ZPP BRUSSELS

FOCUS ON EUROPE

What is Next for EU Health Policy?

3/19/25

Table of Contents

1. Introduction

The European Union (EU) is entering a crucial period for health policy. The 2024-2029 term will shape how the EU responds to ongoing and new health challenges. Aging populations, rising chronic diseases, and mental health concerns are straining healthcare systems while advancements in medical research, digital health, and pharmaceutical innovation are accelerating. At the same time, the lingering effects of past crises, particularly COVID-19, have exposed both strengths and weaknesses in EU health systems—highlighting gaps in preparedness, medicine shortages, and workforce limitations. While coordination between EU institutions and national governments played a key role in crisis response, it also underscored the limits of subsidiarity in health policy.

Moving forward, EU policies must be proactive rather than reactive. Strengthening crisis preparedness, workforce planning, and regulatory flexibility is essential, but this must be balanced with avoiding unnecessary burdens on innovation. Resources are limited, yet investment in infrastructure and healthcare personnel is necessary. Health policy cannot be addressed in isolation—it is deeply linked to economic resilience and technological progress. Medical breakthroughs and AI-driven diagnostics offer potential cost savings and better patient outcomes, but they require stable investment environments, clear regulations, and strong public-private collaboration.

A resilient healthcare system also supports economic growth by improving workforce productivity, lowering long-term costs, and strengthening Europe's position in global healthcare innovation. This paper examines key challenges and opportunities, focusing on systemic health issues, regulatory frameworks, and resilience. The goal is to outline practical, balanced solutions that support public health while supporting European industries to remain competitive.

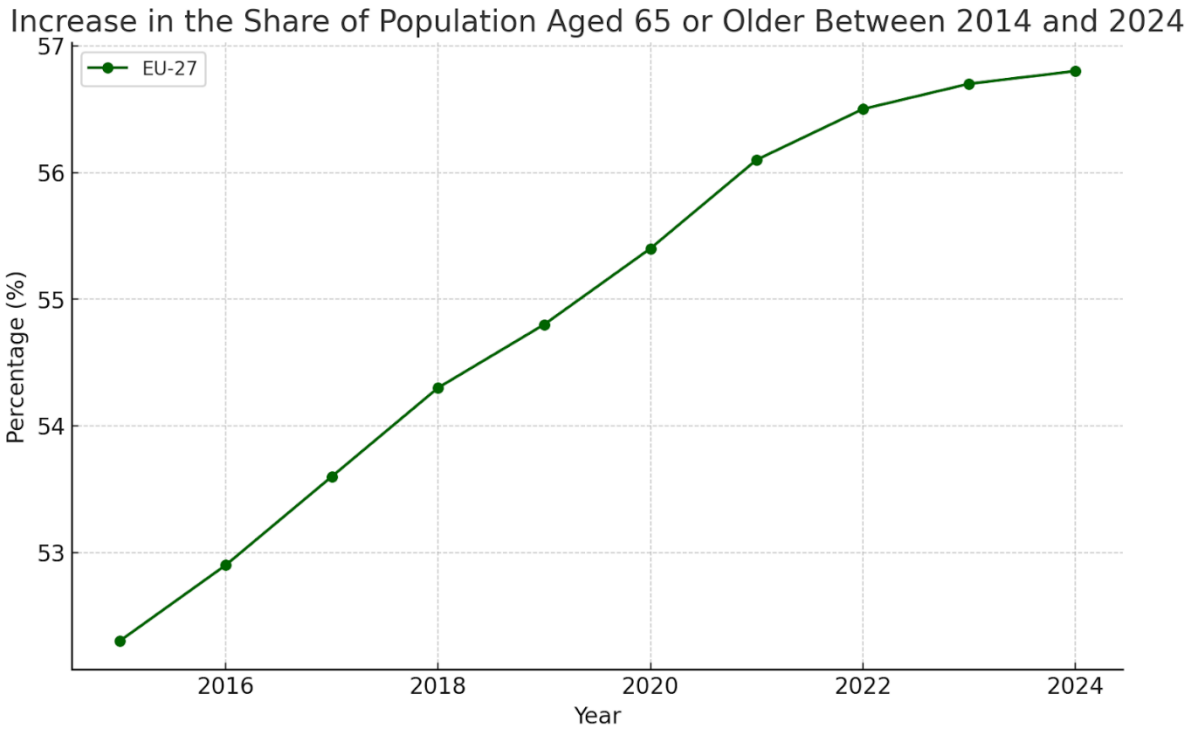
2. Systemic Health Challenges in the EU

The EU faces growing pressure on its healthcare systems. Chronic diseases, aging populations, mental health issues, and lifestyle-related illnesses are increasing the demand for services. Many healthcare systems struggle with staff shortages, funding gaps, and unequal access to care. If these challenges are not addressed, they will lead to higher costs, lower quality of care, and economic strain. Addressing these issues requires a coordinated, long-term strategy that strengthens both public health systems and industry resilience.

Aging Populations

Europe's population is aging rapidly. As of January 2024, 21.6% of the EU population was over 65, and this share is expected to rise to nearly one-third (32.5%) by 2100. [1] Already, in 2050, projections indicate that there will be less than two people of working age for every elderly person in the EU. [2]

Figure 1: Increase in the Share of Population Aged 65 or Older Between 2014 and 2024



Source: Eurostat

The graph illustrates the steady rise in the share of the EU population aged 65 and older over the past decade, reflecting a broader demographic trend. As life expectancy increases and birth rates decline, the proportion of elderly individuals continues to grow, exacerbating healthcare and pension system pressures. With fewer working-age adults to support an expanding elderly population, the old-age dependency ratio is set to rise, requiring urgent policy responses. Without sufficient investments in geriatric care, workforce retention, and sustainable healthcare financing, these demographic shifts will challenge the resilience of EU healthcare systems. Moreover, this demographic shift creates serious economic challenges. The old-age dependency ratio—the number of retirees per working-age individual—was 33% in 2022 and is projected to reach nearly 60% by 2100. [3] This means there will be fewer than two working-age adults per senior, significantly impacting pension systems and healthcare financing. At the same time, 84% of all deaths in the EU occur among people aged 65 and over, reflecting the healthcare burden of aging-related conditions. [4] As a result, public spending on health and long-term care is expected to rise from 6.9% of GDP in 2022 to 7.3% by 2070, adding further strain on government budgets. [5]

Aging populations also exacerbate workforce shortages in healthcare. As older workers retire, the availability of healthcare professionals declines. Currently, the EU faces a shortfall of about 1.2 million doctors, nurses, and midwives, and over one-third of doctors are over 55 years old. [6] Without new investments in workforce development, these shortages will worsen. Unequal access to geriatric care is another challenge, particularly in rural areas, where specialized facilities remain limited. To address these issues, policymakers must expand training programs for healthcare workers, develop sustainable pension and healthcare financing, and invest in home-care services to meet growing demand.

Chronic Diseases

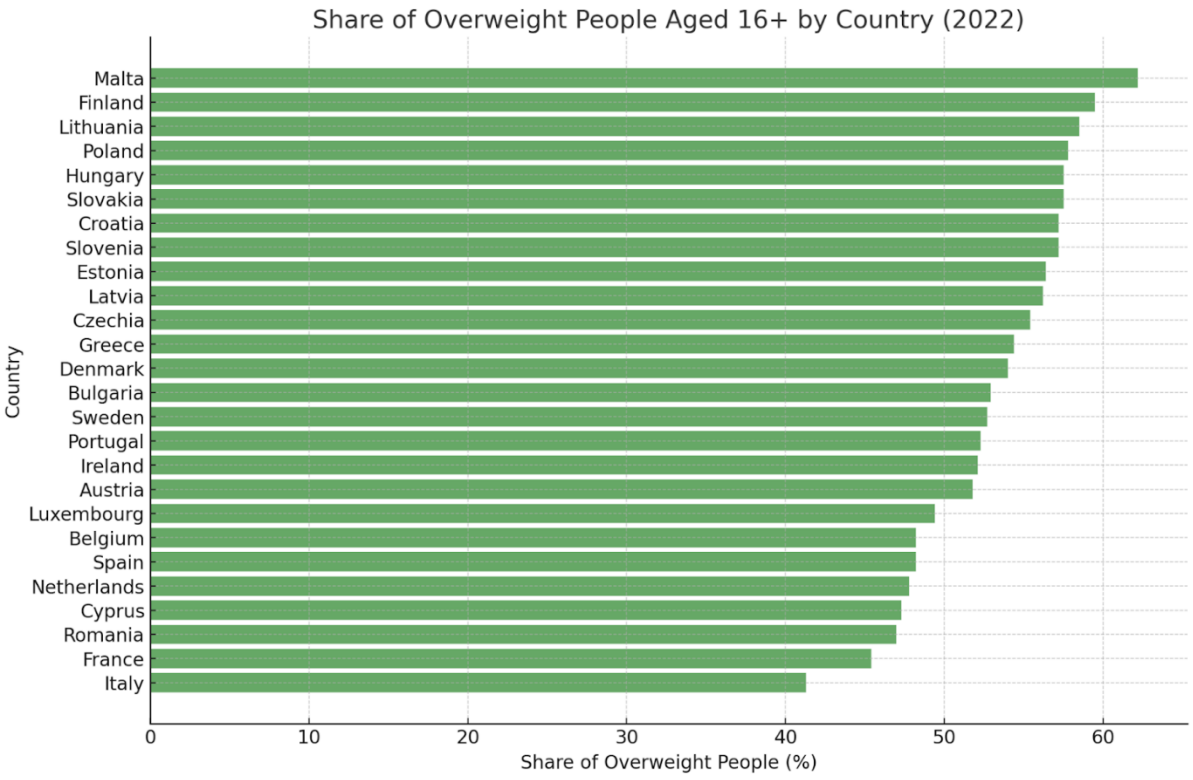
Chronic diseases—cardiovascular conditions, diabetes, cancer, and respiratory illnesses—are responsible for a big portion of deaths in the EU, making them the most significant health challenge in Europe. Cardiovascular diseases alone account for 32.4% of all deaths (2021), followed by cancer (21.6%). [7]

Diabetes is becoming increasingly common, with about 6.9% of EU adults diagnosed—amounting to more than 33 million people. [8] Chronic diseases not only place a burden on healthcare systems but also affect workforce productivity. Higher rates of absenteeism and early retirement due to long-term illnesses reduce economic output and increase employer healthcare costs. To mitigate these issues, the EU must expand early screening programs, strengthen workplace health policies, and promote digital health solutions for disease monitoring.

Obesity and Lifestyle-Related Diseases

Obesity is one of the fastest-growing health concerns in Europe. As of 2022, 50.6% of EU adults are overweight or obese [9], and on average across 32 OECD countries, 54% of the adult population were overweight or obese, and 18% were obese in 2021. [10] Among children, nearly one in three is overweight or obese. [11] It is also the leading risk factor for disability, causing 7% of the total years lived with disability, and obesity is linked to greater morbidity and mortality from COVID-19. [12]

Figure 2: Share of Overweight People Aged 16+ by Country (2022)



Source: Eurostat

This trend is driven by poor diet, lack of exercise, and high consumption of processed foods. However, policy responses across EU member states remain inconsistent—some countries focus on prevention, while others emphasize treatment. Meanwhile, the food and beverage industry has resisted stricter regulations on marketing and labeling.

The economic burden of obesity is significant. Obesity-related conditions account for 8.4% of total health expenditures across OECD countries, amounting to $311 billion annually. [13] The impact on GDP is also substantial—OECD estimates suggest obesity could reduce European GDP by approximately 3.3% due to lost productivity and healthcare costs. [14] For instance, obesity is responsible for an estimated 70% of all diabetes treatment costs and 23% of cardiovascular disease costs. [15] Tackling obesity through prevention strategies could yield enormous savings; for every $1 invested in obesity prevention, the estimated return is $6 in reduced healthcare spending. [16]

Mental Health and Social Media

Mental health issues are on the rise across Europe, particularly among young people. One in six Europeans has experienced mental health disorders such as anxiety or depression. A 2023 EU survey found that 46% of Europeans reported feeling depressed or anxious in the past 12 months. [17]

Young people face unique risks, with social media linked to increased anxiety, depression, and sleep disorders. Heavy social media use has been associated with lower well-being, and young people qualify more as “extreme internet users” who experience greater psychological distress. [18] The pandemic exacerbated these trends, with the share of adolescents experiencing depressive symptoms more than doubling in some EU countries. [19]

Despite the rising demand for services, many people struggle to access mental health care. One in two Europeans with mental health needs does not seek treatment, often due to long wait times or lack of specialists. In 2021, nearly half of young Europeans with mental health concerns reported unmet care needs. [20]

Some preventive measures are already in place. Germany has introduced parental controls and news blockers for children’s devices to limit harmful content exposure. [21] However, more action is needed. The EU should work with tech companies, mental health experts, and educators to develop better online content moderation, mental health awareness campaigns, and stronger digital well-being policies.

Europe invests heavily in health. In 2022, current healthcare expenditure in the EU reached €1,648 billion, which is about 10.4% of the EU’s GDP. [22] This equates to roughly €3,700 per person on healthcare. [23] Health spending rose during the pandemic (with a spike in 2020–2021) and remains high as countries strengthen health systems. Many Western European countries spend above 10% of their GDP on health, whereas some Eastern and Central European members spend slightly less – but the overall trend is upward convergence in health spending. [24] Additionally, there are notable disparities in the density of healthcare professionals across member states. For instance, Greece has about 6.6 physicians per 1,000 inhabitants, one of the highest ratios in the EU, while Finland has only around 2.9 doctors per 1,000 people (2021 data). [25] Similarly, nurse-to-population ratios vary widely. These imbalances mean some countries (or regions within countries) have far more medical staff than others, leading to unequal access. The EU average in 2019 was about 3.9 doctors and 8.4 nurses per 1,000 population, but countries like Germany and Austria are well above this, whereas others like Poland or Romania are below. [26] Efforts such as international

recruitment, training expansion, and incentives for practice in underserved areas are being employed to address these workforce distribution challenges.

Addressing aging, chronic diseases, obesity, and mental health is critical to ensuring the long-term sustainability of EU healthcare systems. However, tackling these challenges will require evidence-based policymaking, investment in innovation, and stronger regulations to promote prevention and early intervention. A proactive strategy can reduce healthcare costs, improve public health outcomes, and support economic resilience in the years ahead.

3. Strengthening Evidence-Based Decision-Making

Health policies must be based on facts, not assumptions. Using data, research, and real-world evidence helps ensure that policies are effective, practical, and sustainable. The EU must improve how it collects, analyzes, and applies health data. As a result, policymakers will be able to identify risks, allocate resources efficiently, and make informed decisions that benefit both public health and industry.

The EU has vast amounts of health data, but much of it remains underused and fragmented. A recent EU-wide assessment found that no Member State is fully prepared for seamless data exchange, and fewer than half have a national health data catalog in place. To address this, the European Health Data Space (EHDS) aims to create a system where researchers, policymakers, and industry can securely access and share data. If implemented effectively, EHDS could significantly enhance disease prevention by enabling early warning systems based on real-time data, which could help detect and contain outbreaks faster. It can also support personalized medicine by giving doctors access to comprehensive patient data, allowing them to tailor treatments more precisely. Additionally, faster data-sharing could improve crisis response, ensuring more effective coordination during pandemics or supply shortages. However, for EHDS to succeed, it must balance data accessibility with privacy protection. Regulations must ensure that data is secure, anonymized, and ethically managed while still being usable for research and policy purposes.

Scientific research must be translated into policy, but this process is often slow. Policymakers need clear, actionable insights from experts, yet several challenges hinder this process. Some health policies still rely on outdated research, slowing the adoption of new evidence. There is also limited collaboration between scientists, businesses, and regulators, which creates inefficiencies in how innovations reach the healthcare system. Moreover, political and economic pressures can sometimes drive policy decisions toward short-term priorities rather than evidence-based recommendations. For example, despite long-standing evidence supporting preventive care, only about 3% of health spending in EU countries is allocated to prevention. [27] To bridge this gap, the EU should establish independent advisory panels to provide policymakers with up-to-date scientific research. Supporting public-private collaborations between governments, universities, and industry could accelerate the development and adoption of medical innovations. Additionally, improving communication is key—research findings should be presented clearly and concisely to decision-makers to ensure their timely integration into policy.

Health policies must also balance public safety with economic sustainability. Overregulation can slow innovation, increase costs, and create market barriers, while underregulation can lead to health risks and public distrust. A prime example of overregulation was the EU's Clinical Trials Directive of 2001, which caused a 25% decline in clinical trial applications due to increased administrative burdens. [28] Conversely, underregulation has led to major safety

issues, such as the PIP breast implant scandal, where weak oversight allowed defective medical devices to reach the market, undermining public confidence in regulatory authorities. To ensure proportionality, regulations should be based on risk levels—high-risk products should undergo stricter scrutiny, while low-risk innovations should have faster approval pathways. Policymaking must also remain flexible to adapt to new scientific discoveries and emerging technologies. Finally, harmonizing regulations across Member States is essential to reducing inefficiencies; inconsistent national rules create barriers for businesses and slow down healthcare improvements. A balanced regulatory approach ensures that policies protect public health while fostering innovation and maintaining the EU's competitiveness in the global healthcare sector.

4. Comprehensive Impact Assessments for Sustainable Health Policy

Health policies must be based on thorough assessments to avoid unintended consequences. Policymakers should evaluate the economic, social, environmental, and industrial impact of new regulations before they are implemented. A balanced approach ensures that policies protect public health without harming innovation, access to care, or business competitiveness. In the EU, healthcare accounts for 11% of the GDP and employs over 13 million people, making it a critical sector for economic stability. [29] Poorly designed policies can have significant ripple effects, influencing industry investment, job creation, and supply chains.

A policy designed to improve public health may also affect jobs, healthcare costs, or pharmaceutical supply chains. Without proper impact assessments, these side effects might be overlooked. Economic impact assessments should analyze how a policy influences healthcare costs, industry investment, and employment. Health regulators should adopt a data-driven approach to assess risks and benefits, particularly concerning noncommunicable diseases and lifestyle choices, to encourage less risky behaviors and reduce social security costs. Social security cost assessment should also be considered to validate the impact of the proposed regulations. For instance, the European pharmaceutical sector alone invested €44.5 billion in R&D in 2022 and employs over 865,000 people, supporting jobs in related industries. [30] Policies that impose excessive financial burdens on companies can lead to reduced R&D investment, delaying innovation. Social factors must also be considered, including whether a regulation improves patient access to care or exacerbates inequalities. In 2022, 2.2% of EU residents reported unmet medical needs, but this figure rose to 6.5% in some countries due to affordability or wait times. [31] Policies must ensure that new regulations do not worsen these disparities. Environmental assessments are increasingly relevant, as the healthcare sector accounts for 4–5% of global carbon emissions and generates significant medical waste. [32] Policies should integrate sustainability measures to prevent unnecessary environmental strain. Finally, the impact on industry and innovation must be assessed to determine whether regulations encourage or restrict research, development, and healthcare advancements. For example, medicine price regulations can lower costs in the short term but may deter pharmaceutical companies from launching new products in certain markets. Canada's experience with price caps on patented drugs raised concerns about reduced clinical trials and delayed access to new medicines, demonstrating how affordability measures must be balanced with long-term innovation. [33]

Poorly designed policies can make healthcare systems less effective. Over-regulation can slow innovation, increase costs, and disrupt healthcare supply chains, as seen in the implementation of the EU Medical Devices Regulation (MDR). While intended to improve patient safety, MDR led to delays in recertifying medical devices due to a shortage of notified

bodies, raising concerns about potential shortages. In response, the EU extended MDR transition deadlines to prevent supply disruptions. Similarly, unrealistic implementation timelines can disrupt patient access if healthcare providers are not given sufficient time to adapt. Regulations must also consider industry feasibility—if compliance is too complex or costly, smaller companies may struggle to meet requirements, reducing market competition. To prevent these issues, the EU should mandate full stakeholder consultations, ensuring that health experts, industry leaders, and patient organizations are involved before laws are drafted. Effective engagement has been key in EU health policy, such as during the Pharmaceutical Strategy for Europe, where broad consultations helped shape policies to support both innovation and patient access. Pilot programs should also be used to test policies on a small scale, allowing potential challenges to be identified before full implementation. The OECD and WHO emphasize that evidence-based policymaking should include ex-post evaluations, meaning policies should be regularly reviewed and updated based on real-world outcomes to remain effective. [34]

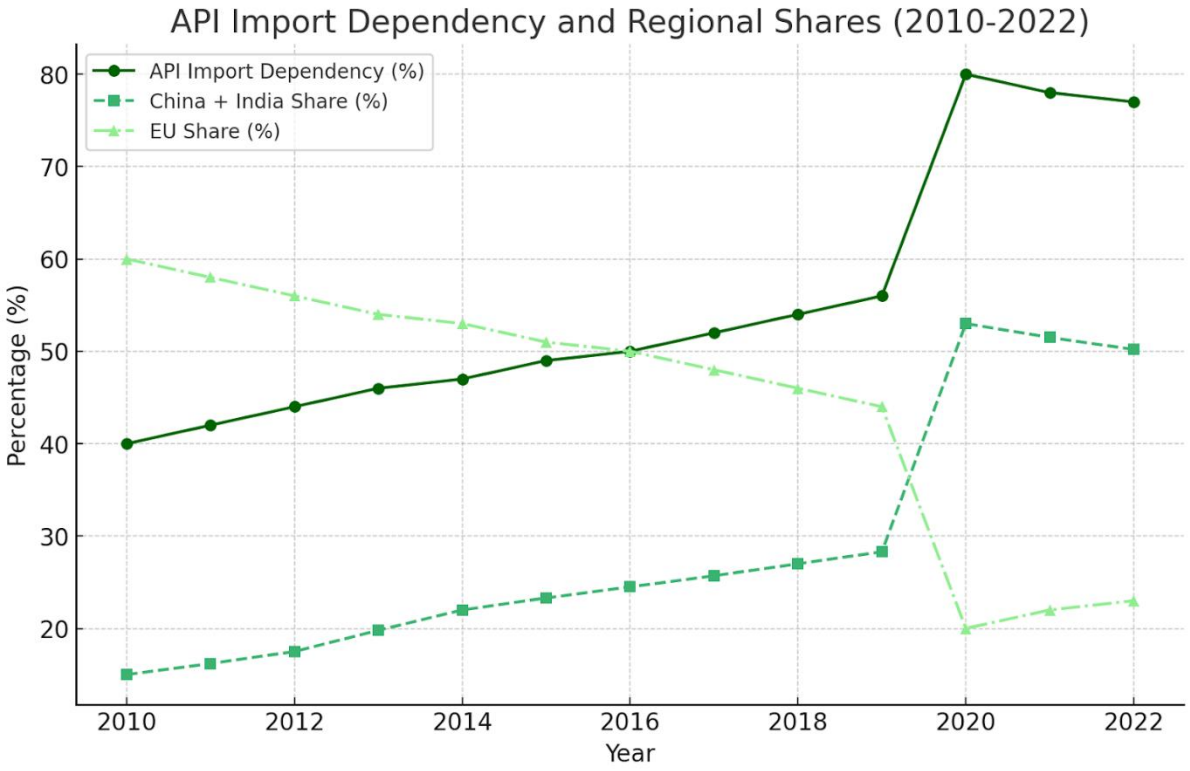
Impact assessments should be transparent, evidence-based, and adaptable. The EU must ensure that health policies are designed with long-term sustainability in mind, avoiding rushed decisions driven by political agendas. Overregulation can discourage investment in new treatments, while underregulation can lead to safety concerns, as seen in past medical device scandals. The EU's Better Regulation framework mandates regulatory impact assessments, but continued refinement is needed to ensure that new health policies strike the right balance. Regulations should remain manageable for businesses and healthcare providers so that compliance does not become an obstacle to efficiency and innovation. A well-structured impact assessment framework ensures that policies achieve their intended goals without damaging economic growth, business competitiveness, or patient care.

5. Building Resilient Healthcare Systems

A strong healthcare system must be prepared for crises, ensure a stable supply of essential medicines, and support long-term industry growth. The COVID-19 pandemic exposed weaknesses in Europe's medical supply chains, highlighting over-reliance on external suppliers and shortages of critical medicines. The EU must act now to strengthen self-sufficiency, infrastructure, and workforce capacity to prevent future disruptions.

Today, 80% of Active Pharmaceutical Ingredients (APIs) used in the EU come from China and India. [35] This reliance creates supply chain risks—any disruption in these countries can delay production, raise costs, and threaten patient access to essential medicines.

Figure 3: API Import Dependency and Regional Shares (2010-2022)



Source: Eurostat

The chart illustrates the EU's increasing reliance on imported Active Pharmaceutical Ingredients (APIs) over the past decade, with a sharp rise after 2019. The share of APIs sourced from China and India has grown significantly, surpassing 50% by 2020, while the EU's domestic share has declined. This trend highlights the vulnerabilities in Europe's pharmaceutical supply chain, particularly during crises when external supply disruptions can lead to shortages. Strengthening local API production and diversifying supplier networks are essential steps to enhancing resilience and ensuring stable access to critical medicines. To improve resilience, the EU should incentivize pharmaceutical companies to produce critical ingredients within the region, reducing dependency by establishing trade agreements with multiple suppliers. Strengthening local manufacturing through tax credits and funding for European companies investing in medicine production will also help build a more stable supply chain.

During the pandemic, many EU countries struggled to source essential medicines and medical equipment. [36] A coordinated EU-wide approach can help prevent shortages in future crises by establishing strategic stockpiles of essential drugs and medical supplies. Implementing early warning systems that use real-time data to monitor supply chain risks will allow authorities to detect and address disruptions before they escalate. Improving cross-border coordination is also essential—countries should share stockpiles and avoid national hoarding to ensure a fair and efficient distribution of critical resources.

A transparent and efficient supply chain ensures timely access to medicines and medical equipment. The EU must invest in modern logistics and digital tracking systems to improve efficiency. Increasing digital tracking and AI monitoring can enhance the visibility of supply

chains and detect risks early. Strengthening cold chain infrastructure will ensure that sensitive medicines, such as vaccines, are stored and transported safely. Supporting local production hubs can also reduce reliance on distant suppliers, making the healthcare supply chain more resilient and responsive.

A resilient healthcare system needs enough skilled workers to meet demand, yet many EU countries face shortages of doctors, nurses, and specialists, particularly in rural areas. An aging workforce presents a significant challenge, as many healthcare professionals are nearing retirement, creating staffing gaps. Additionally, the unequal distribution of medical professionals leaves some regions without access to specialized care, while high burnout rates due to long hours and stressful conditions exacerbate workforce shortages. To address these issues, the EU should offer scholarships and grants to incentivize medical training and attract young professionals to the field. Encouraging cross-border mobility by simplifying EU-wide recognition of medical qualifications can help distribute healthcare workers more effectively across member states. Investing in digital health solutions, such as telemedicine and AI-powered diagnostic tools, can also ease the pressure on overburdened doctors and improve access to care in underserved areas.

6. Innovation and Digital Health: Opportunities and Challenges

Innovation is key to improving healthcare outcomes, reducing costs, and increasing efficiency. The EU must create a policy environment that supports research, accelerates approvals, and expands digital health adoption. Medical breakthroughs depend on strong investment in pharmaceutical research, biotechnology, and medical devices, but high costs, slow approval processes, and regulatory uncertainty can discourage innovation. Developing a new medicine can take over 10 years and cost more than €1 billion, making it difficult for smaller companies and startups to compete. [37] Additionally, research funding remains fragmented, as EU countries invest at different levels, creating gaps in innovation. Slow approval processes further delay life-saving treatments from reaching patients, limiting the impact of medical advancements.

To support research and development, the EU should increase funding for programs like Horizon Europe, which has been instrumental in financing medical innovation across member states. Fast-tracking approvals for breakthrough treatments through conditional authorizations can help patients access high-impact therapies more quickly while maintaining safety standards. Encouraging public-private partnerships between industry, universities, and governments can drive innovation by pooling expertise and resources. By addressing these barriers, the EU can create a more dynamic environment that fosters medical advancements and improves patient care.

Digital health solutions such as telemedicine, AI diagnostics, and wearable health monitors have the potential to revolutionize healthcare by improving access, efficiency, and preventive care. Virtual consultations can reduce pressure on healthcare systems by saving time and expanding access to care, particularly for rural or underserved populations. AI-driven diagnostics enhance accuracy by detecting diseases earlier and assisting doctors in decision-making, which can lead to more effective treatments. Wearable devices, such as smartwatches and health apps, enable preventive care by allowing patients to track vital signs and identify potential health risks before they escalate.

Despite these benefits, digital health adoption across EU countries remains uneven. Data privacy concerns remain a significant challenge, as patients and regulators worry about the security of personal health data. Additionally, regulatory barriers make it difficult for digital health solutions to comply with multiple EU rules, slowing their approval and implementation. Unequal access to technology also poses a problem, as some rural or lower-income populations lack the digital infrastructure needed to benefit from these advancements.

To accelerate digital health adoption, the EU should harmonize regulations to create a clear and consistent approval pathway for digital tools, ensuring that innovation is not stifled by complex compliance requirements. Investing in digital literacy programs can help both patients and healthcare providers effectively use new technologies, ensuring equitable access to digital health solutions. Expanding telemedicine infrastructure across member states will further support the nationwide adoption of virtual healthcare, making it a standard part of healthcare delivery rather than an exception. By addressing these challenges, the EU can fully harness the potential of digital health to improve patient outcomes and enhance the efficiency of its healthcare systems.

7. Ensuring Competitiveness and Resilience in the Healthcare Industry

A strong healthcare industry is essential for economic stability, job creation, and innovation. The EU must support a business-friendly regulatory environment while ensuring that healthcare remains affordable and accessible. Long-term investment in production, supply chains, and workforce planning is necessary to keep Europe's healthcare sector competitive. The pharmaceutical and medical technology industries are major contributors to the EU economy, with the pharmaceutical sector alone investing €44.5 billion in R&D in 2022 and employing over 865,000 people. [38] However, competition from the US, China, and emerging markets is growing. To maintain its global leadership, the EU must encourage investment in new facilities by incentivizing the onshore production of essential medicines and medical devices. Supporting small and mid-sized healthcare businesses (SMEs) through grants and funding will strengthen the sector while simplifying market access for innovative products will ensure that new treatments reach patients faster.

A reliable healthcare supply chain is critical for stable access to medicines, medical equipment, and raw materials. To reduce dependency on non-EU suppliers, the EU should diversify trade agreements and invest in pharmaceutical and medical manufacturing facilities within Europe. Establishing long-term contracts for essential medicines will help secure stable pricing and availability, ensuring that life-saving drugs remain accessible even in times of crisis. Strengthening the EU's production infrastructure will reduce exposure to global supply chain disruptions while promoting self-sufficiency.

Balancing innovation and cost control is another key challenge. While the EU needs affordable healthcare, overly strict pricing policies can discourage investment in medical research. Value-based pricing models, which link drug costs to treatment effectiveness rather than rigid cost limits, can offer a more sustainable solution. Public-private collaboration on drug development, where governments and industry co-develop treatments for high-need conditions, can also help share risks and accelerate breakthroughs. Additionally, improving reimbursement systems by speeding up approval and payment processes will encourage continued investment in innovative medicines.

A strong healthcare sector requires a highly skilled workforce across the medical, pharmaceutical, and digital health fields. However, the EU faces shortages in critical areas such as geriatrics, psychiatry, and AI-driven medicine. [39] Expanding training programs for healthcare workers will help fill these gaps, ensuring that Europe has the medical professionals needed for an aging population. Simplifying cross-border recognition of medical qualifications can also make it easier for doctors and nurses to move freely within the EU, addressing regional shortages. Supporting R&D talent development through grants and scholarships will further strengthen research in biotechnology, medical devices, and pharmaceuticals, ensuring the EU remains a hub for medical innovation.

Private investment plays a crucial role in driving medical innovation, but businesses need a stable and predictable policy environment to commit to long-term projects. The EU should provide tax incentives for healthcare investments, encouraging pharmaceutical and biotech firms to invest in European R&D and production. Reducing regulatory barriers for clinical trials will make the EU a more attractive location for drug development, accelerating the introduction of new treatments. Promoting Europe as a global leader in healthcare innovation through stronger international partnerships will further enhance the region's competitive position. A competitive and resilient healthcare industry ensures that Europe remains at the forefront of medical research, innovation, and patient care, strengthening both public health and economic growth.

8. Addressing Regulatory Challenges Without Stifling Innovation

Regulation is essential for patient safety, product quality, and market stability, but excessive red tape can slow innovation, increase costs, and limit patient access to new treatments. The EU must ensure that regulations are clear, consistent, and adaptable to technological advances. As healthcare evolves with digital health, AI-driven medicine, and advanced therapies, regulatory frameworks must keep pace with innovation while maintaining safety standards.

One of the key challenges in the current system is the lengthy approval process, where it can take several years for new drugs and medical technologies to be approved. [38] This delays patient access to critical treatments and discourages investment in medical research. Additionally, regulatory inconsistencies across EU member states create significant barriers for companies operating in multiple countries, making it difficult for businesses to scale innovative solutions across the single market. Many of the existing regulations were also designed before the rise of digital health, AI, and precision medicine, meaning they do not adequately address the realities of modern healthcare technologies.

To address these challenges, the EU should introduce faster approval pathways for breakthrough treatments, ensuring that innovative therapies reach patients sooner. Regulatory harmonization across the EU is necessary to standardize medical device and pharmaceutical approvals, reducing unnecessary delays caused by national variations. Establishing sandboxing environments for health tech, where companies can test new digital health solutions in a controlled regulatory setting, would also encourage responsible innovation while ensuring compliance with safety standards.

Overregulation can discourage investment and slow patient access to life-saving treatments. In particular, clinical trials in the EU are subject to complex approval requirements that can slow research progress. While safety is paramount, simplifying trial requirements without

compromising oversight would encourage more pharmaceutical and biotech companies to conduct research in Europe. Similarly, market authorization for new therapies should be reformed to ensure faster reviews of innovative treatments without unnecessary bureaucratic delays. Instead of excessive pre-market hurdles, post-market monitoring using real-world evidence can help track the safety and effectiveness of medicines and devices while allowing faster market entry.

While regulation is necessary, excessive compliance costs make it harder for small and mid-sized healthcare companies to compete. A risk-based regulation approach would allow stricter oversight of high-risk products while streamlining the approval process for low-risk innovations. Digitalized compliance processes, including automated reporting and monitoring, could reduce paperwork and administrative delays, making it easier for businesses to navigate regulatory requirements. Providing clearer regulatory guidance and support for SMEs would also help smaller healthcare firms comply with EU rules without excessive financial or administrative burdens.

Regulations should protect public health while ensuring that companies can bring life-saving treatments to market efficiently. The EU must facilitate faster access to innovative medicines by reducing regulatory bottlenecks and creating a more responsive approval system. Adopting a pro-innovation approach to AI and digital health will allow ethical AI-driven healthcare solutions to enter the market more rapidly, benefiting both patients and healthcare providers. Additionally, existing health regulations should be regularly reviewed and updated to remain fit for purpose in the age of precision medicine and AI.

9. Recommendations for a Future-Proof Healthcare Strategy

To build a resilient, innovative, and competitive healthcare system, the EU must take a balanced approach. Policies should ensure high-quality healthcare, support research and innovation, and maintain a strong industry.

Key Recommendations

1. Strengthen Evidence-Based Policymaking

- Fully implement the European Health Data Space (EHDS) to support data-driven decisions.
- Establish independent expert panels to provide real-time policy recommendations.
- Improve data sharing between member states for better disease prevention and crisis response.

2. Improve Healthcare Resilience

- Reduce dependency on non-EU pharmaceutical suppliers by increasing local production.
- Create strategic medicine stockpiles to prevent shortages.
- Invest in healthcare workforce training and retention to address skill gaps.

3. Support Innovation and Digital Health

- Expand funding for R&D in biotechnology, AI, and precision medicine.
- Fast-track approvals for breakthrough treatments and digital health tools.
- Promote public-private partnerships to drive healthcare innovation.

4. Address Systemic Health Challenges

- Expand early screening programs for cancer and chronic diseases.
- Develop coordinated EU-wide obesity prevention strategies.
- Strengthen mental health policies, focusing on social media and youth well-being.

5. Create a Balanced Regulatory Framework

- Implement risk-based regulation to avoid unnecessary compliance burdens.
- Reduce approval timelines for new drugs and medical devices.
- Support regulatory sandboxing for digital health innovations.

10. Conclusion

The EU faces significant healthcare challenges, but smart policy choices can improve health outcomes, support industry growth, and ensure resilience. Strengthening data-driven policies will enhance efficiency, allowing healthcare systems to allocate resources more effectively and improve patient care. Building more resilient supply chains and increasing local production will reduce dependence on external suppliers, ensuring stable access to essential medicines and medical equipment. Innovation-friendly regulations will help the EU remain competitive in global healthcare, fostering research, development, and technological advancements.

References

[1] Eurostat - Population Structure and Ageing

[2] Eurostat - Population Projections

[3] Eurostat - Population Projections

[4] Eurostat - Causes of Death

[5] Bruegel - Beyond Retirement

[6] EC - Health & Ageing

[7] Eurostat - Causes of Death

[8] OECD - Chronic Conditions

[9] Eurostat - Obesity Statistics

[10] OECD - Obesity & Physical Activity

[11] WHO - Health Report

[12] WHO - Health Report

[13] OECD - Obesity Costs & Prevention

[14] OECD - Heavy Burden of Obesity

[15] OECD - Economic Gains of Prevention

[16] OECD - Economic Gains of Prevention

[17] EC - Mental Health

[18] OECD - Digital Age & Mental Health

[19] EC - Health at a Glance

[20] EUR-Lex - Health 2022

[21] Germany - Online Safety

[22] Eurostat - Healthcare Expenditure

[23] Eurostat - Healthcare News

[24] Eurostat - Healthcare News

[25] Eurostat - Healthcare Personnel

[26] EC - Healthcare Companion

[27] Eurostat - Healthcare News

[28] EUR-Lex - Healthcare Directive

[29] EC - Health Strategy

[30] EFPIA - Pharma Industry 2023

[31] Eurostat - Pharma News

[32] ScienceDirect - Healthcare Policy

[33] PMC - Healthcare Research

[34] IFO - Healthcare Report

[35] EESC - Medicine Supply

[36] OECD - Medical Supply Chains

[37] WEF - Blockchain in Pharma

[38] EFPIA - Pharma Industry 2023

[39] EPRS - Healthcare Policy