PHILIPS

Our vision for European Healthcare in 2030

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Availability of medical devices for patients

What is the challenge?

- There are more than 500,000 medical technologies available in hospitals, in community care settings and at home. They save lives and allow people to live longer and better. They improve the quality of care, and the efficiency and sustainability of healthcare systems.

- The med tech sector is among the most innovative, consistently among the technology fields with the largest number of patent filings[1].

- The EU must ensure that medical devices and med tech innovations reach patients evenly across all EU Member States in a timely way.

What does Philips do?

- Over the past 10 years, Philips has undergone a transformation to reshape its portfolio and become a health technology company.

- We produce life-saving equipment, such as automated external defibrillators, patient monitoring systems that are critical for operations in intensive care units.

- We also make minimally invasive therapy equipment, as well as diagnostic equipment: X-ray, magnetic resonance imaging (MRI), and computed tomography (CT).

- For 10 consecutive years, Philips has been the number one med tech company filing patents with the European Patent Office[2].

Our recommendations

- **Mutual recognition agreements for medical devices with the United States of America, Canada, and the United Kingdom.** The requirements to place medical devices on the market in the respective geographies – EU Medical Device Regulation (MDR)[3], US Code of Federal Regulations Title 21[4], Canada's Food and Drugs Act[5] and the new UK Conformity Assessed (UKCA) regulatory framework[6] – are almost identical. Mutual recognition agreements would reduce considerable administrative burden on the companies, but more importantly, it would allow patients to benefit from state-of-the-art treatment, regardless of where they live, in a timely manner.

- **Simple and stable EU research and innovation program.** The successor of Horizon Europe[7] requires sufficient budget to be effective. Industry participation needs to be enabled by simplifying procedures and reducing the burden of reporting and other obligations. It is important that the EU balance open science and intellectual property obligations with commercial interests to ensure a clear path from innovation to clinical implementation. A focus on applied research in healthcare should be maintained, with a clear link to funding allocated to digital innovation.

- **An efficient and fit-for-purpose legislative framework that facilitates medical device innovation.** The current regulatory framework governed by the EU MDR is unpredictable, complex, slow, and costly. As such, it contributes to a growing gap in EU patients' access to medical technologies. This system needs to be revised to establish predictable pathways for certification; to embrace innovation; and to ensure ownership and accountability at the EU level. It should align the requirements of other pieces of legislation, such as the Machinery Regulation[8], the Radio Equipment Directive[9], and the forthcoming Artificial Intelligence Act[10], European Health Data Space (EHDS)[11] proposal, and pharmaceutical legislation[12]. The upcoming review of the MDR should be leveraged to make these updates, and the existing Blue Guide must be revised to properly address digital products.

- **Well-functioning system of harmonized regulatory standards.** The EU standardization system has resulted in a severe backlog in publication of medical device standards. This has had far-reaching consequences: lack of patient access to medical devices, additional costs for EU healthcare systems, and the decreased competitiveness of the EU medical device industry. The EU should revise the Regulation on European Standardisation[13] to allow easy alignment with international standards, and better support companies when demonstrating compliance with EU legislation.

- **A fit-for-purpose, forward-looking and dynamic implementation of Health Technology Assessment (HTA) for digital health solutions and AI.** Many digital medical devices are introduced to the market with little evidence demonstrating effectiveness in real-world healthcare delivery settings (post-market phase). There is also no standardized mechanism for generating evidence that enables transparent pricing and reimbursement decisions. The EU should support the implementation of the HTA regulation[14] to enable timely and equitable patient access to digital healthcare innovations throughout Europe. Potential pathways include piloting reimbursement of selected digital health solutions across Member States, or encouraging interactions between MDR and HTA in a real-world setting.

Patients and health professionals in focus of EU policies

What is the challenge?

- The COVID-19 pandemic exacerbated a dramatic shortage of the health workforce, resulting in delays and non-delivery of necessary care to patients. Another direct result of the pandemic: a continued backlog of diagnostic intervention and treatment across EU Member States, deepening existing inequalities in access to care.

- Noncommunicable diseases are responsible for 80% of the disease burden in the EU countries and are the leading causes of avoidable premature deaths[15].
  - In 2020, 2.7 million people in the EU were diagnosed with cancer. Cancer cases are set to increase by 24% by 2035[16].
  - Cardiovascular diseases, the number one killer in the EU[17], should be given appropriate attention. Mortality can be easily reduced and quality of life improved through prevention, well-trained staff and innovative technologies.

What does Philips do?

- Philips' purpose – to improve people's health and well-being through meaningful innovation – is at the center of everything we do. This core principle has never been more relevant than it is in these challenging times. As a leading health technology company, we believe that patient- and people-centric innovation can improve people's health and healthcare outcomes, as well as making care more convenient and sustainable, both in the hospital and at home.

- Patient safety and quality of care is at the heart of our innovation. Our products and solutions simplify the work of health professionals, leaving them time to take care of their patients.

- Increasingly, we are working together with health systems players on novel business models.

- Our imaging technologies, such as MR and CT, support population-screening programs.

Our recommendations

- **Impactful implementation of Europe's Beating Cancer Plan.** The unprecedented EU Cancer Plan[18], combining policies and funding, demonstrated the value of EU political action in health. After the adoption of the cancer screening recommendation[19], the EU should monitor and incentivize its implementation in Member States. That includes deployment of prostate, breast and lung cancer screening programs.

- **Create a cardiovascular health plan.** Cardiovascular diseases (CVDs) are the leading cause of death globally and in the EU, accounting for 36% of all deaths in the EU. About 60 million people, or 1 in 10 Europeans, suffer from CVDs[20]. Access to prevention, diagnosis and treatment of cardiovascular diseases is uneven across the EU Member States. Following the success of the EU cancer plan, the EU should create an EU cardiovascular health plan. The plan should change the approach to CVDs, taking action from a public health perspective as opposed to a cure-only perspective. One focus area should be wide availability of automatic external defibrillators (AEDs) and the first responder systems that reduce mortality from out-of-hospital cardiac arrest.

- **Enhance skills of healthcare staff.** The curricula of health professionals do not reflect the skills needed to navigate modern healthcare delivery. Digital skills and interdisciplinary patient care are missing. As technologies are evolving (for example, moving toward minimally invasive techniques and procedures), training schemes need to keep up. The EU should encourage a shift from treating an organ to treating the person, for example by creating an EU award to recognize the most patient-friendly facility. Digital skills could also be included in the EU requirements of mutual recognition of professional qualifications.

Resilient & financially sustainable healthcare

What is the challenge?

- The COVID-19 pandemic exposed significant weaknesses and inequalities across all health systems. At the same time, complex new health threats are emerging. Health systems need to be resilient to manage the ongoing chronic crises, such as responding to the burden of disease posed by non-communicable diseases, as well as be prepared to respond to future emergencies, such as shocks brought on by climate change, natural disasters, conflict, and pandemics.

What does Philips do?

- Technology supports effective resilience and crisis response, for example by decentralizing care via telehealth applications and freeing up capacity for hospitals. To help with crisis response, Philips stocks, maintains, and operates a stockpile of medical equipment for the Dutch Ministry of Health on behalf of EU Member States and affiliate countries.

Our recommendations

- Establish Health Emergency Preparedness and Response (HERA) as a stand-alone agency with dedicated resources and skilled staff familiar with medical equipment.

- Create an integrated roadmap for funding healthcare and health innovation in the EU's Multiannual Financial Framework.

- Building on the Recovery and Resilience Facility[21], set up a dedicated program funding healthcare system resilience along targets and milestones aligned to the European semester, with built-in mechanisms for exchanging best practices between Member States and incentives for outcomes-based care.

- Expand EU-level possibilities for innovation procurement, following the example of the US Biomedical Advanced Research and Development Authority.

- Implement strategic stockpiling of medical equipment that can be quickly activated to respond to health emergencies and other crises.

- Designate medical devices as an essential sector, ensuring availability of raw materials and components for the production in times of crisis.

Greening healthcare

What is the challenge?

- Healthcare systems contribute to 4.4% of net global CO_2 emissions – more than the aviation and shipping industries and equivalent to the annual greenhouse gas emissions from 514 coal-fired power plants[22]. Given the negative impact of climate change on public health, communities and society, the healthcare sector must urgently increase its efforts to become part of the solution.

What does Philips do?

- Philips aims to improve people's health and well-being through meaningful innovation. We focus on doing business responsibly and sustainably, as part of our Environmental, Social and Governance (ESG) commitments and our purpose to improve 2.5 billion lives per year by 2030. We are stepping up our actions to set an example and help create safer societies and a healthy planet for all. We embed sustainability across our operations, innovations and supply chain, and we are rapidly adopting more sustainable decision-making at all levels.

- Philips has set long-term CO_2-e emission reduction targets that are approved by the Science Based Targets initiative (SBTi) and in line with the Paris Agreement. We have already achieved carbon neutrality in our operations, with 100% electricity coming from renewable sources. The transition from a linear to a circular economy is essential to create a sustainable world that functions within the boundary conditions of our one planet. At Philips, ecodesign, refurbishment, digitalization and responsible end-of-use management are key elements of our circular strategy. This strategy contributes to delivering sustainable healthcare systems and protecting population health.

Our recommendations

- Develop an EU roadmap for the green transition in healthcare, including the medical technology sector's contribution to the European Green Deal[23], that complements national and regional health systems' plans to reach net-zero healthcare.

- Determine a champion on greening healthcare in the European Commission who also becomes point of contact on sustainability topics for the medical technology sector.

- Harmonize Green Public Procurement criteria across the EU to encourage procurement of sustainable medical equipment.

- Review the New Legislative Framework[24] as well as sectorial legislation, such as the Medical Device Regulation to support circularity and, specifically, refurbishment of medical equipment.

- Align environmental legislation (including measures on chemicals, ecodesign, packaging, and waste) with the innovation and certification cycles of medical technologies, with a goal to ensure the continued availability of safely performing medical devices, while protecting the environment and creating incentives for sustainable innovation.

- With EU funding, support:
  - research and innovation for medical technology development, such as the development and use of alternative materials
  - greening infrastructure and operations of healthcare delivery organizations, including portfolio analysis and life cycle assessment methodology development, investment in sustainable equipment (for example, helium-free MRI or circular equipment), recycling, and waste management infrastructure, as well as digital solutions to reduce carbon footprint
  - capacity-building for purchasers of medical equipment, including training to support the application of Green Public Procurement criteria
  - mapping out and implementing environmental policies and regulations at the level of Member States

Digitalized healthcare

What is the challenge?

- Faced with acute workforce shortages and financial pressures, healthcare organizations across the EU are seeking to alleviate pressure on staff and streamline processes for improved efficiencies. As digital transformation has accelerated, it has redefined patients' and healthcare providers' expectations of how and where care is delivered, including a seamless user experience and on demand information and care services.

What does Philips do?

- Philips is a global leader in health technology and health informatics. Our portfolio includes remote patient monitoring, virtual collaboration, telehealth and other emerging digital technologies. These solutions enable care to move from hospitals into lower-cost settings that are more easily accessible and convenient for patients – such as ambulatory centers, mobile clinics, and the home.

- We view the provision and collection of data from patient monitors, imaging devices, and electronic medical records as the foundation upon which AI propositions can be built to turn clinical data into actionable insights. For example, our interoperability solution enables seamless data capture from over 1,000 medical devices. The same system, informatics, and service solutions also provide improved operational forecasting for better productivity. As one example, our imaging data platform enables radiologists to perform first-time-right diagnosis from its superior images.

Our recommendations

- **Effective and impactful implementation of the European Health Data Space**[25]. To unlock data and turn it into meaningful insights, healthcare organizations must be able to share and interpret it real-time in a seamless, meaningful way. Once the European Health Data Space (EHDS) regulation is adopted, the EU should support and incentivize its implementation by:

  - accompanying the EHDS implementation with a EU roadmap for digitalization of healthcare

  - establishing a uniform health data access and management, including a common standard for data exchange

  - improving interoperability between healthcare systems and health IT infrastructures by harmonizing use of international standards as well as public procurement criteria

  - encouraging the effective and secure use of cloud services in healthcare

- **A harmonized framework for data protection and privacy.** Fragmented national and local rules create privacy and data protection challenges that may affect the success of the EHDS, and in turn reduce the EU competitiveness and innovation potential. Member states do not hold a single position on the legal concept of personal data and non-personal data, and no adequate and recognized standards exist on the anonymization of personal (health) data. Conditions on data processing for scientific research purposes are fragmented. Some member states retain cross-border data transfer restrictions (often as part of the criteria for the public procurement and use of cloud services or within local healthcare regulations). The upcoming review of the General Data Protection Regulation[26] should tackle these to ensure a harmonised and consistent framework for data protection, in support of the EHDS.

- **A dedicated program to support digitalization of healthcare systems.** Funding for the implementation of the EHDS with the aim of achieving the single market, as well as the large-scale deployment of complex solutions, is vital for scaling up and improving access to digital health technologies.

  - EU funds should be allocated to create the infrastructure for access to and seamless exchange/sharing of health data, as demonstrated by the example of the Cancer Imaging Initiative.

  - The roadmap for implementation of the EHDS should identify data gaps and allocate funding for federated data infrastructures, as well as a European network of centers of excellence to promote research and innovation in the health sector through the collection and use of real-world data (RWD), on the model of the European Reference Networks.

  - The program should provide more focus on funding large-scale pilots and deploying digital health technologies and services at scale, through long-term partnerships and collaborations.

  - The program should include funding for digital skills training on data analysis, AI and implementation of RWD standards, with an emphasis on up-skilling healthcare professionals and investing in education to reduce disparities in citizens' digital literacy.

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