A European Health Union
A Blueprint for Generations

Edited by:
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and Gediminas Cerniauskas**

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List of acronyms

ACT-Accelerator (The Access to COVID-19 Tools (ACT) Accelerator)

BARDA (Biomedical Advanced Research and Development Authority)

Blue Card Directive

Clinical Trials Regulation

Committee on Environment, Public Health and Food Safety (DG ENVI)

DG SANTE (Directorate-General for Health and Food Safety)

ECDC (European Centre for Disease Prevention and Control)

EMA (European Medicines Agency)

EPSCO (Employment, Social Policy, Health and Consumer Affairs Council)

ERN (European Reference Networks)

EU4Health programme

European Health Data Space

Europe's Beating Cancer Plan

European Semester

Gavi (The Vaccine Alliance)

HERA (European Health Emergency preparedness and Response Authority)

HSC (Health Security Committee)

HSPA (Health System Performance Assessment)

HSPM (Health System and Policy Monitor)

Joint Action for Health Workforce Planning and Forecasting

Observatory on Health Systems and Policies

One Health

Semashko model

SHI (Social Health Insurance)

WHO Global Code on the International Recruitment of Health Personnel

Executive Summary

Part 1. "Fundamentals of a European Health Union" argues that the recent strengthening of European health policy, commonly referred to as a European Health Union (EHU), is an outcome of decades-long socio-economic developments in Europe. The Covid-19 pandemic was a trigger but not a cause of the EHU, thus pan-European health policy should concentrate on all avenues promising European value added, not just preparedness for future crises.

- Europe has evolved from an industrial society to an economy where services predominate. The economic transformation was accompanied by a demographic transition, and the development of institutional protection. After WWII, social rights stimulated the expansion of health systems. As part of this transformation, the production of health services and goods combined became the largest sector in European economies.
- Today, almost 10% of value added is created by the production of health goods and services within the EU27. National and European market and non-market regulations, as well as international contracts, safeguard these value chains of production.
- Digitalisation of the single market is creating a European health data space, which, together with the further of artificial intelligence, generate new opportunities and challenges far beyond national capacities to govern them.
- The first practical steps towards European integration were partially inspired by the socially oriented Ventotene Manifesto. However, instead of prioritising social development, the European project was mainly aimed at the development of an internal market for goods.
- A solid post-war economic recovery demonstrated that national and pan-European policies that concentrated on agriculture and manufacturing in the 1950s were successful. This evidence contributed to the continuity of these policies in the following decades.
- The internal market of goods remains at the core of today's European integration, but socio-economic transformation and shifting of

national priorities in favour of health and other social sectors are contributing to the growth of the relevant importance of these sectors in pan-European politics. This is translated in the Treaty of Amsterdam (1997)[1] and the 20 principles of the European Pillar of Social Rights (2017).[2]

- Covid-19 undermined the notion that the European Union has very little to do with health and contributed to the European Commission's pledge in 2020 to build "a stronger European Health Union".

- Most breakthrough initiatives of the European project have been launched by Treaty changes and an implementation process. The strengthening of health policy, by contrast, started with policy documents. The greater role of the EU in health policy over time shows that member states and European institutions have an interest in moving towards a European Health Union. However, proponents of a more sustainable development of an EHU argue that without its legal framing in European Treaties, such a health union would be at risk in the long term. The unsuccessful project of the early 1950s regarding the creation of a "European Health Community" (Communauté européenne de la santé – CES) is a reminder of the risks that the EHU faces.

- The relationship between policymaking and public opinion on health is not straightforward in the European Union context. Public opinion evolved from being irrelevant to EU policies to an increasingly crucial factor in the EU integration process (from permissive consensus to constraining dissensus).

- According to Eurobarometer data, Europeans hold a positive perception of the EU, trust the EU more than their national institutions, and want their voice to be heard more within the EU. Moreover, health has consistently ranked among the primary concerns of EU citizens, and Europeans call on the European Union to prioritise public health and to have a common EU health policy.

- During the citizen-led Conference on the Future of Europe 2022, the panel recognised the necessity of revising Article 4 of the Treaty on the Functioning of the European Union to encompass health and

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1   Treaty of Amsterdam (1997), Treaty of Amsterdam (europa.eu)
2   European Commission (2018) *The European Pillar of Social Rights in 20 principles - Employment, Social Affairs & Inclusion* (Brussels: European Commission). Available on-line: https://ec.europa.eu/social/main.jsp?catId=1606&langId=en Publication. European Commission, Secretariat-General, European pillar of social rights, Publications Office, 2018, https://data.europa.eu/doi/10.2792/95934

healthcare as shared competencies between the member states and the EU.

- The evolution of the health role of the EU has been marked by a gradual recognition of the importance of health as a fundamental right and the need for coordinated action at the EU level to address health challenges. But the responsively established health institutions and the scattered capacities and competencies for policymaking on health systems and public health at the EU level are regarded as following the "failing forward" trend of European integration.

- Covid-19 presented the context and gathered the political will behind an enhanced EU role in health. It is in the interest of Europeans to seize this context to anchor a comprehensive EU health policy beyond the pandemic and address relevant health challenges in both communicable and non-communicable diseases.

- The EHU has many co-benefits and synergies with major policy frameworks both in Europe and around the world:
  - The EHU can contribute to European sovereignty, economic prosperity, and promote peace in the continent.
  - The EHU would promote sustainability through its many interlinkages with the European Green Deal and the SDGs.
  - The EHU can enhance the digitalisation objective of the EU.

- European health policy is not about substituting or overtaking the role of member states in health-related areas, nor about consolidating more power in Brussels. It is about equipping the EU with the necessary competence to support and complement the actions of every capital. It is about delivering the promise of ensuring a high level of human health. The EHU is about pursuing the EU's commitment to put people first and to build a more resilient Union for the future.

Part 2. "Main avenues for pan-European cooperation for health" studies fields of pro-health actions that, according to the authors, are the most promising for the health and wellbeing of Europeans.

- Preparedness, or a lack thereof, was a major issue for EU countries during the Covid-19 pandemic. A lack of investment by national governments and patchy implementation of the 2013 decision on serious cross-border threats, meant that many countries' health systems were overwhelmed by the disease. However, the pandemic resulted in greater coordination among EU institutions and the emergence of plans for a "stronger European Health Union".

- The current reforms do not adequately address the problem of preparedness. Three paradigm shifts (joint procurement, scientific agency capacity, and recognition of interdependence) would offer an opportunity to integrate preparedness as a shared competence;
- Innovation in life sciences is the result of the interplay between academia, public institutions and private companies. The EU has a proven record of promoting progress in health technologies through a centralised process to approve new medicines, the orphan medicines regulation, the development of a Covid certificate, and fostering the development of Covid-19 vaccines by creating an EU buying club to invest broadly in a portfolio covering the four identified technology platforms.
- Universal health coverage (UHC) is one of the targets of the 2030 Agenda for Sustainable Development of the United Nations. It is affirmed by the EU as a principle of the European Pillar of Social Rights: "Everyone has the right to timely access to affordable, preventive and curative healthcare of good quality".
- Improving people's access to healthcare services has been a long-standing objective in European countries. It reflects the values and principles underpinning health systems in Europe – universality, access to good quality care, equity and solidarity. The level of social health protection in Europe is high in comparison with other parts of the world, even if the institutional arrangements to organise this financial protection and access to health services varies among countries within the EU.
- Available data already show that there is room for progress towards universal health coverage (UHC), and that there is wide variation and inequity between and within member states. To better understand the root causes of health gaps and to design policies to tackle them, additional tools are required, and the work of the Expert Group on Health System Performance Assessment provides a foundation to build upon.
- Claims that European high-income countries provide universal access to high quality healthcare mask huge gaps in coverage and marginalisation of particularly vulnerable groups in our societies, including people living with rare diseases (RD).
- In recognition of the extraordinary added value of cooperation between MS in the field of rare diseases, the European Commission (EC) has taken decisive steps. Although the organisation of health systems is an autonomous field and the competence of every MS, in many cases, the EC has succeeded in achieving a constructive dialogue between countries.

- European-wide registries show large variations in service provision and gaps in adherence to existing care recommendations. Pan-European cooperation, in the form of European Reference Networks (ERNs), is starting to play a major role in increasing accessibility of highly-specialised services and the spread of knowledge and expertise to countries with a less developed RD field.
- The current initiatives of the EHU are mainly focused on preparedness and response to serious cross border health threats by agencies that coordinate, monitor, produce and procure medical countermeasures. It is questionable, however, whether these initiatives will address the structural inequalities in healthcare capacities across the Union, including inequalities in the sizes of the healthcare workforce.
- The number of doctors per 1000 population within the EU ranges between 2.4 and 5.4, and the number of practising nurses per 1000 population range from 4.4 to 15.4. This disbalance of healthcare workers within the EU is barely addressed at the EU level.
- The view that it is only free movement considerations which *harm the centre of Europe* that need a pan-European solution must be challenged. The need to address the unequal distribution of healthcare workforce capacities in Europe as part of an EHU is required if the EU is serious about access to healthcare for all. The Commission's recognition of the problems in the EU Care Strategy and the explicit mention of the territorial gap in the proposed recommendation on affordable long term care can be seen as a prudential first step.
- Although EU competence in the field of healthcare is, for now, limited, there are no reasons to exclude health workforce matters from the EHU. This includes suggestions on EU managed monitoring, regulation of minimum wages and working conditions, and fiscal solidarity addressing the equal distribution of healthcare workers.
- The EU Global Health Strategy (EU-GHS) is a major historic step in relation to the "external" health activities of the European Union. A strong global dimension is central to EU strategic health autonomy including, for example, supply chains, workforce and digital transformation.
- The EU-GHS gives very high priority to a "Team Europe" approach – this means joint action and pooling of resources, capacities and experience to reach common goals, and carries within it significant potential.
- The next few years will be decisive for the future global health order. In its implementation this EU Global Health Strategy must contribute

to moving away from the undemocratic governance of global health where a few hegemonic players can still set the agenda.

Part 3. "Policies of transition towards a healthier and more socially inclusive Europe" describes pro-health political actions undertaken by European progressives and future scenarios of European health policy development.

- The EU paid with human lives and huge economic and social losses for the fact that, especially in the first phase of the pandemic, the development of a common European health policy progressed slowly. The S&D position paper of 12 May 2020 defined the possible components of an EHU concept.[3]
- There is a risk that the looming, overlapping energy, food, and financial crises associated with the protracted war in Ukraine are relegating health issues to the background. On the other hand, it is an encouraging sign that in January 2023 the European Parliament established its public health subcommittee (SANT).
- It is desirable that European progressives focus on the benefits of a unifying health policy. The growing nationalist and populist forces will claim that only nation states are able to provide quality healthcare. However, this is not true, as the challenges of healthcare (such as cost explosion, pandemic preparedness, rare diseases or health workforce shortage) can only be effectively responded to together.
- The European Commission's competencies on health are currently restricted. While Article 168 of the Treaty on the Functioning of the EU provides a basis for the EU's policies, it also leaves health policy as the responsibility of the member states.
- In its Communication on the results of the Conference on the Future of Europe, the European Commission stated: "just like constitutional texts of the Member States, the EU treaties are living instruments" and "new reforms and policies should not be mutually exclusive to discussions on Treaty change".[4]

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3   S&D (2020) *Letter of the Socialists and Democrats to the presidents of the European Council, the Council and the European Commission of 7 May 2020*.
4   Communication from the commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions Conference on the Future of Europe. Putting Vision into Concrete Action. https://commission.europa.eu/system/files/2022-06/communication_1.pdf

- Covid-19 elevated health to the top of European politics, but proponents of a healthier Europe should not sleep on their laurels. Advocacy is needed to keep health high on the political agenda. Political debates focused on the scope, breadth, and criteria of maturity of the EHU and on bold proposals for a healthier Europe prior to elections to the European Parliament are of critical importance for transforming the EU from a mainly economic project, to one where social factors are treated equally to the internal market.
- The EU needs to speak explicitly about health as an aim of the EU. The health and wellbeing union should appear in the preamble of the TEU in parallel to the internal market and an economic and monetary union, inserting the words "Health" and "Social". The amendment of the TEU by an explicit pledge to promote universal health coverage by establishing a European Health Union would greatly contribute to a healthier Europe, and to the maturity of the European project.
- The demands of Europeans regarding public health issues have been clear and unequivocal. Now, the responsibility lies in the hands of elected politicians to respond to the aspirations of citizens and take the necessary steps towards building a more comprehensive and cohesive European Health Union.

To build a strong and inclusive European Health Union, that has the means to deliver not only in boosting treatment but also prevention, it is recommended to:
- **Think long term**: No quick fixes but long-term vision to build sustainable partnerships, and innovative and caring institutions.
- **A common protection**: To protect from pandemics and public health emergencies, the European Union should be given more competencies.
- **Connect policy initiatives**: The EU Health Union will encompass many policies (care, employment, competition and internal market policy, ect.), and strategic consultations should be put in place with a wide range of stakeholders (national and local governments, insurance, patients' organisations, medical and public health associations, etc.) to improve the proposed initiatives and regulations and ensure implementation.
- **Support vulnerable groups**: More attention needs to be paid to improving the health and care of underprivileged groups (ethnic minorities, the homeless, migrants and refugees), especially in relation to access to care.

- **Define and evaluate healthcare minimum standards**: Implement a timeline to reduce regional disparities when it comes to access, affordability and quality. Progress should be measured with thorough indicators and made public.
- **Strengthen the EU's role in primary prevention**: Invest in people's mental health early on and assess how to implement the WHO best buys to tackle commercial determinants of health, including uniform and strict regulations to curb smoking and drug use.
- **Provide financial resources and invest in a skilled workforce**: Launch several direct tenders to support the implementation of the programs of the European Health Union.

As disease do not stop at borders, neither should policy-making. To deliver on the promise of well-being for its citizens and to upgrade the welfare system that makes our continent unique and resilient, the EU needs to take the next step and play a stronger role in securing health for all: an effective health integration is a prerequisite for a solid and social Union.

Maria Joao Rodrigues

Foreword

At the heart of our progressive vision for a more inclusive and caring society lies the belief that health is not just a privilege for the fortunate, but a fundamental human right for all. This remarkable book dives into the prerequisites for the legal and institutional base of a European Health Union, which, since our recent experience with the COVID-19 pandemic, is needed now more than ever. A European Health Union represents a concept for a more equitable and resilient healthcare system for all European citizens.

In an era marked by unprecedented challenges, better access to healthcare services will improve the wellbeing of our citizens. Moreover, it would help to ensure that future pandemic crises are met with unity. In crafting a European Health Union, paradigm shifts, as outlined in this book in the form of procurement, scientific agency capacity and recognition of interdependence, would pave the way for the healthcare that is needed in the future and for future generations. In other words, as a longstanding goal of EU member states, a European Health Union reflects the values of the European Union in terms of access to quality care, equity, and solidarity. This can be achieved by unlocking the added value of a European Health Union, by strengthening and improving the interplay between academia, public institutions, and private companies in Europe.

However, over the last four years, as the 2023 United Nations Report on Human Development showed, there has been a general backtrack and increasing inequalities in the implementation of the Sustainable Development Goals (SDGs). Universal health coverage is one of those SDGs. By driving forward and implementing a European Health Union, the EU would not only contribute to getting closer to this goal, but it would also provide a worldwide example of a better coordinated healthcare system among countries. This book can be read as a guide for developing the European Health Union.

I extend my strong gratitude to the authors of this book. It outlines the way towards a new era in European health care, one that is marked by inclusivity, caring, bold innovation, resilience, quality, and accessibility.

Introduction

The European Health Union (EHU) appeared in the European political vocabulary in 2020 and, in just three years, became synonymous with the notion of the "Health policy of the EU". The Covid-19 pandemic was undoubtedly the main driver behind the rapid rise in popularity of this novel term, yet Europe is very far from consensus on the real meaning of an EHU. Neither the overall objectives and goals of reformed European health policy, nor the actions and instruments needed to pursue these goals, are yet to be agreed upon, and opinions regarding the future of the EHU are far from unanimous. In contrast to those who consider the growth of pan-European cooperation in health purely in the context of preparedness and/or crisis management, the authors of this book argue for a much broader conceptualisation.

Through this research, we wanted to investigate key questions relating to the EHU.

- Why was the significance of health in European politics low prior to Covid-19, and how sustainable will the prioritisation of the EHU be now that face masks have disappeared from streets across the continent?
- How would a stronger European health policy connect with the EU Pillar of Social Rights, the European Green Deal, and the commitment of the EU and its member states to the United Nations' Sustainable Development Goals (SDGs)?
- Are there actions in health that cannot be sufficiently achieved by member states as well as actions that by reason of their scale or effects, could be implemented more successfully by the EU? What are these actions?
- What institutional changes are needed for the sustainable progress of the EHU?
- What are the most urgent steps on the road towards a genuine EHU, and how important is a discussion on changing European Treaties for the development of a healthier Europe?

The questions indicated above are reflected in the structure of this book.

Part 1. "Fundamentals of a European Health Union" looks into the history of European economic, social, and political development. The main theme of this section is to study developments during the 20th century that transformed Europe from an industrial or even agricultural economy to a service-based society with health playing a key role in employment and creation of value added. The correspondence between an enhanced social fabric and European health policy developments is explored. Evidence that European citizens expect stronger actions for health (that do not always correspond to the speed of change acceptable for member states) is provided in this section too.

Part 2. "Main avenues for pan-European cooperation for health" describes fields of pro-health actions that, according to the authors, are the most promising for the health and wellbeing of Europeans. The list of actions reflects statements declared in the Manifesto for a European Health Union (November 2020)[1]:

- Strengthening of solidarity within and between member states, based on the principle of progressive universalism, providing support, including universal health coverage.
- Solidification of emergency preparedness and response.
- Expansion of European cooperation in R&D.
- Enhancing cooperation on the management of rare diseases.
- Working together to address the unequal distribution of health workforce capacities in Europe.
- Developing a Global Health Policy, working with the UN and its specialised agencies, and especially a strengthened World Health Organization.

Part 3. "Policies of transition towards a healthier and more socially inclusive Europe" studies political pro-health actions undertaken by European progressives and future scenarios of European health policy development. According to the authors, progress in health would be strengthened, with provisions for a European Health Union incorporated into a revised Treaty on European Union, while solidification of European

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1 *Manifesto for a European Health Union*. Available online: https://eihsd.eu/manifesto-for-a-europan-health-union/

Health policy will continue, regardless of the decision to amend or not to amend European treaties.

We hope that the questions raised and arguments provided in this book will help research and medical communities, politicians, and patients to better understand reasons why the EHU has emerged. The findings also aim to provide arguments to explore the most promising avenues of cooperation for the health and wellbeing of Europeans, and the creation of European value added if and when opportunities to work together for better health are exploited.

Part I.

Fundamentals
of a European Health Union

Markus Schneider

1.1 | How Europe's transition from industrial to service-based economies has impacted health systems?

Introduction

Since the middle of the 18th century, Europe has transformed from a predominantly agricultural and rural society to an economy where services predominate, and the population lives mostly in urban areas. Markets have expanded from local to national and international places for the transactions of goods and services, first by industrialisation, then through Europe-wide transportation and energy networks, and lastly by means of information processing. Despite population increase and the decline in fertility, living standards have increased to levels which were unthinkable in the past. This economic transformation has been accompanied by a demographic transition and the development of institutional protection. After WWII, social rights stimulated the expansion of health systems. As part of this transformation, health and welfare increased, and the health sector, producing both goods and services, became the largest sector in European economies. Today, almost 10% of value-added is created by the production of health goods and services within the EU27.[1]

Context

In a global world, European countries are challenged both by internal developments such as ageing societies, as well as by international economic and social change through competition with upcoming nations

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1   See Table 1, last row.

such as China and India, the effects of climate change, international digitalisation, migration, and wars.[2] These international and European challenges raise questions about the need for further development of the frameworks of European institutions for services, and in the current context about health services in particular. What are the key drivers of European health systems as part of the service-based economy? Are there common trends among European countries? Which further challenges must be mastered?

Perceptions about the value and productivity of services have changed during the last 200 years, as have views about how they contribute to economic growth, welfare, and health. For a long time, they have been thought to be unproductive compared to industrial products because of their perishable nature.[3]

Today, most value-added is produced by services. Services relate to goods, such as transportation of goods, postal deliveries, repairs, cleaning, and maintenance, and services related to persons, such as hairdressing, surgery, or personal care.[4] The value of services might be permanent or temporary. For example, the washing and cleaning of a dependent person could be classified as a temporary service, whereas the effects of surgery are permanent. The service-based economy is made up of very heterogeneous economic categories, incorporating very different functions. Distribution and business services serve as inputs to the production of goods and other services. Social and personal services together constitute a combined category of consumption-oriented services. Furthermore, research, education, and health services, in particular, may be seen as investments in human capital and innovation, and are thereby key drivers of welfare.

Since the middle of the 18th century long-term persistent changes took place in the composition of technologies, economic production, skills, and employment, as well as social relations. It is useful to understand these changes and the *economic transition* from agricultural production (primary sector) to industrial production (secondary sector) to services (tertiary sector), and how it affects economic welfare. The economic transition was accompanied by a *demographic transition*, which changed the demand for health and social services. Economic and demographic transitions were

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2   International Monetary Fund (2022) *World Economic Outlook: War Sets Back the Global Recovery* (Washington, DC: IMF).
3   Smith, A. (1776) *The Wealth of Nations, Edited by A. Skinner, Reprinted with revisions 1974*. (Harmondsworth: Penguin Books Ltd. Pelican Classics), p.430.
4   Hill, P. (1977) "On goods and services", *Review of Income and Wealth*, 23(4): 315-38.

accompanied by changes in the law and developments in public health. These regulatory changes are defined as *institutional transitions*.

After WWII, the demographic, economic, and institutional transformation of European countries from industrial to service-based economies continued, leading to regulation of the European markets of goods and services. Together with political and institutional integration of the European countries in the Union, the second largest economic space in the world evolved. Created in 1951 by Belgium, France, Germany, Italy, Luxembourg, and The Netherlands as the Economic Coal and Steel Community, the new European community helped to realise the longest period of peace in Europe, and it brought Western Europe unprecedented social progress partly as a result of the full modernisation of its economies. Central and Eastern Europe followed the western growth path after the fall of the Iron Curtain and the collapse of the Soviet economic planning system. However, there are still tremendous regional variations in income as well as in economic and institutional structures, including access to basic healthcare services, among and within Eastern and Western European countries - leading to economic instability and endangering the cohesion of the European Union.[5]

Economic transformation and growth of services

Industrialisation started in the middle of the 18th century in England. In 1750, most people lived in the countryside in modest conditions, with a life expectancy at birth no higher than 45 years. Very large variations in living standards were common between rural and urban areas. It is likely that England had the highest income per capita in Europe until 1913.[6] In the mid-1830s, the establishment of the German Customs Union (Zoll Verein), and the opening of the first railway line in German territory, ushered in what William Otto Henderson named the "dawn of the industrial era in Germany". The percentage of the German labour force employed in agriculture dropped from 54.6% in 1849-55, to 35.1% in 1910-13, and again to 21.6% in 1950-54.[7]

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5   See chapter of Polton D. (2023), Universal health coverage: current policy status in the EU

6   Bairoch, P. (1976) "Europe's Gross National Product: 1800−1975", *Journal of European Economic History*, 5(2): 273−340.

7   Hoffmann W. et al. (1965) *Das Wachstum der deutschen Wirtschaft seit der Mitte des 19. Jahrhunderts* (Springer: New York).

In his famous book *The Wealth of Nations*, Adam Smith identified three ways in which commercial and manufacturing towns contributed to the improvement and cultivation of countries: (1) by affording a great and ready market; (2) by the profitable use of wealth through their inhabitants; and (3) by the order and good government they introduced in their countries.[8] Services in the form of trade or as public security preceded any significant economic impact of industrialisation. In 1949,[9] Fourastié observed that in countries with a low per capita income, most national income is achieved through production in the primary sector (agriculture, forestry, and fisheries). Countries in a more advanced state of development, with a medium national income, generate their income mostly in the secondary sector (manufacturing and industries). In highly developed countries with a high income, the tertiary sector dominates the total output of the economy. The tertiary sector exists to facilitate the transport, distribution and sale of goods produced in the secondary sector, as well as financial and public services.

The outsourcing of activities inside companies, such as market research, business management, and marketing, contributed to the growth of services. This came about because of the organisational and information limits of inside contracting, and aimed to reduce transaction costs.[10, 11] Outsourcing enabled companies to expand their capabilities, and to reduce the cost of international trade. To sum up, the expansion of services created value-added, or the Gross Domestic Product (GDP) per capita, for the societies in which this took place. Despite some shortcomings, international standardised national accounts provide the basis for measuring value-added and the economic analysis of structural transformation and its contribution to the increase in welfare across countries.[12]

In 1950, agriculture, forestry and fishing still accounted for around 10% of value-added in the countries that later became the EU27. In 1995 this was about 2.8%, and in 2020, 1.8% (see Table 1).[13] Because of missing

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8   Smith, A. (1776) *The Wealth of Nations*.
9   Fourastié, J. (1949) *Le grand espoir du XXe siècle: Progrès technique, progrès économique, progrès social* (Paris: Presses universitaires de France).
10   Williamson, O. (1975) *Markets and Hierarchies: Analysis and Antitrust Implications* (New York: The Free Press).
11   Williamson, O. (1985) *The economic institutions of capitalism* (New York: The Free Press).
12   See critics by Coyle, D. (2014) *GDP, A Brief But Affectionate History, Revised and Expanded Edition* (Princeton and Oxford: Princeton University Press).
13   Eurostat (2022) *National Accounts, Gross value added and income by A*10 industry breakdowns [NAMA_10_A10__custom_3226674]* (Luxembourg City: Eurostat).

revisions of historical time series, only rough estimations for the period before 1990 are possible. However, the general trends have been well studied. And trends in employment move in the same direction.

While the relative importance of agriculture and manufacturing has declined, service activities have been an important driver of EU growth for many years.[14] The contribution of services to annual EU growth in terms of value-added is greater than that of industry. Services markets have also consistently generated job growth in the EU and compensated for the loss of jobs in agriculture and industries. In 1995, agriculture, forestry, and fisheries still represented 9.7% of total employment. In 2020, this had dropped to only 4.5%. The reduction is impressive in absolute numbers: from 17.4 million persons to 9.4 million. At the same time, the number of people working in the various service sectors increased from 110 million to 150.2 million.

Not only has the number of persons across sectors changed significantly, but also the allocation of time between, work, homework, and leisure. Annual hours worked dropped. In manufacturing the working time almost halved since 1870. At that time, for example, in the Netherlands, workers spent on average 3,316 hours for work and were four days on leave and/or holiday.[15] In 2000, the days of leave and holiday were 38 and the annual working time was 1,698, which was more or less the average overall working time in the European Union in this year. Meanwhile the working time dropped further. In EU27, the average working time per worker has declined from 1,679 hours per year in 2000 to 1506 hours per year in 2020.[16]

Although meanwhile 73% of the workforce is already working in the services a further increase of services can be expected. Europe lagged and is still lagging behind the USA in shifting labour from industry to services.[17] These European lags in the process of moving labour are evident in the lower relative share of output and employment represented by services.

14   Mustilli, F. and J. Pelkmans (2012) *Securing EU Growth from Services. CEPS Special Report, No. 67/October 2012* (Brussels: Center for European Policy Studies).
15   Gilmore O. (2021) "The working week in manufacturing since 1820", in OECD (ed.), *How Was Life? Volume II, New Perspectives on Well-being and Global Inequality since 1820* (Paris: OECD).
16   OECD (2023) *Average annual hours worked per worker* (Paris: OECD).
17   Rogerson, R. (2007*) Structural Transformation and the Deterioration of European Labor Market Outcomes. Working Paper 12889* (Cambridge, MA: National Bureau of Economic Research).

Table 1: Selected demographic and economic Indicators EU27

	1960	1970	1980	1990	1995	2000	2010	2020
Demographic Indicators								
Population in millions	356	385	406	419	424	429	441	447
Total Fertility Rate	2.67	2.34	1.98	1.78	1.52	1.47	1.57	1.53
Life expectancy, m	66.8	67.3	68.9	70.2	70.8	72.6	76.7	77.5
Life expectancy, f	72.2	73.6	75.8	77.4	78,2	79.5	82.9	83.2
Crude birth rate	19.1	16.4	14.9	13.1	11.1	10.6	10.9	9.1
Crude death rate	9.9	10.3	10.6	10.6	10.7	10.3	10.1	11.6
Dependency ratio 65+	15.2					23.4		29.2
Dependency ratio 80+	2.3					5.0		8.2
*Population share 65+	9.8	11.3	13.1	13.7	14.6	15.8	17.5	19.4
*Population share 80+					3,5	3.5	4.7	5.9
Economic indicators								
VA agriculture %					2.8	2.5	1.9	1.8
VA industry %					29.7	28.3	25.5	25.6
VA services %					67.5	69.2	72.6	72.6
Labour agriculture %					9.8	9.0	5.9	4.5
Labour industry %					28.5	26.8	23.6	22.5
Labour services %					61.7	64.2	70.5	73.0
HE (% of GDP)	3.7	6.8	7.0	7.7	8.8	8.4	9.9	10.9
VA health (% of GVA)								9.9

VA = Value added, HE= Health Expenditures, GDP = Gross Domestic Product, GVA = Gross Value Added

VA, industry = Industry incl. construction;

Source: Compiled by the authors using a variety of data sources[18]

Why and how the service sector is growing, to the point of becoming the major economic sector, has been intensively discussed by economists. In 1857, the Saxonian statistician Ernst Engel stated that an increase in the income of a family decreases the proportion of their income spent on food, even though the total amount of food expenditure increases.[19] In other words, the structure of expenditure changes towards other expenditures. This implies that when the income per capita of a country grows, the demand for agricultural products will diminish in the country's total economic demand. However, this shrinking agricultural share, not only of the demand for goods but also of the supply of goods, is due to a further factor - namely the high increase in productivity of the production of agricultural products. In fact, structural transformation of this sector of the economy, is the result of changes on the demand and supply side.

In modern economics, the rate of structural transformation of the economy is high.[20] The acceleration in growth of products and productivity in many developed countries reflects a major change in the potential of science-oriented technology. Countries with higher productivity, and as a result with higher per capita income, contain larger shares of service sectors than countries which have lower productivity and lower per capita income, and a concomitant smaller share of the service sector in their economies.

In the 19th-century, Thomas Malthus argued in *An Essay on the Principle of Population* that humans are ultimately tied to their environment.[21] He recognised that "the reason that the greater part of

(2023a) Health care expenditure by function [HLTH_SHA11_HC__custom_7398388], Last Update 26/07/2023 23:00.; VA, health includes health research and medical education; Estimates based on Eurostat (2023a) Health care expenditure by function [HLTH_SHA11_HC__custom_7398388], Last Update 26/07/2023 23:00 and USE table 2019 Eurostat (2023b) *Use table at purchasers' prices [NAIO_10_CP16__custom_7229443], Last Update 04/08/2023 23:00.* by linking data of health accounts with data of national accounts, Schneider M. et al. (2016) Gesundheitswirtschaftliche Gesamtrechnung 2000-2014 (Baden-Baden: Nomos).

19   Engel, E. (1857) "Die Productions- und Consumtionsverhältnisse des Königreichs Sachsen", *Zeitschrift des statistischen Bureaus des Königlich Sächsischen Ministerium des Inneren*. 8–9: 28–29; Pasinetti L. (1981) *Structural change and economic growth: a theoretical essay on the dynamics of the wealth of nations* (New York: Cambridge University Press).

20   Kuznets, S. (1973) "Modern Economic Growth: Findings and Reflections*", The American Economic Review*, 63(3): 247-258.

21   Malthus, T. (1798) *An Essay on the Principle of Population* (London: Printed for J. Johnson, in St. Paul's Church-Yard).

Europe is more populous now than it was in former times, is that the industry of the inhabitants has made these countries produce a greater quantity of human subsistence". Marx, Schumpeter, Kuznets, Piketty, and other economists made another observation.[22] Economic growth creates social problems because it is profoundly disruptive to traditional values and religious beliefs, to long-standing social and family patterns of organisation, and to numerous monopolies of privilege.[23] However, modern economic growth has brought with it tremendous increases in longevity and good health, and has raised standards of living as well as social and economic opportunities previously available only to a tiny minority. But the social restructuring that innovations since the last half of the 18th century, the epoch of modern economic growth, required were still obscure and difficult to predict.[24]

In the 20th century, human capital had become more important than physical capital in explaining both economic growth and the inequality of income distribution.[25, 26, 27] Such considerations also caused economists to emphasise the importance of investment in improving nutrition and health as a key to economic growth in developing countries, and to identify investment in health, education, and skills as essential in dealing with problems of international development.

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22   The consequences of capital accumulation, exploitation of labour, persistence of poverty, and income inequality has been widely discussed; Marx K. (1894) *Capital: A Critique of Political Economy, Vol.* 3. (London: Penguin Classics, 1981); Kuznets, S. (1955) "Economic Growth and Income Inequality", *American Economic Review*, 45(1), 1–28; Schumpeter J. (1939) *Business Cycles - A Theoretical, Historical and Statistical Analysis of the Capitalist Process* (New York Toronto London: McGraw-Hill Book Company); Piketty T. (2014) *Capital in the Twenty-First Century* (Cambridge: The Belknap Press of Harvard University Press).
23   Fogel, R., M. Guglielmo, and N. Grotte (2013) "The Use of National Income Accounting to Study Comparative Economic Growth", in Fogel, R. (ed) *Political Arithmetic: Simon Kuznets and the Empirical Tradition in Economics* (Cambridge, MA: National Bureau of Economic Research).
24   Kuznets, S. (1966) *Modern Economic Growth: Rate, Structure, and Spread* (New Haven: Yale University Press).
25   Schultz, T. (1961) "Investment in Human Capital", *The American Economic Review*, 51(1): 1-17. Barro, R. J. (2001) "Human Capital: Growth, History, and Policy— A Session to Honor Stanley Engerman", AER, 91(2): 12-17.
26   Barro, R. J. (2001) "Human Capital: Growth, History, and Policy— A Session to Honor Stanley Engerman", AER, 91(2): 12-17
27   Romer, P. (1989) *Human Capital and Growth: Theory and Evidence. Working Paper, National Bureau of Economic Research, Working Paper No. 3173* (Cambridge, MA: National Bureau of Economic Research).

Kendrick distinguished two chief types of personal consumption expenditures that fit the definition of investment in human capital: expenditures for education and for health services.[28] However, in analysing the contribution of education and health services to human capital, there is a problem of distinguishing between gross and net investment in personal productive capacity. The proportion of investment-type outlays required to maintain the productivity of a given population at its previous level, is akin to tangible investment designed to offset capital consumption.[29] In practice, different measures of health and human capital were developed to supplement the value-added figures from national accounts, such as 'health income'[30] and 'health capital'.[31]

Demographic transformation

The demographic transformation of European societies began around 1800 with declining mortality in Europe.[32] This transformation, witnessed from the 18th century onward, can be described by the model of first demographic transition which identifies the historical shift from high birth rates and high death rates in societies with minimal technology and economic development, to low birth rates and low death rates in societies with advanced technology and economic development. In northwest Europe, mortality began a secular decline around 1800, Starting with the development of the smallpox vaccine in the late eighteenth century, preventive medicine played a central role in this mortality decline. Another major factor in the early phases of growing life expectancy is improvements in nutrition.[33]

The period since the 1960s is described as the "second demographic transition".[34] This refers to the fall in the fertility level below an average

28   Kendrick, J. (1961) "Productivity and Economic Growth", in Kendrick, J. (ed), *Productivity Trends in the United States* (Princeton: Princeton University Press), pp. 78-110.
29   Ibid.
30   Nordhaus, W.D. (2002) *The Health of Nations: The Contribution of Improved Health to Living Standards. Cowles Foundation Discussion Paper No, 1355* (New Haven: Yale University Press).
31   Cutler, D., and E. Richardson (1997) "Measuring the Health of the U. S. Population. Brookings Papers on Economic Activity", *Microeconomics*, Vol. 1997: 217-282.
32   Lee R. (2003) "The demographic Transition: Three centuries of fundamental change", *Journal of Economic Perspectives*, Vol. 17 (4): 167–190.
33   Ibid., p. 170.
34   Lesthaeghe R. (2014) "The second demographic transition: A concise overview of its development", *Proc Natl Acad Sci USA,* 111(51): 18112–18115.

of 2.1 children per woman, the rate necessary to sustain a population in the long-term.

Long-term changes in the size and age profile of the population depend firstly upon changes in fertility rates, secondly upon mortality rates or life expectancy, and thirdly upon migration. These three factors correlate with the economic transformation discussed above. Lower fertility and lower mortality cause population ageing and raise the demand for investments in physical and human capital needed to provide for old-age consumption.[35] Because birth rates and mortality rates differ greatly across European regions, as a function of cultural and economic conditions, the demographic transition from high fertility and death rates to low fertility and death rates has not been a uniform process in Europe. While in France births were falling from about 40 to 27 per 1000 population in the period 1750 -1870, England had no clear trend, accounting for 37 per 1000 population in 1870[36].

Fertility rates declined sharply in Western Europe after the post-war "baby boom" peak, from around 2.9 in 1960 to below the natural replacement level of 2.1 in 1974 due to the use of contraceptive pills. In some European countries, fertility rates had already fallen below replacement levels by the late 1960s, namely Sweden, Denmark, Finland, Luxembourg, Germany, Hungary, Latvia, and the Czech Republic.[37] By 2020, several MS had very low fertility rates (below 1.4), namely Bulgaria, the Czech Republic, Germany, Estonia, Greece, Spain, Italy, Latvia, Lithuania, Hungary, Austria, Poland, Romania, Slovenia, and Slovakia. Between 2000 and 2015 fertility stabilised in the EU27, with total fertility rates reaching over 1.8 in Ireland, France, Sweden, and the UK. In future, fertility rates in all countries are expected to remain below the natural replacement rate. One can expect that the further decline in fertility will result in an increase in the female labour supply and investments in health and education.[38]

Increases in life expectancy, together with population growth through mortality decline, is one of the most remarkable changes which have

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35   Lee, R. and A. Mason (2010) "Some macroeconomic aspects of global population aging", *Demography*, 47 Supplement: S151–S172.
36   Weir, D. (1984) "Life Under Pressure: France and England, 1670-1870", *The Journal of Economic History,* 44(1): 27-47.
37   European Commission (2021) *The 2021 Ageing Report, Economic & Budgetary, Projections for the EU Member States (2019-2070), Institutional Paper 148* (Brussels: European Commission).
38   Bloom, D., D. Canning, and J. Finlay (2010) "Population Aging and Economic Growth in Asia", in Ito T., Rose A., (eds) *The Economic Consequences of Demographic Change in East Asia,* (Chicago: University of Chicago Press), pp. 61-89.

affected European welfare in the past two centuries. In many European countries, life expectancy trends can be traced back to the 19th century and show that since then life expectancy has doubled.[39] However, in the early stages of industrialisation before the first half of the 19th century, its impact on health was mixed. In the first half of the 19th century, Britain became a net importer of food, and a significant proportion of the British population had diets which were insufficient to maintain weight, contributing to undernutrition in children and women, and to an increase in their mortality rates.[40] Mortality in Britain fell sharply between 1901 and 1950, and people have been getting taller.[41, 42] In Bavaria, Belgium, Denmark, France, Italy, the Netherlands, Norway, Spain, and Sweden, the average heights of army recruits increased between 3.1 and 11.1 centimetres during the first three-quarters of the 20th century.[43]

Since 1960, there have been significant increases in life expectancy at birth in all EU member states. For both males and females, life expectancy at birth on average across the EU increased by more than 10 years between 1960 and 2020. For males it rose from 66.9 years to 77.5 years in 2010, and for females from 72.3 years to 83.2 years (see Table 1).[44]

Demographic projections generally assume that gains in life expectancy at birth will slow down in future compared with historical trends. This is because future gains in life expectancy would require improvements in mortality rates across all ages. But mortality rates at younger ages are already very low, and improvements at older ages have a statistically smaller impact on life expectancy at birth.

The third factor in demographic development is migration. In geographical terms it is useful to distinguish among emigration, immigration, and internal migration. In the 19th century Europeans dreamed of the New World and many emigrated to the USA because

39   Mackenbach, J.P. (2021) "The rise and fall of diseases: reflections on the history of population health in Europe since ca. 1700", *European Journal of Epidemiology*, 36:1199–1205.
40   Fogel, R., and N. Grotte (2011) "The Changing Body: Health, Nutrition, and Human Development in the Western World since 1700", *J Econ Asymmetries*. 8(2): 1–9.
41   Ibid., p. 3
42   Floud R, Harris B. (1997) "Health, Height, and Welfare: Britain, 1700-1980", in: Steckel R.H. and Floud, R. (Eds.) *Health and Welfare during Industrialization* (University of Chicago Press: NBER), pp. 91-126.
43   Floud, R. (1984) *The Heights of Europeans since 1750: A New Source for European Economic History. NBER Working Paper No. 1318* (Cambridge MA: National Bureau of Economic Research).
44   Eurostat (2022) Mortality and life expectancy statistics (Luxembourg City: Eurostat).

wages were more than twice those in Europe. In the period from 1820 to WWI, around 55 million Europeans emigrated to North America (71%), South America (21%) and Australasia (7%).[45] European emigration was brought to an abrupt end by WWI and the Great Depression. After WWII more people immigrated to Europe than emigrated.

Now, 447 million individuals live within the boundaries of EU27, 91 million (25,6%) more than in 1960 (Table 1), and about three times more than 200 years ago, but with a completely different age structure. Europe is currently the oldest continent in the world as measured by the very-old-age dependency ratio (the ratio of over-80-years-old to the working age population), and will remain so until 2070. This high ratio of elderly people means Europe also has a high share of pensioners. Although population growth slowed as a consequence of low birth rates and restricted net migration, a substantial increase of population in the area of European Union member states (EU27) can be noted in last decades due to net immigration.

In an ageing society, the number of old age dependents will increase relative to the number of working age individuals. In the coming decades, the demographic old-age dependency ratio (people aged 65 or above relative to those aged 15-64) is projected to increase significantly in the EU as a whole. From about 25% in 2010, it had risen to 34.4% in 2019 and is projected to eventually reach 59.2% in 2070. This implies that the EU would move from three working-age people for every person aged over 65 years in 2010, to having less than two working-age persons over the projection horizon.[46]

Labour force composition has undergone profound changes in recent decades. While participation rates for prime age men (aged 25–54) remained stable, younger cohorts tend to enter the labour market later, while women and older people have steadily increased their involvement in the labour market. There are basically four sets of facts underlying these changes, namely: (a) social factors, such as longer schooling or change in the role of women in households; (b) demographic factors, including the decline of fertility rates and delays in childbearing; (c) institutional factors, in particular changes in early retirement or changes in the statutory/effective age of retirement; and/or (d) economic factors,

45   Ferrie, J. P., and T. Hatton. (2013) "Two Centuries of International Migration", *IZA Discussion Paper No. 7866.*

46   European Commission (2021) *The 2021 Ageing Report, Economic & Budgetary, Projections for the EU Member States (2019-2070), Institutional Paper 148* (Brussels: European Commission), p.4.

such as, substitution and income effects of labour taxation (particularly relevant for second earners), take-up rates of part-time employment, and the share (relative to prices) of services in the economy.[47]

Institutional transformation

The different economic and demographic transitions across European countries are linked to a further factor which shapes structural development. Organisational and institutional transformation goes hand in hand with technological change. Institutions constitute the rules of economies, or the constraints that shape human interaction.[48] Within Europe, the huge impact of institutional transformation is apparent in the structural transformation of Eastern European economies after the fall of the Iron Court, from planning systems to market systems. Institutional transformation aims to adjust the legal framework for private and public activities to common objectives. Public activities aim, among other things, to improve the allocation of scarce resources, to stabilise economic production, and to increase welfare by securing a socially accepted distribution of income and property rights.[49]

Most goods and services are allocated in regulated markets. Markets and the rules under which markets operate are special institutions, which support the transaction of goods and services. In fact, the history of structural transformation is also a history of the development of market rules and their stability, particularly those of financial markets in order to allocate, distribute, and stabilise the value of money. One of the main tasks of institutions is to reduce uncertainty by establishing a stable structure for human interaction.[50] From its beginnings, the European Union aimed to reduce transaction costs and establish stability in markets of goods and services across Europe. The Treaty of Rome of March 25, 1957, in Article 59, aimed for the stepwise removal of barriers for a single service market.[51]

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47   Ibid.
48   North, D. (1990) *Institutions, Institutional change and economic performance* (Cambridge: Cambridge University Press).
49   Musgrave, R., and P. Musgrave (1984) *Public Finance in Theory and Practice* (New York: McGraw Hill Book Co.).
50   North, D. (1990) *Institutions, Institutional change and economic performance*. P.6.
51   European Parliament (1957) Treaty of Rome (Brussels: European Parliament).

Markets in healthcare face special problems of regulation. Patients frequently lack information. Health markets are highly specialised and therefore patients are in a weak position to assess quality. The physician knows more than the patient, but it is the latter's welfare that is at stake.[52] Prices cannot be set by competition, as a commodity's price and quantity will not reflect its real cost to producers and its real value to buyers. That level of competition does not exist in many healthcare markets. Furthermore, in numerous situations, it is doubtful whether society would benefit if it did.[53] Asymmetric information between individuals, doctors, and pharmaceutical companies is one reason for national and European intervention in the health services and medical goods markets. Certainly, most of these decisions are made locally and are controlled locally, but the increasing international labour division in healthcare, and the spread and interdependence of health risks, require more than local, regional, and national safeguards. Economies of scale and scope advocate for European regulations in health markets.

A common critique of the European Union is that it focusses too much on the economic objectives of a single market in goods, capital, services, and labour, thereby neglecting the social dimension. It is certainly important to consider the optimal role of the EU as compared to national governments with regard to different sectors of the economy and variations in their relative importance between countries. The budget of the EU is clearly not allocated in line with the sectoral structure of European economies - agricultural spending is still the largest part of the EU budget.[54]

Institutions may be growth-enhancing or may block economic development. Social conflict implies that there is no guarantee that policy will adopt growth-enhancing institutions, such as securing property rights and a stable legal framework.[55] The impact of institutions

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52   Arrow, K. J. (1996) "Information, Responsibility, and Human Services", in Fuchs, V. (ed.), *Individual and Social Responsibility: Child Care, Education, Medical Care, and Long-Term Care in America* (Chicago: University of Chicago Press), pp. 229-244.

53   Fuchs, V. (2010) "Health Care Is Different—That's Why Expenditures Matter", *JAMA*, 303(18): 1859-60.

54   See chapter of Andriukaitis V. (2023), From Coal and Steel Community to a Health and Wellbeing Union. The European project finally achieves its original vision? Introduced in 1992 by the Treaty of Rome, the EU's common agricultural policy aims to increase productivity and stabilise markets, to ensure the availability of food at reasonable prices, and to provide fair living standards to farmers.

55   Acemoglu, D. (2009) *Introduction to Modern Economic Growth* (Princeton: Princeton University Press).

on performance varies, depending on the market and technology conditions in which they operate. In particular, the burden of strict product market regulations on productivity seems to be greater the larger the technological gap with the industry/country leader. Strict regulation hinders the adoption of existing technologies, possibly because it reduces competitive pressures or technology spillovers. In addition, strict product market regulations also have a negative impact on the process of innovation itself, insofar as it can be proxied by R&D expenditure.[56] Thus, given the strong impact of R&D on productivity, there is also an indirect channel whereby strict product market regulations may reduce the scope for productivity enhancement.

The institutions of the European Union evolved in the industrial centre of continental Europe. The mission of the European Coal and Steel Community (ECSC), created in 1951 (and completely merged into the European Economic Communities in 2002), was to contribute to economic expansion, the development of employment and the improvement of the standard of living in participating countries, through the institution, in harmony with the general economy of the member states, of a common market (ECSC Art, 2). The guiding social policy principle of the ECSC was of "protecting the worker and his living standards". For example, the High Authority of the ECSC developed programmes of readaptation, and the retraining and reemployment of workers threatened with unemployment.[57] In 1957, The Treaty of Rome established the European Social Fund (ESF), with a view to improving workers' mobility and employment opportunities. The ESF's tasks and its operational rules were subsequently revised, to reflect the economic and employment situation in the member states. The ESF "should take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health".[58]

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56   OECD (2003) *The Sources of Economic Growth in OECD Countries* (Paris: OECD Publishing).
57   European Community Information Service (1996) *Social policy in the European Coal and Steel Community 1953-65* (Luxembourg: European Community Information Service).
58   European Union (2013) *Regulation (EU) No 1304/2013 of the European Parliament and of the Council of 17 December 2013 on the European Social Fund and repealing Council Regulation (EC) No 1081/2006.* (Brussels: European Union).

Transition of health systems

The negative impacts of early industrialisation on health called for solutions. One should remember that between 1750 and 1870, life expectancy was not increasing in some European regions. For this to change, public and private safety nets were needed. As early as 1848, John Stuart Mill pointed out that educational and medical provision had a favourable effect upon producers and thus indirectly on production: "When engaged in safe occupations and living in healthy countries, men are much more apt to be frugal, than in unhealthy or hazardous occupations and in climates pernicious to human life".[59]

Sanitary problems became rampant with increasing urbanisation of the population in the 19th century. Very poor environmental conditions became common in working class areas, and protecting health became a social responsibility. Disease control continued to focus on epidemics, but the manner of control turned from quarantine and isolation of the individual, to cleaning up and improving the common environment. In 1842, Chadwick documented in his report on the sanitary conditions of the labouring population of Great Britain, the extent of disease and suffering in the population. Chadwick promoted sanitation and engineering as means of controlling disease, and laid the foundation for public infrastructure for combating and preventing contagious diseases. The development of public health systems led to increasing life expectancy, with a time lag following industrialisation. Two factors have been important in shaping public health systems: (1) the growth of scientific knowledge about sources and means of controlling disease; and (2) the growth of public acceptance of disease control as both a possibility and a public responsibility.[60] The perception of diseases and the knowledge about diseases changed, and the remedies to treat them grew. Breakthroughs in the prevention, treatment, control, elimination, and potential eradication of infectious diseases are among the most important advances in the history of medicine.[61]

The history of disease offers crucial insights into the notions of disease, the intersections of the understandings of determinants of

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59   Mill, J. S. (1885) *Principles of Political Economy* (New York: D. Appleton And Company). p.142.
60   Institute of Medicine (1988) The Future of Public Health (Washington, DC: The National Academies Press), p.56.
61   Fauci, A. S., and D.M. Morens (2012) "The Perpetual Challenge of Infectious Diseases", *New England Journal of Medicine* 366(2012): 454 – 461.

disease and medicine's impact in order to design systems that foster health. Insofar one can speak also about an "epidemiological transition" that shaped health systems.[62] In 1865, the creation at Munich of the first chair in experimental hygiene signalled the entrance of science into the field of public health.[63] Laboratories and clinics over Europe invented new preventive, diagnostic, rehabilitative, and curative services.[64, 65] Public health activities and the access to clinical medicine have had a significant impact on population health.

At the end of the 19th century, health insurance was implemented in many countries, to secure income in the case of illness. Gradually, access to medical care has become crucial too and an important determinant of health levels amongst populations. In Germany, Bismarck introduced social health insurance in 1883.[66, 67] In the UK, the National Insurance Scheme was introduced in 1911, providing contributors with access to a doctor and sickness benefits. In 1944, the Beveridge Report set out the principles of the post-war welfare state in Britain. Besides providing for a comprehensive, universal health service, free at the point of need, it also proposed major investment in education, full employment, and a system of benefits for people unable to work.[68]

In the first half of the 20th century, all European countries created a health safety net for their citizens.[69] However, the types and size of coverage of health services have varied greatly. Nevertheless, the grids of coverage have become denser in each country. Nowadays, all MS

62   Jones, D., S. Podolsky, and J. Greene (2012) "The Burden of Disease and the Changing Task of Medicine", *New England Journal of Medicine,* 366(2012): 2333-2338.
63   Encyclopaedia Britannica (2023) *Public Health. National developments in the 18th and 19th centuries* (Chicago: The Britannica Group)..
64   Gordon J. (2016) *The Rise and Fall of American Growth* (Princeton and Oxford: Princeton University Press), p. 39.
65   The invention of new services and goods became a growth engine of the heath system and of the economy as a whole. Robert J. Gordon observed for the United States, that in 1940 more than one-third of the consumer budget went toward goods and services that even did not exist in 1869, in 2013 it made up nearly 60% of the consumer budget.
66   Saltman, R.B., and H.F.W. Dubois (2004) "The historical and social base of social health insurance systems", in Saltman R.B et al (ed) *Social health insurance systems in western Europe* (Maidenhead: Open University Press), pp. 21-32.
67   The history of Social Health Insurance in Europe as well as its animating principle of social solidarity, extends considerably earlier than 1883 and more widely than Germany.
68   Abel-Smith B. (1992) "The Beveridge report: Its origins and outcomes", *International Social Security Review,* Vol. 45(1–2): 5–16.
69   Cutler, D., and R. Johnson (2004) "The birth and growth of the social insurance state: Explaining old age and medical insurance across countries", *Public Choice*, 120: 87–121.

offer their citizens a comprehensive spectrum of health services, even if there are areas of very limited access to basic health services in some regions and across Europe.[70] Systematic comparative analyses of health systems have helped to shed light on variations in healthcare services, actual labour shortages, and to forecast future challenges.[71, 72]

The three-sector model helps to describe the sectoral shift of value-added towards the service economy in general. However, it does not sufficiently explain the growth of the health sector and the institutional transformation towards "Health in All Policies" and "Health-for-All-Policies". Health in All Policies is built on the observation that health is determined by various factors outside the medical system, such as education and living conditions.[73, 74] Health for All Policies complements Health in All Policies by drawing attention to win-win solutions for all sectors. The negative consequences of the early industrial revolution, the understanding of human made economic growth by innovations, the development of modern medicine and public health pushed the growth of health services.

Today, health services form the largest service sector in developed countries. It's important to note that health services development has always been closely linked to the innovation and production of pharmaceuticals, medical devices and medical equipment. Therefore, the distinction between industry and services is a little arbitrary. Productivity growth in pharmaceuticals and medical equipment such as diagnostic scanners, prostheses, stents, and dialysis, has been essential for productivity growth in healthcare services.

Since WWII, the share of GDP devoted to health expenditure more than trippled in Europe. In Western European countries, broadly speaking, two main periods can be distinguished in health sector development. From 1950 to 1990, demand and supply were both expanding in the health system, in terms of both financing and of regulation. The result was very strong growth of healthcare expenditures in all Western European countries. In France,

70   See chapter of Schrauwen, A., Hinlopen C. (2023). Equal access to health workers: managing health worker migration in a context of free movement.
71   European Commission (2020) *The 2021 Ageing Report, Underlying Assumptions & Projection Methodologies, Institutional Paper 142* (Brussels: European Commission).
72   OECD (2020) Health at a Glance: Europe 2020: State of Health in the EU Cycle (Paris: OECD Publishing).
73   Ståhl T et al. (eds) (2006) *Health in all policies: prospects and potentials* (Helsinki: Ministry of Social Affairs and Health).
74   Greer S. et al. (2022) "From Health in All Policies to Health for All Policies", *The Lancet Public Health*, 2022(7): 718–20.

between 1960 and 1990, the share of health services in gross domestic product (GDP) rose by 4.5%, in Germany by 3.9%, in the Netherlands, by 4,4%, and in Spain even by 4.8%.[75] This very rapid development is due to several factors, both on the demand and on the supply side.

On one hand, health expenditure has the characteristic, common to so-called 'superior' goods, of demand increasing more rapidly than national income.[76] In particular, there is a strong relationship between the overall income level of a country and how much the population of that country spends on healthcare. The gradual expansion of social health insurance and public protection in this period made it possible to finance this demand for care.

On the other hand, supply of healthcare developed through the growth of new medical services, such as hospital equipment, and an increase in the density of medical and paramedical staff. In the first phase (1950-1990), European health system growth was stimulated primarily by the expansion of medical services, particularly hospital care. Hospital expenditure increased by 16% per year (i.e., +7% per year in volume) and its share in health expenditures (44% in 1950 in France) reached a peak of 55% in 1982. This expansion followed numerous hospital construction programmes. In France, the hospital-university reform of 1958 strengthened the role of hospitals (prevention, diagnosis, functional rehabilitation), created university hospital centres and 'full-time hospital work' for doctors who had previously divided their time between the faculty, the hospital and their private practice. Hospitals gradually became the 'heavy industry' of the health system.[77]

Since 1990, health expenditure growth has diminished due to cost-containment measures. Cost containment policies have included measures such as limiting prices and volumes, budget limits, national targets for increases in health insurance expenditure (e.g., the introduction of the ONDAM in France), the creation of the coordinated care pathway, and the delisting and price reductions of certain drugs, as well as coinsurance measures. Increasing public health expenditures raised contribution rates to sickness funds and earmarked taxes, which called for cost containment measures to limit their impact on labour costs and international

75   OECD (1993) *OECD Health Systems, Facts and Trends 1960 -1991, Vol* 1, *The Socio-economic Environment, Statistical References, Vol. 2* (Paris: OECD Publishing).
76   Mahieu, R. (2002) "Les déterminants des dépenses de santé : une approche macroé-conomique", *Santé, Société et Solidarité*, 2002(1): 79-87.
77   Califano, J. (1986) *America's Health Care Revolution: Who Lives, Who Dies, Who Pays* (New York: Random House).

competitiveness. For example, with the Cost Containment Act of 1 July 1977, Germany started a series of cost-containment acts that had the common goal of bringing the growth of healthcare expenditures into line with the growth of wages and salaries of the sickness fund members. The act implemented a macroeconomic approach to expenditure regulation, which has been both revenue and access oriented. That is, the growth of sickness fund expenditures has accompanied their growth in revenues (mainly based on wages). Furthermore, free access to quality care has been preserved, independently of income.[78]

After the collapse of the socialist economies in 1989, the transformation of health systems of the Central and East European Countries (CEEC) started. Health politicians were forced to integrate market elements into their health sector. "Money follows patient" was the buzzword.[79] The integration of the CEEC into the EU has contributed to this transformation. Distancing from the soviet past was according to the lines liberalising health care markets, decentralizing decision-making in the public sector and the implementation of a statutory health insurance. All CEEC moved to a mix of public/private elements of governance generally favouring more market elements on the provider side than on the financing side. Until today the majority of CEEC is lagging in the modernisation of the health system behind Western Europe. In 2020, Western Europe (16 EU27 MS without the 11 CEEC) spent about 6 times more on health per capita than CEEC. Fortunately, some convergence can be observed, but the difference remains still high. In 2020, still threefold more was spent on health per capita in the Western Member States than in the CEEC.[80]

Furthermore, the ageing societies challenged the health systems. In the last 30 years, because of the increasing number of frail and dependent elderly, long-term care (LTC) has become the fastest growing part of the health services sector. It includes services for the elderly or disabled in institutions, home nursing services, daily allowances, expenditure on institutional prevention, and so on. Between 1995 and 2020, LTC at current prices grew by around 4% per year, significantly faster than

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78   Schneider, M. (1991) "Health care cost containment in the Federal Republic of Germany", *Health Care Financing Review,* 1(3): 87-101.
79   Schneider M., Cerniauskas G., Murauskiene L. (2000) Health Systems of Central and Eastern Europe (Augsburg: BASYS).
80   In the 16 Western EU Member States the average current health spending was EUR 1848 in 2000 and 3989 in 2020; in the 11 CEEC the corresponding figures were EUR 299 and EUR 1217. Author's own compilations based on: WHO (2022) *Global Health Expenditure Database* (Geneva: World Health Organization).

GDP at current prices (3% per year). Following standard economic argumentation, productivity growth in long-term care will be lower than medical services.[81] All else being equal, this 'cost disease' requires higher expenditure in long-term care than medical care, which requires shifting resources within the health sector from cure to care. As growth of LTC is driven by the increasing number of frail persons suffering from Alzheimer's Disease and dementia new supplies of services and medical goods were and needs to be developed.

The expansion of healthcare, and public protection of health coverage, is one of the significant characteristics of the service economy and part of the *acquis Communautaire* of the European Union. Although the EU has limited legislative power in human health, its role as a policymaking authority has been growing, because of cross border care, interoperability of information systems, and its overall involvement in the domain of regulation of markets and non-market activities, such as subsidies, structural investments, and setting of standards.

To sum up, health and long-term care have become the growth industries of the 21st century.[82]

Outlook

Today, the value-chains of the production of most goods and services are interconnected across several countries. National and European market and non-market regulations, as well as international contracts, safeguard these value chains. Digitisation of the single market will create a European health data space, which together with the advances of artificial intelligence generate new opportunities and challenges far beyond national capacities to govern them.[83, 84] Obviously, the European

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81   Baumol, W. (1985) "Productivity policy and the service sector", in Inman R., (ed.), *Managing the Service Economy: Prospects and Problems*, (Cambridge: Cambridge University Press), pp. 301-317.

82   Fogel, R. (2004) *The Escape from Hunger and Premature Death, 1700-2100, Europe, America, and the Third World* (Cambridge: Cambridge University Press), preface. xvii.

83   European Commission (2018) *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society* (Brussels: European Commission).

84   European Commission (2022) *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, Strasbourg, 3.5.2022, COM (2022) 197 final, 2022/0140 (COD)* (Strasbourg: European Commission).

regulatory framework is incomplete and will remain, by its complexity, unfinished. New variants of viruses, bottlenecks in the delivery of medicines, or shortages of medical doctors and nurses, are ample proof of the vulnerability of health services delivery. Furthermore, climate change and decarbonisation require transformation of health systems towards environmentally sustainable health services.[85]

In the EU27, the health sector makes the highest single contribution to GDP, and its impact goes far beyond GDP. The further integration of European health markets and health institutions offers opportunities to make the provision of services less vulnerable, more efficient, and increase the safety net for European citizens. The question is: how can further European integration use best the advantages of economies of scale and scope of expanded markets, and to what extent do we need to reorganise the social institutions of the common European framework for the European citizens?

Conclusion

The pace of transformation during the last 250 years has been considerable and might even accelerate in the near future through the use of artificial intelligence and as a result of climate change. Presently, and in the near future, transformation is stimulated in all sectors by digitalisation, and pressure to reorganise the generation of energy in light of global warming. Investments in the further digitalisation of health systems depends on national and European interoperability. Investments in green energies, although mainly local, are embedded in European networks of infrastructure. Investments in health and human capital are set in families with origins or living in different European countries and will strengthen the relations across Europe.

Economic and social change progress hand in hand. Different types of shock wave, such as the Covid-19 crisis of 2020-2021, the collapse of construction funds in 2008-2009, or the oil price crisis in 1967 are superimposed by long-term waves of technological development such as the use of nuclear power or the digital innovations. The economic, demographic, and institutional transitions to a service-based economy

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85   Van Daalen, K., et al. (2022) "The 2022 Europe report of the Lancet Countdown on health and climate change: towards a climate resilient future", *Lancet Public Health*, 2022(7): e942−65.

have increased the health and welfare of European citizens. In order to further strengthen cost-effective health systems, and Europe, one might focus on:

- Economies of scale and scope in expanding health service and goods markets (European pharmaceutical and device markets) and the function of cross border care.
- Free movement of health labour by securing common medical education standards and working conditions.
- Public health safety and diminishing health risks by environmental hazards in the workplace, at home, and in leisure time.
- Digital standardisation and development of the European health data space / European health platforms.
- Securing and integrating European Health Insurance markets.
- Creating economies of scale and scope in research on rare diseases, ensuring affordable prices and their common protection.
- Decarbonisation of energy-intensive health services and of the rescue system.

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topic/public-health/National-developments-in-the-18th-and-19th-centuries.   Accessed 20230903.

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Vytenis Povilas Andriukaitis

1.2 | From Coal and Steel Community to a Health and Wellbeing Union. The European project finally achieves its original vision?

Introduction

In its first few decades, the European project primarily focused on matters of trade and industry. However, over time, it has evolved to take on a growing range of competencies, with health and wellbeing now part of the picture. This is an evolution and an expansion. But at the same time, it arguably fulfils the original ambitions of the European project's architects.

One of the earliest visions for European integration was developed by Italian thinker Altiero Spinelli in the *Manifesto For a Free and United Europe* (most commonly known as the Ventotene Manifesto) in 1941.[1] The manifesto called for the replacement of militant nation-states by an "organization of the United States of Europe, which can only be based on the republican constitution of the federated countries". Social transformation of Europe was an integral part of Spinelli's vision: "The truly fundamental principle of socialism (…) is the principle which states that the economic forces must not dominate man, but rather — as for the forces of Nature — they must be subject to man, guided and controlled by him in the most rational way".[2]

This chapter traces a history of the European project. It shows how the project initially focused on industrial matters but has, over time, shown a greater interest in healthcare and related social concerns.

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1   Spinelli, A., and E. Rossi (1941) *The Manifesto of Ventotene* (Luxemobourg: CVCE).
2   Ibid.

The beginnings of the European project: a rebirth of an industry

While Spinelli and other Italian socialists were developing an anti-totalitarian and social narrative for a united Europe, the economic realities facing Europe in the aftermath of WWII were also critical for the popular support of European integration. The wartime decline in the GDP of western European economies was hugely challenging. Much of the region was in ruins, large swathes of the population were on the verge of starvation, and the risk of a new (even nuclear) military conflict was relatively high.

Figure 1. Economic Consequences of WWII.[3]

Index of GDP in 1945 versus GDP in 1939 (1939 = 100), in international 1990 dollars
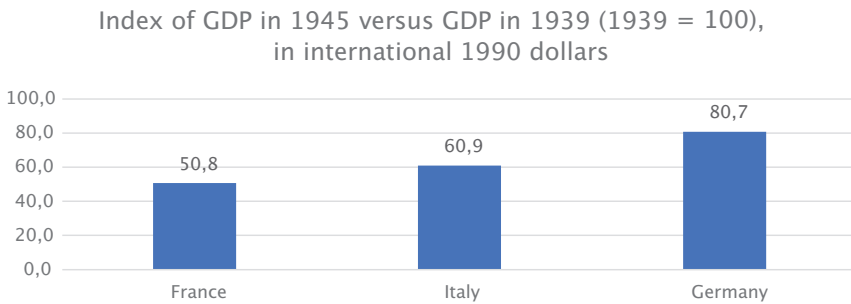
The reconstruction of major industries was an urgent task. However, there was popular demand to not simply rebuild prewar structures, but instead to use the opportunity to create something new. A strong drive towards pan-European cooperation was promoted by both European and global factors:

- The bitter European experience that national monopolies were restricting productivity growth and feeding political rivalries up to the level of military conflict was one internal reason for the movement towards a more united Europe.
- Global American industrial leadership provided evidence that existing industrial, agricultural, and marketing technologies were strong enough to achieve outputs much above prewar levels. The United States

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3   Harrison, M. (ed.) (1998). *The Economics of World War II: Six Great Powers in International Comparison* (Cambridge: Cambridge University Press).

had also provided evidence that the growth of salaries could create a demand strong enough to match the supply created by growing industrial and agricultural production.

This drive for cooperation led to a mix of initiatives to rebuild and modernise Europe. Actions for a more integrated Europe started even before the end of the war. The transitional Netherlands–Belgium–Luxembourg Customs Convention was signed on 5 September 1944 by the governments in exile in London. The 'Benelux' Customs Convention established a tariff community between the three countries and provided for the subsequent creation of an economic union to foster economies of scale. The convention also introduced a common external customs tariff and eliminated customs duties on trade within Benelux. The establishment of supranational institutions, such as a Council of the Economic Union was an integral element of the Customs Convention. Benelux can be considered a proving ground for later organisations that focused on economic cooperation in Europe.

French post-war economic policy provides an example of a national initiative to rebuild Europe. France implemented the Modernization and Re-equipment Plan, which was designed to spur economic recovery (commonly known as the Monnet Plan) in 1946.[4] The formal aims of the Monnet Plan were:

1) To develop national production and foreign trade, particularly in those fields where France was most favourably placed.
2) To increase productivity.
3) To ensure the full employment of manpower.
4) To raise the standard of living and to improve the environment and the conditions of national life.

In pursuit of its objectives, the Monnet Plan set production and other targets, starting with six crucial sectors: coal mining, steel, electricity, rail transport, cement, and farm machinery.[5]

Meanwhile, the United States initiated its European Recovery Program (ERP) - known as the Marshall Plan - which ran for four years, beginning on 3 April 1948.[6] The Marshall Plan's goals were to rebuild war-torn regions,

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4   Milward, A (1987) *The Reconstruction of Western Europe: 1945-1951* (London: Taylor and Francis Group).
5   Monnet, J. (1978) Memoirs (New York: Doubleday & Company).
6   National Archives (2023) *Marshall Plan (1948)* (College Park, MD: The National Archives and Records Administration).

remove trade barriers, modernise industry, improve European prosperity, and prevent the spread of communism.[7]

The positive experience of Benelux, the Monnet Plan and the Marshall Plan contributed to the design of the Schuman Declaration and an agreement between Germany, France, Italy and the Benelux countries to establish the European Coal and Steel Community in 1951.

The initiative inherited the foundations of the Monnet Plan, such as formal aims, an emphasis on the coal and steel industries, as well as elements of "indicative planning". Under indicative planning, the French government used its power to direct investment towards targeted industries, regions, and specific products through communication improvements and tax policies that ensured access to cheap loans for firms. The legacy of the Benelux Customs Convention is also evident because of its emphasis on the liberalisation of regional trade and the establishment of supranational institutions. Member States undertook to remove any restrictions based on nationality upon employment in the coal and steel industries for nationals of Member States and recognised qualifications in coal mining or steel-making occupations.

> Box 1 provides articles of the Treaty of Paris (1951), which are essential for understanding the aims, machinery and institutional structure of the European Coal and Steel Community.
>
> Article 2. The mission of the European Coal and Steel Community is to contribute to economic expansion, the development of employment and the improvement of the standard of living in the participating countries through the institution, in harmony with the general economy of the member States, of a common market.
>
> Article 5. The Community shall accomplish its mission, under the conditions provided for in the present Treaty, with limited direct intervention. To this end, the Community will:
> - enlighten and facilitate the action of the interested parties by collecting information, organising consultations and defining general objectives;
> - place financial means at the disposal of enterprises for their investments and participate in the expenses of readaptation;
> - assure the establishment, the maintenance and the observance of normal conditions of competition and take direct action with respect to production and the operation of the market only when circumstances make it absolutely necessary;
> - publish the justifications for its action and take the necessary measures to ensure observance of the rules set forth in the present Treaty.

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7   Ibid.

The institutions of the Community shall carry out these activities with as little administrative machinery as possible and in close cooperation with the interested parties.

The successful functioning of the European Coal and Steel Community encouraged its founding states to enhance European integration, which led to the Treaty of Rome.

The Treaty of Rome (1957) established a European Economic Community. This fostered European integration far beyond coal and steel by setting goals to establish a common market and progressively approximate the economic policies of Member States by:

(a) the elimination, as between Member States, of customs duties and of quantitative restrictions on the import and export of goods, and of all other measures having equivalent effect;

(b) the establishment of a common customs tariff and of a common commercial policy towards third countries;

(c) the abolition, as between Member States, of obstacles to freedom of movement for persons, services and capital;

(d) the adoption of a common policy in the sphere of agriculture;

(e) the adoption of a common policy in the sphere of transport;

(f) the institution of a system ensuring that competition in the common market is not distorted;

(g) the application of procedures by which the economic policies of Member States can be co-ordinated and disequilibria in their balances of payments remedied;

(h) the approximation of the laws of Member States to the extent required for the proper functioning of the common market;

(i) the creation of a European Social Fund in order to improve employment opportunities for workers and to contribute to the raising of their standard of living;

(j) the establishment of a European Investment Bank to facilitate the economic expansion of the Community by opening up fresh resources;

(k) the association of the overseas countries and territories in order to increase trade and to promote jointly economic and social development.[8]

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8   Official Journal of the European Communities (1992) "Treaty Establishing the European Community", *Official Journal of the European Communities,* No. C 224/6.

Special titles of the Treaty of Rome were developed to regulate the main aspects of a common market for:
1. Free movement of goods
2. Agriculture
3. Free movement of persons, services and capital
4. Transport
5. Social policy.

Social policy provisions were a novelty of the Treaty of Rome. According to the Treaty, close cooperation between member states should focus on:
- employment
- labour law and working conditions
- basic and advanced vocational training
- social security
- prevention of occupational accident and diseases
- occupational hygiene
- the right of association, and collective bargaining between employers and workers.

A list of priorities in social policy with a clear emphasis on workers and employment shows the realities and limits of the 1950s and 1960s. The fact that most social factors (culture, education, health) did not feature in the Treaty of Rome indicates that 1950s Europe was not ripe to embrace the full complexity of modern society.

After WWII, the economic expansion of Western Europe was very strong. Countries managed to eradicate hunger, reach pre-war levels of production by around 1948 and exceed this level almost by a factor of two in 1955 (see Figure 2).

Figure 2. Manufacturing in Western Europe, 1938-1955[9]

Indices of Output in Major Sectors of Manufacturing, Western Europe (1948=100)
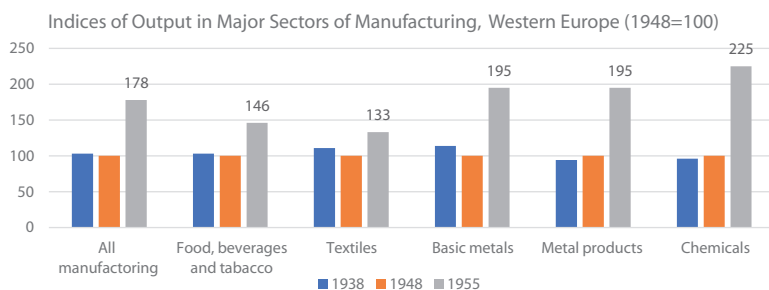
9   Organisation for European Economic Co-operation (1955) *General Statistics, January 1956 and Industrial Statistics, 1900-1955* (Paris: OEEC).

A solid post war economic recovery provided arguments that national and pan-European policies that had concentrated on agriculture and manufacturing in the 1950s worked. The relative success of policies that prioritised cooperation in agriculture and the development of an internal market of goods contributed to the continuity of these policies in decades to come.

The common agricultural policy established itself as the core European action during the 1960s and remained the biggest budget line of the European project until the end of the late 1970s.

Table 1. Expenditure structure of the European Commission (%)[10]

Expenditure titles	In 1975
EXPENDITURE RELATING TO PERSONS WORKING WITH THE INSTITUTION	3.1
BUILDING, EQUIPMENT AND MISCELLANEOUS ADMINISTRATIVE EXPENDITURE	1.4
REPAYMENTS AND AIDS TO MEMBER STATES; MISCELLANEOUS	0.6
SOCIAL AND REGIONAL FUNDS	8.3
EUROPEAN AGRICULTURAL GUIDANCE AND GUARANTEE FUND, GUIDANCE SECTION	74.8
COOPERATION WITH THE DEVELOPING COUNTRIES AND NON-MEMBER COUNTRIES	4.1
OTHER EXPENDITURE	7.7
GRAND TOTAL	100

Up until the late 1970s, the social transformation of Europe - an integral part of Spinelli's vision - was not a key priority of the European project. However, this began to change in the following decades, as is explored in the next section**.**

Europe 1960 - 2020: Reconstruction of the fundamentals of the European economy

After the healing of wounds caused by WWII and rapid industrial and agricultural growth that marked European history in 1950s and 1960s, the next two decades were quite different. Economic sectors that were key to the success of the first period of European integration went into decline.

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10   Official Journal of the European Communities (1977).

The dynamics of the German coal industry are illustrative here. From 1960 to 1980, the number of mines in that country fell from 146 to 39. By the year 2000, only 12 were still operating.[11] Coal production was suppressed by the growth of oil, natural gas and nuclear as the main energy sources in Europe. Meanwhile, the production of steel in France and Germany declined mainly because of competitive pressures from Asian countries.

The absolute decline of European production of steel was partially compensated for by the growth of other sectors of manufacturing, but this was not enough to sustain the role of traditional sectors.

Figure 3. Economy of France in 1970-1985[12]

Value added by sectors, % of total value added, France
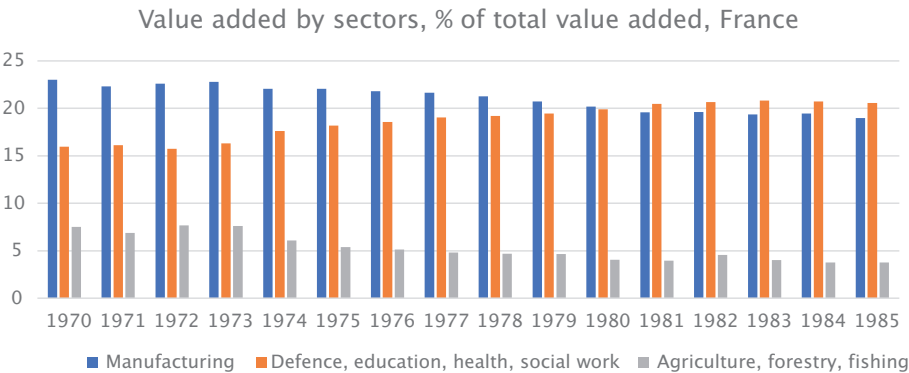
Figure 3 shows radical changes in the European economy. During the period of 1970-1985, the value added share of French agriculture, forestry, and fishing decreased from 7.5% to 3.7%, and the share of manufacturing decreased from 23% to 19%. At the same time, the country's share of value added defence, education, health and social work grew from 16% to 20.6%.

In the second half of the 20th century, Europe was transitioning from an industrial to a service-based economy. That resulted in sharp decline of employment in agriculture, outsourcing of manufacturing, and growing demand for services in education and health. Danish data covering the period of 1966-2021 mirrors trends seen elsewhere in Western Europe.

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11   Deutsche Welle (2007) "Coal mining", 31 January 2007.
12   OECD (2023) *Value added by activity: France* (Paris: OECD)

Figure 4. Economy of Denmark in 1966-2021[13]

Denmark, Gross value added by industry, share of total, percent
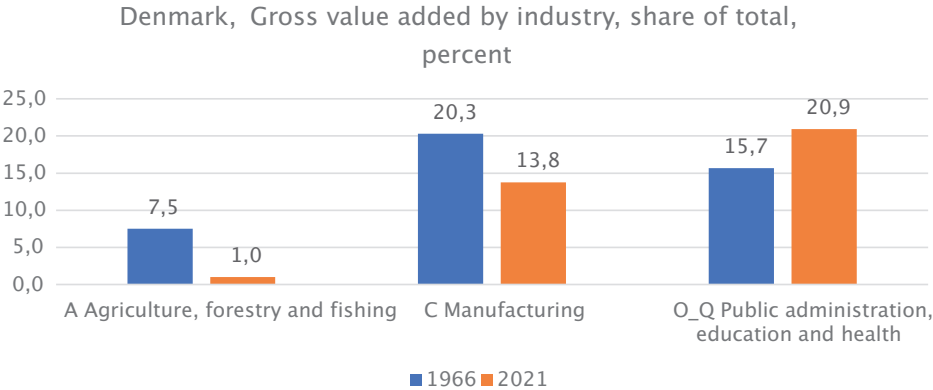
Denmark joined the European project in 1973, during the so-called first enlargement - together with Ireland and the United Kingdom. The first enlargement was followed by the Mediterranean enlargement of 1981-1986, the Nordic enlargement of 1995 and the Eastern enlargement of 2004-2013. Some of the new member states (Denmark, the UK, Sweden) helped to speed up the transition towards a service-based economy. The accession of countries with relatively large agricultural sectors (Lithuania, Poland, Romania and others) slowed the transition, but did not halt the change.

The health sector: impossible to ignore

Unlike other industries, the health sector, which includes the pharmaceutical and medical device industry, hospitals and nursing, pharmacies, dentistry, and other services, has grown in the context of EU expansion.

Eurostat figures for the Eurozone (Figure 5) show that employment in health is now almost twice as large as economic sectors that dominated European policy at the start of European integration (European Coal and Steel Community, Common Agricultural Policy).

13   National Statistics of Denmark (2023) *Economy of Denmark* (Copenhagen: DST).

Figure 5. Employment in Eurozone[14]

National accounts employment data by industry, million persons, Eurozone

■ Agriculture, forestry and fishing; Mining and quarrying; Manufacture of basic metals   ■ Human health activities
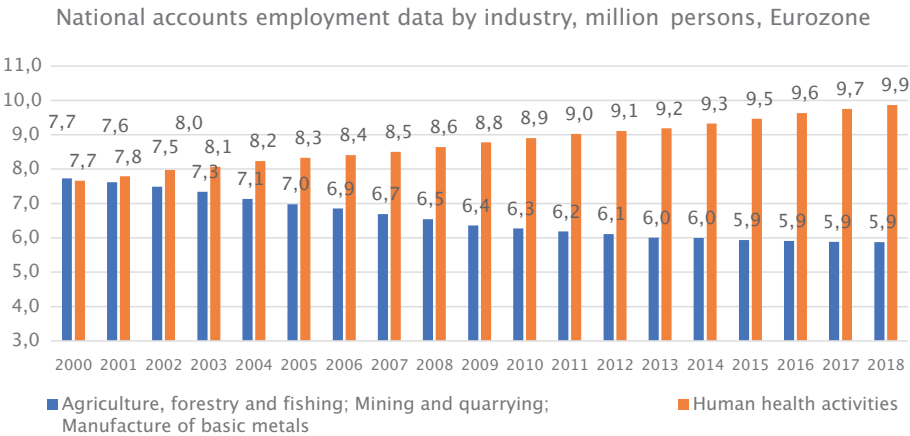
The macroeconomic importance of health, education and other social sectors is reflected by the structure of public finances of European countries, as Table 2 shows.

Table 2. General government expenditures by function as a percentage of GDP, 2019[15]

	General public services	Defence, Public order	Economic affairs	Environmental protection, Housing, Recreation	Health	Education	Social	Total
France	5.5	3.3	6	3.5	8	5.3	23.9	55.5
Germany	5.7	2.7	3.3	2	7.4	4.3	19.7	45.1
Italy	7.5	3.1	4	2.2	6.8	3.9	21	48.5
Poland	4.2	3.7	4.8	2.3	4.9	5	16.7	41.6
Spain	5.5	2.6	4	2.4	6.1	4	17.4	42
Average, unweighted	5.7	3.1	4.4	2.48	6.6	4.5	19.7	46.5

Table 2 shows that:
- Government expenditure of member states equals 40-55% of GDP.
- The social sector has the biggest share of public finances and equals 16-24% of GDP or about 40% of total general government expenditure.

14   Eurostat (2023) *Database* (Luxembourg: Eurostat).
15   OECD (2021) *Government at a Glance 2021* (Paris: OECD Publishing).

- Public expenditure for health in most member states equals 5-8% of GDP or about 14% of total general government expenditure (the second biggest expenditure line).

The rebuilding and modernisation of manufacturing and agriculture were the main national priorities in the aftermath of WWII. Today, national governments in Europe are investing more public resources into health (just one of the social sectors) than into economic affairs.

Spinelli's vision that "economic forces must not dominate man, but rather — as for the forces of Nature — they must be subject to man, guided and controlled by him in the most rational way" looked almost utopian in 1941.[16] Today, it is close to reality across many member states.

A mismatch between national and European policies?

The European project (as it was described in the first section of this chapter) began with policies that were close to national priorities. The objectives of the Monnet Plan and the Paris Treaty that established the European Coal and Steel Community were similar – to modernize and re-equip coal mining, steel, transport and agriculture.

The contemporary development of the European project possesses fewer clear-cut links between the objectives of member states and the pan-European community. Social and health expenditure combined are equal to up to around 55% of total general government expenditure of member states (see Table 2). However, social and health expenditures combined are equal to just up to 7% of the total expenditure of the EU (Figure 6).

Figure 6. Expenditure of the EU in 2010[17]

Expenditure structure of the EU, 2010, %

3,1
0,5
1,7
12,8
6,2
25,6
46,6
3,4

- EMPLOYMENT AND SOCIAL AFFAIRS
- RESEARCH
- EDUCATION AND CULTURE
- AGRICULTURE AND RURAL DEVELOPMENT
- REGIONAL POLICY
- EXTERNAL RELATIONS
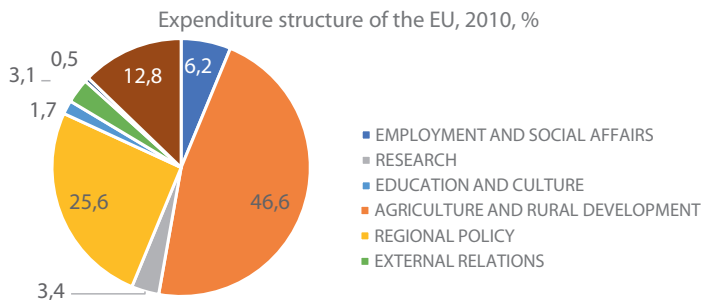
16   Spinelli, A., and E. Rossi (1941) *The Manifesto of Ventotene*
17   Official Journal of the European Union (2012) "Legislation", *OJ,* L 201, 27 July 2012.

Figure 6 shows that:
- The agriculture sector has the biggest share of public finances of the EU - equal to almost 47% of total EU expenditure in 2010.
- Regional policy is the second biggest budget item of the EU, with about 26% of total EU expenditure.
- Culture, Education and Health are the sectors with the most limited support of EU institutions, with health and consumer protection commanding just 0.5% of total EU expenditure.

However, the structure of pan-European expenditure has evolved over time. Comparison of data for 1975 (Table 1) and 2010 (Figure 6) shows that during a period of 35 years:
- The agriculture sector remains the biggest financial beneficiary of pan-European cooperation but its share of EU funding declined from almost 75% to just below 47%.
- The share of social and regional policy increased from about 8% of European financing in 1975 to about 32% in 2010. The majority of funding, through the structural funds, goes to sectors with explicitly indicated responsibilities of the EU (for example, transport).
- Culture, Education and Health were sectors with no budget lines in 1975. Therefore, even the limited support of the EU institutions in 2010 may be considered a significant development.

Why is social sector spending, including health, an unrecognised "Cinderella" of pan-European action? Why priority of health in EU politics is low even if citizens are asking for it? For many EU citizens, talk about the single market, agriculture, fishing and other issues starts to feel similar to a flea market selling secondhand goods produced 50 years ago. Good, but old stories are not so attractive to many Europeans.

One formal explanation is the relatively weak presentation of social issues in European Treaties. The ideas of Spinelli on social reform are implemented across the majority of member state, but they are not key in pan-European policies. The legacy of the Treaty of Rome, with its emphasis on an internal market for manufactured goods and agricultural policy, is predominant in the bloc.

Another explanation is that the socioeconomic fabric of Europe is changing faster than pan-European political agendas and structures.

The health sector starts to receive recognition

The conservativism of pan-European policy (with its emphasis on policy objectives endorsed by the Treaty of Rome) does not mean the absence of dynamics. Politics of Europe is changing. The main changes to pan-European policies of recent decades (beyond the boundaries fixed by the Treaty of Rome) are those related to the Maastricht, Amsterdam and Lisbon Treaties. Among other things, they helped to develop European social and health policies.

The Maastricht Treaty of 1992 was especially important because:
- It strengthened the economic fundamentals of the European project through the establishment of an economic and monetary union with a European Central Bank, ultimately leading to the creation of a single currency.
- It introduced a robust international dimension through the implementation of a common foreign and security policy including the eventual framing of a common defence policy.
- It emphasised the rights and interests of the nationals of its Member States through the introduction of citizenship of the Union.

According to the common provisions of the Maastricht Treaty, the purpose of the European Union "shall be to organize, in a manner demonstrating consistency and solidarity, relations between the Member States and between their peoples".[18]

The emphasis on the rights and interests of nationals and solidarity between the Member States and between their peoples contributed to upgraded lists of the activities of the Community. In addition to activities in sectors that were prioritised from the very beginning of the European project (free movement of goods, services, capital and persons; common policy in the sphere of agriculture and fisheries; common policy in the sphere of transport) new avenues of pan-European cooperation were opened. These included:
- The strengthening of economic and social cohesion.
- A policy in the sphere of the environment.
- The promotion of research and technological development.
- A contribution to the attainment of a high level of health protection.

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18 European Parliament (1992) *Treaty on European Union (TEU) / Maastricht Treaty* (Brussels: European Parliament).

- A contribution to education and training of quality and to the flowering of the cultures of the Member States.

Article 129 of the Maastricht Treaty describes competences of the EU in health: [19]

> 1. The Community shall contribute towards ensuring a high level of human health protection by *encouraging cooperation between the Member States* and, if necessary, lending support to their action.
> Community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education.
> Health protection requirements shall form a constituent part of the Community's other policies.
> 2. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.
> 3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

Public health provisions were strengthened in the Treaty of Amsterdam (1997) with an exclusive emphasis on human health protection and the prevention of human illness and diseases.[20]

The first paragraph of Article 152 (Treaty of Amsterdam) states:

> 1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.
> Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.
> The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

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19   Ibid.
20   European Parliament (1997) *Treaty of Amsterdam* (Brussels: European Parliament).

The Treaty of Amsterdam facilitated the establishment of the Directorate General (DG) dealing with health matters. The DG SANCO (the predecessor of current Directorate General for Health and Food Safety (DG SANTE)) was established in 1999 by augmenting the existing DG on consumer protection.

Reference to a high level of health protection in the Treaty of Amsterdam had a legal background, but the main trigger for the establishment of DG SANCO/DG SANTE was the BSE outbreak that devastated British cattle farming (the largest sector of British agriculture). Food safety remained the main responsibility of DG SANTE, consuming up to 75% of the DG's budget until the start of the Covid-19 pandemic.

Avenues of pan-European cooperation are based on, but not limited to, the Treaties. Other developments at the end of the 20th century (including Schengen, Kohll and Decker, and the Charter of Fundamental Rights) also contributed to a stronger European health policy:

- The Schengen Agreement was signed in 1985 separately from the European Communities, and is an example of an action when consensus could not be reached among all ECember states. The Agreement and its related conventions were incorporated into the mainstream of European Union law by the Amsterdam Treaty. Schengen contributed to the growth of interstate travel in Europe. The European Union became an area without internal frontiers, which facilitated the free movement of persons. Increasing numbers of patients then sought to receive treatment from doctors in other member states.

- In 1998, the European Court of Justice adjudicated two cases in which patients did not request or obtain prior authorisation but nevertheless wished health expenditure to be reimbursed by their health insurance. In delivering the judgments in Kohll and Decker on 28 April 1998, the Court of Justice initiated a long series of judgments, on the basis of which the European Union legislature has substantially altered EU legislation on healthcare.

- The Charter of Fundamental Rights of the European Union was declared in 2000. Article 35 of the Charter (health care) states that: "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities".

Since 2007, the European Union has been governed by the Lisbon Treaty. Article 2 of the Lisbon Treaty states that:

"The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail".

The Lisbon Treaty speaks about matters that reflect progress in Europe since the Maastricht Treaty and far beyond the goals enshrined in the Treaty of Rome. It emphasises:

- A highly competitive social market economy, aiming at full employment and social progress.
- A high level of protection and improvement of the quality of the environment.
- Combating social exclusion and discrimination, promoting social justice and protection, equality between women and men, solidarity between generations, and the protection of the rights of the child.
- Economic, social and territorial cohesion, and solidarity among Member States.
- A respect for Europe's rich cultural and linguistic diversity.
- Ensuring that Europe's cultural heritage is safeguarded and enhanced.

The Maastricht, Amsterdam and Lisbon Treaties shifted the policy objectives of the European project from being focused purely on the production of tangible goods towards the sustainable development of a value-based social market economy. However, the shift has not closed the gap between the current priorities of member states and those of the European Union.

Health - which during recent decades has been established as a key priority and one of biggest sectors at the member state level - is not even mentioned in the Preamble of the Lisbon Treaty or the main articles of the Treaty on European Union. The gap between socioeconomic development of modern societies where health is central, and the legislative and budgetary policy of the EU, where health plays a marginal role, indicates contradictions embedded in the European architecture.

Box 2. Assessment of the functional capacity of the European Commission in health

"Overall, the capacities at EU level for policy making on health systems and public health are scattered. First, regulative power is predominantly with [Member States (MS)] on the basis of Article 168 of the Lisbon Treaty [20]. Article 168(7) grants that the responsibilities for the organisation and financing of healthcare systems rest with MS's. The EU is supposed to complement and coordinate MS actions by establishing guidelines, exchanging best practices, funding research and supporting health monitoring and surveillance (Article 168(1−2)). Only in a limited number of public health domains, such as cross-border threats, substances of human origin, veterinary and phytosanitary measures, medicinal products and medical devices the EU has legislative power (Article 168(4)). The implementation and application of EU legislation in the above described areas remains with MS's like in social policy in general".[21]

Modernisation of the EU during the Juncker Commission (November 2014 - November 2019)

The gap between the socioeconomic development of modern societies where health is central and the legislative and budgetary policy of the EU, where health plays a marginal role, is just one of the issues questioned by European citizens. The Juncker Commission must be credited for publicly recognising the cracks in the European project and for looking at how to fix them.

A call for reassessing the European project was delivered in 2015. The president of the Commission Jean-Claude Juncker, stated: "There is not enough Europe in this Union. And there is not enough union in this Union".

The thesis regarding the weaknesses of the EU was elaborated in an Address 2016. President Juncker used strong words to rally Europeans for reform:

"Our European Union is, at least in part, in an existential crisis (...) Never before have I seen such little common ground between our Member States. So few areas where they agree to work together. Never before

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21   Clemens, T., K. Sørensen, N. Rosenkötter, K. Michelsen, and Brand H (2017) "The Directorate-General for Health and Consumers 1999−2014: An assessment of its functional capacities", *Health Policy,* 121(6): 594-603.

have I heard so many leaders speak only of their domestic problems, with Europe mentioned only in passing, if at all. Never before have I seen representatives of the EU institutions setting very different priorities, sometimes in direct opposition to national governments and national Parliaments. It is as if there is almost no intersection between the EU and its national capitals anymore. Never before have I seen national governments so weakened by the forces of populism and paralysed by the risk of defeat in the next elections. Never before have I seen so much fragmentation, and so little commonality in our Union".

The words of the EC President reflected difficulties in policy making, partially caused by the UK-led movement to take powers back from the EU. The United Kingdom's European Union Membership Referendum of 2016 which resulted in the country leaving the EU was the low point of internal tensions in the community.

Juncker's vision of the mid-term future of Europe in the 2017 Address[22] was concentrated on the genuine implementation of policies already voted into the European Treaties. Themes included:

- The completion of an Energy Union, a Security Union, a Capital Markets Union, a Banking Union and a Digital Single Market.
- Strengthened trade agenda, stronger and more competitive industry, leadership in fighting climate change, digitalisation, and a proper migration policy.
- To be big on big issues and small on the small ones; limited number of new initiatives; giving back competences to Member States where it made sense.

An analysis of a whitepaper on the future of Europe: Reflections and scenarios for the EU27 by 2025 helps to better understand the 2017 Address.[23] The five scenarios presented in this White Paper were developed to help steer a debate on the future of Europe:

Scenario 1: Carrying on: the European Union focuses on delivering its positive reform agenda.

Scenario 2: Nothing but the single market: the European Union is gradually re-centred on the single market.

Scenario 3: For those who want more do more, the European Union allows willing member states to do more together in specific areas.

22   European Parliament (2017) *FUTURE OF EUROPE: European Parliament sets out its vision* (Brussels: European Parliament).
23   European Commission (2017a) *WHITE PAPER. ON THE FUTURE OF EUROPE. Reflections and scenarios for the EU27 by 2025* (Brussels: European Commission).

Scenario 4: Doing less more efficiently, the European Union focuses on delivering more and faster in selected policy areas, while doing less elsewhere.

A scenario where there is a consensus on the need to better tackle certain priorities together, the EU27 decides to focus its attention and limited resources on a reduced number of areas.

Scenario 5: Doing much more together, the European Union decides to do much more together across all policy areas.

Comparing the scenarios described in the white paper with Juncker's 2017 address, "to be big on big issues and small on the small ones" indicates that the Commission's mid-term preferences were mostly with *Scenario 4: Doing less more efficiently, the European Union focuses on delivering more and faster in selected policy areas, while doing less elsewhere.* The assumption that the EU stops acting or does less in areas not directly related to the functioning of the single market indicated that the already limited European cooperation on health might be reduced even further.

In a follow-up of the vision on the future of Europe declared in Address 2017, the Task Force on Subsidiarity, Proportionality and 'Doing Less More Efficiently' was established. In order to directly confront the policy trend of "taking back control from Brussels" the Task Force was asked to look at three issues: (1) the role of local and regional authorities in policymaking and implementation of European Union policies; (2) the role of subsidiarity and proportionality in the work of the Union's institutions and bodies; (3) whether responsibility for particular policy areas should be re-delegated to Member States.

Contrary to the expectations of Eurosceptic politicians, the report of the Task Force proved European value added to most of the pan-European policies and revealed no major policy areas that should be re-delegated to the Member States.

The Juncker Commission was focused on the completion of numerous policies that were enshrined in the Treaties but not completed because of reasons described in Address 2016. At the same time, social policies not explicitly declared in Treaties were on the rise. The Agenda for Sustainable Development and the European Pillar of Social Rights were the main milestones of social progress during this period.

- The 2030 Agenda for Sustainable Development (2015). The agenda confirmed the commitment of its signatories to actively engage in global action for good health. The agenda is framed by 17 sustainable development goals (SDGs). The call enshrined in SDG 3, 'Ensure

healthy lives and promote well-being for all at all ages' is more strongly charged by solidarity for health in comparison to a statement of the Universal Declaration of Human Rights (1948): "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family".[24]

- The European Pillar of Social Rights (2017). The Pillar jointly proclaimed by the main EU institutions during the Gothenburg Social Summit sets out 20 key principles guiding the EU towards a strong, social Europe.[25] Four of these principals explicitly stress the importance of health: 10) Healthy, safe and well-adapted work enviroment and data protection; 11) Childcare and support to children; 16) Health care; 18) Long-term care. Principle 16 of the Pillar (health care) states that: "Everyone has the right to timely access to affordable, preventive and curative health care of good quality".

A European Health Union: Byproduct of Covid-19 or the genuine recognition of fundamentals of European society?

At the time of writing (autumn 2022), Ursula von der Leyen's Commission was in the middle of its first term. It is still too soon to say what the long-term effects of her presidency will be for healthcare.

However, the start of her term was marked by a focus on issues that could transform Europe (for example, the European Green Deal, the fight against cancer, and reforming the finances of the EU). These novelties President-elect of the European Commission indicated speaking to the European Parliament in November 2019.

The Von der Leyen Commission began in December 2019. Just a few months later, the Covid-19 pandemic struck Europe. The pandemic caused thousands of deaths, paralysis of social life, and economic downturn. It revealed weakness in - and at the same time the resilience of - the European project. Critically, it led to the emergence of a new narrative around European Union health policy.

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24   United Nations (1948) *Universal Declaration of Human Rights. United Nations General Assembly in Paris on 10 December 1948 (General Assembly resolution 217 A)* (New York: United Nations).
25   European Commission (2017b) *European Pillar of Social Rights* (Brussels: European Commission).

Covid-19 undermined the notion that the European Union has little to do with health. The inclusion of a question related to health as a European priority in the Standard Eurobarometer survey revealed that EU citizens are very serious about health policy at the national as well as European levels.[26] The findings of the very first pan-European survey on European health policy came as a surprise to protagonists of the EU as a mainly economic project. According to the Standard Eurobarometer (summer 2020), citizens in most Member States ranked health among the four most important issues facing the EU.[27]

Findings of recent sociological surveys that indicate strong pro-health sentiments,[28] according to the understanding of authors, were surprising to conservatives who prioritise EU policy topics related to the internal market and economic unions (customs, monetary, banking) - and who believe that the European Union does not and should not care about health and social matters. The same findings strengthened the positions of those who were looking for a stronger social dimension in Europe. The introduction of the term "European Health Union" (EHU) to the European Parliament in the spring of 2020 by S&D[29] was a novelty that appeared to be instrumental in rallying Europeans to resist Covid-19 and was helpful in opening new horizons of European integration (the role of progressives in the development of a contemporary European health policy will be described in a chapter 3.1 of the book).

The 2020 State of the Union Address endorsed the idea of protecting lives and livelihoods in Europe, the health of our citizens and the stability of our economy as a priority, by building "a stronger European Health Union".[30] The initiative was supported by a series of bold proposals:
- Increased funding for the new EU4Health programme.
- Strengthening of crisis preparedness and management of cross-border health threats.

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26   European Commission (2023) *Eurobarometer* (Brussels: European Commission).
27   European Commission (2020) *Standard Eurobarometer 93 - Summer 2020* (Brussels: European Commission).
28   European Commission (2023) *Eurobarometer*.
29   S&D (2020) *Letter of the Socialists and Democrats to the presidents of the European Council, the Council and the European Commission of 7 May 2020; Socialists and Democrats Position Paper A EUROPEAN HEALTH UNION - INCREASING EU COMPETENCE IN HEALTH - COPING WITH COVID19 AND LOOKING TO THE FUTURE*. 12 May 2020 (Brussels: S&D)
30   Von der Leyen, U (2020). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Brussels, 16 September 2020.

- Reinforcement and empowerment of the European Medicines Agency (EMA) and ECDC (European Centre for Disease Prevention and Control).
- Building a European BARDA – a U.S. agency for Biomedical Advanced Research and Development (the initiative was downsized to Health Emergency Preparedness and Response (HERA) in 2021).
- Strategic stockpiling to address supply chain dependencies, notably for pharmaceutical products.

The proposal to discuss the question of health competencies on the platform of the Conference on the Future of Europe was voiced by the President of the EC in the 2020 address.

The 2021 address elaborated on progress in health since the previous presentation:[31]
- More than 70% of adults in the EU were fully vaccinated.
- The EU delivered more than 700 million doses to the European people, and more than another 700 million doses to the rest of the world to more than 130 countries.
- The HERA authority was up and running.
- More than 400 million EU digital certificates have been generated across Europe. Forty-two countries in four continents were plugged into the system.

Evidence of European value-added - that the net benefits of European action exceeded the net benefits of a Member State acting alone - is needed to promote pan-European actions in health. The Covid-19 experiences noted in Address 2021 provide this evidence.

In the case of vaccines, the EU prefinanced research and development (R&D) and jointly procured Covid-19 vaccines through an Advanced Purchasing Agreement. The pooling of European public resources for the vaccines as European public goods appeared to be more efficient in comparison to market-driven R&D of private goods and competitive bidding for vaccines by Member States. Similarly, the EU Digital Covid Certificate pooled European digital and administrative resources to develop a gateway through which all Covid certificates issued by national authorities could be verified across the EU. The novel public health tool was instrumental in restoring the free movement of people across the EU and beyond.

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31   Von der Leyen, U (2021). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Strasbourg, 15 September 2021.

The 2022 Address elaborated on new political initiatives in health:[32]
- Continuing the vaccination efforts in Europe and speeding up vaccination globally, as well as strengthening pandemic preparedness.
- Ensuring fairer working conditions and better healthcare, and creating more opportunities for Europe's youth to benefit from the European social market economy.
- New health preparedness and resilience mission for the whole of the EU, backed up by Team Europe investment of €50 billion by 2027.
- The implementation of the European Pillar of Social Rights – to ensure decent jobs, fairer working conditions, better healthcare and better balance in people's lives.
- A new European Care Strategy to support men and women in finding the best care and the best life balance for them.

Although the 2022 Address was mainly about the containment of shock waves created by the war in Ukraine, a new European mental health initiative was introduced. This is an indication that a call to strengthen European health policy and the pledge to create a genuine European Health Union would continue after the Covid-19 pandemic had receded.

The scope of health-related policy initiatives of the EU during 2020-2022 is unprecedented. Covid-19 triggered developments the EU was getting ready for during its transformation from an industrial to a service-based society.

Conclusion: Can a European Health Union happen without Treaty change?

Most breakthrough initiatives of the European project (such as the common agricultural policy, monetary union, defense union and others) have been launched by Treaty changes and an implementation process. The strengthening of health policy, by contrast, started with policy documents[33], as well as article 168 of the Treaty of Functioning of the European Union (TFEU).

The EU has great powers to regulate the functioning of the internal market, and to protect the rights of consumers, and this is enshrined in

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32   Von der Leyen, U (2022). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Strasbourg, 14 September 2022.

33   *European Social Charter; The Charter of the Fundamental Rights of the European Union*; *The European Pillar of Social Rights*

the Treaty of Lisbon as a sharing competence. But in the field of health, the EU's powers are weak, and this is highlighted as a constitutional asymmetry in the legal regulation of health matters.

There *is* public support for an EU to improve health. The strengthening of health policy over time shows that member states and European institutions have an interest in moving towards a European Health Union, with or without Treaty change. However, proponents of a more sustainable development of a European Health Union argue that without its legal framing in European Treaties, such a health union would be at risk in the long term. But, one way or another, Spinelli's original vision of a more social Europe appears to finally be within reach.

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Helmut Brand

1.3 | Public Opinion on a European Health Union

Introduction

The role of public opinion is of prominent importance in representative democracies, where one of the fundamental expectations is that public policy is a function of public opinion – regardless of whether this expectation is met in practice.[1] However, this relationship between policy and public opinion is not straightforward in the European Union context. Public opinion evolved from being irrelevant to EU policies to an increasingly crucial factor in the EU integration process. This change in the role of public opinion is partially ascribed to the increasing politicisation of the EU in domestic politics.

In the preceding chapters, we delved into the economic, demographic, and institutional changes in Europe and the progressive development of the European project. In this chapter, we will concisely explore the evolution of EU public opinion over the history of the EU and its role in EU and national policies. Moreover, we will touch on the avenues through which public opinion can affect EU policies and the tools that the EU uses to probe the views of its citizens. Finally, the most recent opinion surveys will be analysed and verified against the citizen-led Conference on the Future of Europe's proposals to establish the public opinion climate regarding health-related issues within the EU.

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1   Wlezien, C., and S. N. Soroka (2016) "Public opinion and public policy", in *Oxford Research Encyclopedia of Politics* (Oxford: Oxford University Press).

1. Overview of the Role of Citizens' Will in the Political Process of the EU

During the early stages of the European project (1958 until the 1990s), European governance and legal system were mainly pushed by economic dispute adjudication between firms. This highly technocratic impetus drove the EU's policymaking process and rendered public opinion quiescent.[2] During those decades, the national and European elites shepherded European integration. Public opinion was peripheral to following European political and economic integration during this period, and was referred to as *permissive consensus*.

Nonetheless, since the final decade of the last century, public opinion has shifted to a more central role in the EU policy scene, coined by theorists as *constraining dissensus*.[3] Over time, EU integration has deepened, and EU issues (like the Eurozone debt crisis, the immigration challenge, Brexit, the Covid-19 pandemic response, etc.) have become increasingly politicised in national and European elections. Moreover, the rise of Eurosceptic parties and the increased salience of EU issues to domestic politics made understanding public opinion instrumental for political leaders to consider during their regional negotiations and cooperation strategies.[4, 5] This shift closed the political circle in the EU. On the one hand, the EU's policy choices are stimulated by domestic politics, which reflects the goals and constraints of the public. On the other hand, domestic politics, in turn, is influenced by these policy choices.[6] This circle is demonstrated in Figure 1.

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2   Hooghe, L., and G. Marks (2009) "A Postfunctionalist Theory of European Integration: From Permissive Consensus to Constraining", *British Journal of Political Science*, 39(1): 1–23.

3   Ibid.

4   Schneider, C. J. (2013) "Globalizing electoral politics: Political competence and distributional bargaining in the European Union", in *World Politics*, 65(3): 452-490.

5   Hobolt, S. B., and C. E. de Vries (2016) "Public Support for European Integration", *Annual Review of Political Science,* 19 (1): 413–432.

6   Schneider, C. J. (2017) "The Political Economy of Regional Integration", *Annual Review of Political Science*, 20(1): 229–248.

Figure 1. The EU policy influence circle.
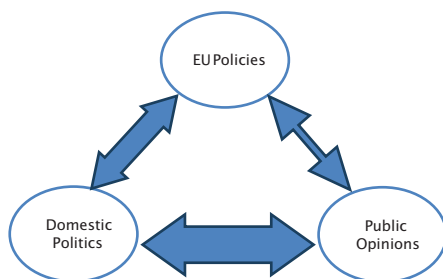
Source – authors' own design

2. How Does Public Opinion Affect the EU Policymaking Process?

The EU public can voice their views, goals, and constraints on EU politics through referendums, European and national parliamentary elections, and the EU policymaking process.[7] These avenues through which the EU public can affect the EU will be demonstrated with examples to convey the relevancy of each.

Referendums

Since 1972, EU member states have witnessed more than 45 referendums on EU-related issues, most of which are on whether to become a member of the EU. That said, referendums have touched on other EU-related issues, such as adopting the euro and other EU policies. In this regard, the Maastricht Treaty (the Treaty on the Functioning of the European Union) in 1992 and the following ratification process triggered several referendums around the EU. Ireland ratified the Treaty readily with around 70% support in the public votes; but Denmark rejected it (50.7% of the population voted against), leading to four Danish opt-outs from the Treaty regarding the economic and monetary union and common defence, among others. The Danish referendum of 1992 is among the first examples of when public opinion constrains the governmental effort in European integration.[8]

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7   De Vries, C. E. (2020) "Public opinion in European Union politics", in *Oxford Research Encyclopedia of Politics* (Oxford: Oxford University Press).
8   Ibid.

European and National Parliamentary elections

The European Parliament (EP) elections were regarded, traditionally, as "second-order national elections" where domestic concerns overshadowed the political agenda.[9] That entails a lower turnout in the EP elections compared to the national ones, a high proportion of protest votes, and more support for more minor and ideologically more extreme parties. The EP elections were perceived as a means to voice voters' discontent with domestic politics and to punish and reward the current government. Nevertheless, more recent work by EU scholars has suggested that due to the growing role of the European Parliament in EU policymaking, the behaviour of EU voters became increasingly influenced by the attitudes taken by the EU. Eurosceptic political entrepreneurs spotted and capitalised on the gap between mainstream parties' pro-European position and the Eurosceptic attitudes of a large proportion of EU voters due to a more infringing role of the EU in domestic policymaking. In particular, those more extreme Eurosceptic parties could link issues like austerity and immigration to the European integration project and achieve many electoral successes. EU scholars attributed the surge in Eurosceptic party support in the 2014 EP elections to voters who had been adversely affected by the economic crisis of 2008 and discontent with the EU's handling of the crisis. This electoral reaction suggests that European issues have an impact on EP elections.

That being said, national elections are an instrumental avenue through which public opinions could feed into the EU policymaking process too. The importance of national elections to EU policy is attributed to the fact that national governments are represented in the Council of the EU, which remains the single most powerful decision-making body in the EU. As the ministers in the Council are ultimately accountable to their national parliament, not the EP, national elections might prove more effective for voters to voice their opinions about European integration.[10, 11]

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9   Reif, K., and H. Schmitt (1980) "Nine second-order national elections: A conceptual framework for the analysis of European election results", *European Journal of Political Research*, 8(1): 3−44.

10   De Vries, C. E. (2007) "Sleeping giant: Fact or fairytale? How European integration affects national elections", *European Union Politics*, 8(3), 363−385

11   De Vries, C. E. (2020) "Public opinion in European Union politics".

EU Policy Making

The extent to which public opinion shapes policymaking on European integration has been explored by EU scholars to determine to which degree the priorities of EU and government officials reflect the contours of European public opinion. Some authors have concluded that since the Eurozone crisis, the agenda of the Council of the EU has closely mirrored the ranking of public concerns. This alignment is pushed by the responsiveness of national governments to public opinions in the Council. Especially when those governments face a Eurosceptic domestic electorate or when the EU issue is more salient in domestic party competition. This may largely be the result of an increased likelihood of ratification failures or punishment in domestic elections.[12]

3. Eurobarometer: the EU polling instrument

As noted above, the significance of public opinion has grown in prominence and influence in the policymaking process of the European Union. Consequently, the EU has proactively engaged in polling to gain a comprehensive understanding of public sentiment. This polling has taken various forms. This section will focus on the Eurobarometer, as well as insights from the citizen-led Conference on the Future of Europe.

The Eurobarometer is the polling instrument used by the European Commission, the European Parliament and other EU institutions and agencies to regularly monitor the state of public opinion in Europe on issues related to the European Union as well as attitudes on subjects of a political or social nature. The data produced by the Eurobarometer is provided for experts in public opinion, researchers, media and the public.[13]

The Eurobarometer project was initiated in 1974 within the European Commission and was conceived to "reveal Europeans to themselves".[14] Since then, it has evolved and expanded significantly with different survey tools. In 2007, the European Parliament started commissioning its own regular series of Eurobarometer surveys, focussing on topics specific to

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12   Ibid.
13   European Commission (2023) *Eurobarometer - Retrieved 31 May 2023* (Brussels: European Commission).
14   European Commission (2023) *Eurobarometer - Retrieved 31 May 2023* (Brussels: European Commission).

the European Parliament, including the European elections. Eurobarometer surveys may employ different methodological approaches, depending on the type or topic of the survey. Each survey publication contains technical specifications and explanations on the methodology (face-to-face, telephone, and Online) and sample size used in each of the countries or territories surveyed, as well as information on confidence levels.[15]

The wide range of topics covered consistently over a long time, the regularity of publications, and geographical coverage make the Eurobarometer a unique source of knowledge and information in the European Union. The Eurobarometer data will be used in this chapter to examine the opinions of European citizens and investigate their attitudes towards the European Health Union.

4. Analysis of the recent Eurobarometer surveys

Data were gathered from six Eurobarometer standard surveys (no. 87 and nos. 94-98 conducted between Spring 2017 and Winter 2022-2023), a special European Parliament Autumn 2021 survey, and the Future of Europe 2020 Special Eurobarometer.

Perception of the EU

Tens of thousands of Europeans of different jurisdictions and demographics were surveyed for their views. Some of the health-relevant opinions were obtained and demonstrated in this chapter. Starting with the image of the EU, the vast majority of Europeans hold either a positive or, to a lesser extent, a neutral image of the EU (45% and 36%, respectively). Less than 15% have a negative view - see Figure 2. Notably, a discernible pattern emerges wherein the EU experiences a decline in positive perception following each major challenge it has encountered since 2006. This is evident after the 2008 financial crisis, the Eurozone debt crisis debate in 2011, and the immigration crisis of 2014. However, this pattern reversed after the Covid-19 pandemic, with an increase in positive views of the EU and a reduction in negative sentiments. This distinct pattern is observed in optimism about the EU's future and the trust in EU institutions, as we will see later.

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15   Ibid.

Figure 2. The image of the European Union – a trend over time[16]

This overall positive view of the EU is coupled with optimism about the EU's future, as around 65% of respondents are optimistic about its future. In figure 3, we can identify the same distinct pattern seen in the trends regarding citizens' image of the EU. Optimism has consistently waned following every EU crisis since 2006, apart from during Covid-19, the most devastating global health crisis witnessed in the past century.

Figure 3. The Future of the European Union – a trend over time[17]

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16   European Commission (2023b) *Public opinion in the European Union – First results: winter 2022-2023* (Brussels: European Commission).
17   Ibid.

Despite this optimism, European citizens still feel that their voices do not count in the EU and want to be heard more. This is discernible in that 53% of the surveyed EU citizens disagree with the statement: "My voice counts in the EU". Figure 4 shows the percentages for each MS. When examining countries below the EU average of agreement with the mentioned statement, it is evident that many citizens of eastern and southern EU member states feel their voices hold little weight within the EU. However, there are exceptions to this trend, including France (western) and the Balkan countries (northern), which share similar sentiments. Conversely, surveyed Croatians, Maltese, and Portuguese stand out among southern European countries in feeling that their voices are heard within the EU. Furthermore, the vast majority of Europeans (90% of respondents) want their voices to be heard more in decisions relating to the future of the EU, as demonstrated in Figure 5.
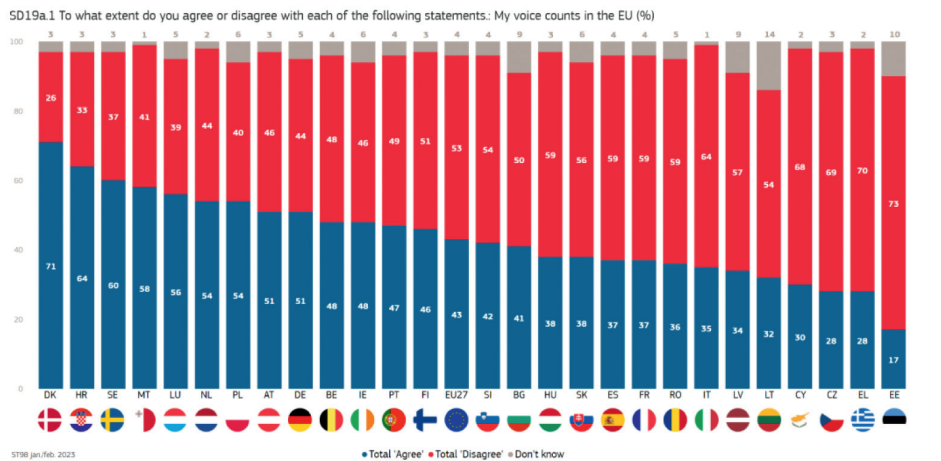
It is evident that Europeans hold a positive perception of the EU and desire to have a more active role and involvement in shaping the future of the Union. This outlook prompts a timely exploration of the concerns voiced by EU citizens and the specific actions they seek from European institutions.

Figure 4. Country percentages of agreement/disagreement with the statement: "My voice counts in the EU".[18]

SD19a.1 To what extent do you agree or disagree with each of the following statements.: My voice counts in the EU (%)

ST98 jan/feb. 2023

● Total 'Agree' ● Total 'Disagree' ● Don't know

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18   European Commission (2023c). *Europeans' opinions about the European Union's priorities – Report* (Brussels: European Commission).

Figure 5. Agreement with the statement: "EU citizens' voice should be more taken into account for decisions relating to the future of Europe".[19]

EU citizens' concerns and demands

EU citizens clearly want to be heard. So, when they were surveyed regarding the most crucial issues at both national and EU levels, the topic of health featured prominently in their responses. Health has consistently ranked among the primary concerns of EU citizens for an extended period. Figure 6 illustrates the long-term trend of major "country-level" concerns since 2007, where health remains a prevalent answer despite fluctuations in other concerns, such as "Unemployment" during the global financial crisis and the Eurozone crisis, or "Immigration" in 2014 and 2015. As might be expected, during the winter of 2020-2021, the health-related concern reached its peak, emerging as the most significant national issue for respondents, as depicted in Figure 7.

Prior to 2019, health was not included as a response option in Eurobarometer surveys regarding the most important issue at the "EU level". However, once introduced in 2019, health quickly emerged as one of the top concerns. Similarly, on country-level issues, during the winter of 2020-2021 (during the second wave of the Covid-19 pandemic), health became the foremost concern among EU citizens, surpassing other

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19   European Commission, European Parliament, Directorate-General for Communication, Directorate-General for Communication, (2021). *Future of Europe – First results: report* (Brussels: European Commission).

concerns such as the economic and financial situation, climate change, immigration, unemployment, and the cost of living, as illustrated in Figure 8.

Figure 6. The most important issues facing EU citizens at the country level between 2007 and 2017[20]

QA3a What do you think are the two most important issues facing (OUR COUNTRY) at the moment?
(% - EU)

Two answers maximum – six most mentioned items

Figure 7. Most important issues facing EU citizens on the country level in 2020 and 2021[21]

QA3a What do you think are the two most important issues facing (OUR COUNTRY) at the moment? (MAX. 2 ANSWERS)
(% - EU)

20   European Commission (2017) *Public opinion in the European Union – First results* (Brussels: European Commission).
21   European Commission (2021) *Public opinion in the European Union   Report* (Brussels: European Commission).

Figure 8. The Most important issues facing the EU at the moment, Summer 2020 and Winter 2020-2021[22]

QA5 What do you think are the two most important issues facing the EU at the moment? (MAX. 2 ANSWERS)
(% - EU)

Further, the European Parliament survey of Autumn 2021 asked EU citizens to prioritise the topics they want the EP to address. Figure 9 shows that most respondents (42%) wanted to see the EP prioritising "public health", followed by "the fight against poverty and social exclusion" (40%) and "action against climate change" (39%). In different orders, though, those priority areas were identified by other Eurobarometer surveys – like the Special Eurobarometer Survey on the Future of Europe 2021. The identified priority topics of action demanded to be addressed by the EU parliament show that Europeans would like to see the European project, through its institutions, growing more social and to have a role in public health and social inequalities.

In addition, the European Commission asked EU citizens about the actions the EU should prioritise in response to the Covid-19 health threat. Consistently, answers leant mainly towards a joint European preparedness and response strategy and a European health policy. Figure 10 presents the responses for spring 2020 and winter 2020-2021. However, this line of answers is comparable with other surveys conducted before and after those years. Notably, during the summer of 2022, the Eurobarometer survey posed a question to Europeans regarding their stance on a "common

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22   Ibid.

EU health policy". The survey results revealed a resounding consensus among Europeans, with an overwhelming 70% of respondents expressing support for the establishment of a common EU health policy.[23]

Finally, trust is the foundation of effective governance and institutional functioning, and when individuals trust institutions such as government agencies, regulatory bodies, and healthcare organisations, they are more likely to comply with policies, seek services, and believe in the system's fairness. Moreover, trust in institutions can positively impact public health outcomes by encouraging cooperation, adherence to public health guidelines, and engagement in preventive measures. This positive impact of trust was evident in the response to the Covid-19 pandemic and other health crises like SARS, H1N1 and Ebola.[24]

Figure 9. Topics that should prioritised by the European Parliament, Autumn 2021[25]

QA4ab Which of the following topics would you like to see addressed in priority by the European Parliament? Firstly? And then? (MAX. 3 ANSWERS) (% - EU27)

Topic	%
PUBLIC HEALTH	42
THE FIGHT AGAINST POVERTY AND SOCIAL EXCLUSION	40
ACTION AGAINST CLIMATE CHANGE	39
SUPPORT TO THE ECONOMY AND THE CREATION OF NEW JOBS	32
DEMOCRACY AND THE RULE OF LAW	25
THE FUTURE OF EUROPE	24
MIGRATION AND ASYLUM	23
THE FIGHT AGAINST TERRORISM AND ORGANISED CRIME	23
THE EU'S DEFENCE AND SECURITY, INCLUDING THE PROTECTION OF EU'S EXTERNAL BORDERS	19
INTERNATIONAL COOPERATION: EXTERNAL RELATIONS, HUMANITARIAN AID, DEVELOPMENT AND TRADE	15
CONSUMER RIGHTS	14
GENDER EQUALITY, INCLUSION AND DIVERSITY	14
AGRICULTURAL POLICY	13
THE EU'S AUTONOMY IN THE FIELDS OF INDUSTRY AND ENERGY	11
THE DIGITALISATION OF THE EUROPEAN ECONOMY AND SOCIETY	9
OTHER (SPONTANEOUS)	1
NONE (SPONTANEOUS)	1
DON'T KNOW	1

23 European Commission (2022) *Public Opinion in the European Union − Annex: summer 2022* (Brussels: European Commission).
24 OECD (2022) *Building Trust to Reinforce Democracy: Main Findings from the 2021 OECD Survey on Drivers of Trust in Public Institutions* (Paris: OECD).
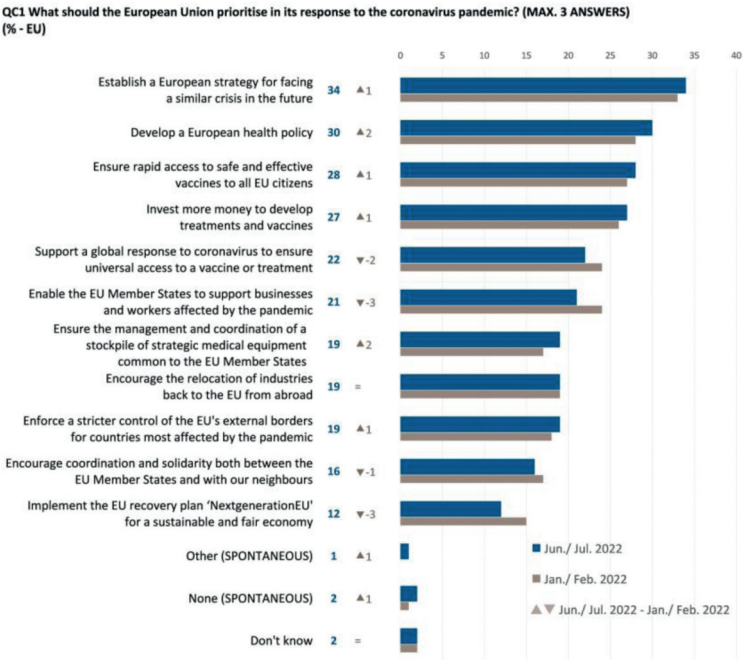25 European Parliament, D. Tsoulou Malakoudi, M. Alpoegger, M. Büttner (2022) *European Parliament Eurobarometer − Defending democracy, empowering citizens: public opinion at the legislature's midpoint* (Brussels: European Parliament).

To gauge trust levels, Europeans were asked to express their trust in the European Union, their national parliament, and their national government. The survey[26] revealed that respondents place significantly higher trust in the EU than in their national institutions. Figure 11 shows this difference amounted to around 15 percentage points in 2022, with 47% for the EU and 32% and 33% for national governments and parliaments.

In the context of European opinions, it is evident that the predominant sentiment is for the EU to enhance its social dimension and play a more prominent role in health governance and policymaking. This sentiment is accompanied by a positive and optimistic perception of the EU and a noteworthy level of trust in the EU that surpasses many citizens' trust in their own national institutions.

Figure 10. Priorities for the coronavirus pandemic response, Winter 2021-2022 and Summer 2022[27]

QC1 What should the European Union prioritise in its response to the coronavirus pandemic? (MAX. 3 ANSWERS) (% - EU)
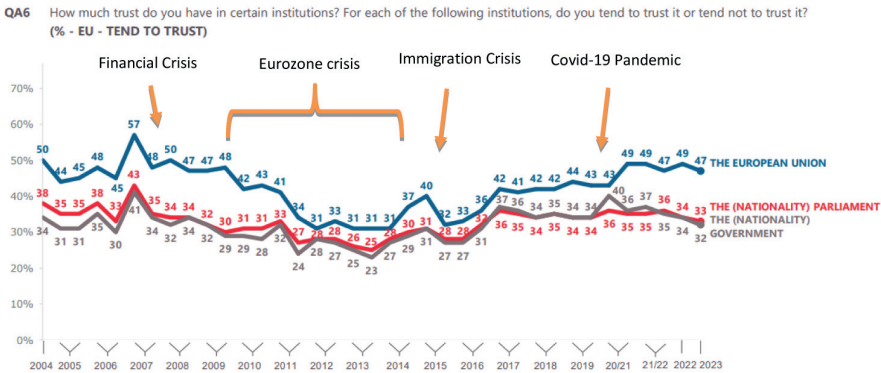
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26   European Commission (2022) *Public Opinion in the European Union − Annex: summer 2022*

27   European Commission (2023a) *Public opinion in the European Union − Report* (Brussels: European Commission).

Figure 11. Trust in national and EU institutions – a trend over time.[28]

1.3.5 The Conference on the Future of Europe

The above-mentioned public opinion surveys will be examined against the Conference on the Future of Europe proposals to give a more complete picture of EU citizens' opinion on health and the desired action from EU institutions.

The Conference on the Future of Europe was a citizen-led series of debates and discussions from April 2021 to May 2022. It was the first of its kind, as a major pan-European democratic exercise with citizen-led debates, enabling people from across Europe to share their ideas and help shape our common future. This was done via an innovative Multilingual Digital Platform where any European could share ideas, as well as via national panels and European Citizens' Panels. There were more than 5 million unique visitors to the platform and more than 700,000 event attendees participated in the Conference.[29]

After an exceptional yearlong journey of discussions, deliberations and collaboration by citizens from across Europe on the kind of Europe they would like to live in, the citizens' panels came up with multiple health-related proposals. European participants called for various health-related objectives and several concrete actions to be considered by the three European institutions on how to follow up effectively on them, each within

their own spheres of competences and in accordance with the Treaties. On the one hand, some of the health-related proposals can be pursued under the current treaties, like those about healthy food and healthy lifestyles, resilience and quality of the healthcare system, and a broader understanding of health (applying the One Health approach) - see Table 1. On the other hand, some of the required actions clearly demanded the amendment of the Treaties, namely Article 4 of the Treaty on the Functioning of the European Union (TFEU), to make Health a shared competence between the two. Table 1 shows the proposed objectives and actions from the Health Panel of the Conference on the Future of Europe.

Box: National Attitudes to an EU Health Union – The Case of Hungary
Publicus Institute, commissioned by the commission of the European Parliament's S&D group, measured public opinion towards the European Health Union by surveying 2,499 individuals in a representative telephone survey in December, 2020.*
The results showed**:
- 71% of the surveyed Hungarians support the creation of the European Health Union.
- 61% would improve/rather improve their opinion about the European Union if a health union were realised.
- 60% rather agree that it would be better if the European Union could have a say in how its member states run their healthcare systems, in order to improve their quality.
- 87% rather agree that a minimum standard of healthcare is needed, that all member states must provide for their citizens.
- 64% rather agree that the European Union should establish a minimum amount that member states must spend on healthcare.

Moreover, in an online consultation regarding the European Health Union in 2020, which primarily involved respondents from professional unions and local governments, revealed that 54% believe that there is a need for a European directive to guarantee universal, non-discriminatory access to publicly funded health services, so that all people have access to socially guaranteed healthcare at a cost that does not affect their quality of life. Conversely, 15% did not agree with the previous statement and 31% did not give a clear answer.***

* Publicus Research (2020) European Health Union – Telephone Survey: December 2020 (Budapest: Publicus Research).
** Note. Political orientation affects the answers. The respondents that favour the opposition party in Hungary are more likely to support a bigger role of the EU in health than those who favour the government in Hungary.
*** Kökèny M., O. Süli, and I. Ujhelyi (2021 *How Could the European Health Union Help the Hungarian Healthcare to Catch-Up?* (Brussels: Foundation for European Progressive Studies).

Table I. The health-related proposals and measures of the Conference on the Future of Europe

Objectives	Measures
Healthy food and healthy lifestyle	- The Conference Plenary proposes setting minimum standards for food quality, and traceability, including limiting the use of antibiotics and other animal medicinal products. - Equally important is educating people about healthy habits from an early age and encouraging them to make safe and healthy choices through better consumer information and labelling. They also recommend investing in research on the impact of the use of antibiotics and the effects of hormonal substances and endocrine disruptors on human health.
Resilience and quality of healthcare systems	Ensuring adequate working conditions and harmonisation of training and certification standards for health professionals, as well as the creation of a European health data space. Investment in health systems should be increased, in particular public and not-for-profit, infrastructure and digital health, and existing health research and innovation programmes should be further developed, coordinated and funded. The Conference Plenary also recommends ensuring strategic autonomy at the EU level to avoid dependency on third countries for medicines and medical devices, as well as coordinated strategic stockpiling throughout the EU.
A broader understanding of health	The EU should adopt a holistic approach to health, addressing, beyond diseases and cures, health literacy and prevention, and fostering a shared understanding of the challenges faced by those who are ill or disabled, in line with the "One Health" approach, which should be emphasised as a horizontal and fundamental principle encompassing all EU policies. The Plenary recommends improving the understanding of mental health issues and ways of addressing them, including the development of an EU Action Plan on mental health. First aid courses should be developed and made available free of charge, and a standard educational programme on healthy lifestyles, also covering sexual education, should be created.
Equal access to health for all	The adopted proposals recommend that a "right to health" should be established to guarantee that all Europeans have equal and universal access to affordable, preventive, curative and quality health care. Access to existing treatments should be ensured, through facilitating cross-border cooperation, notably on rare diseases, cancer, cardiovascular diseases and highly specialised treatments. In order to achieve the necessary coordinated, long-term action at the Union level through an enhanced European Health Union, health and healthcare should be included among the shared competencies between the EU and its member states by amending Article 4 TFEU.

Conclusion

The legitimacy of the European Union heavily relies on public support. Over time, the role of public opinion has evolved and gained more significance in European politics and the integration process. Despite this progress, there is a prevailing sentiment among the majority of EU citizens that their opinions should be given greater consideration.

One prominent issue that concerns Europeans is health. They strongly desire the EU to address public health matters and effectively respond to future health threats through a unified European policy. Recognising the magnitude of this task, Europeans understand that achieving such a policy would necessitate amending the Treaties of the EU.

The demands of Europeans regarding public health issues have been clear and unequivocal. Now, it is up to the politicians of the Union to take action. The responsibility lies in their hands to respond to the aspirations of citizens and take the necessary steps towards building a more comprehensive and cohesive European Health Union. By acknowledging and addressing the public's concerns, politicians can enhance the legitimacy and effectiveness of the EU in matters of public health and strengthen the overall integration process.

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1.4 | European Health Union & Progressive Policy Frameworks

Introduction

This chapter examines how an EHU would interlink with prominent European and global policy frameworks. We will conceptualise the essential components of the EHU against the current Commission's efforts to strengthen it. Subsequently, we will explore the potential alignment and impact of an enhanced EU role in health on crucial policy domains such as the United Nations' Sustainable Development Goals (SDGs) and the European Green Deal. Additionally, we will analyse the interconnectedness between the EHU and the overarching objectives of fostering peace and safeguarding sovereignty in Europe.

1. History and Context

The institutionalisation of EU health policy is relatively recent. Nonetheless, a European health project existed even before the birth of the European Economic Community (EEC). In 1952, the French Council of Ministers adopted a project regarding the creation of a "European Health Community" (*Communauté européenne de la santé* – CES), or "White Pool" (*Pool Blanc*). This project was submitted for discussion at the Organization for European Economic Cooperation meeting by the French Minister of Public Health and Population. The principle of a European Health Community seemed close to being adopted by the states participating in the preparatory conference. However, this project did not materialise.[1]

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1   Davesne, A., and S. Guigner (2013) "La Communauté européenne de la santé (1952-1954): Une redécouverte intergouvernementaliste du projet fonctionnaliste de «pool blanc»", Politique européenne, 41: 40-63.

Those who have looked into this aborted European health community have concluded that it confirms states' hostility to any loss of sovereignty in health matters. For example, writing in 1989, Maryse Cassan considered that "the failure of a Europe of health within the framework of a treaty seems to stem from [....] States' attachment to their sovereignty over health resources".[2] However, an in-depth historical analysis of this case conducted by Davense and Guigner in 2013, concluded that *the situation* and *context* determine what governments can accept to integrate, more than the intrinsic characteristics of the sectors of activity.[3] This highlights the importance of context and political will in the European integration process.

Half a century later, EU institutions concerned with EU health governance have risen in the European health arena. Although those institutions were not inspired by the "White Pool" project, they came as a response to global health challenges. This evolution of the health role of the EU has been marked by a gradual recognition of the importance of health as a fundamental right and the need for coordinated action at the EU level to address health challenges effectively. The European Centre for Disease Prevention and Control (ECDC) (which was created in 2005 to strengthen Europe's defence against infectious diseases following the SARS CoV-1 pandemic) and the Health Security Committee (HSC) (which was strengthened in 2013 and mandated to reinforce the coordination and sharing of best practice and information on national preparedness activities following the H1N1 swine flu pandemic) are examples of this health-related institutionalisation at the EU-level. Although those steps, among many others, were and still are crucial for protecting the health of EU citizens, this evolution of health governance within the EU is regarded by some EU scholars as following the trend of "failing forward"[4] in the EU integration dynamic.[5,6,7]

2   Cassan Maryse (1989) *L'Europe communautaire de la santé* (Paris: Economica), p. 25.
3   Davesne, A., and S. Guigner (2013) "La Communauté européenne de la santé (1952-1954): Une redécouverte intergouvernementaliste du projet fonctionnaliste de « pool blanc »"
4   "Failing forward" happens when the existing level of EU integration creates a shared, European, crisis for which responses need to be European. Member States, defending their freedom of action, take an integrative step forward- but take care to make it the smallest possible step. The result is that while they might address their present crisis, they take what look in future crises like half measures. See Deruelle & Greer, 2022.
5   Deruelle, T., and S. L. Greer (2022) "Will the Covid-19 crisis make the European Health Union?", *Eurohealth*, 28(3).
6   Greer, S. L., et al (2022) E*verything you always wanted to know about European Union health policies but were afraid to ask* (Copenhagen: World Health Organization).
7   Jones, E., R. D. Kelemen, and S. Meunier (2016) "Failing Forward? The Euro Crisis and the Incomplete Nature of European Integration", *Comparative Political Studies*, 49(7): 1010−1034.

In the present context, the Covid-19 pandemic has challenged health systems globally. In spring 2020, the EU was the epicentre of the pandemic, and the efficiency of the current health governance of the union was put on public display. Reactively established institutions, scattered capacities and competencies for policymaking on health systems and public health at the EU level resulted in the fragmented and weak response of the union.[8, 9] It challenged European citizens' vision of on the EU, and meant that people realised that there is no real health competence at the EU level.[10, 11] This realisation translated into European citizens' proposals during the Conference on the Future of Europe (See Chapter 1.3). The political leadership recognised the need for a more significant role for the union in health, as its untapped potential in health governance was made more evident.

2. A European Health Union

The Current EHU

In the 2020 state of the union address, president of the European Commission Ursula von der Leyen said: "*We are changing the way we address cross-border health threats. Today, we start building a European Health Union*".[12] In 2020, the European Commission suggested a package of European Health Union policies, mainly concerned with pandemic prevention, preparedness, and response (PPR) and the fight against cancer. Measures such as reinforcing the mandates of the European Centre for Disease Prevention and Control (ECDC) and European Medicines Agency (EMA), establishing the Health Emergency Response Authority (HERA), and more funding and competences for existing programmes such as the EU4Health programme.

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8   Anderson, M., M. Mckee, and E. Mossialos, (2020) "Covid-19 exposes weaknesses in European response to outbreaks". *Bmj*, 368.

9   David Townend et al (2020) "What Is the Role of the European Union in the COVID-19 Pandemic?", *Medicine and Law,* 39(2), 249

10   Greer, S. L., et al (2022) E*verything you always wanted to know about European Union health policies but were afraid to ask.*

11   European Union (2020) *Uncertainty/EU/Hope: Public Opinion in Times of Covid-19* (Brussels: European Union).

12   Von der Leyen, U (2020). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Brussels, 16 September 2020.

Although an important step, this can still be seen as a "fail forward", in the sense that these measures are incomplete. The Covid-19 pandemic focused interest only on health protection from the virus, prevention, and treatment. Other equally important areas of health and public health remain out of focus. If the virus had occurred due to global warming, measures to control global warming would now be number one on the hit list of political talk shows and interventions. Focusing EU health policy purely on ongoing pandemic control would, therefore, fall short in the medium term.[13]

A True European Health Union

We envision the European Health Union as the "European Union's concern about health for all".[14] This definition aligns with the WHO's "health for all" concept,[15] which indicates that health is to be brought within reach of everyone. "Health for all" is a holistic concept which calls for efforts in agriculture, industry, education, housing, and communications, just as much as in medicine and public health. Medical care alone cannot bring health to hungry people living in poverty. Health for such people requires a whole new way of life and fresh opportunities to provide themselves with a higher standard of living.[16] Appropriately, the European Union is well-positioned to address this comprehensive health perspective through its role in critical policy areas, like the economy and agriculture, and its efforts within other policy frameworks like the SDGs, the Digital Agenda, and the European Green Deal.

European health integration is not about substituting or overtaking the role of member states (MS) in health-related areas, nor about consolidating more power in Brussels. It is about equipping the EU with the necessary competence to support and complement the actions of every MS. It is about delivering the promises of the MS and the EU to their

13   Brand, H (2021) "Auf dem Weg zu einer Europäischen Gesundheitsunion - im Zeichen der Corona-Krise", in A. Gärber (ed.), *Europa.Besser.Machen: Vorschläge für eine progressive Wirtschaftspolitik* (Fanrkfurt: Campus Verlag) pp. 320-330.
14   Nabbe, M., and H. Brand (2021) "The European Health Union: European Union's Concern about Health for All. Concepts, Definition, and Scenarios", *Healthcare*, 9(12): 1741.
15   World Health Organization. Regional Office for Europe (1999) "HEALTH21: the health for all policy framework for the WHO European Region". *World Health Organization. Regional Office for Europe*.
16   Mahler, H. (1981) "The meaning of health for all by the year 2000", *World Health Forum,* Vol. 2, pp. 5-22.

citizens - the promise of ensuring a high level of human health. The EHU is about pursuing the EU's commitment to put people first and to build a more resilient union for the future.

We must seize this opportune moment following the Covid-19 pandemic to anchor an EU health policy beyond pandemic PPR and comprehensively addresses relevant health challenges in both communicable and non-communicable diseases. Nonetheless, the defining elements of the areas where the EHU is expected to be involved are still developing. Therefore, we envision the following set of criteria as the parameters that would determine the eligible areas of EHU action:

- When a member state is overburdened with the issue at hand.
- Cooperation between different member states on an issue brings added value.
- There are evident consequences to health.
- When a health issue causes public distress.
- There is a cross-border nature to the health issue at hand.
- There is a possible, timely, and socially accepted action at the EU level to address it.

3. The EHU interlinkage with other policy frameworks

The context of Covid-19 accelerated the discussion about a more integrated and comprehensive approach to health within the EU. However, The EHU is not only a response to the current crisis but also a vision for a healthier and more prosperous future for all Europeans – the EU's concern about "health for all".[17] The EHU is, therefore, a comprehensive and holistic approach to improving health outcomes and wellbeing for all Europeans while also advancing other strategic goals of the EU. The success of the EHU lies not only in its individual merits but also in its ability to synergise and interlink with other key policy frameworks and objectives.

In this section, we will explore the interlinkage and alignment of an EU with a greater role in health with other crucial European and global policy frameworks like the European Green Deal, the European Pillar of Social Rights, the Digital Agenda, SDGs, Peace in Europe, and European Sovereignty.

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17   Nabbe, M., and H. Brand (2021) "The European Health Union: European Union's Concern about Health for All. Concepts, Definition, and Scenarios", *Healthcare*, 9(12): 1741.

The European Health Union and the European Green Deal

The European Green Deal is a comprehensive set of policy initiatives that strive to make Europe the first climate-neutral continent by 2050 and to protect human health and well-being from environment-related risks and impacts.[18] The measures needed to implement the European Green Deal demonstrate the urgent need for a stronger and more ambitious EU health policy. A greater role of the European Union in health can significantly affect the European Green Deal on many levels and through different aspects. The following are some of those aspects:

- The EHU would enhance the *co-benefits* of the green transition for health and well-being, such as reducing air pollution, improving diets, promoting physical activity, and preventing disease.
- It would support the *resilience* of health systems and communities to cope with the impacts of climate change and environmental degradation, such as heatwaves, floods, droughts, wildfires, infectious diseases, and mental stress. This would require investing in adaptation measures, health workforce training, emergency preparedness, and health surveillance[19, 20]
- An EHU would *foster innovation* in health technologies and practices that can contribute to the green transition, such as digital health solutions, circular economy models, sustainable procurement, and green public health interventions. According to the IPCC's Sixth Assessment Report, *Climate Change 2023*,[21] public health policies can advance a transition to sustainable and healthy diets, bringing significant co-benefits for the economy, climate and health. It can also create space to tackle antimicrobial resistance (AMR) and other food systems challenges, including biodiversity loss, GHG-intensive consumption, and agriculture-related air pollution.[22]
- It would *strengthen the governance* of health and environmental policies at the EU level to reinforce the mainstreaming of sustainability

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18   European Council (2022) *European Green Deal - Consilium* (Brussels: European Council).
19   WHO (2023) *Building climate-resilient health systems* (Geneva: WHO).
20   European Council (2022) *European Green Deal - Consilium*
21   Lee, H., et al (2023) *AR6 Synthesis Report: Climate Change 2023, Synthesis Report* (Geneva: IPCC).
22   Shukla, P. R., et al (2019) *IPCC, 2019: Climate Change and Land: an IPCC special report on climate change, desertification, land degradation, sustainable land management, food security, and greenhouse gas fluxes in terrestrial ecosystems* (Geneva: IPCC).

in all EU policies and climate emergency mitigation and adaptation into EU sectoral policies and EU funds as an essential component of a successful comprehensive policy. This process will include infrastructure, agriculture and forestry, marine, fisheries and coastal areas, water management, biodiversity, disaster risk reduction, and health. This strengthened governance would ensure coherence, coordination, and participation of all relevant actors and stakeholders.

The European Green Deal has the potential to implement the principles of the "Health in All Policies" approach so that health policy breaks outside the healthcare silo. Given that the European Green Deal was formulated before the Covid-19 pandemic, it necessitates reassessment to ensure its alignment with a post-pandemic healthy recovery. A coherent public health narrative injected into this strategy could unleash Europe's hidden potential to improve population health and well-being while ensuring climate and environmental sustainability.

The European Health Union and the European Pillar of Social Rights

The European Pillar of Social Rights (EPSR) sets out 20 key principles which represent the beacon guiding us towards a strong social Europe that is fair, inclusive and full of opportunity in the 21st century (Figure 1).[23] Initiated by the European Commission and proclaimed by the European Parliament, the European Commission and the Council in November 2017 in Gothenburg, the EPSR is built around three main principles: equal opportunities and access to the labour market, fair working conditions, and social protection and inclusion. A greater role for the EU in health can affect several health-related and non-health-related principles of the EPSR. Some possible effects include:

- Contribute to realising the right to *access quality healthcare*, a key principle of the European Pillar of Social Rights. By strengthening its role in health, the EU can work towards achieving universal access to healthcare across member states. This can include initiatives to reduce healthcare inequalities, improve infrastructure, and ensure affordable and timely access to healthcare services.

23 European Commission (2018) *European pillar of social rights, Publications Office* (Brussels: European Commission).

- Health-related issues often have significant social and economic consequences for individuals and communities. By addressing health challenges more comprehensively, the EU can *enhance social protection measures* within the pillar. This can involve strengthening social safety nets, supporting individuals facing health-related financial burdens, and implementing measures to protect vulnerable populations, such as those with chronic illnesses or disabilities.
- The EU's increased role in health can affect the relationship between *employment and health* within the pillar. Promoting healthy work environments, occupational safety, and workers' well-being is crucial to the pillar's principle of fair working conditions. The EU can support initiatives prioritising workers' health, such as promoting work-life balance, addressing workplace stress, and ensuring access to occupational health services.
- By addressing the social determinants of health and promoting health equity, the EHU can advance the pillar's central principles of *social inclusion and the fight against poverty*. The EHU can contribute to reducing health-related disparities and promoting social inclusion. This can involve targeted initiatives to address health inequalities among different social groups, ensuring that everyone has access to quality healthcare regardless of socioeconomic status.
- The EU's focus on health can also impact the pillar's objectives related to active ageing and long-term care. By promoting healthy ageing strategies, supporting preventive healthcare measures, and investing in long-term care services, the EU can contribute to enabling older adults to live independently, with dignity, and actively participate in society. This aligns with the pillar's principles of *equal opportunities, non-discrimination, and support for older persons.*

In short, a greater role of the EU in health has the potential to reinforce and interlink with various dimensions of the EPSR. By addressing access to healthcare, social protection, employment, social inclusion, and active ageing, the EU can contribute to realising a social Europe that embodies fairness, inclusivity, and opportunity for all.

Figure 1. The principles of the European Pillar of Social Rights[24]

The European Health Union and the Digital Agenda

In 2020, the second five-year digital strategy – Shaping Europe's Digital Future – was developed, focusing on three key objectives: technology that works for people, a fair and competitive economy, and an open, democratic and sustainable society. In 2021, the strategy was complemented by the 10-year digital compass: *The European way for the digital decade*, which puts the EU's digital ambitions for 2030 into concrete terms.[25] The EHU and the EU digital agenda mutually affect each other in several ways:

- An enhanced health role of the EU would support the development and deployment of *digital technologies that can improve health and care services*, such as artificial intelligence, 5G, cloud computing, blockchain, and supercomputing. The EU has been investing in research and innovation projects, as well as in digital infrastructure and connectivity, to enable the creation and use of digital solutions that can enhance the prevention, diagnosis, treatment, and monitoring of diseases, as well as the empowerment and participation of citizens and patients. The EU has also been promoting common standards

24   European Commission (2023) *Employment, Social Affairs & Inclusion* (Brussels: European Commission).
25   European Parliament (2022) *Digital Agenda for Europe: Fact Sheets on the European Union* (Brussels: European Parliament).

and interoperability for health data and systems, as well as ensuring data protection and cybersecurity for health information.

- The EHU would foster the creation of the *European Health Data Space* that can facilitate the access, exchange, and use of health data across the EU for different purposes, such as healthcare delivery, public health, research and innovation, policymaking, and regulation. The EU has been working on a European Health Data Space legislative proposal. The proposal aims to provide a clear and harmonised framework for the governance, quality, and reuse of health data and to ensure respect for patients' rights and ethical principles. The European Health Data Space is expected to benefit citizens, health professionals, researchers, innovators, public authorities, and industry.[26]
- The EHU would contribute to *society's digital transformation* and the achievement of the EU's strategic objectives for 2030. The EU has adopted a digital compass that sets out four cardinal points for the digital decade: 1) digitally skilled citizens and highly skilled digital professionals; 2) secure, performant and sustainable digital infrastructures; 3) digital transformation of businesses; and 4) digitalisation of public services.[27] The EU has also identified several areas where digital technologies can positively impact people's lives and the planet's sustainability, such as the environment, education, mobility, agriculture, energy, finance, public administration and skills. Health is one of these areas where digital can make a difference by improving health outcomes, reducing health inequalities, enhancing health system resilience, and supporting the green transition.[28]

The European Health Union and Peace in Europe

The EU has been developing its common foreign and security policy, as well as its defence and security cooperation, to address the changing geopolitical environment and the increasing threats to European security, such as Russia's aggression against Ukraine, terrorism, cyberattacks, disinformation, climate change, and the proliferation of weapons of mass

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26 European Commission (2022a) *Shaping Europe's Digital Future: eHealth* (Brussels: European Commission).
27 European Commission (2021b) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS 2030 Digital Compass: the European way for the Digital Decade* (Brussels: European Commission).
28 European Commission (2022a) *Shaping Europe's Digital Future: eHealth*

destruction. By enhancing its health capacity and resilience, the EU would strengthen the EU's strategic autonomy and its ability to act as a global actor in promoting peace and security internationally. Furthermore, it would also be able to protect its citizens and values and support its partners and allies in the face of health emergencies that may have political, economic, social, or humanitarian implications.[29] The following are dimensions of possible EHU actions to promote peace in Europe and the globe:

- The EHU would foster *solidarity and cooperation* among EU member states and other countries and regions. The Covid-19 pandemic has shown the importance of coordination and collaboration among European countries to protect people's health, both during a crisis and in normal times when we can tackle underlying health conditions, invest in strong health systems and train the healthcare workforce. As previously mentioned, the EU has been working to improve its crisis preparedness and response mechanisms, such as the joint procurement of medicines and medical devices, the European Health Data Space, and reinforcing the mandate of the ECDC and the EMA. The EU has also supported global health initiatives, such as COVAX, ACT-Accelerator, and Gavi,[30] to ensure equitable access to vaccines, diagnostics, and treatments for Covid-19 and other diseases.[31] By enhancing its health solidarity and cooperation, the EU would also be able to build trust and confidence among its member states and partners, as well as prevent or resolve potential conflicts or tensions that may arise from health disparities or inequalities.[32, 33]

- It would contribute to the *well-being and human rights* of its citizens and of people around the world. The EHU pursues a comprehensive approach to health that encompasses not only the prevention and

29   Lazarou, E. and I. Zamfir (2022) *Peace and Security in 2022 – Overview of EU action and outlook for the future* (Brussels: European Parliament).
30   COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator. The ACT Accelerator is a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. GAVI, The Vaccine Alliance (GAVI) was set up as a Global Health Partnership in 2000 with the goal of creating equal access to new and underused vaccines for children living in the world's poorest countries.
31   European Commission (2021a) *Factsheet - Team Europe Covid-19 global solidarity* (Brussels: European Commission)
32   Lazarou, E. and I. Zamfir (2022) *Peace and Security in 2022 – Overview of EU action and outlook for the future*.
33   European Union (2022) *World Health Assembly: Health for peace, peace for health* (Brussels: European Union).

treatment of diseases but also the promotion of healthy lifestyles, mental health, environmental health, social determinants of health, gender equality, and digital health.[34] It would also improve the quality of life and dignity of its citizens and people around the world, as well as advance the respect for human rights and democracy that are essential for peace.

- The EU's increased engagement in health can serve as a platform for *diplomatic efforts and international cooperation*. The EU can actively participate in global health initiatives, collaborate with international organisations, and engage in health diplomacy with non-EU countries. By promoting dialogue, sharing best practices, and supporting global health initiatives, the EU can build bridges, foster international cooperation, and maintain peaceful relations.
- A stronger EU role in health can help *improve the resilience and effectiveness of national health systems*. The EU can provide support and guidance to member states in areas such as healthcare infrastructure development, healthcare workforce training, and the coordination of health services. Robust and well-functioning health systems are essential for responding to health crises, and their strengthening can enhance overall societal stability and contribute to peace.

In conclusion, the European Union's efforts to enhance its health capacity and resilience hold significant implications for peace and security, both within Europe and globally. By fostering solidarity and cooperation among member states and beyond, the EU can effectively address health emergencies, protect its citizens, and support its partners and allies. Furthermore, the EU's engagement in health provides a platform for diplomatic efforts, international cooperation, and the improvement of national health systems, ultimately bolstering societal stability and contributing to a peaceful environment. As the EU continues to prioritise and strengthen its role in health, it can position itself as a global actor capable of effectively addressing and leading efforts to combat global challenges.

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34   Habimana, K., M. A. Haasis, and S. Vogler (2022) *The 75th World Health Assembly "Health for peace and peace for health"* (Brussels: European Parliament).

The European Health Union and European Sovereignty

Facing the current dynamic global health landscape, realising a health union will affect European sovereignty. Aiming to enhance self-reliance, support integration in health policies and governance, and boost EU influence in global health, the EHU can be interlinked with many dimensions of sovereignty:

- The European Health Union would enhance the *autonomy and resilience* of the EU and its member states to cope with health emergencies, such as pandemics, bioterrorism, or environmental disasters, without depending on external actors or supplies. This would require building common strategic stocks, diversifying and reshoring supply chains, strengthening health security and surveillance, and ensuring access to quality healthcare for all.[35]
- It would boost the *influence and leadership* of the EU in shaping the global health agenda and promoting its values and standards, such as human rights, democracy, and multilateralism. The EU can exert greater influence in international health organisations and negotiations by speaking with a unified voice and pooling resources. This could enhance the EU's ability to shape global health policies and standards. Nonetheless, this would require coordinating the external actions of the EU and its member states, engaging with strategic partners and regions, and supporting the reform and strengthening of multilateral health institutions, such as the World Health Organization.[36]
- It would foster *innovation and competitiveness* of the EU in health technologies and industries, such as digital health, biotechnology, pharmaceuticals, and medical devices. This would require investing in research and development, protecting intellectual property rights, enhancing investment screening and export controls, and creating a single market for health.[37]
- A greater EU role in health can *promote coordination and cooperation* among member states in addressing health challenges. By pooling resources, sharing expertise, and coordinating responses to health crises, the EU can enhance the collective ability of European nations

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35   Hackenbroich, J., J. Shapiro, and T. Varma (2020) "Health sovereignty: How to build a resilient European response to pandemics", *European View,* 19(2).

36   Leonard, M., and J. Shapiro (2020) Sovereign Europe, Dangerous World: Five Agendas to Protect Europe's Capacity to Act (Berlin: ECFR).

37   European Commission (2022b) *Supporting policy with scientific evidence* (Brussels: European Commission).

to protect public health. This collaborative approach could strengthen European sovereignty by demonstrating the capacity to tackle health issues collectively and ensuring that decisions are made with the input and cooperation of multiple member states.

- An EHU would support the *integration and cohesion* of the EU and its member states in health policies and governance by enhancing the role of EU institutions, agencies, and mechanisms in coordinating, regulating, and financing health actions. This would require applying the principles of solidarity, subsidiarity, proportionality, and health in all policies.
- As the EU expands its role in health, questions may arise regarding *democratic legitimacy and accountability*. Some argue that a greater EU role in health should be accompanied by mechanisms to ensure transparency, citizen engagement, and accountability. These mechanisms can help preserve European sovereignty by ensuring that decisions related to health are made through democratic processes and with public participation.

Ultimately, establishing an EHU would present an opportunity to promote cohesion across the continent and fortify European sovereignty.

The European Health Union and the Sustainable Development Goals 2030

The UN Sustainable Development Goals (SDGs) are a set of global targets that provides a shared blueprint for peace and prosperity for people and the planet, adopted by the United Nations' member states in 2015. Health is recognised as a critical component of sustainable development. Improving health contributes to achieving multiple SDG targets, and achieving certain goals simultaneously contributes to realising the goal of Good Health and Well-Being (see Figure 2).[38] The EU's actions in the health domain interconnect and reciprocally contribute to attaining multiple SDGs:[39]

- Reducing healthcare costs, promoting equitable access to healthcare, and providing financial protection against health-related expenses are all relevant actions under the EHU. In addition, with the increased

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38   United Nations (2015) *The 17 Goals* (New York: United Nations).
39   European Commission (2023) *Sustainable Development Goals* (Brussels: European Commission).

productivity and economic wellbeing resulting from improved health, the EHU can *help alleviate poverty*, contributing to SDG 1 (No Poverty).

- The EHU could help reduce inequalities in access to quality healthcare by *strengthening health systems and advancing universal health coverage*, especially for vulnerable groups such as migrants, refugees, older people, and people with disabilities. This could also contribute to reducing maternal and child mortality, improving sexual and reproductive health, and preventing and treating communicable and non-communicable diseases – all targets of SDG 3 (Good Health and Well-Being).

- The EHU can play a crucial role in achieving multiple SDGs by promoting equitable access to healthcare, addressing social determinants of health, and implementing policies that target vulnerable populations. In addition to SDG 1, the EHU can address health disparity and promote gender equity (SDG 5) by advancing gender-responsive health policies and programs that address specific health needs and challenges that women and girls face, which include ensuring access to sexual and reproductive health services, addressing gender-based violence, and promoting women's empowerment in healthcare decision-making and leadership roles.

- By *preventing and combating health threats*, including pandemics, and applying a *One Health approach*, the EU could help address the interconnections between human, animal and environmental health and the impact of climate change on health. This could also help preserve biodiversity, reduce greenhouse gas emissions, and promote sustainable consumption and production patterns – targets of SDG 13 (Climate Action) and SDG15 (Life on Land). Additionally, by promoting sustainable and low-carbon practices, reducing air pollution, and ensuring environmental sustainability, the EU can improve public health outcomes and reduce the burden of climate-related health risks.

- By *supporting research and innovation for treatments and vaccines*, the EU could help foster scientific excellence, technological development and innovation in the health sector. This could also help improve access to affordable and effective medicines and medical devices, enhance public-private partnerships, and strengthen the role of the EU as a global leader in health research – all targets of SDG 9 (Industry, Innovation and Infrastructure).

- By *promoting a holistic approach to sustainable development* and a strong partnership with the United Nations and other actors, the

EU could help advance the implementation of the 2030 Agenda for Sustainable Development and its 17 SDGs. This could also help enhance policy coherence, coordination and cooperation at all levels, mobilise resources and expertise, and support developing countries in achieving their health-related goals – tying in with SDG 17 (Partnerships for the Goals). Furthermore, by sharing knowledge, expertise, and resources, the EU can strengthen health systems, address global health challenges, and promote sustainable development worldwide.

The EHU's actions have multiple connections with many SDGs. However, to effectively link the EU's role in health with the SDGs, the EU needs to adopt a comprehensive approach that considers the social, economic, and environmental dimensions of health. This entails adopting the One Health approach and integrating health considerations into various policy areas, such as climate, gender, poverty reduction, and education.[40] It also requires coordination and collaboration across different sectors involving stakeholders at all levels to ensure a holistic and sustainable approach to health and wellbeing.

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40   McKee, M. (2022) "One health through the lens of the Sustainable Development Goals." *Eurohealth*, 28(3).

Figure 2: The Sustainable Development Goals and Targets 2030 and their synergies with SDG3 – Good Health and Wellbeing[41]

Conclusion: an opportunity for far-sighted policymaking

This chapter has highlighted the need for a more integrated and comprehensive approach to health within the EU, emphasising the potential for the EHU to contribute to multiple policy objectives and improve health outcomes and wellbeing for all Europeans. By taking a comprehensive and interconnected approach to health, the EU can improve health outcomes, advance social objectives, promote sustainability, and enhance the

41   United Nations Environment Programme (2016) *Healthy Environment, Healthy People. Thematic Report, Ministerial Policy Review Session* (Nairobi: UNEP).

well-being of all Europeans. This pivotal moment following the Covid-19 pandemic presents an opportunity to anchor a far-sighted EU health policy that delivers on the promises made to citizens and fosters the best possible health for everyone, and, ultimately, brings the EU closer to its people - a core goal of the whole European integration project.

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Part II.

**Main avenues for Pan-European
cooperation for health**

Thibaud Deruelle

2.1 | Preparedness – the missing ingredient to cope with future health emergencies?

Introduction

The Covid-19 crisis shone a light on the relevance of the European Union (EU) in managing health threats. During the pandemic, member states were able to coordinate health threat management measures, such as restrictions on freedom of circulation, as well as the joint purchasing of medical devices, such as vaccines. This was possible because, unlike healthcare, public health is a coordinating competence of the EU.[1, 2, 3, 4] However, coordinating competencies can limit how efficient the EU may be. Crucially, in the absence of coercive measures, a coordinated - rather than integrated - approach relies on member states' commitment to coordinate, in order to function smoothly.[5, 6]

1   Hervey, T., and B. Vanhercke (2010) "Health Care and the EU: The Law and Policy Patchwork", in E. Mossialos, G. Permanand, R. Baeten, and T. Hervey (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy (Health Economics, Policy and Management)* (Cambridge: Cambridge University Press), pp: 84–133.
2   Hood, C., H. Rothstein, and R. Baldwin (2001) *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford: Oxford University Press).
3   Weimer, M, and A., de Ruijter (2017) *Regulating Risks in the European Union: The Co-Production of Expert and Executive Power* (London: Bloomsbury Publishing).
4   Greer, S., and H. Jarman (2021) "What Is EU Public Health and Why? Explaining the Scope and Organization of Public Health in the European Union*", Journal of Health Politics, Policy and Law,* 46 (1): 23–47.
5   Deruelle, T., and I. Engeli (2021) "The COVID-19 Crisis and the Rise of the European Centre for Disease Prevention and Control (ECDC)", *West European Politics,* 44 (5–6): 1376–1400.
6   Greer, S., and A. de Ruijter (2020) "EU Health Law and Policy in and after the COVID-19 Crisis", *European Journal of Public Health*.

The "stronger European Health Union" [7] advocated by European Commission President Ursula von der Leyen in her first State of the Union address (16 September 2020) is, optimistically, the first step towards an ambitious reform of the EU's role in matters related to public health and specifically health threat management.[8], [9] As of 2023, the European Commission has already led a series of reforms reinforcing the EU's capacity to coordinate health threat management, presented as the first steps toward a stronger European Health Union. This includes a reinforcement of coordination regarding crisis-relevant medical countermeasures, and especially emergency joint purchasing.[10] In the same vein, preparedness (that is, the state of readiness to respond to threats), has been reinforced with national preparedness audits and commitments to strategic stockpiling amid crisis, under the rescEU scheme.

The implementation of these objectives is supported by the European Health Emergency preparedness and Response Authority (HERA) created within the European Commission in 2021. Moreover, the reforms included a change in the mandates of both the European Medicine Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC), to be better suited to crisis situations. Ultimately, because of the pandemic, the EU has gained better funding and more sophisticated means to manage health crises.

Nevertheless, the ambition of a fully-fledged European Health Union can hardly be satisfied by the development of its technical and scientific features.[11] Ultimately, evoking a European Health Union conveys the image of an integrated health policy in the EU, with binding effects on member states' health systems, rather than mechanisms of coordination.

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7   Von der Leyen, U (2020). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Brussels, 16 September 2020.
8   Deruelle, T. (2021b) *Discreet Power through Reputation: Bureaucratic Empowerment and Disease Control in the EU*. Ph.D., University of Exeter.
9   Deruelle, T. (2021a) "Covid-19 as a Catalyst for a European Health Union: Recent Developments in Health Threats Management", in B. Vanhercke and S. Spasova (eds), *Social Policy in the European Union: State of Play 2021* (Brussels: European Trade Union Institute (ETUI) and European Social Observatory (OSE)), pp. 127.
10   European Union (2021) *Proposal for a COUNCIL REGULATION on a Framework of Measures for Ensuring the Supply of Crisis-Relevant Medical Countermeasures in the Event of a Public Health Emergency at Union Level* (Brussels: European Union).
11   Greer, S., and A. de Ruijter, and E. Brooks (2021) "The COVID-19 Pandemic: Failing Forward in Public Health", in *The Palgrave Handbook of EU Crises* (New York: Springer), pp. 747–64.

This chapter offers food for thought on how, and under which conditions, some prerogatives related to health threat management could offer relevant avenues for further integration and become areas of shared – rather than coordinating – competences. First, the chapter provides a review of the legislative reforms made since the beginning of the pandemic and shows that there is little room to manoeuvre left within the confines of coordinating competences. Second, the chapter recontextualises those reforms as the product of paradigm changes catalysed by the Covid-19 crisis; many former taboos have fallen, and the window of opportunity for ambitious reform is still open. Finally, the chapter highlights areas wherein EU competences could become shared competences. It suggests that preparedness for pandemics should be an area of shared competences, with binding common decisions (such as benchmarked stockpiling) while day-to-day crisis management remains based on reinforced mechanisms for coordination.

The legislative and institutional heritage of the pandemic

The Covid-19 pandemic has led to two waves of legislative reforms that built capacity for health threat management and response. The first wave was launched in November 2020 and ultimately completed in December 2022. It was dedicated to enhancing coordination between member states both in terms of crisis management and preparedness. Nested within this first wave of reforms, the second wave (launched in September 2021), further developed policy instruments dedicated to coordinating member states' action. It was, however, much more focused on the production and the procurement of medical countermeasures (primarily, vaccines). Ultimately, the breadth of these reforms demonstrates the creativity necessary to build capacity in the context of coordinating competences. But this breadth also indicates that the legal basis has become too narrow for further reform. What follows is an overview of those two waves of reforms.

Following von der Leyen's "stronger European Health Union" speech, the European Commission published a communication on *'reinforcing the EU's resilience for cross-border health threats'* on 11 November 2020.[12]

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12   European Commission (2020f) *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Building a European Health Union: Reinforcing the EU's Resilience for Cross-Border Health Threats* (Brussels: European Commission).

The communication contained three proposals for new regulations,[13, 14, 15] including a reinforcement of cooperation mechanisms in the face of health threats and a change in the ECDC's and EMA's respective mandates.

The Regulation on serious cross-border health threats[16] was proposed following immediate lessons learnt from the lack of preparedness that characterized the beginning of the crisis. Indeed, member states had – to varying degrees – neglected preparedness in the years leading up to the Covid-19 crisis, due to the mildness of the previous respiratory virus crisis pandemic, H1N1 in 2009.[17] The new legislation thus provides for measures to strengthen the crisis-preparedness framework, including the establishment of an EU health crisis and pandemic plan, and national plans drawn up by member states themselves. Coordination is the crux of the regulation. When drawing up their national plans, member states will liaise with each other and with the Commission to ensure their plan is coherent with the EU's. This would create a framework for crisis preparedness and response, with audits regarding member states' preparedness (albeit entirely based on coordination), with coercive levers for the European Commission. Nevertheless, the text also provides that the Commission can recognise a public health emergency at the EU level, thereby triggering mechanisms to monitor shortages of medicines and activate the support of the ECDC.

The Regulation on serious cross-border health threats also reinforces the role of the Health Security Committee (HSC), the technical group of

13   European Commission (2020h) *Proposal for a REGULATION OF THE EUROPEAN PAR-LIAMENT AND OF THE COUNCIL Amending Regulation (EC) No 851/2004 Establishing a European Centre for Disease Prevention and Control* (Brussels: European Commission). Available online: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020PC0726.
14   European Commission (2020i) *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a Reinforced Role for the European Medicines Agency in Crisis Preparedness and Management for Medicinal Products and Medical Devices* (Brussels: European Commission). Available online https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0725.
15   European Commission (2020j) *Proposal for a REGULATION OF THE EUROPEAN PAR-LIAMENT AND OF THE COUNCIL on Serious Cross-Border Threats to Health and Repealing Decision No 1082/2013/EU* (Brussels: European Commission). Available online https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0727.
16   Official Journal of the European Union (2022) "Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU" OJ L 314/26 34 November 2023.
17   Deruelle, T. (2021a) "Covid-19 as a Catalyst for a European Health Union: Recent Developments in Health Threats Management".

ministry representatives on communicable diseases. The HSC started as an informal group under the auspices of zealous Commission civil servants,[18] and was then formalized in 2013, post-H1N1. The legislative reform confers a more important role, as the HSC may adopt opinions and guidance on response measures, by a two-thirds majority. Here, the high threshold for a decision that only amounts to guidance reflects not only a logic of coordination but the clear limits that such logic imposes on common action.

The change in the ECDC's mandate actually formalized tasks that were taken-on by the centre amid the Covid-19 crisis. Chief among all those changes is the ability for the ECDC to express guidance on crisis management, a move not allowed under the previous ECDC Regulation, but that the agency had taken on anyway after the beginning of the crisis (this change will be discussed in detail later on, as it is a true paradigm shift in the governance of communicable diseases).

The proposal also put forward tasks related to preparedness which were already informally taken-on by the ECDC prior to the Covid-19 crisis. These includes contributing to preparedness plans at the EU level and monitoring preparedness in member states. Finally, the reform also conferred an operational dimension to the ECDC, with the creation of the EU task force, which will provide scientific support in the field (i.e., at the site of outbreaks).

While the change in the ECDC's mandate was a seismic shock for the agency, the change in the mandate of the EMA led to a much smoother adaptation. Notably, it gave a legal basis to swifter regulatory procedures which were needed amid the crisis. The new regulation also includes new tasks such as monitoring shortages of medicinal products, as well as providing advice on medicinal products which have the potential to treat, prevent or diagnose.

However, and despite crisis conditions, the proposed new institutional architecture only came into force at the turn December 2022. For a matter of comparison, the creation of the ECDC took a year of legislative work, from proposal to entry into force, in the context of a relatively minor health crisis.[19] If the legislative process was lengthier than expected, it is because of the rather brutal attention-shift on the issue of vaccine procurement

18   Sauer, F. (2014) "[Major milestones for European pharmaceutical policy]", *Revue d'histoire de la pharmacie,* 62 (381): 61–74.
19   Deruelle, T. (2016) "Bricolage or Entrepreneurship? Lessons from the Creation of the European Centre for Disease Prevention and Control», *European Policy Analysis,* 2(2): 43–67.

from January 2021 onward. Indeed, even though the first wave of reform had yet to be passed by the co-legislators, von der Leyen presented two legislative texts tackling the procurement of medical countermeasures[20] during her second speech on the State of the Union.[21]

The first was a legislative proposal for a Council Regulation on the supply of crisis-relevant medical countermeasures. It included the establishment of mechanisms for the activation of emergency funding for procurement of crisis-relevant medical countermeasures, an emergency research and innovation plan to speed-up clinical trials and, finally, measures for monitoring, including the establishment of an inventory of production and production facilities. The second was a legislative act of the Commission entering into force the same day, setting up the Health Emergency Response Authority (HERA), to implement provisions in the Council Regulation, as well as the Regulation on serious cross-border health threats proposed a year earlier. The model presented by the Commission is inspired by the U.S. Biomedical Advanced Research and Development Authority (BARDA), which funnelled billions of dollars to develop Covid-19 vaccines and therapies at the start of the pandemic.[22] The new authority's role is to support the supply chain for medical countermeasures, with a €6 billion fund for grants in the 2022-2027 period. It is also tasked with evaluating EU member states' needs and capacities regarding medical countermeasures, and developing logistical infrastructures dedicated to the production of medical countermeasures (including support for research and manufacturing). Amid crisis, it will assist in strategic stockpiling of relevant products, thus implementing the Regulation on cross-border health threats.

The timing of von der Leyen's announcement for a second wave of reform had a tremendous impact on the legislative train. Indeed, the European Parliament had voted and amended the three legislative proposals a mere two days before the announcement of a proposal for a council regulation and the creation of HERA. HERA specifically attracted criticisms as it is an authority "within the Commission",[23]

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20   European Union (2021) *Proposal for a COUNCIL REGULATION on a Framework of Measures for Ensuring the Supply of Crisis-Relevant Medical Countermeasures in the Event of a Public Health Emergency at Union Level* (Brussels: European Union).

21   Von der Leyen, U (2021) "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Brussels, 15 September 2021.

22   Deutsch, J. (2021) "Commission Launches Talks with BioNTech/Pfizer for 1.8B More Doses", *POLITICO*, 14 April 2021.

23   Deruelle, T., and E. Ruiz Cairó (2021) "The EU Health Emergency Response and Pre-paredness Authority (HERA): Institutional Impact", *EU Law Live*, 11 November 2021.

which is not subject to the parliamentary scrutiny that the ECDC or EMA would undergo. Moreover, unlike the first wave of reforms, the European Parliament would not be involved in the decision-making process as a co-legislator. This created some friction, as there was some overlap between the texts, especially with regards to the framework for crisis preparedness and response, including audits regarding member states' preparedness. Ultimately, tasks are well defined in the new institutional architecture: where the ECDC formulates recommendations for preparedness, HERA assists the material implementation of measures including funding in times of crisis. Where EMA monitors the stock of medicines, HERA anticipates their procurement.[24]

Overall, health threat management in the EU has become a fully realised system of coordination, taking full advantage of the legal basis in the Treaty by developing to an important degree policy instruments of coordination. But the legislative and institutional heritage of the pandemic is – so far – grounded in capacity-building, as the EU is still limited to coordinating management, with no coercion on member states' strategies to fight health threats. Nevertheless, there are areas in which a shift from coordinating to shared competence could be beneficial, especially in terms of readiness. Before describing that shift, it is however necessary to evaluate the extent to which member states would be ready for a new transfer of competence to the supranational level. Indeed, it is of paramount importance that any proposal for a treaty change does not remain a hopeful bottle to the sea. Such a proposal must thus remain grounded in what would be acceptable and appropriate to national governments, who ultimately consent to such change. In the next section, the paradigm shifts inherited from the pandemic are described, to highlight where further change could be acceptable to member states.

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24   European Commission (2021a) *Commission Decision of 16 September 2021 Establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02* (Brussels: European Commission).

Three paradigm changes following the pandemic

While crises are considered to be golden opportunities for reforms,[25, 26, 27] opportunities for radical change are rather limited in the field of European public health. In this area, crises are catalysts:[28] they precipitate rather than provoke paradigm changes. The Covid-19 pandemic created a context propitious to three paradigm changes for communicable diseases in Europe. First, member states took stock of their interdependence in facing the pandemic. Second, scientific agencies were given the leeway to contribute to coordinating member states' response, and third, member states agreed on a joint strategy for procurement.

1. Taking stock of member states' interdependence

The Covid-19 pandemic has led national governments to revaluate the trade-off between maintaining their prerogatives over public health competences and the need to develop a coordinated and coherent response mechanism for (present and future) health crises.[29] More open to coordination than in the past, member states have increasingly relied on coordinated action, an unprecedented move in the history of recent public health crises.[30, 31]

This shift towards coordination occurred as soon as European governments became aware of the severity of the crisis. On 9 March 2020, the Italian government imposed a national lockdown, following local lockdowns enforced since 21 February 2020. In a European Council videoconference on 10 March 2020, member states undertook to further

25   Boin, A., M. Busuioc, and M., Groenleer (2013) "Building European Union Capacity to Manage Transboundary Crises: Network or Lead-Agency Model?", *Regulation & Governance,* 8(4): 418–436.

26   Greer, S., and A. de Ruijter (2020) "EU Health Law and Policy in and after the COVID-19 Crisis".

27   Wolbers, J., S. Kuipers, and A. Boin (2021) "A Systematic Review of 20 Years of Crisis and Disaster Research: Trends and Progress", *Risk, Hazards & Crisis in Public Policy,* 12(4): 374–92.

28   Deruelle, T., and I. Engeli (2021) "The COVID-19 Crisis and the Rise of the European Centre for Disease Prevention and Control (ECDC)".

29   Ibid.

30   Pacces, A., and M. Weimer (2020) "From Diversity to Coordination: A European Approach to COVID-19", *European Journal of Risk Regulation*, April 16: 1–14.

31   Renda, A, and R. Castro (2020) "Towards Stronger EU Governance of Health Threats after the COVID-19 Pandemic", *European Journal of Risk Regulation*, April 9: 1–10.

coordinate management measures. This led to a domino-like coordinated entry into the first lockdowns following the Italian example: Slovakia and the Czech Republic enforced lockdowns on 12 March. Denmark, Poland, Latvia, Lithuania and Cyprus followed suit the next day, while Germany, Spain and France initiated restrictions on 16 March.[32]

Italy – the first Member State to institute a lockdown – lifted some containment measures on 4 May 2020, while France, Belgium, the Netherlands Germany, Austria, the Czech Republic, Greece, Bulgaria, Estonia, Finland, Ireland and Romania eased containment measures on 11 May 2020.[33] This was a sign of sustained coordination. However, as severe restrictions were lifted, the issue of reopening borders subsisted.[34] The ECDC had consistently advocated that closing borders had little impact on the management of Covid-19, due to its (already) global distribution and respiratory transmission.[35] This led member states to adopt Council Recommendations on a coordinated approach to limit the restriction of free movement in response to the Covid-19 pandemic on 13 October 2020 and 28 January 2021.[36]

The goal of this coordinated approach was to maintain free movement within the EU under safe conditions, by identifying measures applicable to persons moving between member states, depending on the level of risk of transmission. The same coordinated approach prevailed when the Commission proposed on 10 May 2021 that member states ease current restrictions on non-essential travel into the EU,[37] and develop a Digital Covid Certificate (previously known as Digital Green Certificates), an information system ensuring freedom of movement for persons who were less likely to spread the disease. As of 1 July 2021, member states were able to issue such certificates and preserve freedom of movement.

32   HSC (2020c) *Flash report of the 11th Health Security Committee, 13 March 2020* (Brussels: European Commission).
33   HSC (2020d) Flash report of the 20th Health Security Committee, *14 May 2020* (Brussels: European Commission).
34   European Commission (2020d) *Tourism and Transport: Commission's Guidance on How to Safe, May 13, 2020* (Brussels: European Commission).
35   ECDC (2020d) "Rapid Risk Assessment: Coronavirus Disease 2019 (COVID-19) in the EU/EEA and the UK – Eleventh Update: Resurgence of Cases" (Stockholm: ECDC).
36   Official Journal of the European Union (2021) "Council Recommendation amending Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic", OJ, L 337/3, 13 October 2020.
37   European Commission (2021a) *Commission Decision of 16 September 2021 Establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02*.

The role of crises was decisive in inciting[38] and legitimizing collective action among EU member states.[39, 40] This was a first paradigm change for communicable diseases which led to the Regulation on serious cross-border health threats.

2. Unleashing expertise

The change in the mandate of the ECDC (described earlier as a seismic shock) capped off a long debate on whether or not the agency should have a say in matters of risk management - that is, how the pandemic ought to be managed by member states.[41] Indeed, at its creation, the ECDC was confined to risk assessment - the identification of risks through evaluating the magnitude, mechanisms and seriousness of threats to public health. The agency performs these tasks by gathering epidemiological information from EEA's health agencies. The ECDC was thus expected to take on a fire alarm role, but was barred from advising on how to put out the fire. Member states have shown to be weary[42] that the ECDC avoid crossing that fine line between risk assessment and management, as exemplified by the H1N1 crisis, ten years prior to Covid-19.[43]

However, from the beginning of the Covid-19 crisis, the distinction between risk assessment and risk management was routinely disregarded, even before a formal change was evoked by the Commission on 28 May 2020, in its proposal for the next Health programme.[44] At first the ECDC

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38   Boin, A., M. Busuioc, and M. Groenleer (2013) "Building European Union Capacity to Manage Transboundary Crises: Network or Lead-Agency Model?".
39   Rhinard, Mark (2019) "The Crisisification of Policy-Making in the European Union", *JCMS: Journal of Common Market Studies,* 57 (3): 616–33.
40   Vanhercke B., Spasova S. and Fronteddu D. (2020) "Conclusions Facing the economic and social consequences of the pandemic: domestic and EU responses", in Vanhercke B., Spasova S. and Fronteddu B. (eds.) *Social policy in the European Union: state of play 2020, Facing the pandemic* (Brussels: European Trade Union Institute (ETUI) and European Social Observatory (OSE)).
41   Deruelle, T. (2016) "Bricolage or Entrepreneurship? Lessons from the Creation of the European Centre for Disease Prevention and Control", *European Policy Analysis,* 2 (2): 43–67.
42   Ibid.
43   Deruelle, T., and I. Engeli (2021) "The COVID-19 Crisis and the Rise of the European Centre for Disease Prevention and Control (ECDC)", *West European Politics,* 44(5–6): 1376–1400.
44   European Commission (2020b) *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Establishment of a Programme for the Union's Action in the Field of Health – for the Period 2021-2027 and Repealing Regulation (EU) No 282/2014 ("EU4Health Programme")* (Brussels: European Commission).

played its role of fire alarm in the early days of January 2020, and member states scrambled to come to terms with the scope of the crisis. The ECDC – like numerous other public health agencies – struggled to assess the Covid-19 threat, as little data was available.[45] But as soon as the risk of person-to-person transmission was confirmed, the ECDC re-assessed the potential impact of Covid-19 as high.[46] This served as a reality check for member states who started, under the coordination of the Commission, to request ECDC advice on risk management measures such as lockdowns and the use of personal protective equipment (PPE), despite the Centre's limited competences. For instance, early on, the ECDC developed advice on management measures in February 2020,[47] and published guidelines on non-pharmaceutical mitigation measures.[48] The agency also advised on lifting lockdowns - ECDC guidance for discharge and ending isolation[49] formed the basis for the 15 April European Commission communication on the *European roadmap to lifting coronavirus containment measures*.[50]

Such contributions from the ECDC would have been considered inappropriate by member states before Covid-19. From the onset of the pandemic, the proverbial Rubicon was crossed, breaking the taboo of a contribution of the ECDC to risk management. To provide this advice was a change in paradigm in the *raison d'être* of the Centre, as explained by ECDC Director Andrea Ammon in an interview to the media prior to the change in mandate:

"Our mandate is very clear. It's regarding infectious diseases. And it says that ECDC does risk assessment, not risk management. Now, in this situation, we were first of all, expected to assess and give advice on control measures in sectors like airplane, train, cruise ship, meat, factory, and so forth. And people are expected all of a sudden to tell member

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45   HSC (2020a) *Flash report of the 3rd Health Security Committee, 27 January 2020* (Brussels: European Commission).
46   HSC (2020b) *Flash report of the 4th Health Security Committee, 31 January 2020* (Brussels: European Commission).
47   ECDC (2020b) *Risk Assessment: Outbreak of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2): Increased Transmission beyond China – Fourth Update* (Stockholm: ECDC).
48   ECDC (2020a) *Guidelines for the Use of Non-Pharmaceutical Measures to Delay and Mitigate the Impact of 2019-NCoV* (Stockholm: ECDC).
49   ECDC (2020c) *Guidance for Discharge and Ending Isolation in the Context of Wide-spread Community Transmission of COVID-19 – First Update* (Stockholm: ECDC).
50   European Commission (2020c) *Communication - A European Roadmap to Lifting Coronavirus Containment Measures* (Brussels: European Commission).

states what to do. [...] Telling member states what to do is not part of our mandate, and it's not even part of the EU competence in health".[51]

This paradigm change led to the new ECDC mandate, formalising that its scientific input was no longer confined to risk assessment. The Centre is now able to advise member states on coordinated responses to health threats by producing explicit guidelines.

3. The choice for a strategy based on joint procurement

On 28 February 2020, member states activated the mechanism of joint procurement of medical equipment to purchase personal protective equipment (PPE).[52] It was the first time that the mechanism for joint procurement, created in 2013 in the aftermath of the 2009 H1N1 crisis was put to use. While it can be seen as another avatar of the coordinated approach embraced by member states, it has been crucial for vaccine procurement, a central issue of pandemic management.

Coordination regarding vaccine procurement started months before they came into existence. In a health minister video conference held on 7 May 2020, many member states expressed their strong support for a Covid-19 vaccination plan for the EU and EEA and expressed their interest in the possible joint procurement of Covid-19 vaccines. The question of scarcity of vaccine doses had even been evoked early on in the crisis, as soon as member states expressed their interest in the possible joint procurement of Covid-19 vaccines at the beginning of May 2020. At the same time, once vaccines were available, Germany, France, Italy and the Netherlands joined forces to reach a deal with AstraZeneca on the supply of up to 400 million doses of its vaccine candidate.[53] Taking place outside the EU framework the negotiations excluded some of the smaller member states which would have benefited the most from joint procurement. The question of equitable access was key.

To avoid a race for vaccines among EU member states, the Commission presented a Communication on an EU strategy for Covid-19 vaccines on 17 June 2020.[54] It was based on ECDC considerations in

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51   Gottlieb, D., (2021) *European Health Union, Now!* (Stockholm: Spotify).
52   European Commission (2020a) *Coronavirus Response* (Brussels: European Commission).
53   Deutsch, J. (2021) "Commission Launches Talks with BioNTech/Pfizer for 1.8B More Doses".
54   European Commission (2020e) *EU Strategy for COVID-19 Vaccines* (Brussels: European Commission).

prioritising access to Covid-19 vaccines communicated on 28 May 2020. The Communication mentioned adapting the EU's regulatory framework to the current urgency, which would be part of the change in the EMA's mandate, as well as securing the production of vaccines in the EU and sufficient supplies for its member states, an issue that would be soon become central to the European Health Union. In the immediate term, it led the Commission to secure a mandate from member states to make "advance purchase agreements". From August 2020 until January 2021, the Commission signed with six different companies, for a total of 2.3bn doses, with a budget of €2 billion fixed by member states.[55], [56]

Nevertheless, while the joint procurement of vaccines prevented a race between member states, the global race was only just beginning. Countries such as the United Kingdom and the United States aggressively purchased doses at higher prices.[57] In an already complex situation, the issue of manufacturing bottlenecks with the question of AstraZeneca's undelivered doses added to the complexity of pinpointing the cause of the slow roll-out.[58] The dispute with AstraZeneca was settled with the CJEU in September 2021, with a delayed delivery,[59] while the larger problem of procurement had already been overcome through the EU's gargantuan and historic purchase of 1.8 billion additional doses of Pfizer vaccines in May 2021.[60]

Ultimately, this paradigm change translated into the second wave of reforms with the Council Regulation on supply of crisis-relevant medical countermeasures[61] and the creation of HERA, which facilitates and anticipates joint purchasing.

55   Sánchez, N., and E. Zalan (2021) "The EU's Vaccine Strategy - the Key Points", *EUobserver*, 19 May 2021.
56   Reuters (2021) "How the EU Filled Its Basket in COVID-19 Shopping Spree", *Reuters*, 6 January 2021.
57   Deutsch, J. (2021) "Commission Launches Talks with BioNTech/Pfizer for 1.8B More Doses".
58   Hirsch, C, and J. Deutsch (2021) "Coronavirus Vaccine Deliveries in Europe — by the Numbers", *POLITICO*, 9 March 2021.
59   European Commission (2021b) *Press Release: The EU and AstraZeneca* (Brussels: European Commission).
60   Deutsch, J. (2021) "Commission Launches Talks with BioNTech/Pfizer for 1.8B More Doses".
61   Official Journal of the European Union (2022) "COUNCIL REGULATION (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level", *OJ, L, 314/64*.

Conclusion: towards a fourth paradigm change?

The Covid-19 pandemic has led to important paradigm changes, broken taboos and incited coordination. The catalytic power of the pandemic has given way to a fully implemented system of coordination, taking full advantage of the legal basis in the Treaty and in which all institutions are able to cooperate much more than in previous crises. The breadth of change is already important, but more work can be done to achieve the "stronger European Health Union" with competence change. Changing the treaties requires in itself a paradigm shift in European integration, nevertheless, it is not necessary to 'upgrade' all matters of health threats management to a domain of shared competences. Regarding health threats, a corner stone of the future European Health Union could be matters of preparedness, in which shared competence would be beneficial. At the same time, matters of pandemic management would remain a simple coordinating competence, to avoid hampering a reactive response on the ground.

Preparedness was a major problem at the beginning of the pandemic. The 2009 H1N1 pandemic had somewhat shifted the attention on preparedness, which was rapidly eclipsed by the budgetary crisis. In effect, national governments investments in preparedness were patchy between 2010 and 2019 [62]. The 2013 Decision on serious cross-border threats which focuses on influenza viruses such as H1N1 but ultimately is relevant for respiratory viruses, requires member states to report every three years on influenza pandemic preparedness plans. The ECDC website[63] shows that out of 27 member states only six of them had updated plans following the H1N1 pandemic. Moreover, because the H1N1 crisis was not as severe as expected,[64] this had an important effect on member states' expectations regarding pandemic risks and likely led national governments to minimize potential threats[65]. Shared competences for matters of preparedness would prevent member states from falling into the same traps as with H1N1 and ultimately overlook preparedness and stockpiling. It would also allow for a common rather

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62   Deruelle, T., and I. Engeli (2021) "The COVID-19 Crisis and the Rise of the European Centre for Disease Prevention and Control (ECDC)".
63   ECDC (2021) *Influenza Pandemic Preparedness Plans* (Stockholm: ECDC).
64   Nicoll, A., and M. McKee (2010) "Moderate Pandemic, Not Many Dead—Learning the Right Lessons in Europe from the 2009 Pandemic", *European Journal of Public Health* 20(5): 486−88.
65   Ibid.

than joint approach in constituting stocks of medical countermeasures.

Evidently, a lot has been done already on the matter, but new policy instruments such as emergency funding and joint stockpiling have been planned for crisis times. This is problematic as the literature is eloquent on how collective action is rather difficult in non-crisis situations.[66], [67] During the preparedness phase (i.e., when the context is not one of crisis), there is only a 'framework' for member states preparedness, with no coercive lever. While more means have been attributed to auditing national plans, this ultimately represents little progress compared to the 2013 Decision on serious cross-border threats[68] which required member states to report every three years on preparedness plans, and with the consequences highlighted earlier.

Ultimately, the current reforms do not address the fundamental problem regarding preparedness: coordination is subject to the goodwill of member states. Indeed, if the willingness to coordinate was the active compound that holds the Union together, the EU might just as well be a simple forum in which member states cooperate and help each other. The internal market and associated four freedoms are built on strictly enforced legal ties. Member states act in concert because a complex legal order binds them together in domains of shared competences rather than because of the attractiveness of collective action.

The three paradigm changes crystalised by the pandemic have created optimal conditions to change how national government look at preparedness:

- The joint procurement mechanism is a policy instrument that has been neglected in the past. Arguably, a strategy based on joint purchase could be of service to member states' preparedness rather than being mostly instrumental in times of crisis. This is a role that HERA could fill.
- Scientific agencies have been endowed with more capacity to assist member states since the pandemic. The duo of EMA and ECDC offers solid guarantees of credible and independent scientific expertise which

66 Boin, A., M. Busuioc, and M. Groenleer (2013) "Building European Union Capacity to Manage Transboundary Crises: Network or Lead-Agency Model?" *Regulation & Governance,* 8(4): 418–436.

67 Greer, S. L. (2012) "The European Centre for Disease Prevention and Control: Hub or Hollow Core?", *Journal of Health Politics, Policy and Law,* 37 (6): 1001–30.

68 Official Journal of the European Union (2013) "Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC Text with EEA relevance", *OJ, L 293/1.*

would be an asset in legitimising shared competences in matters of preparedness.

- Finally, the most important paradigm change is that member states took stock of their interdependence in facing the pandemic. This lesson from the pandemic needs to be taken further. Not only do we know that Europe was ill-prepared for Covid-19, but we also know that lessons from the previous crisis were rapidly forgotten. At the present time, the window is still open for a qualitative leap forward towards further integration in public health. In the same vein, preparedness has been mostly discussed in the first wave of reforms. Yet, Europe has collectively progressed on issues of health threats management since these proposals.

It is thus necessary to seize the opportunity to look back on the crisis and learn its lessons now, rather than learning them (yet again) the hard way when the next pandemic comes. The EU is not doomed to "fail forward" [69], when Member states, backed to the wall take an integrative step forward but make it the smallest possible.[70] Rather, the European Health Union could be a prime example of lesson learning and ambitious reforms, by taking a substantial step forward in integrating preparedness as a shared competence. This objective is within Europeans' reach, especially as the EU and its member states are investing in the production chain of medical countermeasures and the question of the EU's leadership in health technologies becomes increasingly relevant.

69   Kelemen, R. D., and T. Pavone (2021) Where Have the Guardians Gone? Law Enforcement and the Politics of Supranational Forbearance in the European Union (Rochester, NY: Social Science Research Network).
70   Greer, S., and A. de Ruijter, and E. Brooks (2021) "The COVID-19 Pandemic: Failing Forward in Public Health", in *The Palgrave Handbook of EU Crises*, pp. 747–64.

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ECDC (2020b) *Risk Assessment: Outbreak of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2): Increased Transmission beyond China – Fourth Update* (Stockholm: ECDC). Available online: https://www.ecdc.europa.eu/sites/default/files/documents/SARS-CoV-2-risk-assessment-14-feb-2020.pdf.

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Richard Bergstrom

2.2 | Global leadership in research and development of health technologies

Introduction

Innovation in life sciences is the result of the interplay between academia, public institutions and private companies. Academia provides a skilled workforce and brilliant minds. Public authorities regulate, control, as well as fund basic research. The private sector stands for entrepreneurship and risk-taking, including raising capital for early- and late-stage development.

This chapter aims to describe how the European Union, its regulations, and its institutions have enabled, supported and stimulated innovation in Europe in the field of health. Indeed, without having a single market, there wouldn't be as many companies operating in Europe as we see today. The EU's regulatory system provides predictability, simplicity, and effectiveness, and the ability to go and ask for advice from regulators like the European Medicines Agency (EMA) is something that is now standard in drug development.

European Union regulation for pharma and bio-tech innovation

The EU's pharmaceutical legislation stems back to 1965 (Directive 1965/65 EC), when tighter regulations were established in the aftermath of the thalidomide scandal (a sedative that was approved in the 1950s for pregnant women, but which caused severe birth defects)[1]. Legislation

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1   Official Journal of the European Union (1965) "Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products", *OJ*, 22, 9.2

was, however, enforced locally in each member state – at a time when there were fewer members -- and regulatory approvals remained a national competency.

In 1978, member states started collaborating, and while they set up a joint scientific committee, the Committee for Proprietary Medicinal Products (CPMP) and then the Committee for Human Medicinal Products (CHMP) for assessing new medicines, the applications for marketing authorisation were still subject to national decisions. It was not until 1993 that lawmakers in Europe decided to establish a centralised process to approve new medicines and that resulted in the formation of the European Medicines Agency (then EMEA, now EMA) that opened its doors in London in 1995. Due to Brexit, however, the agency was moved to Amsterdam.

In the beginning, the centralised approval procedure was mandatory for biotech products and voluntary for all new active substances. In parallel, there have also been national procedures (when you seek approval only in one country) and two versions of national but coordinated procedures: mutual recognition and the decentralised procedure. What they have in common is that any dispute results in arbitration at the EMA.

During the decade following the establishment of the EMA, most companies realised that this single pathway was preferable. Under the MRP procedure, one EUMS (Reference Member State) makes its own final decision to be recognised by other EUMS. The Decentralised Procedure is different in the sense that the Reference Member State, before issuing its own authorisation, consult other member states involved in the procedure. Subsequently, almost all new medicines have been approved by the EMA (or the European Commission, to be precise). From the author's experience, many executives from small and mid-size pharma companies, especially American ones (typically referred to as US Biotech) say that they may never have entered the EU had it not been for the EMA and its centralised procedure.

Even those medicines that are approved nationally are, in the post-approval phase, still monitored collectively at the European level for safety and effectiveness, with EMA committees playing a very important role. This includes many legacy products that pre-date the procedures mentioned above. Over the years, the EMA has been given a stronger role, with the possibility of mandating companies to conduct post-approval safety studies (PASS) and post-approval efficacy studies (PAES).

Although there is just a single network of regulators, individuals within the network wear different hats depending on the product and procedure to be approved. For example, one medicines agency may be the reference

member state in a mutual recognition or decentralised procedure, while its CHMP member may be the rapporteur under the centralised procedure run by the EMA. In addition, national competent authorities (NCAs – the formal name for medicines agencies) are responsible for enforcement and inspections at the national level. Inspections cover manufacturing (good manufacturing practice, GMP; good laboratory practice, GLP; good distribution practice, GDP; and good clinical practice, GCP) and are co-ordinated for inspections outside the EU/EEA. An important point about the European Economic Area is that Norway and Iceland take part in all procedures and are full members of the network even though they are not members of the EU.

Over the years, additional pieces of legislation were introduced to foster innovation and also to nudge and steer the private sector in the right direction in terms of incentives to adress unmet medical need:

- The most prominent and most successful example of this was the orphan regulation from year 2000 that aims to stimulate new therapies against rare diseases (defined as a prevalence of less than 1 in 5,000 people).[2] Developers can ask for orphan designation, which confers the right to free scientific advice (called protocol assistance) and a standalone market exclusivity of 10 years regardless of the patent status. The orphan drug regulation is widely seen as a success, with more than 2,500 candidates designated and more than 200 medicines approved since the start. There are, however, some critical voices that argue that developers are "slicing up" indications in order to obtain several designations.[3]

- In the same spirit, in order to stimulate the development of formulations and indications for children, the European Union adopted the Pediatric Regulation in 2007.[4] It requires companies to provide a prior-to-approval Pediatric Investigation Plan (PIP) for studies and pharmaceutical development that is conducted after approval of the adult version. The EMA can agree a waiver, such as for conditions rarely affecting children. In return for this commitment by developers, companies

2   Official Journal of the European Union (1999) "Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal prod-ucts", *OJ*, *L,* 018

3   Kanavos, P. and E. Nicod (2012) "What Is Wrong with Orphan Drug Policies? Sugges-tions for Ways Forward", *Value in Health*, 15(8):1182-1184.

4   Official Journal of the European Union (2006) "Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Direc-tive 2001/83/EC and Regulation (EC) No 726/2004", *OJ*, *L,* 378/1

will get an additional six months of regulatory data protection, thus delaying the entry of generics. There is also a seldom-used instrument for the development of entirely new products (pediatric use medicinal product, or PUMA) that confers market exclusivity regardless of patents.

- Lawmakers realised that emerging technologies were not precisely regulated and that there was a grey zone between pharmaceuticals and medical devices that needed to be addressed. In 2007 the Advanced Therapy Medicinal Products (ATMP) regulation was established,[5] including with its own committee (CAT) at the EMA. The aim was to create a predictable pathway for regulatory approval and access to patients. Despite 600 designations, only around 30 products have been approved and less than 20 are available to patients. The shortcomings of this model are being addressed in the proposed revision to the general pharma legislation (COM 2023/192 and 2023/193) and through the pending legislative proposal from the European Commission on Substances of Human Origin (SOHO) that also incorporates recent advances in cell and gene therapies.[6]
- The most resource-intensive part of drug development is the clinical development phase with clinical trials. Most trials are multi-centre and multi-country, involving several member states. In 2014, EU lawmakers agreed on a Clinical Trial Regulation that enables developers (called 'sponsors' in the context of clinical trials) to make a single application in a procedure coordinated by the European Commission. The objective was to shorten timelines and lower costs for developers, pharma companies and academic researchers. Since early 2022 it has been mandatory to use the Clinical Trials Information System (CTIS) for submissions.
- In the field of intellectual property (IP), which is an essential backbone for any investment, the European Union decided to introduce a patent restoration scheme modelled on what was available in the United States. Patents for products last for 20 years from the time of

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5   Official Journal of the European Union (2007) "Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance)", *OJ, L,* 324/121

6   European Commission (2022) *Proposal for a Regulation of the European Parliament and of the council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC* (Brussels: European Commission).

application. As the time for development and regulatory approval can sometimes be as long as 12 to 15 years, the net time of protection is sometimes short. The time during which investors can recoup their investments in R&D is often shorter for the pharmaceuticals sector than in other sectors. Against this background, lawmakers decided in 1992 to introduce a supplementary protection certificate (SPC) which gives an additional five years of patent exclusivity. Furthermore, in the area of IP, the European Union, beyond its already existing European Patent Office, decided to make it voluntary to have a unitary legal procedure, and a EU-level court, for the enforcement of EU patents. In the beginning, a European patent from EPO was enforced in each member state which could result in different interpretations, and above all, lots of costs and delays. An extension of the unitary patent is now being considered, to get a unitary granting and enforcement not only for basic patents but also to SPCs.

- Once a medicine has been approved by the European Commission, EU member states have processes for deciding on pricing and reimbursement. These have moved from cost-plus pricing (calculating the price based on the cost of development and production) via international price referencing to more sophisticated models for assessing the value of medicines using health economics. The science of health economics is not new: it emerged in the United States at the Office of Technology Assessment, that produced its first report in 1976. It then came to Europe in the 1980s through the Nordic countries. In the beginning, HTA was done *ex-post* several years after introduction, taking into account post-approval and comparative data, often in the shape of Cochrane systematic reviews and meta-analyses. In 1992 formal HTA with cost-effectiveness thresholds was institutionalised in the United Kingdom as an *ex-ante* (before introduction and reimbursement) assessment through the National Institute for Health and Care Excellence (NICE), which became a role model for many, albeit the methodologies still vary significantly between the different operators such as the Swedish TLV agency, the French HAS, and the German G-BA run system. Recognising the fragmentation and delays in patient access, European lawmakers decided on an EU regulation for health technology assessment (HTA)[7] which is currently being

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7   Official Journal of the European Union (2021) "Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance)", *OJ, L,* 458/1

implemented. It was a long time in the making but is now underway and will provide a common clinical assessment for relative effectiveness for all member states to use as a basis for their own decisions on cost-effectiveness, budgets and willingness to pay.

- To complete this brief review of European legislation relevant to innovation, it is necessary to mention health data, specifically the proposed legislation for a European Health Data Space (EHDS). This proposal, which is subject to standard 'co-decision', is only one of many European acts that have been adopted or are under review on the important regulation of data: Data Act, Data Governance Act, Digital Services Act, Digital Markets Act and the AI Act. The current commission has made the very audacious proposal for EHDS under which all health data, in the spirit of altruism and open science, should be available for secondary use to anyone as long as patient privacy is preserved. Central in the proposal for the EHDS is the setting up of data access bodies in each member state to which researchers, companies, and academics can put in requests for the secondary use of data. This comprehensive vision for 'liberating while controlling' data for secondary use predates the Covid-19 pandemic. However, it seems there is renewed energy for an expanded role for the EU in healthcare post-pandemic.

The EU's legislation has provided a framework under which the pharma industry can operate. But the EU has also gradually taken steps to more actively support the industry too.

European Union funding for innovation in (health and) pharma

The Innovative Medicines Initiative (IMI), the world's largest public-private partnership in life sciences, functions as a joint undertaking between the European Commission and the pharmaceutical industry through EFPIA (the European Federation of Pharmaceutical Industries and Associations). The underlying idea is to set up consortia in a competitive process that brings together academia and private companies. The Commission funds academic research and SMEs while pharma companies contribute in kind (e.g., work hours, lab or data resources). For every euro spent by the Commission, EFPIA members spend one euro in kind. The program has been very successful in gaining

new knowledge and setting up models, resources and platforms.[8] The initial IMI, named IMI-1 was extended to IMI-2 and under the current budgetary framework it is called IHI (Innovative Health Initiative), and includes the medtech sector.

Other European Union programs that support innovation are EU4Health, Digital Europe Programme, European Regional Development Fund (EDRF), European Social Funds (ESF), Structural Reform Support Programme (SRSP), Just Transition Fund (JTF), Invest-EU, European Investment Bank (EIB), including its COSME programme, and EIT (European Institute of Innovation and Technology). The Recovery and Resilience Facility under NextGenerationEU also has significant funds for investments in healthcare, in particular for green investments and for digital transformation.

Covid-19 forced a step forward

While the EU has a relatively limited role in health, the directive on cross-border healthcare opened up the door for more cooperation[9]. Of course, this happened due to cases in the European Court of Justice at the time.[10] In addition, the pandemic changed the role of the EU in public health and healthcare. The beginning of the pandemic was not Europe's proudest moment: borders were closed so governments could keep equipment and medicine to themselves. Commuting for work over many borders was prevented, without social security systems being able to compensate for loss of income for cross-border workers. However, as the pandemic progressed, the EU began to play a much larger role.

The first exhibit of this renewed European political cooperation was the Covid-19 vaccination certificate, which very quickly became interoperable across Europe: at airports, at border controls, at restaurants, in hotels and even at concerts. For years, The EU has struggled with the interoperability of health records and systems, and despite having, on paper, a model for sending prescriptions across member states, only eight member states collaborated, posing question about its real effectiveness. The European

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8   See, for example, the IMI's 'success stories' on their website: https://www.imi.europa. eu/projects-results/success-stories-projects
9   Official Journal of the European Union (2011) "Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare", *OJ, L,* 88/45
10   Krajewski-Siuda, K., and P. Romaniuk (2006) "European Union health systems and the case of Yvonne Watts", *The Lancet,* 368(9535):580

Covid-19 certificate shows that 'if there is a will, there is a way' - even in the very complicated space of health IT.

A second demonstration of the EU's changing role was the approach to vaccines. The EU created a bloc-wide buying club and invested broadly in a portfolio covering the four identified technology platforms (the author was one of the EU's negotiators for the Covid-19 vaccine contracts). On the other side of the Atlantic, the United States was early out with the WARP Speed initiative from the White House.[11] The UK similarly set up a task force, but the EU was struggling in the beginning with figuring out how to do this. In Europe, one of the key political moments was the Commission Communication on 17 June 2020.[12] This document was clearly the result of several weeks of careful deliberation within the European Commission and likely in consultation with some member states. It set out a vaccine strategy for what ought to be done: develop a portfolio approach where the EU was to hedge its bets, pool the risks, and in particular, avoid picking a winner upfront before it know what was going to work, what would be safe, and which vaccinations would be approved and if the companies could deliver vaccine doses according to the contracts.

The focus on the portfolio approach was essential. At the early stages of the pandemic, in May/June 2020, many experts, including many public health authorities, were very sceptical and didn't believe that vaccines would be available for many years, if at all. The Commission communication also set out an approach for how to do procurement for Europe with advanced purchase agreements to be followed by purchase agreements once the vaccines have been approved.

A few days after the publication of this Commission communication, there was a provocation by four member states: Germany, Netherlands, France, and Italy. This was the 'inclusive vaccine alliance', where they announced over the weekend that they had agreed on a principal agreement or principal term sheet with AstraZeneca for its vaccine. Interestingly, the contract would be for all of Europe, including Switzerland. This inclusive action alliance was replaced after just a few days by an official mandate to the European Commission. In fact, after checking intergovernmental agreements among member states and with the Commission, the latter

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11   U.S. Government Accountability Office (2021) *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges* (Washington DC: GAO).
12   European Commission (2020) *Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank EU Strategy for COVID-19 vaccines, COM/2020/245 final* (Brussels: European Commission).

was granted the exclusive right to negotiate contracts for all member states. As long as at least four member states were interested in signing an advanced purchase agreement, then the Commission would initiate a negotiation to sign a contract.

The agreement worked as follows. Either a contract would not be binding in volume or, if binding volumes were agreed, the member states would have five days to opt-out. The day after this mandate-deal between member states and the Commission was finalised, a steering board comprised of one person per member state was established, and it was co-chaired by the EC and one representative from the member states. In the beginning, it was co-chaired by Sandra Gallina, newly appointed Director General of DG SANTE, at the EC, and Clemens Auer, Director General at the Austrian Ministry of Health. The steering board elected a joint negotiation team which took care of the day-to-day negotiations with the companies.

In the beginning, there were, on paper, 141 vaccines in development. But the steering board realised that it did not have to deal with that many because many of these firms were unknown in the field and were far from having any product on the market, therefore selecting only around a dozen interesting candidates. The steering committee also rapidly agreed that the portfolio needed to include the core technologies that were the most advanced, and to provide at least two products per platform. This turned out to be a crucial decision. In the end, two of the vaccines from Moderna and Pfizer/BioNtech from the same mRNA platform were used. It was a new technology, which was researched widely but with very little applications and it was developed into a vaccine in record time, despite the scepticism of many.

Having a buying club for the vaccines with a broad portfolio would have been unthinkable only a year before the pandemic. In fact, many officials had been resisting doing joint procurement via EU institutions, and the pharma industry wasn't favourable either. The fear was that joint European procurement and tendering would compress profit margins. In the lexicon of the pharma industry, it would only be a race to the bottom without recognition for innovation. However, the urgency of the pandemic convinced member states to prefer fast and coordinated provision of vaccines thanks to the mandate to the European Commission, over complete sovereignty and freedom of direct negotiations with the pharma industry. Finally, member states understood and accepted, through a procedure in which their viewpoints (and representatives) were included, that using the power of European coordination could be useful.

It was also a moment in which public opinion was more supportive than ever of financing pharma companies and boosting public investments for vaccine development. Both Pfizer/BioNtech and Moderna made big profits on these contracts, which has resulted in controversy in some quarters, including in the report adopted by the European Parliament.[13]

EU action for preparedness

One year into the Covid-19 pandemic, the EC decided to set up a new DG (Directorate-General) for Health Emergency Preparedness and Response (DG HERA). The HERA work program[14] includes the establishment of an IT system for intelligence gathering, threat assessment, mapping medical countermeasures, supply chain risk management and management systems for stockpiling (HERA MCMI platform). There is also a financing mechanism (HERA INVEST) with a budget of €100 million, to leverage private investment for the development and production of a wide range of medical countermeasures. HERA will also develop a strategy on EU-level stockpiling of medical countermeasures.

Beyond the Advance Purchase Agreements (APAs) and Purchase Agreements for Covid-19 vaccines, the EC agreed to several Joint Procurement Agreements (JPAs) for antiviral therapies and monoclonal antibodies against Covid-19. One interesting case study is monkeypox (Mpox) which has nothing to do with Covid-19 but coincided in time with the Covid-19 response, and hence the Covid-19 Steering Board was consulted. Interestingly the US government, through BARDA (Biomedical Advanced Research and Development Authority) had invested in an antiviral drug (tecoviromat) against smallpox that is also effective against monkeypox. Equally, the US government had funded the development of a next-generation vaccine against smallpox by the Danish company Bavarian Nordic. Once EU officials recognised the potential health threat from Mpox, the EC chose to buy all available stock of the vaccine from Bavarian Nordic and donated the doses to EU member states.

The Joint Procurement Instrument is in place and has the potential to be the approach for future pandemics. However, the model is built on a 'bottom-up' approach where contact points in member states ask

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13   European Parliament (2022) *022/2076(INI) COVID-19 pandemic: lessons learned and recommendations for the future* (Strasbourg: European Parliament).
14   European Commission (2023) *ANNEX 2023 Annual Work Plan of the Health Emergency, Preparedness and Response Authority (HERA)* (Brussels: European Commission).

healthcare providers (or regions) what they need. This is a 'Catch 22' situation, however. Healthcare providers do not know what will work or what will be approved, nor what will be recommended by their public health authority.

Pharma sector: remaining challenges for Europe

While the EU's role, legislative framework and processes have become better defined in recent years, the pharmaceuticals industry still faces uncertainty in several areas.

1. Clinical trials

Even if Europe sees the same number of clinical trials per year as have occurred over the last decade, its share of global trials is going down. Europe needs to make sure hospitals and healthcare professionals are incentivised to take part in clinical research. This is easier said than done – doctors are busy taking care of patients and we face a shortage of healthcare professionals in the coming years. While the focus on healthcare 'production' is understandable, we need to discuss how to make sure healthcare professionals can take part in research and development – both to ensure that new knowledge is generated and to recognise that research work is rewarding for staff and to help secure retention of talents.

While the legal framework for data privacy in Europe (GDPR) is heralded as the best in the world, we see disparate interpretations at the national level, making it more complicated to attract clinical trials.

2. Advanced therapies

Although the EU was a front-runner in recognising that novel technologies needed defined pathways for development and regulatory approvals, and the ATMP model, with its CAT committee, may have been a success on paper, the reality is that most of the designated advanced therapies do not reach patients, probably more due to commercial (market access) challenges than regulatory hurdles. The new SOHO (substances of human origin) legislative proposal looks very promising in this regard, even if the market access and HTA part remains a member state

jurisdiction. One possible solution might be to consider joint purchasing approaches – see below.

One particular challenge in the cell- and gene therapy is the hospital exemption that allows clinics (or rather their hospital pharmacies) to continue producing even if the product has been approved by a pharma company through EMA and the European Commission.

3. New models for paying for innovation and outcomes

Pharma companies and payers have agreed in principle for many years that the price for a medicine should be linked to patient outcomes and not to milligrams for the production or compensating for out-of-pocket R&D spending. However, the ambition to price medicines based on 'value' has worked in the pre-introduction phase thanks to HTA, but it has proven more difficult to track performance and outcomes in everyday clinical practice. Reflecting on current 'disruptive' introductions in the area of Alzheimer's, obesity (re-purposing anti-diabetics) and gene therapy, it seems new payment models are needed. One aspect is to agree on which patients should be treated, the other is the overall budget impact. We need to move away from looking at a price per pill, but rather paying for outcomes while managing healthcare budgets. The European Commission Expert Panel on effective ways of investing in health has presented several interesting reports in this direction.[15]

Conclusion: From payers to buyers

Circling back to the Covid-19 vaccine learnings, it is clear that payers, who are a very fragmented community across the EU that decides on pricing and reimbursement, need to view themselves as buyers. This means that they are not passive actors who pay the bill that results from physicians' free prescribing, but ex-ante negotiators on what should be used and under what terms. At least in the space of countermeasures and preparedness, the EU's institutions (e.g., HERA) and processes can play such a role.

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15   European Commission (2023) *Expert Panel on effective ways of investing in health - Publications* (Brussels: European Commission).

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Dominique Polton

2.3 | Universal health coverage: current policy status in the EU

Background

For the concept of a European Health Union to progress, it is valuable to understand the current policy status. This chapter explores current healthcare policy, provision, and gaps in the EU.

Promoting and protecting health is essential to human welfare and sustained economic and social development. Even though many of the determinants of ill health lie outside the healthcare sector (notably social environments where people live),[1] access to health services is also a critical element.

Universal health coverage (UHC) ensures that all people are able to access effective, good-quality health services when they need them, without experiencing financial hardship.[2] UHC also is one of the targets of the 2030 Agenda for Sustainable Development of the United Nations: "Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all".[3] It is affirmed by the EU as a principle of the European Pillar of Social Rights: "Everyone has the right to timely access to affordable, preventive and curative healthcare of good quality".[4]

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1   CSDH (2008) *Closing the gap in a generation: health equity through action on the social determinants of health - Final Report of the Commission on Social Determinants of Health.* (Geneva: World Health Organization). https://apps.who.int/iris/bitstream/handle/10665/43943/9789241563703_eng.pdf
2   World Health Organization (2010) *World health report. Health systems financing: the path to universal coverage.* (Geneva: World Health Organization). p. ix. https://apps.who.int/iris/bitstream/handle/10665/44371/9789241564021_eng.pdf?sequence=1&isAllowed=y
3   United Nations (2015). *Transforming our World: The 2030 Agenda for Sustainable Development, 2015* (New York: United Nations).
4   European Commission (2017) *European pillar of social rights* (Luxembourg: Publications Office of the European Union).

Improving people's access to healthcare services has been a longstanding objective in European countries. It reflects the values and principles underpinning health systems in Europe – universality, access to good-quality care, equity and solidarity. Hence, the level of social health protection in Europe is high in comparison with other parts of the world, as discussed in part 1 of this chapter.

The institutional arrangements to organise financial protection and access to health services vary among countries within the EU, but some convergences may be seen with the reforms undergone by health systems during the last decades. The global trend is towards expansion of universal health coverage, albeit with variation across countries, as explored in part 2.

However, recent experience has shown that the ability to provide universal access to good quality care can be jeopardised by the effects of external shocks, such as the economic crisis of 2008 or, more recently, the Covid-19 pandemic, and that setbacks can be observed.

Despite an overall favourable situation, gaps in access to care, unmet needs, inequalities between EU member states and between groups of population within each country remain a major concern. Better measurement tools are needed to strengthen the evidence further, but the existing data show that there is room for progress to achieve the goal of universal coverage in Europe (as described in part 3).

1. A generally high level of coverage in the EU

Universal health coverage is traditionally assessed according to three dimensions, which can be illustrated through a cube diagram as proposed by the World Health Organization (WHO):[5] the proportion of the population covered, the range of benefits covered and the proportion of the costs covered ("breadth", "scope" and "depth") (Figure 1).

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5   World Health Organization (2010) *World health report. Health systems financing: the path to universal coverage,* p. xv.

Figure 1 - Coverage dimensions: population, service and cost.[6]
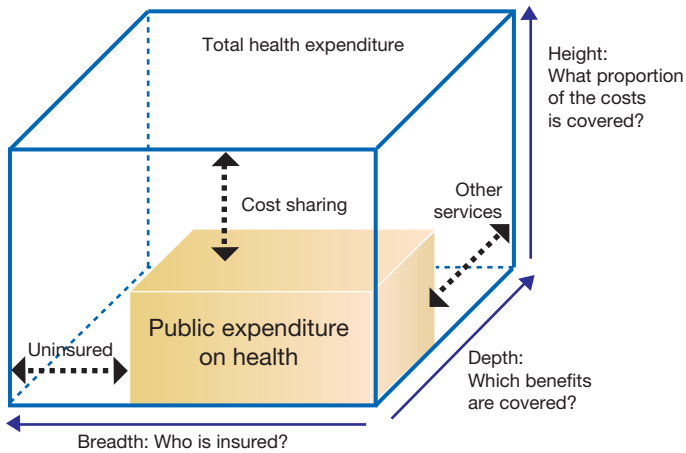
It must be emphasised, however, that no country covers 100% of the population for 100% of the services available, for 100% of the cost, with no waiting lists. "Each country fills the bo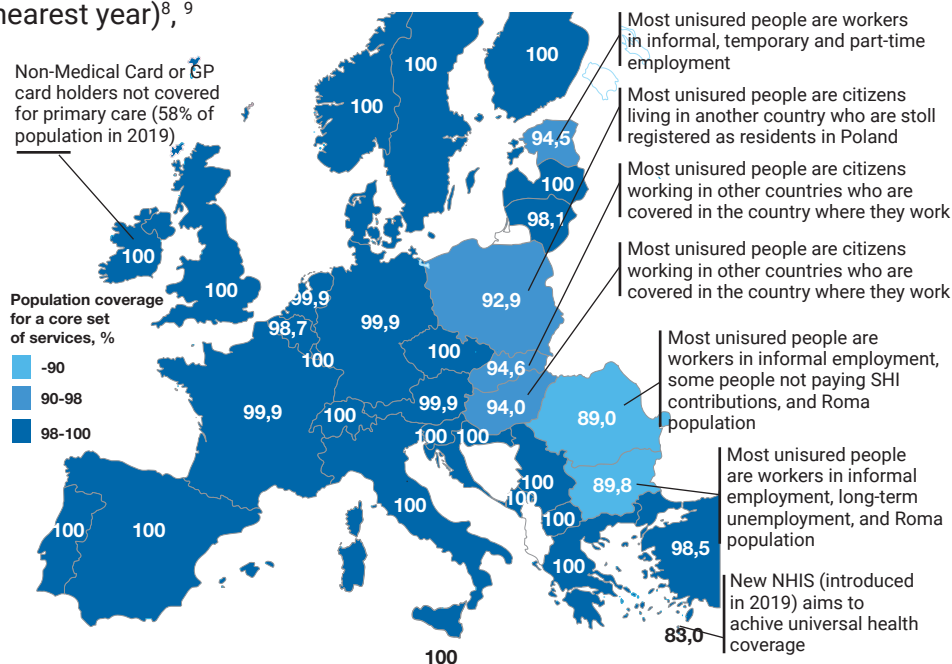x in its own way, trading off the proportion of services and the proportion of the costs to be met from pooled funds".[7] Notably, a key issue for policymakers is to allow access to services and goods which are appropriate, cost-effective and affordable for available public budgets.

With regards to the first dimension (breadth), most European countries have achieved universal or near-universal coverage in terms of population covered (Figure 2).

6   Busse R., J. Schreyögg, and C. Gericke (2007) *Analyzing changes in health financing arrangements in high-income countries: a comprehensive framework approach. Health, nutrition and population (HNP) discussion paper.* (Washington DC: World Bank).
7   World Health Organization (2010) *World health report. Health systems financing: the path to universal coverage*, p. xvi

Figure 2 – Population covered for a core set of services, 2018 (or nearest year)[8], [9]

Most unisured people are workers in informal, temporary and part-time employment

Most unisured people are citizens living in another country who are stoll registered as residents in Poland

Most unisured people are citizens working in other countries who are covered in the country where they work

Most unisured people are citizens working in other countries who are covered in the country where they work

Non-Medical Card or GP card holders not covered for primary care (58% of population in 2019)

Most unisured people are workers in informal employment, some people not paying SHI contributions, and Roma population

Most unisured people are workers in informal employment, long-term unemployment, and Roma population

New NHIS (introduced in 2019) aims to achive universal health coverage

Population coverage for a core set of services, %

- -90
- 90-98
- 98-100

Values on map: 100, 100, 100, 94,5, 100, 98,1, 100, 100, 99,9, 92,9, 98,7, 99,9, 100, 100, 94,6, 99,9, 100, 99,9, 94,0, 89,0, 100, 100, 100, 89,8, 100, 100, 100, 98,5, 100, 100, 100, 85,0, 100

Benefit packages are relatively comprehensive across member states, although there is some cross-national variation. They include consultations with doctors, tests and examinations, hospital care and pharmaceuticals, albeit with limitations regarding innovative and expensive treatments.
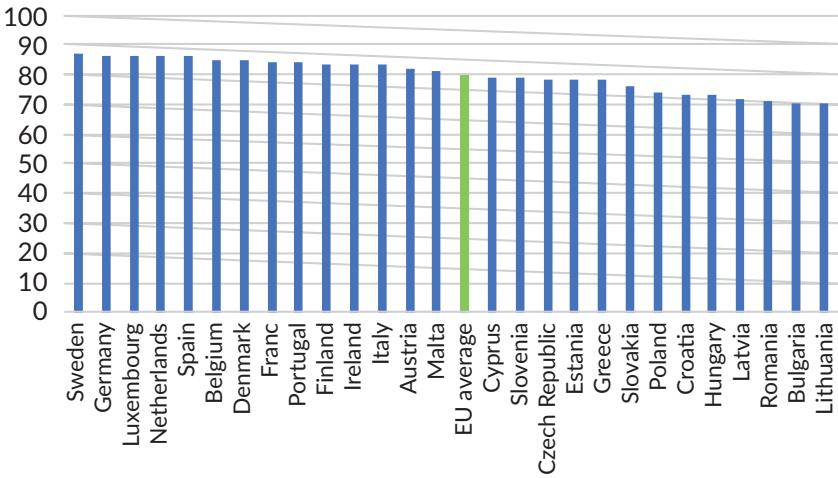
While it is not easy to precisely measure the extent of benefit packages, one of the indicators used to assess progress towards the UN's Sustainable Development Goals (SDGs) suggests coverage of essential health services[10] exceeds 70% in all EU countries (and 80% on average).

8   This includes public coverage and primary private coverage
9   OECD (2020) *Health at a Glance: Europe 2020. State of Health in the EU Cycle* (Paris: OECD).
10   The indicator 3.8.1 "Coverage of essential health services" is defined as "the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population". The indicator is an index reported on a unitless scale of 0 to 100, which is computed as the geometric mean of 14 tracer indicators of health service coverage. More information available on the UN website: https://unstats.un.org/sdgs/metadata/files/Metadata-03-08-01.pdf. The World Health Organization (WHO) is the international organisation responsible for global monitoring of this indicator. Data can be accessed at: https://www.who.int/data/gho/data/indicators/indicator-details/GHO/uhc-index-of-service-coverage

Figure 3 – SDG 3.8.1. Coverage of essential health services in the UE (2019 or nearest year)[11], [12]

Another commonly used indicator to assess the extent of coverage is the proportion of healthcare spending which comes directly from patients through out-of-pocket (OOP) payments, since people may forego care or be pushed into poverty if the burden of these payments is too large.

Health services are mostly financed from public sources in virtually all EU Member States. In 2020, on average, 78.8% of health spending was financed through governments and compulsory insurance, 4.5% by voluntary insurance and 16.6% by out-of-pocket payments.[13, 14] On average, these OOP payments made up 3% of total household consumption in 2018, ranging from 1.3% to 7.5% across countries.[15]

These figures show a good level of financial protection, reflecting common values of solidarity and equity in the EU. These values are also reflected in the low proportion of the population with perceived unmet need. In 2021, according to a Eurostat survey on income and living conditions, 2% of the population aged 16 and above in the EU reported that they had unmet needs for a medical examination or treatment because of financial reasons (too expensive), transportation (too far to

11   The EU average is unweighted
12   World Health Organization (2023) *The global health observatory* (Geneva: WHO).
13   OECD (2022) Health statistics 2022 (Paris: OECD)
14   Note: Data refer to 2020 except for Malta (2019). The EU average is weighted.
15   OECD (2020) Health at a Glance: Europe 2020. State of Health in the EU Cycle (Paris: OECD). Pp. 206-207.

travel) or timeliness (long waiting lists).[16, 17] Considering only the cost barrier, which is most closely related to the degree of financial protection, the proportion is 1%.[18, 19]

2. Progress towards the development of universal health coverage in recent decades

Historically, Western Europe's health systems have been classified into two broad categories: national health services (NHS), providing universal coverage and predominantly funded through general taxation, and social health insurance systems (SHI) funded by contributions on labour income, in which coverage is associated with labour status. The United Kingdom and Germany were the archetypes of these two models, often named after their founding fathers Beveridge (NHS) and Bismarck (SHI). In their "pure", original form, these two conceptions were associated with different features in terms of organisation. The NHS model was directly controlled by the government, tended to be more hierarchical, and there was limited freedom of choice and defined patient pathways. SHI systems, by contrast, were often managed by several insurance funds contracting with independent providers, were more pluralistic and more loosely organised.

The characteristics of the Semashko model, in force in Central and Eastern Europe were close to those of the British NHS, at least as it was in its early stage: a centralised and nationalised system providing universal coverage, a hierarchical organisation of different levels of care according to the severity of the disease, with a differentiated network of service providers, and a strict control of the patient care pathway.

Although differently organised, all these models shared the same core value of solidarity. It is reflected in a fundamental mechanism, the pooling

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16   Eurostat (2023) Unmet health care needs statistics (Luxembourg: Eurostat).

17   These three reasons may be considered as related to the organisation and functioning of health care services. Other reasons are explored, which are more personal: "no time", "fear of doctors", "wanted to wait and see if problem got better on its own", "didn't know any good medical doctor", "other reasons". Considering all reasons, 4.8 % of the population aged 16 and over in the EU reported that they had unmet needs for a medical examination or treatment in 2021.

18   OECD (2020) *Unmet need for health care: comparing approaches and results from international surveys* (Paris: OECD).

19   Eurostat (2022) *Unmet health care needs statistics.* (Luxembourg: Publications Office of the European Union). Pp. 1-16.

of risks and resources and the distribution of benefits according to need, in contrast with liberal models relying on a voluntary health insurance market, as in the US.

Historically, one of the main features differentiating tax-financed and social health insurance systems was the universality of coverage, with different criteria for entitlement.[20] Universal coverage has been, from the beginning, a central feature in countries with tax-financed models.[21] In contrast, the SHI systems were work-related insurance programs, limited by design to workers and their families. The underlying rationale was that public mandatory insurance should be established only for the part of the population that could not rely on its own resources, notably salaried workers. Those who were wealthy enough could take care of themselves, and had the choice of taking out private insurance on a voluntary basis if they wished to. In Germany, sickness fund membership was compulsory for employees whose gross income did not exceed a certain level, and voluntary for those above that level. In the Netherlands, there was a strict income-based separation between statutory health insurance, which covered only 63% of the population in 2004, and private voluntary health insurance. In France and Belgium, self-employed workers had a more limited benefit package than salaried workers.[22]

A major trend that has occurred in recent decades in Western Europe's SHI systems is the evolution towards universality in terms of population coverage. That is, a shift from health coverage as a right of labour to health coverage as a universal right.

In France, coverage was progressively expanded, and since 2000, it has been granted on the basis of legal residence, regardless of labour status. Mandatory health insurance became universal in the Netherlands with a 2006 reform. In Germany, health insurance also became mandatory for the entire population in 2009 (including 11% of the population covered by private insurance, which was until then voluntary). Universal coverage was achieved in Switzerland in 1996, when the revised health insurance

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20   Busse R., J. Schreyögg, and C. Gericke (2007) *Analyzing changes in health financing arrangements in high-income countries: a comprehensive framework approach. Health, nutrition and population (HNP) discussion paper*, pp. 2-3

21   Although some NHS were not designed as totally universal: e.g., in Spain, public servants have a right to opt out of the public system and get coverage from private health insurers.

22   It should be noted that the differentiation according to the income level also exists in tax-based systems: in Ireland, coverage is universal but the extent of coverage varies: all services are free at the point of use for 30% of the population, for the others the benefit package covers only secondary care.

law introduced the obligation to purchase compulsory health insurance for all residents, and in Belgium in 1998.[23, 24, 25]

This move towards universal population coverage often went with a diversification of revenue sources, and more mixed funding, including general revenues subsidies or tax revenue.[26]

At the same time, the healthcare systems of Central and Eastern European (CEE) countries underwent enormous transformation after the fall of USSR, departing from the NHS-type Semashko model to introduce new organisations based on social health insurance. However, unlike historical SHI systems, those new models were conceived as more universal from the start. The objective was to cover the entire population with mandatory insurance, and in most countries, non-contributors were insured without contribution or with a contribution paid by the state.[27, 28] Instead of multiple sickness funds, leading to a fragmented coverage, CEE countries generally implemented a single health insurance scheme, managed by a unique institution acting at arm's length of the government, thus also mixing elements of both NHS and SHI models.

The achievement of population-wide or nearly population-wide coverage in Europe is indeed a major step forward on the road to UHC.

Simultaneously, the index of coverage of essential services[29] has increased: in the EU27, on average, it rose from 69 in 2000 to 80 in 2019. The trend is positive for all countries, with a process of convergence. Gaps between countries on the coverage of these services have substantially reduced over the past 20 years.

23   Busse R., J. Schreyögg, and C. Gericke (2007) *Analyzing changes in health financing arrangements in high-income countries: a comprehensive framework approach. Health, nutrition and population (HNP) discussion paper*, p. 2

24   Jeurissen P., and H. Maarse (2021) "The market reform in Dutch health care: Results, lessons and prospects", *Health Policy Series 55* (Copenhagen: WHO).

25   Blümel M., A. Spranger, K. Achstetter, A. Maresso, and R. Busse (2020) *Germany: Health system review. Health Systems in Transition* (Copenhagen: WHO). p. 79

26   For example, in France, the tax base of the health insurance contribution was broadened to include all incomes, wages, pensions, capital income, and unemployment benefits

27   Tambor M., J. Klich, and A. Domagała (2021) "Financing Healthcare in Central and Eastern European Countries: How Far Are We from Universal Health Coverage?" *International journal of environmental research and public health*, 18(4): 2-26.

28   However, effective universality of population coverage varies among countries. In countries were entitlement is strictly linked to payment of contributions, people may be excluded and they generally belong to vulnerable groups (workers in the informal economy, temporary or unstable employment, atypical work contracts…).

29   See footnote 9 for more detail on the indicator.

A positive trend may also be observed in the height of coverage (See Figure 1, where "height" refers to proportion of cost covered), although not for all countries. On average in the EU,[30] the share of out-of-pocket payments has decreased from 21.5% in 2010 to 19.0 % in 2020. In the majority of countries (18 out of 27) it has decreased and has remained stable or close to stable in four countries, most of which had low OOP payments in 2010. However, the level of cost-sharing remains highly variable among EU members (from 8.5% to 35.6% in 2020), and in five countries it has increased in the last ten years, particularly in countries which were heavily affected by the consequences of the 2008 economic crisis, such as Greece.

Overall, the long-term trend is towards expansion of universal health coverage in most countries and towards convergences in policies to improve the performance of health systems, which are favoured by international cooperation.[31] The EU as a whole sits among the countries and regions with the highest standards of social protection, including protection against health risks.

There is, however, still room for improvement to achieve the goal of the European Pillar of Social Rights, that is, the right to timely access to affordable, preventive and curative health care of good quality. As noted by reports into the state of health in the EU, gaps in healthcare accessibility are still very much a reality, and the most vulnerable part of the population is not always adequately protected.[32]

3. Further progress by tackling coverage gaps and inequalities: an agenda for the European Union

Indicators mentioned in part 1 give a positive image of healthcare in the EU. However, this small set of aggregate figures do not capture the whole picture to assess the real accessibility of healthcare for everyone in Europe.

First, beyond averages, there is significant cross-EU variation in, for example, the level and the design of cost sharing, as already seen, or in the extent of services and goods covered.

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30   The average is unweighted (each country counts for 1), contrary to the calculation in part 1.
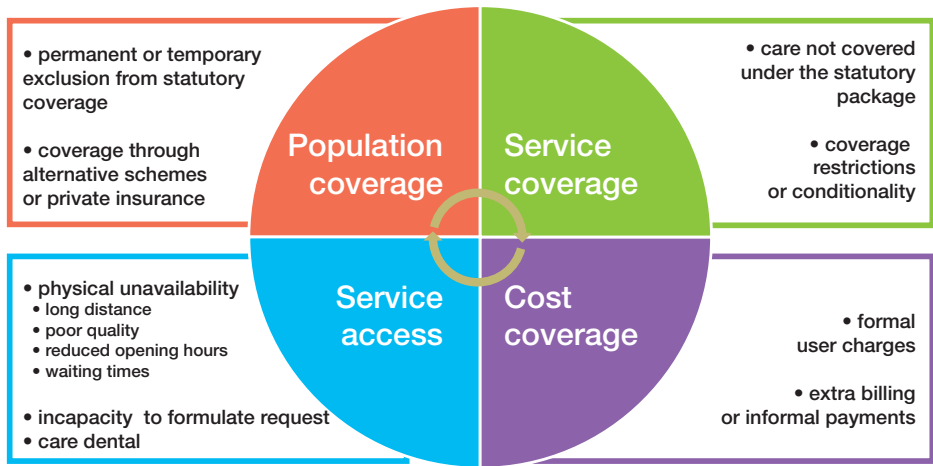
31   This common work is supported by a growing body of data and evidence on good practices provided by the European Commission services, the OECD and the European Observatory on Health Systems and Policies.

32   European Commission (2019) *State of Health in the EU. Companion Report*. (Luxembourg: Publications Office of the European Union). Pp. 30-38.

Secondly, what matters to ensure access to care for all is not only the average situation, but the distribution. Some groups are more exposed to financial hardship, such as poor households, or those who have to pay for long-term treatments. A major objective of healthcare systems is to ensure that care is affordable for these vulnerable populations. More granular measures of access to healthcare are therefore necessary to capture inequalities within countries.

Thirdly, formal entitlement to coverage does not always result in real access, as individuals may face other barriers: availability of the health workforce, distance due to its unequal geographical distribution, waiting lists (exacerbated by the service backlogs accumulated throughout the Covid-19 pandemic), difficulty to obtain care because of functional capacity (e.g., people with cognitive impairment), language barriers, or discrimination by providers. It may also result in services of poor quality. This is why some experts have proposed adding a fourth dimension of "service access" to the three traditional dimensions of coverage (population coverage, service coverage and cost coverage) (Figure 4).[33, 34, 35]

Figure 4 - Coverage dimensions: adding "service access"

• permanent or temporary exclusion from statutory coverage

• coverage through alternative schemes or private insurance

Population coverage

Service coverage

• care not covered under the statutory package

• coverage restrictions or conditionality

• physical unavailability
 • long distance
 • poor quality
 • reduced opening hours
 • waiting times
• incapacity to formulate request
• care dental

Service access

Cost coverage

• formal user charges

• extra billing or informal payments

33   Palm W., E. Webb, C. Hernández-Quevedoc, G. Scarpettib, S. Lessofd, L. Sicilianie, and E. van Ginneken (2021) "Gaps in Coverage and Access in the European Union", *Health-Policy* 125(3): 341–50.

34   European Commission (2014) *Communication from the commission on effective, accessible and resilient health systems* (Brussels: European Commission), p.8.

35   The framework was designed by Palm et al, elaborating on a framework published by the European Commission (see footnote 29).

The WHO Regional Office for Europe and the European Observatory for Health Systems and Policies has conducted important work in recent years to highlight these gaps in coverage, and a large part of the following analysis builds on their findings.[36]

Financial hardship and unmet need, two sides of the same coin

People who are faced with out-of-pocket payments that are too high in relation to their income can become impoverished. Alternatively, they may forego care and experience unmet needs. In both cases, it is a failure with regards to the objective of universal health coverage, which is to ensure that everyone can use the health services they need without experiencing financial hardship.

Across all countries, poorer households (i.e., those in the bottom consumption quintile) are most likely to experience "catastrophic health spending", despite the fact that many countries have put in place policies to safeguard financial protection.

Financial hardship is commonly assessed through the notion of "catastrophic health spending", and it is one of the SDG indicators concerning universal health coverage. It is defined as OOP payments that exceed a predefined percentage of the resources available to a household to pay for healthcare. Different calculation methods can be used with regards to the definition of a household's ability to pay for healthcare (considering the total household expenditure or income or subtracting spending for basic needs) and in the choice of the threshold to identify catastrophic payments – these methods have equity and policy implications.[37, 38]

Here, the resources are defined as household consumption minus a standard amount representing basic spending on food, rent and

36   Thomson S., J. Cylus, and T Evetovits (2019) *Can people afford to pay for health care? New evidence on financial protection in Europe. Summary*. (Copenhagen: WHO).

37   Cylus, J., S. Thomson, and T. Evetovits (2018). "Catastrophic health spending in Europe: equity and policy implications of different calculation methods", *Bulletin of the World Health Organization*, 96:599–609.

38   The authors show that the budget share method (i.e., considering health spending in relation to total household expenditure or income, without subtracting spending for basic needs) tends to underestimate financial hardship among poor people and overestimates hardship among rich people.

utilities, and the threshold is 40%.[39] Thus defined, the share of households confronted by catastrophic health spending varies widely among EU countries, from less than 2% in Slovenia, the Czech Republic, Ireland, Spain and Sweden to more than 10% in Portugal, Hungary, Romania, and more than 15% in Latvia, Lithuania and Bulgaria. In all countries, those who are most likely to experience financial hardship are the poorest (Figure 5). More than 20% of poor households (defined as households in the first quintile of income) are exposed to catastrophic health spending in half of EU countries.[40]

Figure 5 - Share of households with catastrophic health spending by consumption quintile, latest year available.[41](Note: The EU average is unweighted)
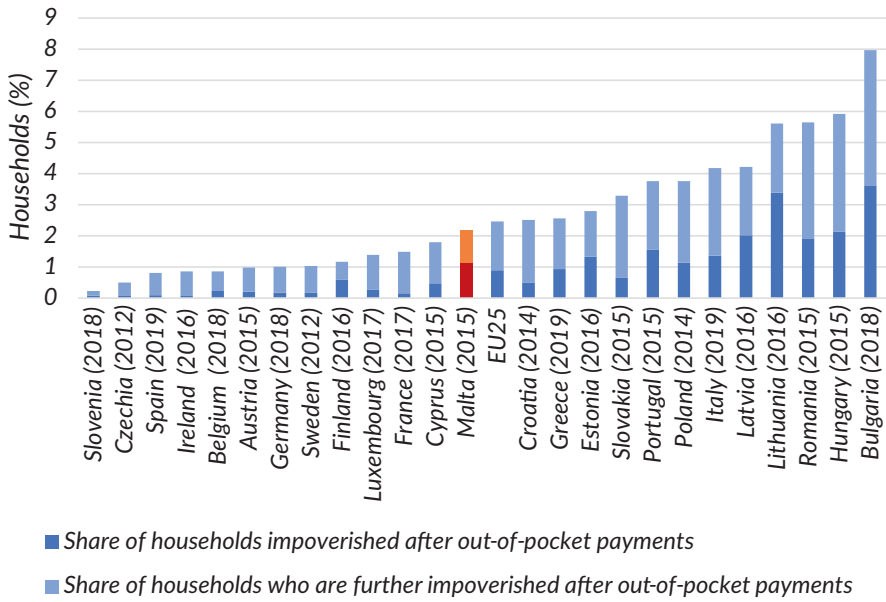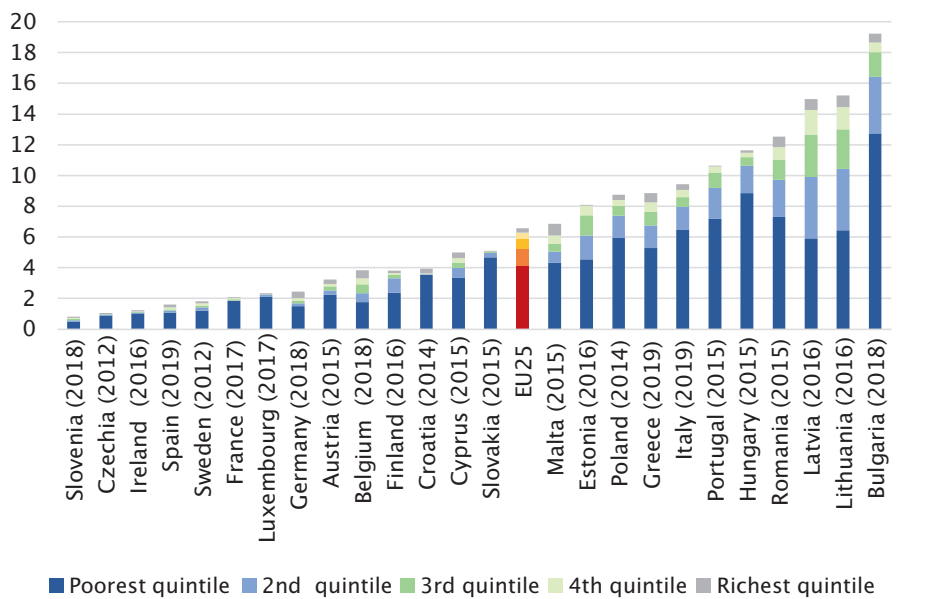

39   The indicator is monitored by the WHO regional office for Europe. It can be assessed in most European countries by national household budget surveys. No data are available for Denmark and the Netherlands.
40   More than 20% of poor households (defined as households in the first quintile of income) are exposed to catastrophic health spending in half of EU countries.
41   World Health Organization (2023) *European Health Information Gateway. Financial protection in the European Region* (Copenhagen: WHO).

In all countries, a proportion of the population is pushed into poverty or further into poverty[42] by health expenditures (to an extent which is highly variable).

Figure 6 - Share of households with impoverishing health spending, latest year available.[43] (Note: The EU average is unweighted)

Share of households impoverished after out-of-pocket payments

Share of households who are further impoverished after out-of-pocket payments
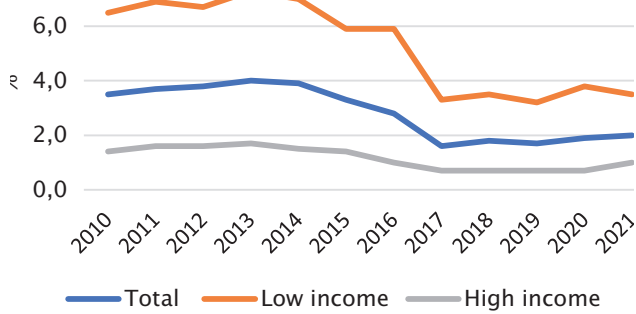
Poor people are also more likely to experience unmet needs for medical care. As seen above, the average level of unmet need in the EU is low: 1% for financial reasons and another 1% because of distance or waiting lists in 2020, according to EU-SILC. However, among the poorest quintile of the population, it climbed up to more than 7% during the last decade, and if it subsequently fell (3.5% in 2020), progress seems to have stalled since 2017 (Figure 7).

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42 A household is considered to be impoverished if its per adult equivalent consumption is above the poverty line before spending out of pocket and below it after spending out of pocket. A household can also experience impoverishing health spending if its consumption before spending out of pocket was already below the poverty line; it is further impoverished after spending out of pocket (WHO Regional office for Europe, *datasets on financial protection*).

43 World Health Organization (2023) *World Health Organization Regional Office for Europe. European Health Information Gateway. Financial protection in the European Region.*
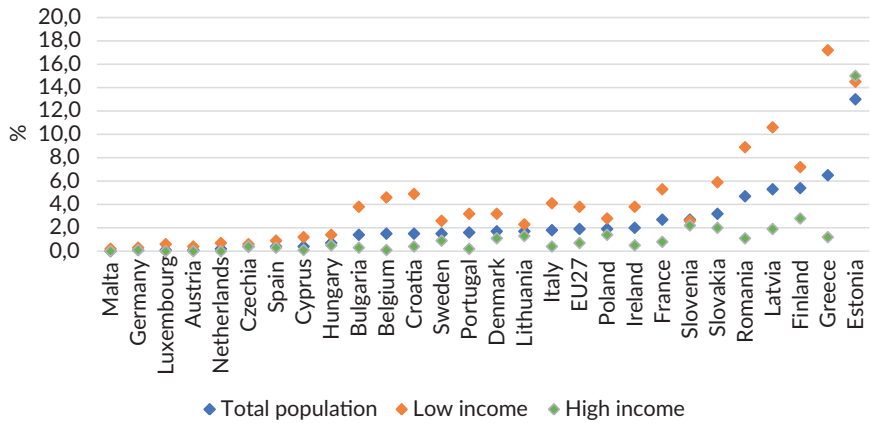
Figure 7 - Evolution in unmet medical care need due to financial, geographic or waiting time reasons, all EU27 countries, 2010-21 [44]

Again, the average level of unmet need for medical care varies between countries, as does the magnitude of social inequalities (Figure 8). The gap between the rich and the poor is the greatest where cost is the main reason for not seeking care. Social disparities are wider for dental care than for medical care, since coverage is generally limited, and OOP payments are high. In several EU countries, 20% or more of low-income people are affected.

Figure 8 - Unmet need for medical examination due to financial, geographic or waiting time reasons, 2020 or nearest year[45]

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44   Eurostat (2023) *Data browser* (Luxembourg City: Eurostat). Available online: https://ec.europa.eu/eurostat/databrowser/view/HLTH_SILC_08/default/table?lang=en
45   Ibid.

Financial hardship and unmet need are linked, as demonstrated by a recent report of the WHO Regional office for Europe[46]: "*In countries where the incidence of catastrophic health spending is very low, unmet need also tends to be low and without significant income inequality. The incidence of catastrophic health spending and levels of unmet need are both relatively high in many countries, and income inequality in unmet need is also significant, indicating that health services in these countries are not affordable, especially for poorer households*".

Gaps on the different dimensions of coverage

Data on financial hardship and unmet needs highlight that gaps in coverage are still a reality in the EU, in spite of a high level of public investment in health systems.

At the request of the European Commission, in 2019, the Observatory on Health Systems and Policies and the Health System and Policy Monitor (HSPM) network conducted a survey of all EU countries to explore these gaps on the four dimensions mentioned above (population coverage, service coverage, cost coverage and service access).[47]

Although population coverage in the EU is generally high, certain groups remain excluded in some countries. A survey of all EU countries showed that the groups most frequently excluded from regular statutory coverage are irregular residents and asylum seekers, although some countries have specific mechanisms to ensure access for these populations (but sometimes with administrative hurdles). Marginalised populations (ethnic minorities such as Roma, or homeless people) are also excluded in some countries due to difficulties in complying with administrative requirements (such as valid identity documents or permanent residency). In countries where the payment of SHI contributions is a condition for coverage, people who are unemployed, or informally employed, or with unstable employment may find themselves uninsured. These exclusions may account for up to one tenth of the population, and tend to be concentrated among the less well-off.

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46   Thomson S., J. Cylus, and T. Evetovits (2019) *Can people afford to pay for health care? New evidence on financial protection in Europe. Summary*. P. 13.

47   Palm W., E. Webb, C. Hernández-Quevedoc, G. Scarpettib, S. Lessofd, L. Sicilianie, and E. van Ginneken (2021) "Gaps in Coverage and Access in the European Union". HealthPolicy 125(3): 341–50.

Services covered are relatively comprehensive across member states, though there is some cross-national variation. The most frequent exceptions to the benefit packages are optical treatments, dental care for adults, physiotherapy, and psychotherapy treatments.

There is also unequal access to very expensive novel pharmaceuticals, particularly for rare diseases or for cancer patients. An analysis conducted by the OECD[48] on a subgroup of 15 member states[49] showed that at the end of 2019, on a sample of 109 products/indications in oncology, around 90% were approved and covered in Denmark and Germany, whereas the proportion was under 60% in Malta, Cyprus, Latvia and Hungary. However, access was more homogeneous across countries for products/indications included in the WHO's 21st Model List of Essential Medicines (more than 90% in all 15 countries surveyed, except for Hungary).[50]

The issue of access to medicines goes beyond these high-cost treatments, because patients often face higher user charges than for services. On average, in the EU, the share of the costs covered is 59% for pharmaceuticals in 2020, compared to 91% for inpatient care and 78% for outpatient medical care. [51] As a result, medicines represent a high proportion of OOP payments for households with catastrophic expenditures, and it is even higher among poor households: 80% or more in Slovakia, Croatia, Estonia, Poland, Hungary, Latvia, Lithuania.[52] User charges are high also for dental care, and here they lead to a high level of unmet need, as already mentioned.

More generally, catastrophic spending generally increases with the level of OOP payments (Figure 9).

48   Chapman S., V. Paris, and R. Lopert (2020) "Challenges in access to oncology medi-cines: Policies and practices across the OECD and the EU", *OECD Health Working Papers, 123*. (Paris: OECD). Pp. 50-52.

49   Belgium, Cyprus, Czechia, Denmark, Estonia, France, Germany, Greece, Hungary, Ire-land, Italy, Latvia, Lithuania, Malta, Sweden.

50   It should be stressed that providing affordable access to new treatments in oncol-ogy is a challenge for even the wealthiest countries, due to the flow of new medicines and the magnitude of launch prices, in addition to the growth in the number of patients being treated. All the more so as the cost per life gain is generally very high, with often a signifi-cant uncertainty surrounding the degree of clinical benefit at the time of market entry.

51   OECD (2022), *Health at a Glance: Europe 2022: State of Health in the EU Cycle* (Paris: OECD).

52   Thomson S., J. Cylus, and T Evetovits (2019) *Can people afford to pay for health care? New evidence on financial protection in Europe. Summary.*

Figure 9 - Incidence of catastrophic health spending and the out-of-pocket payment share of current spending on health, latest year available[53][54]

% of households with catastrophic spending

% of out-of-pocket payments as a share of health
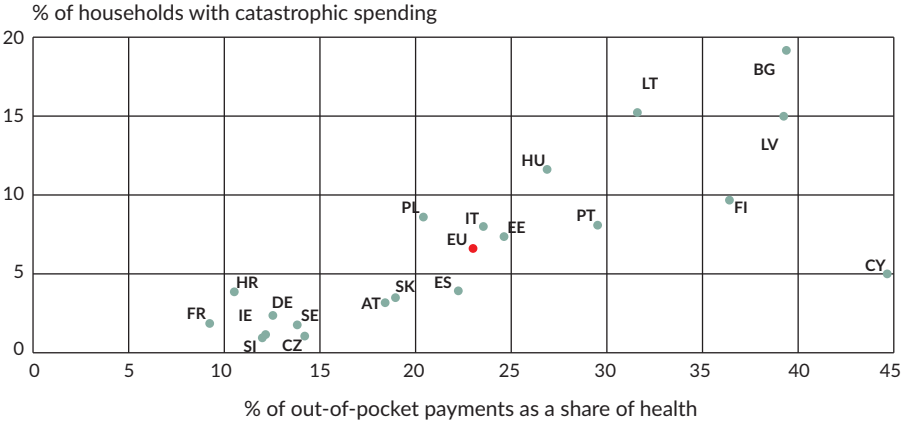
The level, but also the design of cost-sharing arrangements, may be more or less protective for vulnerable populations. User charges can take many forms, including co-insurance, co-payment, deductible, extra-billing, and can be mitigated by exemptions, annual caps, safety nets, and so on.[55]

Regular users of services - the chronically ill, the elderly - are particularly exposed when user charges are in the form of co-insurance, if there are no protection mechanisms such as annual caps or generalised complementary insurance. Exemptions or reductions may also be necessary to avoid financial hardship for low-income people. Various examples of these mechanisms exist among EU countries. In its recent report on affordability of health care in Europe, the WHO Regional Office for Europe issued recommendations on the design of coverage policy to minimise access barriers. The recommendations included: limited out-of-pocket payments (less than or close to 15% of current spending on

53   World Health Organization (2023) *European Health Information Gateway. Financial protection in the European Region* (Copenhagen: WHO).
54   OECD (2022), Health at a Glance: Europe 2022: State of Health in the EU Cycle (Paris: OECD).
55   Co-insurance: percentage of the cost; Co-payment: fixed sum for an item of services (per hospital day, per prescription item…); Deductible: lump sum threshold below which the person must pay the full cost before insurance coverage begins; Extra-billing: difference between the price charged and the price used as a basis for reimbursement purpose; Cap or safety net: thresholds beyond which a person may receive care at lower cost or at no cost.

health), exemptions and caps to protect those who need it most (older people, people with chronic illness, low income people), and fixed co-payments rather than percentage co-payments affecting the sickest.[56]

In terms of service access, the 2019 survey of the Observatory for Health Systems and Policy highlighted:

- Geographical inequalities in the distribution of the healthcare supply which are a common problem. Countries struggle to ensure access to primary care and specialised referrals in rural communities and suburban areas of concentrated poor populations.
- Long waiting times. A major issue in many countries, as shown by the data on unmet need.
- The difficulty of vulnerable populations such as frail elderly, patients with cognitive impairment or mental illness to formulate their needs.
- The discrimination experienced by certain groups (Roma population, irregular residents, homeless people, individuals with stigmatised illnesses, individuals with same-sex orientation or transgender people, among others). In France, for instance, although poor people are financially protected by a specific mechanism, they may be denied treatment by some providers. In a recent survey such situations were found for 9% of dentists, 11% of gynaecologists and 15% of psychiatrists.[57]

Clinical and social vulnerability are often intermingled, and the different barriers to access tend to focus on the same deprived populations.

Capacity to maintain access to health services in times of crisis

In the last 15 years, health systems have been hit by two major crises.

The economic crisis of 2008, which pushed the global economy into the worst recession for more than six decades, posed considerable challenges to maintaining access to health services and medical care. With rising unemployment, growing insecurity and financial pressure for many households, the need for protection increased while health and

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56   Thomson S., J. Cylus, and T Evetovits (2019) *Can people afford to pay for health care? New evidence on financial protection in Europe. Summary.*

57   Défenseur des droits. (2019) *Les refus de soins discriminatoires liés à l'origine et à la vulnérabilité économique : tests dans trois spécialités médicales en France* (Paris: Défenseur des droits). https://www.defenseurdesdroits.fr/sites/default/files/atoms/files/etres-refussoins-num-21.10.19.pdf

social systems' funding was put under strain by the lack of resources and subsequent budgetary constraints. In two-thirds of EU countries, unmet needs increased between 2008 and 2012.[58] Among the poorest households, it peaked at 15% in Italy and Romania, 25% in Bulgaria and Latvia, one-third in Greece.[59]

The Covid-19 pandemic that arrived in Europe in the beginning of 2020 also led to a major economic shock, with real GDP falling by 6.1% in the EU, more than during the global financial crisis. Moreover, it put healthcare systems across the EU under unprecedented pressure. In addition to the immediate damage caused by the virus in terms of life years lost, the pandemic forced healthcare systems across Europe to adapt and reconfigure their resources to meet the unprecedented surge in demand for Covid-19 care. Essential treatment for chronic and non-communicable diseases during the pandemic was postponed for many patients, as well as elective surgery. This subsequently led to longer waiting lists and waiting times in virtually all countries, and delays in diagnosis and treatment[60].

For example, in France, breast cancer screening volumes in the second quarter of 2020 dropped by 44% compared to the same period in 2019. Similarly, in the first wave of the pandemic, the number of cancer diagnoses in the Netherlands decreased by 25%.[61] According to Eurofound data from April 2021, 21% of EU citizens have missed a medical examination or treatment during the pandemic, and 18% reported still having a medical issue for which they could not get treatment.[62] For almost half of them, the need concerned hospital or specialist care; 20% to 30% needed dental care, preventive screening or test or mental health care. It is also clear that Covid-19 exacerbated existing socio-economic health inequalities. In all countries, research evidence shows that low-income people, people living in the most deprived areas, ethnic minorities and immigrants were

58   Thomson, S., et al. (2014) *Economic crisis, health systems and health in Europe: impact and implications for policy* (Copenhagen: WHO).

59   Eurostat (2023) *EU Survey on income and living conditions (SILC)* (Luxembourg: Publications Office of the European Union).

60   Van Ginneken E., S. Reed, L. Siciliani, et al. (2022) "Addressing backlogs and managing waiting lists during and beyond the COVID-19 pandemic", *Policy brief 47*. (Copenhagen: European Observatory on Health Systems and Policies).

61   European Commission (2021) *State of Health in the EU. Companion Report.* (Luxembourg: Publications Office of the European Union). Pp. 12-17.

62   Eurofound (2022) *Living, working and COVID-19 (Update April 2022): Mental health and trust decline across EU as pandemic enters another year* (Luxembourg: Publications Office of the European Union).

disproportionally affected by the pandemic, with a much higher risk of dying among people from these groups who were diagnosed with Covid-19.[63] It is a striking example that while universal health coverage is a prerequisite, it is not enough to tackle health inequalities.

The economic crisis of 2008, and even more so with the Covid-19 pandemic, have been stress tests for the accessibility of EU health systems. They have exposed pre-existing barriers in access to healthcare while exacerbating others. In particular, during the Covid-19 crisis the most vulnerable people bore the brunt of the pandemic's health impacts. It stresses the need for better protection and safety nets for these populations.

Further progress is needed to measure effective access

As highlighted by a 2022 study,[64] while European countries have improved data availability on access and coverage in the EU, indicators are still insufficient to design targeted policy responses. They do not assess the real effectiveness of health coverage (for example, whether or not the care is provided according to the need of the person). Among other limits, patients' experiences are not routinely measured; OOP are not disaggregated enough to understand the link with the different dimensions of coverage, breadth, scope and depth; and surveys do not capture the situation of the most vulnerable groups of people who tend to be excluded from the regular statistical apparatus.[65, 66]

To better understand what drives gaps in access to healthcare and identify policies and approaches to tackle them, the European Commission's Expert Group on Health System Performance Assessment (HSPA) has recently issued suggestions to improve methods to assess health system accessibility, by adapting existing tools and developing new instruments providing more granular data.[67]

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63   OECD (2020) *Health at a Glance: Europe 2020. State of Health in the EU Cycle.*
64   Webb E., J. Offe and E. van Ginneken (2022) "Universal health coverage in the EU: what do we know (and not know) about gaps in access?" *Eurohealth* 38(3): 13-17.
65   Médecins du Monde (2021) *Unseen, unheard, and untreated: health inequalities in Europe today. 2021 Observatory report* (Paris: Médecins du Monde).
66   The *Médecins du Monde* report shows that 80% of the patients coming to MDM clinics in six European countries do not live in personal flat or house, which means that they are not included in statistical surveys such as EU-SILC, and their unmet need is not visible.
67   European Commission (2021) *Expert group on health system performance assessment. Improving access to healthcare through more powerful measurement tools.* (Luxembourg: Publications Office of the European Union). Pp. 75-77.

Conclusion: the weakest link

During the Covid-19 pandemic, the adage that "a chain is only as strong as its weakest link" was often used to describe disease control measures. But beyond the specific problem of infectious disease management, it also applies well to the entire system of health coverage and access to health services. The promise of UHC - that no one should forgo healthcare or suffer financial hardship - means that effective access must be ensured for all and that nobody is left behind, particularly the most vulnerable people.

Available data already show that there is room for progress, and that there is wide variation and inequity between and within member states. Lessons can be drawn from the existing evidence, as shown in the recent work of the WHO's Regional Office for Europe. But standard indicators are too crude to measure effective accessibility according to need, and to capture the multi-dimensional character of the challenge. The 2019 State of Health in the EU Companion Report stressed the need to strengthen the evidence-base on access to healthcare.[68] To better understand the root causes of health gaps and design policies to tackle them, additional tools are required, and the work of the Expert Group on Health System Performance Assessment provides a basis to build upon. It warrants an EU project as such, involving all member states, international organisations, academia and statistical bodies, and might be a first step towards a European Health Union.

If better data are a prerequisite to inform policies, the ultimate goal is to fulfil the commitment to ensure access to healthcare, expressed in principle 16 of the European Pillar of Social Rights. Enhancing solidary and equity of health coverage in the EU should be the overarching objective of a European Health Union. It is an ongoing challenge, requiring strong involvement and coordination of all member states.

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68   European Commission (2019). *State of Health in the EU*. Pp. 30-38.

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Thomson S., J. Cylus, and T. Evetovits (2019) *Can people afford to pay for health care? New evidence on financial protection in Europe. Summary*. (Copenhagen: WHO).

Thomson, S., et al. (2014) *Economic crisis, health systems and health in Europe: impact and implications for policy* (Copenhagen: WHO).

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Van Ginneken E., S. Reed, L. Siciliani, et al. (2022) "Addressing backlogs and managing waiting lists during and beyond the COVID-19 pandemic", *Policy brief 47*. (Copenhagen: European Observatory on Health Systems and Policies).

Webb E., J. Offe and E. van Ginneken (2022) "Universal health coverage in the EU: what do we know (and not know) about gaps in access?", *Eurohealth* 38(3): 13-17.

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2.4 | Rare diseases: at the crossroads of national and European policies

Introduction

Every EU member state (MS) spends a significant share of its budget on healthcare, and EU policies are increasingly focusing on collaboration between MS in health areas where the concentration of knowledge, resources and data has a high added value. One such area is undoubtedly rare diseases (RD), which affect at least 6% of populations,[1] and rare cancers, which collectively represent about 20% of all cancers.[2] The specific characteristics of these diseases demand special solutions in healthcare organisation, and in many cases successful solutions are based on collaborations - between stakeholders, institutions, sectors, regions and countries.

In Europe, RD were defined just over 20 years ago as diseases affecting less than 5 persons per 10,000 inhabitants.[3] Since then, RD have entered into health policy agendas, and there have been significant policy breakthroughs at both EU and national level. One of the major current achievements, the European Reference Networks (ERNs), were founded on the principle that many rare disease issues are pan-European, and no single member state can solve them alone. ERNs were born from the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare,[4] and are an unprecedented example of EU cooperation

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1   Nguengang Wakap S, et al. (2020) "Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database". *Eur J Hum Genet*, 28(2): 165-173.
2   Gatta G, et al. (2011) "Rare cancers are not so rare: the rare cancer burden in Europe". *Eur J Cancer,* 47(17): 2493-511.
3   Official Journal of the European Union (2000) "Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products"
4   Official Journal of the European Union (2011) "Directive 2011/24/EU on the application of patients' rights in cross-border healthcare".

in healthcare. Three ERNs are dedicated to rare cancers, and 21 ERNs are dedicated to rare and complex conditions. Altogether, they encompass more than 1,600 Centres of Excellence (CoE) across all EU MS.

Significant breakthroughs at the EU level could not be achieved without coordinated and concomitant actions in national RD policies. The most important changes that have occurred in many MS over the last 20 years were the development of national plans or national strategies (NP/NS) and CoE for rare diseases. NP/NS created the legal and organisational framework for national RD multistakeholder collaboration and responsiblity-sharing, while CoE comprised the crucial hubs in both national and European networks. These national and European breakthroughs give us a powerful arsenal to change the lives of millions of RD patients and their families. However, many challenges still remain that may endanger the sustainability of these achievements, and preclude EU citizens from reaping the full benefits of the solutions created so far.

The unique features of rare diseases demand unique solutions

Unique features of RD create unique challenges in healthcare systems, and effective solutions to these challenges are different when compared to common diseases (table 1). Some 6,000 to 8,000 RD that are currently known may affect any organ or body system at any age, and in many cases RD are multisystem. This rarity, numerosity and heterogeneity, together with the fact that a large portion of current medical staff received their medical education well before the RD concept and innovative diagnostics appeared, creates a major hurdle to recognising and diagnosing rare diseases at the primary or local care level – which is where patients usually seek help when symptoms develop.

The multisystem nature of RD is also a challenge. This requires a multidisciplinary approach, where teams of experts carefully put together separate parts into complex diagnostic puzzles. Innovative, efficient diagnostics are usually only provided through highly specialised testing that is available at CoE only.

Time is also an important factor. The diagnosis of RD takes five to six years on average, and some patients may wait decades for a precise diagnosis.[5] This situation creates intricate diagnostic labyrinths and

5   Austin, C. P., et al. (2018) "Future of Rare Diseases Research 2017-2027: An IRDiRC Perspective". *Clin Transl Sci*, 11(1): 21-27.

lengthy diagnostic odysseys that are tedious and frustrating for patients and their families and are resource-intensive and expensive for healthcare systems. In fact, a significant proportion of RD patients do not get timely diagnosis purely because they are stuck in healthcare systems and do not get timely highly-specialized diagnostics.[6]

Another part of the problem lies at the primary or local care level. Family doctors often lack a sufficient index of suspicion for RD. They may also lack healthcare system literacy for referring patients to the right level and point of care. In at least 50% of all EU healthcare systems a formal referral for highly specialized services is required from family physicians (a so-called gatekeeper function); proper adjustments of these gatekeeper functions may also play a role.[7]

Finally, approximately 50% of RD are undiagnosable with all current measures in clinical practice. These patients should have a direct interface between highly-specialised healthcare and research facilities. Such a link is frequently available in CoE for RD and may provide clues to diagnosis through international cooperation in undiagnosed disease networks or usage of innovative technologies.[8]

Treatment option challenges

Once a RD is diagnosed, appropriate treatment and long-term management should be instituted. Approximately 6% of RD have specific, prognosis-changing treatments.[9] The regulation on Orphan Medicinal Products (OMP) provided strong incentives for the development of Orphan drugs, that have gained momentum since 2000 with almost 3000 applications submitted to European Medicines Agency in the period 2000-2017.[10] The attractiveness of exemptions secured through the regulation on OMP, and a so-called orphanisation of common diseases through fragmentation into rare subtypes, led to a growth in orphan indications. At

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6   Black, N., et al. (2015) *Diagnostic odyssey for rare diseases: exploration of potential indicators*. (London: Policy Innovation Research Unit)

7   European Commission (2017) *State of Health in the EU: Companion Report 2017* (Luxembourg: European Commission)

8   Boycott K. M., et al. (2019a) "A Diagnosis for All Rare Genetic Diseases: The Horizon and the Next Frontiers". *Cell*. 177(1): 32-37.

9   Austin, C. P., et al. (2018) "Future of Rare Diseases Research 2017-2027: An IRDiRC Perspective".

10   European Medicines Agency (2018) *Orphan Medicinal Product Designation* (Amsterdam: EMA)

the same time, the prices of drugs reached unprecedented highs, raising affordability issues even for wealthy healthcare systems.[11]

Meanwhile, the range of orphan indications remains restricted to a small minority of RD: at present, 40% of drugs with OMP status are approved for specific rare types of cancer, and only 25% of orphan designations in 2000-2017 were for new conditions.[12] At present, pharmaceutical companies compete for a handful of well-known, well-studied, and relatively prevalent RD, while the vast majority of RD are left out of the scope of clinical research.[13]

Although these issues have been a subject of intense discussions in various fora in recent years, it should be stressed that the much larger proportion of 95% of RD currently do not have specific treatment options and raise significantly more health inequity issues. Many of these diseases are undrugable, i.e., they will never have specific, substantially prognosis-changing treatments. Nevertheless, appropriate symptomatic treatments, prevention of complications and long-term follow-up are very important in all cases and can profoundly change health and quality of life of patients and their families.

Unfortunately, in many countries, and for large numbers of rare diseases, both clinical guidelines and care pathways are missing. Primary healthcare or local professionals are often unaware of where the patient should be referred for services and are not prepared for long term management of RD and coordination of complex care. Therefore, a burden of care organisation and coordination frequently lies on the shoulders of patients and their families and induces significant social and financial difficulties.[14]

In comparison to common diseases, RD care pathways are highly complex with parts of services inevitably highly-specialised and provided by experts. These services have to be centralised in CoE for quality, safety and cost-effectiveness and are usually provided far away from patients' homes. Hence, in every RD care pathway, the aim is to strike the right balance between costly, highly-specialised and remote services

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11   Luzzatto, L., et al. (2018) "Outrageous prices of orphan drugs: a call for collaboration". *Lancet*, 392(10149): 791-794.
12   European Medicines Agency (2018) *Orphan Medicinal Product Designation* (Amsterdam: EMA)
13   Boycott K. M., et al. (2019b) "International collaborative actions and transparency to understand, diagnose, and develop therapies for rare diseases". *EMBO Mol Med*, 11(5).
14   EURODRIS (2017) "Juggling care and daily life: the balancing act of the rare disease community". *A Rare Barometer survey* (Paris: EURODRIS).

provided at a CoE, and less sophisticated services that can be provided by local healthcare providers. Besides, many CoEs do not have effective communication with local service providers and a smooth transmission of patients' data and funds across healthcare systems is not always ensured. Additional hurdles for the movements of patients, their data and funds arise in regionalised healthcare systems.[15, 16]

Finally, the crucial prerequisites for organising care pathways are clinical guidelines. However, there is a critical lack of them in the field of RD. Although the usual developers of best practices are professional and scientific organisations, very few of them actively issue clinical guidelines for RD. For all these reasons, RD patients and their families comprise a particularly vulnerable part of societies and are suffering from major health inequities.[17]

Invisible diseases, invisible patients

RD patients remain invisible in the majority of EU healthcare systems, largely due to the lack of codification. The only specific codification system for RD are ORPHA codes[18], yet just a small number of countries have so far implemented strategies to use ORPHA codes and produce statistics on RD at national level.[19] Usual widespread codification systems have few codes for RD: ICD10 includes 559 specific codes, SNOMED CT - 38% of ORPHA codes, and ICD11 includes 3718 of approximately 7000 ORPHA codes. This lack of codification, statistics and traceability results in limited possibilities to evaluate the real situations in MS and across Europe, to justify and assess applied and possible measures and solutions, and finally, to convince authorities and to put RD into policy agendas.

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15   Nuti S., et al. (2017) "Comparing regional models of congenital bleeding disorders: preliminary steps in the Italian context". *BMC Res Notes,* 10(1): 229.
16   Busco S, et al. (2015) "Italian cancer figures. Report 2015: The burden of rare cancers in Italy". *Epidemiol Prev,* 40(1 Suppl 2): 1-120.
17   UNHCR (2019) *Report of the United Nations High Commissioner for Human Rights* (Geneva: UNHCR).
18   ORPHA codes are unique and stable numerical identifiers of rare diseases; ORHA codification system is developed by the international organization Orphanet (https://www.orpha.net/consor/cgi-bin/index.php)
19   RD-ACTION (2017) *WP5. Implementation of rare disease patient coding across member states, 2017* (Brussels: RD-ACTION)

In 2019, the United Nations declared that RD patients are among the most vulnerable groups still on the fringes of universal health coverage.[20] Claims that European high income countries already provide universal access to high quality healthcare are widespread,[21] and these claims are usually supported by ever improving health indicators - increasing life expectancy, decreasing infant and maternal mortality, diminishing incidence of communicable diseases. However, in many cases, average values across the whole population mask huge gaps in coverage and marginalisation of particularly vulnerable groups in our societies, including people living with RD. At present, the healthcare systems of EU MS are not ready to tackle the unique challenges presented by RD.

Table 1. Unique features of rare diseases.

Features of rare diseases	Challenges	Possible solutions
Rare, numerous, heterogeneous diseases	Limited ability to recognise/ diagnose and to provide care at a primary/local medical contact point.	*Workforce education ("red flags", healthcare system literacy); established care pathways and referral systems to CoE; clinical guidelines; vertical care integration, care coordination and case management; transitions of care; reducing barriers in regionalised HC systems.*
Heterogeneous multisystem involvement	Heterogeneity of care pathways, multiple contacts with fragmented healthcare systems.	*Horizontal care integration, multidisciplinary teams; care coordination, case management.*
Complexity in diagnostics, treatment, long-term care	Limited expertise and resources, expensive facilities, infrastructures and services.	*Centralisation of expertise, infrastructure and human resources; establishment of tertiary-tertiary care interface where necessary.*

20   United Nations (2019) *Political Declaration of the High-level Meeting on Universal Health Coverage: Universal health coverage: moving together to build a healthier world* (New York: United Nations)
21   World Health Organization (2023) *Regional Office for Europe: Health care systems in transition* (Copenhagen: WHO).

Chronic, disabling, childhood-onset in 75%, life-long, inducing complex needs	Complex and multiple trajectories across systems, socioeconomic burden.	*Care integration: horizontal, vertical, longitudinal; balanced provision of centralised/ decentralised services; transitions of care (across healthcare system levels, social – health sectors, pediatric – adult); care coordination, case management; patient empowerment, involvement of communities, patient organisations, non-governmental organisations.*
Invisible in health systems	Limited possibilities to evaluate the real situation in MS and across Europe, to justify and assess applied measures and solutions.	*Implementation of RD codification in national healthcare systems; production of national and European RD statistics for benchmarking and situation analysis.*
Very scarce knowledge on the majority of RD	Placed in the interface between healthcare and research; "scientific uncertainty"; limited resources for RD research (cohorts of patients, biospecimen).	*Intersectoral collaboration, including health, research and education sectors; ethicolegal measures to ensure smooth highly-specialised healthcare and research interface; research-oriented medical education; proper communication of scientific uncertainty, patient education and empowerment.*

Source: Authors' own design

National policies to address RD issues

The complexity of the RD field requires particularly close collaboration between different levels of healthcare systems, various stakeholders, institutions and sectors. Therefore, the division of responsibilities and accountability is not possible without a national consensus. In 2009, MS were encouraged by the European Council to adopt national RD plans or strategies by 2013. Although not all countries succeeded in meeting the deadline, 28 of the 30 EU and EEA countries eventually adopted NP/NS for RD. One of the important drivers for the successful development of NP/NS was an EU-cofunded project called EUROPLAN; it developed tools and recommendations for NP/NS.[22] Moreover, together with the subsequent

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22   EUROPLAN (2023a) *EUROPLAN Project* (Brussels: European Commission).

RD-Action project and European umbrella RD patients' organisation EURORDIS, an extensive programme of 59 national conferences and meetings was implemented across Europe, where RD stakeholders had opportunities to meet, discuss and find consensus.[23]

France was the first country in Europe to adopt an NP for RD in 2004,[24] and its leadership was demonstrated by the launch of its third NP for the period 2018-2022.[25] All French National Plans meet EUROPLAN criteria and the WHO Strategic Vision for National Health Policies, Strategies and Plans:[26] France has clearly stated areas of activities with division of responsibilities, timelines, monitoring, accountability and dedicated budgets, intersectoral cooperation, including health, social, education and research sectors, coherence of national and EU policies and reflection of current needs.

Unfortunately, not all member states' RD NP/NS are sustainable or of sufficient quality, and there is a huge gap not only between the documents themselves but also in NP/NS implementation.[27] Some NP/NS are more a declaration of good intentions than a coordinated programme of action. Just a small minority of NP/NS have dedicated budgets, and many of them are signed by Ministers of Health only and do not ensure intersectoral collaboration. Furthermore, a lack of monitoring limits accountability and lack of coordination prevents proper implementation. Finally, many of the previously adopted NP/NS no longer meet today's requirements. For example, they do not encompass measures for integrating newly developed ERNs into national systems and are not coherent with European RD policies. Thus, many European countries would benefit from revising and updating their NP/NS to the current needs and standards.

One major achievement of national health systems in the field of RD are Centers of Expertise (CoE). The first CoEs for RD patients and their families were established in the Nordic countries,[28] while health authorities in EU13 were frequently reluctant to identify and formally recognise CoE

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23   EUROPLAN (2015) *National Conferences, final reports, 2012-2015* (Brussels: European Commission).

24   Ministère de la Santé et la Prévention (2008) *French National Plan for Rare Diseases, 2005 – 2008* (Paris: Ministère de la Santé et la Prévention).

25   Ministre des Solidarités et de la Santé (2018) *French National Plan for Rare Diseases 2018-2022.* (Paris: Ministre des Solidarités et de la Santé).

26   WHO(2023) Supporting National health policies, strategies, plans: https://www.who.int/activities/supporting-national-health-policies-strategies-plans

27   EUROPLAN (2023b) *National Plans* (Brussels: European Commission).

28   Hedley, V. et al. (2018) "2018 Report on the State of the Art of Rare Disease Activities in Europe", *RD-Action WP6 Output*

that existed "by reputation" only. A call for ERN membership in 2016 induced a new wave of identification, accreditation and designation of CoE for RD across Europe. However, a lack of previous CoE recognition together with a lack of funding may have been one of the reasons for the less active participation of EU13 countries in ERN Full Membership.[29]

CoE are the most important hubs for national and European RD multistakeholder networks. Many CoE are established in university tertiary hospitals, where highly-specialised services, sophisticated infrastructure, expertise and interfaces between healthcare, education and research are ensured. When properly supported, equipped and integrated into national systems, CoE have an enormous potential to significantly improve RD diagnostics, treatment and management and to ensure efficient and timely translation of innovations into clinical practice.

The most important rationale behind the concept of CoE is the need to concentrate expertise, human and technological resources They are the only way to ensure patient safety, and qualitative, cost-effective, highly-specialised services for RD patients. Unfortunately, the establishment, accreditation and centralisation of CoEs are not equally successful across Europe. In some countries, there is a lack of and/or uneven distribution of CoE, while many countries do not have sufficient and adequate care pathways to them.

Although there is no uniform definition of a CoE in the EU, they usually meet EUCERD criteria,[30] while ERN Full Members have to conform to the stringent general and RD-specific criteria.[31] However, due to a natural inclination among professionals and institutions to competition and leadership, some centres that lack expertise and resources may still seek to provide highly-specialised services for RD patients, despite inherent risks in doing so.[32] Eventually, all these factors create a postcode lottery situation where the chances of a patient with an RD getting a proper diagnosis and treatment depends on where they live, and there are huge, unwarranted variations between and within member states. Without appropriate measures to ensure centralisation and quality of

29   European Commission (2023) *European Reference Networks* (Brussels: European Commission).
30   EUCERD (2011) *Recommendations on Quality Criteria for Centres of Expertise for Rare Diseases in Member State* (Brussels: European Commission).
31   ERN (2016) *Assessment Manual for Applicants. Operational Criteria for the Assessment of Healthcare Providers* (European Commission: Brussels).
32   Perrier L., et al. (2018) "The cost-saving effect of centralized histological reviews with soft tissue and visceral sarcomas, GIST, and desmoid tumors: The experiences of the pathologists of the French Sarcoma Group". *PLoS One*, 13(4).

highly-specialised services for RD patients, significant deterioration of patients' health - and enormous waste of health systems' resources - is likely.[33, 34, 35]

EU efforts to develop and support RD policies

In recognition of the extraordinary added value of cooperation between MS in the field of RD, the EC has taken decisive steps. Although the organisation of health systems is an autonomous field and competence of every MS, in many cases, the EC has succeeded in achieving a constructive dialogue between countries. In 2009, a landmark council recommendation on an action in the field of rare diseases was issued with a call for actions in the development of NP/NS, RD codification, research, CoE, European collaboration and patient empowerment.[36] After five years, it was recognized that "by and large the objectives of the Communication and the Council Recommendation have been reached". However, "despite such encouraging progress, there is still a long way to go to ensure that people suffering from a rare disease can obtain the right diagnosis and best possible treatment throughout the EU".[37] Therefore, one of the recommendations of European Court of Auditors released in 2019 was to "assess the results of the rare disease strategy (including the role of the European Reference Networks) and decide whether this strategy needs to be updated, adapted or replaced".[38]

Directive 2011/24/EU on the application of patients' rights in cross-

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33   Sandrucci S., et al. (2019) "Centers of excellence or excellence networks: The surgical challenge and quality issues in rare cancers". *Eur J Surg Oncol* 45(1): 19-21.

34   Perrier L., et al. (2018) "The cost-saving effect of centralized histological reviews with soft tissue and visceral sarcomas, GIST, and desmoid tumors: The experiences of the pathologists of the French Sarcoma Group". *PLoS One*, 13(4).

35   Derbel O., et al. (2017) "Survival impact of centralization and clinical guidelines for soft tissue sarcoma (A prospective and exhaustive population-based cohort)". *PLoS One*, 12(2).

36   Official Journal of the European Union (2009) "Council Recommendation on an action in the field of rare diseases" *OJ, C,* 151/7.

37   European Union (2009)*Implementation report on the Commission Communication on Rare Diseases: Europe's challenges [COM(2008) 679 final] and Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02), 2014* (Brussels: European Commission).

38   European Court of Auditors (2019) *EU actions for cross-border healthcare: significant ambitions but improved management required*. (Luxembourg: European Court of Auditors)

border healthcare set the stage for new forms of cooperation between MS in both content and scope.[39] One of the main results of the directive are European Reference Networks. The first wave of ERN revealed the true scope of RD in Europe: 24 networks, more than 900 CoE across 26 countries, at least 700,000 RD patients per year.[40] In 2022, ERNs encompass more than 1,600 CoE across the entire EU and EEA. Moreover, ERN accessibility is ensured through Affiliated Partnership in countries where capacities in RD care are limited. Exceptional ERN inclusivity compared to, for example, programmes for EU research funding,[41, 42] is demonstrated by the number of ERN Full Members (FM) and ERN Affiliated Partners (AP) in the EU-13 countries, where approximately 20% of EU inhabitants live. After the first call for ERN FM, the percentage of ERN FM in EU-13 MS was 11.3%, while after the call for ERN AP, 20% of all ERN FM and ERN AP were in the EU-13 MS. These ERN scopes clearly demonstrate the true scale and importance of RD in public health, but also open up unforeseen problems. The large number of ERN members places a huge administrative burden on ERN coordinators and threatens ERN manageability.

Furthermore, huge inequities among all MS still remain. The number of ERN centres per million inhabitants ranges from < 1 ERN Center per million inhabitants (GR, RO, PL, IE, BG) to > 10 ERN Centers per million inhabitants (LT, CY, LV, EE). Indeed, although ERNs may provide economies of scale, scope and time in many tasks (including development and implementation of RD clinical guidelines, collection of cohorts and data of RD patients, creation of curricula for RD education, clinical and translational RD research, monitoring of RD activities for policy decisions, etc.) some MS are still reluctant to find the organisational, legal and financial mechanisms to support these activities.

At present, the EC funds a significant portion of ERN activities, but in some cases even a basic agreement between countries on how to implement innovations brought by ERNs is lacking. One of the most prominent examples are virtual clinical consultations made through

39 Official Journal of the European Union (2011) "Directive 2011/24/EU on the application of patients' rights in cross-border healthcare", *OJ, L, I88/45*.

40 European Commission (2023) *European Reference Networks* (Brussels: European Commission).

41 Conte A., and K. Ozbolat Nida (2016). "Synergies for Innovation: Lessons Learnt from the S2E National Events", Stairway to Excellence Brief Series, Issue #1, JRC104861 (European Commission: Seville)

42 Kaló Z., et al. (2019) "Is there a fair allocation of healthcare research funds by the European Union?" *PLoS One* 14(4).

the Clinical Patient Management System (CPMS). The system was developed to implement the principle that "expertise goes first, not the patient", but unfortunately, no consensus has been reached between MS on how these services should be reimbursed. Hence, among the main recommendations of a recently issued European Court of Auditors report were that: "in consultation with the Member States, set out ways forward to address the challenges faced by the European Reference Networks (including integration of the European Reference Networks into national healthcare systems, and patients' registries)" and „work towards a simpler structure for any future EU funding to the European Reference Networks and reduce their administrative burden". A statement of the ERN Board of member states on integration of the European Reference Networks into the healthcare systems of member states further defined five key areas of intervention and provided a non-exhaustive list of potential actions that may be taken by MS.[43] Indeed, the full integration of ERN into national systems may require MS to make bold and innovative solutions and to adapt the organisation and regulation of their health systems. Ultimately, it is the only way to reap the full benefits that ERNs can offer.

One fifth of EU citizens live in EU13 countries. RD patients in these countries may be especially vulnerable due to a lack of expertise and resources. Although data are limited, some European-wide registries show large variation in service provision and gaps in adherence to existing care recommendations.[44, 45, 46] ERNs may play a major role in increasing accessibility of highly-specialised services and spread of knowledge and expertise to countries with a less developed RD field.

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43   ERN (2019) *Board of Members States. Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member States, 2019* (European Commission: Brussels).

44   Huemer M., et al. (2019) "Phenotype, treatment practice and outcome in the cobalamin-dependent remethylation disorders and MTHFR deficiency: Data from the E-HOD registry", *J Inherit Metab Dis*. 42(2): 333-352.

45   Charron P., et al. (2018) "The Cardiomyopathy Registry of the EURObservational Research Programme of the European Society of Cardiology: baseline data and contemporary management of adult patients with cardiomyopathies". *Eur Heart J*. 39(20): 1784-1793.

46   Gatta G, et al. (2019) "Epidemiology of rare cancers and inequalities in oncologic outcomes", *Eur J Surg Oncol*. 45(1): 3-11.

Importance of collaboration in RD research

Equally important is an extensive EU and international collaboration in RD research. According to the European Medicines Agency, fewer than 1,000 diseases benefit from even minimal amounts of scientific knowledge;[47] the remainder of RD lack crucial opportunities for the development of specific treatments and high-quality healthcare services.

In recognition that Orphan drug (i.e., medicines for rare diseases) development requires additional incentives, the Regulation on Orphan Drugs was introduced in EU in 1999. However, all other areas, including basic, preclinical, translational and socioeconomic research on RD, require just as much support and cooperation. According to the State of Art Resource of the RD-ACTION project, eleven countries out of 29 (EU plus Norway) had dedicated programs or funds for national RD research in 2014-2016.[48] The fragmentation and scarcity of RD research across the EU puts an especially high added value on transnational collaboration. In the RD field, every patient with a novel or underinvestigated RD may become a precious resource for further research. Collection and sharing of data, samples and resources in European and international networks have already proven to be of enormous importance in disclosing etiologies of previously undiagnosed RD[49, 50, 51, 52] revealing natural histories and mechanisms of RD.[53] Even more significant breakthroughs could be achieved by opening data currently stored in individual countries, institutions and laboratories, ensuring the interoperability and accessibility of these data in accordance with FAIR principles,[54] and building interactions with European Research Infrastructures.

At the EU level, a call for systematic and coherent collaboration in research and innovation was expressed by multiple actions, including

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47 European Medicines Agency (2023) *Orphan designation: Overview* (Amsterdam: EMA).
48 Hedley, V. et al. (2018) *2018 Report on the State of the Art of Rare Disease Activities in Europe: RD-Action WP6 Output* (Brussels: RD-ACTION).
49 Philippakis A. A., et al. (2015) "The Matchmaker Exchange: a platform for rare disease gene discovery". *Hum Mutat*, 36(10): 915-21.
50 Ibid.
51 Lochmüller, H., et al. (2018) "RD-Connect, NeurOmics and EURenOmics: collaborative European initiative for rare diseases". *Eur J Hum Genet*, 26(6): 778-785.
52 Solve RD (2023) *Homepage* (Tübingen: Solve-RD).
53 E-RARE (2023) *Research Programmes on Rare Diseases* (Brussels: European Union).
54 Wilkinson, M. D., et al. (2016) "The FAIR Guiding Principles for scientific data management and stewardship". *Sci Data,* 3:160018.

the development of the European Research Area (ERA),[55, 56, 57] the establishment of a range of partnership instruments,[58] and the legal/organisational basis for European Research Infrastructures.[59, 60]

The need for a coherent policy approach for all kinds of partnerships is clearly addressed in Horizon Europe.[61] Systematic and coherent European and transnational collaborations in RD research evolved from ERA-NETs (E-Rare-1, 2006-2010, and E-Rare-2, 2010-2014) to ERA-NET Cofund (E-Rare-3, 2014-2019) to, finally, European Joint Programme on Rare Diseases (EJP RD), launched in 2019[62]. The goal of E-Rare was to foster collaborative funding of relatively small and focused research consortia.[63] The importance of joint research projects was demonstrated by the remarkable growth of E-Rare from six funding agencies in the first Joint Transnational Call (JTC) to 26 funding agencies from 18 countries in E-Rare-3.[64] Through JTCs in E-Rare-1 and E-Rare-2, €56.4 million were invested to fund 79 research projects involving 347 research teams. Hundreds of new genes were identified, new diagnostic protocols and guidelines established, and many outstanding papers (with an average

55   European Commission (2012) *A Reinforced European Research Area Partnership for Excellence and Growth. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.* (Brussels: European Commission).

56   Council of the European Union (2015) *Draft Council conclusions on the European Research Area Roadmap 2015-2020* (Brussels: European Union).

57   European Commission (2018a). *A renewed European Agenda for Research and Innovation - Europe's chance to shape its future. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions*. (Brussels: European Commission).

58   European Commission (2011) *Partnering in Research and Innovation (SEC(2011) 1072). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions*. (Brussels: European Commission)

59   Official Journal of the European Union (2009) "Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC)", *OJ, L, 206/1*.

60   ESFRI (2018) *Strategy Report and Roadmap on Research Infrastructures* (Milan: ESFRI).

61   European Commission (2018b) *Decision of the European Parliament and of the Council on establishing the specific programme implementing Horizon Europe – the Framework Programme for Research and Innovation.* (Brussels: European Commission)

62   EJP Rare Diseases (2023) *Homepage* (Ivry-sur-Seine: EJP Rare Diseases).

63   Julkowska D, et al. (2017) "The importance of international collaboration for rare diseases research: a European perspective", Gene Ther, 24(9): 563-571. DOI: https://pubmed.ncbi.nlm.nih.gov/28440796/

64   E-RARE (2023) *Research Programmes on Rare Diseases*

impact factor of 9.5) were published.[65] In 2012, the EC and E-Rare Group of Funders joined the International Rare Diseases Research Consortium (IRDiRC)[66] with the aim of contributing to its vision and aims and to accelerate the development of diagnostics and treatments for RD through worldwide collaborations.[67]

In the European Joint Program on Rare Diseases (EJP RD) that was launched in 2019, European and international cooperation in RD research has taken new forms and scopes.[68] With a budget of approximately €110 million, this program involves more than 130 partners (including research funding bodies, research institutes, universities, EU research infrastructures, patient organisations and ERN) from 35 countries (27 EU Member States, seven Associated, and one third country) and provides a mission-like approach to support translational research from bench to bedside and back again, and to develop a sustainable ecosystem for a virtuous circle between rare disease care, research and medical innovation. Arranged into four interconnected Pillars, EJP RD encompasses the whole range of activities including direct funding of JTCs, funding schemes for networking and public-private partnerships, support to innovative clinical research, the creation of a virtual platform of RD data and services, education and training, patient empowerment and translation into clinical practice.

Aside from the many benefits brought by collaborative research, EJP RD creates a global multistakeholder community and a fruitful RD research ecosystem. The sharing of common values and standards on many aspects, including ontologies, registries, omic data analysis, data and biospecimen management and beyond, may enable a powerful spread of high standards and best practices and increase the quality of RD research globally. EJP RD involvement in IRDiRC and its collaboration with GA4GH are especially important in this regard.[69, 70] What is more, crucial interconnections with RD-relevant European Research Infrastructures were ensured, including BBMRI, EATRIS, ECRIN, ELIXIR, INFRAFRONTIER.

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65   Ibid.
66   IRDiRC (2023) *Homepage* (Ivry-sur-Seine: IRDiRC)
67   Dawkins, H. J. S., et al. (2018) "Progress in Rare Diseases Research 2010-2016: An IRDiRC Perspective". *Clin Transl Sci*. 11(1): 11-20.
68   EJP Rare Diseases (2023) *Homepage* (Ivry-sur-Seine: EJP Rare Diseases).
69   Lochmüller, H., et al. (2017) "The International Rare Diseases Research Consortium: Policies and Guidelines to maximize impact". *Eur J Hum Genet*. 25(12): 1293-1302.
70   GA4GH (2019) *New GA4GH Driver Projects in 2019* (Toronto: GA4GH).

Despite the progress outlined above, RD research is in a disadvantaged position in EU13 countries. General research and development expenditure as a share of GDP remains very low in the EU13 as compared to EU15 countries. In 2016, nine EU13 countries spent less than 1% of GDP on research and development and were far away not only from the EU2020 Strategy target of 3%, but also from the EU average of 2.03%.[71] Although specific funding allocations to RD research exist in some of these countries (e.g., HU, SI), none of the EU13 countries have specific dedicated RD research programmes.[72] Hence, EU13 countries are especially dependent on collaborative research; not only can it increase efficiency, effectiveness and excellence of research in the EU13, but also break some "closed club" relations composed of tight networks of scientific organisations in EU15 MS.

Meanwhile, the level of international collaboration in EU13 countries is lower and sometimes much lower than in most EU15 countries. In the 7th Framework Programme (FP7), the main instrument for EU funding for research in 2007-2013,[73] the EU13 countries had low participation and were largely on the periphery of research networks. For example, while Germany was involved in as many as 70% of projects, Poland, the highest placed EU13 country, was involved in just 14% of projects. In the 2007-2013 period, the overall international co-publication intensity of EU13 countries was low compared to EU15 countries. Throughout the Framework Programmes, EU15 Member States have always been the biggest recipients of EU support, with allocated EU funding of 90% in FP6, 88% in FP7 and 95% in Horizon 2020, while EU13 members states got 3%, 2% and 2% of allocations in FP6, FP7 and Horizon 2020 (up to January 2017), respectively.[74] Even when EU13 beneficiaries managed to get a grant, there was a significant difference in the average grant amounts between EU15 and EU13 beneficiaries (€475,048 vs. €217,031).[75] Very

71   EUROSTAT (2018) *Smarter, greener, more inclusive? Indicators to support the Europe 2020 strategy* (European Union: Luxembourg)

72   Hedley, V. et al. (2018) *2018 Report on the State of the Art of Rare Disease Activities in Europe: RD-Action WP6 Output* (Brussels: RD-ACTION).

73   European Commission (2016) *Commission presents its evaluation of the 7th Framework Programme for Research* (Brussels: European Commission).

74   Conte A., and K. Ozbolat Nida (2016). "Synergies for Innovation: Lessons Learnt from the S2E National Events".

75   Kaló Z., et al. (2019) "Is there a fair allocation of healthcare research funds by the European Union?" *PLoS One* 14(4).

similar results were obtained in the analysis of health-related projects in the EU's FP5 and FP6 programmes.[76]

The level of participation and success rates of EU13 countries were very low in both E-Rare-1 and E-Rare-2 too. However, specific measures for spreading excellence and widening participation have been applied in E-Rare-3 since 2015. These measures resulted in eight projects with the involvement of research teams from usually underrepresented countries.[77] In EJP RD, the widening principles in JTC were supplemented by additional measures in education and training activities – spreading of educational courses into Eastern and Central European countries and fellowships for EU13 participants. These measures will, hopefully, further increase the participation of EU13 countries in RD research. [78]

Conclusion - no one left behind

Much work has been done to tackle rare diseases, but even greater challenges lie ahead for Europe. Only when patients no longer have to wait for five or six years to get an accurate diagnosis (and sometimes pass away before reaching it), when high-quality, effective, integrated and coordinated treatments are given to at least 95% of patients (rather than a mere 5%), when patients and their families become happy and fully integrated members of our societies – only then will we have a right to say that we did not leave the most vulnerable behind.

76   Galsworthy M. J., et al. (2014) "An analysis of subject areas and country participation for all health-related projects in the EU's FP5 and FP6 programmes", *Eur J Public Health*,. 24(3): 514-20.
77   Julkowska D, et al. (2017) "The importance of international collaboration for rare diseases research: a European perspective"
78   EJP Rare Diseases (2023) *Homepage*

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Busco S, et al. (2015) "Italian cancer figures. Report 2015: The burden of rare cancers in Italy". *Epidemiol Prev,* 40(1 Suppl 2): 1-120. DOI: 10.19191/EP16.1S2.P001.035.

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Conte A., and K. Ozbolat Nida (2016). "Synergies for Innovation: Lessons Learnt from the S2E National Events", *Stairway to Excellence Brief Series*, Issue #1, JRC104861 (European Commission: Seville)

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ERN (2019) *Board of Members States. Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member States, 2019* (European Commission: Brussels). Available online: https://health.ec.europa.eu/system/files/2019-07/integration_healthcaresystems_en_0.pdf

ERN (2019) *Annex to the Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member States, 2019*. Available online: https://health.ec.europa.eu/system/files/2019-07/integration_healthcaresystems_en_0.pdf

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EURODIS (2018) "Rare disease patients' participation in research". A Rare Barometer survey (Paris: EURODIS). Available online: http://download2.eurordis.org.s3.amazonaws.com/rbv/2018_02_12_rdd-research-survey-analysis.pdf.

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European Commission). Available online: https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=celex:52014DC0548

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2.5 | Equal access to health workers: managing health worker migration in a context of free movement

Introduction

Since EU Commission President Ursula von der Leyen endorsed political calls for its creation in 2020, the European Health Union (EHU) has started to materialise. [1, 2, 3] This is evidenced by (among other things) the inclusion of the concept in explanatory memoranda of legislative proposals and the publication of various policy documents, including the final report from the Conference on the Future of Europe. [4, 5, 6, 7]

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1   Von der Leyen, U. (2020). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Brussels, 16 September 2020.
2   S&D (2020) *Letter of the Socialists and Democrats to the presidents of the European Council, the Council and the European Commission of 7 May 2020; Socialists and Democrats Position Paper A European Health Union - Increasing EU Competence in Health - Coping with COVID19 and Looking to the Future* (Brussels: S&D).
3   European Parliament (2020) *European Parliament Resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 (2020/2691/RSP)* (Brussels: European Parliament).
4   Council of the European Union, General Secretariat of the Council (2022) *Conference on the Future of Europe – Report on the final outcome: May 2022* (Luxembourg: Publications Office of the European Union).
5   European Commission (2020) *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control. Explanatory Memorandum* (Brussels: European Commission).
6   European Commission (2022) *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space COM/2022/197 final* (Strasbourg: European Commission).
7   Official Journal of the European Union (2021) "Council Conclusions on strengthening the European Health Union (2021/C 512 I/02)", *OJ*, C 512I, pp. 2-11.

The Commission's initial European Health Union Package focused on preparedness and response to serious cross-border health threats by agencies that coordinate and surveille (European Centre for Disease Prevention and Control, European Medicines Agency) or that produce and procure medical countermeasures (European Health Emergency Preparedness and Response Authority, HERA).[8] Next, a Pharmaceutical Strategy for Europe and a Europe's Beating Cancer Plan were announced as key pillars of a European Health Union.[9, 10] More recently, the European Health Data Space for the use of health data was launched.[11] These are all laudable initiatives, as the importance of ensuring the supply of medicines and medical devices and the usefulness of monitoring, surveillance and coordinated action for public health, is evident.

Equal access to care? Health workforce inequalities

It is questionable however, whether these initiatives will address the structural inequalities in healthcare capacities across the European Union, including inequalities in the sizes of the healthcare workforce.[12] Exact figures are lacking, and statistical data coverage is variable per year and member state. Furthermore, some data are based on the nationality of health workers and others on their country of training. Nevertheless, important trends can be detected in OECD data. A 2020 OECD report indicates that the number of doctors varies widely between EU countries, ranging from 2.4 to 5.4 physicians per

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8   European Commission (2020) *COM(2020) 724 final Communication from the Commission 'Building a European Health Union: Reinforcing the EU's Resilience for cross-border health threats'* (Brussels: European Commission).

9   European Commission (2020) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Pharmaceutical Strategy for Europe* (Brussels: European Commission).

10   European Commission (2021) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Europe's Beating Cancer Plan. COM/2021/44 final* (Brussels: European Commission).

11   European Commission (2022) *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. COM/2022/197 final 197 final*.

12   Alemanno, A. (2020) "Towards a European Health Union: Time to Level Up", *European Journal of Risk Regulation* 11(4): 725.

1000 citizens.[13, 14] For rural and remote areas, the number might even be lower than 2.4 per 1000. Similarly, the number of practicing nurses per 1000 population also ranges significantly, from 4.4 per 1000 population in Latvia to 15.4 in Finland.[15]

In their recent report *Health and care workforce in Europe: Time to act,*[16] the WHO Regional Office for Europe studied densities of doctors, nurses, midwives, dentists and pharmacists across all 53 countries in the WHO European region. For the purposes of this article, the authors extracted the data for the 27 EU member states. Figure 1 shows the density of doctors, nurses and midwives for EU member states, and Figure 2 shows their Universal Health Coverage (UHC) service coverage index.[17]

Figure 1: Medical doctor, nurse and midwife total density in EU Member States, compared to EU average of 127,9 per 10,000 population.
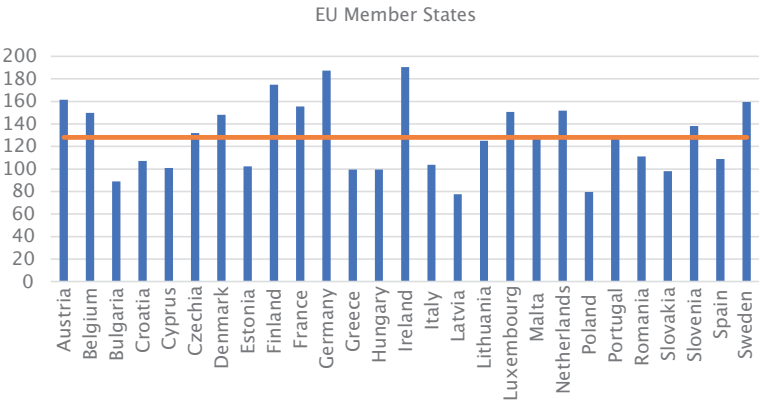
Source: Adapted from WHO European Regional Committee data.

13   OECD (2020), *Health at a Glance: Europe 2020. State of Health in the EU Cycle* (Paris: OECD), p. 213.
14   Data refer to all doctors having a licence to practice, and is a large over-estimation of the number of practising doctors. For an overview of physician density across regions, see OECD/European Union (2021) *Health at a Glance: Europe 2021. State of Health in the EU Cycle* (OECD Publishing, Paris), p. 217.
15   OECD (2021) *Health at a Glance: Europe 2021. State of Health in the EU Cycle* (Paris: OECD), p. 220.
16   WHO (2022) *Health and care workforce in Europe: time to act.* (Copenhagen: WHO Regional Office for Europe).
17   Coverage of essential health services is defined as: the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, noncommunicable diseases and service capacity and access, among the general and the most disadvantaged populations.

Figure 2: UHC service coverage index in EU Member States, 2019.

UHC service coverage index, 2019,
EU Member States
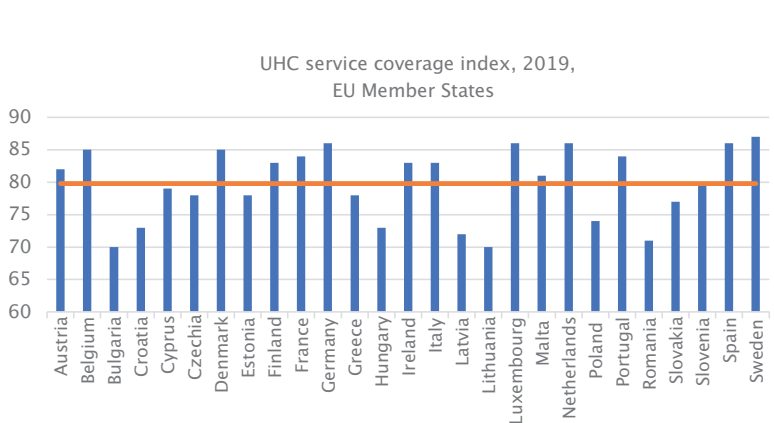
Source: Adapted from WHO European Regional Committee data.

Not by coincidence, some of the countries with the highest densities of doctors, nurses and midwives (Ireland, Germany, Austria, Sweden) are also countries with high levels of foreign-born, foreign-trained health workers, i.e. immigrant health workers. The countries with the lowest densities include major health worker source countries, such as Hungary, Poland, Latvia, Bulgaria. At the same time, a correlation can be observed between high health worker densities and high UHC index (Austria, Belgium, Denmark, Finland, France, Germany, Luxembourg, Netherlands, Sweden), and low health worker densities and low UHC index (such as Bulgaria, Croatia, Hungary, Latvia, Poland, Slovakia).

The correlations are not causal *per se*, as other circumstances such as numbers of medical graduates, absorption capacity of trained health workers in the health system, health worker outflow, and health system (service delivery) characteristics also play an important role in explaining the differences.
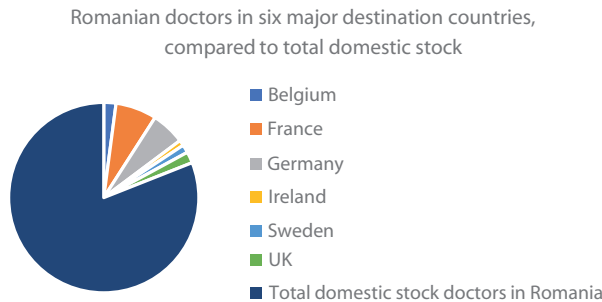
Health worker migration contributes to inequalities

The impact of intra-EU health worker migration on health workforce availability in countries of origin has long been recognised. And even though the exact impact of health worker outflow remains difficult to establish, implementing effective retention policies is seen as an important

and priority remedial action.[18] By way of illustration, the following data on doctors' mobility trends from Poland and Romania to Northwest Europe were taken from OECD statistics.[19]

Data on annual inflow of foreign trained doctors show how accession to the EU and the subsequent end of a transition period in which free movement of workers was still restricted led to an increase of Romanian trained doctors in Belgium (from 126 new immigrant doctors in 2007 to 176 in 2011, and decreasing to an annual inflow of around 55 as of 2017). Comparable trends can be seen in France (439 in 2011 to 208 in 2020), Germany (54 in 2007, to 579 in 2012 and 225 in 2020), Ireland (83 in 2010, 194 in 2015 and 62 in 2021), Sweden (from 52 in 2007, to 116 in 2014 to 90 in 2019) or the United Kingdom (from 175 in 2007, 667 in 2010 to 279 in 2021). In 2020, there were 1,501 doctors with Romanian nationality in Belgium, 5,060 in France, 4,116 in Germany, 686 in Ireland, 994 in Sweden in 2019 and 1,388 in the United Kingdom in 2020. If all these doctors returned to Romania, they would increase the domestic doctor workforce by approximately 19%, which in 2017 numbered around 58,583 (see Figure 3).[20]

Figure 3: Number of Romanian doctors in six major destination countries (2020), and total domestic stock (2017)

Romanian doctors in six major destination countries, compared to total domestic stock

- Belgium
- France
- Germany
- Ireland
- Sweden
- UK
- Total domestic stock doctors in Romania

Source: Retrieved from WHO's National Health Workers Accounts Database,

Similar observations can be made for Poland. In 2020 there were 109 doctors with Polish nationality in Belgium, 248 in France, 1,776 in Germany,

18   Zapata T. et al. (2023) "Fixing the health workforce crisis in Europe: retention must be the priority", *British Medical Journal*, 381:947.
19   OECD (2023) OECD.Stat (Paris: OECD).
20   WHO (2023) *National Health Workers Accounts Database* (Geneva: WHO).

310 in Ireland, 1,143 in Sweden and 1,029 doctors in the United Kingdom. The data show that most foreign trained doctors entering Poland in 2021 had completed their training in Ukraine (511) or Belarus (277).

It is noteworthy that these data are retrieved from official data sources, and comprise health workers with higher qualifications who follow formal procedures for recognition of qualifications and accreditation to practise, in line with Directive 2005/36/EC on the recognition of Professional Qualifications.[21] It is next to impossible to track health and care workers with lower (or no) qualifications who migrate, or health and care workers who have a nursing qualification, but decide to work in lower qualified jobs in destination countries, without the need to officially register there. This seems to be the case for many nurses from Central and Eastern Europe (such as Romania, Bulgaria, Poland), who are working in underqualified jobs in Germany, the Netherlands, and other high income EU countries. They are lost in official statistics, in the sense that they leave the health labour market in their home country, but do not reappear in health labour market statistics in the destination country.

The numbers concerned with this phenomenon are staggering. According to one estimate, there are 300,000 to 700,000 Eastern European women, many of whom have full nursing qualifications, working in 24/7 homecare in Germany alone.[22] Needless to say, this constitutes an enormous brain drain for Central and Eastern European health systems, a brain waste for the migrant health workers concerned, and a simultaneous gain for health systems in the more affluent EU member states. But without systematic data collection, the extent and potential impact of this phenomenon are impossible to ascertain.

The disbalance of healthcare workers within the EU is hardly addressed at EU level. The European Parliament's Resolution calling for an EHU does not mention it, and the policy paper by the Progressive Alliance of Socialists and Democrats (S&D) only addresses it implicitly by suggesting a directive on minimum standards for quality healthcare.[23] This directive

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21 Directive 2005/36 of the European Parliament and the Council of 7 September 2005 on the recognition of professional qualifications, as amended by Directive 2013/55/EU of the European Parliament and the Council of 20 November 2013. For an account of obstacles to recognition at national level a.o. in the healthcare sector see Kortese, L.S.J. (2020) *The Recognition of Qualifications in the EU. Blurring the Lines of Competence between the Internal Market and Education*, PhD thesis Maastricht.
22 Pillars of Health Project (2022) *Country Report on health worker mobility and migration – Germany* (Amsterdam: Wemos).
23 S&D (2020) *Letter of the Socialists and Democrats to the presidents of the European Council, the Council and the European Commission of 7 May 2020*.

would introduce common criteria to be reported to the European Commission, "using parameters such as hospital beds per head, critical care capacities, numbers of doctors and nurses per head, rate of health expenditure and access and affordability of healthcare for all, including for vulnerable populations".[24] The EPSCO council conclusions on strengthening the European Health Union are silent on health workforce capacity. [25]

However, the Manifesto for a European Health Union[26], initiated by leading political figures and academics working in the field of health policy, does address the problem explicitly and postulates a policy for the EHU:

> "Recognising the importance of the health workforce, the European Union and the Member States will work together to address the unequal distribution of health workforce capacities in Europe, providing support to regions that have difficulties in attracting health workers as well as promoting the training and education of health professionals according to common standards, coupled with measures to safeguard the rights of health workers, including those from other parts of the world".[27]

Free movement rights have been among the most positive achievements of European integration. In March 2020, at the start of the Covid-19 pandemic, it became clear how important free movement is in the EU economy, especially in border regions and in "key areas". Crossborder workers, self-employed persons with clients across the border, students and pupils as well as families living on both sides of the border were specifically harmed by certain measures taken without the necessary cross-border coordination.[28] At the outbreak of Covid-19, around 250.000 Romanian seasonal workers had to return to Romania from other EU Member States, but very soon were asked to come back as they proved to be 'essential' for the economy of the receiving states. A similar observation can be made for mobile workers in health care, child

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24   Ibid.
25   Official Journal of the European Union (2021) "Employment, Social Policy, Health and Consumer Affairs Council Conclusions", *OJ,* C/512/2.
26   EIHSD (2020) *Manifesto for a European Health Union* (Brussels: EIHSD).
27   See: EIHSD (2020) *Manifesto for a European Health Union policies and other measures,* under e.
28   Schneider, H., L. Kortese, P. Mertens and S. Sivonen (2021) *Cross-Border Mobility in times of Covid-19. Assessing Covid-19 Measures and their Effects on Cross-border Regions within the EU* (Maastricht: EU-CITZEN - Academic Network on European Citizenship Rights), p. 2.

care and elderly care.[29] As shown above, there is an east-west asymmetry in cross-border movement resulting in a shrinking access to essential health workers and health care in eastern and southern Member States of the EU. Therefore, as Goldner-Lang has argued, a reflection on the downsides of free movement needs to focus on further European integration that would aim to reduce disparities between EU member states and between regions.[30, 31, 32, 33, 34] This follows also from the framework of free movement law. It imposes severe restrictions on the regulatory possibilities to address the disbalance in healthcare professional capacity. The European Court of Justice has ruled that any national measure interfering with free movement in order to prevent the loss of qualified workers should be suitable to protect the domestic labour market against loss of qualified healthcare workers, cannot go beyond what is necessary to protect it, and can never lead to being tantamount to a negation of free movement rights.[35] Measures that encourage free movement are considered a less restrictive alternative to address shortages than measures that hinder free movement.[36]

As Damjan Kukovec wrote in 2015, there has been no serious discussion in daily EU legal reasoning about the distributional consequences of free movement law among different countries and regions in the EU.[37] He demonstrates how EU legal discourse has

29   Robin-Olivier, S. (2020) "Free Movement of Workers in the Light of the COVID-19 Sanitary Crisis: From Restrictive Selection to Selective Mobility", *European Papers*, 5: 613-619.

30   Goldner-Lang, I., and M. Lang (2020) "The Dark Side of Free Movement: When Individual and Social Interests Clash" in S. Mantu, P. Minderhoud and E. Guild (eds.), *EU Citizenship and Free Movement: Taking Supranational Citizenship Seriously* (Brill: Leiden).

31   For illustrations of these downsides see also Rothman-Herrmann, J. and B. Toebes (2011), "The European Union and Health and Human Rights" in *Human Rights Law Review* 2011(4) p. 419-436

32   Hervey, T.K. and McHale, J.V. (2015) *European Union Health Law : Themes and Implications, Law in Context* (Cambridge: Cambridge University Press), p. 130;

33   Papassiopi-Passia, Z., E. Pasia, and D. Varadinis (2014) "Migration and Law. Greece", *Revue Hellenique de Droit Internationals*, 2014: 64.

34   Humphries, N. et al. (2021) "COVID-19 and doctor emigration: the case of Ireland", *Human Resources for Health,* 19(29).

35   Case C-208/05, *ITC Innovative Technology Center*, para. 44, ECLI:EU:C:2007:16.

36   The Court of Justice in Case C-73/08, *Bressol*, para. 78, ECLI:EU:C:2010:181, with respect to Belgian restrictive measures to prevent an alleged risk of shortages of professionals in the medical and paramedical sector.

37   Kukovec, D. (2015) "Law and the Periphery", *European Law Journal*, 21(3): 406-428.

distributional consequences between countries, between regions, and between centre and periphery.[38] Kukovec argues that only free movement considerations which harm the *centre* are discussed in terms of a concern in need of a solution. This might explain why challenges such as shortages of healthcare workers in the *periphery* are not discussed in mainstream EU legal literature,[39] and are hardly mentioned in the EU documents calling for the creation of an EHU or for strengthening the EHU. If we agree with Kukovec that the EU should "acknowledge and resist the negative externalities of universalized social and autonomy claims and decisions on workers and companies of the periphery",[40] and if the EU is serious about access to healthcare for all, then including the need to address unequal distribution of healthcare workforce capacities in Europe as part of a EHU would be a first step.

Any measure addressing the unequal distribution of the healthcare workforce should respect the (social) right of every healthcare worker in the EU to move to another member state for whatever reason, including to improve their livelihood. Therefore, measures should be directed at addressing the reasons why health workers from the periphery move away. The literature mentions several factors related to the organisation of the healthcare system that inspire medical professionals to leave their country, regardless of whether the sending member state is Poland, Romania or Ireland. These include low salaries (in relation to richer member states), tough working conditions (long working hours and excessive workload), and limited career development prospects. In addition, dissatisfaction with the social and political situation in the home state, a lack of high-quality public goods such as education, housing, availability of infrastructure, leisure activities and social provisions are

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38   "Periphery" is understood as countries or regions with a much lower GDP per capita, less capital and less foreign direct investment, and whose actors, products and services have less prestige than countries or regions of the centre.

39   In our attempt to get an overview of the literature we used (a combination of) search terms such as 'healthcare professionals/workers/workforce, doctors, nurses, careworkers in mainstream European law Journals (Common Market Law Review, European Law Journal, European Law Review, European Journal of Health Law). It resulted in a list of articles on free movement, migration and health care that focus on cross-border patient mobility, access to health care for migrants and asylum seekers, mutual recognition of diplomas and access to medical studies for foreign students. Our broader search in law journals showed that problems related to doctors and nurses leaving the country are mainly found in journals published by sending states and/or authors originating from sending states.

40   Kukovec, D. (2015) "Law and the Periphery".

relevant in the decisions of health professionals to leave their country of origin.[41]

It is also notable that women, who represent around 70% of the health workforce globally, are disproportionally affected by income disparities, denial of professional development opportunities, discrimination, harassment and violence in the workplace, including in their home countries. [42] For female workers, these are additional incentives to migrate. However, migration simultaneously increases their exposure to abuse and discrimination during the migration process and in destination countries. Therefore, excessive health worker migration does not only have a quantitative aspect, but may also undermine ambitions to structurally improve the position and experiences of female health workers.[43, 44]

EU competences for health workforce matters

Although EU competence in the field of healthcare is, for now, limited,[45] there are no reasons to exclude health workforce matters from the EHU. A creative use of existing competences would allow multiple measures and actions at EU level.[46] Below are several suggestions distilled from the broader academic literature.

First, it would be possible to enact a directive on EU standards for minimum healthcare throughout the EU via compulsory reporting to the Commission on common criteria including number of doctors and

41   Goldner-Lang, I., and M. Lang (2020) "The Dark Side of Free Movement: When Individual and Social Interests Clash", pp. 382-409.

42   WHO (2021) *Closing the leadership gap: gender equity and leadership in the global health and care workforce. Policy action paper* (Geneva: WHO).

43   Open Society Foundations (2020) *Working Together to Address Health Workforce Mobility in Europe. Recommendations for Action. Recommendations for Action* (New York: Open Society Foundations).

44   Bourgeault, I.L., Runnels, V., Atanackovic, J. *et al.* (2021) "Hiding in plain sight: the absence of consideration of the gendered dimensions in 'source' country perspectives on health worker migration", *Hum Resour Health* 19(40).

45   Citizens' panels in the Conference on the Future of Europe called for Treaty change in order to include health in the shared competence of the EU, see also the concrete proposal for such inclusion in the Position Paper *Treaty Change for European Health Union*. However, it is questionable whether the Treaty will be changed in the near future, see also European Council Conclusions of 23 and 24 June 2022 points 27-29 presenting a flawed response to the final report.

46   Hervey, T., and A. de Ruijter (2020) "The Dynamic Potential of European Union Health Law", *European Journal of Risk Regulation,* 11(4): 297-306.

nurses per head based on Article 168(5) TFEU.[47] The obligation to report contributes to the visibility of medical deserts at EU level, especially when data are collected at the level of districts, counties or municipalities, and would (hopefully) render it more difficult to ignore the problem.[48] The preamble of the EU4Health programme regulation, based on Article 168(5) TFEU, refers to supporting actions that "reduce inequalities in the provision of healthcare, in particular in rural and remote areas",[49] but does not aim for more structural quality standards. The voluntary stress test included in the regulation could be adjusted via binding methodologies and preparedness templates to ensure convergence of national plans on healthcare resilience without intruding on member states' domestic responsibilities.[50] Furthermore, instead of performing self-assessments, national healthcare systems included in the regulation could be monitored at EU level by the ECDC, or for instance by the intergovernmental Health Security Committee that could also formulate recommendations.[51]

Thus, coordination could become more binding and the substance of information more detailed, while also enhancing mutual trust.[52] Data on professional health capacity and better mobility data could be part of such coordination. Such data have been generated and shared in several successive Joint Actions initiated by the Commission, such as the

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47   See A. Alemanno (fn. 12) at 725 and S&D Position Paper of 12 May 2020 (fn.2). A contrario: General Secretariat of the Council, Preliminary technical assessment of the proposals and related specific measures contained in the report on the final outcome of the Conference on the Future of the Union, 10033/22 ADD 1en of 10 June 2022, p.47, point 10.1.

48   DG Sante is currently funding three project on the topic of medical deserts, under the 3rd Health Programme, the results of which are expected in 2023-2024, and which will yield recommendations and tools to help measure, identify and recognise medical deserts and medical 'desertification'.

49   Official Journal of the European Union (2021) "Regulation (EU) REGULATION (EU) 2021/522 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027", *OJ, L* 107/1.

50   Beaussier, A., and L. Cabana (2020) "Strengthening the EU's Response Capacity to Health Emergencies: Insights from EU Crisis Management Mechanisms", *European Journal of Risk Regulation,* 11(4): 808–20.

51   The EU Health Security Committee consists of representatives of the EU Member States and is mandated to reinforce the coordination and sharing of best practice and information on national preparedness activities. See Decision 1082/2013/EU, OJEU 2013, L239/1 of 5 November 2013.

52   Beaussier, A., and L. Cabana (2020) "Strengthening the EU's Response Capacity to Health Emergencies: Insights from EU Crisis Management Mechanisms", pp. 818-820.

SEPEN network[53], and are also expected to be a key element in the new Joint Action for Health Workforce Planning and Forecasting, HEROES, launched in the spring of 2023.[54] However, member states participate on a voluntary basis in such joint actions, and up to now, these initiatives have not led to more, better and more systematically collected EU-wide data on health worker migration and mobility. This has hindered the development of targeted interventions by the EU.

Secondly, legislative action could also be undertaken to address decent minimum wages, a maximum number of working hours and equivalent training standards, for the same certifications, for healthcare professionals across the European Union - as recommended by Citizens' Panel 3 of the Conference on the Future of Europe.[55] One could imagine a revision of the derogation for healthcare workers related to minimum rest periods and length of night work in the Working Time Directive,[56] and an adjustment of the directive on recognition of professional qualifications.[57] The recently adopted Directive on adequate minimum wages could help to tackle the disbalance in health workforce capacity.[58] The directive promotes collective bargaining on wage setting and obliges member states with statutory minimum wages to set wages that aim to achieve decent working and living conditions, social cohesion and upward convergence. It could potentially lead to better salaries for healthcare workers and take away one of the reasons why they leave the sector entirely or consider

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53   Support for the health workforce planning and forecasting expert network, see archive.healthworkforce.eu.
54   HEROES Joint Action (HEalth woRkfOrce to meet health challEngeS), the successor of SEPEN, see healthworkforce.eu.
55   Conference on the Future of Europe, Final Report (fn. 8), Annex p. 60. Four citizens' panels participated in the Conference on the Future of Europe, allowing citizens to jointly think about the future they want for the European Union. Each panel consisted of 200 European citizens each chosen through random selection, from the 27 Member States. Panel 3 dealt with climate change, environment and health.
56   Oficial Journal of the European Union (2003) "Article 17(3) under c) of Directive 2003/88/EC of the European Parliament and the Council of 4 November 2003 concerning certain aspects of the organization of working time", *OJ, L, 299/9.*
57   Directive 2005/36 of the European Parliament and the Council of 7 September 2005 on the recognition of professional qualifications, as amended by Directive 2013/55/EU of the European Parliament and the Council of 20 November 2013. For an account of obstacles to recognition at national level a.o. in the healthcare sector see Kortese, L.S.J. (2020) *The Recognition of Qualifications in the EU. Blurring the Lines of Competence between the Internal Market and Education*, PhD thesis Maastricht.
58   Oficial Journal of the European Union (2022) "Directive 2022/2041 of the European Parliament and of the Council on adequate minimum wages in the European Union", *OJ L 275/33.*

migration for better salaries. The directive also provides cooperation between state authorities and social partners to ensure that minimum wages are complied with.

According to the citizens' panel, a lack of common healthcare standards, common wages and common training for healthcare workers could result in differences between the member states and lead to unbalanced situations across the European Union. Standardisation of healthcare could help in having a stronger, more efficient and more resilient system and would also facilitate knowledge and information sharing in the healthcare professional sector.[59] The council's preliminary technical assessment of these proposals is not very responsive (merely defensive) to the citizens' panels. It refers to the existing working time and recognition of qualification directives and the existing Erasmus+ program as if no further action would be necessary. It also signals that taking up measures on a minimum wage has to respect limitations imposed by Article 153(5) TFEU that excludes pay from the EU competence under Article 153.[60]

Thirdly, the citizens' panels had an additional idea that can be realised with existing competences. This involved setting up a separate Erasmus exchange program for medical schools, which could contribute to skills development throughout the EU.[61] True, the aims of the Erasmus+ program also include "to foster the development of transnational and transdisciplinary curricula (…) with the objective of tackling societal challenges".[62] However, a targeted approach for training the healthcare workforce would probably have more impact – not only because standardisation might lead to a more resilient system, but also because it could enhance visibility of practices where qualified healthcare professionals are recruited from the periphery to work in lower qualified positions in the core. We can also imagine that such a specific Erasmus facility would accommodate the possibility for healthcare workers in the core (northern and western EU) to interrupt their careers for six months or a year in order to work in the periphery (southern and eastern EU). In this way, the internal EU freedom of movement could be made to work to the advantage of the health labour market and help address existing inequalities.

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59   Council of the European Union, General Secretariat of the Council (2022) *Conference on the Future of Europe – Report on the final outcome.*
60   Ibid.
61   Ibid.
62   European Commission (2022) *Erasmusplus programme guide 2022* (Brussels: European Commission), p. 40.

Fourthly, in addition to legislative action, fiscal solidarity addressing equal distribution of healthcare workers in the EU could form part of the EHU. To our knowledge, there are no reliable data or detailed empirical studies on the relationship between remittances, the cost of training healthcare professionals and positive and negative impact of their migration.[63, 64] Structural development of the periphery could help in the retention of healthcare workers. In the preamble of the 2021 Regulation on the European Regional Development Fund and the Cohesion Fund, the resilience of public health systems is addressed, without any mention of healthcare professionals.[65] National plans submitted under the Recovery and Resilience Facility can however address domestic economic and social cohesion in order to mitigate disbalance of healthcare professional capacity between urban regions and the periphery.[66] Recital 15 of the RRF Regulation highlights the importance of accessibility *and capacity* of healthcare systems. The scope of the Facility covers health, *inter alia* (so not only) in crisis situations.[67] Explicit inclusion of retention of healthcare workers in the periphery as an objective of these funding instruments might help, though in itself is not enough to address the distributional consequences of EU free movement law in healthcare.[68] Interestingly, an analysis of national recovery and resilience plans performed by DG Sante yielded examples from 15 member states that have proposed reforms and investments relating to the strengthening of their health systems, especially in remote regions and in primary care

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63   See also: Aginam, O. (2010) "Predatory Globalization: The WTO Agreement on Trade in Services, Migration and Public Health in Africa", *American Society of International Law Proceedings* 104 (2010), p. 139-146, at 145, for the view that remittances are not a remedy.

64   Goga, C.I. (2020) "Is Romania in a Social and Economic Crisis Caused by Emigration? The New Policy of the Romanian State on Migration", *Sociology and Social Work Review* 4, nr. 1 (2020): 31–37, p. 33-34.

65   European Parliament (2021) *Regulation (EU) 2021/1058 of 24 June 2021, preamble recital 23* (Brussels: European Parliament).

66   Official Journal of the European Union (2021) "Regulation (EU) 2021/241 of 12 February 2021 establishing the Recovery and Resilience Facility", *OJ, L, 57/17.*

67   Ibid. Article 3, under (e). Furthermore, point 92 of annex VI mentions 'health infrastructure'.

68   See also Goldner-Lang, I. and M. Lang (2020) "The Dark Side of Free Movement: When Individual and Social Interests Clash". See also Article 1 under s of Annex I to Regulation 2021/552 of 24 March 2021 establishing the EU4Health programme. It indicates support, in synergy with other programmes, "for actions to improve the geographical distribution of the healthcare workforce and actions for the avoidance of 'medical deserts', without prejudice to Member State competences" and is eligible for funding.

facilities. However, it gave little explicit attention to retention of health workers to avoid brain drain.

Within the European Semester, a framework for the coordination of fiscal policy and national budgets, data on healthcare are reported. In the context of the European Semester the Commission delivers country-specific recommendations explaining how Member States can better align their policies with the economic and social objectives agreed at EU level. In the country-specific recommendations of 2020[69] it is noted that "in many member states, shortages of healthcare staff have become critical due to working conditions that discourage the attractiveness of these professions".[70] The potential of eHealth for making care more effective and accessible in particular through telemedicine is suggested as part of a solution to health worker shortages. The recommendations do not further address possible ways to remedy healthcare staff shortages, such as the need to structurally improve working conditions and the need to educate, train and deploy more health workers. They also do not mention the downsides of international health worker recruitment as a quick fix to remedy existing shortages. We could imagine that an indicator on the percentage of healthcare workforce not recruited from abroad ('self-sufficiency') is included in European Semester data reporting, alongside an indicator that sheds light on the reliance on foreign-born, foreign-trained health workers. It would allow the Commission to address the need to invest in the domestically educated health workforce in country-specific recommendations and might divert from the "quick fix solution" of recruitment from abroad.

International recruitment: remedy for health worker shortages?

At a global level, excessive emigration of highly skilled health personnel from developing countries has long been seen as problematic.[71] In order

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69   European Commission (2020) *Communication from the Commission, 2020 European Semester: Country-Specific recommendations* (Brussels: European Commission).

70   Ibid., Box 3. Besides unattractive working conditions such as low salary, high work-load, difficult working hours and low career prospects, healthcare workers in recent years have faced aggression, violence and sexual harassment.

71   See for instance *WHO (2010) Report on the First Global Forum on Human Resources for Health, 2008* (Geneva: WHO), particularly Theme 4: Migration and retention. The report states that migration of health workers is not a new phenomenon, and warns that current (2008!) increases in the speed and global scale of migration is creating imbalances in the geographical concentration of health professionals.

to manage the emigration from developing countries, member states of the WHO adopted the WHO Global Code of Practice on International Recruitment of Health Personnel in May 2010. Though the relationship between the EU and the WHO is based on an exchange of letters dating back to 1972 and the EU has only observer status,[72] there is a web of relations between the two organisations.[73]

The WHO Code is a non-binding instrument that aims to establish "ethical principles applicable to the international recruitment of health personnel in a manner that strengthens the health systems of developing countries, countries with an economy in transition and small island states".[74] For the purposes of this chapter, it is important to note that the Code not only stipulates that all member states should strive to meet their health personnel needs with their own human resources for health, but also that member states should discourage active recruitment of health personnel from developing countries facing critical shortages of health workers.[75] Despite its current status of observer, and despite the nature of the WHO Code, the EU has included ethical recruitment principles in the preamble of the Blue Card Directive under reference to the 2010 WHO Global Code on the International Recruitment of Health Personnel.[76] The Blue Card Directive concerns migration from outside the EU. However, practices of active and targeted recruitment exist also within the EU.

The role of recruiters

Recruiters also play an important role here. Glinos et al., note that:

> «Concerns about recruitment arise when agencies and employers from wealthier destination countries organise recruitment fairs and promotional events, for example around university campuses in source countries, or contact final year students to recruit them abroad before they have even

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72   In its 2022 Global Health Strategy, the EU has communicated its ambition to eventually obtain full WHO membership.
73   Berger, S., R. van de Pas, L. van Schaik and M. Voss (2020) "Upholding the World Health Organisation. Next Steps for the EU", *SWP Comments,* 47, October 2020.
74   WHO (2010) *Global Code of Practice* Geneva: WHO). Article 2.3.
75   Ibid., article 5.1 and 5.4.
76   Directive 2021/1883 of 20 October 2021 on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment, and repealing Council Directive 2009/50/EC, recital 41: "Ethical recruitment policies and principles that apply to public and private sector employers should be developed in key sectors, for example in the health sector".

qualified. While this is entirely legal, the question from an EU perspective is whether these (aggressive) techniques are fair. Source countries such as Estonia, Greece, Hungary, Italy and Romania can hardly compete when certain destinations offer salaries five to ten times higher than what newly trained health professionals can expect to earn at home".[77]

Arguably, internal EU recruitment does not fall under "international recruitment" covered by the WHO Code. And the 2023 WHO list of countries with critical health workforce shortages that justify discouragement of active recruitment of health workforce does not include any country in the European region.[78] But the question of 'fairness' remains. Furthermore, active and targeted intra-EU recruitment might lead to chain migration which could ultimately result in increased targeting of health professionals in third countries facing critical shortages. In addition, intra-European migration seems to be stabilising somewhat (see earlier in this article) while health worker shortages in all EU Member States are growing, which could drive international recruitment of health workers from third countries.[79] Therefore, it would be appropriate for the EU to address ethical recruitment within the EU and regulate the recruitment sector.

According to Harvey et al., recruitment agents have become commonplace in healthcare where employers need to quickly fill shortages with skilled migrants.[80] The growth of labour market intermediaries in healthcare is caused by three main factors: (1) increased demand of healthworkers in receiving countries; (2) rising unemployment in sending countries and the wish for better pay; and (3) changes in regulations in receiving and sending countries.[81] Harvey et al. argue that with a growing group of recruitment agents and other intermediaries influencing the flows of skilled migrants, recruitment is increasingly out of control of national

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77   Glinos, I. A., et al. (2015) *How can countries address the efficiency and equity implications of health professional mobility in Europe? Adapting policies in the context of the WHO Code of Practice and EU freedom of movement* (Geneva: WHO).
78   WHO (2023) *Health workforce support and safeguards list 2023* (Geneva: WHO).
79   On a minor scale (Netherlands), this is already discernible in the figures of the BIG-register, the register for Professions in Individual Health Care.
80   Harvey, W., D. Groutsis, D. van den Broek (2018) "Intermediaries and destination reputations: explaining flows of skilled migration", *Journal of Ethnic and Migration Studies*, 44(4): 644-662.
81   Žabko O., A. Aasland, and S. B. Endresen (2018) "Facilitating labour migration from Latvia: strategies of various categories of intermediaries", *Journal of Ethnic and Migration Studies*, 44(4): 575-591.

governments.[82] Increased regulation of various forms of intermediaries will help to reduce misconduct towards migrants and also ensure that governments and organisations are more aware of how these actors shape the flows of skilled migrants.[83] This could be an argument to take supportive actions a step further and regulate intra-EU recruitment at EU level.

As the market on which intermediaries operate becomes more competitive, recruitment agencies develop survival strategies and, for instance, expand abroad and seek market potentials.[84] This might explain more aggressive recruitment tactics and is something to take into account when considering regulation to guarantee ethical rectruitment, notably to prevent active and targeted recruitment of health personnel from countries facing shortages of health workers, regardless of whether these countries are developing countries.

The EU's role in improved recruitment and retention

In 2015, a report from the European Commission included recommendations for actions at European level on recruitment and retention.[85] It acknowledged that European wide cooperation or knowledge exchange in this area is underdeveloped given the national, regional and local organisational context for recruitment and retention strategies. It suggested a number of measures consisting of supportive and coordination actions, notably sharing of good practices in recruitment and retention in the health sector. It should be noted that retention measures can be problematic if they focus solely on prevention of migration of healthcare workers and do not take into account the contextual root causes of migration, which may be specific to each Member State. As Katinatė shows, good retention practices in one Member State can do more harm than good when introduced in another Member State.[86]

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82   Ibid., p. 655.
83   Ibid., p. 656.
84   Ibid., p. 588.
85   European Commission (2015) *Recruitment and Retention of the Health Workforce in Europe* (Brussels: European Commission), p. 8.
86   Katinatė, S., (2023) "Healthcare Personnel Recruitment and Retention Regulation in the EU. The Lithuanian Perspective", *Amsterdam Centre for European Law and Governance Research Paper 2023-02*.

In the European Care Strategy 2022,[87] the Commission goes a step further and seems to acknowledge there might be a problem with available healthcare in remote areas – with a focus on long-term care:

> **"Rural and remote areas and regions with low population density are particularly affected** by the lack or shortage of available care services, both early childhood education and care as well as long-term care, due to long distances or limited public transport options. Access to and the variety of long-term care options are insufficient, raising equity concerns. The traditional choice of care options has been between informal care (usually provided by family members or friends, very predominantly women) and residential facilities. Other options such as home care and community-based care, have started to expand, though not evenly, across the EU".[88]

In its strategy, the Commission mentions better working conditions and wages, supported by strong social dialogue, education and training to make care jobs more attractive. However, the Commission also sees legal migration as "a key driver to remedy labour shortages". It refers to legal pathways for migration from non-EU countries and possible EU tools to help admission of migrant care workers to the EU "while ensuring the ethical recruitment of migrants".[89] The European Care Strategy is innovative in considering the tension between promoting accessible care for all and ensuring decent and attractive working conditions for care workers, including domestic workers in the long term care sector.[90] Together with the European Care Strategy, the Commission has proposed a council recommendation on access to affordable high-quality long-term care. The proposal includes the recommendation that member states should increase the supply of long-term care services including by "closing territorial gaps in availability of and access to long-term care, in

87   European Commission (2022) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the European care strategy COM(2022)440 final of 7 September 2022* (Brussels: European Commission).

88   European Commission (2015) *Recruitment and Retention of the Health Workforce in Europe*, p. 6.

89   Ibid., p. 14

90   Chieregato, E. (2023) "Care at the intersection of multiple discriminations: the European Care Strategy and migrant domestic workers", in Thissen, L. and A. Mach (eds.), *The European Care Strategy. A Chance to Ensure Inclusive Care for All?* FEPS Policy Study, March 2023, p.97.

particular in rural and depopulating areas".[91] According to the explanatory memorandum, the proposed recommendation links with the New Pact on Migration and Asylum, notably the Skills and Talent package,[92] which includes a focus on attracting workers to the long-term care sector. However, the Commission does not address the higher risk of exploitative working conditions and abusive and fraudulent practices of temporary work agencies that migrant care workers face.[93]

Changing labour market regulations may affect the demand of recruitment agencies in sending or receiving states. Research focusing on intermediaries between employers in Norway and workers from Latvia, shows how intermediaries have to take into account changing domestic regulations.[94] When labour market regulations in Norway improved and included equal wages for Norwegian and foreign workers, it was no longer necessary to sign contracts in Latvia that allowed employers to pay Latvians less. Contracting was gradually transferred to Norway and duties of local branches were reduced to the recruitment and preparation of migrant workers.

Furthermore, this research includes a typology of intermediaries. Formal intermediaries are supplemented by informal ones, which may facilitate labour migration via social networks. The authors maintain that perspectives of sending countries in the debate on the migration industry should be strengthened. First of all because it would give a better insight into intentions that influence strategies of intermediaries, and secondly because migrant experience may shed a light on the performance of intermediaries.[95] These are important recommendations to take into account whenever the Commission decides to propose regulation on recruitment activities.

A first step to regulation could be the creation of an "ethical recruiters list" of recruiting organisations in the EU that adhere to the standards

91   European Commission (2022) *Proposal for a Council Recommendation on access to affordable, high-quality long-term care, COM(2022) 441 final of 7 September 2022* (Brussels: European Commission).
92   European Commission (2022) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. Attracting skills and talent to the EU* (Brussels: European Commission).
93   Chieregato, E. (2023) "Care at the intersection of multiple discriminations: the European Care Strategy and migrant domestic workers", pp. 96-97.
94   Žabko O., A. Aasland, and S. B. Endresen (2017) "Facilitating labour migration from Latvia: strategies of various categories of intermediaries".
95   Ibid., p. 576.

on ethical and fair recruitment, comparable to the UK's NHS Ethical Recruiters List.[96] After all, if the EU wants to "remain globally competitive, the EU needs to become more attractive for talent from around the world".[97] An additional benefit of requiring recruiters to register, is the possibility to obtain data on the numbers of migrating health workers, their country of origin and/or training, their qualifications, length of stay, etc., to complement official statistics and acquire a more comprehensive picture of health labour migration and mobility.

Conclusion

There is no single "magic bullet solution" to address the disbalance of healthcare workers in the EU. It requires an approach in which multiple measures and actions should co-exist, both at member state level and at the EU level. First and foremost, explicit recognition of the problem and its wider discussion is necessary. Therefore, explicit inclusion of this issue in EU documents preparing and developing for a European Health Union is an indispensable step. The Commission's recognition of the problem in the EU Care Strategy and the explicit mention of the territorial gap in the proposed recommendation on affordable long-term care can be seen as a prudent first step.

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96   Department of Health & Social Care (2022) *UK Code of practice for the international recruitment of health and social care personnel* (London: DHSC).
97   European Commission (2022) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. Attracting skills and talent to the EU,* p.6.

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European Commission (2022) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. Attracting skills and talent to the EU* (Brussels: European Commission).

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2.6 | The External Dimension of the European Health Union – the new EU Global Health Strategy

Introduction

This chapter describes the political process which took place between 2019 and 2022 and led to the creation of the EU Global Health Strategy. It analyses the context within which the strategy was developed and the process that supported its finalisation. It further describes the priorities of the strategy and how it helps the positioning of the EU in global health. Finally, it draws attention to gaps and contradictions. We refer to the key values and the support for multilateralism, which is reflected in the strong support for WHO in the strategy. The next steps for the strategy are indicated.

A new context for a new strategy

The European Commission presented the new EU Global Health Strategy, "Better Health for All in a Changing World", on 30 November 2022 in Brussels.[1] It was written during a year when the response to the Covid-19 pandemic was still on everyone's mind but was beginning to be overshadowed by the geopolitics of the Russo-Ukrainian War, starting on 24 February 2022. The fate of the Global Health Strategy might be further defined by this geopolitical context as the memories of the pandemic fade.

In 2021 and 2022, the EU positioned itself as a key player in the pandemic response and at the World Health Organization. It had also taken a wide

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1   European Commission (2022) *EU Global Health Strategy to improve global health security and deliver better health for all* (Brussels: European Commission).

range of internal actions following the pandemic and had intensified the move towards a European Health Union, including the creation of a new European Health Emergency Preparedness and Response Authority (HERA).[2] In the international arena, the President of the EU Council, Charles Michel, proposed in 2021 that a "pandemic treaty" be developed and adopted in the context of the WHO.[3] By 2022, the negotiations had finally begun at the WHO with an EU member state (the Netherlands) as one of the co-chairs of the Intergovernmental Negotiating Body.[4]

Meanwhile, the President of the European Commission, Ursula von der Leyen, played a highly visible role in the establishment of mechanisms to fight the pandemic, such as the Access to Covid-19 Tools (ACT) Accelerator, which included the COVAX vaccination programme.[5] In the context of the G20 Presidency of Indonesia, Team Europe[6] helped shape a new funding mechanism - the Pandemic Fund with a secretariat at the World Bank – of which the EU is the largest contributor and has ensured that it is firmly linked to the World Health Organization.[7]

The revised EU Global Health Strategy (EU-GHS) strategy was therefore written during a highly demanding time in global health diplomacy.[8] It is no surprise, therefore, that when presenting it in November 2022, the representatives of the European Commission highlighted that there is a "massive unfinished agenda in global health" and that what is required is a "new global health order".[9]

The EU-GHS starts from the re-commitment to the achievement of the UN's Sustainable Development Goals (SDG) by 2030, especially because

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2   European Commission (2023) *Health Emergency Preparedness and Response (HERA)* (Brussels: European Commission).
3   European Council (2020) *Press release by President Charles Michel on an international Treaty on Pandemics* (Brussels: European Council).
4   WHO (2022) *WHO Director-General's opening remarks at first meeting of the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response – 24 February 2022*
5   European Union (2020) *Coronavirus Global Response: United to make the world a safer place* (Brussels: European Union).
6   Team Europe consists of the European Union, EU Member States — including their implementing agencies and public development banks — as well as the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD).
7   World Bank (2023) *The Pandemic Fund* (Washington DC: World Bank).
8   European Commission (2022). *EU Global Health Strategy: Better Health for All in a Changing World* (Brussels: European Commission).
9   European Commission (2022) *EU Global Health Strategy to improve global health security and deliver better health for all* (Brussels: European Commission).

the progress towards the SDGs has reversed in many countries. Indeed, just eight months later, the SDG report issued in July 2023 confirmed that health is an area that is particularly off-track[10] – a consequence of the fact that there is neither improvement on health determinants (such as poverty and education) nor in building affordable primary healthcare. This roll-back not only applies to low and middle-income countries, but is a global challenge. The UN High Level Mission (UNHLM) on Universal Health Coverage (UHC) planned for September 2023 could be critical in addressing this failure.[11]

As regards health security, there was still a strong will – for example in the G7 and G20 - to strengthen global health security swiftly and to better prevent future pandemics and other threats to health by the end of 2022. At the time of writing (summer 2023), that too seems to be waning and geopolitical priorities have shifted. The negotiations on the pandemic treaty have moved forward with great difficulty this year, and the latest draft of the political declaration for the high-level Pandemic Summit planned at the UN for September 2023 shows that it will not provide major impetus for change.[12]

The cycle of panic and neglect has set in for pandemic preparedness and response. Health is being overshadowed by the "polycrisis" – the interface of war, climate crisis, inflation, food crisis, migration and significant increases in poverty world-wide. However, if there was ever a time in which the European Union needed a global health strategy it is now. Not only in terms of health but also related to the intention of the EU to promote European values and interests at a difficult time as set out in its priorities for 2019-2024.[13] But it must be recognised that the member states of the European Union no longer seem to think there is a need for urgency. At the time of writing, there is no political commitment of all EU member states to the EU-GHS. Indeed, leaked drafts of the council conclusions in the spring of 2023 had watered down the ambitions significantly.

As the Swedish EU presidency could not, as expected, adopt council conclusions on global health, this falls to the Spanish presidency (2023/2).

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10   United Nations (2023) *Global Sustainable Development Report (GSDR) 2023* (New York: United Nations).

11   WHO (2023) *The UN High-Level Meeting on UHC 2023* (Geneva: WHO).

12   IISD (2023) *UNGA High-level Meeting on Pandemic Prevention, Preparedness and Response* (New York: IISD)

13   European Union (2019) *European Union priorities 2019-2024* (Brussels: European Union).

There is, however, still no agreement on values. Many commentators had foreseen that the strong position the strategy has taken on sexual and reproductive health and rights (SRHR) would not be supported by all governments. This, too, reflects a general trend in global health, where major policy papers are held up, because an increasing number of countries do not agree to the basic human rights premise of SRHR. Once more, internal EU divisions are endangering a strong EU position and voice in the international arena and working against the EU's own strategic priorities. In short, the leadership the European Commission has shown in global health has not been pursued by the EU's member states.

The process towards the strategy

The EU-GHS is clearly a major historic step in relation to the "external" health activities of the European Union. The Covid-19 pandemic showed that the EU needed to step up its health actions within the Union as expressed through the adoption of a European Health Union. But it also became clear – as some had argued for several years – that European health could not be ensured without strong international cooperation.[14]

The European Union already had a Global Health Strategy and Council Conclusions on Global Health which had been adopted in 2010,[15] but it was clear that this strategy had lost momentum, needed to be updated, and needed to be more forceful in its implementation. It no longer carried weight – and definitely did not cover the many new challenges facing global health.

The first major step towards a revision of the existing strategy was taken when a group of member states decided to take the call for a new strategy forward in 2019/2020 and Finland (EU presidency 2019/2) and Germany (EU presidency 2020/2) established an expert working group on global health to discuss the need for a revised strategy. A working paper was commissioned, and it outlined the development and challenges in global health for the EU and its member states.[16] There was a strong

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14   Kickbusch, I., and A. de Ruitjer (2021) "How a European health union can strengthen global health", *The Lancet,* VOLUME 1, 100025, FEBRUARY 2021.
15   European Council (2010) *Council conclusions on the EU role in Global Health* (Brussels: European Council).
16   Geneva Graduate Institute (2020) *Towards a synergistic global health strategy in the EU* (Geneva: Geneva Graduate Institute).

consensus among the countries present that a momentum should be built towards a new revised EU global health strategy – a momentum that then emerged with the pandemic. A meeting of this global health working group was organised by each of the consecutive presidencies, with participation of member states increasing from meeting to meeting. The final meeting was organized by the Czech presidency in the second term of 2022. With the Covid-19 pandemic ongoing, discussions in the working group meetings had gained a new sense of urgency, and especially the trio of Finland, Croatia (EU presidency 2020/1) and Germany was challenged in having to deal with the vehement attacks on the World Health Organization by the Trump administration, which were successfully defended.[17]

The attack on the WHO throughout the pandemic years was an attack on multilateralism in general and in health in particular. However, the EU and its member states clearly positioned themselves in support of the organisation. As the role of the WHO was the subject of many international political meetings on the pandemic response it became obvious that any action by the EU and its member states on global health carried with it a strong geo-political dimension. Indeed, earlier working papers had always made this point: global health had changed and could no longer be attained through a purely professional, development oriented and technical mindset. During the Covid-19 pandemic the president of the Commission, Ursula von der Leyen (herself a physician and public health expert) and the President of the EU Council Charles Michel, as well as the Josep Borrell (High Representative of the Union for Foreign Affairs and Security Policy) took strong public positions in support of multilateral approaches to fighting the Covid-19 pandemic. As one of the largest funders, the EU also made significant resources available to fight the pandemic.[18]

The second major step towards an EU-GHS came during the G7 Development and Health Ministerial meeting in Berlin on the 19th of May 2022. Commissioners Stella Kyriakides (Director General for Health and Food Safety DG SANTE) and Jutta Urpilainen (Director-General for International Partnerships DG INTPA) announced the launch of work on a new EU Global Health Strategy. They argued that "health is the foundation for resilient, equal and just societies, but viruses know no borders. To

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17   Politico (2020) "Trump announces, then reverses, freeze on funding for World Health Organization". *Politico,* 4 July 2020.
18   European Commission (2020) *Coronavirus: EU global response to fight the pandemic* (Brussels: European Commission).

secure the health all our citizens deserve, we must tackle health globally, and we must do this together".[19]

Positioning the strategy globally and regionally

A basis for writing the new strategy were the lessons from Covid-19 and from the implementation of the 2010 Global Health Strategy. But even more important was the need to look forward: which are the challenges that Europe and the world will face in relation to global heath at the time of a polycrisis? Which technological developments will drive global health? Which key challenges are faced by health systems as they move into the future? What actually keeps people healthy? The experiences with the first global health strategy showed the need for the EU to be better prepared for major changes, to support research and innovation and to act with foresight.

The EU-GHS also wanted to take into account that the EU and its member states are now collectively among the largest funders of global health and together, the EU's institutions and MS are the world's leading donors of development assistance and cooperation providing over €50 billion per year. The new EU-GHS strategy states quite bluntly that "the EU's influence in shaping the agenda must match its financing support as a champion of global health".[20] Health is defined as an essential pillar of the EU's external policy and a critical geopolitical sector. This means being a much more proactive voice in international organisations and having a seat at the table, agenda-setting in the G20 and the G7, new types of partnerships with other regional organisations and a better understanding of the health dimensions in the many other international policies of the European Union.[21]

In an extraordinary tour de force, which included wide ranging consultations within the European Commission, public consultations with different stakeholder, including a meeting with LMICs, the strategy was made public on 30 November 2022 at a meeting in Brussels. As

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19   European Commission (2022) *Statement by Commissioners Stella Kyriakides and Jutta Urpilainen – Towards a new EU Global Health Strategy* (Brussels: European Commission).
20   European Commission (2022). *EU Global Health Strategy: Better Health for All in a Changing World* (Brussels: European Commission).
21   CGD (2023) *Here's How the EU Can Step Up and Lead in Global Health [blog]* (Washington DC: CGD).

a strong political signal for the full commitment to the WHO expressed by the EU-GHS, the Director General of the WHO attended the launch. It was followed by a strategic dialogue meeting to discuss how to "further bolster a strong multilateral system with the WHO at its core, powered by a strong EU".[22] All Team Europe global health negotiations have had this dictum at the centre, which is an essential position as other actors have aimed to establish entities in parallel to the WHO or to diminish its role.

The EU Global Health Strategy is a very ambitious and political document. Several political balancing acts will need to be addressed in its implementation. First and foremost it needs to support a strengthening of the nexus between the EU's reforms to consolidate its internal capacities, especially in the field of health security, termed a European Health Union (EHU). It will also need to leverage its active global role to deliver better health for all, living up to its global responsibilities,[23] following the realisation that "no one is safe until everyone is safe" . One thing clearly argued in the EU-GHS is that the EHU can only succeed if it recognises that a strong global dimension is central to EU strategic health autonomy, including, for example, supply chains, workforce and digital transformation.

Second, the EU-GHS is clear that many of the required global health actions lie with other key EU policies and their interests must be balanced with health interests. For example, the EU-GHS is weak on one of the most important present health determinants: the climate crisis. A consensus on the health-climate interface – including the European Green Deal – could not be found within the Commission. Therefore, there was strong hope that the Council Conclusions under the Swedish presidency might pick up on this weakness. We must now look to Spain to take this forward based on the experiences of the heat waves in Europe in 2023.[24]

Third, there are significant policy ramifications to strengthening the national/regional/global interface, as both the EHU and the global health strategy are further developed as political projects. Everything in Brussels is defined through understandings of where the respective competences lie, and a strengthening of the role of the Commission in health is a direction not all member states agree with. Yet an issue that has found less attention – possibly because the global health strategy

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22   WHO (2022) *The European Commission and WHO extend their strategic cooperation to deliver better health for all* (Geneva: WHO).

23   European Commission (2020) *European Health Union: Protecting our health together* (Brussels: European Commission).

24   "EU Global Health Strategy lacks ambition on climate change, says expert". *Euractiv*, 7 December 2022.

is mainly discussed by the global health community – is that the EU-GHS is a joint strategy by DG SANTE and DG INTPA. While Article 168 of the Treaty on the Functioning of the European Union (TFEU) defines quite a narrow scope of action for health, the articles on development cooperation - Article 208 TFEU and Article 4 (4) TFEU - allow for more shared competences and could possibly provide greater leverage.[25]

Great opportunities lie in the integration in the Global Gateway programme.[26] Health is one of the five areas for action, and the other four – digital, climate and energy, transport, education, and research – are all major health determinants.

Fourth, the EU-GHS is clear that its actions need to be based on eye-level partnerships and that it needs to find the right balance in its cooperation with low- or middle-income countries (LMIC) as the world shifts from a donor driven development approach. This includes a strong follow-through of the agreements reached at the Sixth European Union-African Union Summit, which took place in Brussels, on February 17-18, 2022[27]. At the summit, African states had initially criticised the EU for its vaccine nationalism and its positions at the World Trade Organization regarding the TRIPS waiver. This would involve a temporary global easing of intellectual property rights on COVID-19 vaccines and treatments to enable them to be produced on a far larger scale, to support global health and a way out of the pandemic. Just a day before the Brussels launch, African countries called for a new public health order for Africa.[28] This discussion continues in the negotiations on the pandemic treaty where the call for equity has moved centre stage and the conflict between the Global North and the Global South on matters of intellectual property rights on vaccines, treatments and diagnostics has made negotiations difficult. Oxfam, in its commentary on the EU-GHS, draws attention to the conflict inherent in EU trade interests.[29] The EU-GHS does reference the need to take on issues in relation to trade agreements concerned with agricultural products, for example, but this is surely one of the most complex issues to be discussed in the context of the strategy.

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25   European Union (2007) *Treaty on the Functioning of the European Union* (Brussels: European Union).

26   European Union (2023) *Global Gateway* (Brussels: European Union).

27   European Commission (2022) 6th European Union - African Union Summit: A Joint Vision for 2030 (Brussels: European Commission).

28   ACDC (2023) *The New Public Health Order: Africa's health security Agenda* (Addis Ababa: ACDC).

29   Oxfam (2022) *EU Global Health Strategy needs to be more than just a slogan* (Brussels: Oxfam).

Fifth, the strong value base of the EU-GHS can continuously serve as a point of dissonance between the European Commission and some of the member states. Shortly after the launch of the EU-GHS the Commission launched a flagship programme to enhance sexual and reproductive health and rights in Africa in December 2022. This is a key action under the Global Gateway package. It would be near impossible to find a common Team Europe approach in this area or to speak with one voice in international bodies.[30]

The multipolar world also finds its expression in a multitude of very diverse global health programmes, networks and alliances. Regional initiatives also need to include Latin America and the Caribbean, the Indo-Pacific, and in the European neighbourhood, and the impact of the war in Ukraine. The United States is recognized as an important partner – especially in the G7 context - even though it often takes distinct policy positions. For example, it was very difficult to reach an agreement with the USA to start negotiations on a pandemic treaty. The EU-GHS proposes an EU-US taskforce on health cooperation. This could indeed be helpful in clarifying, if not always overcoming, differences.

Priorities of the strategy

The EU-GHS sets three priorities that also reflect the priorities of the 13th General programme of Work of the WHO:[31]
1. Deliver better health and wellbeing of people across the life course.
2. Strengthen health systems and advance universal health coverage.
3. Prevent and combat health threats, including pandemics, applying a One Health approach.

In all three areas, the strategy identifies what it considers "a different approach"— addressing new drivers and determinants of health in an integrated manner, maximising powerful enablers such as a skilled workforce, research and digitalisation and AI to innovate in health systems, enhancing the One Health approach, and strengthening international rules and cooperation mechanisms on health, including the probable adoption of the pandemic treaty. Some commentators have missed a clear setting out of the actions needed to achieve the goals as well as the governance mechanisms for their delivery. For many issues, success depends on the

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30 "International Women's Day: EU takes landmark decisions, but women's rights are under attack globally", *Ideas powered for business*, 08 March 2023.
31 WHO (2019) *Thirteenth General Programme of Work 2019-2023* (WHO: Geneva).

cooperation within the European Commission (Health in All Policies) and between the Commission and its associated institutions and the member states (Team Europe).

The EU-GHS makes clear, though, that it aims to develop such a new approach that tackles global challenges and shapes a new global health order through a more strategic, assertive, and effective engagement, and by working in meaningful strategic partnerships as mentioned above. It prioritises supporting low- and middle-income countries that are seeking health sovereignty. At the core of the strategy are twenty guiding principles which are based on the premise of a new approach to multilateral governance. The EU-GHS tries to make them concrete by identifying lines of action. While it maintains some bilateral initiatives, it puts a special emphasis on expanding partnerships in health at a regional level.

As part of its wide consultation process, the Commission reached out to Global South partners to consult while drafting the strategy. Their concerns are reflected in much of the tone of the strategy, the focus on health sovereignty for all countries, and in guiding principle number 8, which aims to "work towards a permanent global mechanism that fosters the development of and equitable access to vaccines and countermeasures for low- and middle-income countries".

Many commentators especially from the civil society, on the strategy have welcomed the focus on health systems strengthening and Universal Health Coverage, addressing the root causes of ill health, and the realisation of human rights, including sexual and reproductive health and rights. The EU-GHS does send a clear message that global health is about much more than providing resources to important global health initiatives and organisations through development finance. It wants to give the significant funding it provides a new direction. Guiding principle 19 of the strategy calls to "enhance EU finance for global health with maximum impact". Nine lines of action are proposed including pooled funding and co-investments.

WEMOS[32] has called for the implementation to focus on expanding public budgets for health and introducing measures to support domestic resource mobilisation and broader financial reforms, such as international cooperation on global tax justice and reducing illicit financial flows.[33]

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32   Wemos is an advocacy group, which aims to improve the health of men, women and children in developing countries by influencing international policy.
33   WEMOS (2022) *European global health strategy* (Amsterdam: WEMOS).

Many NGOs want to see the EU be proactive in reforms of the international financial architecture, especially in view of the debt burden of many low- and middle-income countries, which precludes fiscal space for countries to invest in health systems. Added to this is the need to increase the sustainability of future financing for global health – including pandemic prevention, preparedness and response. The EU could lead the way by adopting principles for Global Public Investment.[34] This includes the increased and sustainable funding of the WHO.

The key enablers which fulfil the criteria of futureproofing will need to gain very high attention in the implementation of the strategy, but many of the commentators don't focus enough on this part of the strategy. There is a strong focus in the EU-GHS on evidence-based policies and boosting research through international cooperation, supporting end-to-end research processes from fundamental to clinical research and to strengthen research capacity in LMICs. This explicitly includes transdisciplinary research, referring in particular to the need for a better understanding of One Health approaches.[35]

Especially in relation to a strong health workforce, the internal and external EU policies will need to be clearly aligned. Not only are there significant internal EU imbalances, but individual member states have also launched campaigns in LMICs to attract health workers, despite the enormous needs these countries have to expand their workforce. This will be – next to the tensions on intellectual property – another key area for conflict and competition within the EU itself and in relation to equity and access issues arising in the Global South.[36]

Values and contradictions, blind spots and gaps

There are many issues to consider when analysing the twenty-four pages of the strategy. Some issues are not highlighted enough, such as the climate-health interface where Europe (with its Green Deal)[37] could be contributing significantly, as well as a recognition of a planetary health approach. Other issues include big challenges such as digitalisation,

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34   UNCTAD (2020) *Guiding principles ofr investment policymaking* (Geneva: UNCTAD).
35   ISGlobal (2023) What Opportunities and Challenges Does the EU Global Health Strategy Present? (Barcelona: ISGlobal)
36   WEMOS (2022) *European global health strategy*
37   Swtich2Green (2023) *The EU Green Deal – a roadmap to sustainable economies* (Brussels: Switch2Green).

especially in the light of new AI developments, and its implications for health.[38]

The EU-GHS refers to fundamental "European values" such as solidarity, equity and the respect of human rights. This also includes a particular focus on sexual and reproductive health and rights and on the rights of women, children, and young people, LGBTIQ people, and other groups with unique needs. The position taken in the EU-GHS has led to major disputes with some member states. The rights of migrants, refugees, and internally displaced people are mentioned, but European policies in this regard do not hold up. Global health advocates will miss clear positions on intellectual property and weighing health over trade interests.

The EU-GHS correctly acknowledges the importance of medical products and countermeasures, but contains blind spots, especially regarding equitable distribution of, and access to, medical products. It does not address how the benefits of research and development (R&D) can be shared equitably. The strategy does mention the establishment of a "permanent global mechanism" to foster the development and equitable access to vaccines and countermeasures, but the details of this mechanism have not been revealed. They will depend on the agreements reached in the negotiations in the pandemic treaty. More clarity on the support for technology transfer initiatives, such as the Covid-19 Technology Access Pool (C-TAP) and the mRNA technology transfer hub, and to the enhancement of local production capacity in low- and middle-income countries, would have strengthened the EU-GHS.[39]

The most traction will probably be gained from areas where the EU already has a strong mandate and where its ways of working make a difference—especially where it has leverage through its financial strength and regulatory power. This is the process of the EU externalising its laws outside its borders through market mechanisms with other actors complying with EU laws even outside the EU for a variety of reasons. This can prove particularly critical in the areas of digital transformation and workforce imbalances. But it obviously applies to trade rules, climate standards, immigration policies, and One Health.

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38   European Commission (2021) Artificial Intelligence in Healthcare report (Brussels: European Commission).
39   WEMOS (2022) *European global health strategy.*

WHO at the Centre

The EU strategy is very clear on positioning the WHO at the centre of any new global health order. Therefore, the presence of the director general of the World Health Organization (WHO) at the launch of the EU strategy was much more than symbolic. The two organizations engaged in what was the first ever EU-WHO Strategic Dialogue and agreed to 'further bolster a strong multilateral system with the WHO at its core.' The EU wants a seat at the WHO table—first as a formal observer with full participation rights and then as a full member to ensure due EU presence and a decision-making role in international organizations. The WHO, in turn, needs the EU as one of its strongest supporters politically and financially.

Team Europe—the EU, EU member states, and European financial institutions - supported the 50% increase of the assessed contributions to WHO and also contributed significantly to financing the new mechanisms ACT-A and COVAX, and most recently, the newly created Pandemic Fund. The Global Health Strategy states that during the Covid-19 pandemic, Team Europe committed €53.7 billion to support a wide range of responses in 140 partner countries[40]. Just before the launch meeting in Brussels, the WHO received a new EU contribution of €125 million for the period 2023–2027 to the EU Universal Health Coverage Partnership with the WHO.

At the first EU-WHO Strategic Dialogue on Health between the European Commissioner for Health and Food Safety Stella Kyriakides and WHO Director-General Dr Tedros Adhanom Ghebreyesus, the European Commission and WHO agreed to enhance strategic cooperation in global health security and architecture. They will also cooperate on the implementation of major initiatives, such as the EU-GHS and WHO priorities for the 2022-2026 period.

Next Steps

As indicated above, the EU-GHS is highly ambitious. It is set out to be a strategically sound "work in progress" – especially as regards the governance mechanisms that need to be put in place within the

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40   Ibid.

Commission, the associated institutions and the member states – but also the relationship with international organisations and other non-EU countries. The EU must build deep and meaningful partnerships, backed up with sufficient funding and robust monitoring if it is to become a stronger player in global health.

For that it needs strong commitment from within the Commission – the office of the president and the two directorates general (SANTE and INTPA) that are in the lead, health and partnerships – but also on a regular basis from the EU Council and presidencies to help build a strong common voice and approach. The support of the European Parliament will also be critical.[41]

This will also mean revisiting national Global Health Strategies where they exist in EU member states and perhaps to motivate some additional countries to lay out such strategies based on the thinking of the EU-GHS. The EU-GHS gives very high priority to a Team Europe approach – this means joint action and pooling of resources, capacities and experience to reach common goals and carries within it significant potential – especially as the major donor counties are faced with significant cuts in development aid due to other priorities related to the polycrisis.

The "Health in All Policies" approach[42] would safeguard that many other areas of Commission work would contribute to these priorities, as would EU budget financing programs. Ensuring that health is a strong pillar[43] of the Global Gateway strategy is as critical as ensuring that it is part of the European Union-African Union or European Union – Latin America and Caribbean (EU-LAC) strategic cooperation.

The strategy will probably be most successful in those areas in which the European Union has a strong mandate and established role. But it must venture into new arenas in order to be well prepared for new global challenges. The inclusion of three key enablers (digitalisation, skilled workforce and research) are central to the EU-GHS and they provide a key link into the internal health policies of the EU – for example the pharmaceutical strategy and the European Health Data

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41   European Parliament (2022) *New EU global health strategy* (Brussels: European Parliament).

42   European Commission (2021) *Neighbourhood, Development and International Cooperation Instrument – Global Europe (NDICI – Global Europe)* (Brussels: European Commission).

43   European Union (2023) *Global Gateway*

Space. In the area of NCDs the European cancer plan plays a critical role.[44]

Yet there is an inherent contradiction in the aims set in the strategy - to build a new global health order and promote innovative approaches to partnerships - and the 20 projects listed in the annex of the document, some of which clearly reinforce path dependency. Many comments on the EU-GHS refer to its vagueness in relation to the financing of the strategy.[45] It does call for a prioritisation of global health funding within a range of financing mechanisms: EU4Health, Horizon and NDICI GlobalEurope, and the latter has already programmed €4.4. billion in grants for global health. The EU-GHS wants to foster new funding approaches too (for example, finance-pooling within a Team Europe approach, co-investment approaches and co-ownership with countries). However, addressing the larger determinants of health, will always be part of the budgets of other directorates and strategies of the Commission and hard to put a number on, as well as differentiating between global impact and impact within the EU.

As of July 2023, the EU Global Health Strategy is a Commission Communication that now awaits Council Conclusions - to be adopted by consensus between all EU member states. The Spanish presidency will have to revisit the approach to the council conclusions. It may require a joint meeting of health, environment, development and foreign affairs ministers given the scope of the EU-GHS. In this respect it is interesting to note that within the European Parliament - which would formally respond to a Council Conclusion through a non-legislative resolution - the EU-GHS was assigned to the Committee on Environment, Public Health and Food Safety (ENVI) which will draw up the report. The two committees for opinion are the Committee on Development (DEVE) and the Committee on Foreign Affairs (AFET)VI).

Conclusion

The next few years will have a decisive influence on the future global health order. In its implementation, the EU's Global Health Strategy must contribute to moving away from the undemocratic governance of

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44   European Commission (2021) *Europe's Beating Cancer Plan: Communication from the commission to the European Parliament and the Council* (Brussels: European Commission).

45   McKee, M., et al. (2023) " The EU has a global health strategy: the challenge will be in the implementation", *The Lancet*, 16 February 2023.

global health where a few hegemonic players still can set the agenda. The EU-GHS has included a monitoring mechanism, it proposes a mid-term review and a final evaluation in 2030. High-level exchanges on progress, conversations with civil society and a regular report are part of this monitoring process and can help with the democratisation process. Many EU member states are also confronted with a decolonization agenda related to their global health activities, and this must surely also be addressed.[46]

But first and foremost, the momentum and the sense of urgency must not be lost. It is critical that the decisions on the strategy in the form of council conclusions and a strong resolution from the European Parliament be taken before the elections in May 2024 that will mark the start of a new mandate in the EU's institutions. We would do well to remember that in these difficult times, the EU – even though far from perfect - is one of the few global actors committed to democracy, human rights, rule of law, and multilateralism.

This contribution partly builds on an earlier article written for Think Global Health[47].

Disclaimer: Ilona Kickbusch was one of the advisors to the European Commission on the EU Global Health Strategy. She had also been involved in advocating for the first EU Global Health Strategy.

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46   Forsberg, B., and J. Sundewall (2023) "Decolonizing global health what does it mean for us?", *European Journal of Public Health*, 33(3): 356.
47   "Team Europe Takes on Global Health: A new and ambitious strategy", *Think Global Health*, 3 January 2023.

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Part 3.

Policies of transition towards healthier and more socially inclusive Europe

Mihály Kökény

3.1 | What are Progressives standing for? Left-wing initiatives to advance the European Health Union

Introduction

On 4 October 2022, the European Parliament approved an extended mandate for the European Centre for Disease Prevention and Control (ECDC), as well as a new law on cross border threats to health. The ECDC, along with the European Medicines Agency (EMA) and the recently established Health Emergency Preparedness and Response Authority (HERA), aims to put into practice lessons learned from the Covid-19 pandemic. To improve global health security and deliver better health for all in a changing world, the Commission adopted a new EU Global Health Strategy in November 2022.[1]

These steps have been hailed by many as important milestones on the road to a European Health Union (EHU), but others have their doubts due to the weak legal grounds of EU health.[2] Is the EU staying on the right track?

Antecedents

Traditionally, EU member states have been opposed to a greater role for European institutions in health policy. Some of the main reasons for this 'national health sovereignty' are that health is a sensitive issue, has

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1   European Commission (2022) *EU Global Health Strategy: Better Health for All in a Changing World:. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 30 November 2022* (Brussels: European Commission).
2   Biedermann, F (2022) "European Health Union a step closer", *The Lancet*, 15 October 2022, 10360 (400): 1294.

large budgets, and has a complex organisation involving subnational levels of government. Furthermore, via its related industries, health policy becomes political capital for national decisionmakers, and they are reluctant to let this out of their hands.

On the surface, it has always been emphasised that the current Treaties of the European Union, which were last modified more than a decade ago by the Lisbon Treaty (2007), provide sufficient room for manoeuvre in the formulation and implementation of public health policies at EU level – mainly of a complementary nature – and that no more is needed because the organisation and financing of healthcare belong to the competence of the member states.[3]

Another reason behind the lack of greater cooperation at EU level is the substantial difference across the health systems of EU countries, which makes joint efforts considerably harder. Indeed, the state of health and health indicators vary greatly between member states, and there are strong differences in the degree of concern on the matter, as well as very significant inequality in health and healthcare among member states.

EU policies affecting health have nevertheless become widespread - but through the back door. There is thus already a substantial impact of EU decision-making on health outcomes, but it is disguised behind other policy fields such as fiscal governance, research and innovation, cohesion policy and structural funds, environmental protection, labour or social policy (particularly in the field of safety in the workplace), consumer protection, public procurement, and, last but not least, internal market regulation.[4] Despite this, it has become increasingly apparent that the fulfilment of the four freedoms at the heart of the EU - the freedoms of movement of goods, people, services and capital - cannot be envisaged in the long run without increasing the EU's competence in health policy. Increasing mobility also carries unaddressed health risks.

Inequalities in health status indicators and healthcare are constantly increasing, according to the OECD.[5] For example, preventable mortality per 100,000 inhabitants in Latvia is two and a half times higher than the French value. In Hungary, the proportion of private healthcare expenditure is around 30%, which is double the Swedish or German share. And it is also

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3   Official Journal of the European Union (2012) "Consolidated version of the Treaty on the Functioning of the European Union", *OJ, C, 326/47.*
4   Greer, S., et al (2022) *Everything you always wanted to know about European Union health policies but were afraid to ask. 3rd, revised edition* (Copenhagen: World Health Organization).
5   OECD (2021) *Health at a Glance 2021, OECD indicators* (Paris: OECD).

worrying that the number of practicing nurses per thousand inhabitants is only one third as large in Poland as in Finland.

Growing disparities with alarming inequalities[6] as to the health status of people across the 27 EU member states, and the differences in these people's access to quality healthcare, have the potential to seriously undermine the fundamental right to health. This is a basic right under the Charter of the Fundamental Rights of the EU and is provided to all European citizens in a legally binding manner.[7] If these disparities remain unchallenged, health inequalities can ultimately lead to people and politicians questioning the rationale of European integration.

In the 2019 European Parliament election campaign, the candidates of the left-wing and green parties felt most strongly that the majority of EU citizens do not just want a single capital and labour market, but a Social Europe. The European progressive left has recognised that it is necessary to invest in people, and for this it is necessary to strengthen social and welfare systems, including health systems, and eliminate the intolerable inequalities in access to care.

The vision of the European Health Union

Health is essential when it comes to the fair, resilient and sustainable development of our societies. It is one of the greatest underlying factors in creating wealth, contributing to the well-being of individuals and paving the way for prosperous societies. Health thus plays a strong role in delivering a truly Social Europe. Indeed, it has always been the European progressives' vision to promote and strengthen health through a stronger role for both public institutions and welfare states, so that quality healthcare is accessible to all European citizens. It is only by having healthy citizens, who are able to participate in social and working life, that the development of our societies is ensured. It is only by fighting inequalities at every stage of life that European societies can become fairer, and it is only by investing strongly in public healthcare systems and in health professionals that the wellbeing of people is guaranteed. Spending on health cannot be seen as a cost, but rather must be seen as an efficient investment for sustainable growth.

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6   EuroHealthNet (2023) *Health Inequalities Portal* (Brussels: EuroHealthNet).
7   Official Journal of the European Union (2012) "Charter of Fundamental Rights of the European Union", *OJ C 326*, 26.10.2012, p. 391–407.

Health and care services are central to the public good. Like other pillars of society - education, culture, water, sanitation - health is not a commodity. It is a right that cannot be solely subjected to market forces. Access to high-quality services is an inherent social right for all people and it must remain so in Europe. An EHU would thus enable member states to take all the necessary measures to support national health systems.

Numerous declarations, including the Constitution of the World Health Organization (WHO),[8] have enshrined the idea that all individuals have the right to the highest attainable standard of healthcare. The global dimension of attaining health is also reflected in United Nations (UN) Sustainable Development Goals (SDG No. 3),[9] of ensuring healthy lives at all ages. This idea is also found in the political declaration of the UN's high-level meeting on universal health coverage.[10] It is worth noting that these documents were adopted by broad consensus, with the approval of all EU countries. In addition, the importance of health is covered in the European Pillar of Social Rights that was adopted at the European summit in Gothenburg in 2017.[11]

The progress so far

The European Parliament's Group of the Progressive Alliance of Socialists and Democrats (S&D) has recognised - along the lines of the proposals by Hungarian MEP István Ujhelyi among others - that the coronavirus pandemic caught the member states of the EU and its institutions unprepared for managing such a public health crisis. The alliance also recognises that it exacerbated the inequalities between member states' health systems. Covid-19 thus resulted in the first demand for an EHU strategy. The S&D position paper of 12 May 2020 defined the

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8   WHO (1948) *Constitution of the World Health Organization. Basic Documents, Forty-fifth edition, 2020* (Geneva: WHO).

9   United Nations (2015) *Transforming our world: the 2030 Agenda for Sustainable Development. United Nations General Assembly Resolution (25 September 2015)* (New York: United Nations).

10   United Nations (2019) *Universal health coverage: moving together to build a healthier world. Political Declaration of the High-level Meeting on Universal Health Coverage* (New York: United Nations).

11   European Commission (2017) *European Pillar of Social Rights* (Brussels: European Commission).

possible components of this concept in detail.[12] In the shadow of threats to public health, the larger groups of the European Parliament also caught up with the progressives and supported the concept and measures of the EHU.[13, 14]

The S&D proposals have largely been incorporated into the European Parliament's landmark public health resolution, with the concept of the EHU. This resolution calls for cooperation, and includes the elaboration of quality standards for healthcare in all member states. This objective would be achieved through stress tests in EU countries to assess the resilience of national health systems as a matter of urgency, to identify weaknesses, and to check whether the system could cope with possible further outbreaks of epidemics. An important aspect of the document is how to address health inequalities through, for example, equal access to medicines and medical devices.[15]

In order to further frame the legal basis of the EHU, an explanatory memorandum accompanying the Manifesto for a European Health Union was developed under the leadership of the former health commissioner Vytenis Andriukaitis in November 2020[16] listing 22 proposals as identified by various stakeholders including the S&D family.[17] Amendments to the Treaties were already emphasised in the Manifesto in order to strengthen the legal status of EU health policy, but its time-consuming nature and the lack of majority political will, have blocked this until now.

From the autumn of 2020, work on the establishment of the EHU has been accelerated in the European Commission and its directorates. The official website of EHU summarises the practical elements of the programme initiated or implemented such as the pharmaceutical strategy, the European Health Data Space and the Europe's Beating Cancer Plan.[18] A promising development has been achieved with the EU budget 2021-

12   S&D (2020) *A European Health Union. Increasing EU competence in health – coping with Covid19 and looking to the future* (Brussels: S&D).
13   EPP Group (2020) *EPP Group Position Paper on a European Union for Health* (Brussels: EPP Group).
14   Renew Europe (2020) renew Europe welcomes the European Health Union starting to take shape (Brussels: Renew Europe).
15   Official Journal of the European Union (2021) "European Parliament resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 (2020/2691(RSP))", *OJ, C, 371/102.*
16   EIHSD (2020) *Manifesto for a European Health Union* (Brussels: EIHSD).
17   Andriukaitis, V. (2021) "A European Health Union as the way forward for the health of the continent", *FEPS Policy Brief*.
18   European Commission (2023) *Official website of the European Health Union* (Brussels: European Commission).

2027, which has 13 times more funds than the previous envelope, with around €5.3 billion for health programmes (EU4Health).[19]

At the end of 2021, even EPSCO (the competent Council of Member States) advocated the strengthening of the EHU in unusually long, 24-page conclusions, which of course also emphasised the importance of maintaining national competences.[20]

At the same time, there is no doubt that the EU paid with human lives and huge economic and social losses for the fact that, especially in the first phase of the pandemic, the development of a common European health policy progressed slowly. If EU health competencies were stronger during the pandemic, one can assume that there would not have been fragmented and over-politicised responses, data provision and communication would have been uniform, non-medical measures would have been linked to epidemiological indicators and only vaccines approved by the European Medicines Agency would have been used. Unfortunately, the political selfishness of some member states did not comply with this expectation and for the time being, it does not allow this reasonable and logical position to prevail. However, the joint vaccine procurement and the uniform vaccination certificate are among the few success stories.

Uncertainty

The potential scope for further actions within the EHU is vast, with some avenues for moving forward being clear. However, the risk of a return to a policy where the EU does not act remains. Especially in the countries of the Visegrád group, there is opposition to providing greater health powers to the EU. It seems unlikely that the current conservative Polish government will advocate such changes, as it presents a different approach to issues such as abortion, euthanasia, infertility treatment and contraception to most member states.[21] Some German parties also have reservations about closer EU health cooperation.[22]

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19 European Commission (2023) *EU4Health programme 2021-2027 – a vision for a healthier European Union* (Brussels: European Commission).
20 EPSCO Council (2021) *Conclusions on strengthening the European Health Union. Draft for the meeting of 7 December* (Brussels: EPSCO Council).
21 Visegrád Info (2021) "Some in the V4 are reluctant to give up healthcare competencies to the EU". 5 March 2021.
22 EurActiv (2021) "Ahead of German election, parties split on strengthening EU health cooperation". 2 September 2021.

In parallel with the gradual abatement of the pandemic, the enthusiasm and commitment to a unified European health policy also unfortunately decreased in the EU's institutions. The French presidency for the first half of 2022 has still remained health committed while focused on the continuation of the EHU projects that had already been launched and prioritized the discussions started on the global health strategy.[23] The programmes of the subsequent Czech and Swedish presidencies did not include the advocacy of an EHU, and they only mentioned the management of specific health regulations and measures, carefully avoiding the expansion of community health competencies.[24, 25] According to preliminary statements it is likely that the Spanish, Belgian and Hungarian presidencies will not tackle the topic of EHU and stronger community health competences in their programmes.[26]

The statements of EU leaders are not consistent enough either. In 2020, Commission President Ursula von der Leyen argued for a strong EHU.[27] However, in her speech to the European Parliament on the state of the EU in 2022, she did not even mention the issue of common EU health competences and only emphasised the importance of mental health.[28] A few months later, she showed optimism again. In May 2023, welcoming the WHO's announcement that Covid-19 is no longer an emergency of international concern, von der Leyen said: "The pandemic (...) has taught us that the EU's strength lies in its unity, including when confronted with major health crises (...) changed the face of the EU, which has become a true European Health Union".[29]

The resolution of the 2022 congress of the Party of European Socialists in Berlin also treated the idea of the EHU with caution. Although the importance of mitigating health inequalities appears in the text, some important steps in completing the EHU (for example, one point supported

23 Loerke, S., Hervas, C (2022) The health agenda of the EU French Presidency (Brussels: Edelman).
24 European Commission (2022) *Programme of the Czech presidency (2022)* (Brussels: European Commission).
25 European Commission (2023) *The Swedish Presidency programme (2023)* (Brussels: European Commission).
26 La Moncloa (2023) "Spain, Hungary and Belgium address key health issues during the EU Council Presidency", *La Moncoloa*, 5 May 2023
27 Von der Leyen, U (2020). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Brussels, 16 September 2020.
28 Von der Leyen, U (2022). "State of the Union Address by President von Der Leyen at the European Parliament Plenary". Strasbourg, 14 September 2022.
29 Von der Leyen, U. (2023) "Statement by President von der Leyen on the end of the COVID-19 pandemic". Brussels, 5 May 2023.

in 2020 - the creation of common minimum quality requirements for healthcare systems), are already missing from the document.[30]

These developments indicate the political division that exists on the issue of the EHU. Analysis by Nabbe and Brand sheds light on the background of this division, and outlines possible scenarios.[31] There is reason to assume that the looming, overlapping energy, food, and financial crises associated with the protracted war in Ukraine are relegating health issues to the background anyway, even though the "no one is left behind" principle should prevail right now in overcoming obstacles concerning access to health services.

However, it is an encouraging sign that in January 2023 the European Parliament established its public health subcommittee (SANT) within the Committee on Environment, Public Health and Food Safety (ENVI). This is certainly a message that the issue of health is a priority for European Parliament members and foreshadows the possibility that the area will receive an independent main committee in the next cycle.[32]

Why should progressives stand up for the European Health Union?

Writing in 2021,[33] Frank Vandenbroucke, Belgium's then Socialist Minister of Health, stated that standing in favour of the EHU means that the EU cares, protects and serves, and this coincides with the view of civil and professional organisations.

It would be important to assess the strengths, weaknesses and quality problems of the member states' care with stress tests similar to the rating of banks, and then, after evaluating the data, to set up a European criteria system that must be guaranteed by the healthcare systems of all EU countries. The content of these demands must be discussed with a multitude of professional and civil society organisations. However, the criteria should include minimum requirements in terms of primary care,

30   PES (2022) "Congress Resolution. With courage for Europe". Berlin, 14-15 October 2022

31   Nabbe, M., and H. Brand (2021) "The European Health Union: European Union's Concern about Health for All. Concepts, Definition, and Scenarios". *Healthcare*, 9(12), 1741. 1

32   European Parliament (2023) *Official website. Public health subcommittee of the European Parliament (SANT)* (Brussels: European Parliament).

33   Vandenbroucke, F. (2021) "We need a Europe that cares and that is seen to care", *The Progressive Post, FEPS.* #15, Winter.

health workforce density, share of health expenditure in the government budget and more.

Sooner or later, it is inevitable that we amend the basic EU treaties, to include the introduction of shared health competences in a series of issues. A specialised council configuration for health should also be created to strengthen the voice of national health representation at EU level.

It is a legitimate suggestion that common EU-level decisions are needed in a public health emergency, such as when the WHO declares a pandemic. All the more so, because the experiences of Covid-19 have confirmed that isolation and separate solutions represent a dead end. From a moral point of view, it is also unacceptable to object to the expansion of the EU's health powers by referring to health inequalities arising from insurmountable economic and cultural differences and different administrative arrangements.

It is desirable that the 2024 election campaign of the progressives for the European Parliament focuses on the benefits of a unifying health policy. The growing nationalist and populist forces, relying on the fears of the losers of the current crises, will blame Brussels and the planned EHU for the weakening of health care. They will claim that only strong nation states are able to provide quality healthcare. However, this is not true, as the challenges of healthcare such as cost explosion, pandemic preparedness, rare diseases or health workforce shortages can only be effectively resolved together. Hungarian public opinion polls have confirmed that the overwhelming majority of the healthcare profession and local governments are in favour of the EHU.[34] This was supported by what was said at the recently concluded large-scale civil consultation on the Future of Europe covering all member states.[35] According to a multinational survey commissioned by the European Parliament, over two-thirds of respondents (69%) want "the EU (to) have more competences to deal with crises such as the coronavirus pandemic".[36]

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34   Kökény, M., O. Süli, I. Ujhelyi (2021) "How could the European Health Union help the Hungarian healthcare to catch up?" *Policy study, Foundation for European Progressive Studies, July 2021* (Brussels: FEPS).

35   Council of the European Union, General Secretariat of the Council (2022) *Conference on the Future of Europe – Report on the final outcome: May 2022* (Luxembourg: Publications Office of the European Union).

36   European Union (2020) *Uncertainty/EU/Hope: Public Opinion in Times of Covid-19* (Brussels: European Union). Available online: https://op.europa.eu/en/publication-detail/-/publication/d98bae75-0c32-11eb-bc07-01aa75ed71a1

Progressives may also point out that the creation of the EHU could strengthen the global position of the European Union. The WHO is working hard to elaborate a so-called pandemic treaty, a new binding instrument to respond to future public health threats. The European Union, with the majority of its member states, is playing a forward-looking role during these deliberations. With the pandemic, the world has experienced how the geopolitics of global health have immediate, ruthless repercussions for the lives and livelihoods of billions. The challenge of this negotiation process is to be responsive to these interconnected levels of geopolitics, and the EU could do a lot for positive outcomes. The same applies to other international regulations and the approaches of development assistance for poor countries. All this underlines the significance of the EU's global health strategy. The EHU and the global health strategy represent two sides of the same coin. The former is an internal dimension with a strong grounding in the social pillar, the latter is external and should reflect European values such as solidarity, equity and more.[37]

Conclusion

The political family of the progressives, based on their values, should carry on with their previous commitments in order to implement the EHU without delay or tactical games. If they remain consistent and determined, it will strengthen their credibility. This is a historic opportunity for the European social democrats, but also their responsibility.

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37   Kickbusch, I., M. Kökény (2022) "Europe's role in global health: What to expect from a new strategy?" *Eurohealth* 28(3): 43-46.

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3.2 | Scenarios for the EHU's evolution: Legislative process, resources, narrative, and political will

Introduction

The first two parts of this book described healthcare as a key sector of the modern economy, its still minor but increasingly important place in European politics, and analysed some of the most promising directions for a stronger pan-European health policy. The final part of this book discusses the steps that should be undertaken on European and national levels to define a genuine European Health Union, and to identify the changes needed for agreed objectives to be achieved.

The term European Health Union (EHU) is just three years old at the time of writing of this book, and its final meaning is not yet a given; the concept is still evolving in political debates at the national and European levels.

1. Initiatives of 2020-2023 to strengthen European health policies

The mutual enrichment of ideas of Italian antifascists expressed in the Ventotene manifesto and those of French government officials presented by the Schuman Declaration contributed to the dawn of the European project. The EHU is an example of policies where public initiatives go hand in hand with those designed by governments, parliaments and European institutions. The Manifesto for a European Health Union is one of the public initiatives that contributed to the development of EHU.

1.1 Manifesto for a European Health Union

The Manifesto for a European Health Union,[1] published in November 2020, addresses three issues:

- It calls on the political leaders of Europe in the frame of the Conference on the Future of Europe to commit to creating a European Health Union.
- It invites the people of Europe to take strong public action to build a union where the lives and health of everyone matters beyond the necessity of fighting Covid-19.
- The Manifesto sets out a vision of a European Health Union (with goals, policies, measures, principles) developed by the signatories of the Manifesto.

According to the explanatory memorandum to the Manifesto:[2]

> The challenge is not to make the EU responsible for all matters in health; that would be a great mistake. Rather it is to find the best ways to enable cooperation among the EU and its Member States, enabling them to act more strongly and more effectively in both 'normal' and 'pandemic' times. Progress in achieving this will go hand in hand with actions mapped out in other policy initiatives such as the social market economy, the Green Deal, and the digitalisation agenda. This progress must first and foremost build on the EU Pillar of Social Rights and the commitment of the EU and its Member States to the SDGs.

The Manifesto presents the goals of a European Health Union as they are understood by the authors of the document:

a) Strive for health and wellbeing of all Europeans, with no one left behind.

b) Strengthen solidarity within and among member states, based on the principle of progressive universalism, providing support, including universal health coverage, for all, but with particular attention to the needs of those who are disadvantaged.

c) Ensure environmental sustainability, by adopting the European Green Deal[3] and prioritising measures to promote One Health, the concept that links our health with that of the animals with which we share this planet.

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1   *Manifesto for a European Health Union. Available online: https://eihsd.eu/manifesto-for-a-europan-health-union/*

2   Ibid.

3   European Commission (December 2019) *A European Green Deal* (Brussels: European Commission).

d) Provide security for all Europeans, protecting them from the major threats to health and from the vulnerability that is created by living a precarious existence.

e) Enable everyone's voice to be heard, so that policies that affect their health are created with them and not for them.

Policies to achieve these goals are explicitly listed in the manifesto:

a) The status of health policy in the European Treaties will be strengthened, with provisions for a European Health Union incorporated into a revised Treaty on European Union.

b) The voice of the citizens of Europe, expressed through their representatives in the European Parliament, will be heard more strongly.

c) Recognising the cross-border nature of many threats to health, the Health Threats regulatory framework will be revised, including the proposed creation of a Health Emergency Preparedness and Response Authority (HERA), enhanced mechanisms and provisions to procure adequate supplies in emergencies, to enable the rapid publication of consistently defined health data (including strengthened roles for EUROSTAT and ECDC, working closely with Member States), to strengthen the mechanisms for rapid generation of accurate and trusted evidence from research and practice, and to counter the threat from "fake news".

d) The European Union's activities in health research will be expanded, with an enhanced health programme within Horizon Europe, the creation of a European equivalent of the US Biomedical Advanced Research and Development Authority (BARDA), a strengthened EMA, and other measures to promote research collaboration across Europe.

e) Recognising the importance of the health workforce, the European Union and member states will work together to address the unequal distribution of health workforce capacities in Europe, providing support to regions that have difficulties in attracting health workers as well as promoting training and education of health professionals according to common standards, coupled with measures to safeguard the rights of health workers, including those from other parts of the world.

f) Recognising the benefits of European collaboration on rare diseases, and measures to support those who are affected by them.

g) Recognising the global nature of many threats to health, the EU will develop a Global Health Policy, working with the UN and its specialised agencies, and especially a strengthened World Health Organization,

and other multinational organisations contributing to health, to achieve the health-related Sustainable Development Goals.

The European Commission's (EC) competences on health are currently restricted. While Article 168 of the Treaty on the Functioning of the EU (TFEU) provides a basis for the EU's policies, it leaves health policy as the responsibility of the member states. The EC may only complement, coordinate, and encourage cooperation or sometimes supplement it. The manifesto calls for a reconsideration of policies that restrict pan-European cooperation on health.

1.2. Growth of European financing of public health projects

The financial commitments of the EU for health-related issues were marginal until the health crisis caused by Covid-19. Before the pandemic, the European Commission's main vehicle for funding collaborative public health actions in Europe were the Health Programmes (HP), which began in 2003. The scope of HPs grew from programme to programme, but did so very slowly and from a low base level.

The slow growth of pan-European financing of health was somewhat surprising, given the evidence that European health projects were efficient. For example, the final report of Ex-post Evaluation[4] of the Health Programme (2008-2013) states that "the Programme has demonstrated significant EU added value" and that it is "wrong to focus the HP too narrowly on health promotion issues that appear most directly relevant for growth, since these do not always coincide with areas where there is the strongest case for EU-level collaboration".

Statistics presented in Figure 1 show that the latest and the largest pre-pandemic Health Programme, lasting seven years (2014-2020), had a budget of just €449.4 million. By comparison, general government expenditure of EU member states on health exceeds one trillion euro for the year 2020 alone.

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4 European Commission (2015) *Ex-post Evaluation of the Health Programme (2008-2013),* (Brussels: European Commission).

Figure 1. Financing of EU Health Programmes

Budget of EU health programmes (million euro)
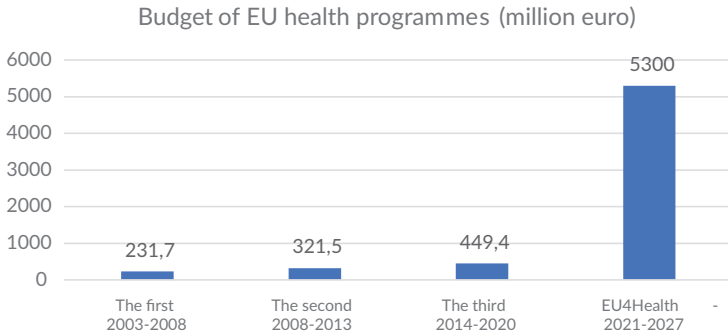
Source: own design

The new EU4Health budget for the years 2021-2027 is €5.3 billion, and therefore marks a considerable increase in comparison to budgets of previous periods. Nevertheless, proponents of a strong European health policy believe much more could be done. Even after this substantial increase, the budget will not exceed 1% of total annual public health expenditure of the EU member states.

Scepticism about the progress in pan-European financing of HP's is based not just on the comparatively small EU4Health budget. Discussions around the budget for EU4Health revealed limited interest among member states to work together for the health of Europeans. The main milestones of the discussion on the scope of EU4Health were:[5]

- The initial proposal of the European Commission was €9.4 billion for a 'standalone' EU4Health which would operate alongside the bloc's R&D programme Horizon Europe. The Commission proposed to invest in prevention, crisis preparedness, the procurement of vital medicines and equipment and improving long-term health outcomes.
- EU leaders at July's 2020 EU summit reduced the fund to a mere €1.7 billion.
- The European parliament expressed support for the initial proposal of the EC (€9.4 billion) in October 2020.
- The EU Council and the European Parliament reached a compromise, fixing the budget with the initial ambition halved (€5.3 billion) on 10th November 2020.

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5 European Parliament (2020) *The EU's new health programme: EU4Health* (Brussels: European Parliament).

EU4Health is not the EU's only source of financing for public health, however. The most important alternative EU funds which can be used to improve people's health and reduce health inequalities are combined into the European Structural and Investment Funds (ESIF). Three of the funds from ESIF are particularly relevant to health: the European Regional Development Fund, the European Social Fund Plus, and the European Rural Development Fund. MS can use those funds to invest in infrastructure, including in healthcare facilities. The Cohesion Fund can also be used as key assets for regional, urban and territorial developments, including health.

Additionally, Horizon Europe and the Digital Europe programme incorporate research and innovation projects across the EU. Health-related topics are a significant part of these programmes.

During the Covid-19 pandemic, MS and EU institutions agreed to establish a recovery fund called "Next Generation EU" in parallel to the multiannual financial framework. Part of this recovery fund will be transferred via a new recovery and resilience facility into investments and reforms in the MS, including, but not limited to, their healthcare systems.

Various additional EU funding mechanisms (especially the ESIF) are used to improve people's health and reduce health inequalities. However, scattered capacities and competencies for policymaking on health systems and public health at the EU and MS levels have resulted in the perception that there is no real strategic cooperation between MS for expenditure in the area of health.

Health expenditure per capita and as a share of GDP varies greatly from one MS to another. And current levels of investment and funding in many MS' mean public health systems are not providing a sustainable background to tackle major challenges such as non-communicable diseases, equal access to innovative treatments, etc. Extra investments into public health and healthcare systems (including those from the EU budget) are needed to overcome those challenges.

Greater EU financing of health would require the EU to have a stronger own financial resource base. Currently, however, the EU's budget for health is formed using four EU own resources,[6] and these are not enough to provide a larger and more autonomous health budget.

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6 These resources are: (1) customs duties, which are levied on imports, (2) value added tax (VAT), and (3) gross national income (GNI), and finally (4) a new resource based on recycled plastic packaging waste.

In 2023, the EC presented a package of three new own resources: revenue generated by emissions trading, revenue generated by the Carbon Border Adjustment Mechanism and a share of the residual profits of the largest multinational enterprises that are reallocated to EU MS. There are also debates around including a Financial Transaction Tax and Digital Tax for large companies.

On 6 July 2023 the EC published a strategic foresight report on sustainability and people's wellbeing.[7] It examined the key intersections between the structural trends and dynamics affecting the social and economic aspects of sustainability to clarify the potential choices and trade-offs that the EU is likely to face in the future. And it stressed 10 priority areas for action, including reconciling well-being and prosperity, ensuring a new European social contract, moving towards a "Europe of Investments", making public budgets fit for sustainability and further shifting policy and economic indicators toward a sustainable and inclusive wellbeing. It echoed the idea of strengthening the European Health Union. No doubt, this would require much bigger EU financial capacities and it should open discussions about a larger EU budget.

1.3. European projects in health policies since 2020: bringing the EU closer to human health issues

Cooperation in managing the Covid-19 pandemic is undoubtedly one of the most successful recent examples of pan-European collaboration. In this section, we will look at four novel health initiatives that have been introduced since the start of the pandemic: the Pharmaceutical Strategy for Europe;[8] Europe Beating Cancer Plan; the European Care Strategy and the EU Strategy on Mental Health.

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7 European Commission (2023) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL 2023 Strategic Foresight Report Sustainability and people's wellbeing at the heart of Europe's Open Strategic Autonomy* (Brussels: European Commission).
8 European Commission (2020) *COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS: Pharmaceutical Strategy for Europe* (Brussels: European Commission).

1.3.1. The Pharmaceutical Strategy for Europe (November 2020)[9]

The strategy aims to support industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs while addressing market failures. It will also take into account the weaknesses exposed by the coronavirus pandemic.

What does the initiative aim to achieve and how?

The strategy is based on four pillars, which include legislative and non-legislative action:

- Ensuring medicines for patients and addressing unmet medical needs (in the areas of antimicrobial resistance and rare diseases, for example).
- Supporting competitiveness, innovation and the sustainability of the EU s pharmaceutical industry and the development of high quality, safe, effective and greener medicines.
- Enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, and addressing medicines shortages.
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

The Communication on a Pharmaceutical Strategy for Europe includes a set of actions, and work is already well underway in many areas, such as the revision of the legislation on rare diseases. The implementation of the strategy will span the mandate of this Commission.

In April 2023, the Commission proposed a revision of the EU's pharmaceutical legislation to make it more agile, flexible, and adapted to the needs of citizens and businesses across the EU.[10] Pharmaceutical policy being in the domain of health as well as of the internal market is a sphere where the EU already has a long and reasonably positive record of performance.

This revision would foster innovation and competitiveness in health technologies, pharmaceuticals and medical devices and strengthen efforts in the future to create a single market for those products, overcoming today's 27 separate markets. It could also help to decrease prices for pharmaceuticals in the EU.

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9   Ibid.
10   European Commission (2023) *Reform of the EU pharmaceutical legislation* (Brussels: European Commission).

1.3.2. Europe Beating Cancer Plan (February 2021)

The EU has been actively working to reduce the incidence of cancer for decades, and its work has paid off. The first 'Europe Against Cancer Plan', dating back to the late 1980s, resulted in important EU legislation on tobacco and occupational health. Since then, EU member states have taken a number of actions and have committed, in line with the United Nations Sustainable Development Goals (SDG's), to reduce premature mortality from chronic diseases, including cancer, by one third by 2030. They have also committed to meeting the WHO targets on non-communicable diseases by reducing mortality from cancer by 25%.

What does the initiative aim to achieve and how?

The overall objective of the EU beating cancer plan is to improve the prevention, detection, treatment and management of cancer in the EU while reducing health inequalities between and within member states. It will set out actions that support, coordinate or supplement member states' efforts. To be efficient and patient oriented, increased collaboration and teamwork within the health sector, and with other sectors, is needed. Different health professionals - such as radiologists, surgeons, oncologists, nursing staff, medical physicists and researchers – continue working in silos. There is also a need for a more holistic approach in the training of healthcare workers, involving non-healthcare staff and informal carers to improve, for instance, palliative care and pain management.

Potential instruments of the plan

- *Prevention.* This area focuses on taxation of alcohol and tobacco consumption, access to affordable healthy food, and pollution of air, water and soil. It also covers further legislative and soft measures to reduce exposure to carcinogenic substances in the workplace, in products and in the environment, and to UV and ionising radiation from natural and artificial sources. Education is also essential, so it aims to improve young people's awareness of what causes cancer and how to avoid these risks.
- *Early detection and diagnosis.* Technical support to member states could help increase screening rates, while guidelines and structural support can help ensure a high level of quality throughout Europe. Measures in the digital realm include training, the use of artificial intelligence and remote access to high-quality care. The European Rare Diseases Network could be strengthened too.

- *Treatment and care.* Working in line with the planned pharmaceutical and chemical strategies as well as Horizon Europe, the plan could facilitate access to high-quality treatment and uptake of new therapies, ensure the availability and affordability of essential medicines, incentivise innovation (particularly for rare, paediatric, or otherwise 'neglected' cancers with poor prognosis and boost aligned public and private research investment), as well as collaborative clinical research to maximise impact and knowledge translation into new therapies and clinical practice.
- *Quality of life for cancer patients, survivors and carers*. Platforms, structures and resources could support the dissemination of best practices on issues such as psychological support, pain management, professional re-integration, exploring measures such as "the right to be forgotten" or facilitating the portability of medical records data. Person-centred care, underpinned by digital solutions such as wearables and mobile health applications could support the growing number of cancer survivors. Measures could address the specific situation of informal carers and parents of children with cancer, in particular by providing practical support and social protection, and helping member states in the provision of palliative care and supporting transfer of best practices.
- *Knowledge, data and scientific evidence.* This would include the Cancer Mission[11], research and innovation actions, dedicated digital infrastructures and the European Health Data Space. Artificial Intelligence would enable the fast processing of large amounts of pooled genomic and health data available through the 1+ Million Genomes Initiative. Also, interoperable electronic health records could improve understanding of disease mechanisms leading to the development of new treatments. The establishment of a European Cancer Knowledge Centre could be explored, building on existing work and pooling expertise in the areas of research, cancer prevention, cancer data and registries, as well as on European Guidelines and Quality Assurance for cancer screening, diagnosis and care.

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11   European Commission (2023) *EU Mission: Cancer* (Brussels: European Commission).

1.3.3. European Care Strategy (September 2022)[12]

The European care strategy has the objective of ensuring quality, affordable and accessible care services across the European Union and improving the situation for both care receivers and the people caring for them, professionally or informally. The strategy[13] supports the implementation of the principles enshrined in the European Pillar of Social Rights,[14] in particular the principles on gender equality, work-life balance, childcare and support to children and those in long-term care.

The European Care Strategy will also contribute to achieving the three EU social headline targets on employment, skills and poverty reduction for 2030,[15] welcomed by EU leaders at the Porto Summit in May 2021 and by the European Council. [16, 17]

What does the initiative aim to achieve and how?

Early childhood education and care. The Commission is proposing that member states revise the targets on early childhood education and care to enhance women's labour market participation, also called 'the Barcelona Targets', set in 2002. The current targets call on member states to provide childcare to 33% of children under three years of age, and to 90% of children from age three until mandatory school age. The Commission proposes to set new ambitious yet realistic targets so that by 2030 at least:

- 50% of children below the age of three are in early childhood education and care**.**
- 96% of children between the age of three and the starting age for compulsory primary education are in early childhood education and care, as already agreed in the European Education Area framework.[18]

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12   European Commission (2022) *A European Care Strategy for caregivers and care receivers* (Brussels: European Commission).
13   Ibid.
14   European Commission (2017) *The European Pillar of Social Rights in 20 principles - Employment, Social Affairs & Inclusion* (Brussels: European Commission). n
15   European Commission (2022) *Commission welcomes targets for a more social Europe by 2030* (Brussels: European Commission).
16   European Commission (2021) *Porto Social Summit: all partners commit to 2030 social targets* (Brussels: European Commission).
17   European Council (2021) *European Council meeting (24 and 25 June 2021) – Conclusions* (Brussels: European Council).
18   European Commission (2021) Council Resolution on a strategic framework for European cooperation in education and training towards the European Education Area and beyond (2021-2030) 2021/C 66/01 (Brussels: European Commission).

The Commission also recommends that member states:
- Ensure that childcare services are affordable, accessible and of high quality, available in urban as well as rural or disadvantaged areas.
- Introduce a legal entitlement to early childhood education and care, ideally with no gap between the end of paid family leave and the legal entitlement.
- Have targeted measures in place to enable and increase participation of children from disadvantaged backgrounds, with disabilities or with special needs in education and care, to close the gap with the overall population of children.
- Look at the number of hours children spend in childcare ('time-intensity') and ensure that childcare is available for a duration that allows parents to engage meaningfully in paid work.
- Encourage equal sharing of childcare between parents by combating gender stereotypes and support family-friendly working-time arrangements.

Long-term care. The Commission recommends that member states draw up national action plans to make care in the EU more available, accessible and of better quality for all, for instance by:
- Ensuring that long-term care is timely, comprehensive and affordable, allowing a decent standard of living for people with long-term care needs.
- Increasing the offer and mix of professional long-term care services (homecare, community-based care and residential care), close territorial gaps in the access to long-term care, roll-out accessible digital solutions in the provision of care services, and ensure that long-term care services and facilities are accessible to people with disabilities.
- Ensuring high-quality criteria and standards for long-term care providers.
- Supporting informal carers, who are often women and relatives of care receivers, through training, counselling, psychological and financial support.
- Mobilising adequate and sustainable funding for long-term care, including by using EU funds.

Fair working conditions and training for care staff. To improve working conditions and attract more people – in particular men – to the care sector, member states are recommended to:

- Promote collective bargaining and social dialogue with a view to improving wages and working conditions.
- Ensure the highest standards of occupational health and safety.
- Design continuous education and training for care workers.
- Tackle gender stereotypes around care and launch communication campaigns.
- Ratify and implement ILO Convention 189 on domestic workers.

For deeper analysis of the Strategy please see work of The European Care Strategy developed by FEPS[19].

1.3.4. A Comprehensive Approach to Mental Health (2023)[20]

The Comprehensive Approach to Mental Health sets out how action at EU level can help promote good mental health and prevent, mitigate and respond to mental health challenges. It also details how mental health considerations should be factored into a wide variety of resilient EU and national policies for the benefit of people across the EU.

The initiative aims to tackle serious mental health problems:
- According to the EC prior to the pandemic, more than 84 million people in the EU were affected by mental illness. Around 5% of the working age population had a severe mental health condition, while a further 15% were affected by a more common condition, reducing their employment prospects, productivity and wages.[21]
- Mental health has deteriorated further since the onset of the Covid-19 pandemic in general but the impact is particularly striking among young people, older people, and other vulnerable groups.[22]
- More recently, the Russian aggression against Ukraine and its consequences for the cost of living, as well as uncertainty about the future, have created new stresses, with long-term impacts on mental health. Nationals of non-EU countries such as those fleeing Ukraine may face particular mental health challenges due to traumatic experiences.

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19   FEPS (2023) *Policy study: The European Care Strategy* (Brussels: Foundation for European Progressive Studies).
20   European Commission (2023) *A comprehensive approach to mental health* (Brussels: European Commission).
21   European Commission (2023) *Communication from the commission to the European Parliament, the council, the European economic and social committee and the committee of the regions on a comprehensive approach to mental health European Commission (2023) A comprehensive approach to mental health* (Brussels: European Commission).
22   Ibid.

- Triggered by a mix of individual, family, socioeconomic and environmental circumstances, mental health disorders carry a high financial and human cost. Investing in improving people's mental health is not only about health; it is about ensuring that European society is citizen-centred, resilient and cohesive.

What does the initiative aim to achieve and how?
The initiative seeks to promote a comprehensive, prevention-oriented approach to mental health as a public health issue and to mainstream mental health into EU policies. It will set out possible future workstreams, focusing on clearly-defined EU added value to facilitate the work of Member States and those on the frontline. This will include:

- *Promotion of good mental health and prevention of mental health problems*, looking at policies, actions and funding for mental health literacy, awareness-raising, citizen empowerment and education across society, from individuals and healthcare professionals to policymakers, social services, networks and public authorities in society as a whole. It also includes addressing the key socioeconomic and environmental risk factors of mental health problems.
- *Early detection and screening of mental health problems*, focusing on where an improved approach could have the biggest impact, such as in educational settings, the workplace, retirement homes, community-based care and healthcare.
- *Actions to further tackle psychosocial risks at work*, focusing on the outcomes of discussions with member states and social partners, with the input of the EU agency for safety and health at work (EUOSHA).
- *Support and improving access to treatment and care of mental health problems*, focusing on evidence-based innovative, promising and personalised approaches and interventions, effective treatments and high-quality care, addressing inequalities in access to affordable treatments and medicines, strengthening the capacities of the health workforce, supporting the families of patients affected by mental health disorders and promoting integrated care pathways.
- *Improved quality of life,* appropriate and patient-centred follow-up care, facilitating return to school and work, and advancing on key elements such as de-stigmatisation and rights.
- *Cross-cutting issues*, including research, development and innovation, the role of digital tools, training and support, including inter-disciplinary training for the health workforce, improved exchange and networking among mental health professionals, patient organisations,

social services and scientists, focusing on the specific needs of vulnerable groups (e.g., children, elderly, migrants and refugees) and socioeconomic disadvantaged groups (low education, low income, unemployed or at risk being unemployed), and global cooperation on mental health.

1.4. A more prominent role for health and wellbeing indicators in measurement of socio-economic progress across Europe

Economic indicators like Gross Domestic Product (GDP) or Gross National income (GNI) measured according to exchange rate or purchasing power parity (PPP) are the main tools used for assessing the progress of modern societies. However, recognising the limits of purely economic indicators to measure socio-economic progress has provided ground for composite indexes. The Humane Development Index (HDI) is one of the most popular of these composite indicators. HDI reflects life expectancy, education (mean years of schooling completed and expected years of schooling), and per capita income indicators. HDI is used by United Nations Development Programme but has a limited role in European policies.
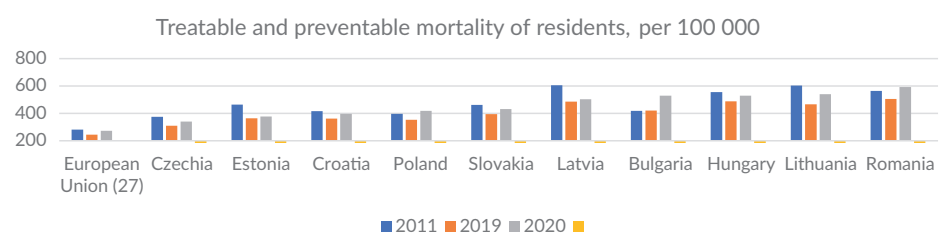
Covid-19 increased interest in health-related data among Europeans. Before 2020, most countries of the EU relied on annual figures on morbidity and mortality that were usually published months or even years after the accounting period. Regardless of pledges for health in all policies, few experts (mainly those specialised in public health) were interested in comparative analysis of health inputs, outputs and outcomes. However, health statistics flooded the public information space during the period of 2020-2022. Covid-19 data on new and active cases, and new and cumulative deaths was gathered, was published and discussed on a daily basis.

In line with the retreat of the pandemic in 2023, the interest of the general public and politicians in detailed Covid-19 statistics has diminished, but it is in the interest of Europe not to forget public health lessons learned during the crisis. The prioritisation of health data in European politics is one of preconditions of a genuine European Health Union. Broader usage of indicators on treatable and preventable mortality and excess mortality are tools with the potential to enhance stronger European health policy.

Comparative analysis of treatable and preventable mortality[23] shows that all countries of the EU have potential in saving lives. Even Sweden, famous for having one of most advanced health systems in the world, has the possibility of saving 185 people per 100,000 annually[24]. Reserves available for countries with treatable and preventable mortality rates exceeding the EU average are presented in Figure 2.

Figure 2. Treatable and preventable mortality of residents, per 100 000 in EU countries with public health results below the EU average[25]

Treatable and preventable mortality of residents, per 100 000

■2011 ■2019 ■2020 ■

European statistics on treatable and preventable mortality reveal important findings:
- The divide in health status between the western and eastern parts of the EU is far from being closed. All countries with figures below the EU average are from Central and Eastern Europe (CEE).
- Health status improved across CEE countries from 2011-2019, but it was not sustained during the Covid-19 pandemic. In 2020 an increase of treatable and preventable mortality in comparison to 2011 was recorded in Bulgaria, Poland, and Romania.
- The reduction of treatable and preventable mortality in CEE countries to the level of the EU average would save up to 150,000 lives annually.

The pan-European management of Covid-19 provided evidence for the efficiency of cooperation around health. The lessons learned should be applied in fighting cancer, managing mental health problems and rare diseases, and in cooperation for tackling social determinants of health.

One of the most useful tools for measuring health in Europe is the excess mortality indicator, which is part of the European Statistical Recovery Dashboard[26]. It takes the number of people who died from any cause in a given period, and compares it with a historical baseline

23   OECD (2019) *Health at a Glance 2019: Avoidable mortality* (Paris: OECD).
24   Ibid.
25   Eurostat. Last update of data 07/03/2023
26   Eurostat (2023) *European Statistical Recovery Dashboard* (Luxembourg: Eurostat).

from previous years. In the case of Covid-19, the baseline consists of the average number of deaths that occurred in each month during the period 2016-2019. The excess mortality indicator highlights the magnitude of the pandemic by providing a comprehensive comparison of additional deaths among European countries.

Indicators of excess mortality served the public health community well for the assessment of the impacts of Covid-19. Unfortunately, Covid-19 is not the only health crises to have devastated the lives of Europeans. The application of an approach based on excess mortality provides an opportunity to analyse dynamics in the health status of Europeans by comparing mortality during 1991-2020 with average mortality in 1986-1990. The crude death rate was used as a mortality indicator. Assessment of health status in Estonia (MS since 2004) and Georgia (a country that is still hoping for accession) is provided by measurement of cumulative excess mortality in 1991-2020 (see Box 1).

Box 1. Excess mortality in European WHO region in 1991-2020

The 1990's are renowned for dramatic socioeconomic changes in Central and Eastern Europe. As a result of the collapse of the Soviet Union many countries gained independence and an opportunity to choose a path of reforms towards a market economy, democracy, and liberalism. The overall successful reforms were rewarded (for most of the CEE countries) by membership of the EU. However, progress was not without the sacrifice. At the beginning of 1990's mortality soared in most of CEE (analysis of causes of health status decline is beyond the scope of the chapter) and it took years or even decades to manage the health crises.

Figure 3. Excess deaths in WHO European region in 1991-2020

Comulative excess deaths per 1 million population

European Union — Estonia — Georgia
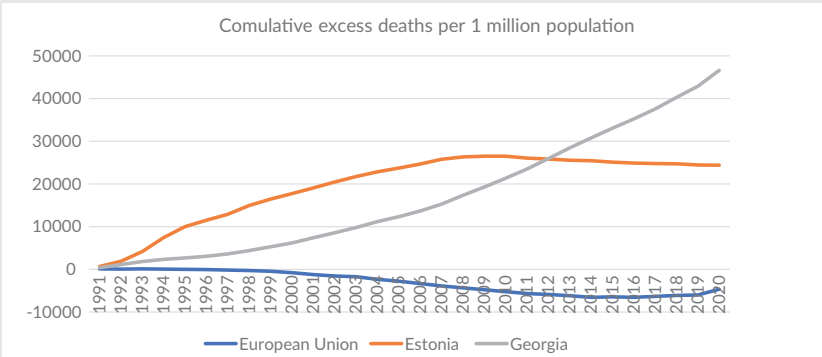
Source: Calculation by the authors according to crude death rates provided by World Development Indicators

Data provided in Figure 3 shows that mortality patterns (cumulative excess deaths per 1 million population) during the period of 1991-2020 differed across Europe:

- For the EU as a bloc, 1991-2020 was A period of sustainable development of population health with negative cumulative excess mortality. The cumulative number of excess deaths stands at − 4,677 per 1 million population.
- Estonia witnessed growth of crude mortality rate and cumulative excess mortality in 1991-2008, but since 2009 cumulative excess mortality is in decline. The cumulative number of excess deaths stands at 24,400 per 1 million population.
- Georgia witnessed weaker (in comparison to Estonia) deterioration of health status in the 1990's but did not manage to maintain health crises in the 2010's. The cumulative number of excess deaths stands at 46,607 per 1 million population.

Unfortunately, there are countries that lost even more lives than Georgia. Excess mortality data for Ukraine amounts to 92,200 excess deaths per 1 million population, or more than four million people during 1991-2020.

The fact that a staggering 4 million+ excess deaths in Ukraine, 160,000+ in Georgia or 30,000+ in Estonia were almost unnoticed by European politicians and almost not reflected in EU policies and the budget indicates the long journey towards the genuine European Health Union and big opportunities for improvement of solidarity in Europe. No doubt, most of excess deaths recorded in the Central and Eastern Europe from 1991-2020 were preventable and treatable. Europeans should work hard to prevent hundreds, even thousands, of avoidable and preventable deaths from slipping through the lenses of health monitors, and attention in the European semester.

Reports and studies into the costs of preventive actions in the EU are numerous, however, they only represent the tip of the iceberg as they often focus on one set of measures linked to a particular health risk thus failing to capture cascade effects and the real benefits of a systemic preventive approach with health and wellbeing at its core, leading to suboptimal decision making and inaccurate assessment of costs of preventive measures.

The cross-sectoral work of experts to collectively reflect on health challenges and opportunities as well to formulate measures, recommendations, and toolkits for better health has to be strengthened. Creating a European hub for preventive policies would be instrumental in the development of evidence-based health policy in the EU.

1.5. Working for a bigger focus on health in the European Semester

The European Union's health policy has evolved gradually, learning lessons from every crisis. And the nature of EU health policies, their logic and reason for being, and their potential to affect the health of Europeans for the better is also enshrined today in the Lisbon Treaty.

The EU operates on the basis of enumerated powers: it has the powers that its founding treaties allocate to it and no more. Until now, health is absent from the main articles of the Treaty on the European Union (TEU), and appears as one of the shared competencies between the Union and MS only in article 4 of the Treaty on the Functioning of the EU (TFEU) in a limited form as "common safety concerns in public health matters, for the aspects defined in this Treaty". Articles 6, 9 and 168 of the TFHU are devoted to public health and healthcare issues, but emphasise limited EU actions to support, coordinate or supplement the actions of MS.

Weak representation of health in the Treaties is manifested in myriads of ways. One of the very clear examples of this representation is the frequency of ministerial-level meetings. Ministers of agriculture gather in Brussels from eight to twelve times per year. By contrast, ministers of health of the EU countries gather only twice per year. This example of the frequency of ministerial meetings provides hints regarding difficulties the EU is facing on the path of development of an EHU. Full respect of the responsibilities of the MS to define their health policies is the right job to do but reluctance to act in case of an opportunity to create European Value added is a questionable feature of current pan-European cooperation for health.

As Greer S., Wismar M. and others have argued, there are three broad faces of EU health policy:[27]

- The first face relates to Article 168(1) of the TFEU, which authorises the distribution of responsibilities in health. The organisation and finance of healthcare is a member state power, and the EU's work in public health and healthcare shall be restricted to helpful coordinating measures. This "public health" face of the EU is fully respectful of subsidiarity, the principle that the EU shall only do what cannot be done by MS.

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27   Greer, S. et al. (2022) *Everything you always wanted to know about European Union health policies but were afraid to ask. 2nd, revised edition*. (Copenhagen: WHO).

That being said, health is enshrined in the TFEU in other ways. There are articles about the environment (191), labour in the Social Policy chapter (153, 156) and consumer protection (169) that specify health as an objective. Finally, article 9 calls for all EU activities to "take into account" a "high level of protection of human health".

- A second face of EU health policy is based on the legal basis of its internal market. For example, the regulation of pharmaceuticals and professional qualifications effectively functions as a part of the development of the internal market. Powerful EU regulation helps override discriminatory MS rules and raises the floor for standards. A very good example is the EU Directive on the cross-border mobility of patients, the most visible EU healthcare policy issue for many years. [28]

- The third face of EU health policy is fiscal governance and was developed in the aftermath of the debt crisis in 2008, and involves European surveillance of MS fiscal policies including taxes, spending and policies that affect the state's fiscal trajectory. The 2011 and 2013 reforms of the Stability and Growth Pact (SGP) were the EU's response to the high and rising debt levels seen in a number of MS. The SGP now has two arms: a preventive arm and a corrective arm. MS are expected to make progress towards predefined objectives, with this progress assessed during an annual review process called the European Semester. The European Semester allows the European Commission to review a raft of information that is pertinent to the SGP and other financial documents and publish its in-depth reviews and provide country specific recommendations (CSR).

The initial Semester CSR's reflected a political, legal and organisational focus on fiscal sustainability as understood by finance ministers. But after pressure from health ministers and other health actors (using the State of Health in the EU cycle, launched in 2016) [29], a process that was initially quite exclusive and focused on narrow fiscal policy goals was broadened out as other priorities were pushed onto the agenda. This resulted in more sensitive recommendations to the MS related to health and healthcare systems issues.

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28   European Commission (2022) *REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL*
on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (Brussels: European Commission).
29   OECD (2016) *Health at a Glance: Europe 2016. State of health in the EU cycle* (Paris: OECD).

These three so-called 'faces' of EU health policy look upon many of the social determinants of health, starting from food labelling, through to access to healthy food and beyond. They provide new opportunities to include aspects of public health and healthcare policies in European Semester cycles and to encourage governments to address health challenges in both prevention and healthcare areas. It is for this reason that the European Semester must be used much more effectively in the new cycle of activities of European institutions in area of the EHU.

The stronger recommendations of the European Semester also open greater opportunities for cooperation among MS governments, especially by making use of their EU presidency cycles. A recent example of this followed the World Health Organization's definition of health ("health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity")[30]. In 2019, the Finnish Presidency of the Council released the Council conclusions on the economy of well-being as a "policy orientation and governance approach".[31] It "brings into focus the raison d'être of the EU as enshrined in the treaties and in the Charter of Fundamental Rights of EU". An economy of well-being entails cross-sectoral collaborations and includes access to healthcare, promotion of health and preventative measures and occupational health and safety.

The definition of a European Health Union (EHU) aligns with the WHO's Health for All concept[32], which indicates that health is to be brought within reach of everyone, and is a holistic concept. This calls for efforts to address a comprehensive health perspective in policy areas like the European Green Deal, the European Pillar of Social Rights, The European Digital Agenda, the UN SDGs, the European Peace Policy and European sovereignty.

This EHU concept is not about substituting or overtaking the role of the MS in health-related areas, nor about consolidating more powers in Brussels. It is about delivering the promises of the MS and the EU to their citizens. The EU principles of solidarity, subsidiarity, proportionality, and health in all policies could be applied in co-ordination, regulation, financial support and implementation of health actions at EU and MS

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30   WHO (2023) *Constitution of the World Health Organization* (Geneva: WHO).
31   Official Journal of the European Union (2019) "Council conclusions on the Economy of Wellbeing (2019/C 400/09)", *OJ, C, 400/9*.
32   For broader description of the Universal health Coverage see chapter 2.3 of the book.

levels. It should be accompanied by mechanisms to ensure transparency, accountability, and citizen engagement.

A regulatory and deregulatory approach grounded in subsidiarity and the construction of a single European market might be logically coherent and well established in practice, but it has its limits. Multiple contradictions at MS levels can result in a very slow speed of implementation. Therefore, a bigger role for health in the European Semester would help to overcome those contradictions and to realise initiatives proposed by the EC.

There is scope for novelties in better coordinated EU health policies, including approaches that focus on health and wellbeing, on rule of law, on protection of the vulnerable, on fulfilling the Pillar of Social Rights and SDG's, the Green Deal and Digital Agenda. If EU institutions and MS were to declare that implementation of those proposed initiatives was a priority, then a method of coordination and country specific recommendations in the cycle of the European Semester could be useful tools in this direction. Proposals of the authors for strengthening of coordinated EU health policies are presented below.

1.6. Health-related recommendations from the Conference on the Future of Europe

The Conference on the Future of Europe ran from April 2021 to May 2022 and enabled people from across Europe to share their ideas, and help shape our common future. With more than five million unique visitors to the platform and more than 700,000 event participants, the Conference succeeded in creating a public forum for an open, inclusive, and transparent debate with citizens. These proposals covered nine topics, including health.

The Conference developed four main proposals on strengthening health:
1) *Healthy food and healthy lifestyle*
   Objective: Ensure that all Europeans have access to education on healthy food and access to healthy and affordable food, as a building block of a healthy lifestyle
2) *Reinforce the healthcare system*
   Objective: Reinforce the resilience and quality of our healthcare systems
   Note: Making health or healthcare a matter of shared competence of the EU would require Treaty change ("include health and healthcare

among the shared competencies between the EU and the EU Member States by amending Article 4 TFUE").[33]

3) *A broader understanding of health*

Objective: Adopt a holistic approach to health, addressing, beyond diseases and cures, health literacy and prevention, and fostering a shared understanding of the challenges faced by those who are ill or disabled, in line with the "One Health Approach", which should be emphasised as a horizontal and fundamental principle encompassing all EU policies.

4) *Equal access to health for all*

Objective: Establish a "right to health" by guaranteeing all Europeans have equal and universal access to affordable, preventive, curative and quality healthcare.

Note: Enabling the EU to adopt legislative provisions harmonising healthcare standards in a mandatory way would require Treaty change (Source: "Establish common minimum healthcare standards at EU level"[34]).

Additionally, plenty of health-related proposals were included in other fields. Some of these proposals are listed below:

1) *Stronger social policies*

Enabling the EU to provide for an obligation for member states to grant access to persons below 16 years with medical services not available nationally. This would require Treaty change (Source: "**Granting access to medical services to all persons below 16 years old** across the EU in case these services are not available in the national context"[35]).

2) *Demographic transition*

If the measure aims at enabling the EU to establish an obligation on member states to guarantee social and healthcare to older persons, this would require Treaty change (Source: "Guaranteeing appropriate social and health care to older persons"[36]).

3) *Reducing dependency of the EU on foreign actors in economically strategic sectors*

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33   Council of the European Union, General Secretariat of the Council (2022) *Conference on the Future of Europe – Report on the final outcome: May 2022* (Luxembourg: Publications Office of the European Union).

34   Ibid, p. 52.

35   Ibid, p. 58.

36   Ibid, p. 59

Objective: We propose that the EU take measures to strengthen its autonomy in key strategic sectors such as agricultural products, strategic economic goods, semiconductors, **medical products, innovative digital and environmental technologies** and energy.

4) *Digital innovation to strengthen the social and sustainable economy*

Objective: Make Europe a world leader in digital transformation and in **human centric digitalisation.**

In its Communication[37] on the results of the Conference, the European Commission noted:

- Some of the ideas set out by the Conference are truly innovative, calling on the EU to take new, as yet unexplored, avenues. Within these, some proposals explicitly call for treaty change. This includes areas such as **health**. While the EC warned about risks related to treaty change, it is open to discussion and said: "Just like constitutional texts of the Member States, the EU treaties are living instruments" and "new reforms and policies should not be mutually exclusive to discussions on Treaty change".

Attitudes have changed fast. In November 2020 the notion that sustainable European health policy required changing of European Treaties was supported by just a few coauthors of the Manifesto for a European Health Union. But by 2022, the likelihood of Treaty change was acknowledged by the EC. Actions prior to and during the Conference indicate that the role of health is growing in European politics, and that Europe is ripe for change:

- The European Commission and the European Parliament designated health as the second thematic topic of the Conference. Such a high priority of health would have been highly unlikely just few years ago, when health topics were missing from the standard Eurobarometer survey.
- During the Conference, citizens actively responded to the proposal of organisers to reflect on European health policy by formulating numerous proposals about how to have more Europe in health and more health in Europe. The fact that some proposals of Europeans for stronger European health policy are reaching as far as a call for Treaty change is an indication that people expect stronger pan-European

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37   European Commission (2022) *Commission sets out first analysis of the proposals stemming from the Conference on the Future of Europe* (Brussels: European Commission).

cooperation for health, and that they are looking for a genuine European Health Union.

• Proposals on health policy generated by the Conference are noted and are under scrutiny by the European Council, the EC and the EP.

Finally, the results of the Conference are an encouragement that the development of stronger pan-European health actions will continue after the pandemic. However, proponents of a healthier Europe should not sleep on their laurels. Advocacy is needed to keep health high on the political agenda. Political debates focused on bold proposals for a healthier Europe prior to elections to the European Parliament are of critical importance for transforming the EU from a mainly economic project to a project with a social pillar (that includes health and wellbeing) as strong as the pillar of the internal market.

2. Modelling the European Health Union

2.1. Progress towards an EHU without Treaty changes

Different scenarios were listed in the Explanatory Memorandum to the Manifesto for a European Health Union to develop an EHU.

2.1.1. Scenarios "a", "b",and "c" were listed ~~without Treaty changes~~:

a) Measures to make progress in health concentrate on what can be done with existing legal, financial, and managerial instruments, upgrading already functioning institutions, and improving implementation of already agreed policies.

b) Development of secondary legislation and establishment of new institutions that are supposed to create European added value in parallel to the fine tuning of existing instruments of health policy. The scenario does not foresee amendments to the European Treaties.

c) The status of health policy in the European Treaties is strengthened, with provisions for a European Health Union incorporated into the Treaty on European Union, giving the European Union some shared competences in health policy in very concrete areas, while preserving the principle of subsidiarity as a core.

All three scenarios have their own advantages and disadvantages. None is perfect and none can be implemented immediately. Scenario "c" is, of course, the most ambitious. By opting for scenario "a" or "b" Europeans would restrict the benefits they would obtain from deeper cooperation on health.

Keeping in mind the expectations of citizens expressed during the Conference, and taking into account the existing legal and institutional framework under the current Treaty, there is a necessity (keeping in mind the above "b" scenario) to force progress in proposing new activities for a healthier Europe without Treaty change. The current legal framework offers certain opportunities:

- Strengthen the EU health security framework and actively promote cooperation between MS on cross-border healthcare. Transform the Commission's Department for Health Emergency Preparedness and Response (HERA) into an independent European Agency. The response addressing possible health emergencies could be strengthened by a health solidarity clause, that will work in a similar way as the EU civil protection clause.
- Strengthen European health agencies, their competences, budget and staff (ECDC, EMA, EU HTA) and ensure better cooperation among them and with other EU agencies (EFSA, EU-OSHA, EEA, ECHA, EMCDDA, JRC) in health-related issues.
- Establish an EU equivalent of the US Biomedical Advanced Research and Development Authority (EU BARDA), explore the potential to create a fully integrated European Health Agency, and strengthen further European health research.
- Strengthen European health response mechanisms to carry out stress testing of the MS healthcare systems to assess their preparedness for epidemics and ability to meet SDG targets. To consider opportunities to adapt an EU Directive for minimum standards for Quality Healthcare.
- Strengthen the joint procurement mechanisms guaranteeing equal asses to critical medicines and medical devices whilst avoiding price speculations between MS, and revising the Transparency Directive on pricing of medicines.
- Create a pro-growth long term fiscal framework that safeguards quality health care services to all EU citizens, residents and migrants, increase investment in both urban and rural areas.
- Enforce the respect of women's fundamental rights to sexual and reproductive health. Promote gender equality in public health and healthcare.

- Progress on the new proposed policies of a European Health Union that are declared by the EC, especially keeping in mind EU tools enshrined in the EU Digital Agenda, reduce the digital divide and increase digital literacy in all MS. Work for common Digital and eHealth standards across MS. Procedures for standardisation and data sharing in a European Health Data Space should be strengthened.
- Increase the mandate and scope of the European Reference Networks, developing them as legal entities and assisting them to take advantage of developments in digitalisation and artificial intelligence. Full implementation of the Cross-Border Healthcare Directive and the Clinical Trials Regulation is essential. Explore the feasibility of a European Health Insurance Fund for rare diseases.
- Upgrade monitoring of accessibility of health services with the emphasis on equitable distribution of the healthcare workforce across the EU. A system of incentives is needed to promote optimal levels of training, recruitment and retaining of health personnel. Brain drains and brain waste of health professionals due to aggressive promotion of cross border mobility of health professionals should be discouraged.
- Supplement existing instruments by means of secondary legislation and strengthen the newly created institutions.
- Continue deep analysis of the most promising pan-European policies in areas of new governance, good European practices, and benchmarking. Strengthen the role of Health in Country Specific recommendations for the member states in the cycle of the European Semester, using the "State of Health in the EU. Country profiles" instrument
- Introduce systematic health impact assessments and develop health impact assessment guidance, develop and adopt updated health and wellbeing indicators and metrics.
- Support and coordinate functioning of public health, which encompasses the provision of funding, research and some degree of technical support, as well as soft policy guidance (recommendations, communications) and promotion of cooperation between MS.
- Establish robust institutional structures and mechanisms, appointing a vice-presidency for One Health and supporting it by a clear governance structure to keep focus on health and wellbeing across all policies within the EC. The portfolio would help the integration of health and wellbeing into various policy areas at EC level.
- Set up a "health in all policies" taskforce at EC level to ensure systematic implementation of health matters in all policies across different policy areas.

- Create a separate committee for Health and Wellbeing within the European Parliament (EP) to further strengthen the focus on public health and wellbeing issues in the EP.
- Create a health in all policies Task Forces at the EP level to ensure continuity of health in all policies.
- Create an inter-group for health and wellbeing in all policies in the EP as a possible platform for collaboration, knowledge-sharing and advocacy across different policy areas.
- Re-structure the composition of the EU Council, by establishing a separate EU Health and wellbeing council of ministers.

According to the authors, progress on all above-indicated opportunities would contribute to health and wellbeing in Europe, but the road forward is going to be bumpy without Treaty change.

During multiple public debates, authors of the article understood that citizens expect the European Union and local and national authorities to provide equal access to affordable and good quality healthcare now, to avoid the burden of out-of-pocket payments, to have electronic prescribing available across Europe, to see better organisation of healthcare services not only at home but in a European framework also, especially when they are suffering from rare or complex diseases. They wish to have equal access to innovative treatment, no matter in which country they are living. In other words, people ask all political leaders to help them to solve their healthcare and cure problems now, not in the decades to come.

People are expecting stronger[38] and more effective actions related to health at the EU level. Health is so close to people's hearts, and people demand to see an EU that cares about their health in the broadest understanding of the term. A One Health approach is especially attractive,[39] integrating animal health, plant health, soil health, quality of water and air, and human health. Such a sustainable health policy must first and foremost build on the EU Pillar of Social Rights, on environmental protection and on human health. The components of a future genuine EHU are already mapped in policy areas such as the Green Deal, the Social Pillar, the Resilience and Recovery Fund, and the Digital Union agenda. The EU and MS have also already committed themselves to implementing the SDG's.

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38   Eurobarometer (2023) *Standard Eurobarometer. All surveys* (Brussels: European Commission).
39   WHO (2023) *One Health* (Geneva: WHO). Available online: https://www.who.int/europe/initiatives/one-health

Designers of the European Health Union are facing a dilemma about how to reflect the complexity of health-related issues, while avoiding the approach going far beyond the sensitivities of patients and medical professionals. A Health and Wellbeing Deal may be the right way to work towards a European Health Union that would promote wellbeing for all people of all ages and guarantee universal health coverage for all.

2.3. Progress towards an EHU with Treaty changes.

The current official EHU-related initiatives are based on the existing legal framework. However, Treaty changes would be needed to harness the full potential of an EHU. The main proposals regarding a stronger representation of health policies in the EU's constitution are as follows:

- The EU needs to speak explicitly about health as an aim of the EU and its commitment to build an EHU as a tool to assure good health and longevity of Europeans. The Health and Wellbeing Union should appear in paragraph 10 of the Preamble of the TEU in parallel to the internal market and an economic and monetary union by inserting the words "Health" and "Social". Part 3 of article 3 of the TEU should be amended with one last sentence: "It shall promote universal health coverage by establishing a health union".
- Indication of health as an aim of the EU in TEU should be followed by the amendments of the TFEU. Shared competencies between the EU and MS in the area of health and healthcare of patients with rare diseases and rare cancers should be stated in part 2 of article 4 of the TFEU. Article 6 para (a) and the article 168 of the TFEU should be redesigned to promote health by supporting MS in reducing inequalities in access to medicines and unmet health needs, by strengthening interoperability of their health systems, as well as building capacity for tackling future threats and cross border health challenges. Finally, article 222 of the TFEU should be amended by a health solidarity clause that works in similar way as the EU civil protection clause.

The need for discussion on health-related Treaty changes is based on the dynamics of European health policies (mainly shaped by Covid-19) as well as broader developments in Europe. Europeans are looking for the new stage of the EU. The Lisbon Treaty has limits not only in areas of health but also in other areas like common defence and security issues, and migration.

The probability that Europe will soon start official talks on Treaty change (for example, by convening an European Convention on the Future of the European Union) is not clear at the time of writing (summer 2023), but proponents of much stronger pan-European health policies should use the window of opportunity to be prepared to present health related amendments if and when those talks begin.

3. Narrative and political will

3.1. The vision of a European Health Union and its institutional framework: Insights on the scope, breadth, and criteria of maturity represent the authors' vision of EHU.

The scope, legal ground of the genuine *EHU*
The legal ground for the EHU evolved on year-by-year basis upscaling political commitments to assure equity in health across the EU (marks by italic is done by authors):
1. The Universal Declaration of Human Rights (1948)[40] declares: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family".
2. Article 129 of the Maastricht Treaty (1992)[41] states The Community shall contribute towards ensuring a high level of human *health protection* by encouraging cooperation between the Member States
3. The first paragraph of Article 152 of the Treaty of Amsterdam (1997)[42] declares A high level of *human health protection* shall be ensured in the definition and implementation of all Community policies and activities.
4. Article 35 of the Charter of Fundamental Rights of the European Union (2000)[43] affirms: "Everyone has the right of access to *preventive health care* and the right to benefit from *medical treatment* under the conditions established by national laws and practices".

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40   United Nations (1948) *Universal Declaration of Human Rights* (1948) (New York: United Nations).
41   European Parliament (1992) *Treaty on European Union (TEU) / Maastricht Treaty* (Brussels: European Parliament).
42   European Parliament (1997) *Treaty of Amsterdam* (Brussels: European Parliament).
43   Official Journal of the European Union (2000) "Charter of Fundamental Rights of the European Union (2000)", *OJ, C, 364/1*.

5. The 2030 Agenda for Sustainable Development (2015)[44] pledges to 'Ensure *healthy lives and* promote *well-being* for all at all ages'.
6. The European Pillar of Social Rights (2017)[45] proclaimed that: "*Everyone has the right to timely access to affordable, preventive and curative health care of good quality*".

Political commitments reflected above that were developed before the term European Health Union was coined are helpful for agreeing on the substance of EHU. Health protection and disease treatment are essential pillars of a EHU. Everything else should be dealt with at local, regional, and national level according to the principle of subsidiarity and policies in health protection, disease prevention and cure for all should be integrated in a European framework by the concept of EHU.

EHU initiative started with emphasis on preparedness to withstand health emergences, but the genuine EHU should overcome limits of this narrow approach and include public health measures protecting health from different risks factors and the organizing healthcare and cure services in areas of rare cancers, multi-complex and rare diseases at MS and the EU levels.

It requires amending Treaties with shared competencies strictly following the principle of subsidiarity. European integration in health is about those areas where MS are overburdened or where cooperation between MS brings added value for all in the EU. The European networks, such as the one on rare diseases, create conditions for improving care, learning from each other and for disseminating good practices across the EU.

The breadth of the EHU
Covid-19 indicated limits of narratives that member states alone are perfectly fit for ensuring a high level of human health protection. Pan-European cooperation in cross border health threats expanded in 2020-2023 but majority of health-related actions are still performed and in foreseeable future will continue to be performed by local, regional, and national authorities. National execution of health policies does not mean that there is no pan-European content in health policies of member states. Drive towards Universal Health Coverage described in chapter 2.3 of the book engulfed member states because of shared values and learning

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44 United Nations (2015) *The 2030 Agenda for Sustainable Development* (New York: United Nations).
45 European Union (2017) *The European Pillar of Social Rights (2017)* (Brussels: European Union).

from each other and resulted, but was not caused, by unanimous voting on Sustainable Development Goals. EHU is not just about health-related regulations and execution of it at the institutional EU level. Integral parts of the EHU are:

- Pan-European networking between public and private actors in health research, public and humane health.
- Development of comparable indicators and regular stress tests of healthcare systems in the EU, European Registry of Intense Care Hospital beds.
- Coordinated efforts to develop therapies, diagnostics and measure to assure availability of prevention and treatment methods in all member states.
- Mobility of medical students and healthcare workforce across the Europe.
- Cross-border provision of health services, video conferences in diagnostics and consultations of patients and electronic prescriptions of medicines.
- Production, market authorisation and arrangements of reimbursement of medicines and other medical goods. European institutions formally have nothing to do with reimbursement of medicines, but ministries of health and health insurance funds are learning from sister institutions in other member states.
- The European Health Data Space is an initiation promising better health for Europeans.

What about inclusion of health-related values and expectations of European citizens into the list of integral parts of EHU?

The broad understanding of breadth of the EHU provides opportunity to develop clearer picture of the future (for example, expectations shared by majority of Europeans have high probability to be transformed into regulation of the EU and the speed of national implementation of European Council recommendations that have broad public support has potential to be faster) but EHU should not become synonym of a term "health care systems in Europe" or a call necessity to create a one European healthcare system as such. It would be a big mistake. The broad understanding of EHU is about networks and clusters, about centres of excellence, about sharing of goods practices and knowledge through the EU, it is about the promise to guarantee access to affordable and high-quality healthcare for all in every member state. It is one of reasons why proponents of stronger pan-European health may be somehow optimistic about Treaty change.

European treaties will have stronger references to health because equity, solidarity in health is in the hearts of Europeans and already manifesting themselves (not without setbacks) in the development of national and European legislation.

Most recent debates on the EU level (for example Informal Meeting of Health Ministers in Las Palmas in July 2023)[46] indicate the interest of member states to consider EHU as a development much broader than an institutional framework to assure preparedness to withstand health emergencies.

Criteria of maturity of EHU

Criteria of maturity of EHU are conditioned by the understanding of the content of the phenomenon and will be developed as an integral part of debates on the future of European health policy. These criteria should be evidence based and patient centred. Suggestions of these criterion that are reflecting main avenues of Pan European cooperation for health are as follows:

- The EU is prepared for health emergencies with institutional capacities, reserves of humane, material and financial resources in place.
- The EU leads the World in development of health technologies and what is more important is assuring accessibility of health technologies with proven value added to all EU citizens.
- Progress towards universal health coverage across the EU is proven by statistically reliable date on convergence of average life expectancy.
- Pan-European cooperation in diagnostics and treatment of rare cancers, multi complex and rare diseases through the use of the European Reference Networks, clusters, centres of excellence assures equal care for all EU citizens, suffering from those diseases regardless in which member state patients live.
- Priority of health in the foreign policy of the EU is upgraded and this development is recognised by the UN.

Institutional criteria of maturity of EHU are also of importance:

- A EHU is enshrined in the Treaties.
- The increased role of health in EU politics is recognised by establishing robust institutional structures, appointing a vice president for One Health and supporting it with a clear governance structure, setting

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46   European Union (2023) *Informal Meeting of Health Ministers in Las Palmas in July 2023* (Brussels: European Union).

up a "health in all policies" task force within the EC, creating similar structures in the EP, establishing the separate EU Health and wellbeing council of ministers and the growing frequency of those council meetings.

3.2. European Parliament Elections in 2024 a platform to facilitate a genuine European Health Union?

After the outbreak of Covid-19 in 2020, the Progressive Alliance of Socialists and Democrats, together with other pro-European parties, came up with a set of proposals that would establish a EHU. Since September 2020, the EU Commission has supported the initiative by designing the specific building blocks of an EHU. These relate to a stronger capacity to respond to cross-border health threats and better crisis preparedness capacities, to encourage MS to develop their more comprehensive national plans for beating cancer, to propose better regulation related to orphan drugs, and to prioritise EU actions improving the mental health of Europeans.

There are plenty of questions to be raised during the electoral period:
- Healthcare is currently almost exclusively a competence of MS, and the EU institutions have little direct influence over it. Should current self-limitation of pan-European actions for health continue?
- Because of the war in Ukraine, we are facing the biggest crisis in the European Continent since WWII. Until recently, development goals such as saving lives, promoting good health and increasing longevity were off the radar of European policy. Europe just recovered from pandemic and currently is confronted with the war in Ukraine. Should Europeans consider those tragedies as an argument to put saving lives and other health related matters at the centre of pan-European policies?
- The current European Parliament is much more in favour of discussing new ways to strengthen EU mechanisms, and is well-positioned to initiate discussions on a stronger EHU, including the necessity to amend the existing EU treaties. What about a strong mandate for the new EP to act pro-health?
- According to Eurobarometer, European health policies in 2020-2022 are constantly among the top five priorities of Europeans. Numerous recommendations from the Conference on the Future of Europe on health offer proof that health looms large in public opinion and should remain high on the political agenda. How should future MEPs respond to expectations of citizens?

- Proponents of EHU are aware that some people see it as a nice political slogan that will fall out of fashion as memories of quarantines and face masks fade. What about coordinated actions of pro-health activists to guarantee the continuity of EHU related initiatives in the political cycle of the European institutions that start after European elections in 2024?

Conclusion

The citizens require better access to preventive and curative services, medicines of good quality, reducing inequalities in health status among population groups, tackling uneven distribution of healthcare recourses among and within MS, and eliminating healthcare worker shortages and medical deserts. People require universal health coverage across the EU.

The 2024 elections to the European Parliament will be a very good opportunity to facilitate the discussion about a genuine EHU. There are certain themes that may be reflected in electoral manifestos of European parties calling for a shift towards stronger EHU:

- The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions. A "health in all policies" approach should be enshrined in the treaties and should be supported by toolkits not only at MS level, but also at the EU level.
- No one country alone has enough instruments to address the burden of noncommunicable diseases on their healthcare systems without common actions at EU level, none of them alone is capable of treating all patients with rare diseases or address issues related to unmet needs in area of orphan drugs.
- Multiple challenges – healthcare workforce shortages, medical deserts within or between countries, unequal access to innovative treatments, long waiting lists, out of pocket payments and commercialisation of healthcare services – are all more efficiently solved through cooperation.
- The Health and Wellbeing Union must first and foremost build on the EU Pillar of Social Rights and the commitments of the EU to implement Sustainable Development Goals. Value of health is the cultural backbone of our European civilisation. Where better can the EU reach out to its citizens than with health solidarity?

All pro-European political parties have an opportunity to look for answers related to the health of Europeans and formulate narratives related to an EHU. Let us be inspired by the words of Robert Schuman. Paraphrasing his declaration intended for peace into words intended for health we may say, that world health "cannot be safeguarded without the making of creative efforts proportionate to the dangers which threaten it".[47]

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47   European Union (1950) *Schuman declaration May 1950* (Brussels: European Union).

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An EHU is not just a concept. EHU is the reflection of myriads of cross-border interactions between civil servants, researchers, clinicians, healthcare institutions, patients and medical professionals. These interactions are the essence of EHU. All Europeans are actors in the development that inspired the writing of the book on EHU.

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She is the Founder of the Global Health Centre at the Graduate Institute in Geneva. Her areas of expertise include the political determinants of health, health in all policies and global health. She advises countries on their global health strategies, trains health specialists, and is involved in German G7 and G20 health activities. She publishes widely and serves on various commissions and boards. Ilona is a member of the Global Preparedness Monitoring Board and Co-Chair of UHC 2030, and the Lancet and Financial Times Commission on "Governing health futures 2030: growing up in a digital world". She has had a distinguished career with the WHO. She was a key instigator of the Ottawa Charter for Health Promotion and WHO's Healthy Cities Network and has remained a leader in this field, most recently advising on WHO's activities related to Health in the SDGs. She was the Director of the Global Health Division at Yale University School of Public Health and was responsible for the first major Fulbright Programme on global health.

Dominique Polton

She is a health economist. From 2005 to 2016, she was Director of strategy, research and statistics and advisor to the Director-General at the French National Health Insurance Fund (CNAM). Before joining the NHI, she was Director of the Institute for Research and Information in Health Economics (IRDES), a research centre in public health and health economics. She chairs the National Health Accounts Commission and is a member of several boards and committees in the health care system.

Maurizio Scarpa, MD, PhD

He earned his medical degree and doctorate and completed his residency in Paediatrics at the University of Padova. He completed a postdoctoral fellowship in molecular biology and gene expression at the European Molecular Biology Laboratory in Heidelberg (Germany), and in genetics/gene therapy at Baylor College of Medicine in Houston, Texas, USA. He has been the Director of the PhD Course on Genetics and Biochemistry at the Dept. for the Woman and Child Health at the University of Padova, Italy. He served as vice-Dean for the International Affairs at the University of Padova and

Director of the International Affairs Office at the Faculty of Medicine of the University of Padova, Italy. Prof Scarpa has extensive expertise as a basic scientist in genetics and biotechnology, and as a clinician in the diagnosis and treatment of paediatric rare disorders, neurometabolic diseases in particular. He is especially interested in developing innovative health approaches for the diagnosis and treatment of metabolic inherited diseases, to this aim, he is also collaborating with the major Biotech Companies as an external independent expert.

Markus Schneider, Ph.D
He is CEO of BASYS, Applied Systems Research Consulting Corporation Ltd, with a proven record in research and modelling healthcare systems of Western Europe and consultancy in most countries of Central and Eastern Europe – 40-years' experience in the fields of health, social and economic systems on a national and international level. Through BASYS he provides knowledge to the Commission of the European Union, The World Bank, OECD, World Health Organisation, Ministries and other organisations.

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She is Professor of European Integration at the Centre for European Law and Governance (ACELG) at the University of Amsterdam. She is chair of the editorial board of *Legal Issues of Economic Integration*. Her research spans the field of citizenship theory, EU migration and free movement law, and law of the internal market. Publications include *Money Matters in Migration. Policy, Participation, and Citizenship* (Cambridge University Press).

Birutė Tumienė
She is a member of the Society for Study of Inborn Errors of Metabolism, SSIEM, since 2006 she is one of the founders and a board member of the Baltic Society of Inherited Metabolic Diseases (Baltic Metabolic Group). She received professional training in traineeships in the Institute for Medical Genetics, University of Ljubljana Medical Centre(Slovenia), Service d' Endocrinologie, Maladies Osseuses, Génétique et Gynécologie Médicales, CHU de Toulouse (France), National Centre for Inherited Metabolic Disorders,

Dublin (Ireland), St Radboud Universitety Hospital, Department of Inherited Metabolic Diseases (the Netherlands), Amsterdam VU Medical Centre, Laboratory for Inherited Metabolic Disorders (the Netherlands), Children Memorial Health Institute, Department of Inherited Metabolic Diseases (Poland), SSIEM Academy Courses in Lisbon (Portugal) and Amsterdam (the Netherlands). Her current interests include metabolic epilepsies.

A European Health Union
A Blueprint for Generations

Why doesn't a European Health Union exist yet?

As the global health crises put the world to a halt, European citizens might question the lack of advancement of official European cooperation on health policy. Indeed, neither the overall objectives and goals of reformed European health policy, nor the actions and instruments, are yet to be agreed upon, and opinions regarding the future of the EHU are far from unanimous.

With this compilation of essays from world-renowned experts, we first explore the origins and legal background of the concept of a European Health Union. Then, we recognise that there has been development and a strengthening of relations between European members, carried out by progressive decision-makers, and look into the strong backing of citizens for investment in health at a European level. Finally, as the path towards a Union will be challenging, we look into the most promising avenues of cooperation for the health and well-being of European citizens.

This book delves into the connections with other European policies, explores the potential institutional and treaty changes, and, discerns what the most urgent steps are on the road towards an inclusive and social EHU.
Extend your perspective beyond the context of preparedness and crisis management and discover what a progressive European Health Union could mean for generations to come.

Issam Alsamara, Vytenis Andriukaitis, Richard Bergstrom, Helmut Brand, Gediminas Cerniauskas, Thibaud Deruelle, Corinne Hinlopen, Ilona Kickbusch, Mihály Kökény, Dominique Polton, Maurizio Scarpa, Markus Schneider, Annette Schrauwen and Birutė Tumienė