I-Com Study

TAKING CARE OF EU HEALTH POLICY

Coupling European Industrial Leadership with a Patient-Centered Approach

Abstract

Health systems across Europe still show bottlenecks and, moreover, they are facing new challenges in the near future. This study will try to describe the state of the art in terms of effectiveness, accessibility and resilience of healthcare systems in Europe meanwhile highlighting that business as usual is not enough to avoid growing inequalities among countries both in term of sustainability and in health outcomes. The study highlights some crucial aspects of the state of the health in the EU, focusing on the prevailing issues that can lead the paradigm shift needed to support the improvement of healthcare systems around Europe towards a patient-centered and policy-integrated approach. The main content deals with three subjects, relevant to the ability of healthcare systems to improve their level of effectiveness, accessibility and resilience under a European common approach: the role of digital health; the role of value-based healthcare and the role of life science sector.

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Executive summary

Chapter 1 focuses on the state of the art and challenges that health systems across Europe show and face in the near future. Health status and main risk factors among European countries show common elements and characteristics, but despite this, significant differences in outcomes still exist. For example, life expectancy now exceeds 80 years in two-thirds of EU countries, but still remains at only around 75 years in Bulgaria, Latvia, Romania and Lithuania. Moreover, overall mortality rates vary widely across Europe. France, Spain and Italy show the lowest death rates, with the age-standardized rate between 829 and 843 deaths per 100,000 population in 2016. Instead, mortality rates are highest in Romania, Latvia and Bulgaria with age-standardized rates at least 50% higher than the EU average in 2016. Risk factors also highlight differences among European countries. For example, smoking rates range from 10% in Sweden to 27% in Greece. The same can be found for alcohol consumption and overweight conditions. Overall alcohol consumption averaged 10 litres per person across EU countries in 2017, down from 11.4 litres in 2007. Lithuania reported the highest consumption (12.3 litres), followed by Austria, France, the Czech Republic, Luxembourg, Ireland, Latvia and Hungary, all with over 11 litres per person. Moreover, 55% of adults were overweight or obese in 2017, on average, in the EU. For the UK, Finland and Portugal that figure exceeded 64%.

Addressing the social determinants of health is essential in order to build fairer, healthier and more sustainable communities for all, resulting in better health outcomes and, thus, economic benefits. Health promotion is a key tool to reach this objective, sustaining the design and implementation of actions on the social determinants of health that are finally able to tackle health inequalities. According to EuroHealthNet (European partnership for improving health outcomes and inequalities)[1], it is generally true that the lower a person's socio-economic status, the worse the health outcomes. This social gradient in health exists in all countries, but the steepness of the curve varies.

The second part of this chapter investigates the importance of health promotion and disease prevention and the extent to which health services are able to achieve the desired results or outcomes at the patient or population level (effectiveness) resulting in a health system being able to become more sustainable. This entails a transition from the traditional hospital-centric approach to more community based and integrated care structures, the focus being on person-centered care, chronic disease management and, more importantly, prevention measures.

[1] Health Inequalities in Europe, EuroHealthNet factsheet, October 2019.

Significant differences in systems and structures concerning health promotion and prevention policies, programs and practice within European countries exist but, in general, health promotion seems to receive limited attention from policy makers and prevention measures are not at the forefront of government health services or current thinking.

The last part of the chapter focuses on unmet needs and challenges to face, starting from the EU's 2019 Companion Report 2019, and recognizing that everyone has the right to timely access to good quality affordable, preventive and curative healthcare, accessibility being a vital and multi-dimensional aspect of health system performance. The barriers that could inhibit universal access to health services are both financial and non-financial: population coverage, scope of services, level of coverage (cost-sharing), geographical factors, attitudinal barriers in seeking medical care, provider choice, organizational barriers, patient preferences and socio-economic aspects. According to Eurostat, there is a significant cross-EU variation in both the country average level of unmet needs and income disparities. The percentage of people declaring to report unmet medical needs is 5.5% in Europe, the highest at 35.2% in Estonia to the lowest at 0.4% in Austria.

The chapter concludes with a list of the main health system challenges. It focuses on the management of chronic diseases, on the drop in vaccinations and on antibiotic resistance.

Chapter 2 focuses on digital health in Europe. Technology is a central part of healthcare development with e-Health solutions having a great potential to increase the efficiency of healthcare systems and to transform the face of health service delivery across the EU. They offer many advantages to patients and healthcare providers and the use of ICT in healthcare also allows for the reduction in costs and improvement in treatment and care. Despite these advantages, many individuals either do not use the technology that is available to them or do not even have the means to manage their healthcare online.

Although most individuals would be willing to give access to their health data, either to their care providers or others, to improve treatment, diagnosis and prevention of diseases, the health data security is a worrying issue across the EU. Trust and confidence are key elements for ensuring the swift uptake of digital health applications by end-users.

According to the new HIMSS Analytics Annual European eHealth Survey (2019), IT security is the top priority among respondents in Europe, followed by EMR implementation and patient access to information. The outlook for the coming years suggests that the main progress will regard: patient medical records, provision of telemedicine services, health information exchange with external providers, patient self-monitoring initiatives, personalized medicine, EMR implementation and artificial intelligence projects. On the contrary, few blockchain-based solutions and augmented reality applications will be implemented.

Among the European countries, the northern countries display the best performance in terms of eHealth. In 2018, in the Netherlands, Finland and Denmark more than 65% of individuals searched

for health information on the Internet. Moreover, the highest number of patients (more than 40% in 2018) making an appointment with a practitioner via a website can be found in Finland, Denmark and Spain. Instead, in the Eastern Europe, Internet use for searching health information and making appointments with a doctor is well below the EU average.

The best performance of Northern Europe is also confirmed by the I-Com Index on the Level of Preparedness for eHealth in the Member States. Denmark tops the ranking with a score of 100. The Netherlands, Finland, Sweden and Estonia follow with a score of 98, 91, 90 and 88, respectively. Instead, most Eastern European countries show resistance to implementing eHealth.

In the second part, the chapter describes the role of AI in EU healthcare. According to HIMMS Analytics, the main benefits of AI in healthcare are improved quality of care, improved medical decision-making, improved diagnostics and the ability to process large amounts of data. One example of the usefulness of AI in healthcare is the use of algorithms that have been able to detect 95% of skincare instances in images. In 2020, the Commission will support via Horizon 2020, in coordination with Member States, the development of a common database of health images (anonymized, and based on patients voluntarily donating their data). This image database will initially focus on the most common forms of cancer, using AI to improve diagnosis and treatment. Despite these promised benefits in healthcare, only 16% of healthcare facilities in Europe already use AI, 25% have a specific plan and 59% of respondents do not use AI tools and have no plan to do so. Considering sectors in which European healthcare facilities use AI tools, Workflow Assistance and Research are the main areas, closely followed by Medication Administration and Radiology. These areas, plus Oncology, are also where healthcare providers have most of their AI investment plans. Adopting AI requires addressing some challenges and risks. According to the HIMSS Analytics survey, lack of product maturity and trust from medical staff are perceived to be the biggest challenges for a more widespread use of AI in healthcare, followed by data privacy and interoperability. Moreover, the chapter will analyze the European regulatory framework relative to using digital solutions in the healthcare sector and the European AI initiatives.

Chapter 3 follows by analyzing the role of value-based healthcare (VBHC) in improving health system performance and accountability. Traditionally, efficiency in healthcare has been interpreted in terms of cost reduction, however, more recently, healthcare policymakers in developed economies have interpreted the notion of value according to the willingness of health systems or individual health providers to follow the best clinical practice. Moreover, European governments are feeling the strain on their health budgets caused by an ageing population, a rise in the prevalence of chronic conditions and the acceleration of medical innovation that have increased demand for state-of-the-art-treatments. Consequently, governments are now putting a good deal of effort into defining frameworks for evaluating and implementing value-based healthcare. For these reasons, the concept of "value-based healthcare (VBHC)" is seen as a way to

improve our healthcare systems, yet there is no unanimously agreed definition of VBHC, although the EXPH, the European Expert Panel, is paving the way for European countries with the adoption of the final Opinion on Defining Value in "Value-based Healthcare" at its 16th plenary on 26 June 2019, after a public hearing on 4 June 2019. The opinion is based on the idea that access and equity, quality and performance, as well as efficiency and productivity can be seen as indicators for achieving the goal of a fair distribution of solidarity-raised healthcare resources to those in need.

The chapter also describes the history of VBHC, its different definitions and the changes that have occurred in how member states have interpreted and implemented it, providing experiences and tools at national and European level. The chapter ends by pinpointing the main shortcomings in implementing VBHC across Europe, recognizing that the increased dialogue around VBHC emphasizes the need for a systemic healthcare system evolution throughout Europe. A shift towards VBHC will highlight a new point of view which recognizes healthcare expenditure not as just an expenditure but an investment, calculated by multi-disciplinary expertise. This also means that in the future healthcare intervention should be promoted on outcomes rather than volume.

Chapter 4 focuses on the role that new technologies have played in revolutionizing healthcare, particularly by delivering benefits to patients and reducing healthcare costs. The life science industry is a high value manufacturing sector and involves an important part in innovation worldwide through high investments in research and development. Innovation in pharmaceuticals, medical devices, diagnostic technologies and, increasingly, digital health has transformed the way we deliver and manage treatment and organize healthcare systems. Although each type of health technology has its own distinct challenges, the increasing use of integrated, combined treatment options (that combine pharmaceuticals, medical devices, diagnostics and digital health solutions) is posing new challenges for the healthcare system. As Europe moves into the new legislative cycle, the time is ripe to examine the challenges and opportunities facing the healthcare life sciences sector in Europe over the next years, and to identify some of the common challenges arising across the wider life science sector, as well as those that result from the combined use of health technologies. This is the aim this chapter.

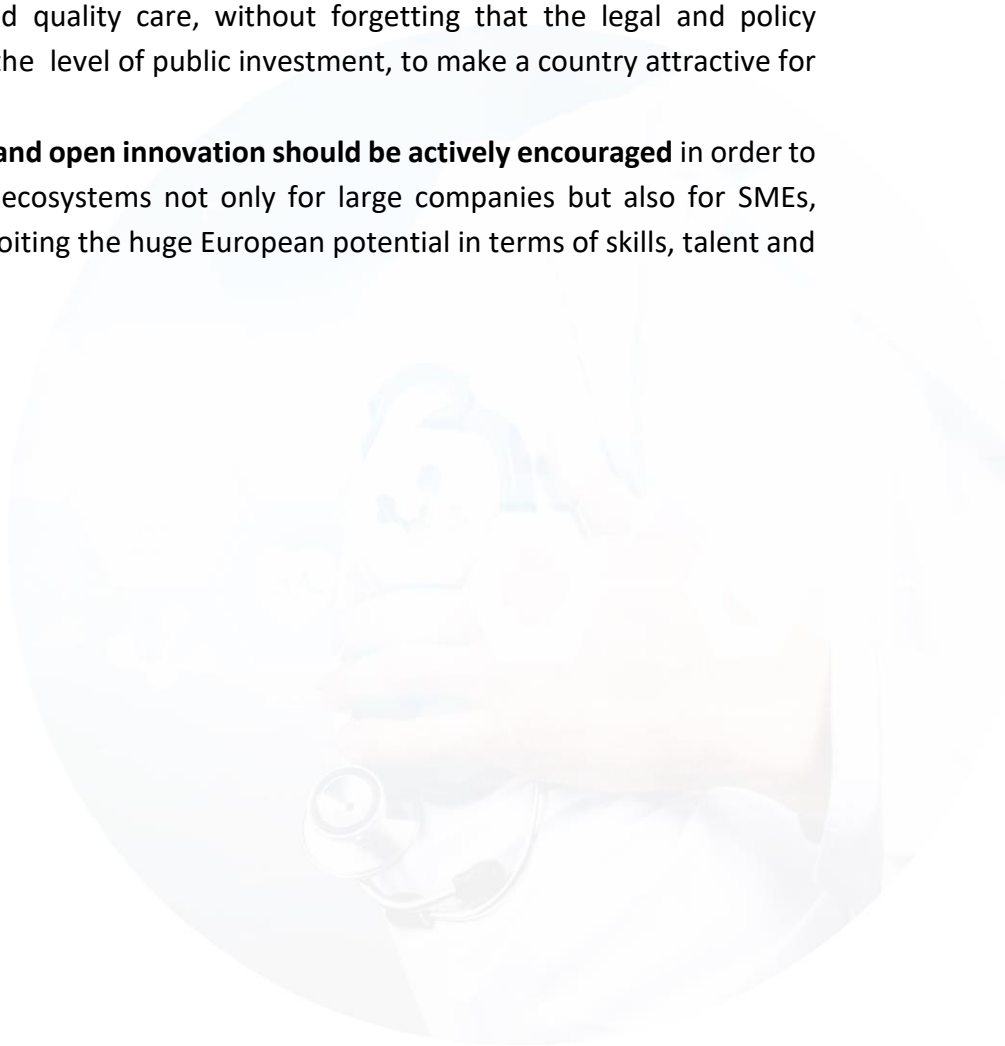
After a description of the industrial sector and its potential through a comparison of the main European countries, the US and Japan, both in terms of value and investments in innovation, the chapter continues by highlighting the main issues and challenges Europe is facing in attracting high value investment. When deciding where to locate their key value drivers, such as regional headquarters and R&D centers, life science companies consider factors such as ease of academic collaboration, existence of clusters, quality of life for the workforce, tec. Entering the European market for a life science company can be costly and time-intensive, also because the regulatory

and healthcare landscape, as well as pricing and reimbursement frameworks are complex and fragmented among the different European countries, notwithstanding the EU effort to harmonize.

The conclusions contain the following policy recommendations:

- **Health promotion and disease prevention should be important objectives for European policy.** Reducing the differences in social and economic backgrounds across the population through health promotion and disease prevention is the first step in reducing differences in health outcomes and respond to unmet needs. Acting through inclusive and consistent strategies, is essential in order to cut wasteful spending while guaranteeing equity in access to care for all. In this context vaccination has to be considered a powerful and cost-effective public health prevention tool.
- **The digital healthcare transformation can be a major tool in enhancing the efficiency and integration of healthcare systems**. The European Commission is working to guarantee a secure access and exchange of health data and to find a way for medical research to benefit from this pooled data creating a common data space in healthcare. Another important target deriving from digital transformation would be citizen empowerment, enabling them to access their health data, allowing for the exchange of data across borders and enabling all EU countries to reach the same level of healthcare standards. An important step is represented by the European Commission's recently adopted "Recommendation on a European Electronic Health Record Exchange Format", to further develop HER exchanges. The Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure cross-border access to electronic health data in the EU. The new EU institutions should thus reasonably consider further policy actions to facilitate the creation of health registries and increased interoperability of existing datasets to overcome fragmentation of outcome measurements and guarantee European healthcare system efficiency.
- **An exchange of data among national health systems must be based on a series of ethical and legal principles alongside the existing data protection framework.** Citizens and stakeholders are increasingly worried about issues of data privacy and protection since medical data is particularly sensitive and requires strong protection, as it concerns extremely personal and detailed information. These worries coincide with the need for data collection to navigate through a complex legal environment, as legislation at EU level, such as the GDPR, and national level has been injecting a density of data regulation into the European legal sphere. The EU institutions should thus consider a governance structure including relevant public and private stakeholders to increase trust, address concerns and look at the potential benefits of data driven healthcare.

- **Artificial Intelligence in healthcare must be more accurate and accessible for all.** The benefits AI can offer are unquestionable, from the possibility to process large amounts of data to reducing medical errors and improving precision medicine and diagnostics. If used effectively, AI can make healthcare more accurate and accessible for all. In line with this, the High-Level Expert Group on AI presented the Ethics Guidelines for Trustworthy AI. In the over-regulated heath sector, regulatory sandboxes (valid throughout the EU) could be very helpful in promoting innovation provided basic safety is not put at risk.
- **Level of public investment in healthcare sector should be increased to guarantee efficiency and quality care.** In Europe, the low level of public investment in the health sector has resulted in a number of harmful effects on research and healthcare. Firstly, this lack has inhibited the development of innovative technologies and, at the same time, impacted the attractiveness for venture capital. Therefore, the ideal strategy should be aimed at making Member States an attractive environment for life science investment. To do so, a constructive dialogue needs to be set in motion among the different stakeholders, including the industrial sector, to identify the policy measures to be introduced to foster innovation, investment and quality care, without forgetting that the legal and policy framework, together with the level of public investment, to make a country attractive for scientific R&D.
- **Corporate venture capital and open innovation should be actively encouraged** in order to create thriving innovative ecosystems not only for large companies but also for SMEs, startups and scaleups, exploiting the huge European potential in terms of skills, talent and research.

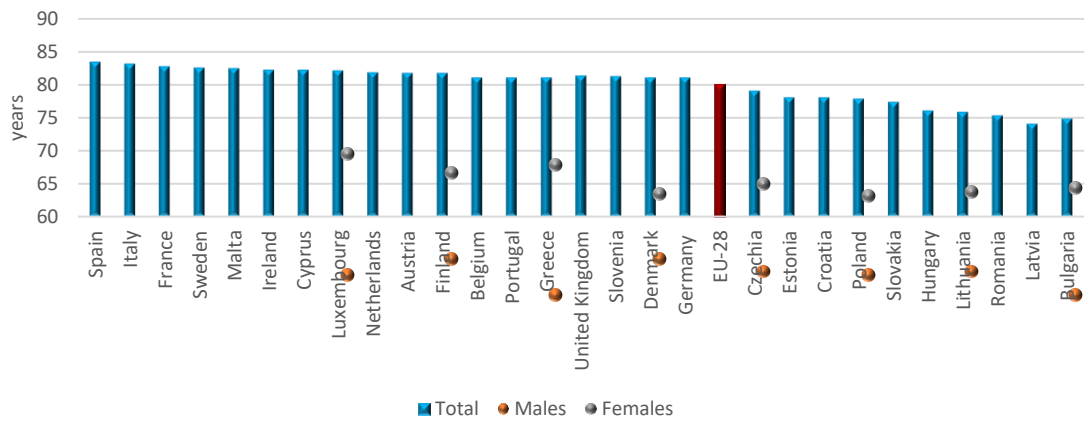


1. EFFECTIVENESS, ACCESSIBILITY AND RESILIENCE OF EU HEALTH SYSTEMS

1.1 Health status and main risk factors among European countries

One of the indicators most used to measure population health status is life expectancy at birth[2]. It is the mean number of years that a person can expect to live at birth if subjected to current mortality conditions throughout the rest of their life. According to Eurostat data, life expectancy at birth in the EU was estimated to be 80.9 years in 2017 and has increased over the past decades. Spain and Italy have the highest life expectancy among EU countries, with life expectancy reaching over 83 years in 2017 in both countries. Life expectancy at birth now exceeds 80 years in two-thirds of EU countries, but still remains at only around 75 years in Bulgaria, Latvia and Romania (Fig. 1.1).

Fig. 1.1: Life expectancy at birth in EU-28 (2017)

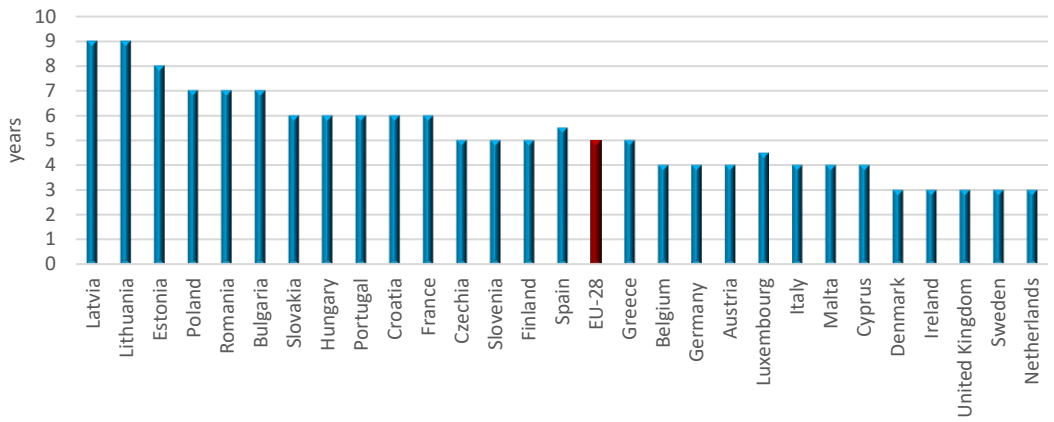


Source: Eurostat (2019)

Women live longer than men in EU countries. In fact, life expectancy at birth tops 83.5 years for women and 78.3 years for men, a difference of 5.2 years. The largest differences between genders are in Latvia (9.9 years), Lithuania (9.8 years) and Estonia (8.8 years). The smallest differences are in Sweden (3.3 years) and the Netherlands (3.2 years) (Fig. 1.2).

[2] https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1577098422&id=id&accname=guest&checksum=6E1FF554030A51EBCC6EC362B4ECF740

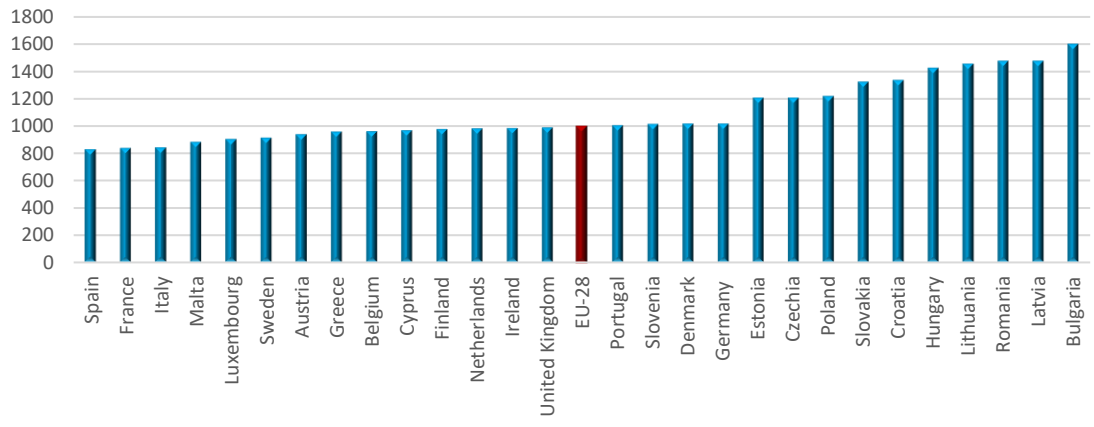
Fig. 1.2: Life expectancy at birth, gender gap (2017)



Source: Eurostat (2019)
Note: female life expectancy at birth – male life expectancy at birth

Over 5,100,000 people died in EU countries in 2016, equivalent to about 1,002 deaths per 100,000 population. Overall mortality rates vary widely across Europe. France, Spain and Italy have the lowest death rate, with an age-standardized rate between 829 and 843 deaths per 100,000 population in 2016. Instead, mortality rates are highest in Romania, Latvia and Bulgaria with age-standardized rates at least 50% higher than the EU average in 2016 (Fig. 1.3).

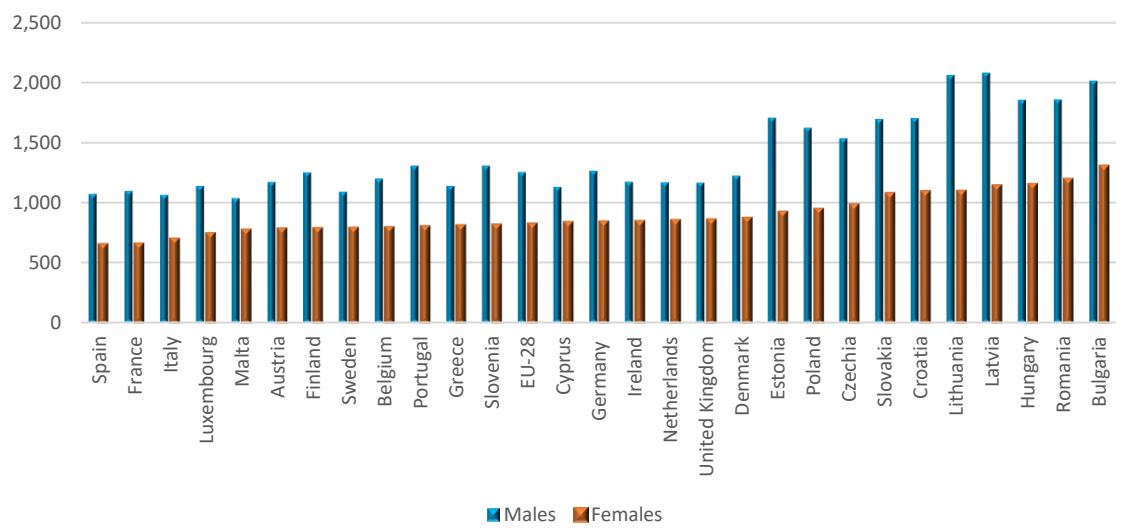
Fig. 1.3: Standardised death rate in the EU countries (2016)



Source: Eurostat (2019)

Slightly more women than men died across EU countries in 2016 but if we consider age-standardized mortality rates, it was about 50% higher among men across the EU as a whole (1,250 deaths per 100,000 men compared with 818 deaths per 100,000 women) (Fig. 1.4).

Fig. 1.4: Standardized death rates in the EU countries, by gender (2016)

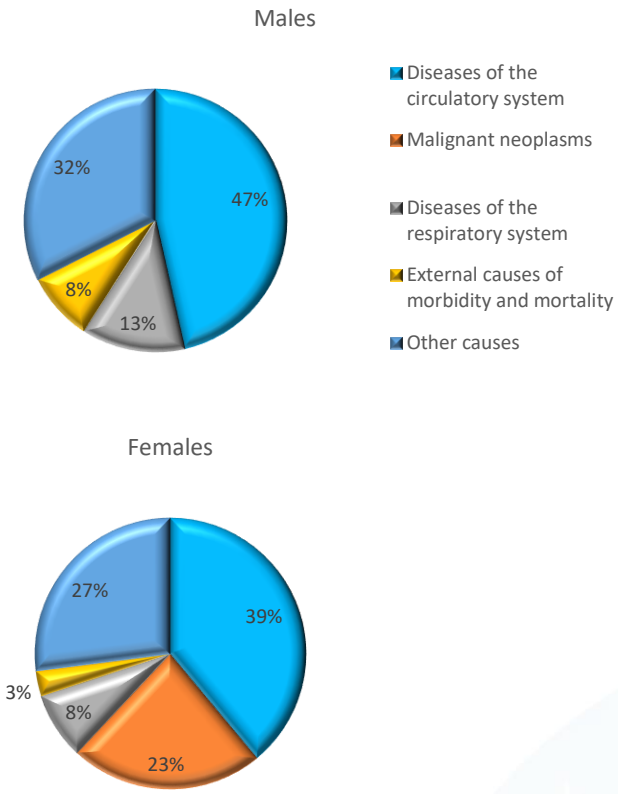


Source: Eurostat (2019)

The main causes of death in EU countries are circulatory diseases (especially ischaemic heart disease and strokes) and malignant neoplasms, followed by respiratory diseases and external causes of death (accidents, suicides, homicides, etc.).

Circulatory diseases caused over 1,800,000 deaths in 2016, especially in women (39%). Over 1,330,000 people died of cancer in 2016 accounting for 23% of all deaths among women and 29% among men. Breast cancer and lung cancer are the leading causes of cancer death among women, whereas lung cancer and colorectal cancer are the two main causes of cancer death for men. Respiratory diseases are the third cause of death in Europe, being responsible for 8% of all deaths among women and 9% among men. Finally, external causes of death caused over 200,000 deaths (3% among women and 6% among men) (Fig. 1.5).

Fig. 1.5: Main causes of mortality among women and men in EU (2016)

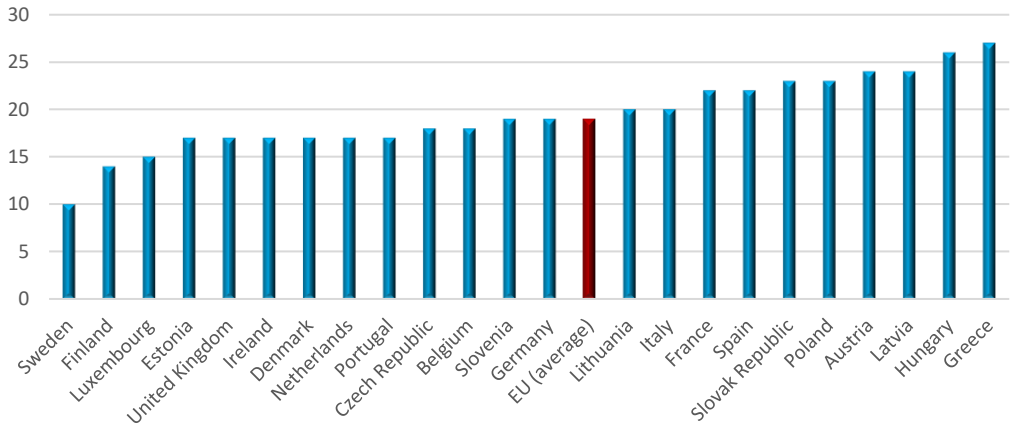


Source: Eurostat (2019)

Smoking is a major risk factor for at least two of the leading causes of mortality - circulatory disease and cancer, increasing the risk of heart attacks, strokes, lung cancer, and cancers of the larynx and mouth. In addition, smoking is an important contributing factor to respiratory diseases[3]. Across EU countries, about 19% of adults (population aged 15+) smoke tobacco daily. Smoking rates range from 10% in Sweden to 27% in Greece (Fig. 1.6).

[3] https://data.oecd.org/healthrisk/daily-smokers.htm

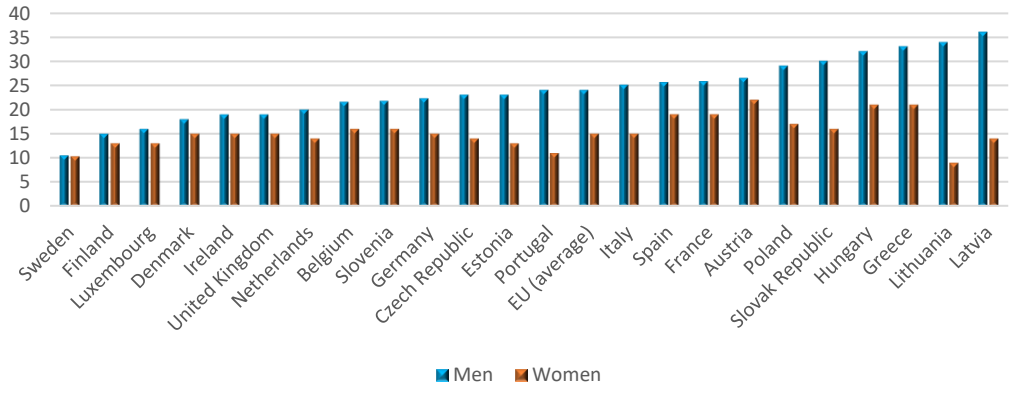
Fig. 1.6: % of adult population smoking daily across European countries (2018 or latest available)



Source: OECD (2019)

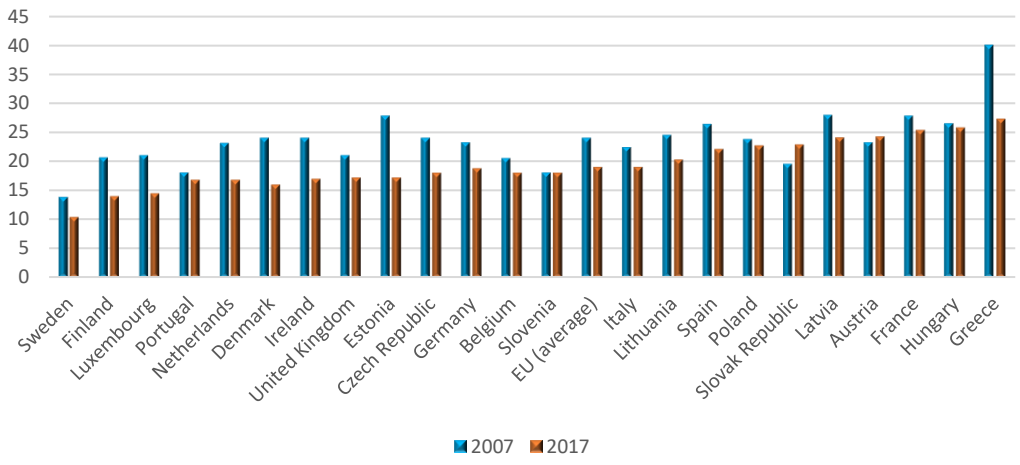
Men smoke more than women in all European countries. On average, 24% of men smoke daily compared to 15% among women. The gender gap in smoking rates is very evident in Lithuania and Latvia (Fig.1.7). Daily smoking rates have decreased in most EU countries over the last decade, from an average of 24% in 2007 to 19% in 2017 (Fig. 1.8).

Fig. 1.7: % of adult population smoking daily across European countries, by gender (2018 or latest available)



Source: OECD (2019)

Fig. 1.8: % of adult population smoking daily across European countries

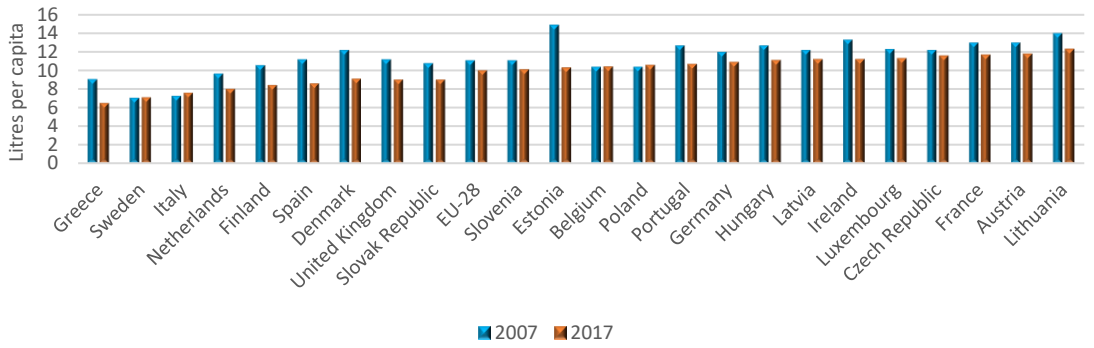


Source: OECD (2019)

Another risk factor for health is alcohol consumption. Alcohol use is associated with numerous harmful health and social consequences, including an increased risk of a range of cancers, stroke and liver cirrhosis. Alcohol also contributes to death and disability through accidents and injuries, assault, violence, homicide and suicide[4]. Overall alcohol consumption averaged 10 liters per person across EU countries in 2017, down from 11.4 liters in 2007. Lithuania reported the highest consumption (12.3 liters), followed by Austria, France, the Czech Republic, Luxembourg, Ireland, Latvia and Hungary, all with over 11 liters per person (Fig. 1.9).

[4] https://data.oecd.org/healthrisk/alcohol-consumption.htm

Fig. 1.9: Recorded alcohol consumption among adults

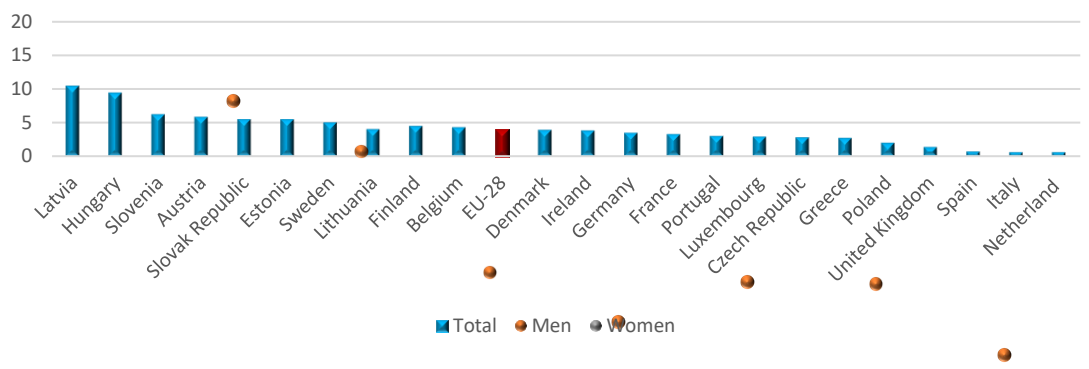


Source: OECD (2019)

While overall consumption per capita helps assess long-term trends, it does not identify sub-populations at risk from harmful drinking patterns. Heavy drinking and alcohol dependence account for an important share of the disease burden. On average, across EU countries, 4% of adults were alcohol dependent in 2016 (Fig. 1.10). In all countries, men are more likely to be alcohol dependent - with 6.7% of men and 1.7% of women. Dependence is most common in Latvia and Hungary (more than 9% of adults). In these countries, gender gaps are also high, with the share of alcohol dependent men five times higher than for women. The share of dependent drinkers does not always correlate with overall alcohol consumption levels, reflecting differences in consumption patterns and diagnosis of alcohol dependence. France, for instance, had the third highest alcohol consumption in 2017, yet rates of alcohol dependence below the EU average[5].

[5] OECD, Health at a Glance 2019

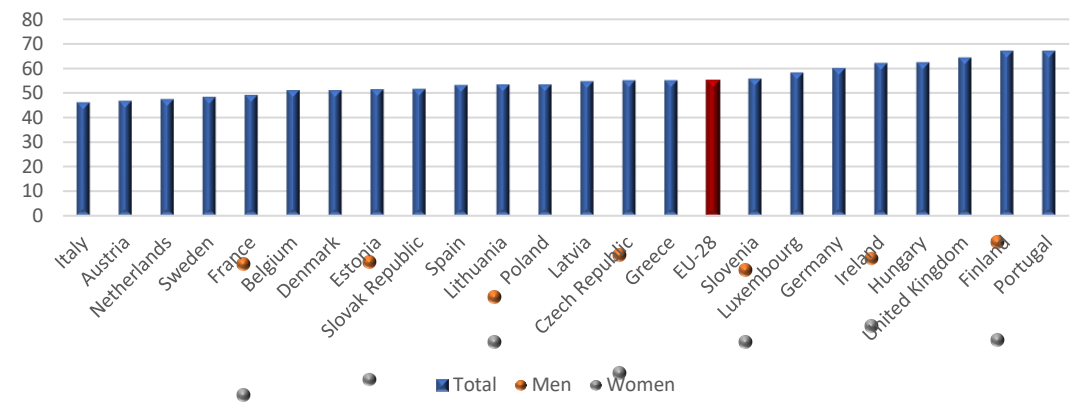
Fig. 1.10: Share of dependent drinkers, by gender (2016)



Source: OECD (2019)

Being overweight, including pre-obesity and obesity, is a major risk factor for various non-communicable diseases including diabetes, cardiovascular diseases and certain cancers. High consumption of calorie-dense food and increasingly sedentary lifestyles have contributed to growing global obesity rates[6]. 55% of adults were overweight or obese in 2017, on average across EU countries (Fig. 1.11). For the UK, Finland and Portugal, this figure exceeds 64%. In all countries, men are more likely than women to be overweight.

Fig. 1.11: Overweight including obesity among adults by gender (2017 or nearest year)

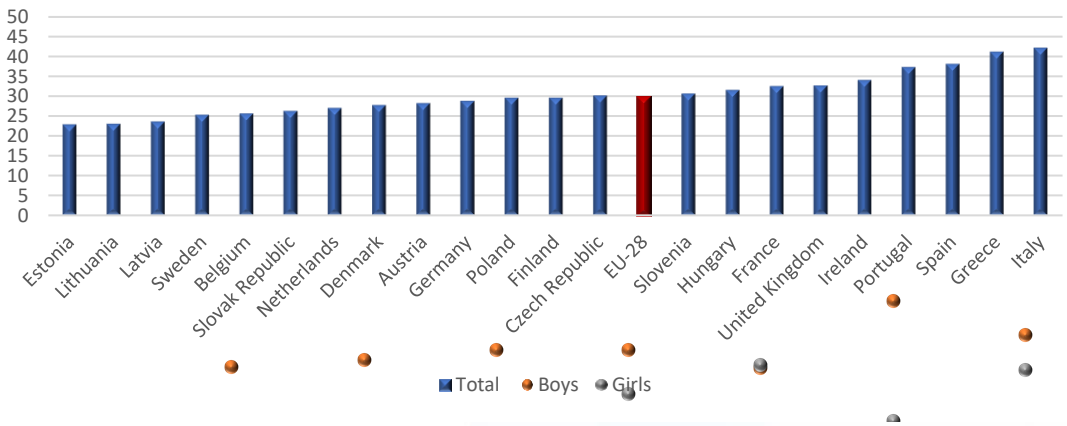


Source: OECD (2019)

[6] Ibidem

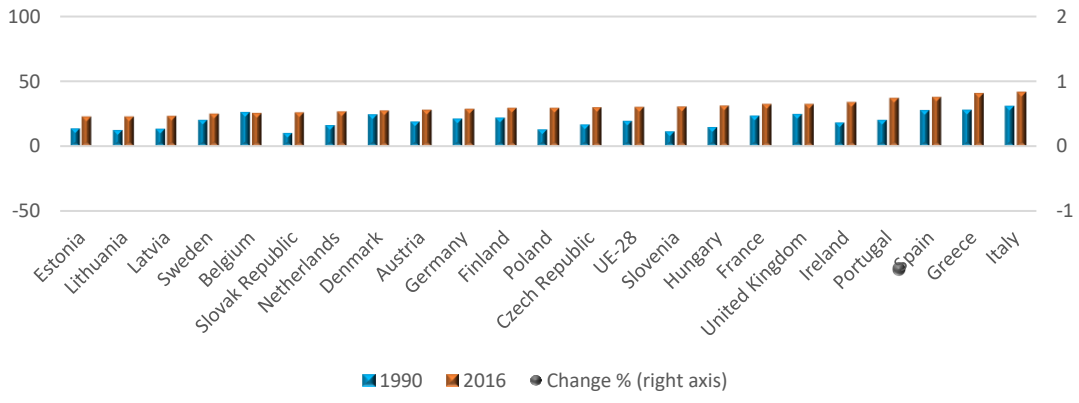
Where childhood overweight is concerned, almost one-third (30%) of children aged 5-9 years living in EU countries are overweight (Fig. 1.12). In Italy and Greece, this figure exceeds 40%. The proportion of overweight boys exceeds that of girls in all countries. Countries with the greatest disparity between genders are Poland, the Czech Republic, the Slovak Republic and Hungary. The rate of overweight children increased from 19% to 30% across EU countries between 1990 and 2016 (Fig. 1.13). Only in Belgium did this rate fall, albeit marginally. Growth was greatest in Hungary, Poland, Slovenia and the Slovak Republic whose rates increased by more than 100%.

Fig. 1.12: Overweight including obesity among 5-9 year olds by gender, 2016



Source: OECD (2019)

Fig. 1.13: Changes in overweight including obesity among 5-9 year olds



Source: OECD (2019)

1.2 Health promotion and disease prevention

"Health is promoted by providing a decent standard of living, good labour conditions, education, physical culture, means of rest and recreation' and requires the coordinated efforts of statesmen, labour, industry, educators and physicians"[7]. Health promotion was introduced in 1945 as one of the four major goals of medicine along with disease prevention, care and cure of the sick and rehabilitation. The term health promotion was revisited in 1986, in the Ottawa Charter for Health Promotion where it is defined as "the process of enabling people to increase control over, and to improve, their health". The Ottawa Charter indicates three basic strategies for health promotion:

- Advocate. Health advocacy helps in establishing political, economic, social, cultural, environmental, behavioral, and biological factors important for effective health outcomes;
- Enable. The aim of health promotion is to achieve equity in health. It aims to reduce differences in current health status and ensure equal opportunities and resources;
- Mediate. The prerequisites and prospects for health cannot be ensured by the health sector alone; coordinated action is also required by other sectors such as governments, non-governmental and voluntary organizations, local authorities, industry and the media.

Based on the latter, the Ottawa Charter recognizes that improvement in health requires a solid foundation of prerequisites, such as education, food, decent income, stable eco-system, sustainable resources, social justice and equity. For this reason, the Charter identifies five integrated health promotion actions needed to reach the objective of health improvement:

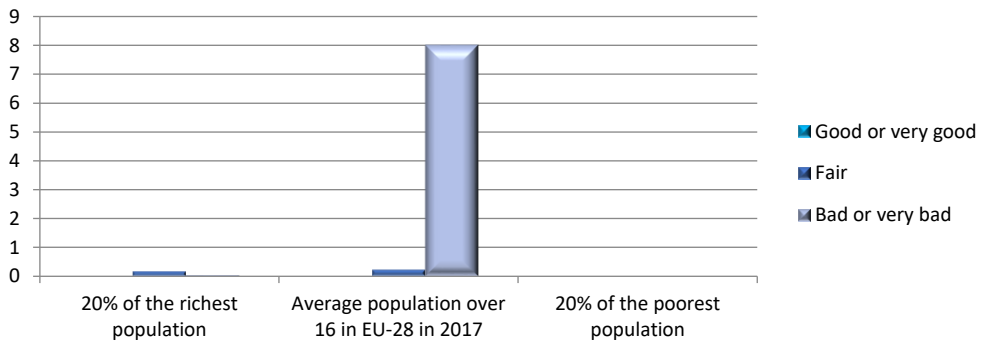
- Building healthy public policy
- Creating supportive environments
- Strengthening community actions
- Developing personal skills
- Re-orienting health services

Addressing the social determinants of health is essential in order to build fairer, healthier and more sustainable communities for all, able to lead to better health outcomes and, thus, economic benefits. Health promotion is a key tool to reach these objectives, sustaining the design and implementation of actions on the social determinants of health that are finally able to tackle health inequalities. According to EuroHealthNet (European partnership for improving health outcomes and inequalities)[8] it is generally true that the lower a person's socio-economic status, the worse the health outcomes. This social gradient in health exists in all countries, but the steepness of the

[7] Breslow L. (1999), From Disease Prevention to Health Promotion, JAMA. 1999;281(11):1030-1033
[8] Health Inequalities in Europe, EuroHealthNet factsheet, October 2019.

curve varies. Health outcomes and health inequalities are mainly affected by the social, economic, and environmental determinants of health, such as the conditions in which we are born, grow, live, work, and age. The latter evidence is at a first glance observable by looking at the share of people in the EU that describe their health as "good" or "very good" according to their level of education and income (Fig. 1.14). Among the 20% of the richest population, the 80.4% of the group declare to perceive its health as "good or very good". This declines to 69.7% when considering the average population over 16 in the EU, and to 61.2% when considering the 20% of the poorest population.

Fig. 1.14: Self perceived health in the EU (aged 16 or above, 2019)



Source: EuroHealthNet 2019

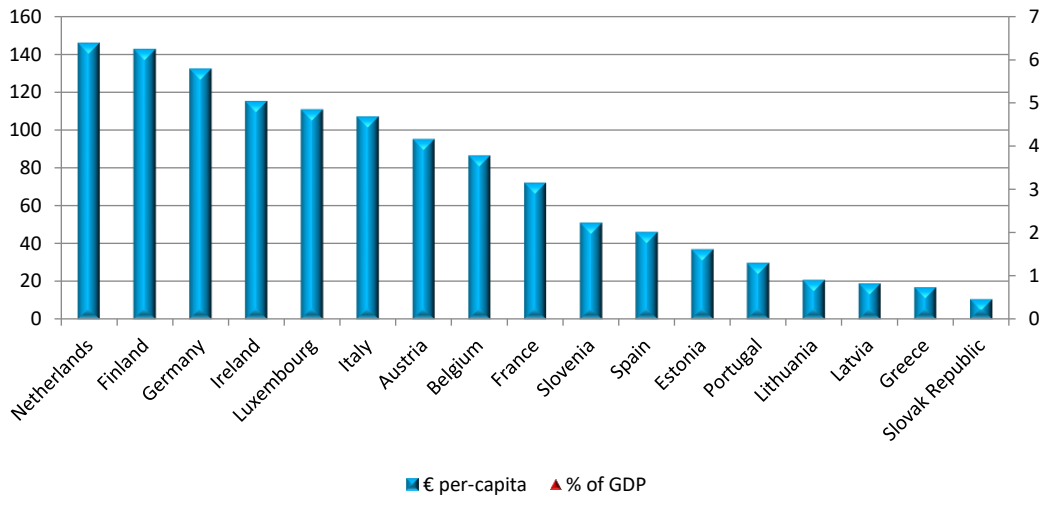
Together with health promotion, disease prevention is crucial in improving health outcomes, reducing health inequalities and rationalizing economic resources. Disease prevention commonly refers to intervention (either population or individual-based) which aims at minimizing the burden of diseases and associated risk factors. It is frequently categorized as primary, secondary and tertiary prevention, while quaternary prevention has been more recently introduced.

Primary prevention refers to actions that avoid the manifestation of a disease. It may include actions to improve health through changing the impact of social and economic determinants, the provision of information on behavioral and medical health risks, and measures to decrease them. Secondary prevention is associated with early detection of a disease which may result in improved chances for positive health outcomes. It encompasses evidence- and population-based screening programs, including production and purchasing of screening tests for early disease detection. Tertiary prevention is associated with services that promote better quality of life for those living with a disease. It includes rehabilitation, disease management programs and support for patients with an established disease to minimize residual disabilities and complications.

Quaternary prevention is related to avoiding over-medicalization of patients, protecting them from unnecessary operations and suggesting ethical alternatives. The extent to which health services are able to achieve the desired results or outcomes at the patient or population level (effectiveness) influence the ability of a health system to be less complex and more sustainable. It entails a transition from the traditional hospital-centric approach to more community-based and integrated care structures, focusing on person-centered care, chronic disease management and, more importantly, prevention measures. One of the reasons for this shift lays in the increasing demand for health care due to population ageing and the subsequent rise in chronic disease burden and multi-morbidity, all set against a backdrop of constrained public resources.

The State of Health in the EU's 2019 Companion Report[9] reaffirms the priority of health promotion and prevention as preconditions for effective and resilient health systems. According to the country reports, there is a diversity of systems and structures in health promotion and prevention policies, programs and practices but, in general, health promotion seems to receive limited attention from policy makers and prevention measures are not at the forefront of government health services or current thinking. Figure 1.15 shows the health expenditure for preventive care across EU countries where more recent data is available (OECD), both in euro per-capita and in percentage of GDP. Differences between countries are significant - in the Netherlands, the per-capita health expenditure for preventive care is €145.7, while in the Slovak Republic it amounts at €10.6.

Fig. 1.15: Health expenditure for preventive care (2017)

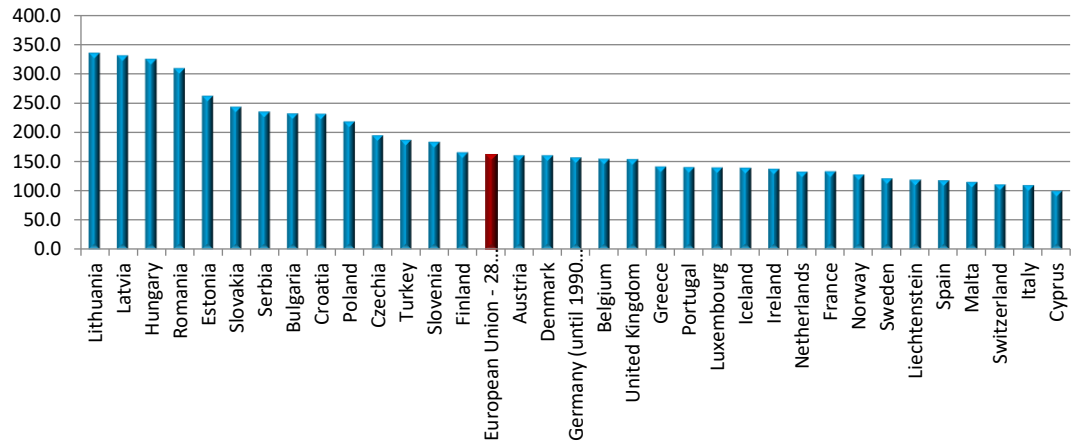


Source: OECD

[9] State of Health in the EU Companion Report, Publications Office of the European Union, 2019.

Similarly, the concept of preventable deaths is useful in understanding the efficacy of prevention and health promotion measures since it is a broad concept that includes deaths which could have been avoided by public health intervention focusing on wider determinants of public health, such as behaviour and lifestyle factors, socio-economic status and environmental factors. The concept of preventable mortality is based on the idea that certain deaths (for specific diseases/conditions, a disease/condition leading to a preventable death is one which, in the light of understanding of the determinants of health at the time of death, all or most deaths from that cause could be avoided by public health intervention in the broadest sense) could be avoided among people aged less than 75 years. In other words, these avoidable deaths would not have occurred at this stage (below 75 years) if there had been more effective public health and/or medical intervention in place. Figure 1.16 highlights the preventable death rate for European countries.

Fig. 1.16: Preventable death rate standardized rate per 100,000 inhabitants 2016)



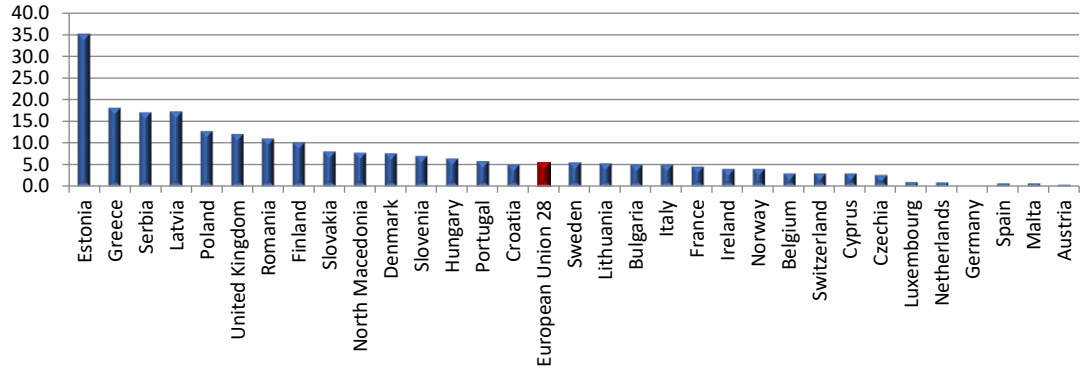
Source: Eurostat

1.3 Unmet needs and evidence-based healthcare management

The State of Health in the EU's 2019 Companion Report recalls that after the financial crisis, the Commission drew up through the European Pillar of Social Rights a set of principles to support EU citizen rights and safeguard social standards in a fast-changing world. One of these principles declares that everyone has the right to timely access to good quality affordable, preventive and curative health care, accessibility being a vital and multi-dimensional aspect of health system performance. The barriers that could inhibit universal access to health services are both financial and non-financial: population coverage, scope of services, level of coverage (cost-sharing), geographical factors, attitudinal barriers in seeking medical care, provider choice, organizational barriers, patient preferences and socio-economic aspects. According to Eurostat, there is a

significant cross-EU variation in both the country average level of unmet needs and income disparities. The percentage of people reporting unmet medical needs is 5.5% in Europe, from the highest at 35.2% in Estonia to the lowest at 0.4% in Austria. Yet, of the Member States with a level of unmet needs above the EU average, only half reveal costs as the most prominent reason. Waiting lists are the most common cause for unmet medical needs in the remaining above-average EU Member States (Estonia, Finland, Slovenia, the UK, Poland, Ireland and Slovakia). A waiting list hindering a medical examination or treatment was the most frequent reason given for unmet medical needs in Estonia, Poland, the UK, Finland, Slovakia, Slovenia, Ireland and Lithuania. Patients wanting to wait and see whether their problem resolved itself was the most common reason in Denmark, Hungary, Croatia, France, the Czech Republic and Luxembourg. Due to the very low overall prevalence of unmet needs in Germany, the Netherlands, Spain, Malta and Austria, there were no big differences in the reported rates for the main specific reasons. In eight EU Member States (Latvia, Greece, Romania, Portugal, Bulgaria, Italy, Belgium and Cyprus), the expense of a medical examination or treatment was the most frequent reason for unmet medical needs.

Fig. 1.17: Self-reported unmet needs for medical examination (percentage)



Source: I-Com on Eurostat data

Unmet needs often hide deeper gaps in healthcare access that are still very much a reality in the EU. Problems regarding accessibility and the extent to which EU citizens experience them vary enormously. However, standard data routinely used across the EU is not granular enough to capture the multi-dimensional character of the challenge, and struggles to reveal how differences in covered services and medical goods relate to socio-economic factors or clinical needs and to capture the huge variation within and across countries. According to the previously mentioned

companion report, the gap between demand for healthcare and actual investments is widening and, as a result, financial sustainability and access to universal healthcare are increasingly endangered. While healthcare is one of the EU policy priorities to build a more inclusive and fairer environment and to ensure social cohesion, for health systems to adequately and appropriately ration and prioritize healthcare services, there is a need to factor in epidemiology, severity of needs, and outcome-based data. The latter requires a clear and mutually recognized definition of outcomes whereby it could implement a more holistic approach to measuring access taking into account both the system's cost-effectiveness and the patient's perspective. Such an approach is needed to give valuable input to creating healthier, more equal and sustainable systems. The value-based healthcare concept seems to be in line with this objective since its main goal is to intervene in order to increase value. Value is generally created from health outcomes which matter to patients relative to the cost of achieving those outcomes, but the health outcomes should include all domains of health in a full cycle of care. To implement value-based healthcare, changes need to occur for both health providers and patients. This involves establishing true health outcomes, strengthening primary care, building integrated health systems, implementing appropriate health payment schemes that promote value and reduce moral hazards, enabling health information technology, and creating a policy that fits well with a community. In Chapter 3 of this study we will analyze more deeply the actual role and definition of VBHC (value-based healthcare), to understand its role in increasing and improving accessibility and efficiency in national healthcare systems.

1.4 Upcoming challenges

Population ageing and chronic diseases, threats to health such as antimicrobial resistance, vaccination prejudice, and the persistent digital divide are among the main challenges for EU healthcare systems.

Chronic diseases are the leading cause of mortality and morbidity in Europe and research suggests that complex conditions such as diabetes and depression will be an even heavier burden in the future. Many chronic diseases and conditions are linked to an ageing society, but also to lifestyle choices such as smoking, sexual behavior, diet and exercise, as well as to genetic predispositions.

The management of chronic disease is increasingly considered an important issue by policy-makers and researchers. Policy-makers across Europe are searching for interventions and strategies to tackle chronic disease[10].

Health promotion is the process that allows people to increase control over and improve their health. It is an integral element of health systems, essential to helping them become efficient and sustainable and improve health outcomes. For this reason, investing in health promotion is

[10] http://www.euro.who.int/__data/assets/pdf_file/0008/96632/E93736.pdf

fundamental. Moreover, investments in disease prevention and early detection are important. Digital tools, services and platforms have a great potential when it comes to health promotion and disease prevention. Such digital solutions, be it apps, wearable technology or online fora, may empower people to enjoy a healthy lifestyle and prevent them from developing an illness. Some mobile health (mHealth) tools even reveal early symptoms or disease indicators, provide feedback to health workers and assist in patient adherence to treatment programs[11]. For these reasons, it is essential to harness the digital transformation of health promotion and disease prevention and overcome the digital divide found in some European countries.

Declining vaccination coverage is a major risk for health in Europe and the world. For example, in 2018, only five countries (Hungary, Portugal, Slovakia, Sweden and Malta) reported at least 95% childhood vaccination coverage rates for doses of the measles, mumps and rubella (MMR) vaccine. Moreover, it is important to highlight that none of the 30 countries covered by the State of Health in the EU's 2019 Country Health Profiles reaches the WHO target of 75% for vaccination coverage for influenza among older people. The EU average coverage rate is just 43%. Moreover, in the last years, several countries have been experiencing a dramatic decline: Belgium from 64% in 2004 to 58% in 2018; Ireland from 64% in 2010 to 58% in 2017; Spain from 65% in 2008 to 56% in 2017; Sweden from 55% in 2010, to 49% in 2017; Bulgaria and Estonia, with the lowest EU coverage rates at 2% and 5% in 2014 and 2017, respectively. The decline in vaccination coverage is influenced by multiple factors, including complacency, convenience, and confidence. Complacency and convenience relate to the perceived risk of acquiring the disease, as well as the effort involved in accessing vaccination services. Confidence relates to the perception of the safety and effectiveness of vaccines and the importance of the diseases that are to be prevented. Low confidence is driven by misconceptions about immunization. Such misconceptions are often related to safety and the side effects of vaccination, as well as the lack of awareness of the benefits that vaccination brings to individuals and the general population.

Therefore, vaccination hesitancy, a major public health threat across Europe, can be tackled by improving health literacy and countering disinformation head-on, with health workers actively involved[12].

Finally, according to the WHO[13] , antibiotic resistance is one of the biggest threats today to global health, food security and development. It is accelerated by the misuse and overuse of antibiotics, as well as poor infection prevention and control. Its consequences are truly harmful to the health of the population. In fact, a growing number of infections – such as pneumonia, tuberculosis, gonorrhea and salmonellosis – are becoming harder to treat as the antibiotics used to treat them

[11] European Commission, State of Health in the EU, Companion Report 2019
[12] Ibidem
[13] https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance

become less effective. It is essential to take steps at all levels of society to reduce the impact and limit the spread of resistance.

To prevent and control the spread of antibiotic resistance, individuals should:

- only use antibiotics when prescribed by a certified health professional;
- never demand antibiotics if your health worker says you don't need them;
- always follow your health worker's advice when using antibiotics;
- never share or use leftover antibiotics;
- prevent infections by regularly washing hands, preparing food hygienically, avoiding close contact with sick people and keeping vaccinations up to date.

Instead, policy makers should:

- ensure a robust national action plan to tackle antibiotic resistance is in place;
- improve surveillance of antibiotic-resistant infections;
- strengthen policies, programs, and implementation of infection prevention and control measures;
- regulate and promote the appropriate use and disposal of quality medicines;
- make information available on the impact of antibiotic resistance;
- set up incentives to boost early research, as well as the development of novel antimicrobials and innovative alternative medicinal products (e.g. vaccines, antibacterial, antifungal, antiviral agents) and diagnostics;
- develop new Health Technology Assessment methodologies and reimbursement reforms, to better capture the added value of new antimicrobials, alternatives and diagnostics.

Health professionals should only prescribe and dispense antibiotics when they are needed, according to current guidelines, and talk to their patients about how to take antibiotics correctly, antibiotic resistance and the dangers of misuse.

The health industry should invest in research and development of new antibiotics, vaccines, diagnostics and other tools. While in order to prevent and control the spread of antibiotic resistance, the agribusiness sector should:

- only give antibiotics to animals under veterinary supervision;
- not use antibiotics for growth promotion or to prevent diseases in healthy animals;
- vaccinate animals to reduce the need for antibiotics and use alternatives to antibiotics when available;
- promote and apply good practices at all steps of production and processing of foods from animal and plant sources;
- improve biosecurity on farms and prevent infections through improved hygiene and animal welfare.

2. THE FUTURE OF E-HEALTH IN THE AI ERA

2.1 Digital health in the European context

Digital innovation in the healthcare sector is becoming increasingly important globally, above all in managing the growing number of chronic diseases due to the ageing population and the increase in the efficiency of healthcare systems. eHealth offers many advantages and benefits, including patients becoming more aware of their health and healthcare opportunities. For example, Information and Communication Technologies (ICT) can help patients manage their own health thanks to a better flow of information and interaction with health professionals (teleconsultations). Moreover, the use of digital devices could help healthcare professionals or paramedic staff reduce medical errors, as well as assisting governments and healthcare providers in increasing access to care or in managing epidemics. Through a greater access to personal health data for patients and health professionals, digital health solutions enable faster diagnosis, improved monitoring, more effective treatment and better health outcomes.

Despite these advantages, many individuals either do not use the technology that is available to them or do not even have the means to manage their healthcare online.

According to a 2017 European Commission study[14], only 18% of respondents had used online health services in the past 12 months. However, 52% of all respondents would like to have online access to their medical and health records (52%), while 43% would not. In addition, 70% of respondents would be willing to give their health and personal wellbeing data, mostly for access by their doctor or other relevant healthcare professionals.

Although it is clear that most individuals surveyed would be willing to give access to their health data, either to their care providers or others, to improve treatment, diagnosis and prevention of diseases across the EU, the most worrying issue concerning health data is security. Data security and privacy are areas that require legal and policy attention to ensure that patient data is properly protected. Trust and confidence are key elements for ensuring the swift uptake of digital health applications by end-users. Individuals have concerns about whether companies or government entities will have access to their data and, therefore, many individuals would prefer only their doctors to have access to their data after their consent. According to an infographic on transformation of healthcare in the Digital Single Market[15], 80% of EU citizens agree to share their health data if privacy and security are ensured.

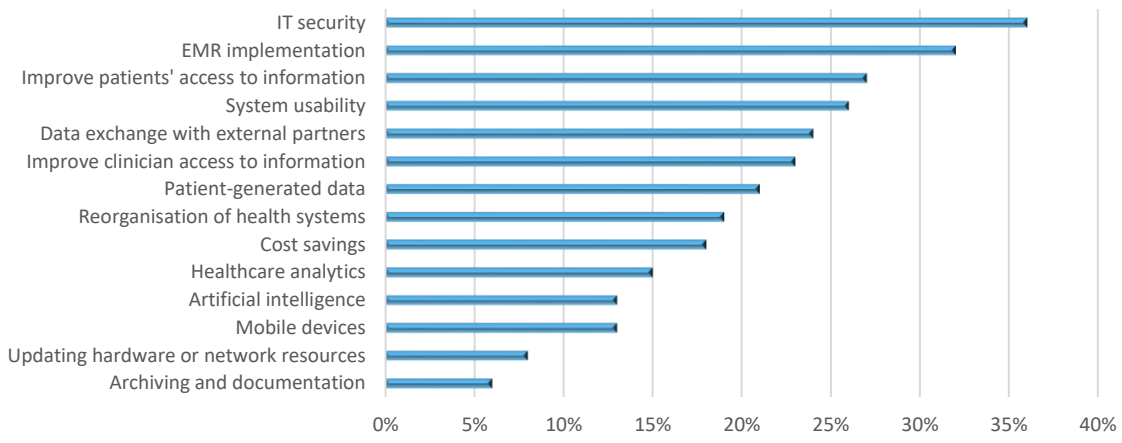
The new HIMSS Analytics Annual European eHealth Survey (2019)[16] provides an insight into top health IT priorities in Europe. The survey involved 537 respondents in Europe that operate in

[14] Eurobarometer, Special Eurobarometer 460: Attitudes towards the impact of digitization and automation on daily life, 2017
[15] https://ec.europa.eu/digital-single-market/en/news/infographic-digital-health-and-care-eu
[16] https://europe.himssanalytics.org/europe/ehealth-barometer/ehealth-trend-barometer-annual-european-ehealth-survey-2019

different contexts (governmental health authorities, consulting companies, software vendors, health facilities, etc.).

For healthcare providers, IT Security is the top priority among respondents in Europe (36%). Its relative importance has increased compared to last year. Electronical medical reports (EMR) implementation also continues to be a top priority (32%), despite dropping from first to second position. Patient access to information remains third, similar to one year ago. (Fig. 2.1).

Fig. 2.1: The biggest eHealth priorities for healthcare providers at the moment



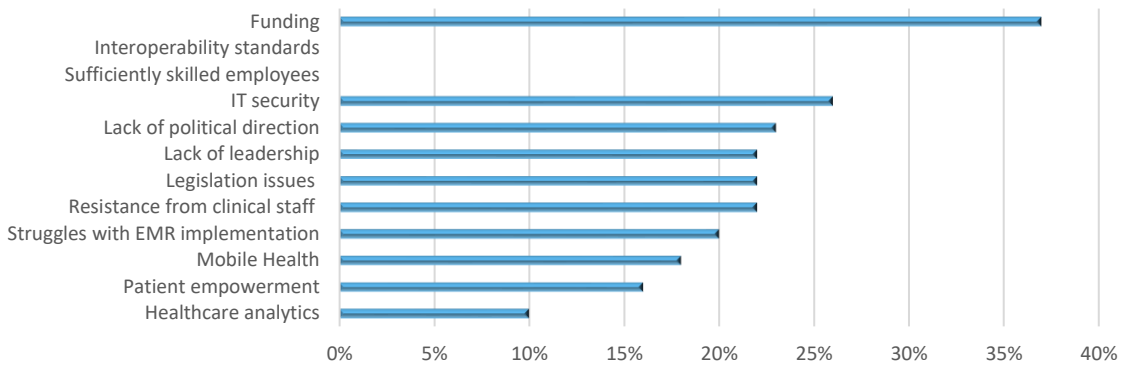
Source: HIMSS Analytics Annual European eHealth Survey (2019)

However, eHealth priorities diverge by country. EMR implementations are a top priority in Germany (54% of respondents) and the UK (37%), while they are of lower priority in more EMR-mature countries like the Netherlands (12%) and Spain (12%). Instead, IT security is a top priority in Italy (50%) and Austria (43%).

Relative to current eHealth challenges, funding is perceived as the major challenge by 37% of respondents. Other main challenges are interoperability (29%), skill of employees (28%) and IT security (26%) (Fig. 2.2).

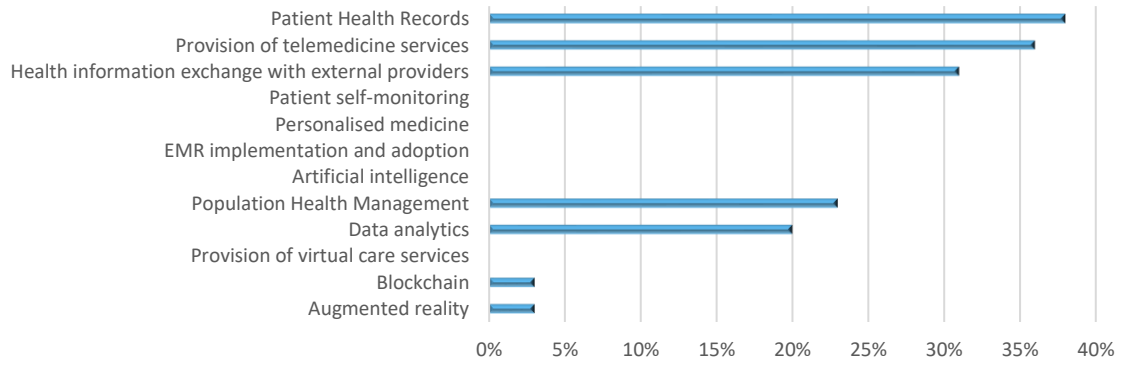
The outlook for the coming years suggests that the main progress will regard: patient medical records, provision of telemedicine services, health information exchange with external providers, patient self-monitoring initiatives, personalized medicine, EMR implementations and artificial intelligence projects. On the contrary, few blockchain-based solutions and augmented reality applications will be implemented (Fig. 2.3).

Fig. 2.2: The main eHealth challenges for healthcare providers



Source: HIMSS Analytics Annual European eHealth Survey (2019)

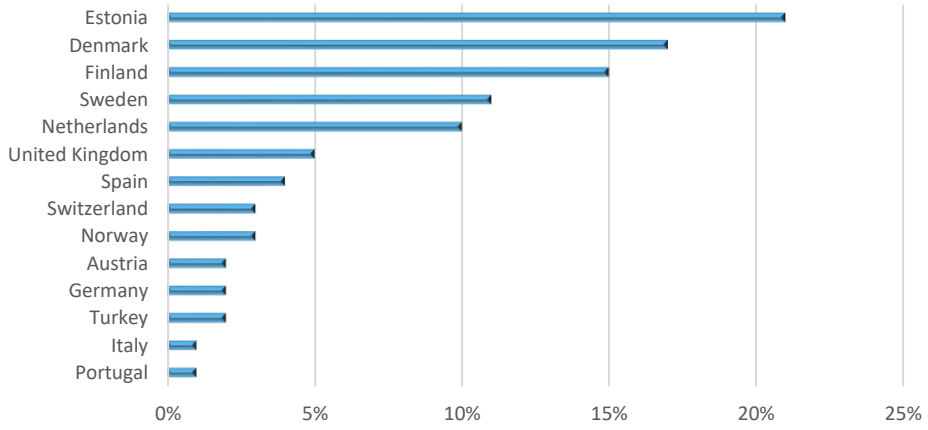
Fig. 2.3: The biggest eHealth trend in Europe in the coming years



Source: HIMSS Analytics Annual European eHealth Survey (2019)

Finally, according to this survey, Estonia is seen as the leading country for eHealth innovation in Europe (21% of respondents), followed by Denmark (17%) and Finland (15%) (Fig. 2.4).

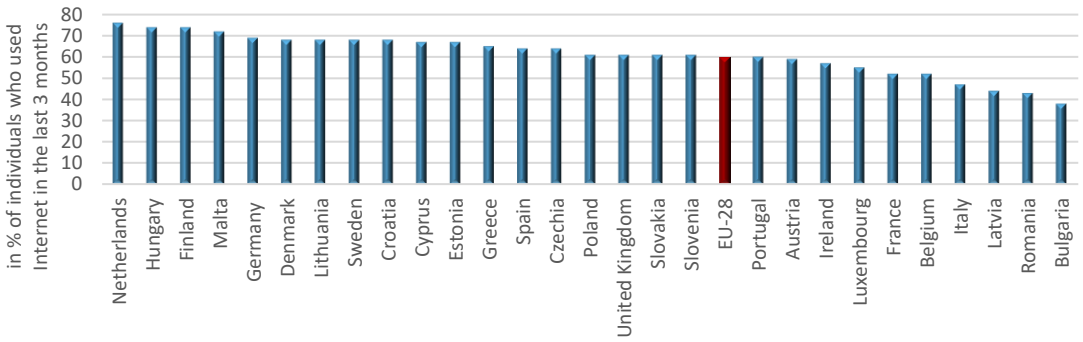
Fig. 2.4: European countries with the best performance in terms of eHealth



Source: HIMSS Analytics Annual European eHealth Survey (2019)

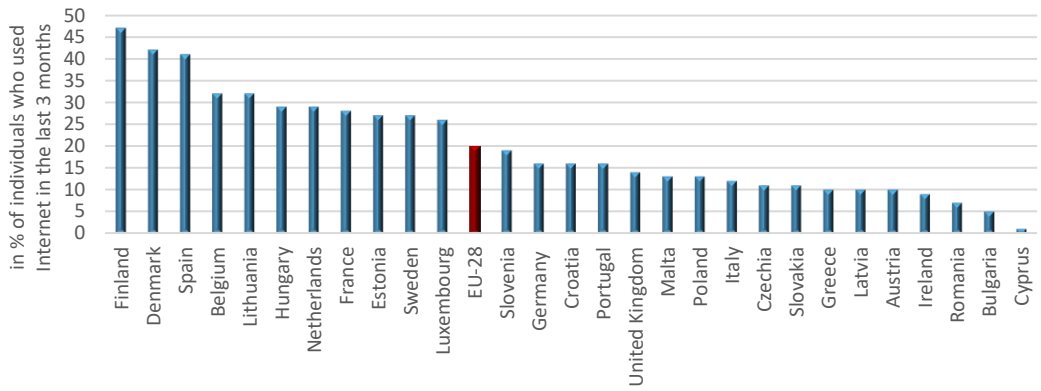
In general, the Northern European countries - according to some of the most recent Digital Agenda Scoreboard key indicators of the European Commission - display the best performance in terms of eHealth. In 2018, in the Netherlands, Finland and Denmark, more than 65% of individuals searched for health information on the Internet (Fig. 2.5). Moreover, the highest number of patients (more than 40% in 2018) making an appointment with a practitioner via a website can be found in Finland, Denmark and Spain (Fig. 2.6). Instead, in Eastern Europe, Internet use for searching health information and making appointments with a doctor is well below the EU average.

Fig. 2.5: Individuals using the Internet seeking information about health (2018)



Source: European Commission

Fig. 2.6: Patients making an appointment with a practitioner via a website (2018)



Source: European Commission

The best performance in terms of eHealth of the Northern European countries is also confirmed by the I-Com Index on the Level of Preparedness for eHealth in the Member States (Fig. 2.7). It is a synthetic index based on eleven variables that are either directly or indirectly related to the development of digital health in Europe. The variables are listed below and refer to four categories: Internet use in the healthcare sector, infrastructure development, digital skills and awareness of security and privacy.

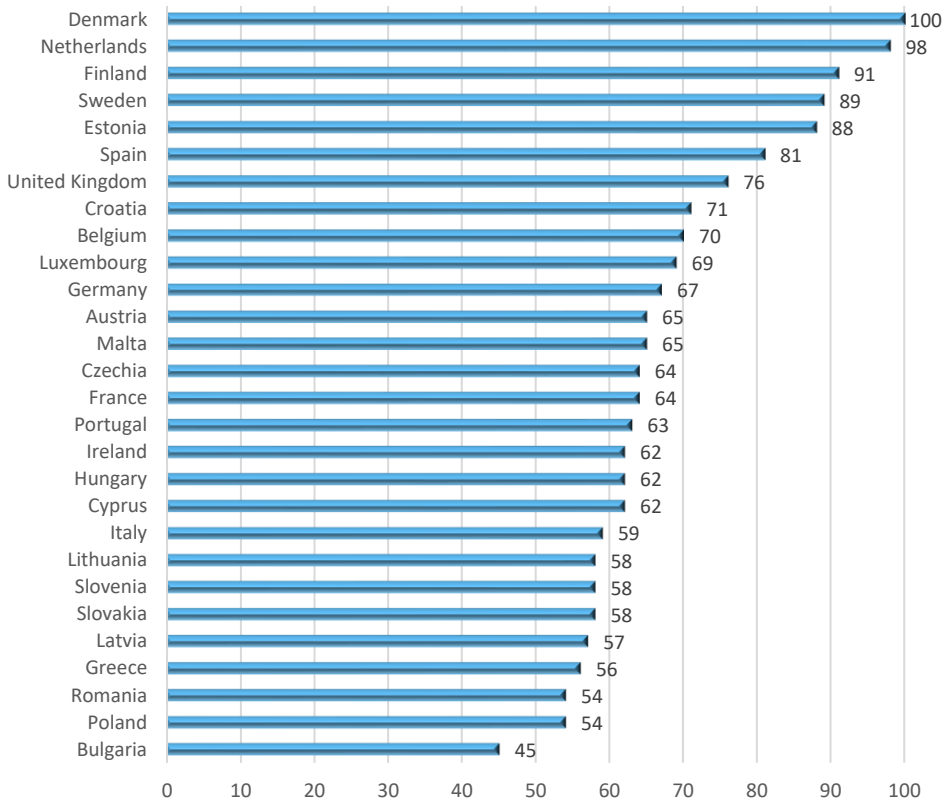
- Individuals using Internet seeking information about health;
- Patients making an appointment with a practitioner via a website;
- GPs using electronic networks to transfer prescriptions to a pharmacist;
- GPs exchanging medical patient data with other healthcare providers and professionals;
- NGA broadband coverage;
- 4G coverage;
- Individuals who have basic or above basic overall digital skills;
- Individuals using simple login with username and password as identification procedure for online services;
- Individuals using social media login for other services as identification procedure for online services;
- Individuals using a procedure involving their mobile phone (a code received via a message) as identification procedure for online services;
- Individuals using a single use pin code list as identification procedure for online services.

Each variable was weighted. It is worth noting that the variables from 1 to 4 are specific to eHealth. For this reason, a greater weight was assigned to them. Then, for each country, a compound average of the variables was calculated. The values obtained were normalized relative to the best performer country, so as to establish a ranking from 0 to 100.

Denmark tops the ranking with a score of 100. The Netherlands, Finland, Sweden and Estonia follow with a score of 98, 91, 90 and 88, respectively. These countries have in common a high number of patients who use mobile and Internet technologies for searching health information and making appointments online with doctors. Also, the level of digital skills is high in the Northern European countries. Moreover, these countries boast a large infrastructural development and best practices in security and privacy.

On the contrary, most Eastern European countries show resistance to implementing eHealth.

Fig. 2.7: I-Com Index 2019 on the Level of Preparedness for eHealth in the Member States



Source: I-Com elaboration on Eurostat and European Commission data

2.2 European regulatory framework

The digital revolution is also impacting health and healthcare systems. Information and communication technologies can improve healthcare system efficiency and the quality of life of patients allowing them to manage their own health (also known as patient “self-care” or “self-management”). Moreover, they provide greater access to personal health data for patients and health professionals, enabling faster diagnosis, improved monitoring, more effective treatment and better health outcomes, improving healthcare efficiency, simplifying access to healthcare services across Europe, offering hospitals the possibility to improve care procedures and assisting governments and healthcare providers in increasing access to care or managing epidemics.

Being aware of the benefits associated with eHealth, European institutions adopted the first **eHealth Action Plan in 2004**, followed by several policy initiatives developed to foster the adoption of eHealth throughout the EU.

eHealth can benefit citizens, patients and health and care professionals, as well as health organizations and public authorities enabling them to deliver more personalized ‘citizen-centric’ healthcare. This is more targeted, effective and efficient and helps reduce errors, as well as the length of hospitalization, facilitating socio-economic inclusion and equality, quality of life and patient empowerment through greater transparency, access to services and information and the use of social media for health.

The adoption in **2011** of the **Directive on the Application of Patients' Rights in Cross-Border Healthcare** (Directive 2011/24/EU) marked a further step towards formal cooperation on eHealth aiming to maximize social and economic benefits through interoperability and the implementation of eHealth systems. The Cross-Border Healthcare Directive aims at giving patients the right to receive medical treatment in another EU Member State and its Article 14 establishes the eHealth Network with the objective to enhance interoperability between electronic health systems and continuity of care and to ensure access to safe and quality healthcare. The eHealth Network is the main decision-making body on eHealth at the EU level and brings together national authorities responsible for eHealth designated by the Member States.

For patients with rare or complex disorders searching for a diagnosis or struggling to access expert care, the dream of cross-border care is about to become a reality, partly thanks to the European Reference Networks (ERNs) (Directive 2011/24/EU). These Networks, launched in March 2017, involve more than 900 highly-specialized healthcare units from over 300 hospitals in 26 EU countries and aim to tackle complex or rare diseases and conditions that require highly specialized treatment and concentrated knowledge and resources. Using a dedicated IT platform and telemedicine tools, a “virtual” advisory board of medical specialists will link up information and

expertise that are scattered across the EU, ensuring that information travels to the patient, who has the convenience of staying in their own supportive home environment[17].

In order to facilitate the mobility of patients seeking cross-border healthcare, the EU Commission is building an **EU-wide eHealth Digital Service Infrastructure (eHDSI)** allowing health data to be exchanged across national borders with a first focus on ePrescriptions and Patient Summaries. Member States can connect their health systems to the eHDSI through a national contact point for eHealth (NCPeH). When building the necessary NCPeH, Member States are required to take into consideration the guidelines approved by the eHealth Network to support interoperability of national health systems in the EU[18].

To improve safety, quality and access to healthcare the following have been set up: the **electronic prescription (ePrescription)** allowing patients to obtain their pharmaceuticals in another EU country; **Patient Summary**, a standardized set of basic medical data including a patient's most important clinical facts and providing health professionals with the essential information they need to provide care in the case of an unexpected or unscheduled medical situation; and the **electronic health record**, a record of the patient's medical history, diagnoses and treatment, medications, allergies and immunizations, as well as radiology images and laboratory results[19].

Moreover, making EHRs interoperable will contribute to more effective and efficient patient care by facilitating the retrieval and processing of clinical information about a patient from different sites.

Direct objectives of interoperable EHRs include [20]:

- Direct patient care
- Patient care management
- Patient care support process
- Financial and other administrative procedures
- Patient self-management.

On 7 December 2012, the European Commission adopted the "**eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century**" which clarifies the policy domain and outlines the vision for eHealth in Europe. This is in line with the objectives of the Europe 2020 Strategy and the Digital Agenda for Europe, aiming at addressing and removing existing barriers to reap all the benefits from a fully mature and interoperable European eHealth system. The barriers to deployment of eHealth are identified in: 1) lack of awareness of, and confidence in eHealth solutions among patients, citizens and healthcare professionals; 2) lack of interoperability; 3) limited large-scale evidence of the cost-effectiveness of eHealth tools and services; 4) lack of legal

[17] European Commission, European Reference Networks, Conference Report, 2017.
[18] European Commission, eHealth: connecting health systems in Europe, June 2016.
[19] WHO, From innovation to implementation. eHealth in the WHO European Region, 2016.
[20] Ingenico, e-Health in Europe, June 2012.

clarity for health and well-being mobile applications and the lack of transparency regarding the use of data collected by such applications; 5) inadequate or fragmented legal frameworks including the lack of reimbursement schemes for eHealth services; 6) high start-up costs involved in setting up eHealth systems; and 7) regional differences in accessing ICT services with limited access in deprived areas.

The strategy also underlines the most pressing health and healthcare system challenges. These involve clear objectives for improving chronic disease and multi-morbidity management and strengthening effective prevention and health promotion practices, increasing sustainability and efficiency of health systems, fostering cross-border healthcare, health security, solidarity, universality and equity and improving legal and market conditions for developing eHealth products and services. Specifically, the Commission strategy aims to: 1) achieve wider interoperability in eHealth services, addressing the technical and semantic levels (by fostering EU-wide standards, interoperability testing and certification), the organizational layer and legal issues (reviewing data protection rules and clarifying legal and other issues around mobile mHealth and "health and well-being applications"); 2) support research, innovation and competitiveness in eHealth, encouraging Public-Private Partnerships and other actions involving research and innovation and translation of knowledge to clinical trials and demonstration projects, Pre-Commercial Procurement and Public Procurement of Innovation for new products, scalability, interoperability and effective eHealth solutions supported by defined standards and common guidelines and mechanisms such as SME networking, eHealth Week, and business modeling studies to facilitate closer cooperation among stakeholders, research bodies, industry and those responsible for implementing ICT tools and services, to enable faster and wider take-up of research results in the market; 3) facilitate deployment and adoption of eHealth (through CEF, cohesion policy, digital literacy, measuring eHealth added value); and 4) promote international cooperation on eHealth at a global level.

In March 2015, the Commission developed the **Digital Single Market Strategy** which is built on three pillars: 1) better access for consumers and businesses to digital goods and services across Europe; 2) creating the right conditions and a level playing field for digital networks and innovative services to flourish; and 3) maximizing the growth potential of the digital economy. To achieve these ambitious goals, focusing specifically on health services, the Commission has launched several initiatives to ensure personal data protection and the opportunity for patients and authorities to benefit from new applications such as, for example, artificial intelligence and high-performance computing (also encouraging investments in telecommunications networks and technologies).

On 10 May 2017, the European Commission published **the mid-term review** of its Digital Single Market Strategy which identifies, regarding eHealth deployment, three priorities for EU actions: 1) enabling citizen's secure access to and use of health data across-borders; 2) supporting a cross-

border data infrastructure to advance research and personalized medicine; and 3) facilitating feedback and interaction between patients and health care providers, supporting citizen empowerment.

Envisaging a new policy communication by the end of 2017, the Commission launched a public consultation between July and October of 2017 on the healthcare transformation in the Digital Single Market to identify the need for further policy measures. The responses to the consultation largely identified important challenges preventing digital health and care solutions from being adopted across the EU and underserve people's needs, such as access to health data, diversity of Electronic Health Records, lack of technical interoperability, access to digital health services, the risk of privacy breaches, cybersecurity risks and the quality and reliability of data. After analyzing the results of this consultation, **on 25 April 2018**, the European Commission published a Staff Working Document and a **Communication on Digital Transformation of Health and Care in the Digital Single Market**, empowering citizens and building a healthier society giving direction to EU activities in this field for the coming years.

This communication identifies three priorities. The first is citizens' secure access to their health data, also across borders. The document defines several actions and initiatives to be developed, namely: a) review Commission Implementing Decision 2011/89037 pursuant to Article 14 of the Directive on patients’ rights in cross-border healthcare, in order to clarify the role of the eHealth Network in the governance of the eHealth digital service infrastructure and its operational requirements, as well as to improve the interoperability of patient data and access by the citizen; b) adopt a Commission recommendation on the technical specifications for a European electronic health record exchange format, while monitoring implementation of relevant EU legislation and considering other measures in the future if needed; c) further support the eHealth Digital Service Infrastructure to enable new services for people; and d) mobilize funds. The second involves personalized medicine through shared European data infrastructures across the EU. The Commission underlines the importance to set up a mechanism for the voluntary coordination of authorities and other stakeholders to share data and infrastructure for prevention and personalized medicine research, support the development of technical specifications for secure access and cross-border exchange of genomic and other health datasets within the internal market for research purposes, launch pilot actions, pooling data and resources across the EU and mobilize funds. Thirdly, citizen empowerment with digital tools for user feedback and person-centered care. The Commission aims to support cooperation to stimulate the supply and uptake of digital health by promoting common principles for validating and certifying health technology and the exchange of innovative and best practices, capacity building and technical assistance for health and care authorities, raise awareness about innovative procurement and investment possibilities for digital transformation in public health and healthcare, mobilizing relevant EU program and

financial tools, and promote knowledge and skills of citizens, patients and health and care professionals in using digital solutions in collaboration with health professional organizations and academia.

On 1 January 2019, **DigitalHealthEurope** – a co-ordination and support action on the digital transformation of health and care in European Union – was launched. The project will create multi-stakeholder collaborative platforms that directly reflect the digital transformation priorities. The platforms will work towards producing white papers and recommendations in the following three areas: better citizen access and control of data, better use of data infrastructure platforms to support secondary uses of health data, and active cooperation between patients and health and care professionals and providers.

Finally, considering that Member States have already started to make some parts of electronic health records accessible and exchangeable across borders (since 21 January 2019 - Finnish citizens can buy medicines using their ePrescriptions in Estonia and Luxembourg, and doctors will soon be able to access the patient summaries of Czech patients) - **on 6 February 2019**, the Commission presented **a set of recommendations for the creation of a secure system that will enable citizens to access their electronic health files across Member States**. Specifically, the recommendations propose that Member States extend this work to three new areas of the health record, namely to laboratory tests, medical discharge reports and images and imaging reports. In parallel, the initiative paves the way for development of the technical specifications to be used to exchange health records in each case.

2.3 Artificial intelligence in EU healthcare

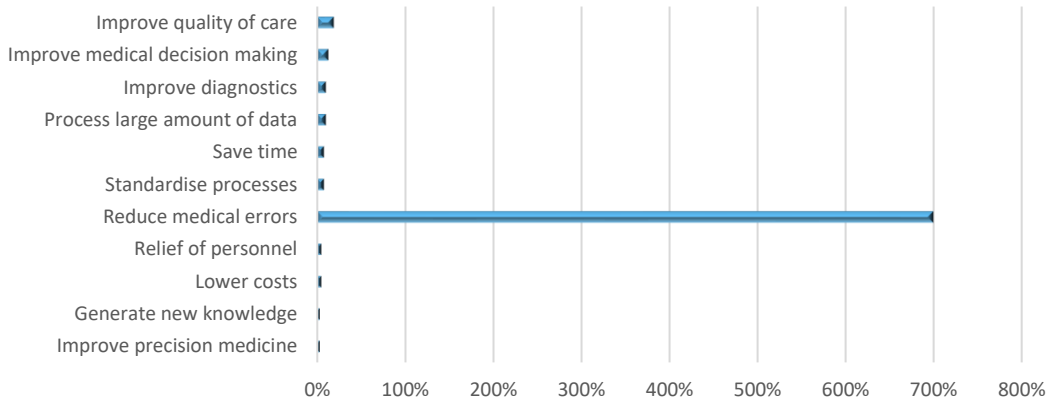
The list of things that artificial intelligence (AI) can do for the health sector is very long. AI has the potential to help doctors improve their diagnoses, forecast the spread of diseases, and customize treatment. AI combined with healthcare digitization can allow providers to monitor or diagnose patients remotely as well as transform the way we treat chronic diseases that account for a large share of health-care budgets[21]. AI is well known for advancing "precision medicine", an emerging approach to disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle. Now, thanks to cognitive computers, it is possible to make early and precise diagnosis and so identify a lifesaving therapy much faster than traditional methods where the patient's genetic data are manually examined. Another advance in healthcare through the use of AI is the ability to mine information that is held in electronic medical records. AI is also helping to speed up telemedicine. In addition, AI and robotics will open up new opportunities and will free up clinicians for other types of work that enable them to spend more meaningful time

[21] McKinsey Global Institute, ARTIFICIAL INTELLIGENCE: THE NEXT DIGITAL FRONTIER?, 2017

with their patients. Use of AI will also help with administrative matters in healthcare, which providers spend a lot of time doing, such as filling out charts, scheduling appointments, etc. This will allow providers to spend more time on giving actual patient care, which will improve outcomes and allow them to see more patients, increasing the accessibility of healthcare. AI can also help to cut healthcare costs.

One example of the usefulness of AI in healthcare is the use of algorithms that have been able to detect 95% of skincare instances in images. In 2020, the Commission will support via Horizon 2020, in coordination with Member States, the development of a common database of health images (anonymized, and based on patients voluntarily donating their data). This image database will initially focus on the most common forms of cancer, using AI to improve diagnosis and treatment[22]. Therefore, the main benefits of AI in healthcare have been identified by HIMMS Analytics[23] in its survey about AI use in European healthcare as improved quality of care (19%), improved medical decision-making (13%), improved diagnostics (10%) and the ability to process large amounts of data (10%) (Fig. 2.8).

Fig. 2.8: The biggest benefits from using AI in healthcare



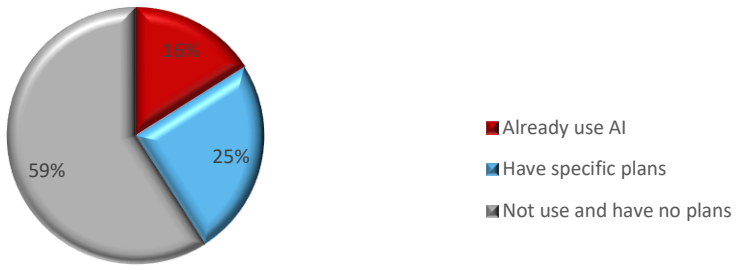
Source: Himss Analytics, eHealth Trend Barometer, May 2018

Despite these promised AI benefits in healthcare, only 16% of healthcare facilities in Europe already use AI, 25% have a specific plan and 59% of respondents do not use AI tools and have no plan to do so (Fig. 2.9).

[22] European Commission, "Questions and Answers: coordinated plan for Artificial Intelligence "made in Europe" *European Commission*, 7 December 2018, http://europa.eu/rapid/press-release_MEMO-18-6690_en.htm

[23] HIMMS Analytics, eHealth Trend Barometer, May 2018

Fig. 2.9: % of European health facilities using AI tools



Source: Himss Analytics, eHealth Trend Barometer, May 2018

Considering sectors in which European healthcare facilities use AI tools, Workflow Assistance (14%) and Research (13%) are the main areas, closely followed by Medication Administration (12%) and Radiology (11%). These areas, plus Oncology, are also where healthcare providers have most of their AI investment plans (Fig. 2.10).

Adopting AI requires addressing some challenges and risks. The main risks concern low accuracy, security and understanding that may cause various problems. Accuracy is important to preserve trust in these new technologies. A likely lack of trust in AI systems may significantly impinge on the adoption of technologies that may otherwise offer significant improvements in patient outcomes. Trust can be gained through greater transparency in how results are achieved, as well as putting into place some best practices that increase transparency and the level of information provided to patients relative to their data processing, and avoid collecting an amount of data greater than required to use AI models. Moreover, there is a need to draft clear policies that safeguard the privacy and the security of health data. All personal data can be identifiable. Therefore, it is critical that all data used is safeguarded. Given that there is an important distinction between clinical and non-clinical use, and the fact that data from non-clinical smart wearables may feed into clinical AI systems, it will be necessary to identify where clinical-level accuracy and reliability need to be implemented.

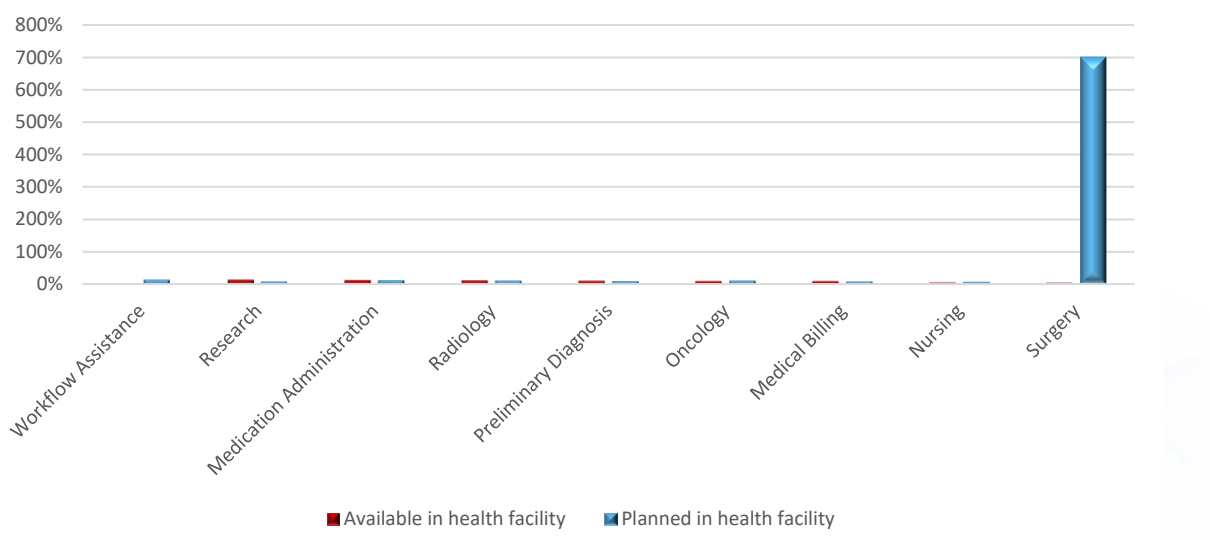
Another aspect concerns healthcare professionals' skills. Medical education would also need to be broadened to better include new technology and digital skills. For AI systems to be fully appreciated and implemented as they are intended within clinical practice, there would need to be dedicated training in understanding and working with these new technologies which will even take on certain clinical tasks with complete autonomy, such as diagnosis and surgery.

According to the HIMSS Analytics survey, lack of product maturity (13%) and trust from medical staff (13%) are perceived to be the biggest challenges for a more widespread use of AI in healthcare

by healthcare organizations in Europe, followed by data privacy (12%) and interoperability (11%) (Fig. 2.11).

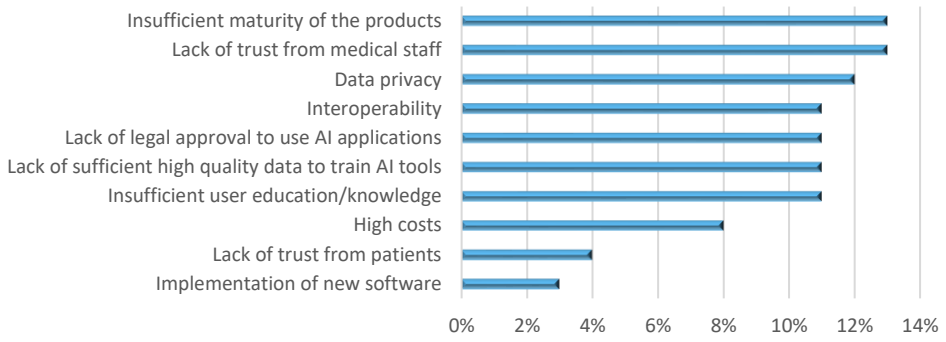
Italian eHealth professionals identify legal approval issues (21%) and lack of trust (20%) from medical staff as the biggest roadblocks for the more widespread use of AI solutions. Professionals from the Nordic countries are waiting for more mature AI solutions (18%), while Dutch professionals are challenged by data privacy regulations (17%) and Germans are concerned about high costs (13%).

Fig. 2.10: Fields where health facilities use or plan to implement AI tools



Source: Himss Analytics, eHealth Trend Barometer, May 2018

Fig. 2.11: The biggest challenges for AI in healthcare



Source: Himss Analytics, eHealth Trend Barometer, May 2018

Finally, in summing up market trends, according to some estimations, EU AI in the healthcare market accounted for the second highest revenue share in the global market. For the estimated period 2018-2026, the market is forecasted to grow at a CAGR of 39.27%. At present, the UK market accounts for the highest revenue share, however, German AI in the healthcare market is predicted to showcase the highest CAGR by the end of the projected years. The use of AI in innovative surgeries and its integration with existing systems are touted to provide this market with added advantages[24].

2.4 European initiatives on AI

Artificial intelligence has become an area of strategic importance and a key driver of economic development bringing solutions to many societal challenges, from treating diseases to minimizing the environmental impact of farming. However, there are a lot of socio-economic, legal and ethical problems to be carefully addressed to ensure competitiveness and to shape the conditions for its development and use.

On **16 February 2017**, the European Parliament adopted a resolution with **recommendations to the Commission on Civil Law Rules on Robotics**. It is an important document in which the benefits related to the increasing use of AI have been clearly described in terms, for example, of safeguarding workers in the more difficult or dangerous professions, but also, in general, the impact on the world of work and the skills required from workers.

The Parliament has clearly expressed the need to analyze new issues regarding access to data and the protection of personal data and privacy that have not yet been addressed, considering that applications and equipment communicating with each other and with the databases without

[24] https://www.inkwoodresearch.com/reports/europe-artificial-intelligence-in-healthcare-market/

human intervention represent a complex criticality. In this innovative context, Parliament underlines the necessity to adopt rules governing responsibility, transparency and accountability without, however, influencing the process of research, innovation and development of the robotics sector.

The European Commission is also aware of the opportunities, but also the critical issues linked to AI development.

In **May 2017**, the Commission published its **mid-term review of the Digital Single Market Strategy** underlining the importance of building on Europe's scientific and industrial strengths, as well as on its innovative startups, to be in a leading position in the development of AI technologies, platforms and applications.

On **9 March 2018**, the Commission launched a selection for **the creation of an AI working group** with the task, among other things, of preparing within the year a proposal for guidelines on ethical development and use of AI in compliance with the EU Charter of Fundamental Rights, considering issues such as fairness, security, transparency and the future of the world of work and democracy. On the same date, the Commission also opened a call for the formation of a group of experts on damage and new technology responsibility with the task of advising the Commission on the applicability of the Directive on damage liability regarding defective products to traditional products and new technologies.

Considering the importance of AI and the tremendous opportunities for growth connected to its deployment and usage, on **10 April 2018, 25 European countries[25] signed a Declaration of Cooperation on Artificial Intelligence**. Above all, the Member States agreed to work together on the most important issues raised by AI, to ensure Europe's competitiveness in the research and deployment of AI and deal with social, economic, ethical and legal questions. It was endorsed by the European Council in June 2018.

On **25 April 2018**, the European Commission published a communication putting forward a **European Approach to Artificial Intelligence** based on three pillars: 1) being ahead of technological developments and encouraging uptake by the public and private sectors with the Commission increasing its annual investments in AI by 70% under the research and innovation program Horizon 2020, reaching €1.5 billion for the period 2018-2020, connecting and strengthening AI research centers across Europe and supporting the development of AI applications in key sectors and an "AI-on-demand platform" that will provide access to relevant AI resources in the EU for all users; 2) prepare for socio-economic changes brought about by AI supporting business-education partnerships to attract and keep more AI talent in Europe and training and retraining schemes for professionals, also encouraging the modernization of Member State education and training systems and foreseeing changes in the labor market and skills mismatching; and 3) ensure an appropriate ethical and legal framework - the General Data

[25] Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, the UK, Norway.

Protection Regulation (entering into force from 25 May 2018) ensures a high standard of personal data protection, including the principles of data protection by design and by default guaranteeing the free flow of personal data within the Union and containing provisions on decision-making based solely on automated processing, including profiling. The Commission has also put forward a series of proposals under the Digital Single Market Strategy that will be a key enabler for the development of AI, such as the Regulation on the free flow of non-personal data, the ePrivacy Regulation and the Cybersecurity Act aiming to strengthen citizen and business trust. The Commission has announced that, by the end of the year, it will draw up a framework for stakeholders and experts – the European AI Alliance – to develop draft AI ethic guidelines, with due regard to fundamental rights. As well, in cooperation with the European Group on Ethics in Science and New Technologies, it issued a guidance document on the interpretation of the Product Liability Directive in light of technological developments and published, a report on the broader implications for potential gaps in and orientations for the liability and safety frameworks for AI, Internet of Things and robotics.

On **7 December 2018** the Commission published **The Coordinated Plan on AI** resulting from the work of the 25 Member States which signed the Declaration of Cooperation on Artificial Intelligence on April 2018. It details actions to be started in 2019-2020 and prepares the ground for activities in the following years. It will be reviewed and updated annually. Considering that only five Member States have already adopted a national AI strategy with a specific budget (France, Finland, Sweden, the UK and Germany) while others (Denmark, Luxembourg, the Netherlands, Ireland and Norway) include AI related actions in their broader digitization strategies, the document provides a strategic framework for national AI strategies encouraging their adoption. This Plan identifies some goals and actions: 1) reinforcing cooperation with the private sector; 2) strengthening excellence in trustworthy AI technologies and broader dissemination; 3) adapting learning and training program and systems to better prepare society for AI; 4) building up the European data space essential for AI in Europe, including for the public sector; 5) developing ethics guidelines with a global perspective and ensuring an innovation-friendly legal framework; and 6) better understanding security-related aspects of AI applications and infrastructure.

Moreover, on **8 April 2019**, the High-Level Expert Group on AI presented the **Ethics Guidelines for Trustworthy Artificial Intelligence**. This followed the publication of the guidelines' first draft in December 2018 on which more than 500 comments were received through an open consultation. According to the Guidelines, trustworthy AI should be: lawful - respecting all applicable laws and regulations; ethical - respecting ethical principles and values; robust - both from a technical perspective while taking into account its social environment.

Finally, on **26 June 2019**, the document "**Policy and Investment Recommendations for Trustworthy AI**" of the High-Level Expert Group on Artificial Intelligence was published. This document includes 33 recommendations that can guide Trustworthy AI towards sustainability, growth and competitiveness, as well as inclusion – while empowering, benefiting and protecting human beings. These recommendations focus on four main areas where Trustworthy AI can help

achieve a beneficial impact, starting with humans and society at large (A), and continuing then to focus on the private sector (B), the public sector (C) and Europe’s research and academia (D). In addition, they also address the main enablers needed to facilitate those impacts, focusing on availability of data and infrastructure (E), skills and education (F), appropriate governance and regulation (G), as well as funding and investment (H).

3. BRINGING INNOVATION TO PATIENT: EU VALUE-BASED HEALTHCARE

3.1 What does value-based healthcare really mean?

Improving performance and accountability in any field depends on having a shared goal that combines the interests and activities of all stakeholders. Achieving this is particularly hard in healthcare, where the stakeholders are numerous and often have different needs and goals, including access to services, profitability, high quality, cost containment, safety, convenience, patient-centeredness and satisfaction. Lack of clarity can lead to divergent approaches, a gaming of the system and slow progress in performance improvement. Traditionally, efficiency in healthcare has largely been interpreted in terms of cost reduction. However, more recently, healthcare policymakers in developed economies have interpreted the notion of value according to the willingness of health systems or individual health providers to follow the best clinical practice.

Moreover, European governments, like those in other parts of the world, are feeling the strain on their health budgets caused by an ageing population, a rise in the prevalence of chronic conditions and the acceleration of medical innovation that have increased demand for state-of-the-art-treatments and, consequently, are putting a good deal of effort into defining frameworks for evaluating and implementing value-based healthcare.

Increasingly more often, the concept of "value-based healthcare (VBHC)" is seen as an idea to improve our healthcare systems, yet there is no single agreed on definition of VBHC. Currently, value in the context of healthcare is often defined as "health outcomes relative to monetized inputs", where outcomes are changes in patient health resulting from treatment and care.

Health outcomes include mortality/survival, clinical measurements of treatment effectiveness and quality of life, and are often understood from patient-reported outcomes (such as symptoms, pain, mobility and ability to carry out normal day-to-day activities). Another important source of information on health outcomes is administrative data (e.g., hospital admissions and readmissions). However, this definition seems to focus on a solely provider-centered healthcare management approach aiming at increasing cost-effectiveness without considering wider system externalities.

In the last decades, the transition from the concept of paternalistic medicine to the modern paradigm of healthcare has been defined in clinical practice through evidence-based medicine (EBM) and in public health mainly through evidence-based healthcare (EBH), respectively. The early definition of EBM (Sackett, 1996) is seen as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

The latter emphasizes the need for the more thoughtful identification and compassionate use of an individual patient's predicaments, rights and preferences in making clinical decisions about their care. Evidence based healthcare was launched at the same time as EBM in an article written by J.A. Muir Gray (1997), *Research and Development at the National Health Service (NHS) Executive, Anglia and Oxford Region*, in the UK, the main concept being that decision-making on health services for individuals and populations should be guided by evidence on the need, effectiveness and ways to use resources optimally.

Policies and research could be used to support this approach but, frequently, decision-makers do not have the necessary skills to search for, critique, apply and store research evidence and reports. The author makes a plea for these 4 management skills and describes what they entail. Many changes have occurred since then including demographics and burdens of disease, advances in biomedical research, health technologies and personalized medicine, and the availability of large, population-based data sets.

Policy-makers will have to shape and tailor the future health systems to meet these changes. To address this, Michael E. Porter, in 2010, introduced the concept of value in healthcare describing it as "health outcome achieved per dollar spent" , expressing it as a ratio that prioritizes (i.e. the numerator) as the primary objective of any healthcare organization, the health outcomes achieved, being linked to the resources spent (i.e. the denominator).

Porter refers to a model based on a continuous performance evaluation, mainly referring to the structure and the organizations, transparently defining the process of continuous provider improvement committed to optimizing their health services. He maintains that achieving high value for patients must be the ultimate goal in healthcare delivery, with value being defined as the health outcomes achieved per dollar spent.

In this perspective, value-based healthcare means placing patients – both their experience and outcomes – at the heart of decision-making. In a well-functioning healthcare system, the creation of value for patients should determine the rewards for all other actors in the system.

Since value depends on results, and not on inputs, value in healthcare should be measured by the outcomes achieved and not by the volume of services delivered. Thus, the central challenge involves shifting the focus from volume to value.

The unit for measuring value (outcome relative to costs), Michael E. Porter underlines[26], should encompass all services or activities that jointly and successfully meet a set of patient needs which are determined by the patient's medical condition, defined as an interrelated set of medical circumstances that are dealt with as a whole.

Since care for a medical condition usually involves multiple specialties and numerous interventions, the benefit of any one intervention for an ultimate outcome will depend on the

[26] Michael E. Porter, Ph.D. (2010), "What Is Value in Health Care?", Perspective, The New England Journal of Medicine, December 23, 2010.

effectiveness of the other interventions throughout the care cycle. Because care activities are interdependent, value is revealed over time and is manifested in longer-term outcomes, such as sustainable recovery, need for ongoing interventions or occurrences of treatment-induced illnesses.

The organizational structure and information system of healthcare delivery make it challenging to measure value and providers are thus led to measure only what they can directly control in a particular intervention rather than what really matters in term of outcomes which require engagement from every part of a healthcare system.

Based on Porter's research, a framework for restructuring healthcare systems around the globe with the overarching goal of value for patients – and not access, cost containment, convenience or customer service - has been developed. It is based on 7 pillars that can be summarized as follows:

1. Creating an integrated practice unit. The greatest improvements in healthcare outcomes and efficiency will come from a sustained, team-based focus on a carefully defined set of medically integrated services and practices. Integrated practice units will achieve scope and scale by growing locally and geographically in their areas of strength, rather than expanding the breadth of their service;
2. Measuring outcomes. Outcomes are the ultimate measure of quality. In healthcare, measurement of value should focus on how well the care delivered meets individual patient needs. Measuring success, or the results of treatment, requires following the patient through the process of care, and looking at medical conditions and patients holistically.
   For example, for patients with diabetes, their medical condition includes co-existing hypertension, renal disease and retinal disease and success in treating diabetes incorporates the combined effect of caring for all of these;
3. Measuring costs. Cost is the actual expense of patient care, not the charges billed or collected, and it should be measured around the patient, aggregating it over the full care cycle for the patient's medical condition. It depends on the actual use of resources involved in a patient's care process (i.e. time devoted to each patient by these resources; capacity cost of each resource; support costs required for each patient-facing resource);
4. Bundling prices. Creating a value-based reimbursement system. Episode-based or bundled payments for complete cycles of care do the best job of aligning providers' incentives to deliver the maximum value to their patients. A bundled reimbursement payment covers all the treatments and interventions performed over a full care cycle for an acute medical condition;
5. Integrating systems. Clinically integrating care across separate units and facilities using Integrated Practice Units (IPU) structures;

6. Expanding geographically. Reducing fragmentation and geographic gaps in services by expanding strategically and integrating with community providers to extend the reach of Integrated Practice Units (IPUs);
7. Building an enabling information technology platform. Using information technology to help restructure care delivery and accurately measure results. Employing technology as a tool means establishing common data definitions and precise language definitions to improve reporting capability and effective outcome measurement; combining all types of data (e.g. notes, images) for each patient; aggregating data encompassing the full care cycle for a given medical condition and/or patient, including care by referring entities; allowing access and communication among all involved parties, including patients; creating standardized templates for medical conditions to improve usability and highlight the information most pertinent to managing a specific condition; collecting structured data, rather than free text, in patient records and adopting interoperability standards enabling communication among different providers and payer organizations.

Over time, the approach followed by Porter was recognized to be limited regarding its definition, since it did not take into consideration the sustainability of the entire health system. During the same period, adapting the concept of value to the European context, he introduced the definition of triple value healthcare as a solution to face the challenges of sustainability and innovation without waiving the universal coverage guaranteed by the National Health Service[27].

In an editorial published in the Lancet, Gray proposed a paradigm shift connecting value-based medicine to the population medicine approach: "even if an effective intervention is delivered at high quality without waste, it may still represent a low value activity if greater value could be achieved to treat another group of patients. [...] Clinicians, while still focused on the needs of the individual in front of them, [...], also are called upon to make decisions on the allocation of resources and there is a moral responsibility for doctors and healthcare professionals to maximize the value for all the people in the population they serve"[28].

A decade later, the OECD published its report on *"Wasteful Spending in Health"*[29] bringing to light the enormous amounts of public resources wasted and highlighting the need for health systems to spend their resources wisely and efficiently. The public debate on VBHC led to the concept of value-based healthcare with three distinctive aspects of value in countries committed to universal health coverage. In these countries, value includes efficiency but also the need to ensure that the resources are allocated and used to treat those people who would benefit most and to reduce inequality among the population in health access and outcomes.

[27] Gray J.A. Optimising the value of interventions for populations. BMJ 2012; 345:e6192
[28] Gray, J.A. 2013; The shift to personalised and population medicine. The Lancet, 382(9888), 200-201
[29] Organization for Economic Cooperation and Development (OECD), (2017), Tackling Wasteful Spending on Health.

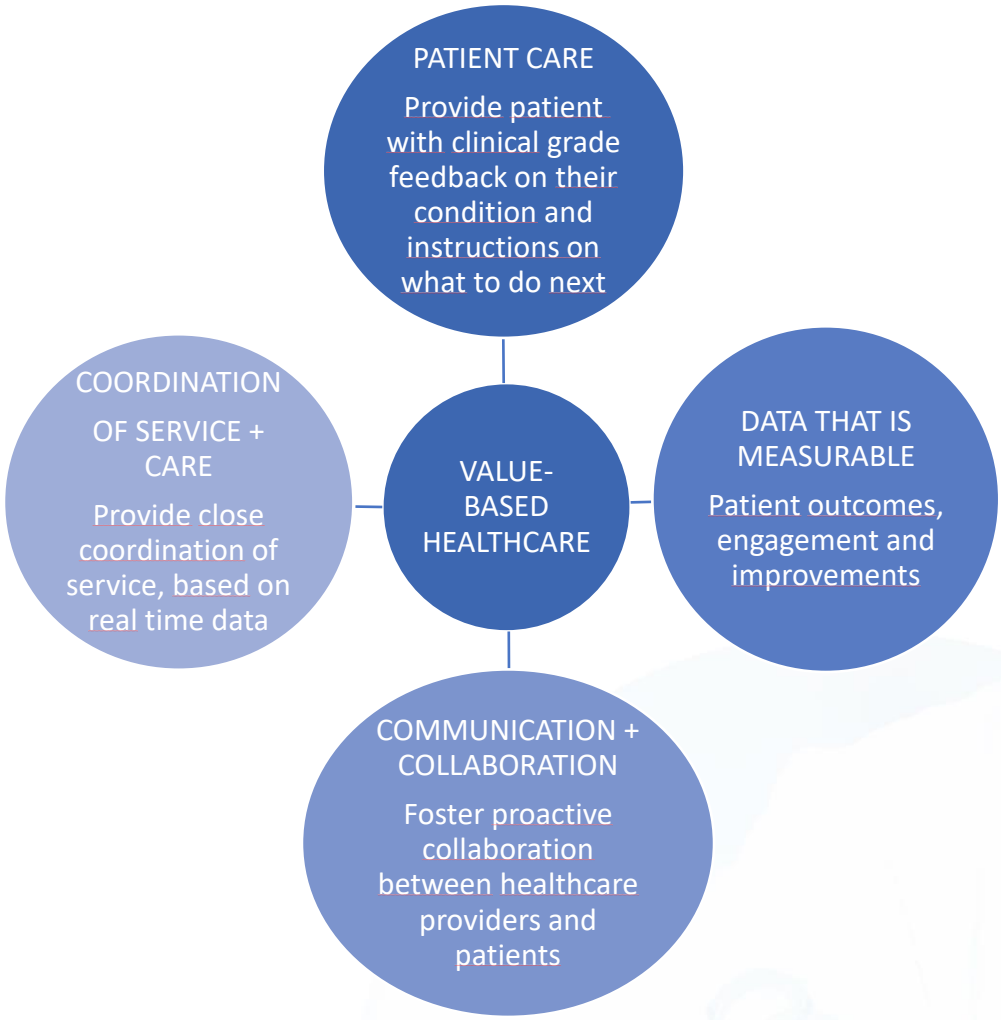
In this broader context, Porter's definition of VBHC and value-based pricing (VBP)[30] are not adapt to address values such as equity and affordability. In what is called a triple value model, supported by the Value Based Healthcare Program at the University of Oxford, the focus for countries with universal health coverage should be on three different types of value:

- Personal value – ensuring that each individual patient's values are used as a basis for decision-making that will optimize the values for him/her
- Technical value – ensuring that resources are used optimally - referred to as technical efficiency or simply efficiency by economists
- Allocative value – ensuring that resources are allocated optimally and equitably - referred to as allocative efficiency by economists.

Personal value, by definition, relates to the individual, technical value to the interventions available for a given condition, while allocative value relates to populations.

[30] VBP is the system of setting the cost for a healthcare service in which healthcare providers are paid based on the quality of care they provide rather than the number of healthcare services they give or the number of patients they treat. Value-based pricing may give patients access to better treatments for lower costs. This may help reduce financial stress or hardship on patients receiving medical care.

Fig. 3.1: Conceptualization of value-based Healthcare (M. Porter's approach)



Source: I-Com

3.2. Value-based healthcare in Europe

While a number of European countries have been measuring the cost and efficiency of healthcare delivery for some time, the focus on outcomes in the context of costs has only been evident over the past couple of years. Health systems are now increasingly looking at how improved patient management can lead to better outcomes, mainly focusing on comorbidities which are one of the factors making a patient expensive during throughout their care and life cycle. The Economist Intelligence Unit in a recent paper (2016) notes that half a dozen pilot projects are already underway in Europe, mainly built on the collaboration between hospital groups.

The Commission Communication from 2014[31] on effective, accessible and resilient health systems, which focused on the need for health systems to be resilient, adapting to changing environments and tackling significant challenges with limited resources, identified the following resilience factors that have helped some health systems safeguard accessible and effective healthcare services for their population:

1. Stable funding mechanisms which allow for effective investment planning and smooth continuity of services in organizing and managing care delivery;
2. Sound risk adjustment methods as a key tool to ensure that resources are spent according to needs;
3. Good governance – with well-defined responsibilities in running the health system and its main components, together with strong leadership, sound accountability mechanisms and a clear organizational structure enabling systems to adapt quickly to new objectives and priorities enhancing their ability to respond to major challenges by identifying and adopting the measures necessary to support smart investment decisions;
4. eHealth - based information systems implemented to strengthen information monitoring, including at the level of individual patients or healthcare providers, to enable health system managers to make tailored, evidence-based decisions in specific sub-sectors in helping to reduce error and minimize the length of hospitalization;
5. Adequate costing of health services Where health technology assessment is key to ensuring a common method in evaluating intervention efficacy and proper costing of services and, hence, allowing decision-makers to allocate resources efficiently;
6. A highly qualified and motivated health workforce with the right skills is essential for finding innovative solutions through organizational and technological change.

Even if the primary responsibility for health systems lies with the Member States, the European Union has taken a number of actions that can support them by providing guidelines as well as monitoring or evaluation tools. The Commission has set up an independent expert panel to provide advice on investing in health. This panel provides analyses and recommendations to the Commission on a number of relevant issues. In December 2018, **the Expert Panel on Effective Ways of Investing in Health** was requested to provide an analysis on the following points:

(a) How do you define value in "value-based healthcare"? What aspects of health systems could the different definitions cover?

(b) How can "value-based healthcare" inform decision-making, contribute to health system transformation and help health systems across the European Union become more effective, accessible and resilient?

[31] Communication from the Commission on effective, accessible and resilient health systems, Brussels 4.4.2014. COM (2014).

The rationale behind the latter involves the aim of the Commission to support its Member States in moving towards effective, accessible and resilient health systems. Effectiveness refers to the health system's ability to produce positive health outcomes improving the health of the population. The Commission recognizes that health systems today are under pressure to adapt and to modernize due to the rising costs associated with ageing populations, new technological developments and the changing epidemiology and, therefore, it is increasingly important to use the available resources wisely and efficiently. Value-based health systems can be seen as able to improve the quality of healthcare for patients, while simultaneously making healthcare more cost-effective. However, the Commission underlines that, at present, there is no single definition of value-based healthcare or even of what value means in the health context. Moreover, the interests and values of different stakeholders, such as payers, healthcare providers or producers of medicines and medical devices could not be aligned.

The expert panel (EXPH) adopted a draft opinion after a public hearing on 4 June 2019. The EXPH has recognized that the gap between needs and demand for healthcare and actual investments, correlated with a country's GNP, has been widening during the past fifteen years, constantly endangering the financial sustainability and access to universal healthcare. Persistent problems, highlighted in the draft, are the unwarranted variation of activities and outcomes of interventions, the underuse of effective interventions as well as inequity by disease and overuse causing a waste of resources and patient harm. A reallocation of resources is thus necessary to obtain sustainable and resilient European healthcare systems. The EXPH bases its opinion on the concept of solidarity, which is deeply rooted in European history. The political commitment to universal healthcare is indeed enshrined in Art. 35 of the EU Charter of Fundamental Rights and the concept of solidarity is perceived as a basic principle for practices, regulations and institutions, rather than only as a value. Access and equity, quality and performance, as well as efficiency and productivity, are the indicators for achieving the goal of a fair distribution of solidarity-raised healthcare resources to those in need and healthcare is considered to be an intrinsic value, i.e. a precondition for a 'good' life and socially cohesive European societies.

Given the above, and recognizing that currently "value" in healthcare is often only discussed related to increasing cost-effectiveness, the EXPH proposed to define "value-based healthcare (VBHC)" as a comprehensive concept built on four value-pillars, rather than three:

- Personal value
- Technical value
- Allocative value
- Societal Value

Societal value is the additional pillar to the previous triple value model. This value relates to whether the impact of the intervention in healthcare contributes to social cohesion, based on

participation, solidarity, mutual respect and recognition of diversity. It is important to note, that the value attached to health gains by patient and by society can conflict, given collective financing and the need for intervention and patient trade-offs. This means that small increases in health/lifetime can be seen as highly valuable for patients but less valuable for society. Both values, the EXPH underlines, should be taken into account and when necessary, trade-offs should be balanced to achieve allocative resource efficiency. Societal value goes one step further than allocative value by explicitly encompassing the broader aspects of health as an enabler for wellbeing, productivity and social cohesion, and recognizing that for eventual equally effective interventions the socially deprived may need to be prioritized.

In order to implement the VBHC as proposed by the expert panel, the main recommendation is to create greater health awareness as an essential investment in an equal and fair European society ('health is wealth'). The development of a standard language to allow for understanding waste, appropriate and inappropriate care, etc., and the training of healthcare leaders need to be part of the long-term strategy to reach this objective. The EXPH recommends fostering R&D methodologies on appropriate care, supporting the creation of learning communities to bring together the best expertise, experience and practice and measuring, benchmarking and learning, adopting actions, such as shifting resources from overuse to disease groups where there is evidence of underuse and inequity. Moreover, health professionals should be encouraged to take responsibility and feel accountable for increasing healthcare, which may require disinvesting resources in low-value care to reinvesting them in high-value care. Last but not least, patients should be involved in the decision-making process, in order to recognize the importance of patient goals, values and preferences through well-informed choices. Here a close interaction should be created at a European and national level in evaluating interventions, monitoring healthcare services delivered and surveying providers.

The main recommendation of the EXPH involves a multiple step strategy encompassing five different principles for implementation:

- Awareness of health for an equal and fair Europe
- Research and development on methodologies for appropriateness and unwarranted variation, including data analysis and quality registers
- Learning Communities for reallocation
- Accountability
- Patient engagement

3.2 The Expert Panel final report on effective ways of investing in Health (EXPH)

The EXPH adopted the final Opinion on Defining value in "value-based healthcare" at its 16th plenary on 26 June 2019 after a public hearing on 4 June 2019. The EXPH underlined again in the final version that the concept of solidarity is deeply rooted in European history and that it can be perceived not only as a value as such but also as a structuring principle for practices, regulations and institutions. Access and equity, quality and performance, as well as efficiency and productivity can be seen as indicators for achieving the goal of a fair distribution of solidarity-raised healthcare resources to those in need. In more detail:

- Access and equity are principles that contribute to the goal of social justice. Equity relates to fairness and recognizes that some people are more disadvantaged than others, resulting in health differences between socio-economic and other population subgroups. There is a responsibility to address this lack of equity by offering public services to reduce this gap. Access is related to the need for healthcare and the ability to benefit: arguments (by industry, patient groups) on "unmet need" for particular - often high cost - interventions fail to recognize that need is defined in terms of ability to benefit and alternative interventions are considered in the context of scarce resources and the necessity to make choices. With increasing examples of "unsustainable prices" for the treatment of some patients, "access to medicine(s)" has become a major topic in recent political discussions. Already within the Belgian Presidency (2010), later with the Dutch Presidency (2016) and lately the Austrian Presidency (2018), the topics of "equitable access and fair pricing" have gained prominence in discussions about innovative policies, as set out in an earlier EXPH opinion that examined initiatives to promote the rational and responsible use of valuable innovative medicinal products so as to obtain an optimal clinical outcome and efficient expenditure (in terms of affordability, accessibility and sustainability). Lack of (public and personal) affordability is a major barrier to access and equal access to high value care.
- Quality and performance: the principle of high quality, and well performing health systems relate to the question of whether the healthcare provided is fit for purpose, and therefore contributes to the goal to provide optimal (and safe) care to all who need it. 2 GINI index or coefficient: its value ranges from 0 (or 0%) to 1 (or 100%), with the former representing perfect equality (wealth distributed evenly within a country's wealthiest and poorest citizens) and the latter representing perfect inequality (wealth held in a few hands). Value-based healthcare 21 Health systems vary widely in performance, and countries with similar levels of income and health expenditure differ in their ability to attain key health goals. Performance is centered around three fundamental goals: improving health, enhancing responsiveness to the needs of the population, and assuring fairness of financial contribution. Health system performance

assessment (HSPA) measures the achievement of high-level health system goals, benchmarking against indicators and targets. Such quality or performance indicators encompass clinical outcomes (e.g. stroke mortality), avoidability of death or morbidity (e.g. diabetes-related burden of disease), avoidability of hospitalizations (e.g. asthma hospitalizations) and increasingly more often indicators of what matters to patients (Patient Reported Outcome Measures [PROMs] and Patient Reported Experience Measures [PREMs]). It is, however, important to appreciate that although low quality care is of low value; high quality care is not necessarily of high value, if the care is given to the wrong individuals, whose preferences have not been ascertained and/or the intervention does not address the problem that is bothering them most. Additionally, more value could be derived by investing those resources in another treatment for other patients.

- Efficiency and productivity: the principle of efficiency - weighing the outcomes against the resources used – contributes to the goal of producing as much value with available resources as possible. It should also take into consideration the fairness of distribution of resources to those in need. In contrast, productivity relates the outputs of the resources used. Productivity can be captured in different ways, for instance the number of knee replacement procedures per physician in a given time period. In contrast, efficiency measures the value produced from the resources spent, for instance how successful knee replacements are in achieving pain reduction.

Health is considered to be an intrinsic value: a precondition for pursuing a "good life", for obtaining other (vital) goals people wish to pursue in life. Since universal healthcare intends to provide health to the population (patient populations as much as the whole population), the "equitable" achievement of health for all is the precondition for social cohesive European societies. Currently, "value" in the context of healthcare is often discussed as "health outcomes relative to monetized inputs", aiming at increasing cost-effectiveness. This interpretation of "value" is perceived by the EXPH as too narrow and the notion of "value-based healthcare "seems more suitable in conveying the guiding principles underlying solidarity-based healthcare systems.

The EXPH therefore proposes to define "value-based healthcare (VBHC)" as a comprehensive concept built on four value-pillars: appropriate care to achieve patients' personal goals (personal value), achievement of best possible outcomes with available resources (technical value), equitable resource distribution across all patient groups (allocative value) and contribution of healthcare to social participation and connectedness (societal value). Propositions for implementation of VBHC (as defined by EXPH): To ensure financial sustainability of universal healthcare a long-term strategy towards a reallocation of resources from low to high value care – as defined in the EXPH concept is proposed. The EXPH recommends to create greater awareness of health as an essential investment in an equal and fair European society ("health is wealth") and

to the centrality of European values of solidarity. The development of a consistent language (of waste, in-/appropriate care, etc.) and the training of "change agents" (leaders) are as much part of this strategy as investments in piloting, monitoring and evaluating the reallocation and shifting of resources. The EXPH recommends to help in the R&D of methodologies for appropriateness of care to support the creation of Learning Communities to bring together the best expertise, experiences and practices and to measure, benchmark and to learn from each other putting in place actions in the EU (including the shifting of resources from budgets where there is overuse to disease groups where there is evidence of underuse), to encourage health professionals to take responsibility and feel accountable for increasing value in health care for populations, which may require freeing resources from low-value care to reinvest in high-value care and finally to support patients´ initiatives for engagement in shared decision-making (SDM), recognizing the importance of patients´ goals, values and preferences, informed by high quality information. To ensure the sustainability of universal health coverage, the EXPH identified value improvement as the single most important means of achieving this. Increasing value in our healthcare systems will require strong collaboration and intensive liaison that encompasses evaluation of interventions (to distinguish true innovation and identify low value interventions), monitoring healthcare services delivered (healthcare services research and planning to identify unwarranted variation and care of high value) and surveys of providers (ensuring that personal value by providing person-centered information to patients).

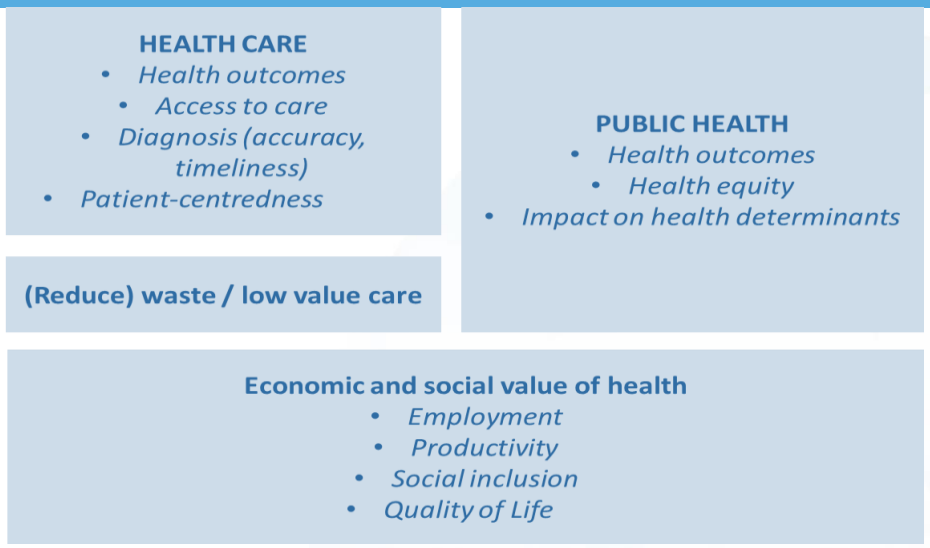
3.3. Health outcomes evaluation and comparability

For health outcomes to be comparable, whether at the level of clinicians, providers or countries (systems), it is important that the same measurement tools are used, and that data collection and coding practices are standardized. A number of organizations are active in developing standard sets of health outcome measures for key medical conditions. The International Consortium for Health Outcome Measurement (ICHOM), founded in 2012**,** is a good example of research and the sharing of knowledge (i.e. learning communities) on value-based healthcare. ICHOM brings together patient representatives, leading physicians and registry leaders to prioritize a core set of outcomes for different medical conditions. These are published in open-access Standard Sets, which hospitals use to guide the outcomes they should measure and provide practical advice and workshops for healthcare providers, so they can regularly measure the outcomes listed in the Standard Sets and help healthcare providers compare outcomes with peers, in order to identify best practices to improve patient outcomes and service quality. Moreover, ICHOM delivers keynotes and organizes workshops on the practice of value-based healthcare, and hosts national and international conferences to review the progress made towards value-based healthcare, encouraging best practice exchanges among healthcare providers.

Outcome Measures in Rheumatology (OMERACT) is another organization active in this field since 1998, focusing on the development of clinical and radiographic outcome measures for rheumatoid arthritis, osteoarthritis, psoriatic arthritis, fibromyalgia and other rheumatic diseases. While the initiative is led by an international group of health professionals, it involves Patient Research Partners at every stage of the OMERACT process. At the level of clinical research, the COMET-initiative (Core Outcome Measures in Effectiveness Trials) supports groups in the development of standardized core outcome sets (COS), representing the minimum set of outcomes that should be measured and reported (for a given medical condition) in clinical trials.

Summing up, the EXPH draft opinion argues that there are other important health system objectives and goals that must be included as part of a comprehensive definition of "value". Figure 3.2 provides an overview of the different dimensions of value in health systems, in healthcare and public health, as well as financial sustainability and the economic and social benefits of good health.

Fig. 3.2: Value-based healthcare, multi-stakeholder perspective



Source: I-Com

3.4. Existing policy tools and initiatives

On the basis of what was presented by the EXPH, it is easily understandable how access to healthcare should play a greater role in incorporating the social value among the four proposed pillars for the EXPH definition of value for healthcare.

To achieve this, some initiatives to increase polices for better value have been introduced and carried out by many countries. However, several of these policies aimed at obtaining greater value

per unit of health spending could have unexpected negative externalities in the long run, since economic agents tend to adapt to the context, modifying their behavior. This can be the case for pay-for-performance (P4P) and the introduction of cost-effectiveness thresholds.

- Pay-for-performance (P4P), also known as "value-based purchasing", is a payment model that offers financial incentives to physicians, hospitals, medical groups and other healthcare providers for meeting certain performance measures. Clinical outcomes, such as longer survival, are difficult to measure, so pay-for- performance systems usually evaluate process quality and efficiency, such as measuring blood pressure, lowering blood pressure or counseling patients to stop smoking. This model also penalizes healthcare providers for poor outcomes, medical errors, or increased costs. Integrated delivery systems where insurers and providers share in the cost are intended to help align incentives for value-based care. This kind of payment according to results often uses activity measures that are easily available, measurable and observable rather than outcome measures, thus leading to incentives given to greater activity in service delivery (input) that do not necessarily correspond to greater outcome.
- Cost-effectiveness thresholds are, instead, used to define prices by comparing the costs and benefits of alternative healthcare treatments. In such evaluations, health effects are compared to costs in monetary terms. The main results of a cost–effectiveness analysis – in which the costs and outcomes of alternative policy options are compared – are cost–effectiveness ratios. In the field of health, a cost–effectiveness ratio usually represents the amount of additional health gained for each additional unit of resources spent. A cost–effectiveness threshold is generally set so that the interventions that appear to be relatively good or very good value for money can be identified. Here, health effects are usually expressed either in terms of natural units (life years saved, fractures avoided, etc.) or in terms of QALY (Quality Adjusted Life Years) which is an outcome combining length and quality of life, based on preferences for different health states. When the incremental costs of a new intervention versus a relevant comparator has been calculated they can be divided by the incremental gain in health effects, resulting in an incremental cost-effectiveness ratio (ICER). This ICES is then compared to the cost-effectiveness threshold defined by policymakers which is often based either on the societal willingness to pay or on the opportunity-cost of healthcare spending. Many factors influence the results of cost–effectiveness analyses – e.g. the data used to estimate costs and effects, the choice of comparator and whether or not subgroups of the target population are analyzed. Variations in the inputs can have substantial effects on the estimate of a cost–effectiveness ratio. If the analyses do not reflect the policy context accurately, over-reliance on cost–effectiveness ratios and a fixed cost–effectiveness threshold, to guide decision-making, may result in the wrong decisions being made.

Cost-effectiveness analyses are being increasingly applied in the framework of Health Technology Assessment (HTA). HTA is generally defined as the systematic evaluation of properties, effects and/or impacts of health technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. The information from HTA should deal with aspects of a medical or health technology such as safety, efficacy, effectiveness, cost and cost-effectiveness and ethical and legal implications, both in absolute terms and compared to other competing technologies. A health technology can be described by its physical nature (drugs, biologics, devices, medical procedures, public health programs), purpose (prevention, screening, diagnosis, treatment) and stage of dissemination (experimental, established, obsolete). A single health technology may fit into more than one category – consider technologies that combine characteristics of drugs, devices or other major categories – and often a technology can be assessed in a report for certain indications and characteristics rather than for others. HTAs can differ in both the technologies assessed and in aspects considered in the assessment. Figure 3.3 reports the main categories of health technologies assessed in WHO countries, together with the different aspects that can be considered in HTA.

Fig. 3.3: Aspects considered in HTA for different health technologies

Types of health technologies	Aspects considered
Medicines	Safety
Vaccines	Clinical effectiveness
Medical devices	Economic consideration
Surgical interventions	Budget impact analysis
Service delivery models	Organization impact
Public health interventions	Equity issue
Clinical interventions	Ethical issue
	Feasibility considerations
	Acceptability of health care providers
	Acceptability of patients

Source: WHO Global Survey on HTA 2015

HTA goes beyond the mere evaluation of therapeutic interventions of EBM, considering evidence from well-controlled randomized clinical trials - essential to demonstrate a causal relationship between an intervention and an outcome and RCTs conducted in routine practice settings - to address broader questions to assess external effectiveness, thus creating a direct link between research outcomes and concrete health policy choices. HTA in Europe has developed through a combination of scientific, political and practical steps thanks to integration among EU Member States. The European network for HTA (EUnetHTA) was set up in 2006 with the mission of

promoting more effective use of financial resources, increasing HTA input in decision-making, strengthening the link between HTA and policy making, and supporting countries with less experience in HTA.

An important outcome from European cooperation through EUnetHTA is the HTA Core Model, which aims at enabling national and transnational production and sharing of HTA results in a common format and at representing a wide range of perspectives. Other outcomes included a handbook on HTA capacity-building, a toolkit for adapting existing HTA reports to other settings, and two databases of on-going projects and additional data collection on new technologies. The whole set of the HTA Core Model domains define a full/comprehensive HTA since they also address economic, ethical, organizational, social and legal aspects of assessment, while the first four domains, which only concern clinical characteristics and testing, are defined as rapid REA (Relative Effectiveness Assessment)[32]. In September 2016, the European Commission launched a public stakeholder consultation to explore how HTA cooperation at EU level could be sustainably carried out as well as being a support for Member States in their HTA activities. The consultation results led to a **proposal for a Regulation on Health Technology Assessment (HTA)** which covers new medicines and certain new medical devices, providing the basis for permanent and sustainable cooperation at the EU level for joint clinical assessments in these areas.

According to the regulation, Member States will be able to use common HTA tools, methodologies and procedures across the EU, working together in four main areas: 1) on joint clinical assessments focusing on the most innovative health technologies with the most potential impact for patients; 2) on joint scientific consultations whereby developers can seek advice from HTA authorities; 3) on identification of emerging health technologies to identify promising technologies early; and 4) on continuing voluntary cooperation in other areas. Thus, individual EU countries will continue to be responsible for assessing non-clinical (e.g. economic, social, ethical) aspects of health technology and making decisions on pricing and reimbursement.

3.5. Main shortcomings for value-based healthcare implementation

Although EU Member States are quite far from implementing pure VBHC models, the increased dialogue around VBHC emphasizes the need for systemic evolution of healthcare systems throughout Europe. Further, VBHC represents a change process and should be framed in a context of sustainability, as there is a monumental effort needed to redesign dimensions of healthcare – such as reimbursement mechanisms, procurement methods, and institutional relations - in order to facilitate VBHC systems. Ultimately, a shift toward VBHC will mark the dominance of a new point of view which recognizes healthcare expenditure not simply as an expenditure but an investment,

[32] I-Com (2017), Health Technology Assessment in the European Union State of Art and Future Scenarios.

which is calculated by multi-disciplinary expertise. This also means that in the future healthcare interventions should be promoted on outcomes rather than volume.

The Committee on Outcomes-based Healthcare, the policy research group created by the European Health Parliament - a movement connecting and empowering the next generation of European health leaders to rethink EU health policies created in 2014 – in its 2017-2018 report *"Boosting healthcare outcomes in Europe"*, highlighted the main shortcomings to drive the transition towards an outcome-based healthcare.

The first shortcoming in the report relates to the fragmented assessments of healthcare systems among European countries. In June 2011, under the Hungarian Presidency, the Council invited Member States and the Commission to reflect on identifying effective ways of investing in health, so as to pursue modern, responsive and sustainable health systems. At the end, in 2014, Member States agreed that they could play a stronger role in developing and exchanging knowledge on how to monitor and measure the performance of health-care systems.

In autumn 2014, the Commission, in cooperation with Sweden, set up the Expert Group on Health Systems Performance Assessment in order to provide participating members with a forum for exchanging experiences on the use of HSPA at national level, and to support national policy-makers by identifying tools and methodologies for developing HSPA.

The Expert Group was open to all EU Member States, EEA EFTA States, the OECD, the WHO Regional Office for Europe and the European Observatory on Health Systems and Policies. In the report published by the Expert Group on Health Systems Performance Assessment in April 2016[33], the Expert Group decided not to use a single, binding definition of quality of care since every participating country presented its experiences according to the definition of quality of care which was implicitly or explicitly adopted at a national level. This means that quality of care indicators is not standardized among countries and, moreover, indicator robustness varies for different diseases.

Last but not least, the interactions between quality and other performance aspects (e.g. efficiency, equity, access) should be further investigated and analyzed in future upgraded models with all indicators referring to the quality dimension being interpreted in a wider context of overall health system performance. In this context, the definition of targets and benchmarks is often problematic and implies degrees of subjective assessments.

In order to overcome this degree of fragmentation, increased Member State-to-Member State and cross-institutional cooperation is essential for addressing disparities and sharpening levels of expertise. EU and international transparent comparison of the performance of different hospitals,

[33] Expert Group on Health Systems Performance Assessment Report, SO WHAT? Strategies across Europe to assess quality of care, Brussels, April 2016.

including publication of patient outcomes per different hospitals, will be key in addressing the disparities

In order to inform policy-makers, the analysis of international comparable data should be complemented by the analysis of national administrative data, registry data and by the use of tools such as key informant surveys, additional focus groups or expert interviews.

Another challenge European countries still need to face, in order to implement a long-term strategy such as described by the EXPH, is data integration. Data integration and interoperability is necessary for the research and development of methodologies for value assessment. A well-functioning health information system is needed to measure quality of care systematically across hospitals, regions, health professionals and health-care units. Information should be relevant, timely available, comparable and reliable. Quality of data is a critical point and should be monitored to identify potential opportunistic behavior. Efforts should be constantly made to improve data collection without adding new administrative burdens, using, for instance, universal patient identification numbers, linkages between datasets and eHealth solutions.

Both health records and socio-economic data need to be codified and analyzed in order to both select the appropriate measure of quality and to weight trade-offs among population sub-groups to protect and attain equity and solidarity in the system regarding health status. At present, not all general practitioners currently record health data electronically, which makes it difficult to perform nation-wide analyses. Furthermore, wide variations have been observed in the definition of medical indicators and the structure of Electronic Health Records (EHRs) used to keep track of the patient's history (e.g. prescriptions, consultations and hospitalisation, etc.).

In this regard, a 2014 report of DG Connect comparing national legislation on EHRs revealed that less than half of EU Member States implemented specific rules and standards on EHR interoperability. Moreover, awareness of the importance of socio-economic data in evaluating the social and economic determinant of health status is often scarce. Unemployment, education, health literacy, living conditions and areas are essential in determining health outcomes and need to be taken into consideration when designing health policies based on value.

Value assessment is still based, in the majority of cases, on measuring input (healthcare spending) and processes rather than outcomes (e.g. preserving quality of life, reducing pain) which for both patients and society are more important. A patient with good outcomes in terms of quality of life, for example, is more productive, needs less healthcare and contributes to the sustainability of the entire system, both in economic and social terms. Analyzing outcomes without considering the positive effects that they have on other spending aspects and on the socio-economic system as a whole contributes to a silo assessment of value, narrowing the possibility for policies to profitably select areas of investment / disinvestment.

4. TOWARDS A EUROPEAN INDUSTRIAL STRATEGY FOR THE LIFE SCIENCE SECTOR

4.1. The life science industry in a nutshell

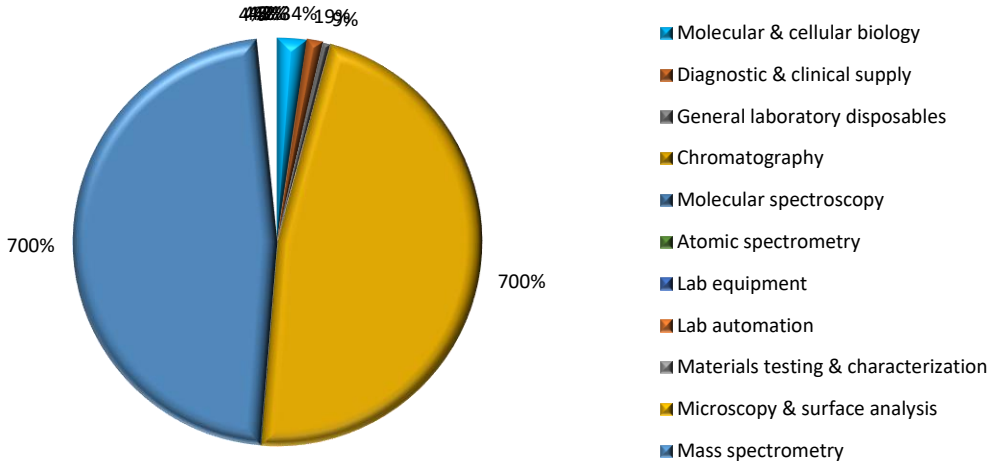
Today, the healthcare industry looks very different from ten years ago. New technologies have revolutionized healthcare – delivering benefits to patients and reducing healthcare costs, allowing patients to contribute to the labor market and the economy. Innovation in pharmaceuticals, medical devices, diagnostic technologies and, increasingly, digital health has transformed the way we deliver and manage treatments and organize healthcare systems. Although each type of health technology has its own distinct challenges, the increasing use of integrated, combined treatment options (that combine pharmaceuticals, medical devices, diagnostics and digital health solutions) are posing new challenges for the healthcare system. As Europe moves into the new legislative cycle (2019-2024), the time is ripe to examine the challenges and opportunities facing the healthcare life sciences sector in Europe over the next years, and to identify some of the common challenges arising across the wider life science sector, as well as those resulting from the combined use of health technologies. Each segment (i.e. medicines, medical devices, diagnostic technologies and digital health) shares some common challenges and, moreover, the use of these technologies in combination introduces additional challenges.

The main technologies included in the life science sector definition are:

- Medicines: any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. Medical technologies are products, services or solutions used to save and improve people's lives. In its many forms, they are with you all the time, from prevention, to diagnosis to cure.
- Medical technologies:
  - *Medical devices (MDs)* are products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means;
  - *In vitro diagnostics (IVDs)* are non-invasive tests used on biological samples (e.g., blood, urine or tissues) to determine the status of one's health.
- *Digital health and care* refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle.

Figure 4.1 shows the composition of the global life science market by segment at the end of 2018. The main portion of the market is represented by molecular and cellular biology (34%), immediately followed by diagnostic and clinical supply (19%) and general laboratory disposable (9%).

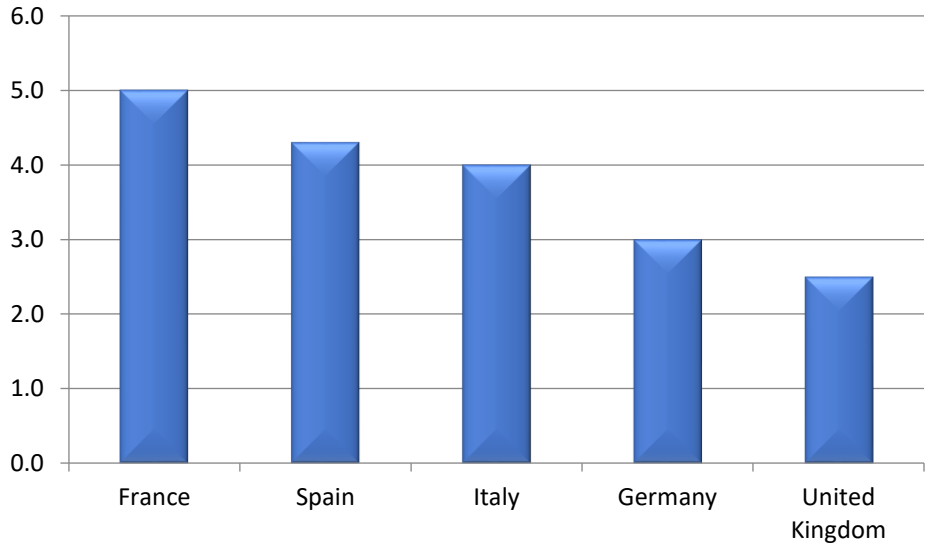
Fig. 4.1: Global life science market by segment (bill. $, 2018)



Source: UBS; Merrill Lynch

Comparing the disposable data for the main European countries, it is interesting to note that the added value of the life science industry, given by the sum of the manufacture of basic pharmaceutical products and pharmaceutical preparations and the manufacture of irradiation, electro-medical and electro-therapeutic equipment, represents a significant share in the total added value manufacturing. In France, this share is 5.5%, in Spain 4.3%, in Italy 4.1%, in Germany 3.3% while in the UK 2.5% (Fig. 4.2).

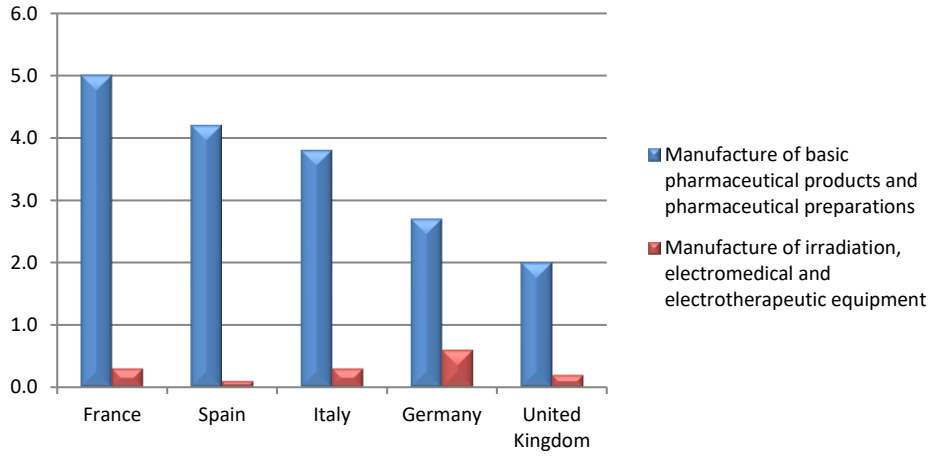
Fig. 4.2: Share of life science industry added value in manufacturing total (%, 2018)



Source: I-Com on OECD data

Nonetheless, in all of the above countries the most important segment in terms of manufacturing added valued share is represented by the manufacture of basic pharmaceutical products and pharmaceutical preparations, while the manufacture of irradiation, electro-medical and electronic therapeutic equipment still represents a lower share of the manufacturing total added value (Fig. 4.3).

Fig. 4.3: Share of added value in manufacturing total by sector (%, 2018)

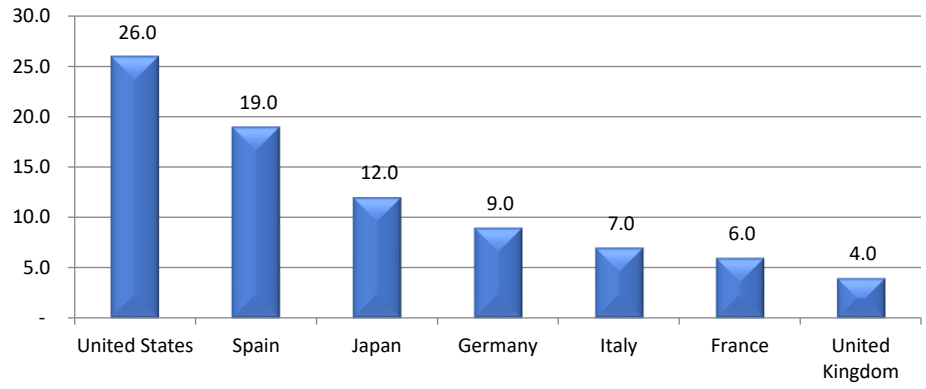


Source: I-Com on OECD data

4.2. Key trends in the EU life science industry

The life science industry, as defined at the end of the previous paragraph, is a highly innovative sector, in which the investments in R&D are crucial in driving medical progress and in improving patient health and quality of life. Comparing the main European countries with the United States and Japan, the gap between the shares in R&D expenditure out of the manufacturing total is worth mentioning. In the United States, this share is 26.8%, followed by Spain (19.5%) and Japan (12.4%). In Germany, Italy, France and the UK this share is, instead, below 10% (Fig. 4.4).

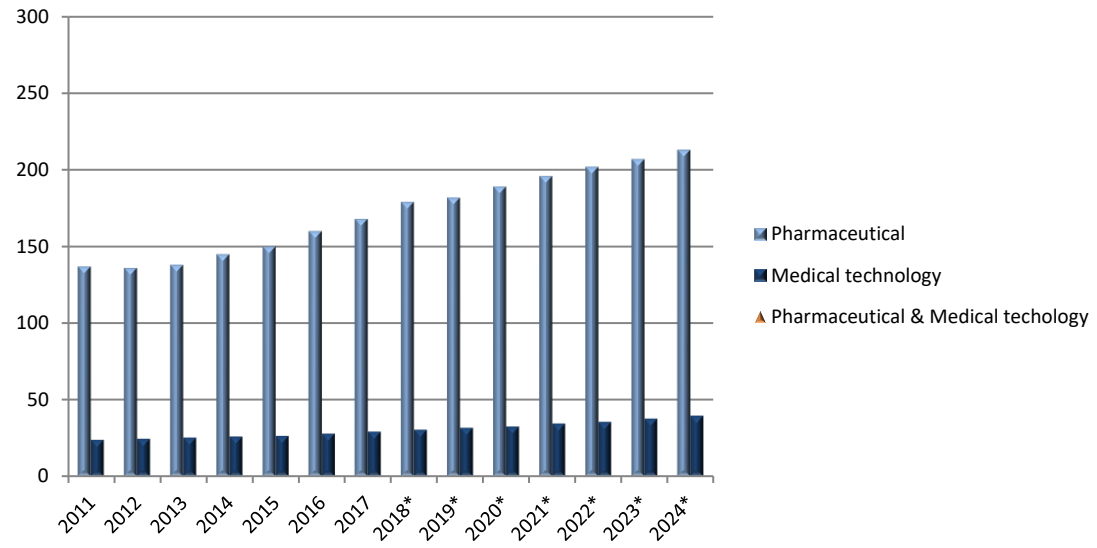
Fig. 4.4: Share of R&D expenditure out of manufacturing total (%, 2016)



Source: I-Com on OECD data

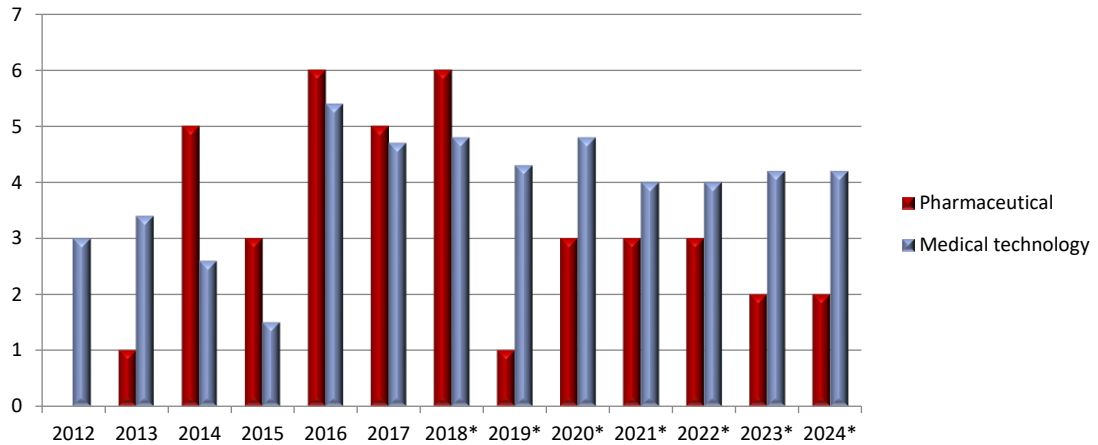
Figure 4.5 and Figure 4.6 show the global market size and R&D expenditure in the pharmaceutical and medical technology industry, respectively. For the pharmaceutical industry, the drivers of growth are predicted to be novel therapies that address key, unmet needs and increased access to medicines, as a result of new pricing policies around the world. Challenges to growth include payer scrutiny, sales losses due to genericization, and competition from bio-similars. At a global level, from 2018 to 2024, the average annual market growth rate is expected to be 6.4%, more than five times the 1.2% registered over 2011–2017. Meanwhile, the medical technology industry is projected to grow at an annual rate of 5.6% CAGR over the forecasted period 2017–2024. In 2019, worldwide medical technology sales are predicted to be US$475 billion, growing to US$595 billion by 2024. Moreover, by 2024, IVDs are expected to be the largest medtech segment with annual sales of US$79.6 billion, followed by Cardiology and Diagnostic Imaging. At the same time, globally, in 2018, pharmaceutical and medical technology companies spent $209 billion on R& D, against the $160 billion registered in 2011 (Fig.4.6) with an annual growth rate that reached its peak in 2018 (6.5%). Investments in R&D have registered a smart growth in the past ten years in both sectors and are projected to grow at a higher tax rate in the coming years.

Fig. 4.5: Global R&D expenditure by industry (bill. $)



Source: I-Com on EvaluateMedtech, EvaluatePharma (World Preview 2019)
*estimation

Fig. 4.6: Global R&D expenditure by industry (growth rate, %)



Source: I-Com on EvaluateMedtech, EvaluatePharma (World Preview 2019)
*estimation

As well as driving medical progress by researching, developing and bringing new medicines to the market that improve patient health and quality of life around the world, the research-based pharmaceutical industry is a key asset of the European economy, employing more than 750,000

people. As can be seen in Fig. 3, EU pharmaceutical production grew by an annual 4% in the 2000-2018 period, while R&D expenditure registered, at the same time, an average annual growth rate of 4.1% for a value of € 36,500 million in 2018. R&D employment reached 115,000 units in 2018 (Fig. 4.7).

Fig. 4.7: The Pharmaceutical Industry in Europe

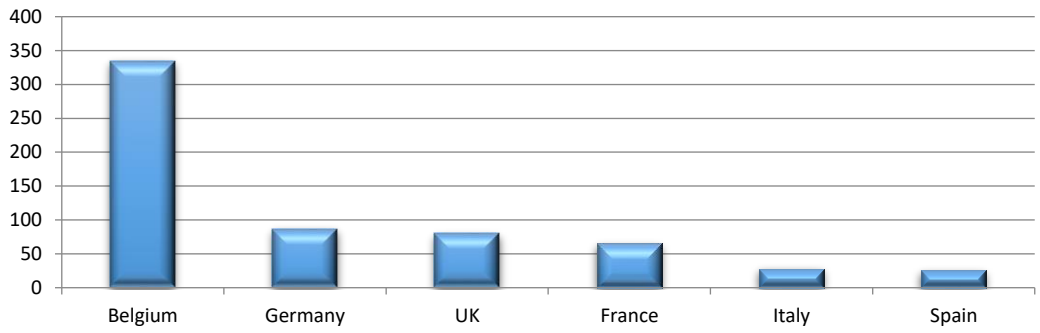
INDICATORS (EU 27)	2000	2010	2017	2018	CAGR 2000-2018
Production (million €)	127,504	199,400	250,868	260,000	4.0
Exports (million €)	90,935	276,357	396,036	410,000	8.7
Imports (million €)	68,841	204,824	294,632	305,000	8.6
Trade balance (million €)	22,094	71,533	101,404	105,000	9.0
R&D expenditure (million €)	17,849	27,920	35,318	36,500	4.1
Employment (units)	554,186	670,088	760,795	765,000	1.8
R&D employment (units)	88,397	117,035	114,655	115,000	1.5
Total pharmaceutical market value at ex-factory prices (million €)	89,449	153,685	208,949	220,000	5.1

Source: EFPIA 2019

However, looking at the pro-capita R&D expenditure in this sector, we find huge differences among EU countries. Italy only registers € 27,000 pro-capita R&D expenditure, while Belgium and Germany lead the list with € 334,000 and € 86,000, respectively. Belgium's result was due to the support that the government offered to the pharmaceutical industry through a series of tax incentives and support for the recruitment of qualified researchers. Through the adoption, therefore, of legislative measures that favour entrepreneurship and taxation for companies, such as deductions and exemptions for R&D investments and taxation incentives for immaterial rights,

Belgium has become one of the most attractive, globalized and fiscally interesting countries in the Eurozone (Fig. 4.8).

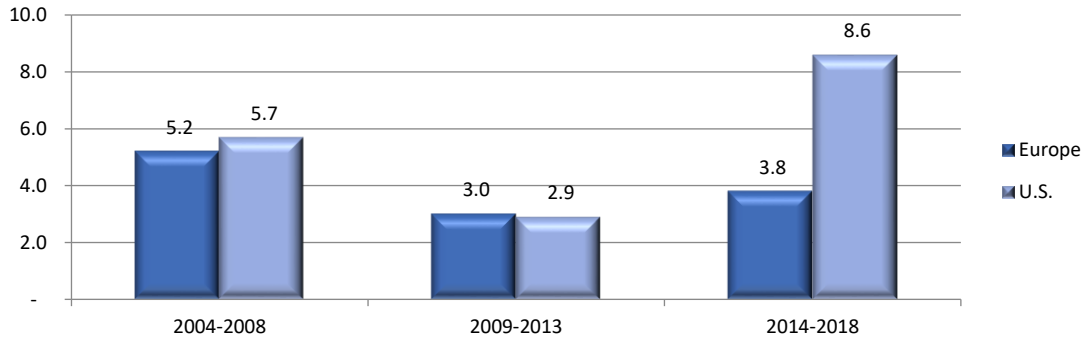
Fig. 4.8: Pharmaceutical R&D expenditure pro-capita (thousands €)



Source: I-Com on Eurostat data

If compared to the U.S, there is a significant gap with EU pharmaceutical R&D expenditure. In the 2014-2018 period, while R&D in Europe was growing at an average annual growth rate of 3.8%, in the U.S, it was at 8.6% (Fig. 4.9).

Fig. 4.9: Pharmaceutical R&D expenditure CAGR (%)

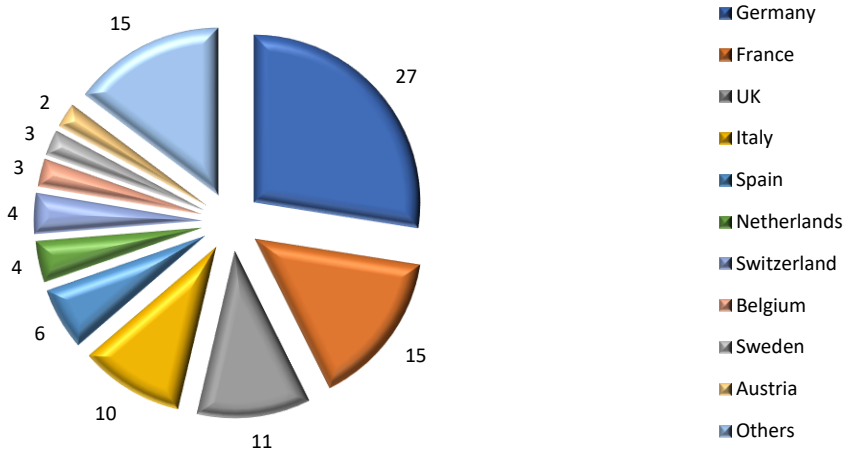


Source: EvaluatePharma (World Preview 2019)

The European medical technology market was estimated at being roughly €115 billion in 2017, employing more than 675,000 people. Based upon manufacturer prices, the European medical technology market is estimated to make up 27% of the world market and is the second largest

medical technology market after the US (43%). In medical technologies, the European medical device market has been growing on average 4.3% per annum over the past 10 years. Demand fell in 2009 due to the economic crisis, resulting in a growth rate of only 1%. The market than recovered in 2010, but growth rates fell again in 2011. European IVD market growth registered a slowing down until 2013, while its annual growth rates in the pre-crisis period had been at between 2% and 4%. The EU medical devices market is mainly represented by Germany (27%) and France (15%), followed by the UK (11%) and Sweden (10%) (Fig. 4.10).

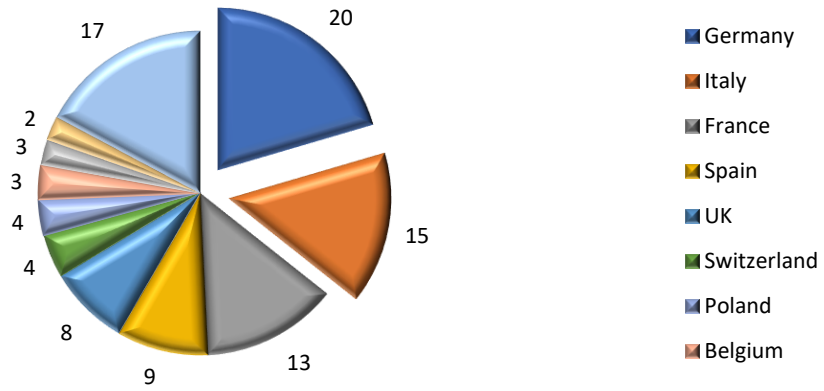
Fig. 4.10: European medical device market by country, based upon manufacturer prices (2017)



Source: MedTech Europe, The European Medical Technology in Figures (2019)

The EU IVD market is again mainly represented by Germany (20%) and Italy (15%), followed by France (13%) and Spain (9%) (Fig. 4.11).

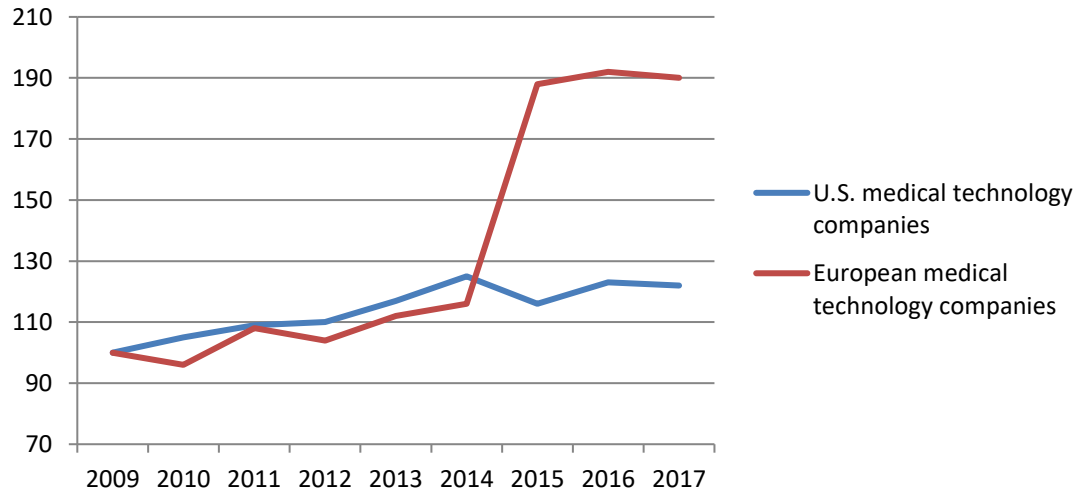
Fig. 4.11: European IVD market by country, based upon manufacturer prices (2017)



Source: MedTech Europe, The European Medical Technology in Figures (2019)

When comparing the R&D expenditure trends in the European and U.S. markets, we can see that European medical technology companies registered a significant increase starting in 2014, while U.S companies remained stable. However, in absolute values these investments were higher for U.S companies in all the 2009-2017 period.

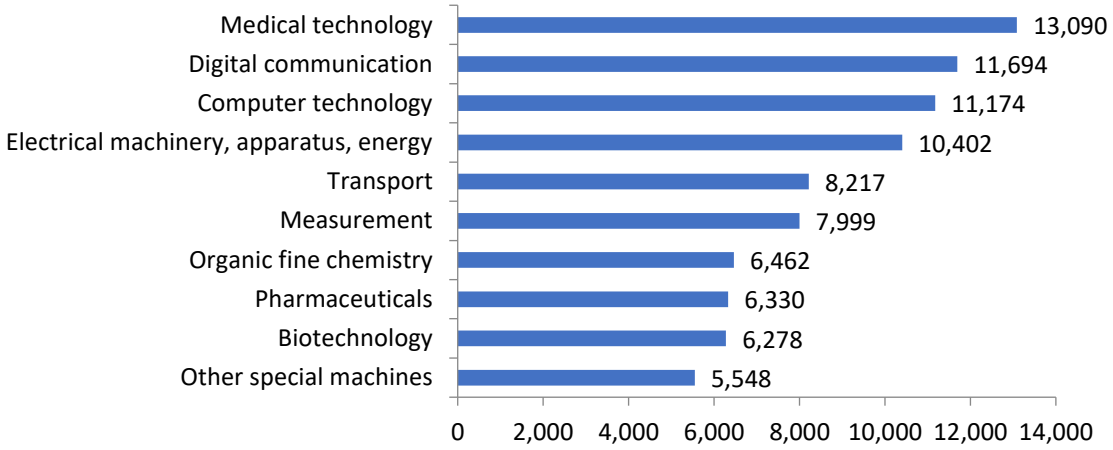
Fig. 4.12: U.S. and European medical technology companies' R&D expenditure (2009=100)



Source: MedTech Europe, The European Medical Technology in Figures (2019)

Medical technology is the first among the top 10 technical fields in patent applications filed with EPO (2017) numbering 13,090. Among the top ten, there are also pharmaceutical and biotechnology applications, with 6,330 and 6,278, respectively (Fig. 4.13).

Fig. 4.13.: Top 10 technical fields in patent applications. Number of patent applications filed with EPO, 2017



Source: EPO

According to the R&D investment scoreboard (2018), worldwide R&D growth was driven by the ICT services and producer sectors (13% and 11%, respectively), followed by the health sector (7.7%), while the lowest R&D performance was seen in other industrial sectors (3.3%) and in aerospace and defence (-4.3%). 577 out of the 2,500 companies investing the largest sums in R&D in the world are based in the European Union, and 111 of them regard the pharmaceutical and biotechnological industry or the healthcare equipment and services industry. The latter invested € 44.6 billion in R&D in 2018.

The knowledge originating from investments in research can be transformed into progress, meeting the many challenges that our modern society faces and, at the same time, guaranteeing more investments, more job opportunities and growth. Despite the necessary precautions to be taken in assessing what follows - related to cause and effect – it should be recalled that high performance in R&D is associated in the empirical literature with higher economic growth. Countries that have first understood the importance of fuelling the virtuous circle innovation-productivity-growth are those that are better positioned in terms of competitiveness and have showed greater resilience to economic crises. It should also be remembered that, in Europe, globalization, digitalization and the recent economic crisis have rewarded those industries with a production involving a higher added value and technological content. A recent analysis by Seboio

Public Affairs, *"Which Countries are Attractive for Life Science Investments in Europe, a Comparative Analysis"*, looks at the ability of different European countries in attracting life science investments by analysing four main categories: the political and social context, the overall industrial attractiveness, the life science research and innovation context, and the healthcare system. For these four categories, the study identifies 20 criteria and indicators that are the most relevant, and for which recent, publicly available and comparable data could be found for the selected countries. It compares European countries (Belgium, Germany, France, Italy, the Netherlands, Russia, Spain, Switzerland and the UK) with the United States and China. What results from this research is that, from a global perspective, the European Union has a much larger internal market than the United States and a wealthier internal market than China. The size and the wealth of the European Union make it attractive to investors. However, in life science and healthcare, this internal European market did not fully materialize. Research funds, health policy and taxation systems remain national and Europe's attractiveness could increase by being less fragmented and by increasing harmonization. Europe lags behind the US in life science research investments and in shifting academic research to commercial value, shown by limited venture capital. Within Europe, most investments go to the largest markets, with Germany, the UK and France attracting 51% of all foreign direct investments. However, smaller countries also manage to make a difference. Ireland scores best for manufacturing and has high scores for labour productivity, corporate and payroll taxes, gender equality, pharmaceutical reputation and quality of care. The Netherlands score well for life science academia, availability of qualified staff and quality of care, although industry-specific scores are much lower.

4.3. Overlapping issues and common challenges

Competition and the speed of technical obsolescence are increasing and the evolution of technology-oriented companies is changing the market structure (consolidation in some areas, fragmentation in others) and shifting to provide new value propositions, with implications across the value chain. However, the policy debate, to date, has still not focused on the shared challenges and opportunities facing different technologies, nor on the implications for policy reform that should be incorporated into a life science strategy. Such a strategy should account for shared challenges posed by integrated, combined use of technologies, but also consider the differences in sector needs. This is consistent with the "the urgent need for a comprehensive and long-term EU industrial strategy which should be in place at the latest at the beginning of the next EU institutional cycle" strengthened by the European Council[34].

[34] European Council meeting (20 June 2019) – Conclusions

When deciding where to locate their key value drivers, such as regional headquarters and R&D centres, life science companies consider factors including ease of academic collaboration, existence of clusters, quality of life for the workforce, and many others. Entering the European market for a life science company can be costly and time-intensive, also because the regulatory and healthcare landscape, as well as pricing and reimbursement frameworks are complex and fragmented among the European countries, notwithstanding the EU effort to harmonize. For the life science industry, the EU has made considerable progress in introducing common standards and regulations. Member States benefit from central regulatory bodies, such as the European Medicines Agency (EMA), but the pharmaceutical industry is heavily regulated with the entire lifecycle of products subject to various rules and regulations. While the procedure to obtain market authorization for a medicinal product in the EU is quite harmonized, EU Member State requirements vary considerably for local subsidiaries seeking authorization to commercialize and distribute a product. Concerning medical technology, the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) came into effect in May 2017 to replace the EU's Medical Device Directive (93/42/EEC), Active Implantable Medical Devices Directive (90/385/EEC) and In Vitro Diagnostic Device Directive (98/79/EEC). The new rules only fully apply after a transitional period. This period will last for 3 years after the regulation on medical devices has entered into force (May 2020), and 5 years after the regulation on in vitro diagnostic medical devices has entered into force (May 2022). The new regulations contain a series of extremely important improvements to modernize the current system, including:

- stricter ex-ante controls for high-risk devices through a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level;
- reinforcement of the criteria for designation and processes for the overseeing of the notified bodies;
- inclusion of certain aesthetic devices that present the same characteristics and risk profile as similar medical devices under the scope of the regulations;
- a new risk classification system for in vitro diagnostic medical devices in line with international guidance;
- improved transparency through a comprehensive EU database on medical devices and a device traceability system based on unique device identification;
- introduction of an 'implant card' for patients containing information about implanted medical devices;
- reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations;
- strengthening of post-market surveillance requirements for manufacturers;

- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.

Although the life science industry involves many different products, it is possible to identify some common issues that affect them in Europe and need to be faced in order to support the development of such an innovative sector. First of all, limited funding and budget silos (separate reimbursement systems). The discrepancies between how diagnostics are funded across markets, can impede access (e.g., budget silos between diagnostics and medicines in the diagnosis-related group (DRG)) and, moreover, funding for digital health is changing as there is no established reimbursement system for this technology. Secondly, evaluation methodologies. A shift to value-based care is a key enabler of personalized medicine and digital technologies, while inappropriate and inconsistent value assessment frameworks make assessment procedures insufficient to account for targeted treatments which are high cost but low volume. In this context managing market access for more innovative medical devices is becoming more challenging and, to date, the value assessment process for medical devices has not helped to facilitate market access. In addition, it is more challenging to calculate the value of the diagnostics, which in turn are important for determining treatment pathways. There is also a pressure to reduce costs and lower prices since healthcare systems are under enormous pressure as funding has not kept up with the increase in societal demand and the innovations entering the market. Meanwhile, the price of technology is becoming cheaper and the costs of diagnostics decreasing (e.g., next generation sequencing (NGS)). Consequently, this is resulting in a new wave of personalized therapies that are more expensive. There is a lack of clear regulatory guidance for new technologies and uncertainties regarding responsibility (e.g., should the EMA do more on eHealth) and the Regulatory framework is more reactive rather than proactive in keeping up with new technology developments or changes (e.g., bio-similars).

For the EU to remain competitive it needs to ensure that there is strategic support at both EU and national levels and that industrial and health policies are aligned. Indeed, foreign investors expanding throughout Europe benefit from a high level of reciprocal recognition of shared standards between the EU Member States. A research conducted by KPMG in 2018, "Site Selection for Life Science Companies in Europe", underlines the key aspects in selecting countries as potential hosts for life science players and investments. The following factors have been found to be particularly important in site selection in Europe:

1. innovation, size and specialisation of the life science industry: the life source of life science often works best in collaboration with peers, universities and suppliers, making life science clusters so valuable;
2. financing environment in the life science industry: the ability to attract financing is a good indicator of a life science cluster's strength and potential;

3. business and political environment;
4. infrastructure and connectivity;
5. workforce and productivity;
6. families and quality of life;
7. taxes and incentives: these are very important factors in site selection, especially true for intellectual property, a key value driver in industries such as life science.

At a first glance, the data is already quite revealing in terms of clusters and innovation hotspots. Figure 4.14 shows that the UK, Germany and France are popular locations for biotech in terms of numbers, while the percentage of therapeutic companies, a good indicator of innovation strength, is particularly high in Sweden and Switzerland (both 34%), Australia (48%) and Denmark (37%). With regard to medtech companies in Europe, Germany leads the field, followed by Sweden and Switzerland. Instead, the UK, Germany, France and Italy are popular locations for pharmaceutical companies. Overall, the research shows that the 56% of all listed companies are engaged in R&D activities, while 46% are in manufacturing. R&D on a contract basis seems to be less popular than manufacturing in countries such as Italy, Germany, Belgium and Ireland, while it seems to dominate in Spain, Switzerland, France, Denmark and Austria.

Fig. 4.14: Number of companies in the life science industry

Country	Biotechnology	Biotech-therapeutics	Medtech	Pharmaceutical
Austria	119	44	23	18
Belgium	260	47	60	40
Denmark	171	68	93	12
Finland	83	21	41	6
France	802	180	182	85
Germany	1073	178	531	102
Ireland	119	28	59	49
Italy	437	58	97	83
Netherlands	459	112	114	41
Norway	151	32	43	7
Spain	525	89	113	94
Sweden	500	170	282	46
Switzerland	463	159	264	76
UK	1180	328	319	121
Australia	219	106	65	31
Canada	940	248	370	111
Israel	275	134	449	28
Singapore	75	19	27	25
Taiwan	194	55	85	41
US-CA	1718	794	506	56

Source: Biotechgate 2018 and KPMG

As far as the financing of life science research in Europe is concerned, three main EU research and innovation programs are listed. According to the EU's official website, Horizon 2020 is the biggest research and innovation program, with nearly € 80 billion in funding available over the period 2014-2020. Then, the European Investment Bank (EIB) offers research and innovation loans to private and public sector organizations. Depending on the country of origin and nature of the entity, the loan may be supported by the European Fund for Strategic Investments (EFSI), Innovfin or other mandates managed by the EIB. Last but not least, the European Investment Fund (EIF) works with a wide range of financial intermediaries to improve access to financing for SMEs and small mid-caps across Europe. The emergence of new healthcare business models is changing the role of the existing innovators and how they interact with healthcare providers. This will require an environment that encourages innovation, adopting a joined-up approach that focuses on the integration of R&D, IP protection, life cycle manufacturing, healthcare system sustainability and fostering innovation in the European life science industry. It is essential for the EU to retain its

global competitiveness, especially vis-à-vis the US. Building on the March 2018 Council conclusions and renewing efforts over the new legislative cycle to develop an industrial strategy that takes into account all the challenges facing medicines, medical devices, diagnostic technologies and digital health, would help to foster a policy environment that can adapt to the changing needs of a new industrial health sector.

CONCLUSIONS

Promoting good health is an integral part of Europe 2020, the EU's 10-year economic-growth strategy. More specifically, health policy is important to Europe 2020 objectives for smart and inclusive growth because keeping people healthy and active for longer has a positive impact on productivity and competitiveness and because innovation can help make the healthcare sector more sustainable and find new cures for health conditions. Today, Europe is the region of the world with the highest life expectancy but this progress is slowing down, while inequalities between and within countries are widening. The challenges facing our continent related to population health status include an ageing population, the spread of chronic diseases together with unhealthy lifestyles and health threats such as antimicrobial resistance. Furthermore, there is also the problem of dealing with differences in the quality and access to healthcare services and the shortage of health professionals in different Member States. All of these pose challenges for the efficiency and thus sustainability of healthcare systems around Europe. Meanwhile the persistent digital divide and a growing polarization endanger the implementation of evidence-based policies, increasingly needed to lead policy maker choices from a “health in all policies” perspective. The cost of inaction in health can be disastrous, in terms of both human lives and economic impact. This report highlighted some crucial aspects of the state of the health in the EU, focusing on the prevailing issues that can lead the paradigm shift needed to support the improvement of healthcare systems around Europe towards a patient-centered, value-based and policy-integrated approach. The path for action starts with health promotion and disease prevention, to a credible evidence-based approach and ends in supporting and guaranteeing the uniform development of innovative solutions. Reducing the differences in social and economic backgrounds across the population through health promotion and disease prevention is the first step to reduce the differences in health outcomes and to attenuate the unmet needs. Acting through inclusive and consistent strategies in this context is thus an essential to reduce wasteful spending while guaranteeing equity in access to care for all the population.

Given the several challenges that the European Union is facing linked to the healthcare of its citizens, the digital healthcare transformation can be a major tool in enhancing the efficiency and integration of healthcare systems. Indeed, the transformation would guarantee the possibility to access to medical data on a European scale, not only by experts and physicians, but also by patients themselves, for this reason Europe should create a connected, interoperable and sustainable European healthcare data ecosystem which benefits from individual, private sector and public healthcare data. To achieve this objective, the European Commission should work to build a “data model” based on a federated network type of model in which different sources of healthcare data act as nodes in a network, in this way granting that data remain on site, unaltered and

uncompromised being only the final output of the data to be shared within the framework, under secure conditions. Another important target would be citizen empowerment, enabling them to access their health data under the abovementioned secure conditions among such a network, allowing for the exchange of data across borders and enabling all EU countries to reach the same level of healthcare standards.

Concerning the above, an important step is represented by the European Commission's recently adopted "Recommendation on a European Electronic Health Record Exchange Format", to further develop exchanges. The Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure cross-border access to electronic health data in the EU. The framework includes a set of principles, common technical specifications and a procedure to develop a European electronic health record exchange format. However, the keyword to develop the latter system should be "trust": an exchange of data among national health systems must be based on a series of ethical and legal principles alongside the existing data protection framework (the GDPR and NIS Directive). A second important issue linked to e-Health is its integration with the increasing development of artificial intelligence in this field. The benefits AI can offer are unquestionable, from the possibility to process large amounts of data to reducing medical errors and improving precision medicine and diagnostics. AI is indeed helping to solve some of the world's biggest challenges, however, it is in this specific field that AI assumes a major role. If used effectively, AI can make healthcare more accurate and accessible for all. Currently, AI clinical applications only amount to 16% in the EU, the reasons mainly being linked to lack of trust, data privacy and interoperability issues. The final EC Communication (2018)137 sets out a European initiative on AI, which aims at boosting technological and industrial capacity and, at the same time, ensuring an appropriate ethical and legal framework, based on the Union's values. Among the EU Commission's and EU Parliament's priorities[35] on the theme it is moreover possible to find the educational and professional upskilling of the workforce: the possibility to make an efficient use of advanced technologies is indeed bound to the ability of citizens and workforce to make a good use of them. In line with this, the High-Level Expert Group on AI presented the Ethics Guidelines for Trustworthy AI. The Commission's commitment also involves the financial aspect with € 2.6 billion being made available for AI-based research in healthcare funding. This is a good example of cooperation among the different DGs within the EC in a cross-cutting perspective, with the common goal of creating a more secure and structured framework for the Union and its citizens.

The possibility to collect, analyze and share data is at the basis of any defined evidence-based approach but, nowadays, this is not the only shortcoming to implementing a common value-based

[35] See European Parliament resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics (2018/2088(INI))

approach for healthcare. Indeed, fragmentation in approaches among Member States acts as a considerable hindrance to the efficiency of European healthcare systems. The lack of common measurements in the healthcare industry prevent a European definition of "value" even if its final definition given by the EXPH is hoped to pave the way for significant development and improvement in this context. Fragmentation is an important problem as, under a value-based healthcare approach (VBHC) framework, the outcomes of healthcare services must be subject to a common measurement to allow for innovation of medical practices. Fragmentation of outcome measurements results in deep inequalities in Member State capabilities, where one country can provide substantially better care than another. Fragmentation also exists between healthcare facilities in Europe, with profound differences in the care services of large hospitals and small hospitals that often lack enough patients with certain conditions so they, in turn, lack the expertise needed to treat these conditions. The impact of this fragmentation is serious, with patients at larger hospitals receiving, comparatively, higher quality care than those receiving treatment from smaller hospitals. Data and digital infrastructure are the quintessence of VBHC systems. Data analysis drives VBHC decision-making, enabling the detection of health trends and refinement of medical practices. In other words, VBHC views data as the ingredient of innovation. For this reason, all partners in the healthcare communities should join forces to bring forward initiatives that incentivize and enable data-driven high-value solutions and potential reallocation of resources in this direction. It is the case to remember that as the importance of data has been stressed by VBHC, citizens and stakeholders are increasingly worried about issues of data privacy and protection since medical data is particularly sensitive and requires stronger protection, as it concerns extremely personal and detailed information. The EU institutions should thus, consequently, consider a governance creation among all relevant stakeholders to increase trust, address concerns and look at the potential benefits of data driven healthcare.

Last but not least, another barrier facing VBHC systems comes from public budget constraints since the adoption of VBHC would demand redesigning state healthcare budgets, by virtue of its patient-centric and interdisciplinary nature. However, daunting this may seem, it would likely deliver substantial benefits in terms of patient outcomes and budgetary savings in the long run. Shifting the structure of state budgets from "reactive" to "proactive" would also allow healthcare services to conduct comprehensive disease monitoring and prevention efforts. This is vital, as late stage treatment is often the most expensive and least successful medical treatment. Moreover, owing to disease monitoring and prevention efforts, patients would receive a more tailored, disease-specific service which will provide superior outcomes compared to those delivered in the current system.

In this context, we cannot avoid considering that the integration of the different innovation in pharmaceuticals, medical devices, diagnostic technologies and, increasingly, digital health has

transformed the way we deliver and manage treatments and organize healthcare systems. Being attractive for the life science sector, investment should thus be considered as a key tool to support, develop, spread and provide equitable access to these solutions. The study by Seboio Public Affairs "*Which countries are attractive for the life science sector in Europe?"* proposed a comparative analysis of country attractiveness[36] for life science investment in Europe in comparison with the United States and China. It was based on four main criteria: the political and economic context, the industrial context, life science innovation and the healthcare environment. The study's main objective was to rank the different countries using the above-mentioned criteria and to finally identify the characteristics of the best possible (i.e. most attractive) country by aggregating the results emerging from the specific country analysis. The first picture resulting from the study appears to be extremely fragmented and limited, especially concerning investments from public and private actors in the life science sector, particularly if compared to the EU's international competitors. However, by aggregating all the data collected from the European countries, it should be highlighted that Europe scores better results in most of the criteria, except for those specifically referring to research, i.e. quality of life sciences academia, number of pharmaceutical staff, number of clinical trials and life science R&D investment. However, US public spending on R&D in the health sector, surprisingly, exceeds $36 billion and is substantially higher than in Europe.

In Europe, the low level of public investment in the health sector has resulted in a number of harmful effects on research and healthcare. Firstly, this lack has inhibited the development of innovative technologies and, at the same time, impacted the attractiveness for venture capital (venture capital in the US is four times higher than in Europe). Therefore, the ideal strategy to be undertaken should be aimed at making Member States an attractive environment for life science investment. To do so, a constructive dialogue needs to be set in motion among the different stakeholders, including the industrial sector, to identify the policy measures to be introduced to foster innovation, investment and quality care. A further point of reflection concerns the imbalance between quality and costs. Yet, the European scenario is extremely heterogeneous, with countries, such as Germany, displaying a high level of quality in terms of research and academic structures that, however, are not equipped with an adequate care system regarding results. On the other hand, countries with high results in healthcare, such as Italy, are facing significant difficulties in identifying a rational industrial strategy for an effective deployment of new technologies in the life science sector. A final point to be taken into account concerns the difficulties in determining the exact amount of investment actually needed for a given project or pathology, as well as the scarce availability of data to support policy decisions. The European Union will need to act in the near future in order to prepare and implement an actual European

[36] Belgium, Germany, France, Italy, the Netherlands, Spain, Switzerland and the UK.

strategy for life sciences and this should involve a more uniform approach to investments, a greater stress on education and skills, and a more accessible market. A first important point for reflection regards the fragmentation of the European scenario, and how it impacts research and innovation investment in the life science sector. An increase in European funding and public investment is undoubtedly a key starting point and, for this, Horizon Europe should be a major tool to foster innovation and, consequently, leverage further investment. However, an effective coordination is the first requirement to make the European scenario more accessible to innovators and investors.

Industrial, financial and health policies have become increasingly linked and should be part of a single rational mechanism. As healthcare is one of the largest areas for public expenditure in the EU, it is difficult for the European regulator to coordinate the different individual initiatives of the different Member States. The low number of countries willing to cooperate, as well as political instability (frequent changes in government), contribute to slowing down the process. Moreover, among the various sectors, the health sector is one of the most difficult to coordinate in terms of Member States' public power. A greater coordination must also take into account taxation and incentives aimed at manufacturing in life sciences. Intervening to facilitate the transition from research to development and, finally, new technology and device deployment is still one of the main goals to be achieved.

Investments in R&D should be understood in a broader sense, and addressed to the entire value chain. For instance, to benefit from the introduction of new technologies and devices on the market and in healthcare systems requires the availability of suitably trained staff. Universities and companies need to work towards a stronger cooperation. Finding ways to create research hubs and to strengthen investments in and by universities are major priorities to increase the European contribution to R&D in life sciences (in the USA, universities spend billions of dollars per year on R&D). Furthermore, the sector needs to become more attractive starting from education, increasing the number of students graduating in biology, chemistry, medicine, etc. Thus, a long-term approach is needed to identify an overall strategy to make education and training a priority and to further strengthen the sector. One of the most critical points regards the transition from research to the development and launch of new technologies and devices. Firstly, the cost of R&D, both for the private sector and for universities, must involve an *a priori* calculation, laying down a rational and planned path to take innovation forward. Market access is also made difficult by uncertainties related to the criteria that public authorities adopt to invest in R&I in healthcare and, especially, to foster the introduction of new devices in the healthcare system.

As well, corporate venture capital and open innovation should be actively encouraged in order to create thriving innovative ecosystems not only for large companies but also for SMEs, startups and scaleups, exploiting the huge European potential in terms of skills, talent and research.