiliency and recovery.
- Advancing digitalisation with the right regulatory frameworks to ensure adequate, equitable and effective distribution and minimise disruption.
- Encouraging strong country-to-country and private sector cooperation and partnerships to enhance resiliency and flexibility and reduce over-reliance in, for example, the adoption of fourth industrial revolution technologies and the upskilling of workforces.
- Avoiding export and import restraints and other barriers to trade. Flexibility is vital in a world of climate and health shocks to ensure consistent supply to all patients.



€13.9 billion

invested in research and development across our businesses in 2022⁶

More than

180 million

patients treated globally with one of our medicines (2022)⁶

Nearly

300 million

patients treated with J&J MedTech products worldwide (2022)⁷

Producing or procuring the equivalent of

100%

renewable electricity for our sites across 12 European countries⁶

#2 ranking

in the 2022 Access to Medicine Index, reflecting our strategy to enable access to our medicines and technologies for people in low- and middle-income countries⁶

6. Johnson & Johnson Health for Humanity Report 2022. Available at: <https://healthforhumanityreport.jnj.com/2022/assets/downloads/johnson-johnson-2022-health-for-humanity-report.pdf>. Last accessed October 2023.

7. Johnson & Johnson MedTech At a Glance. Available at: <https://www.jnjmedtech.com/en-US/at-a-glance>. Last accessed October 2023.

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