INNOVATIVE EUROPE

**THE WAY FORWARD.
TAKING STOCK
AND THINKING AHEAD**

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EXECUTIVE SUMMARY

Chapter 1 provides an overview of the ecological transition of energy systems and transport at global and European levels, analysing their decarbonisation and reduction trends in energy demand within the framework of the UN Sustainable Development Agenda and the 2050 scenarios developed by the International Energy Agency. It emerges that, despite the policies of decarbonisation of energy systems and the commitments made by the States, global CO_2 emissions have increased almost continuously for decades, reaching the historical record of 33.1 Gt of CO_2. Furthermore, the medium / long-term emission scenarios show a wide gap between the trajectories of the current sustainability policies and those consistent with the Paris Conference goal to limit the rise in the average global temperature to well below 2°C. However, an important discrepancy in regional trends has been highlighted. If the Asia Pacific region drives the increase in emissions, the EU Member States reveal a more reassuring performance, highlighting the progressive decoupling between development dynamics and climate impacts obtained through the implementation of EU policies. The EU accounts for a third of CO_2 emissions, among the main global regions, with a share of 9%, which is predicted to decrease in all scenarios by 2050. Similarly, EU ranks third in energy demand, at 11%, which is also declining. Where greenhouse gas emissions are concerned in relation to the European economy, the greenhouse gas emissions

and GDP ratio narrowed by almost 30 percentage points between 2008 and 2017. Instead, energy consumption is still closely linked to the level of economic activity. As well, the share of energy produced from renewable sources in the EU rose from 11.3% in 2008 to 17.5% in 2017, with a significant growth in wind and solar energy - with Italy (18.3%) and Spain (17.5%) leading. The renewable energy consumption has grown continuously and exponentially from 2004 to 2018, from 28 to 160 Mtoe, while between 2004 and 2018, investments in clean energy increased by almost 150%, from US$ 30 billion to US$ 74.5 billion. New investments in clean energy peaked in 2011 to almost US$ 138 billion, growing at an average annual rate of 24% between 2004 and 2011., Instead, between 2011 and 2018, they experienced a marked decline, decreasing at an average annual rate of 8%.

Transport accounts for an important part of the world's energy demand and CO_2 emissions. Currently, it represents 20% of global primary energy consumption, increasing from 18.8% in 2010. This share will be maintained in the two International Energy Agency scenarios predicted for 2040 - between 20.8% of the Current Policies Scenario and 19.7% of the Sustainable Development Scenario. The share of CO_2 emissions produced by the transport sector out of total global CO_2 emissions amounts to 24.6%, compared to 23% in 2010. In the scenarios for 2040, it is expected to be between a minimum of 26.7% for the Stated Policies Scenario and

a maximum of 34.1% for the Sustainable Development Scenario. It is evident that transport sector needs large investments and adequate policies to achieve the desired decarbonisation goals. Transport in the EU registers a considerable share in both GHG emissions (23%) and energy demand (15.6%). The factors that consolidate the weight of transport in the European economic and energy system are manifold - the growth of air passenger transport, the increase in traffic and congestion, the growing number of people moving to (and within) urban areas, or the shift towards an even more individual and personalised mobility.

Chapter 1 also presents the most recent initiatives taken by EU institutions regarding the ecological transition. It focuses mainly on the eight actions of the Clean Energy Package and on the three Mobility Packages. Moreover, the ambitious plan of the European Green Deal is discussed, which fixes the goal of climate neutrality by 2050, analysing measures in in numerous fields (decarbonisation, energy efficiency, industry, production and consumption, large-scale infrastructure, transport, food and agriculture, construction, taxation, R&D and innovation). In order to achieve the goals set by the European Green Deal, consistent investments are needed. The Commission has estimated that in only achieving the current 2030 climate and energy goals, an additional €260 billion in annual investments, about 1.5% of 2018 GDP, will be required. The European Green Deal Investment Plan (EGDIP) is the investment pillar of the Green Deal. It will mobilise more than €1 trillion in sustainable investments over the next decade.

Part of the plan includes the Just Transition Mechanism, which will address a fair and just green transition, based on an ad hoc fund worth €7.5 billion, aimed at supporting the sectors and regions most affected by the energy transition. The Commission proposed 25% of its total budget to contribute to climate action and environmental goals across various programmes. Taken together, the EU budget will provide €503 billion to the European Green Deal Investment Plan, not including the additional national co-financing of around €114 billion on climate and environment projects. Over the period 2021-2030, InvestEU will provide around €279 billion in private and public investment to be used on various projects for climate and the environment. A central role is envisaged for the European Investment Bank, which has committed itself to doubling its climate target, from 25 to 50% by 2025, mobilisng between €25 and 30 billion according to forecasts. Then, in autumn 2020, a sustainable finance strategy will be launched that looks to private sector investments.

Chapter 2 focuses on the digitisation of the economy, services and infrastructures. The European Commission found that an efficiently functioning Digital Single Market could contribute €415 billion per year and create hundreds of thousands of new jobs, opening opportunities for people and businesses and enhancing Europe's position as a world leader in the digital economy. According to DESI, a composite index developed by the European Commission to examine Europe's digital performance and help EU countries identify areas requiring priority investments and actions, connectivity is the dimension

that has experienced the greatest progress since 2014, followed by the integration of human capital. The International DESI, created for comparing the EU with some major world economies, shows that South Korea is the most digitally developed economy, whereas the EU, as a whole, only performs better than China. The latter, way behind in 2013, is set to be catching up quite rapidly. The digital transformation also requires increasing network performance and continuous development in data capacity management. The Commission's strategy on Connectivity for a European Gigabit Society, September 2016, increased the targets set by the previous broadband objectives for 2020. The EU institutions have also set up a funding system which supports the financing of broadband network infrastructures, and the Connecting Europe Facility (CEF) to foster the deployment and modernisation of broadband networks. Looking at the progress made by EU countries in providing connections capable of a download speed of at least 30 Mbps to all households, the threshold reached a 83.1% peak in 2018. For ultrafast networks, almost 60% of European households have already been covered. The fast broadband take-up reached 53% of European households, while subscription for at least 100 Mbps connections were adopted by less than 20%. For mobile networks, 4G (LTE) broadband capacity served almost 99% of European households. The economic benefits resulting from mobile communications development are extremely important and Trinity College, Tech4i2, Real Wireless and InterDigital (2016) found that 5G could produce benefits of up to €113 billion per year by 2025.

On the other hand, investments required for 5G network implementation have been estimated to be more than €515 billion. However, spectrum allocation is very far from being complete, with less than 15% auctioned by September 2019, while only 2 countries (Finland and Italy) have allocated more than half of the dedicated bands. Here, a start to study incentives that could accelerate the spread of 5G within Europe could be a sensible measure. Digital transformation is considerably impacting consumers. E-commerce in Europe is forecasted to be worth €621 billion by the end of 2019. According to Eurostat data, 50% of European citizens made at least one online purchase in the last three months of 2018. Most individuals in the EU buy online exclusively from national sellers. Considering the importance of e-commerce spreading across Europe, the European Commission tabled a package of measures to allow consumers and companies to buy and sell products and services online more easily and confidently across the EU. The E-commerce Package was made up of legislative proposals to address unjustified geo-blocking and other forms of discrimination on the grounds of nationality, residence or establishment, to increase pricing transparency and correct regulatory practices and strengthen the enforcement of consumer rights and guidance to clarify, among others, what qualifies as an unfair trading practice in the digital world.

A cornerstone of the digital economy is represented by data. The data market value – the aggregate value of the demand for digital data without measuring the direct, indirect and induced impacts of data on the economy

as a whole – is expected to increase from the current €71.6 billion to approximately €106 billion in 2025, with the UK, Germany, France and Italy accounting for 64.6% of the total. Manufacturing and financial services lead in terms of data market size, with a value of €15 billion and €14.5 billion, respectively. The overall impact of the data market on the economy as a whole amounted to about €377 billion. Over the next 7 years, the total impact is expected to grow to 83%, reaching €680 billion. The impact of the data market on EU economies is currently low but is growing. The EU average, currently at 2.6%, is expected to increase to 4.2% by 2025. Even if Data Analytics skills are in high demand, supply is critically low, with employers facing severe shortages. In order to use and exploit the progressively increasing amount of data which is being produced, data analytics professionals are needed.

As well, the global artificial intelligence market is expected to experience a massive growth in the coming years. On a geographic basis, the US is expected to deliver more than 50% of all AI spending, led by the retail and banking industries. Among the main players that dominate the world scene of AI, startups account for a significant portion of innovation. According to 2019 CB Insights data, approximately 80% of the 100 most promising AI startups worldwide are based in the US, while Europe, with 769 AI startups, surpasses China.

AI will also have an impact on the labour market, related to organisation, new jobs, skills needed and training. According to the World Economic Forum, while 75 million jobs may be displaced, 133 million additional new jobs may emerge. Among the professions set to experience an increased demand, we find Data Analysts and Scientists, Software and Applications Developers, and Ecommerce and Social Media Specialists. Over the 2018–2022 period, only 58% of skills are expected to remain stable, an average shift of 42% in the required workforce skills.

EU institutions are also trying to enforce network cybersecurity. In recent years, Cybercrime, Cyber Espionage and Information Warfare have seen a marked rise. Cybercrime rose by 43.8% in 2018 compared to 2017, while Cyber Espionage and Information Warfare increased by 35.6% in 2018 compared to 2017. Therefore, in an increasingly digitalised world, cybersecurity has jumped to the top of the company risk agenda. The main and most costly impacts on organisations that suffered cyberattacks are loss of information, business disruption, loss of revenue and damage to equipment. European countries have improved their rankings due to initiatives such as the EU Certification Framework for ICT security products, the implementation of the General Data Protection Regulation (GDPR) and the Directive on Security of Network and Information Systems (NIS Directive). In 2018, six European countries with the highest level of commitment to cybersecurity were in the top ten most committed countries globally.

Finally, recent initiatives undertaken by EU institutions for a European AI strategy are being reviewed.

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 programme, 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 modernisation 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.

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.

Moreover, on 8 April 2019, the High-Level Expert Group on AI, set up by the European Commission, 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; and robust - both from a technical perspective while taking into account its social environment.

Chapter 3 focuses on the challenges that health systems across Europe face in the near future. 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. One of the steps needed for a paradigm shift towards more sustainable healthcare systems is thus integrating patient care across the continuum of life, bridging the gap between acute, treatment-driven demand, and normal, healthy living. In this context health promotion, and prevention are essential channels to invest in 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.

Moreover, 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, organisational 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.

In this context, it is acknowledged that value-based healthcare (VBHC) could give a valuable input to creating healthier, more equal and sustainable systems, improving health system performance and accountability. At the same time, European governments are feeling the strain on their health budgets and are thus putting a good deal of effort into defining frameworks for evaluating and implementing value-based healthcare. Yet, there is no single agreed definition of VBHC, although the EXPH, the European Expert Panel, began 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. 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 and data availability, collection and quality is a critical point.

Technology is thus 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. 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, 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.

Among the European countries, the northern countries display the best performance in terms of eHealth while most Eastern European countries show resistance to implementing this kind of solution. Delivering benefits to patients and reducing healthcare costs also entails significant investment in innovation by the life science industry worldwide. Innovation in pharmaceuticals, medical devices, diagnostic technologies and, increasingly, digital health has transformed the way we deliver and manage treatment and organise healthcare systems. 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.

After a description of the industrial sector and its potential in Europe both in terms of value and investments in innovation, the chapter continues by highlighting the main issues and challenges that the

EU is facing in attracting high value investment. When deciding where to locate their key value drivers, such as regional headquarters and R&D centres, life science companies consider factors such as ease of academic collaboration, existence of clusters, quality of life for the workforce, etc. 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 harmonise.

PART 1

TOWARDS THE EUROPEAN GREEN DEAL

1. TOWARDS THE EUROPEAN GREEN DEAL

1.1. ENERGY AND MOBILITY TOWARDS THE ECOLOGICAL TRANSITION: AN OVERVIEW

1.1.1. Energy: main trends in decarbonisation and consumption

The decarbonisation and efficiency of energy processes for the economic and transport systems is nowadays a shared goal of public policies at all levels. Environmental protection, the fight against climate change and the efficient use of resources are principles that inspire all policy-makers and are among the issues that most interest public opinion. We can see in the 2030 United Nations Agenda, which includes 17 sustainable development objectives, a large part concerns climate, energy and natural resources. Technological progress and the digital transformation that is affecting all areas of our lives contribute to achieving these results, sustaining process efficiency and the responsible use of natural resources. For these reasons, the major countries of the world have chosen to pursue a path leading to a progressive reduction in emissions and economy decarbonisation. In order to achieved this, without affecting income and employment levels, substantial investments and consistent public policies are required. In fact, despite the energy decarbonisation policies and the commitments made by states in the Conferences of the Parties on climate change, global CO_2 emissions have been almost continuously increasing over the decades (Fig. 1.1).
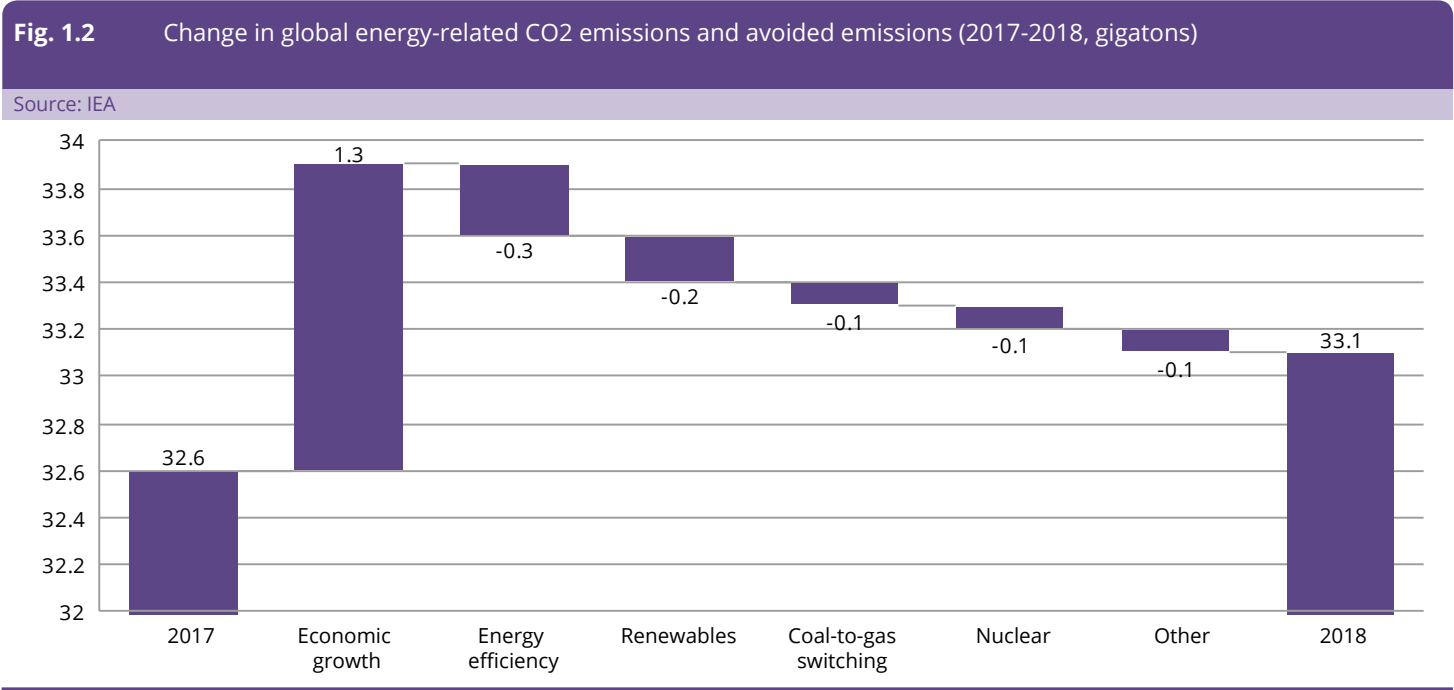
Fig. 1.1	Global CO2 emissions related to energy (1990-2018, gigatons)

Source: IEA
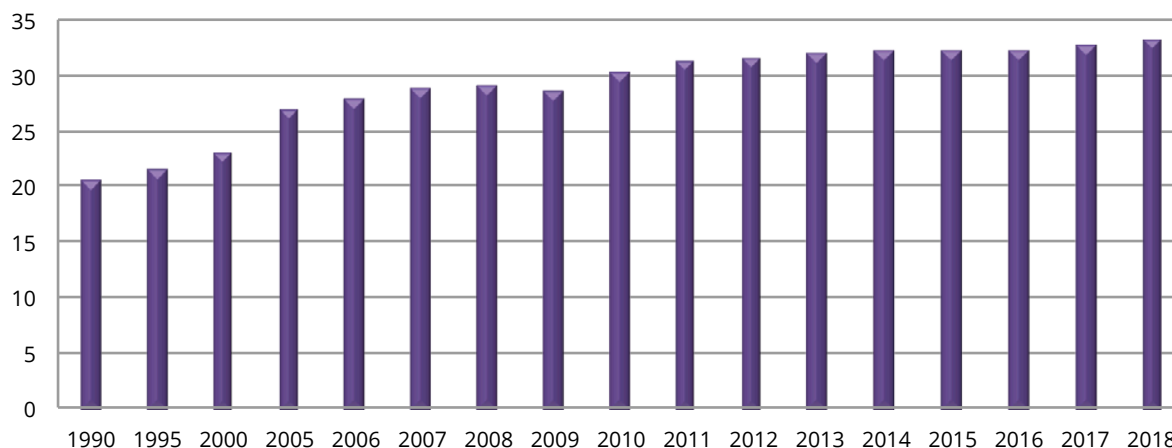
Only in 2018, according to the International Energy Agency, global energy-related CO2 emissions grew 1.7% to reach the historic record of 33.1 Gt of CO2. This was the highest growth rate since 2013, 70% higher than the average increase since 2010. To give an idea, the increase of 560 Mt in the last year is equivalent to the total emissions of international aviation. Similarly, the global average annual concentration of CO2 in the atmosphere amounted to 407.4 ppm in 2018, 2.4 ppm higher than in 2017. This is a significant increase compared to pre-industrial levels, when the concentrations varied from between 180 to 280 ppm. On the other hand, between 2014 and 2016, CO2 emissions had remained almost stable, despite the global economy

expanding. This decoupling between economic growth and increased emissions was achieved thanks to marked improvements in energy efficiency and the deployment of low-carbon technologies that had led to a reduction in coal demand. However, this changed between 2017 and 2018 with an increase in emissions mainly due to a rise in energy consumption linked to sustained economic growth (Fig. 1.2). Economic growth, therefore, was not met by higher energy productivity and the adoption of low-carbon solutions. In addition, climatic conditions in some parts of the world have resulted in an increased energy demand for heating and cooling. According to IEA estimates, CO2 emissions have grown by almost 0.5% for every 1% of global GDP growth, while, since 2010,

Fig. 1.2 Change in global energy-related CO2 emissions and avoided emissions (2017-2018, gigatons)

Source: IEA

the growth of emissions on average has been limited to 0.3%. Moreover, the expansion of renewables and nuclear energy power plants was not enough to limit the increase in emissions.

Therefore, despite the commitments made at the end of 2015 in Paris under the United Nations Framework Convention on Climate Change, and the fact that decarbonisation is considered one of the main drivers of energy policies, the medium / long-term emission scenarios reveal a wide gap between the current sustainability policies and those consistent with the objective of the Paris Conference in limiting the rise of the average global temperature to well below 2° C (Fig. 1.3).

However, an important discrepancy can be noted in regional trends with the Asia-Pacific region clearly driving emission increases. In China, between 2017 and 2018 alone, CO_2 emissions grew by 2.5%, driven by electricity generation from coal-fired power stations. India recorded a 4.8% increase, due to power and transport and industry growth, however, still remaining 40% below the global average for per capita emissions. On the other hand, the United States, which had previously reduced emissions, increased emissions by 3.1% in 2018. Nevertheless, it must be said that the United States has maintained its emissions at the 1990 level, 14% less than the 2000 peak. This is the biggest decrease, in absolute values, among all countries since 2000. In Europe, emissions have decreased by 1.3%. A decrease driven by the 4.5% fall in

Fig. 1.3   CO2 emission scenarios (Mt)

Source: IEA
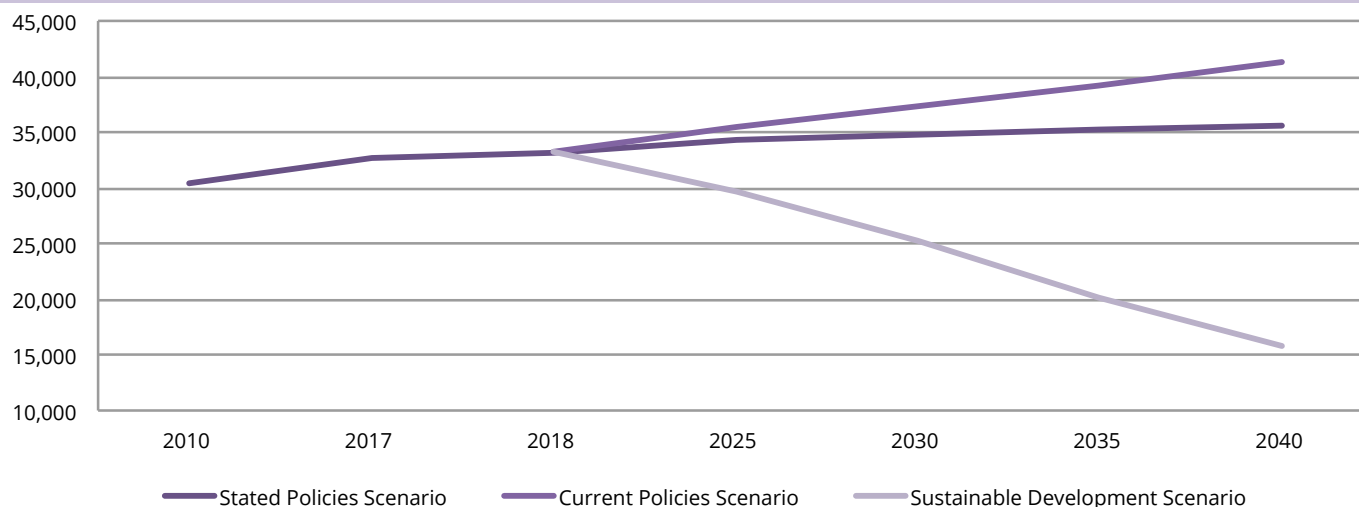
"Stated policies scenario" includes all the policies currently adopted and planned
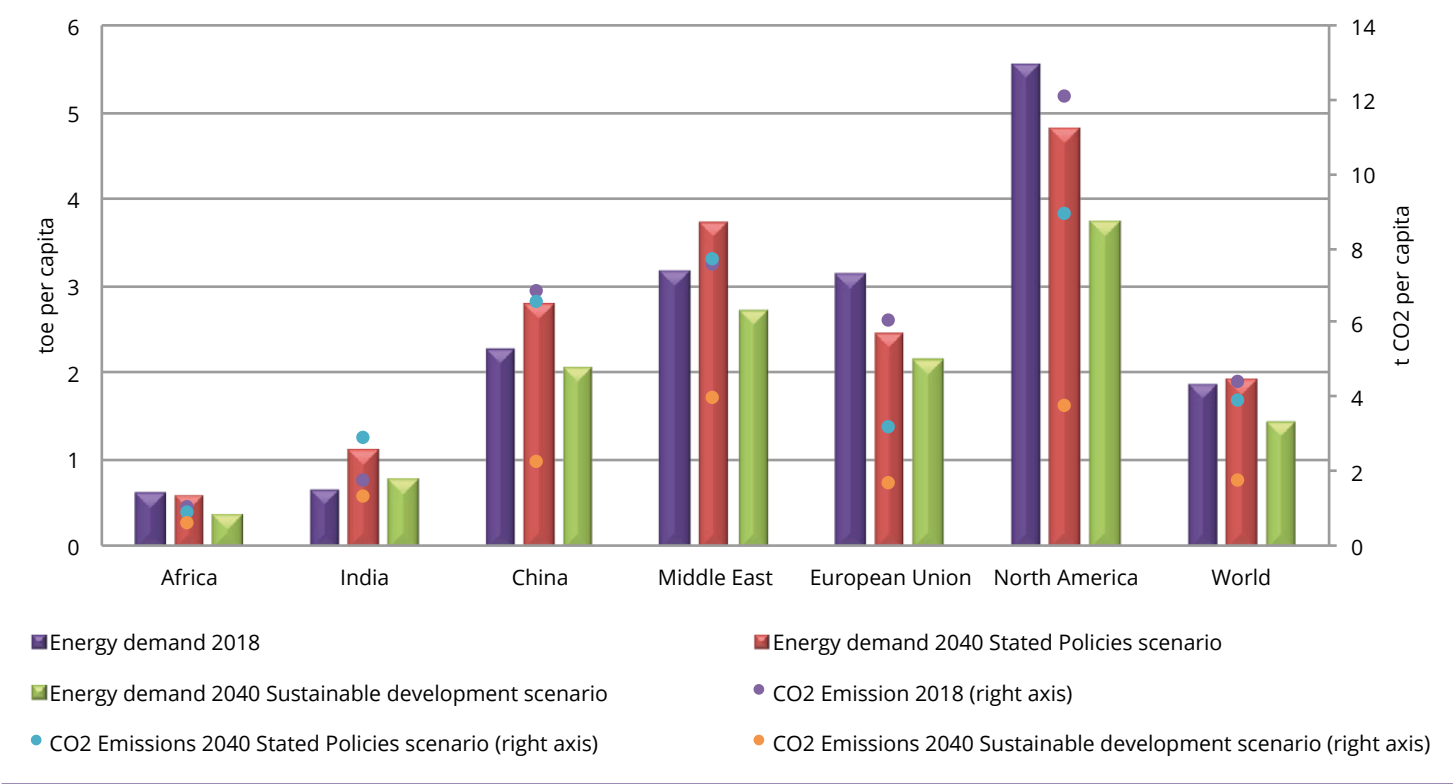*"Current policies scenario" includes all the policies currently adopted*

Germany, where both oil and coal combustion have fallen sharply, while power generation from renewables has reached a record 37% in the electricity mix. In general, EU Member States show a good performance, highlighting the progressive decoupling of development trends and climate impact achieved through EU policies. This virtuosity, however, is outweighed by the development trends in the non-EU emerging countries, and by the scarce attention in current policies of the other advanced

countries (especially, the US and China). According to the projections in the two main IEA scenarios for energy consumption and greenhouse gas emissions per capita aggregated by geographic areas, both for today, and by 2040, there is and will be a marked variability between the different regions considered (Fig. 1.4).

Differences in the diversity of the role of the world's major countries and regions in decarbonisation policies is evident if we consider their respective quotas on

Fig. 1.4 CO2 emissions and energy consumption per capita by region

Source: I-Com elaboration on IEA data

Energy demand 2018
Energy demand 2040 Stated Policies scenario
Energy demand 2040 Sustainable development scenario
CO2 Emission 2018 (right axis)
CO2 Emissions 2040 Stated Policies scenario (right axis)
CO2 Emissions 2040 Sustainable development scenario (right axis)

global CO2 emissions and energy consumption. For CO2 emissions, China is today the largest emitter at 29% (Fig. 1.5), and will maintain this negative record in all scenarios up to 2040, with a minimum of 20% in the Sustainable Development Scenario. North America follows at 18% to date (13% in the Sustainable Development Scenario). The European Union is in third position for CO2 emissions at 9%, however, in the Sustainable Development Scenario, by 2040 it should drop to 5% of global emissions. It would, therefore, fall to 7th place, after China, North America, India, the Middle East, Africa and Asean. India will experience the biggest increase, from the current

7% to 13% in 2040, for both the Stated Policies Scenario and the Sustainable Development Scenario. Similarly, Africa, which is currently at 4%, will reach 5% according to the Stated Policies Scenario, and 7% according to the Sustainable Development Scenario.

Similar results are obtained taking into account energy consumption. China is the world's biggest consumer at 22%, and will remain so in all scenarios up to 2040 (Fig. 1.6). North America follows with currently 16% of global energy consumption, and by 2040 reaching around 12%. The European Union ranks third, at 11%. By 2040, the EU will have consumed 7% to 8% of global primary energy

Fig. 1.5 Share of CO2 emissions by region (%)

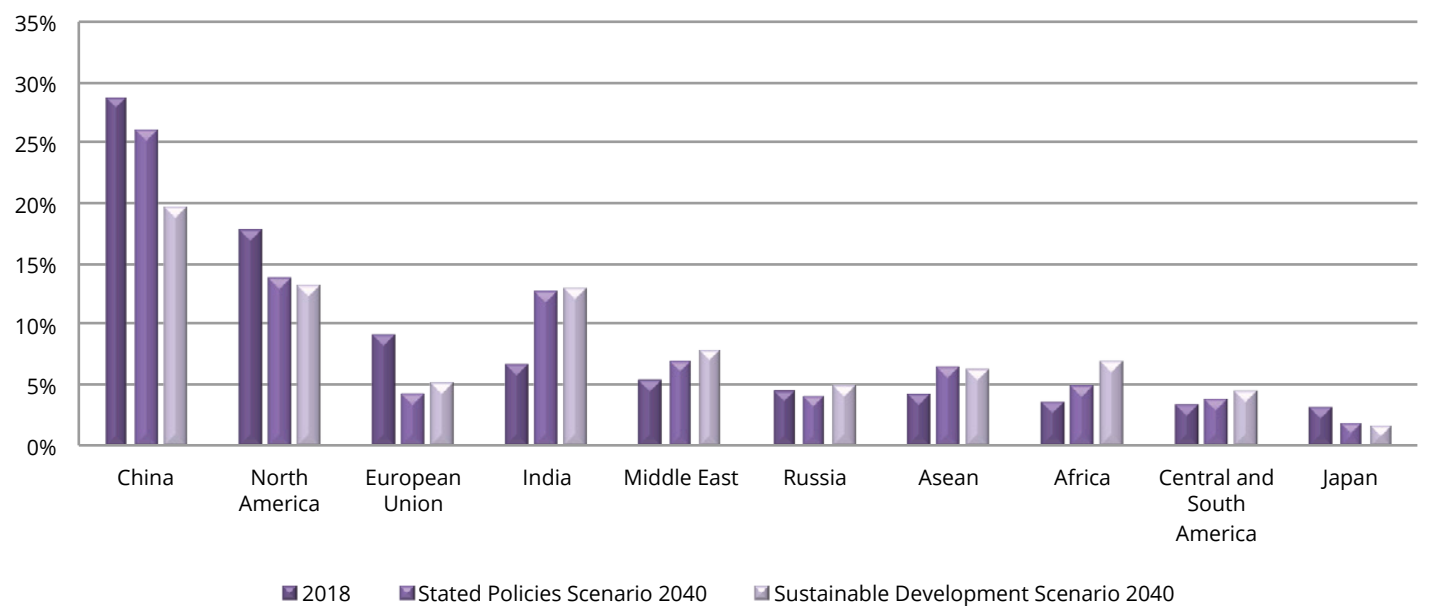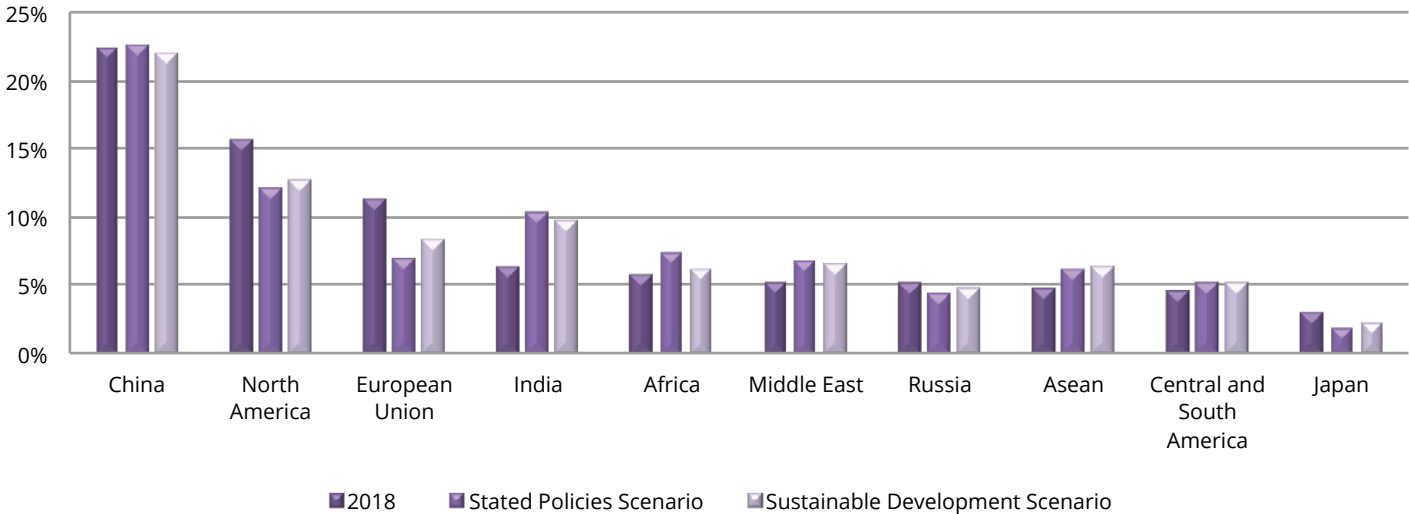Source: I-Com elaboration on IEA data

Fig. 1.6 Share of primary energy consumption by region (%)

Source: I-Com elaboration on IEA data

Legend: 2018 ■ Stated Policies Scenario ■ Sustainable Development Scenario

depending on the scenario considered. According to the projections to 2040, the EU will be surpassed in the ranking of the biggest energy consumers under consideration, by India and, according to the Sustainable Development Scenario, also by the African continent.

The European performance in the global scenario regarding emission reduction and more efficient energy consumption is the outcome of advanced energy and climate policies. The latter has led to a marked decrease in both the emission intensity of the economy and the energy intensity. Looking at the greenhouse gas emission intensity in relation to the European economy, the ratio between greenhouse gas emissions and GDP decreased by almost 30 percentage points between

2008 and 2017 (Fig. 1.7). This trend involves all major European countries: with France and Germany showing the same reduction percentages; Italy and, above all, the UK recording a decrease of 32% and 42%, respectively, compared to 2008; and Spain, on the contrary, showing a reduction of only 22%.

Energy consumption, however, is still closely linked to the level of economic activity. Between 2008 and 2017, the EU increased its energy demand in relation to GDP by 28% (Fig. 1.8). Among the countries considered, the UK and Germany show values higher than the European average (+42% and +35%, respectively). Spain, France and Italy register 12 to 25 percentage points higher in the considered period.

Fig. 1.7 GHG emissions per unit of GDP (2008=100)

Source: I-Com elaboration on IEA data

EU-28 — Germany — Spain — France — Italy — United Kingdom
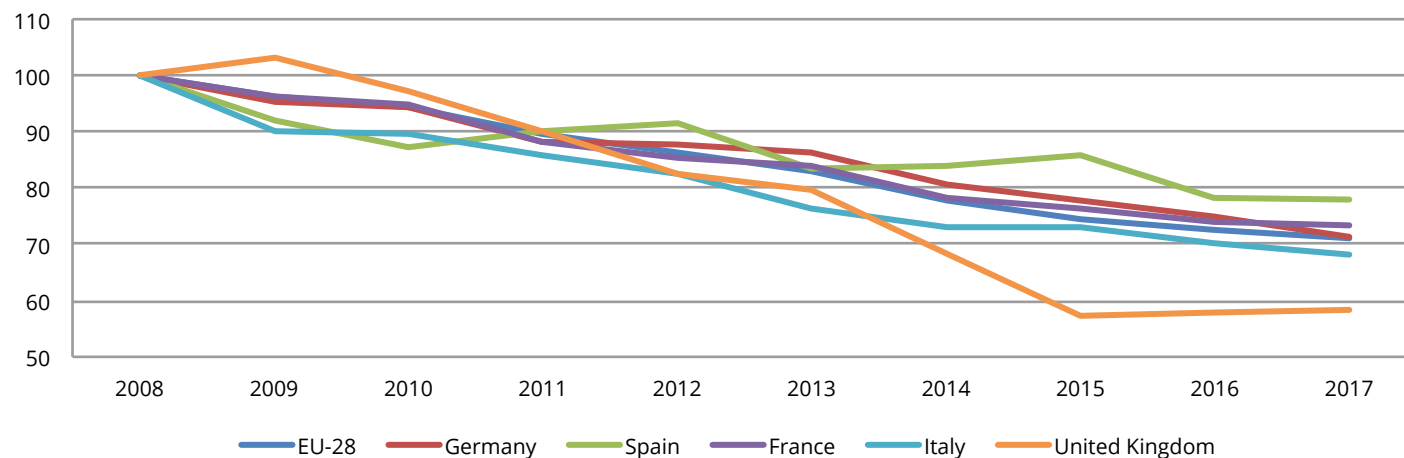
Fig. 1.8 Primary energy consumption per unit of GDP (2008=1000)

Source: I-Com elaboration on Eurostat data

EU-28 — Germany — Spain — France — Italy — United Kingdom
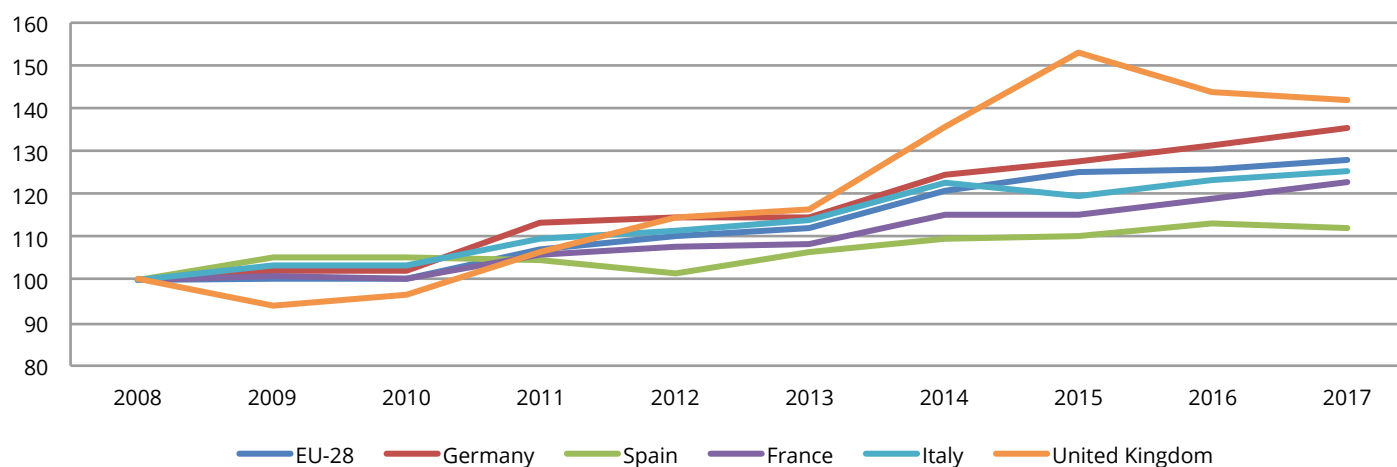
On the other hand, the decarbonisation efforts of the European states over the last decade are evident. It is interesting to note here the share of energy produced from renewable sources (Fig. 1.9), rising from 11.3% in 2008 to 17.5% in 2017. The highest percentages from among the considered countries were reached in Italy (18.3%) and Spain (17.5%). Instead, the UK, Germany and France fell below the European average, at 10.2%, 15.5% and 16.3%, respectively. However, the UK experienced an exponential increase in the share of renewable energy production in the relevant period, almost quadrupling, starting from a meagre 2.7% in 2010.

An important growth of new renewables can also be clearly seen, as depicted by the evolution in the electricity mix originating from renewable sources in 2013-2017

(Fig. 1.10). Hydroelectricity, the most traditional and widespread form of renewable energy, dropped 14 percentage points, from 43% to 29% of the mix. Wind power overtook hydroelectric power during the period considered, gaining 6 percentage points, reaching 34%. Solar energy growth was also significant, from 10% to 19%. Biomass remained constant at 18%. Geothermal energy, on the other hand, played a marginal role.

In absolute values, renewable energy consumption grew continuously and exponentially from 2004 to 2018, from 28 to 160 Mtoe, +460% (Fig. 1.11). The growth was particularly significant in the first half of the period, increasing at an average annual rate of 16.5% between 2004 and 2011. Instead, between 2011 and 2018, this rate decreased by 40%, drooping

Fig. 1.9   Share of energy from renewable sources (%)
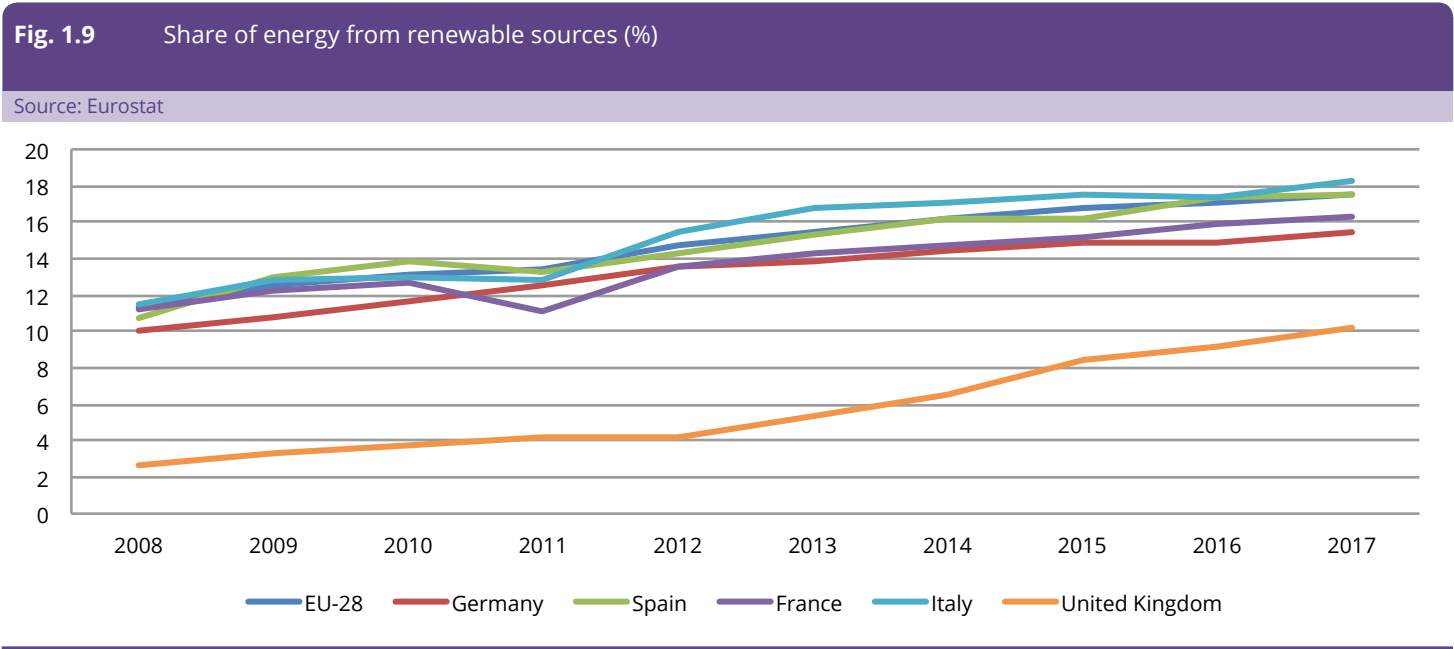
Source: Eurostat

Fig. 1.10   Renewable electricity mix in the EU by energy source (%)

Source: Eurostat

Geothermal — Solar — Biomass — Wind — Hydro
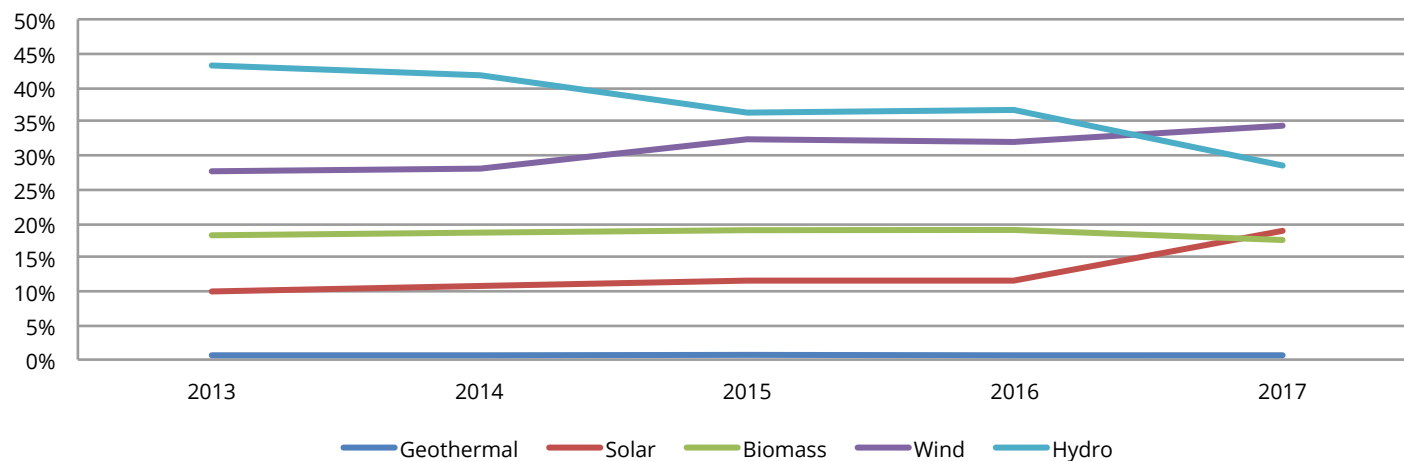
Fig. 1.11   New investments in clean energy and renewable energy consumption in the EU ($bn and Mtoe)

Source: Bloomberg New Energy Finance and BP Statistical Review

New investiment in clean energy — Renewable energy consumption (right axis)
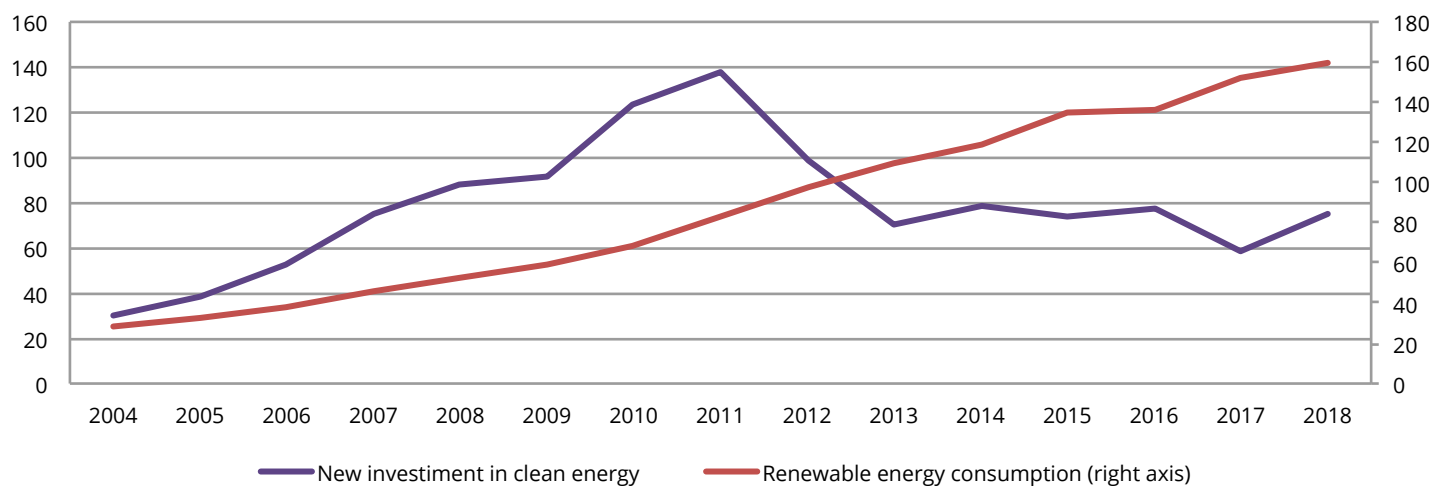
to 9.8%. This gap also reflects a different trend in clean energy investments, with an increase of almost 150%, from $30 billion to $74.5 billion, between 2004 and 2018. New investments in clean energy peaked in 2011 at a value of almost $138 billion. Furthermore, between 2004 and 2011, investments grew at an average annual rate of 24%, although, between 2011 and 2018, they experienced a marked decline at an average annual rate of 8%.

The issue of investments in clean energy holds no secondary value. By comparing investments up to 2018 with the GDP for twenty selected countries in the world, we find that the 3 largest European countries, Germany, France and Italy, are in the last four positions (Fig. 1.12), ranging from 0.3% to 0.1%, less than China

(0.7%), Japan (0.5%), India (0.4%) and slightly below the USA (0.3%). Among EU Member States, the Central-Northern countries - Sweden (1%), Denmark (0.9%) and the Netherlands (0.6%) - performed better.

1.1.2. Mobility: the role of transport in energy demand and CO2 emissions

The mobility sector is expected to undergo a dramatic change in the near future due to different environmental, social, economic and technological factors.

From a social point of view, several trends are leading to changes in the mobility sector. These involve the growing number of people moving to (and within) urban areas, the shift towards an even more individual and personalized mobility - due to the growing number of

Fig. 1.12   Share of investments in clean energy in national GDP of selected countries (2018)

Source: I-Com elaboration on Bloomberg New Energy Finance and World Bank data
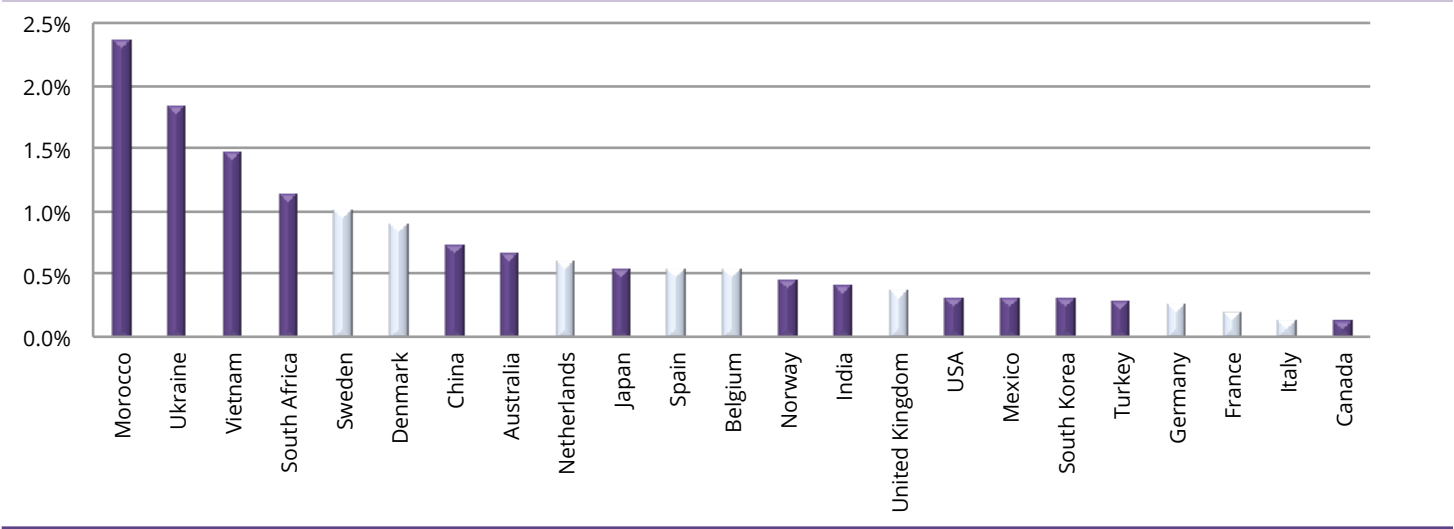
single-person households and longer life expectancy -, the increase in tourism flows and, more generally, in the mobility of people.

In the last 50 years, the percentage of the population moving to urban areas has significantly increased in every part of the world, with China and Sub-Saharan Africa being the regions most affected - from about 15% to almost 60% and 40%, respectively. Instead, the United States and Latin America show the highest percentage of people currently living in urban areas - 80% of the population. The European Union has experienced a smaller growth, even though more than 75% of its inhabitants live in urban areas and this trend is expected to rise. Arthur D. Little's elaboration on UN global data estimates a growth from 6.7 billion in 2010 to 9.5 billion inhabitants by 2050 while, in the same period, the percentage of those living in urban areas will increase from 52% to 66%.

The second social factor that will affect the transport sector will be the growing request for a more individual and personalized mobility, also due to an increasing number of single-person households. For example, EU data shows a decrease in the number of individuals per family in almost every Member State. In 2017, the average European household was made up of 2.3 people (-0.1% compared to 2007). As well, growth of passenger air transport and the increase in road congestion will be analysed here. These are events that call into question the management of energy demand, the need to reduce pollutant emissions and to identify innovative solutions to optimise mobility.

Transport accounts for important part of the world's energy demand and CO_2 emissions. Currently, transport represents 20% of global primary energy demand, an increase from 18.8% in 2010 (Fig. 1.13). This percentage will be maintained in all the IEA scenarios up to 2040, at 20.8% for the Current Policies Scenario and 19.7% for the Sustainable Development Scenario. Therefore, transport energy consumption will remain more than in line with overall energy demand trends. In absolute values, global transport energy demand is expected to grow from 2,863 Mtoe (from 2,422 in 2010) to 3,606 Mtoe in the Stated Policies Scenario and, even more, to 3,981 Mtoe in the Current Policies Scenario. Obviously, the Sustainable Development Scenario has the lowest value, equal to 2,615.

Fig. 1.13   Transport energy demand out of global primary energy demand

Source: I-Com elaboration on IEA data

Stated Policies scenario
Current Policies scenario
Sustainable Development Scenario
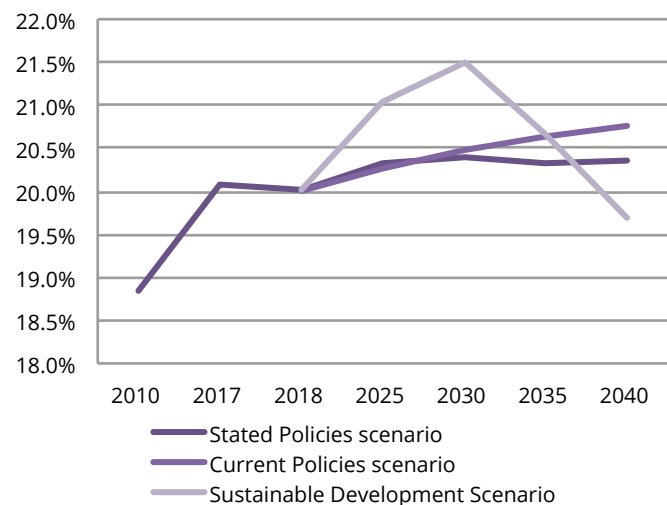
These considerations become even more valid if we look at the amount of CO2 emissions produced by the transport sector out of total global CO2 emissions (Fig. 1.14). Currently, this stands at 24.6% compared to 23% in 2010. By 2040, this is foreseen to reach a minimum of 26.7% according to the Stated Policies Scenario, and a maximum of 34.1% according to the Sustainable Development Scenario. Therefore, transport CO2 emissions will either increase more than the average of other energy consumers (power sector, industry and buildings) or will decrease less. For example, according to the Stated Policies Scenario, if global emissions increase between 2018 and 2040 at an average annual rate of 0.3%, those produced by transport will more than double to 0.7%, up to 9,512 Mt of CO2 produced by 2040. Similarly, according to the Sustainable Development Scenario, if

global emissions decrease in the considered period at an average annual rate of -3.3%, transport emissions will record a reduction rate of only 1.9%. Consequently, the transport sector requires large investments and suitable policies to achieve the desired decarbonisation goals.

The transport sector is the second largest emitter in the western developed countries. In the US, it accounts for 36% of the total, just below the power sector, as in the EU where it accounts for 30% (Fig. 1.15). In the important emerging countries, however, industry, after the power sector, still accounts for a significant part of CO2 emissions, while transport immediately follows. In India transport accounts for 12% of emissions, while in Russia 17%. Japan, as a mature economy, is an exception with transport emissions being limited to 19%.

Fig. 1.14	CO2 emission by transport out of total CO2 emissions

Source: I-Com elaboration on IEA data

Stated Policies scenario
Current Policies scenario
Sustainable Development Scenario
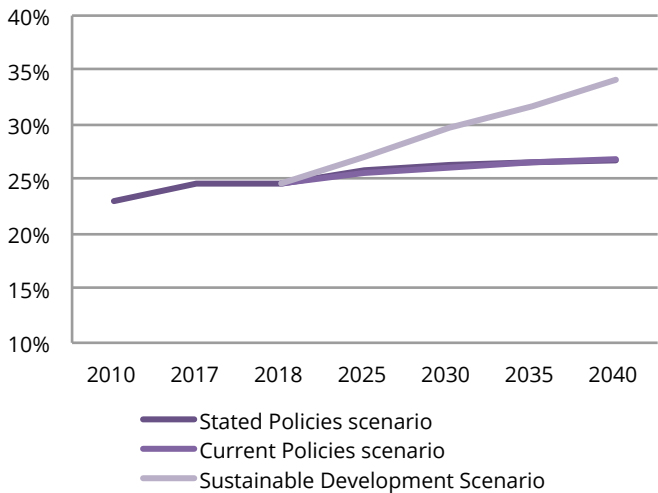
Fig. 1.15	Global annual CO2 emissions by country and sector (2018)

Source: I-Com elaboration on IEA data

■ Power Sector ■ Industry ■ Transport ■ Buildings ■ Other

On the other hand, transport accounts for a considerable share in the EU in both emissions (not only CO2, but all greenhouse gases) and energy demand. This becomes quite clear when analysing GHG emissions and energy consumption over the period 2008-2017 (Fig. 1.16). The percentage of transport energy consumption increased marginally, from 15.1% in 2007 to 15.6% in 2017. It comes third in energy demand, after the power sector and residential and commercial sectors. The percentage of GHG emissions increased more consistently, from 20.1% in 2008 to 23% in 2017.

The factors influencing the weight of transport in the European economic and energy system, as mentioned above, are manifold. Consider, for example, the development of the airline sector. The increase in air passenger transportation between 2008 and 2017 is evident (Fig. 1.17). In 2017, the total number of passengers in Europe reached 1 billion units, an increase of 30% on 2007. Countries with the biggest growth in absolute terms are the most populated ones, such as the UK (about 50 million more passengers per year), Spain (+48 million), Germany (+46 million), Italy (+39 million) and France (+31 million), while those showing the highest percentage increase are Romania (+123% passengers per year), Luxembourg (+107%), Lithuania (+105%) and Poland (+101%).

Changes in the mobility sector are also essential to face the problem of increasing traffic and congestion, as well as the need for pollution reduction. Concerning the former, Europeans spent up to 46 hours per year

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Fig. 1.16   EU energy consumption and GHG emissions for the transport sector

Source: I-Com elaboration on Eurostat data

■ % energy consumption   ◰ % GHG emissions
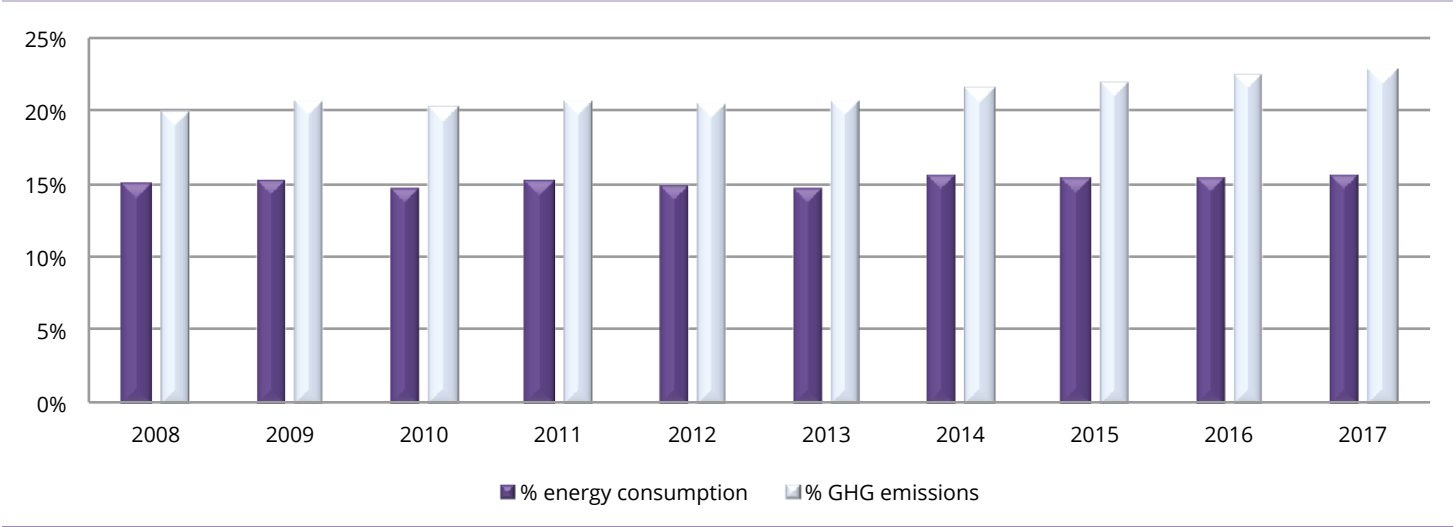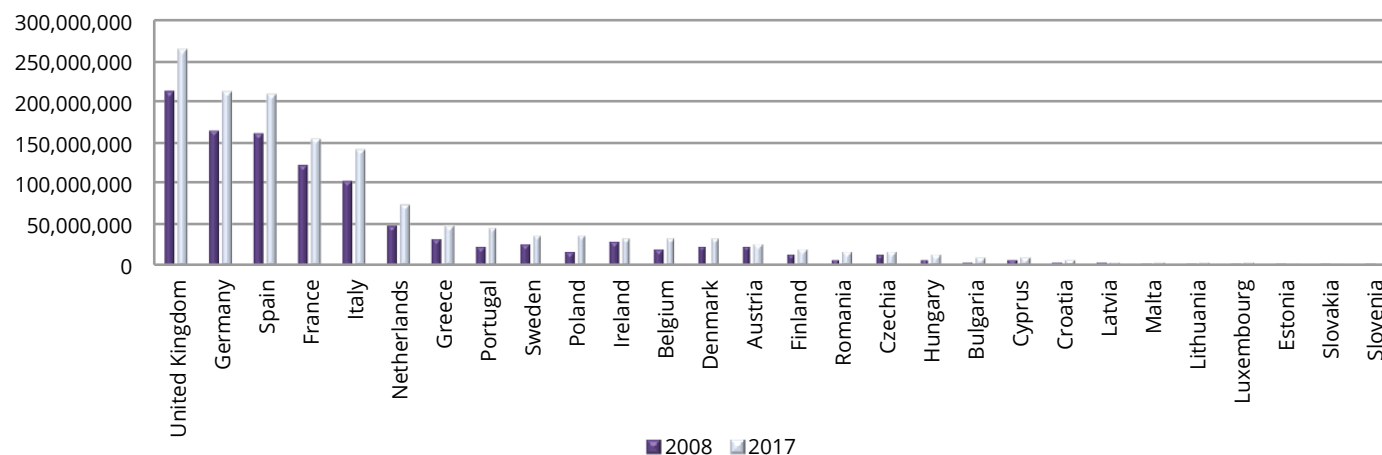
Fig. 1.17   Air passenger transport in Europe (no. of passengers per country per year)
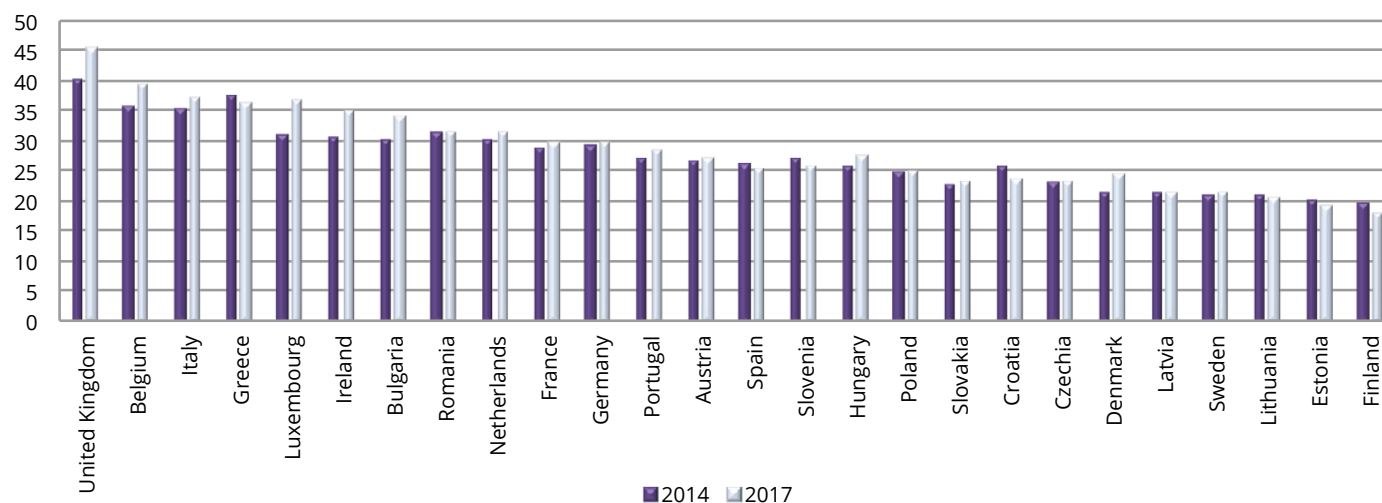
Source: Eurostat

Note: Total number of passengers carried in Europe (arrivals plus departures).

Fig. 1.18   Hours spent in road congestion annually in Europe (breakdown per country per year)

Source: JRC, TomTom

stuck in traffic from 2014 to 2017, and this trend seems to be increasing (Fig.1.18). Out of the 28 Member States considered, only 8 showed a reduction in hours, led by Croatia (-2.1), Finland (-1.7), Greece (-1.4) and Slovenia (-1.2), while a reduction of less than an hour was seen in Spain, Estonia, Lithuania and Poland. Instead, the other 20 countries showed an increasing time spent in traffic congestion, with a significant increase in Luxembourg (+5.7), the UK (+5.5). Ireland (+4.1), Bulgaria (+3.7) and Belgium (+3.5). Generally, data shows that countries with less congested routes result in a reduction in the number of hours inhabitants spend in traffic, while in the Member States where traffic had already been heavy, the traffic conditions tended to worsen.

1.2. THE CHALLENGE OF SUSTAINABILITY: MAIN LEGISLATIVE INITIATIVES

1.2.1. Past legislation: Clean Energy Package and the 3 Mobility Packages

The European Union was the first major economy to present its **climate plan on 6 March 2015**, reflecting the **2030 climate and energy policy framework** set by the October 2014 European Council and the European Commission's blueprint for tackling global climate change beyond 2020. The European Commission has set an ambitious economy-wide domestic target of at least 40% greenhouse gas emission reduction for 2030. In doing so, the EU has agreed to update its energy policy framework in assisting with the transition towards cleaner energy.

The **Clean Energy for all Europeans Package** is the main recent European initiative in the field of energy and climate. It is made up of eight legislative acts entering into force in mid-2019, involving five sectors: energy performance in buildings, renewable sources of energy, energy efficiency, governance regulation and electricity market design. EU countries have 1-2 years to implement the new directives into national law.

Buildings are the largest energy consumer in Europe. They account for 40% of energy consumption and 36% of EU CO_2 emissions in the EU. The **Energy Performance in Buildings Directive (EPBD)** updates and amends many provisions from the 2010 EPBD and settles specific measures for the building sector. In the field of renewable energy, the **Directive on the promotion of the use of energy from renewable sources** aims at the EU becoming a global leader in renewable energy use. It establishes a common framework for the promotion of energy from renewable sources and fixes a binding EU target (the 32%) for the total energy share from renewable sources in the EU's energy mix by 2030. The Directive also provides rules on financial support for electricity from renewable sources, on self-consumption of this electricity and on the use of energy from renewable sources in the heating and cooling sector and in the transport sector. Measures on regional cooperation among Member States, and between Member States and third countries, on administrative procedures, guarantees of origin and information and training are established. As well, the Directive also assigns sustainability and greenhouse gas emissions

saving criteria for biofuels, bioliquids and biomass fuels. Furthermore, the **Energy Efficiency Directive** establishes a common framework of measures aimed at sustaining energy efficiency within the EU in order to reach the EU's 2020 headline targets on energy efficiency of 20% and the 2030 headline targets of at least 32.5% and to encourage further energy efficiency improvements beyond these dates. At the same time, the Directive sets rules aimed at removing barriers in the energy market and overcoming market failures which hinder efficiency in this energy supply. For this purpose, it provides for the establishment of indicative national energy efficiency targets and contributions for both 2020 and 2030.

As regards the governance regulation reform, the Clean Energy Package lays down a solid governance system for the Energy Union. **The Regulation on the governance of the energy union and climate action** requires each Member State to draft integrated 10-year national energy and climate plans (NECPs) for 2021 to 2030. The NECPs also state how EU Member States will achieve their respective targets on all five dimensions of the energy union, taking into account a longer-term view towards 2050. Hence, all EU countries submitted their draft NECPs in early 2019. As established by the rules, the Commission released an analysis of each draft plan, providing recommendations to be taken into account. Subsequently, EU Member States were required to finalise the NECPs by the end of 2019.

The last of the five sectors envisaged in the Clean Energy Package is the **electricity market design**. The Package plans to establish a modern design for the EU electricity market, in order to make it more flexible, more market-oriented and able to integrate a greater share of renewable energy. The Commission, consequently, launched several legislative initiatives, such as a new electricity regulation, an amended electricity directive, risk preparedness and a regulation defining a stronger role for the Agency for the Cooperation of Energy Regulators (ACER).

In addition to the legal acts, in the framework of the Clean Energy for all Europeans Package, the Commission has launched some non-legislative initiatives. These include "the Coal regions in transition" through which the Commission seeks to support coal regions in their path towards decarbonisation and a fair transition, coal still being a main fuel in the European energy mix. It accounts for nearly a quarter of total EU electricity production and is also a considerable economic driver, providing jobs for 240,000 people in mines and power plants in 12 EU Member States. In order not to leave any region behind in the energy transition process, in 2017, the Commission set up the 'Platform for Coal Regions in Transition', an open forum, gathering all relevant parties – local, regional and national governments, businesses and trade unions, NGOs and academia – promoting knowledge sharing and exchanges of experiences among EU coal regions.

Included in the non-legislative initiatives of the Clean Energy Package, there is the Clean Energy for EU Islands initiative with a long-term framework to help Europeans living on the 2,200 inhabited EU islands to generate their

own sustainable and low-cost energy, reducing their dependency on expensive fossil fuel imports.

In conclusion, the Commission is trying to define and better monitor energy poverty in Europe. It is estimated that more than 50 million EU households are in conditions of energy poverty because of energy inefficient buildings and appliances, high energy expenditures, low household incomes and specific household needs. To deal with the emergency, in January 2018, the Commission set up the Energy Poverty Observatory (EPOV) to foster informed decision-making at all government levels by providing a user-friendly and open-access resource. It also supports public engagement on the issue of energy poverty and spreads information and good practices among public and private stakeholders.

Considering that road transport employs 5 million Europeans and contributes to almost a fifth of the EU's greenhouse gas emissions, the European Commission crafted a series of **Mobility Packages** to improve the functioning of the road haulage market and help improve workers' social and employment conditions.

The European Commission presented **the first package on 31 May 2017**, titled **Europe on the Move. An agenda for a socially fair transition towards clean, competitive and connected mobility for all**[1]. This paper aims at ensuring that Europe plays a leading role in clean, competitive and connected mobility, supporting the adoption of the best low-emission mobility solutions, equipment and vehicles and the development of modern infrastructures to support them. Specifically, the first mobility package covers the following areas:

1. access to the road haulage market and to the profession of passenger and freight transport operators;
2. hired freight transport vehicles;
3. road charging and electronic tolling;
4. driving and rest time rules;
5. posting of workers;
6. enforcement;
7. vehicle taxation;
8. CO_2 monitoring and reporting of Heavy-Duty Vehicles.

On 8 November 2017, the Commission launched the **Second Mobility Package**, under the heading **"Clean Mobility Package"**[2]. It involves:

1. Delivering on Low-emission Mobility. The Commission explains that this Second Package addresses three key political priorities: a) Europe that protects the planet, promoting the next generation of CO_2 emission reduction standards for transport, encouraging multimodality and efficiently combining different kinds of transport, stimulating the development of bus connections, thereby offering alternative options to private car use and increasing the use of sustainable public transport modes; b) Europe that empowers its citizens, implementing a robust testing framework for type-approval based on new testing procedures that will ensure effective compliance with

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1   COM (2017) 283 final

2   COM (2017) 675 final

the rules, facilitating consumers' access to affordable new and cleaner forms of mobility and making sure that the benefits of these new mobility services are available to all and boosting investment in alternative fuel infrastructures; c) Europe that defends its industry and workers, promoting the production of connected and automated vehicles, establishing a complete value-chain for the development and manufacturing of advanced batteries in the EU and supporting the resilience and competitiveness of labor markets, addressing skill gaps and mismatches and supporting the development of new skills through learning abroad.

2. Towards the Broadest Use of Alternative Fuels, stablishing a common framework of measures for the deployment of alternative fuel infrastructures in the Union in order to minimize dependence on oil and to mitigate the environmental impact of transport. It sets out minimum requirements for the building-up of alternative fuel infrastructures, including recharging points for electric vehicles and refueling points for natural gas (LNG and CNG) and hydrogen, to be implemented by means of Member States' national policy frameworks, as well as common technical specifications for such recharging and refueling points, and user information requirements.

3. A set of 4 legislative initiatives, targeting road and combined transport, which aim at strengthening CO2 emission standards for new cars and vans from 2020, promoting clean mobility through public procurement, stimulating combined use of trucks

and trains, barges and ships for the transport of goods and, finally, promoting the development of bus connections over long distances.

Finally, **on 17 May 2018**, the Commission presented the **Third Mobility Package**[3], supporting a safe, clean and connected mobility completing the process launched with the 2016 Low Emission Mobility Strategy. This package consists of the Communication, **Europe on the Move. Sustainable Mobility for Europe: Safe, Connected, and Clean**. The Commission underlines that even if road safety in the EU has greatly improved in recent decades, thanks to actions at EU, national, regional and local levels, opportunities to further improve safety performance must be seized. In fact, technological advances, first and foremost in connectivity and automation, create new opportunities to eliminate or compensate for human error and a shift to driverless vehicles should bring more safety for citizens in the long run. The Commission describes the EU's long-term goal that is moving as close as possible to zero fatalities in road transport by 2050 ("Vision Zero") while reducing the number of road deaths and serious injuries by 50 % between 2020 and 2030.

1.2.2. Ongoing initiatives:
The European Green Deal

On 11 December, the European Commission released the Communication **The European Green Deal**[4], pursuing the goal of setting out a European Green Deal

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3   COM (2018) 293 final
4   COM (2019) 640 final

for the European Union and its citizens. This initiative resets the European commitment to tackling climate and environmental-related challenges, fixing the ambitious target (compared to the Stated Policies Scenario) of zero net emissions of greenhouse gases in 2050 (Fig. 1.19). In doing so, the European Union would be the first climate neutral area in the world by the middle of this century.

The document sets numerous objectives in different and horizontal areas. For the European Green Deal to be delivered, policies for clean energy supply across the economy, industry, production and consumption, large-scale infrastructure, transport, food and agriculture, construction, taxation and social benefits must be revised (Fig. 1.20). Additionally, increased value must be placed on protecting and restoring natural ecosystems,

sustainable resource use and improvement in human health. Policy revision is needed, and can be potentially beneficial, for the EU economy, society and natural environment. Digital transformation can be the most essential element to enable such change.

The Green Deal makes use of regulation and standardization, investment and innovation, national reforms, dialogue with social partners and international cooperation, while The European Pillar of Social Rights guides actions to ensure no one is left behind. However, new measures on their own will not be enough to achieve the European Green Deal's objectives. In addition to launching new initiatives, the Commission must work with Member States to step up the EU's efforts, ensuring that current legislation and policies relevant to the Green

Fig. 1.19   European Union GHG emissions scenarios (1990-2050, 1990=100)

Source: I-Com elaboration on IEA and European Commission data
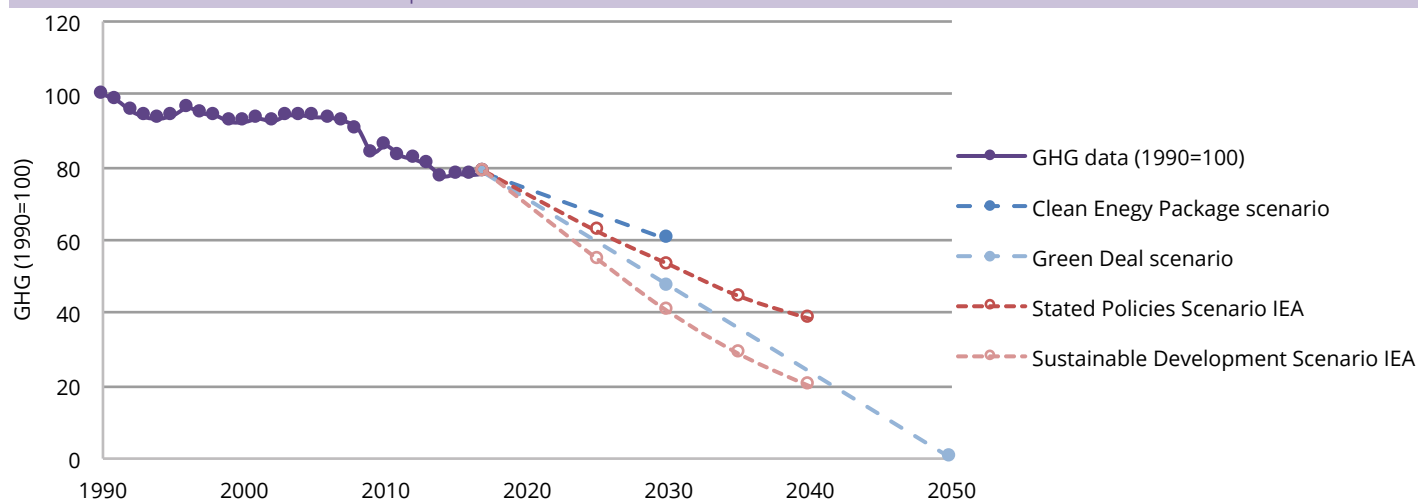
Fig. 1.20   European Green Deal

Source: European Commission

Deal are enforced and effectively implemented.

As mentioned above, the EU has increased its climate ambitions for 2030 and 2050 in a long-term strategy that will be submitted to the United Nations Framework Convention on Climate Change in 2020. These new ambitions outline an effective and fair transition, provide predictability for investors, and ensure that the transition is irreversible. This will enshrine the 2050 climate neutrality objective in legislation. The Commission will adopt a new, more ambitious EU strategy on adaptation to climate change, this being essential, as climate change will continue to create significant stress in Europe in spite of the mitigation efforts. It will be important to ensure that across the EU, investors, insurers, businesses, cities

and citizens are able to access data and to develop instruments to integrate climate change into their risk management practices.

As observed in paragraph 1.1.1 regarding trends in CO2 emissions and decarbonisation, the EU has begun modernising and transforming the economy through climate actions. Nonetheless, currently, policies will only reduce greenhouse gas emissions by 60% by 2050. Such a timeline suggests that much remains to be done. By next summer, the Commission will present an assessed plan to increase the EU's greenhouse gas emission reductions target for 2030 to at least 50%.

Carbon leakage towards international partners may deter such targets from materialising, either because production is transferred from the EU to other countries with lower emission standards, or because EU products are replaced by more carbon-intensive imports. If international ambition levels persist while the EU increases their climate ambition, the Commission will propose a carbon border adjustment mechanism in an attempt to reduce the risk of carbon leakage, aimed at ensuring import prices reflect their carbon content.

Further decarbonisation of the energy system is critical to reach the 2030/2050 climate objectives. 75% of the EU's greenhouse gas emissions come from the production and use of energy across sectors. Therefore, a power sector largely based on renewable sources must be created, while simultaneously phasing out coal and gas. At the same time, the EU's energy supply must be affordable, while the market strives to be integrated, interconnected, digitalised and respecting technological neutrality.

The transition should involve and benefit consumers, where renewable energy will play a major role. The smart integration of renewables, energy efficiency and other sustainable solutions across sectors will help to achieve the highest degree of decarbonisation, at the lowest possible cost for consumers. Effective programmes, such as financing plans for home renovation, will reduce energy consumption and costs, while progressing toward the EU's decarbonisation ambitions.

Smart infrastructure is essential for climate neutrality. The regulatory framework for energy infrastructure must be reviewed, including the regulation regarding the Trans-European Networks, to ensure consistency with objectives. Revisions should affect the development of smart grids, hydrogen networks or carbon capture and energy storage, while enabling sector integration. At the very least, existing infrastructures will require upgrading. Full industry mobilisation is essential to achieving climate neutrality and a circular economy. Almost half of total greenhouse gas emissions, and more than 90% of biodiversity loss and water stress, derive from the extraction of resources and the processing of materials, fuels and food. Specifically, EU industries account for 20% of the EU's greenhouse gas emissions, while only 12% of the materials used come from recycling.

Transition could spur economic activity and supply jobs. The circular economy offers impressive potential for new jobs, but the pace of transformation is too slow, not encompassing nor uniform. The European Green Deal supports and accelerates the EU's industry transition to a sustainable model with inclusive growth.

In March 2020, the Commission will adopt an EU industrial strategy to address challenges of green and digital transformations. Europe has a unique opportunity to maximise its decarbonisation by using new digital technologies, all while helping to modernise the EU's economy.

The decarbonisation and modernisation of energy-intensive industries, such as steel, chemicals and cement, is essential due to their role in Europe's economy. The Circular Economy Action Plan, to be released in March, will include recommendations to support design of products made with a common methodology, that prioritises the reduction and reuse of materials before they are recycled. This will establish new business models and minimum requirements on resource-intensive sectors such as textiles, construction, electronics and plastics. In addition, requirements must be established to ensure that packaging from the EU market is reusable, recyclable, or biodegradable, in an economically responsible manner by 2030.

Companies making 'green claims' should be held to their marketed claims. The Commission will step up its regulatory and non-regulatory efforts to tackle false green claims. Digitalisation can also provide information on the characteristics of products sold in the EU; such as the product's origin, composition, repair and dismantling abilities, and proper means of disposing.

Resource accessibility is a strategic question for Europe's ambition to deliver the Green Deal. Ensuring the supply of sustainable raw materials from both primary and secondary sources is a pre-requisite for transition. New forms of collaboration with industry and investments in strategic value chains are essential. The Commission will support initiatives leading to alliances and to a large-scale pooling of resources.

Digital technologies are critical for attaining the sustainability goals of the Green Deal. Artificial intelligence, 5G, cloud and edge computing and the Internet of Things could maximise benefits, while accelerating the impact of climate change policies to protect the environment. Additionally, digitalisation presents new opportunities for air and water pollution monitoring and the optimisation of how energy and natural resources are used. However, for such ambitions to be achieved, Europe needs a digital sector fully engaged in acknowledging the importance of sustainability.

Buildings account for 40% of energy consumed. To address the challenge of energy efficiency and affordability, the EU and the Member States should begin renovating public and private buildings. Such renovation will boost the construction sector, providing an opportunity to support SMEs and local jobs. In this field, the European Commission expects to launch the "Renovation Wave" initiative during 2020.

As discussed in the previously, transport accounts for a significant part of EU's greenhouse gas emissions. To achieve climate neutrality, a 90% reduction in transport emissions from road, rail, aviation, and waterborne transport is needed by 2050. Multimodal transport will increase the efficiency of the transport system, but a strong boost is needed. Automated and connected multimodal mobility, together with smart traffic

management systems enabled by digitalisation, will play an increasing role in the reduction of gas emissions. The EU transport system will be revised, starting from a Strategy for Sustainable and Smart Mobility to be released in 2020, to support new sustainable mobility services, developed through smart systems for traffic management, reducing congestion and pollution.

However, the price of transport must reflect its environmental and health impact, and fossil-fuel subsidies should be phased-out.

The EU should increase the production and deployment of sustainable alternative transport fuels. By 2025, around 1 million recharging and refueling stations will be needed for the 13 million low-emission vehicles expected to be driving on European roads. The Commission will support from 2020 the deployment of public recharging points where gaps exist. However, separate measures should address emissions (such as Proposal for more stringent air pollutant emissions standards for combustion-engine vehicles by 2021), urban congestion, the improvement of public transportation and tougher standards for combustion-engine vehicles.

Food production results in air, water and soil pollution, contributing to the loss of biodiversity and climate change, while consuming an excessive amount of natural resources. New technologies will benefit all stakeholders. The Commission's proposals for the common agricultural policy for 2021 to 2027 stipulate that at least 40% of the common agricultural policy's overall budget, and at least 30% of the Maritime Fisheries Fund, would contribute to climate action. These funds should be used for precision

agriculture, organic farming, agro-ecology, agro-forestry and stricter animal welfare standards. Farmers should be rewarded for improving environmental and climate performance by managing and storing carbon in their soil, and practicing nutrient management to improve water quality and reduce emissions. In addition, strategic plans must be adopted to significantly reduce the use and risk of chemical pesticides, fertilizers and antibiotics. The Commission will identify measures that help Member States improve and restore damaged ecosystems to good ecological status. In addition, the EU Biodiversity Strategy for 2030, to be published in March 2020, will include proposals to create green European cities and increase biodiversity in urban spaces.

The EU's forested area needs to improve, both in quality and quantity. Therefore, the Commission will prepare a new EU forest strategy aiming at promoting the many services that forests provide. In addition, a sustainable 'blue economy' will play a main role in alleviating the EU land resource demands. More generally, environmental improvements require greater attention to nature-based solutions including healthy and resilient seas and oceans, including ways to manage maritime space more sustainably and the use of offshore renewable energy.

The EU needs to better monitor, report, prevent and remedy pollution from air, water, soil, and consumer products. To address these challenges, the Commission will adopt a zero-pollution action plan for air, water and soil in 2021.

The Commission will present a chemicals strategy for sustainability to deliver on a toxic-free environment.

This will protect citizens and the environment against hazardous chemicals, while encouraging the development of safe alternatives.

In order to achieve the ambitious goals, set by the European Green Deal, massive investments are needed. The Commission has estimated that only achieving the current 2030 climate and energy targets will require €260 billion of additional annual investment, that represents about 1.5% of EU GDP in 2018. It is actually a conservative estimate, as it does not consider, for instance, the investment needed for climate adaptation or for other environmental challenges, such as biodiversity. Besides, these investments are needed to be sustained over time, so a huge mobilisation of both the public and private sector is required.

The **European Green Deal Investment Plan (EGDIP)** is the investment pillar of the Green Deal, that will implement up to €1 trillion in sustainable investments over the next decade (Fig. 1.21).

Part of the plan includes the Just Transition Mechanism, which will address a fair and green transition, based on an ad hoc fund worth €7.5 billion, aimed at supporting the sectors and regions most affected by the energy transition. In order to benefit from them, Member States will have to identify, through specific territorial plans, eligible territories and co-finance the resources received with national or European funds deriving from the community programming. **Just Transition Mechanisms** will mobilise around €143 billion in investments over ten years with financing coming from the EU budget, Member States, contributions from InvestEU and the

European Investment Bank (EIB). Overall, there would be a funding of €30-50 billion, capable of mobilising further investments. Over the period of 2021-2027, this part of the plan will invest at least €100 billion to support workers and citizens of the regions most impacted by the transition.

However, the EU budget cannot tackle climate change alone. To meet the massive global investment needs, Member States and private actors will have to provide significant funds themselves.

The next long-term EU budget, with a duration of seven years (from 2021 to 2027), will substantially invest in climate and environmental related objectives. The Commission proposed that 25% of its total budget may contribute to climate action and environmental goals across various programmes (European Agricultural Fund for Rural Development, European Agricultural Guarantee Fund, European Regional Development Fund, Cohesion Fund, Horizon Europe and Life funds). Taken together, the EU budget will provide €503 billion to the European Green Deal Investment Plan, not including the additional national co-financing of around €114 billion on climate and environment projects.

Over the period 2021-2030, InvestEU will provide around €279 billion in private and public investment to be used in various climate and environment projects. The Innovation and Modernisation Funds, not part of the EU budget, will provide about €25 billion for the EU transition to climate neutrality, placing special attention on lower-income Member States.

A central role is envisaged for the European Investment

Fig. 1.21   European Green Deal financing

At least €1 trillion

EU Budget

€503 billion for Climate and Environment

EU Emissions Trading System (ETS) Funds €25 billion

InvestEU Guarantee

Just Transition Mechanism €100 billion

(€143 billion over 10 years)

National co-financing structural funds €114 billion

InvestEU

European Investment Bank Group

National Promotional Banks and International Financial Institutions

Private & Public

InvestEU towards climate and environment targets = **Mobilised investment of €279 billion**

EU budget

triggered by EU budget

*without prejudice to the future multi-annual financial framework (MFF)

*The numbers shown here are net of any overlaps between climate, environmental and Just Transition Mechanism objectives.

Bank, which has committed itself to doubling its climate target, from 25% to 50% by 2025, mobilising between €25-30 billion, according to forecasts.

In autumn 2020, a sustainable finance strategy will be launched looking to private sector investments.

In conclusion, an important role is contemplated for the new Framework Program for Research and Technological Development, Horizon Europe, where at least 35% of the budget will be used to finance new climate solutions useful for the implementation of the Green Deal.

2. DIGITAL TRANSFORMATION IN EUROPE

2.1. THE EU DIGITAL SINGLE MARKET

Digital technologies are transforming our world, even from the economic point of view. The European Commission found that an efficiently functioning Digital Single Market could contribute €415 billion per year and create hundreds of thousands of new jobs. The DSM aims to open up digital opportunities for people and businesses and enhance Europe's position as a world leader in the digital economy. **On 6 May 2015**, the European Commission launched **A Digital Single Market Strategy for Europe (DSM)**.

The DSM Strategy is built on three pillars, including 16 specific initiatives: 1) better access for consumers and businesses to online goods and services across Europe; 2) creating the right conditions for digital networks and services to flourish; and 3) maximizing the growth potential of our European Digital Economy. The first pillar requires the rapid removal of key differences between the online and offline worlds to break down barriers to cross-border online activity; the second needs high-speed, secure and trustworthy infrastructures and content services, supported by the right regulatory conditions for innovation, investment, fair competition and a level playing field; the third pillar requires investment in ICT infrastructures and technologies, such as Cloud computing and Big Data, and research and innovation to boost industrial competitiveness as well as better public services, inclusiveness and skills.

Connectivity targets for 2025 have been established to create a Gigabit Society and policies are being pursued to address the barriers and seize the opportunities for digital adoption and development in the EU28 Member States. For this reason, it is important to assess the steps undertaken so far by the EU. The Commission has created the Digital Economy and Society Index (DESI), a composite measure that examines Europe's digital performance and helps EU countries identify areas requiring priority investments and actions in order to create a truly Digital Single Market. For the EU as a whole, in the last five-year period the DESI score has increased by 13.5 points, from 39 to 52.5, registering an increase in all countries (Fig. 2.1), with the Northern countries remaining at the forefront of the digital market, and the Eastern (Romania and Bulgaria) and Mediterranean (such as Greece and Italy) still at the bottom of the ranking.

The highest score registered by the EU (Fig. 2.2) is in connectivity (14.8), with the greatest progress occurring since 2014 (+5 points). This is followed by the integration of human capital (12), although the latter has increased the least (only 1.4 points in five years).

For a more global perspective, the European Commission drew up the International DESI (I-DESI), a composite measure allowing for comparing the EU with some major world economies (the US, South Korea, Japan and China). South Korea is the most digitally developed economy (Fig. 2.3), whereas the EU as a whole – with a score of 58.9 – only performs better than China (45.3). Only the best performing EU countries keep up with South Korea, even if the wider gap of 2013 has been narrowed.

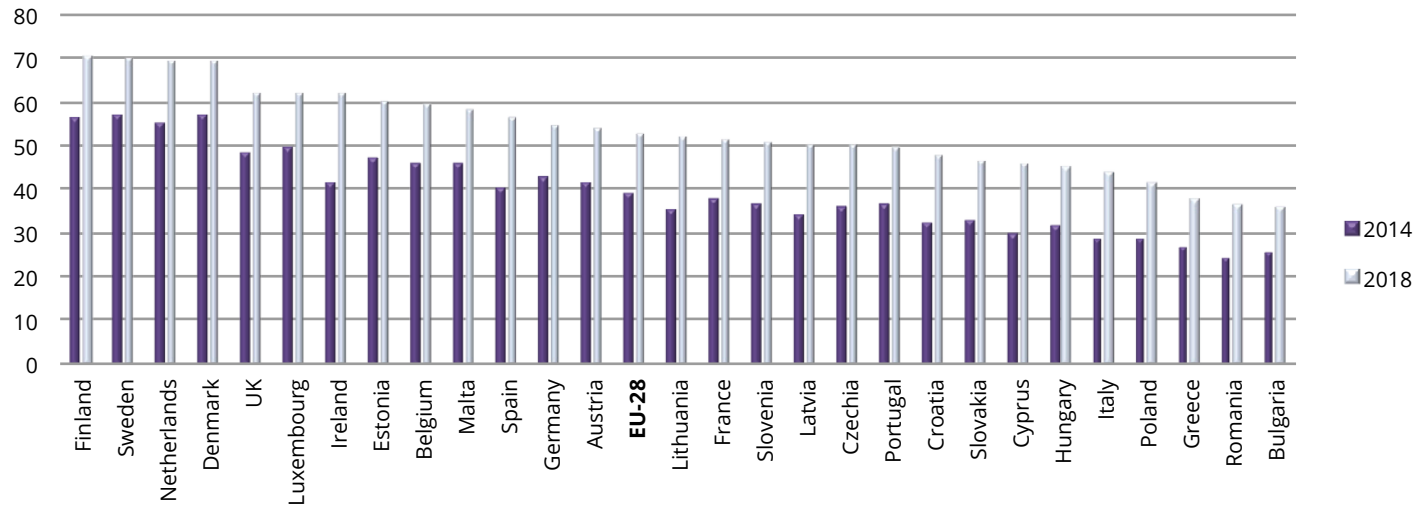**Fig. 2.1**   DESI by Member State

Source: Digital Scoreboard

Fig. 2.2   EU DESI by component
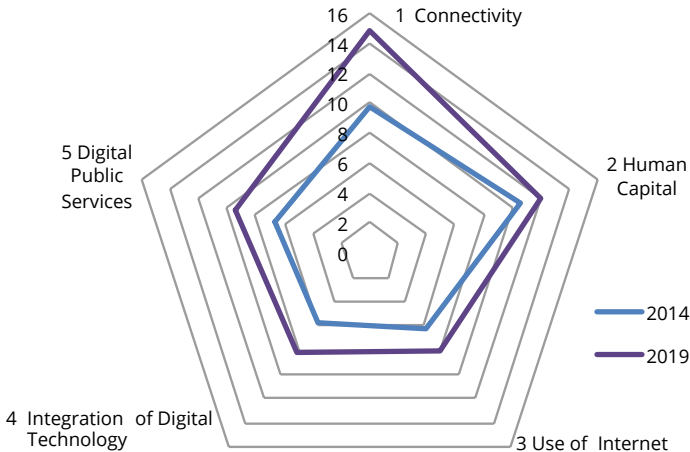
Source: Digital Scoreboard

Fig. 2.3   I-DESI

Source: Digital Scoreboard
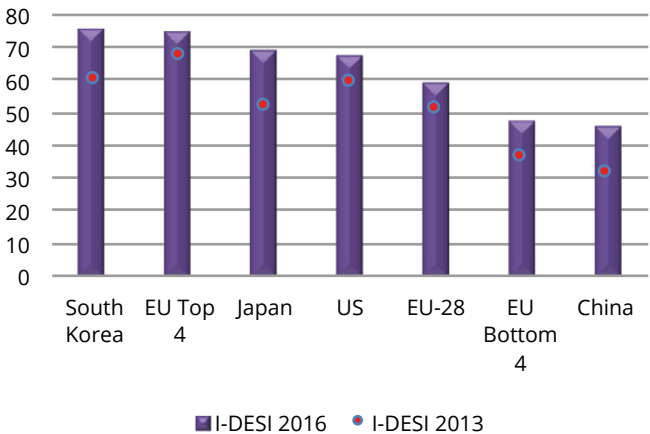
Looking at the single components of the index (Fig. 2.4), the EU improved in all, in the 3-year period. The largest increase occurred in connectivity (+16.9), followed by Internet usage (+8.7). Less progress was made in digital public services and business technology integration. However, though moving forward, the EU continues lag behind the major global economies in all components. On the contrary, China, way behind in 2013, seems to be catching up quite rapidly.

Japan and South Korea, already the most developed in 2013, are those registering the most progress, especially in digital public services and human capital, the components where the EU only made a small improvement.

2.2. DIGITAL INFRASTRUCTURES IN EUROPE

The digital transformation requires increasing network performance and continuous development of data capacity management. The importance of high capacity digital networks is well known at the European level, since their availability and take-up have enabled the widespread use of products, services and applications in the Digital Single Market. For these reasons, digital networks are one of the topics which has received the widest attention from the European institutions in their legislation and monitoring. The Commission's strategy on Connectivity for a European Gigabit Society, September 2016, increased the targets decided by the previous broadband objectives for 2020.

Fig. 2.4   I-DESI by component (2016 vs. 2013)

Source: Digital Scoreboard

2016

2013

EU 28 · · · EU Top 4 — Korea — Japan — US — China
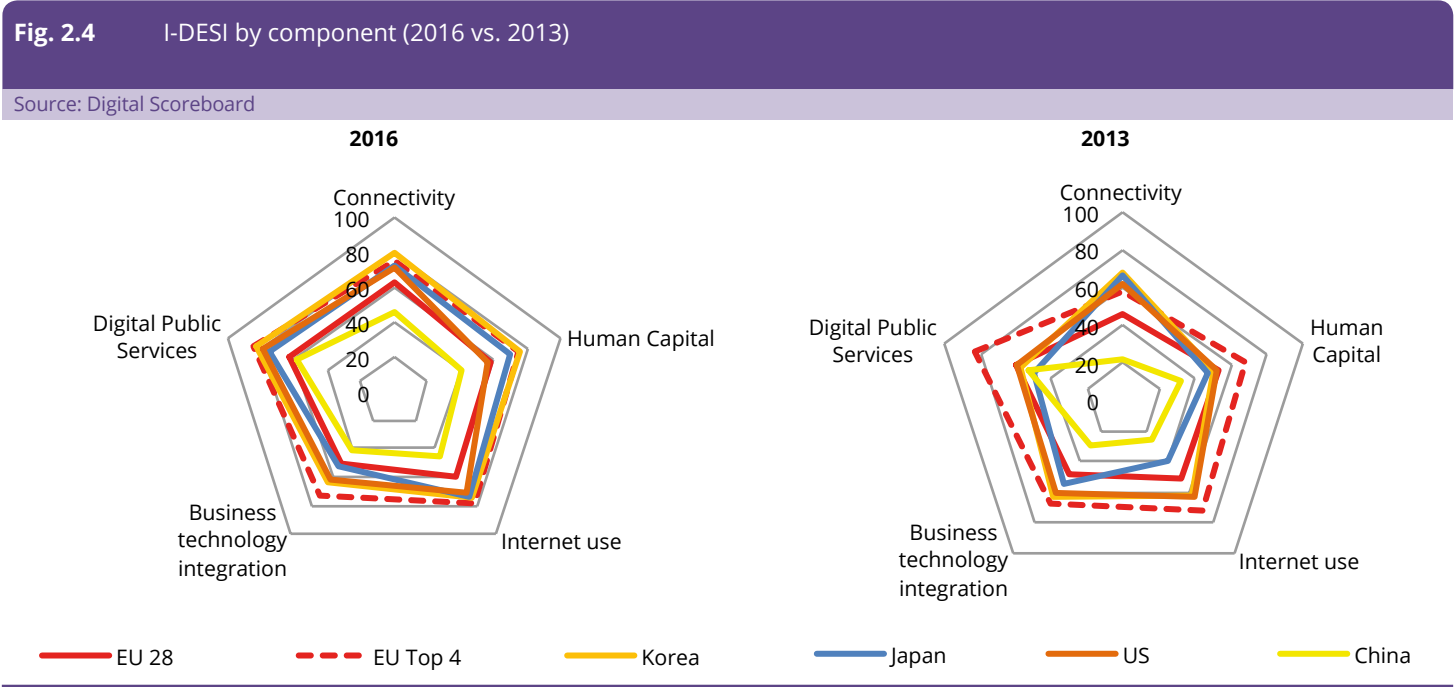
The new targets focus on bringing Internet access with a capacity of at least 100 Mbps to all European households, as well as connecting with performance up to 1 Gigabit the main socio-economics drivers (such as schools, hospitals and other PA entities), covering all urban areas and major land transport routes with a 5G signal.

The EU institutions have also set up a funding system which supports the financing of broadband network infrastructures, and the Connecting Europe Facility (CEF) to foster the deployment and modernisation of broadband networks. The latter, which is part of the new EU 2021-2027 budget, should, with €3 billion in funds, finance strategic digital connectivity infrastructures.

According to the DESI Index, looking at the progress made by EU countries in providing connections capable of a download speed of at least 30 Mbps to all of their households, the threshold reached an 83.1% peak in 2018. On the one hand, the spread of connectivity around Europe appears to have achieved a very good result, but it will be hard for EU countries to reach full coverage by 2020, as established by the European Digital Agenda's previous targets.

For ultrafast networks, the threshold reached by EU infrastructures related to this parameter is in line with the objectives set in 2010 for the second pillar of the European Digital Agenda. In 2019, almost 60% of European households were covered by ultrafast digital networks.

If the availability and coverage of households appear extremely important, another fundamental indicator is related to the effective take up of the Internet access service.

Fig. 2.5   NGA broadband coverage/availability (% of households, 2018)

Source: Digital Scoreboard
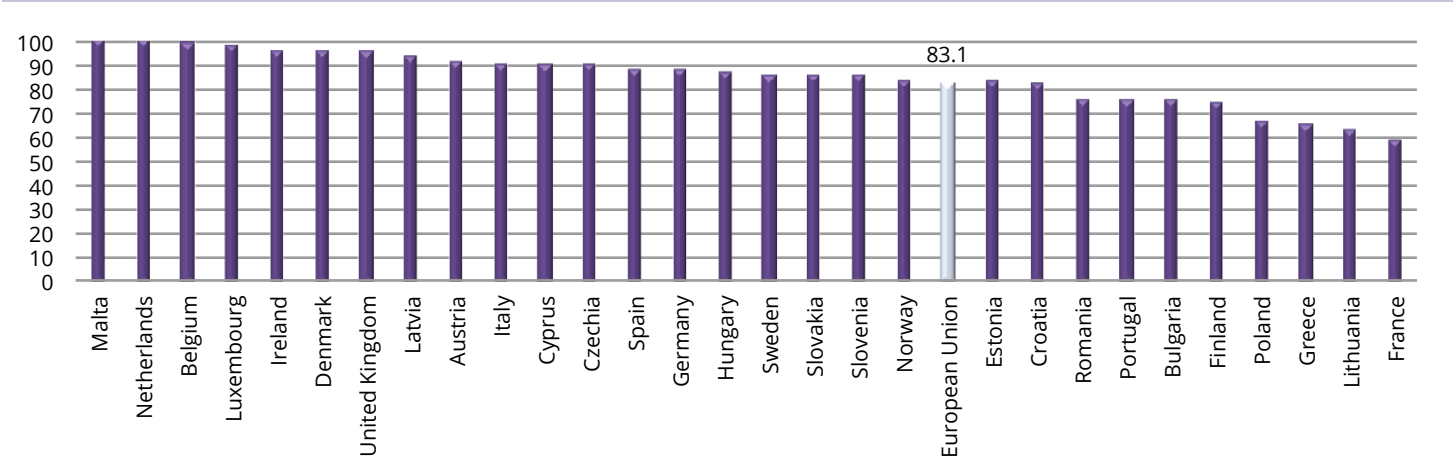
Note: Fast broadband is a connection with download speeds of at least 30 Mbps.

Fig. 2.6   Ultrafast broadband coverage (% of households, 2018)

Source: Digital Scoreboard
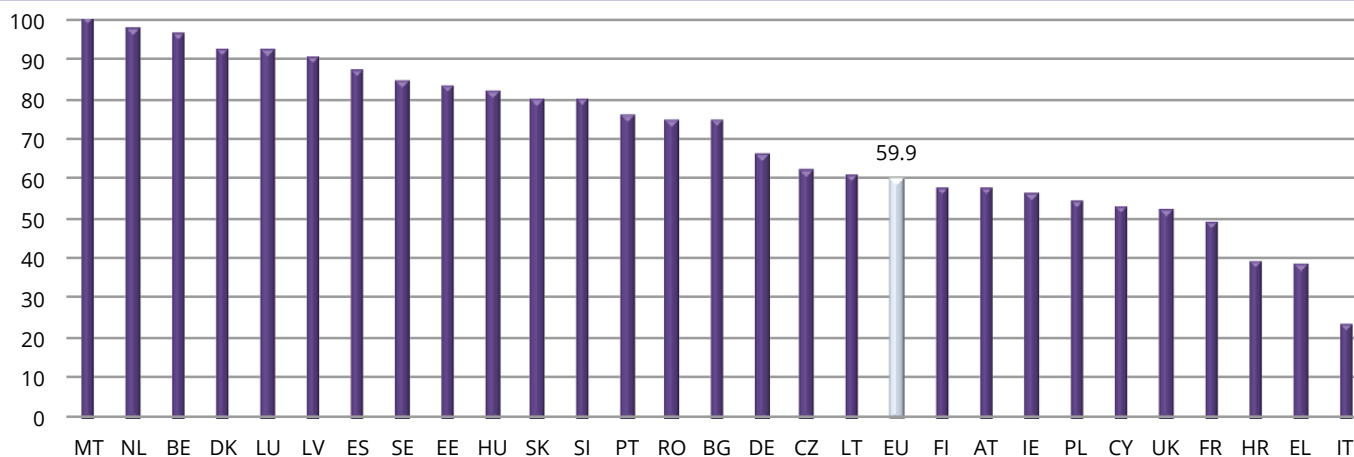
Note: Percentage of households covered by broadband of at least 100 Mbps download. Considered technologies are FTTH, FTTB and Cable Docsis 3.0

Fig. 2.7   Fast Broadband take-up (% of households, 2019)

Source: Digital Scoreboard
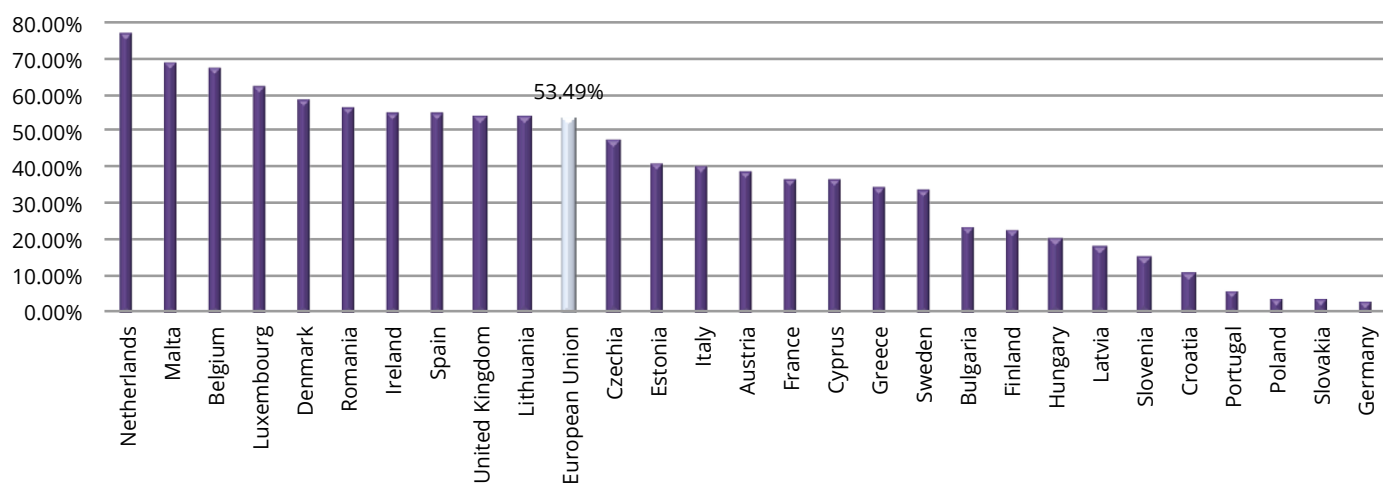
Note: Percentage of households subscribing to broadband of at least 30 Mbps

Currently, fast broadband adoption has reached an average of 53% of households in European countries (Fig. 2.7). For connection adoption of at least 100 Mbps, the current average is actually below 20%, not an excellent result considering the target of 50% of EU households for 2020. Only 2 countries have reached the 50% adoption threshold, while 5 countries have not even reached 10% (Fig. 2.8).

For mobile networks, 4G (LTE) broadband capacity reaches almost 99% of European households. Mobile networks have become such good performers that about 10% of European households only use mobile to connect to the Internet. The economic benefits resulting from mobile communications development are extremely important, and the EU institutions intend to speed up the upgrading to 5G networks and the construction of new infrastructures

supporting the new mobile standard. Trinity College, Tech4i2, Real Wireless and InterDigital (2016) found that 5G could produce benefits of up to €113 billion per year in 2025, coming from automotive (€42 billion), transport (€8 billion), smart workplaces (€30 billion), smart cities (€8 billion) and suburban areas (€10 billion). Generally speaking, investments required for the implementation of the 5G networks have been estimated at more than €515 billion: "business as usual" segments (about €360 billion); Gigabit Society (€98 billion for rural area connectivity; €35 billion socio-economic driver connectivity; and €22 billion for ubiquitous mobility and connection of transport routes. As for now, the investments required to implement the new 5G technical environment were above €16 billion.

Moreover, Fig. 2.10 shows how spectrum allocation is

Fig. 2.8   Households with an ultrafast broadband subscription (% of households, 2018)

Source: European Commission, Digital Scoreboard
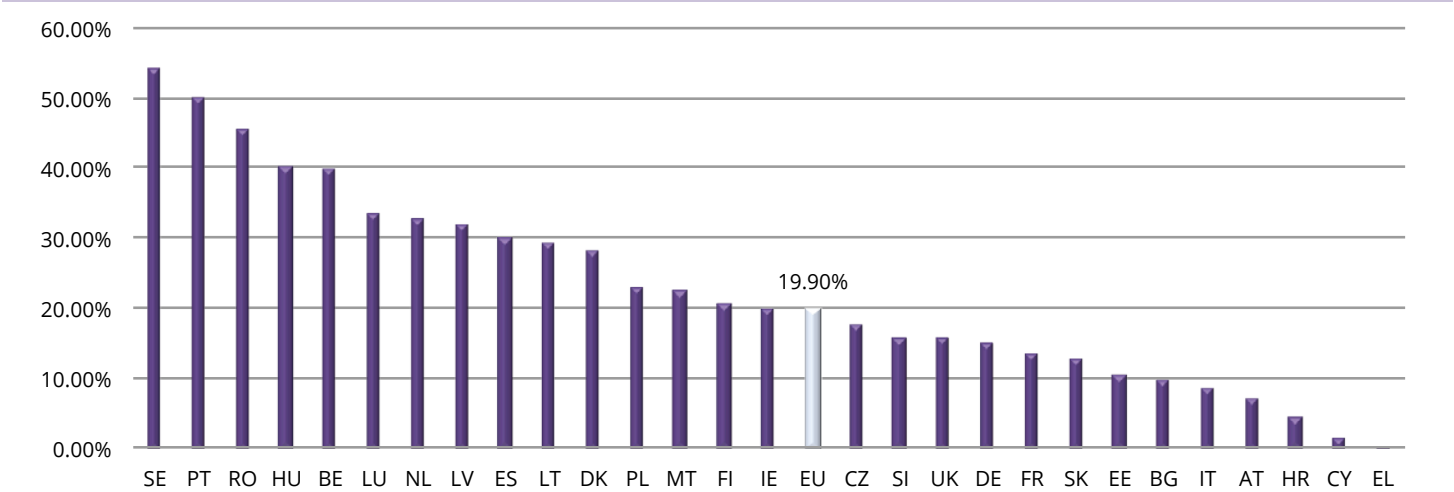
Note: Households with a broadband connection of at least 100 Mbps

Fig. 2.9 Auction results for 5G frequencies in Europe (2018-2019)

Source: I-Com elaboration on various sources, 2019
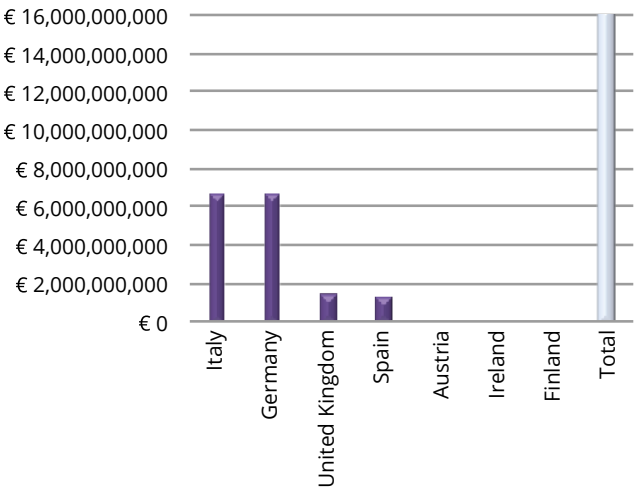
very far from being complete, with less than 15% having been auctioned by September 2019, while there are only 2 countries (Finland and Italy) which have allocated more than half of the dedicated bands. At the same time, several countries (Spain, France, Italy, Germany, United Kingdom and Finland) are conducting a wide number of 5G experiments, showing that the interest of both national bodies and private operators for the new mobile transmission standard is high. Overall, considering the possible economic and social benefits, operator investment efforts, as well as the race of foreign countries - such as South Korea and the economic super powers, China and the US, to implement the new standards, a start to study incentives that could accelerate the spread of 5G within Europe could be a sensible measure.

Fig. 2.10 5G Readiness in European Countries

Source: 5G Observatory, 2019

2.3. CONSUMERS IN THE DIGITAL AGE

The spread of Internet and digital technologies has radically transformed the socio-economic context in which citizens and companies operate. One of the most important activities that individuals perform online is the purchase of goods and services. Where the retail sector, in general, is still facing difficult times, online shopping is continuing to grow. Among the 10 countries with the highest penetration rates of online sales in mid-2017, we find China and South Korea (83%) at the top, followed by the United Kingdom. E-commerce in Europe is forecasted to be worth €621 billion by the end of 2019[5]. This would mean an increase of 13.6% compared

to last year, when it was worth €547 billion. According to Eurostat data, 50% of European citizens made at least one online purchase in the last three months of 2018, with the UK leading (77%), followed by Denmark (73%) and the Netherlands (70%), while Bulgaria and Romania had the lowest percentages (Fig. 2.11).

Most individuals in the EU buy online exclusively from national sellers (Fig. 2.12). Considering the importance of e-commerce spreading across Europe, the European Commission tabled a package of measures to allow consumers and companies to buy and sell products and services online more easily and confidently across the EU. The E-commerce Package was made up of legislative proposals to address unjustified geo-blocking

Fig. 2.11 Internet purchases by individuals in the last 3 months of 2018 (%)

Source: Eurostat
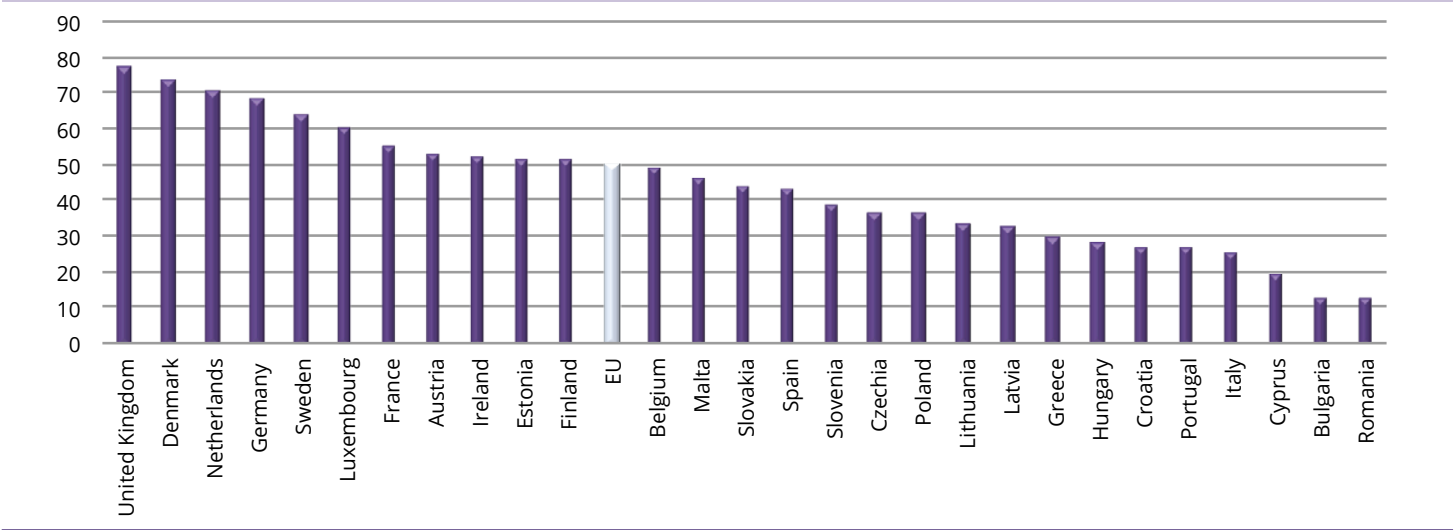
5   European E-commerce Report 2019

and other forms of discrimination on the grounds of nationality, residence or establishment, to increase pricing transparency and correct regulatory practices and strengthen the enforcement of consumer rights and guidance to clarify, among others, what qualifies as an unfair trading practice in the digital world. In particular, high delivery charges in cross-border deliveries - prices charged by postal operators to deliver a small parcel to another Member State are often up to 5 times higher than domestic prices - prevent consumers and small businesses from selling or buying more across the EU. Therefore, the Commission's proposal was to increase pricing transparency and the regulatory controls of cross-border parcel delivery services.

It is therefore necessary to implement new protection systems to ensure that rights are respected even on digital channels. The success of the Digital Single Market depends especially on the confidence and trust of consumers. Millions of European consumers use online platforms (e.g. search engines, social media, e-commerce platforms, app stores, price comparison websites) to access goods and services and these platforms enable consumers to find online information and businesses to exploit the advantages of e-commerce. Online platforms provide opportunities for innovation and growth in the Digital Single Market, but, at the same time, they could pose significant challenges to consumer protection and market competition. According to the policy paper

Fig. 2.12   Online purchases - origin of sellers (%, 2017)

Source: Eurostat

national sellers · sellers from other EU countries · sellers from the rest of the world (non-EU)
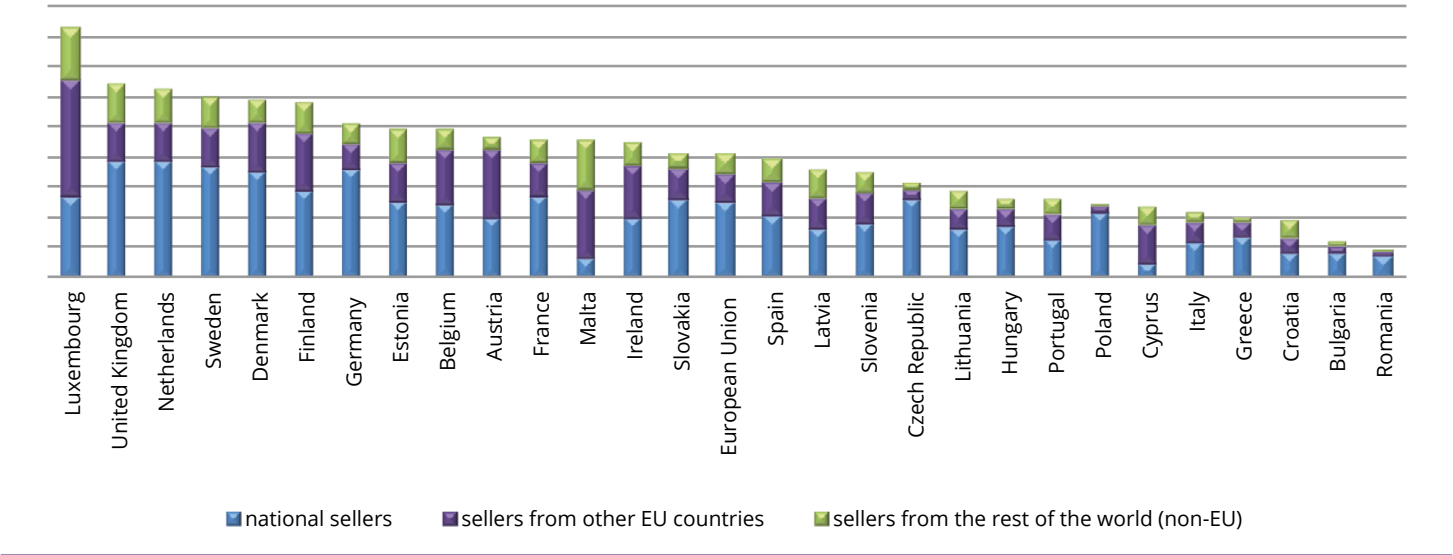
"Online platforms and how to regulate them: an EU overview" (2018), the concerns over the power of online platforms raised in the ongoing political debate can be roughly grouped into two categories - competition and market power and algorithmic discrimination and information asymmetries.

According to a survey (2018) published by the EU Commission, included in a study on the transparency of online platforms, about 82% of respondents said that knowing how results were ranked made them more confident and trusting in the platform. Moreover, the great majority of respondents (83%) think that all platforms should include information on the way they order the results of a search as this would make users more confident and trusting in platforms and,

in general, would lead to a better service for users. Related to contractual party identification, 84% of those interviewed declared that all platforms should include information about who is actually selling the goods or services presented in the platform, and around the same percentage agreed that Internet platforms should be required by law to include information about who is actually selling the goods or services on the platform (Fig. 2.13). Furthermore, the majority of respondents agreed that such information would make users more confident and trusting in platforms and, in general, that this would lead to a better service for users.

Faced with the growing complex information and choices online, consumers are increasingly using digital comparison tools that guide them in making a

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Fig. 2.13   Results of EU survey on online platforms

Source: European Commission, 2018

	Strongly agree	Agree	Indifferent	Disagree	Strongly disagree
Knowing how the platform ordered the results of the search made me more confident and trusting in the platform	0.44	0.38			
All platforms should include information on the way they order the results of a search	0.43	0.4			
All platforms should include information on who is actually selling the goods or services presented in the platform	0.47	0.37			
Internet platforms should be required by law to include information on who is actually selling the goods of services presented in the platform.	0.46	0.37			

decision. Seen as tools of consumer empowerment, price comparison services allow customers to compare product offerings of online sellers, to reveal information on the alternatives and are seen as shifting the traditional asymmetries of information and power between consumers and suppliers. According to the report, "Digital Comparison Tools Market Study" (2017), published by the Competition and Markets Authority in the United Kingdom, these tools offer two types of benefits. Firstly, they save time and effort in searches and make comparing easier and more appealing, above all for household services that are often complicated and not of immediate interest. Secondly, they make suppliers compete more to provide lower prices and better consumer choices.

In 2010, more than 80% of European consumers used price comparison websites in the travel sector, with five out of ten using them at least once a month. The trend has grown further with the growing use of smartphones and tablets which allow consumers to access and compare information on prices, quality and product specifications in all sectors at any time.

2.4. DATA DRIVEN INNOVATION IN EUROPE

Data-driven innovation stands out as a key pillar in the 21st century sources of growth. The confluence of several trends, including the increasing migration of socio-economic activities to the Internet and the decline

Fig. 2.14 Data market value

Source: European Data Market Monitoring Tool, IDC, 2019

* Estimates
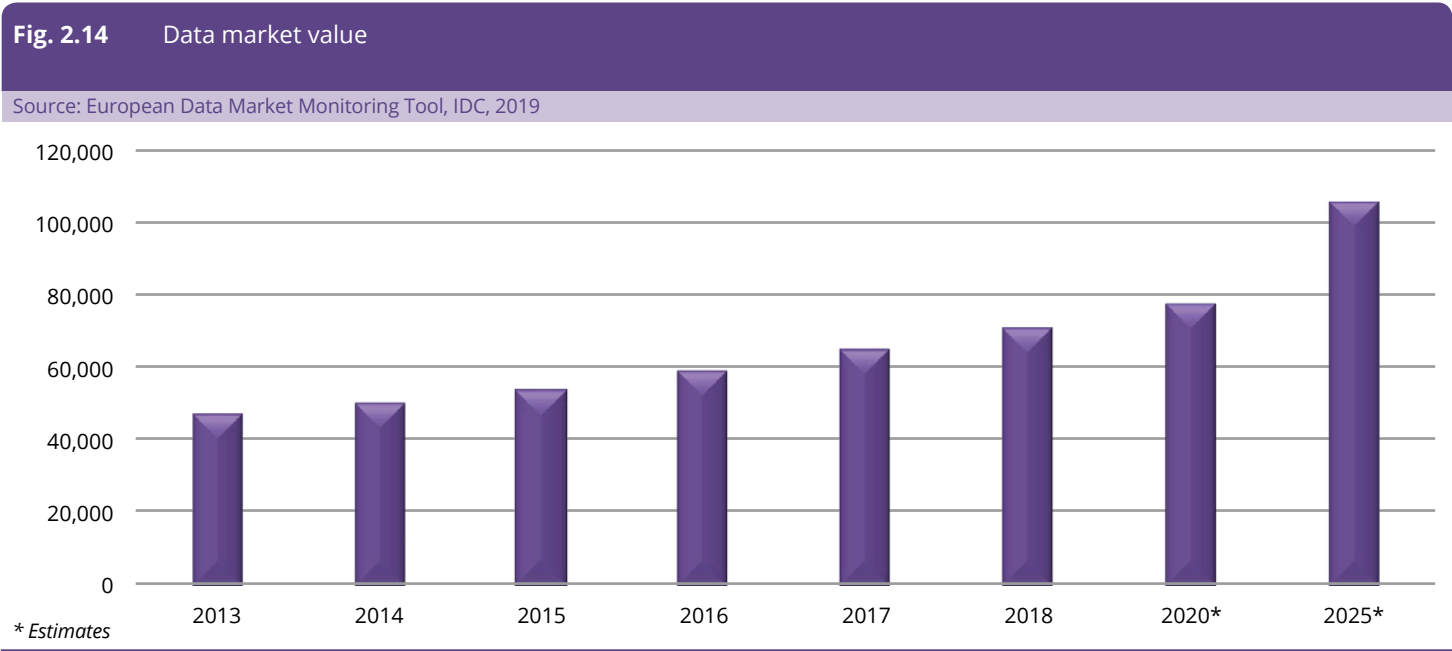
in the cost of data gathering, storage and processing is leading to the generation and use of huge volumes of data. The data market value – meant as the aggregate value of the demand for digital data without measuring the direct, indirect and induced impacts of data on the economy as a whole – is expected to increase from the current €71.6 billion to approximately €78 billion in 2020 and €106 billion in 2025 (Fig. 2.14) in the UK, Germany, France and Italy, accounting for 64.6% of the total. Sweden is the highest-growth country, registering a compound annual growth rate of between 2016 and 2020 of 14.1%, more than twice the EU average (5.8%). Manufacturing and financial services lead in terms of data market size, with a value of €15 billion and €14.5 billion, respectively, equal to 21,3% and 20,3% (Fig. 2.15). Surprisingly, ICT is ranked only fifth, however, after professional services, ICT is the most dynamic vertical market (7% and 6.4%, respectively, of yearly growth rate in the 2018-2025 period for the two sectors). Less dynamic, are the construction and public administration sectors (with an approximately 4% yearly growth).

The data economy measures the overall impact of the data market on the economy as a whole, involving the generation, collection, storage, processing, distribution, analysis elaboration, delivery and exploitation of data enabled by digital technologies, as well as the direct, indirect and induced effects of the data market on the economy.

In 2018, the overall impact of the data market on the economy amounted to about €377 billion (Fig. 2.16), with forward indirect impact accounting for the largest part (47%). Over the next 7 years, the total impact is expected

Fig. 2.15   Data Market Value by Industry (2016)

Source: European Data Market Monitoring Tool, IDC, 2019

- Manufacturing
- Financial services
- Professional services
- Retail
- ICT
- Public administration
- Transport and storage
- Utilities
- Home
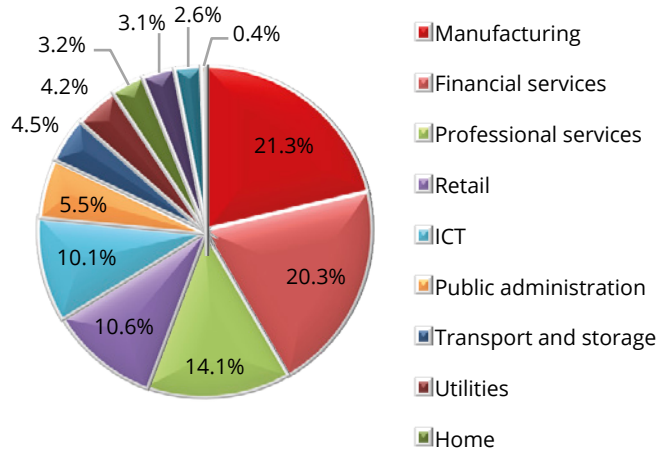
Fig. 2.16   Data economy value in the EU

Source: European Data Market Monitoring Tool, IDC, 2019

- Direct impacts
- Backward Indirect impacts
- Forward Indirect impacts
- Induced impacts
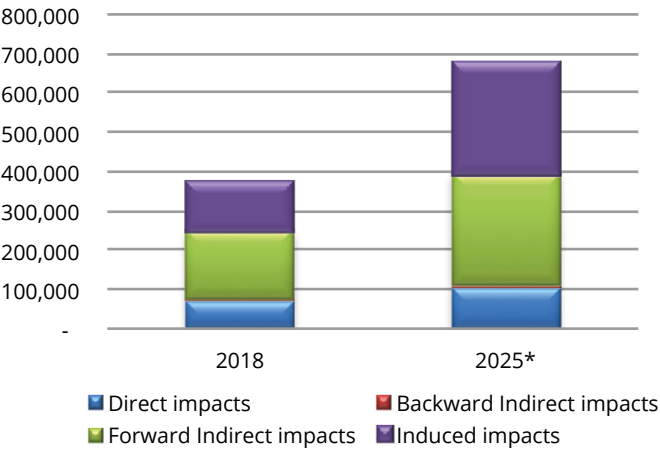
Baseline scenario

Fig. 2.17   Data economy impact on GDP, by Member State

Source: European Data Market Monitoring Tool, IDC, 2019

* Baseline scenario

■2025*   ■2018
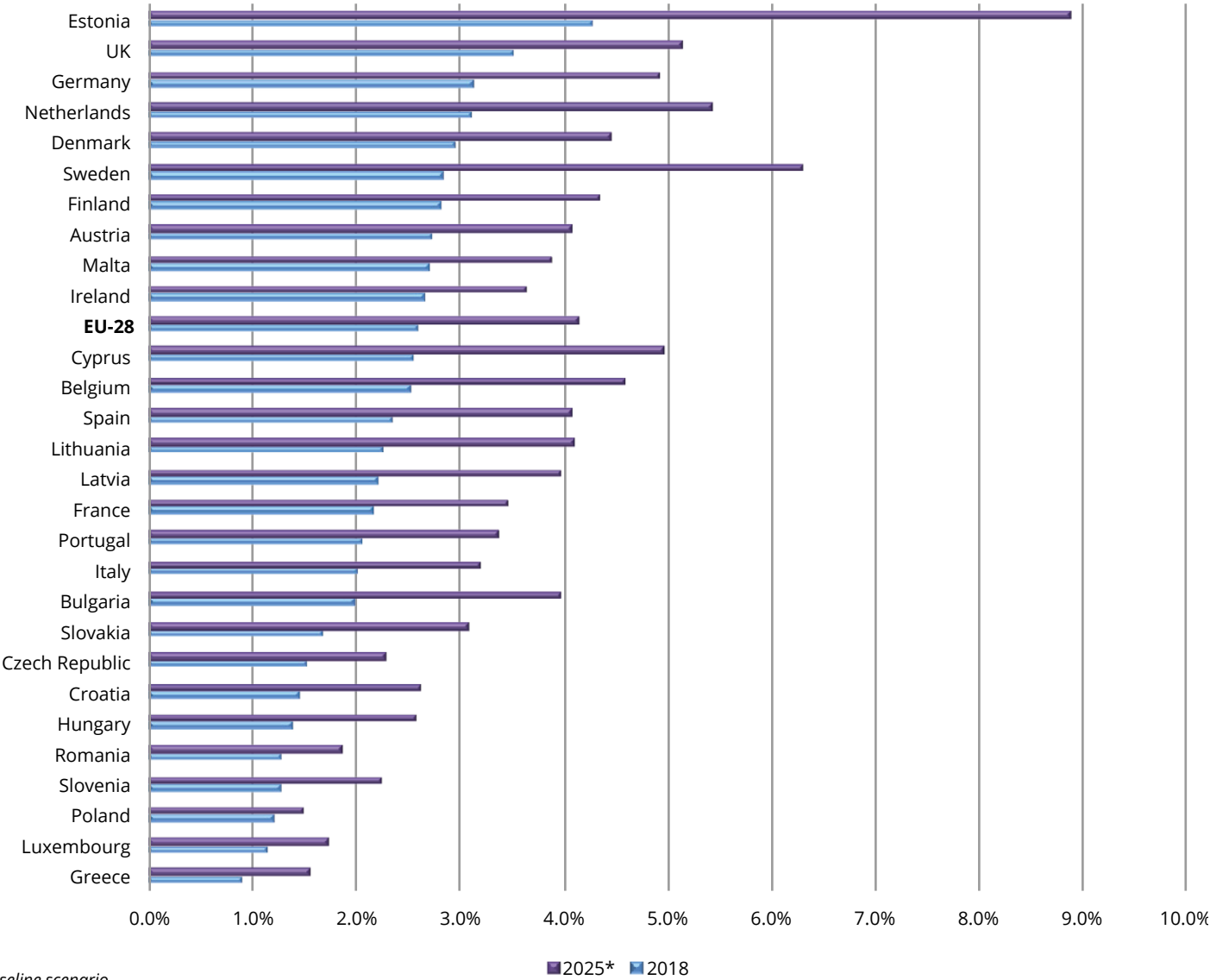
to grow by 83%, reaching €680 billion, with the greatest benefits being induced and forward indirect impacts. The impact of the data market on the EU economies is still low but is becoming more significant (Fig. 2.17). The EU average of 2.6% is expected to increase to 4.2% by 2025, the country with the largest relative impact being Estonia (9% of the overall economy), followed by Sweden (6.3%) and the Netherlands (5.5%), whereas Poland will be the least affected country (1.5%).

Even if Data Analytics skills are in high demand, supply is critically low, with employers facing severe shortages. In order to use and exploit the progressively increasing amount of data which is being produced, data analytics professionals are needed. There were more than 7.2 million data workers in the EU in 2018, with 52%

concentrated in three Member States - the UK, Germany and France (Fig. 2.18).

Data workers represent 3.41% of total EU employment. This varies significantly by country, from 6.3% in Luxembourg to 1.8% in Greece. According to forecasts for 2025, the countries where the number of data workers are expected to increase the most are Slovakia (14.4% yearly), Cyprus (11.3%), Malta (10.3%) and Romania (10.1%), by a rate considerably higher than the EU average (6.6%).

2.5. THE EUROPEAN ROAD TO AI

The global artificial intelligence market is expected to experience a massive growth in the coming years. According to the recently updated International Data Corporation (IDC) Worldwide Artificial Intelligence Systems Spending Guide, spending on AI systems will reach $97.9 billion in 2023, more than two and half times the $37.5 billion that was spent in 2019. The compound annual growth rate (CAGR) for the 2018-2023 forecast period will be 28.4%.

Spending on AI systems will be led by the retail and banking industries, each of which invested more than $5 billion in 2019. The three largest use cases – automated customer service agents, automated threat intelligence and prevention systems, and sales process recommendation and automation – delivered 25% of all spending in 2019. The use cases that will see the fastest spending growth over the 2018-2023 forecast period are automated human

Fig. 2.18 Distribution of data workers across EU 28 (2018)

Source: European Data Market Monitoring Tool, IDC, 2019
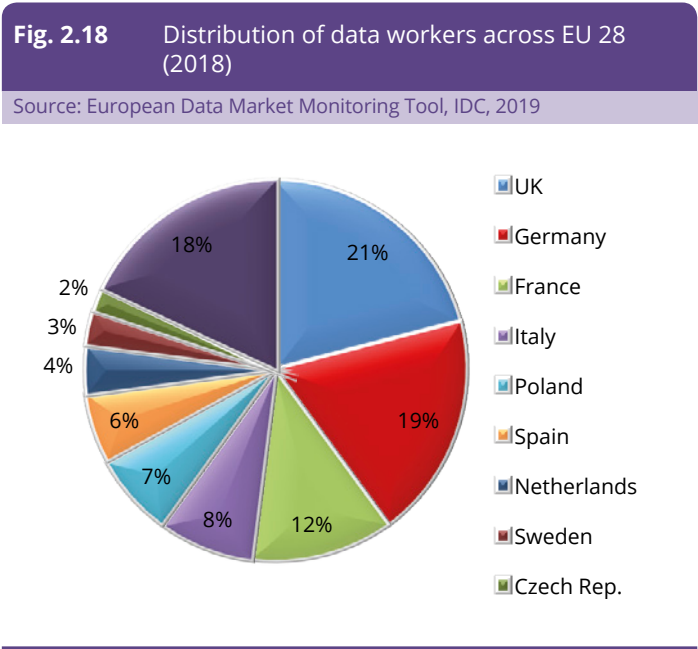
resources (43.3% CAGR) and pharmaceutical research and development (36.7% CAGR). On a geographic basis, the United States is expected to deliver more than 50% of all AI spending, led by the retail and banking industries. Western Europe will be the second largest geographic region, led by banking and discrete manufacturing. China will be the third largest region for AI spending with retail, state/local government and professional services vying for the top position. The strongest spending growth over the five-year forecast will be in Japan (45.3% CAGR) and China (44.9% CAGR)[6]. According to Tractica's latest forecasts, global revenues from the implementation of AI software will increase exponentially, going from $ 9.5 billion in 2018 to $ 118.6 bilioln by 2025 (Fig.2.19).

Among the various AI applications, chat-bots will become very widespread with a market size reaching about $ 1.25 billion in 2025, registering an enormous increase compared to the size of the market in 2016, which stood at $ 190.8 million. Among the main players that dominate the world scene of AI, startups account for a significant portion of innovation. According to 2019 CB Insights data, approximately 80% of the 100 most promising AI startups worldwide are based in the United States, while in the United Kingdom, Israel and China they are equally divided. Furthermore, the sectors in which there is a greater presence of highly professional startups are business technologies, healthcare and the automotive sector (Fig. 2.20).

Fig. 2.19 Global revenue from the implementation of AI software (billion $)

Source: Tractica, 2019

*forecasts

6   https://www.idc.com/getdoc.jsp?containerId=prUS45481219
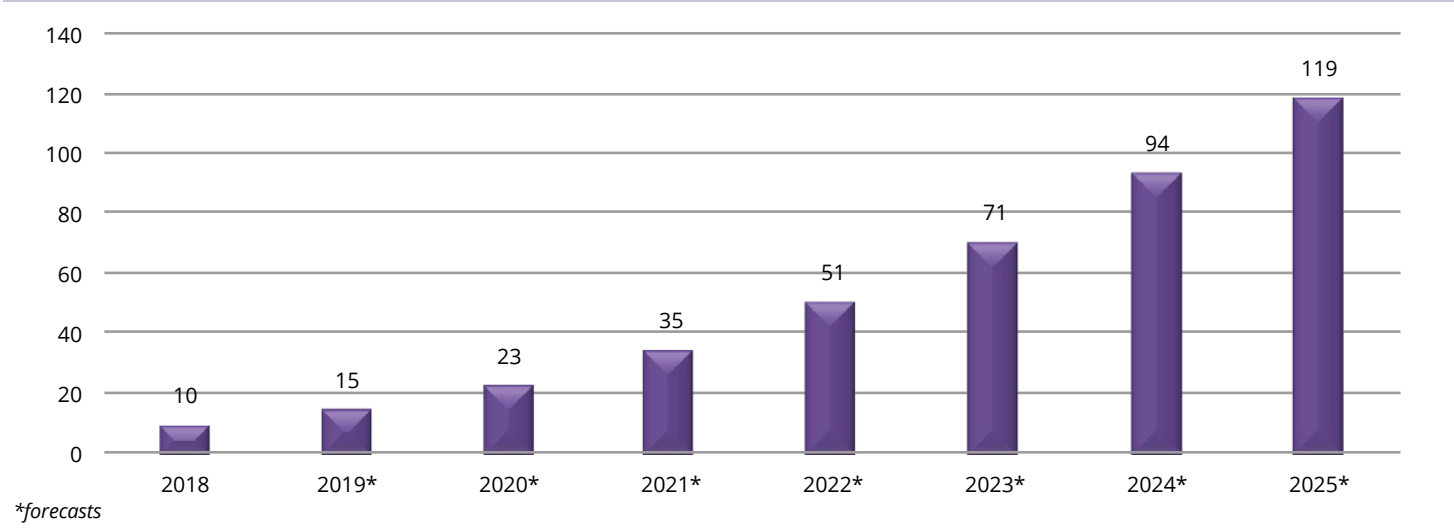
Fig. 2.20   The most promising 100 AI startups

Source: I-Com elaboration on CB Insight, 2019

By country

- United States 77%
- United Kingdom 6%
- Israel 6%
- China 6%
- Sweden 1%
- India 1%
- Germany 1%
- Japan 1%
- Canada 1%

By sector

- Enterprise Tech 33%
- Health Care 14%
- Auto 11%
- Semiconductor 7%
- Finance and Insurance 6%
- Government 6%
- Industrials 6%
- Retail 5%
- Legal, Compliance and HR 4%
- Media 3%
- Agriculture 2%
- Real Estate 2%
- Telecom 1%
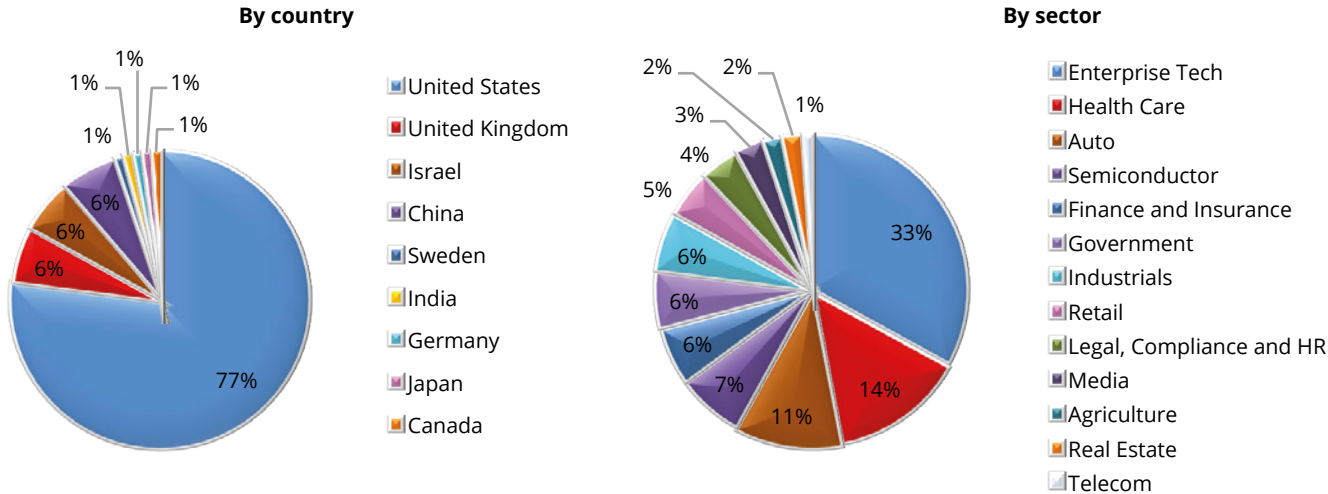
While the US and China have a thriving AI ecosystem, Europe is still struggling to fully open up to smart technologies. If we look at Europe as a whole, with 769 AI startups, it overtakes China. However, no European state has achieved a real critical mass (Fig. 2.21), and the situation could even worsen after Brexit.

However, private equity investment in AI has doubled from 2016 to 2017. In total, it is estimated that more than $ 50 billion was invested in AI startups during the period 2011 through to mid-2018. In this context, the EU accounted for 8% of global AI equity investment in 2017. However, investment levels vary widely among the Member States. (Fig. 2.22).

Furthermore, according to a study by the Joint Research Centre of the European Commission, although the EU is

Fig. 2.22   Private equity investments in AI startups based in the EU (2011 to mid-2018)

Source: OECD

- United Kingdom 55%
- Germany 14%
- France 13%
- Spain 3%
- Ireland 2%
- Others 13%
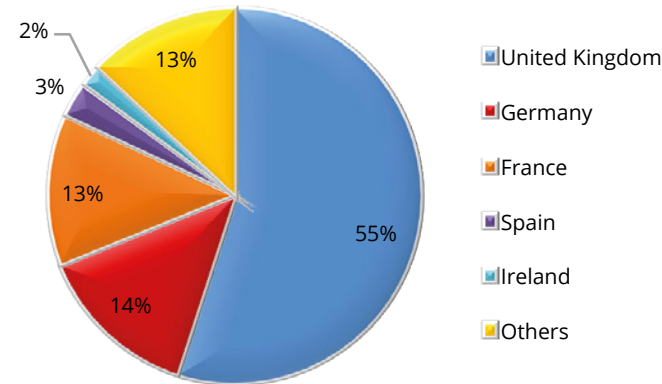
Fig. 2.21   European startups in AI, by country

Source: I-Com elaboration on Asgard and Roland Berger, 2018

Country	Value
United Kingdom	245
France	109
Germany	106
Sweden	55
Finland	46
Spain	39
Switzerland	28
Netherlands	26
Italy	22
Ireland	14
Poland	12
Denmark	12
Norway	6
Hungary	6
Belgium	6
Ukraine	4
Romania	4
Estonia	4
Czech Republic	4
Belarus	4
Lithuania	3
Latvia	3
Slovenia	2
Portugal	2
Malta	2
Austria	2
Slovakia	1
Luxembourg	1
Iceland	1
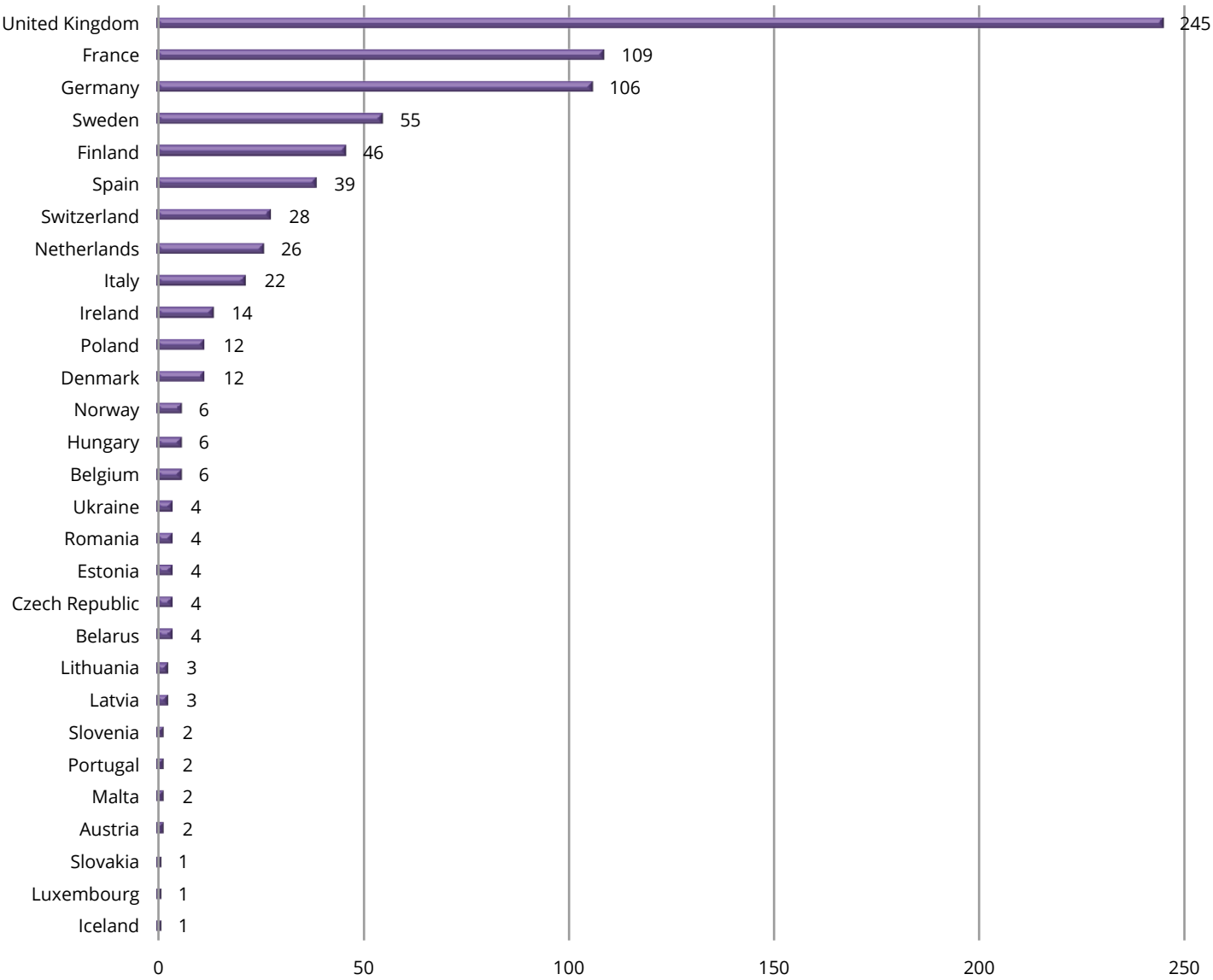
Fig. 2.23 AI Players (% of world total, 2009-2018)

Source: European Commission, Joint Research Center

Policy on Artificial Intelligence and Robotics (February 2019), the Ethics Guidelines for Trustworthy AI (April 2019) and the Policy and Investment Recommendations for Trustworthy Artificial Intelligence (June 2019). The goals include:

- assuring the drawing up and the enforcement of the legal framework, with investments in AI research and production by both public and private entities being encouraged;
- increasing cooperation with the industrial sector;
- addressing the European fragmented AI ecosystem and retaining top talents (possibly attracting more from abroad).

The setting up of a European Institute for AI could play a very significant role here.

among the geographical areas with the largest number of players active in AI - with 25% of the total - just below the US (28%) and above China (23%) (Fig. 2.23) - European companies are still not inclined to adopt more advanced machine learning techniques, as well as AI tools such as intelligent workflows, cognitive agents and natural language processing systems.

In order to foster competitiveness and innovation in the AI field, EU institutions have adopted a series of initiatives, such as the Declaration of Cooperation on Artificial Intelligence (April 2018), the European Approach to Artificial Intelligence (April 2018), the Coordinated Plan on AI (December 2018), the Resolution on a Comprehensive European Industrial

2.6. THE IMPACT OF AI ON THE LABOUR MARKET: ORGANISATION, NEW JOBS, UPSKILLING/ RESKILLING AND THE ROLE OF EDUCATION AND TRAINING

In order to harness the transformative potential of the Fourth Industrial Revolution, business leaders across all industries and regions will increasingly be called upon to formulate a comprehensive workforce strategy ready to meet the challenges of this new era of accelerating change and innovation. Global labour markets are set to undergo significant transformations over the coming years. A cluster of emerging roles will gain importance, while another cluster of job profiles is set to become

Fig. 2.24   Job automation risk, by country (2018)

Source: OECD, 2018

Country	%
Norway	41%
New Zealand	42%
UK	43%
Northern Ireland	43%
US	43%
Finland	43%
Sweden	44%
Canada	45%
Denmark	45%
Netherlands	45%
Korea	46%
Estonia	46%
Belgium	46%
Singapore	46%
Ireland	46%
TOTAL	47%
Russia	47%
Israel	47%
Czech Rep.	48%
Austria	48%
Italy	49%
France	49%
Poland	50%
Spain	51%
Slovenia	51%
Japan	51%
Cyprus	51%
Germany	52%
Turkey	52%
Chile	52%
Lithuania	54%
Greece	54%
Slovakia	57%
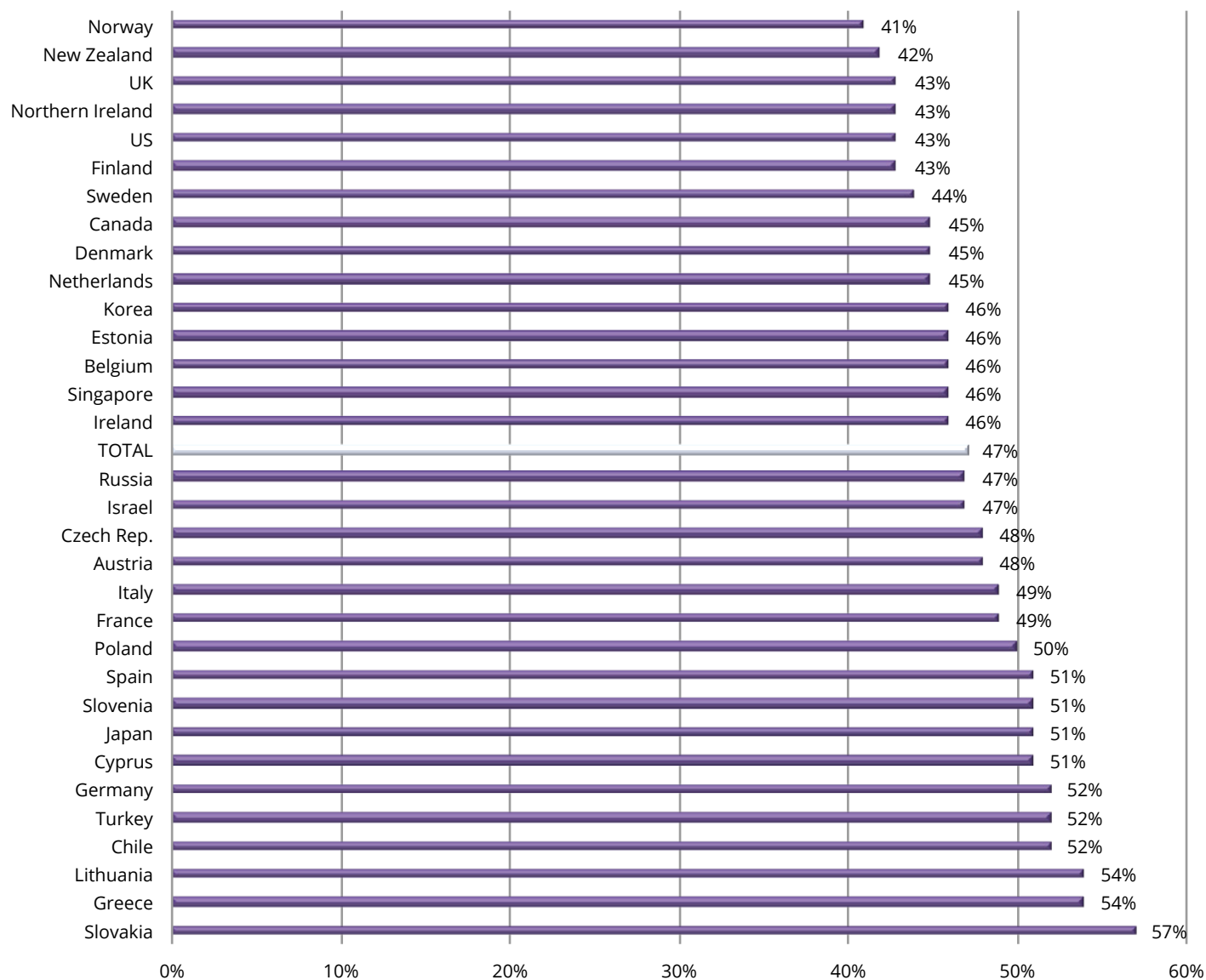
increasingly redundant. According to an OECD[7] study, for a total sample of 32 countries analysed, the average job is estimated to have 47% probability of being automated (Fig. 2.24). The occupational groups that have the highest probability of becoming automated typically do not require specific skills or training. At the other end of the spectrum, we find occupations that require a high level of education and training and which involve a high degree of social interaction, creativity, problem-solving and caring for others (professionals, managers, but also personal care workers). The industries with a higher risk of automation belong mostly to the primary and the secondary sectors. Few service industries – notably, postal and courier services, food and beverage services, land

transport, waste collection and treatment, and services to buildings and landscape – face a high risk of automation. According to a World Economic Forum (WEF) study[8], while 75 million jobs may be displaced, 133 million additional new roles may emerge. Among the roles that are set to experience an increasing demand are Data Analysts and Scientists, Software and Applications Developers, and Ecommerce and Social Media Specialists that are significantly based on and enhanced by the use of technology. Moreover, technology will also create new tasks, from app development to piloting drones to remotely monitoring patient health. Thus, there will be an accelerating demand for a variety of new specialist roles related to understanding and leveraging the
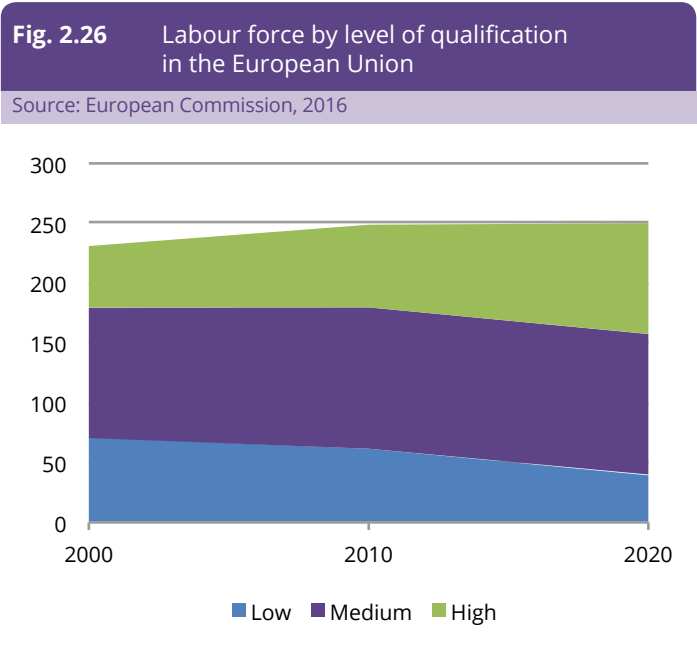
Fig. 2.25 Changes in employment

Source: Accenture, 2018
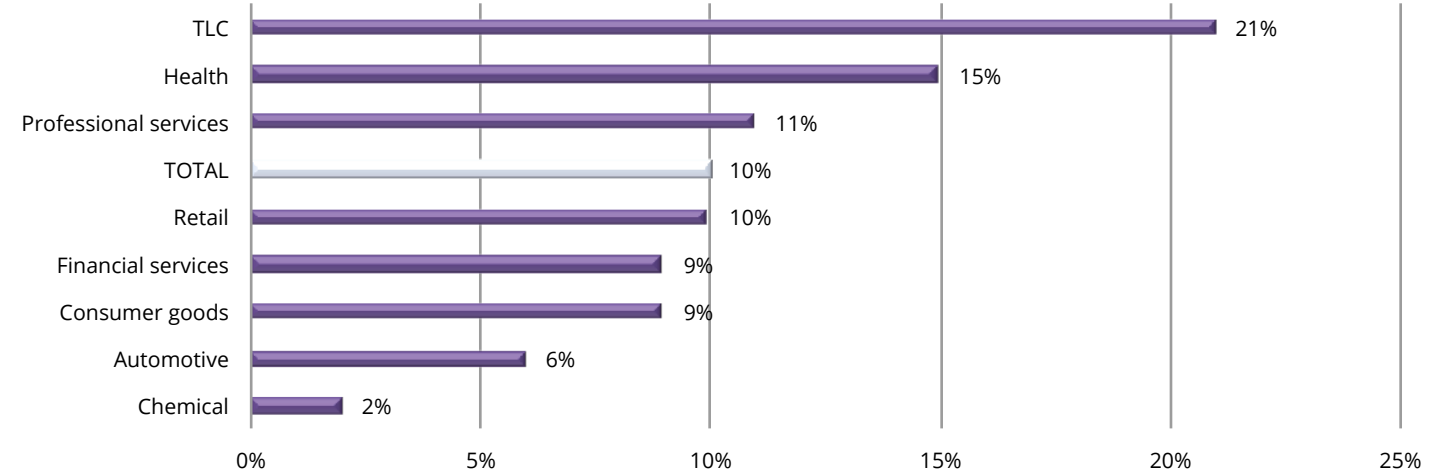
7   L. Nedelkoska, G. Quintini, "Automation, skills use and training", 2018

8   WEF, "The future of jobs 2018", (2018)

latest emerging technologies - AI and Machine Learning Specialists, Big Data Specialists, Process Automation Experts, Information Security Analysts, User Experience and Human-Machine Interaction Designers, Robotics Engineers and Blockchain Specialists. On the other hand, the jobs expected to become increasingly redundant are routine-based, middle-skilled white-collar roles that are susceptible to advances in new technologies and process automation. Accenture[9] estimates that if companies properly invested in AI and in human-machine collaboration, they could boost employment by 10% (Fig. 2.25).

Fig. 2.26	Labour force by level of qualification in the European Union
Source: European Commission, 2016	

Workers with appropriate skills may see their wages and job quality increase considerably. Conversely, even if automation only affects a subset of the tasks within their job role, workers lacking skills needed to adapt to new technologies and to move on to higher value tasks may see their wages and job quality undermined by technology steadily eroding the value of their job. Europe's advantage in the future highly automated world of work lies in its creativity and highly skilled workforce. In 2000, less qualified jobs numbered about 65 million, in 2020 there will be less than 40 million (-40%), 16% of total employment (31% in 2000). Instead, highly skilled work (less than 20% of employment in 2000) will account for 37% in 2020, with a total of 90 million jobs (Figure 2.26).

In the coming years, the skills required to perform most jobs will have markedly changed. According to the World Economic Forum, over the 2018–2022 period, only 58% of skills are expected to remain stable, meaning an average shift of 42% in the required workforce skills, identifying a continued fall in demand for manual skills and physical abilities and, on the other hand, a decrease in demand for skills related to the management of financial and other resources, as well as basic technology installation and maintenance skills. According to other research, currently only about 30% of employees in today's jobs with the highest probability of technological disruption have received any kind of professional training over the past 12 months. In addition, they are, on average, more than three times less likely than employees in less exposed roles to have participated in any on-the-job training or distance learning and about twice less

9   Accenture, "Reworking the Revolution: Are you ready to compete as intelligent technology meets human ingenuity to create the future workforce", 2018

likely to have participated in any formal education. To date, reskilling has been regarded by employers as a strategy only focused on specific subsets of employees, not as a comprehensive strategy to drive workforce transformation.

The development of AI models requires very high levels of competence in several areas. Work in this area requires advanced levels of scientific, mathematical and technical skills that are not easy to acquire, as well as a good understanding of statistics and computer architectures and programming tools[10]. The largest influence of AI adoption is the development of complementary human skills as AI technologies evolve. The two biggest barriers to AI adoption in European companies are linked to having the right workforce in place. The first barrier relates to the ability in using ICT tools at work. The second barrier relates to companies' needs for skills to provide new AI applications and services, such as AI coding and analytic expertise[11]. More in general, enterprises experiencing hard-to-fill vacancies for jobs requiring ICT specialist skills increased from 3% in 2015 to 5% in 2018[12].

A key issue is the need for horizontal skills. As described by the European Commission[13], the right skills needed for "future ready" professionals derive from a combination of the T-shape metaphor together with the leadership skill triangle, resulting in innovators with the necessary high-tech talent and leadership skills. They display:

■ Strategic Leadership: to lead interdisciplinary staff, and influence stakeholders across functional and geographic boundaries;

■ Business Savviness: to innovate business and operating models, delivering value to organisations;

■ High-tech Savviness: to envision and drive change for business performance, exploiting the innovation opportunities in high-tech trends.

The European Commission published the High-tech Leadership Index, based on 24 indicators belonging to the following four domains: e-leadership education, proportion of the workforce with e-leadership potential, structural variables that permit opportunities of e-leadership to be exploited and e-leadership enabling policies or other drivers. It measures the factors likely to affect demand and supply for e-leadership skills in each country. Ireland, the Netherlands, Finland, the UK, Sweden, Belgium and Denmark are the frontrunners, with a performance of more than 20% above the EU average, whereas Cyprus, Croatia, Slovakia, Bulgaria, Italy, Greece and Romania are at the other end of the ranking.

The European Commission estimates that there are 800,000 high-tech leaders in the EU, but a total of an additional 450,000 will be needed by 2025. Of these, about 86% will be leaders in the field of digital leadership, the remaining 14% in the field of KETs[14]. Concerning

10 European Commission, "Artificial Intelligence. A European perspective", 2018
11 McKinsey & Company, "Notes from the AI frontier: Tackling Europe's gap in digital and AI", 2019.
12 Eurostat (2019).
13 European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, "High-Tech Leadership Skills for Europe", 2017

14 Key Enabling Technologies - micro and nano electronics, nanotechnologies, industrial biotechnologies, advanced materials, photonics and advanced manufacturing.

- Demand (left axis)
- Supply (left axis)
- Data workers skill gap (right axis)

■2018 ■2025
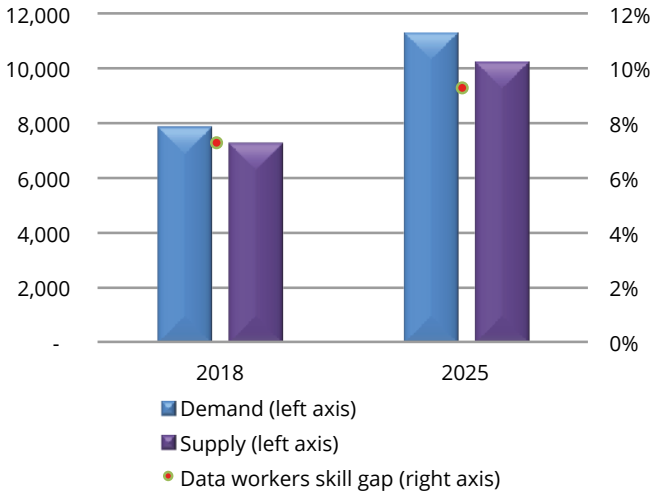
the former, Big Data, Internet of Things and robotics-cognitive systems combinations are the most disruptive technologies, which will produce the largest demand – and then will face the greatest lack – of skills. 40% of European employers have difficulty finding people with the skills needed to grow and innovate. According to current data and estimates for the future, there is (and there will be) a substantial skills gap. According to IDC, in 2018, the gap between total demand and supply of data workers made up 571,000 unfilled data worker positions in the EU (7.2% of total demand) and this is expected to rise to over 1 million (9.2% of total demand) by 2025 (Fig. 2.27). In the scenario to 2025, the skills gap in both Germany and France are expected to more than double – from 5% to 11.3% in the former and from 4.8% to 11%
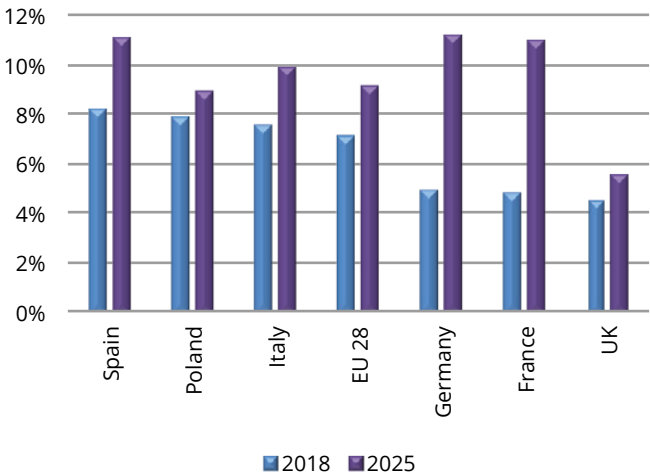
in the latter – thus becoming, together with Spain, the countries that will suffer the most from the shortage of necessary data skills (Fig. 2.28).

While not all jobs will require highly advanced degrees, they will need varying levels of appropriate skills. These skills are likely to become prerequisites for a number of workers, from CEOs to entry-level positions. In terms of the occupational mix, most data workers are professionals, technicians, or associate professionals (70% total), however, there is also a significant number in the manager category (23%), largely focusing on data in order to drive their decisional processes. Existing managers, at all levels, need to become more familiar with and use data and analytics. On the other hand, only 7% of data workers concerns clerical support roles. In order to properly

approach the current and emerging job market, education and training in the field of AI, as well as inter-disciplinarily, is highly encouraged; the promotion of reskilling and up-skilling is necessary; and collaboration between humans and machines is encouraged. To enhance consumers experience, e-commerce, improving price transparency and strengthening the enforcement of consumer rights and guidance to clarify what qualifies as an unfair trading practice in the digital world is necessary; digital comparison tools that work effectively, contributing to lowering transaction costs and delivering better deals by enabling consumers to conveniently and efficiently compare and choose between offers from across the market is important to ensure; and simple, efficient, fast and low-cost ways of resolving disputes which arise from the sale of goods or the supply of services online are important. To create reliable cybersecurity, the adoption of a united and coordinated approach on security is encouraged; European cyber practices by increasing the capacity of all Member States to monitor, prevent and respond to cybercrime should be coordinated; and investments in startups to allow for the burgeoning of new technologies and practices, as well as a procurement policy primarily addressed in this area to EU-based companies, is important.

2.7. CYBERSECURITY IN THE DIGITAL AGE

The IoT (Internet of Things) has led to the spread of a mass of smart devices for people and businesses. However, this relatively new way of living (always accessible, everywhere and at every moment) has brought to light many new problems in terms of security and, specifically, cybersecurity. The digital environment is vast and, consequently, it is ideal ground for cyberattacks that can be either indiscriminate or targeted, aimed at large and small organisations in both the public and private sectors. The new technologies, mobiles, smart devices connected to the IoT and many AI applications expose every organisation to attackers, increasing the risks of, for example, shut downs or subversion of industrial control systems. Threats can even be dangerous to human lives if you imagine an attacker being able to turn off life support systems in hospitals or take control of connected cars on the road. Indeed, the World Economic Forum has included cyberattacks amongst the biggest problems of 2019, along with natural disasters, biodiversity loss and ecosystem collapse and the spread of infectious diseases[15].

According to a 2019 Clusit study, out of a sample 8,417 serious attacks[16] occurring worldwide between 2011 and 2018, 1,552 were recorded during the last year (+77.8% compared to 2014 and +37.7% compared to 2017) (Fig. 2.29). In recent years, Cybercrime, Cyber Espionage and Information Warfare have recorded a strong increase. Cybercrime rose by 43.8% in 2018 compared

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15 https://www.kaspersky.com/about/press-releases/2018_ics-computers-attacked-in-h1
16 Serious attacks are those attacks with a significant impact on victims in terms of economic losses, damage to reputation, the dissemination of sensitive personal and non-personal data, or that herald particularly worrying scenarios

Fig. 2.29   Cyberattacks occurring worldwide (2014-2018)

Source: Clusit, 2019
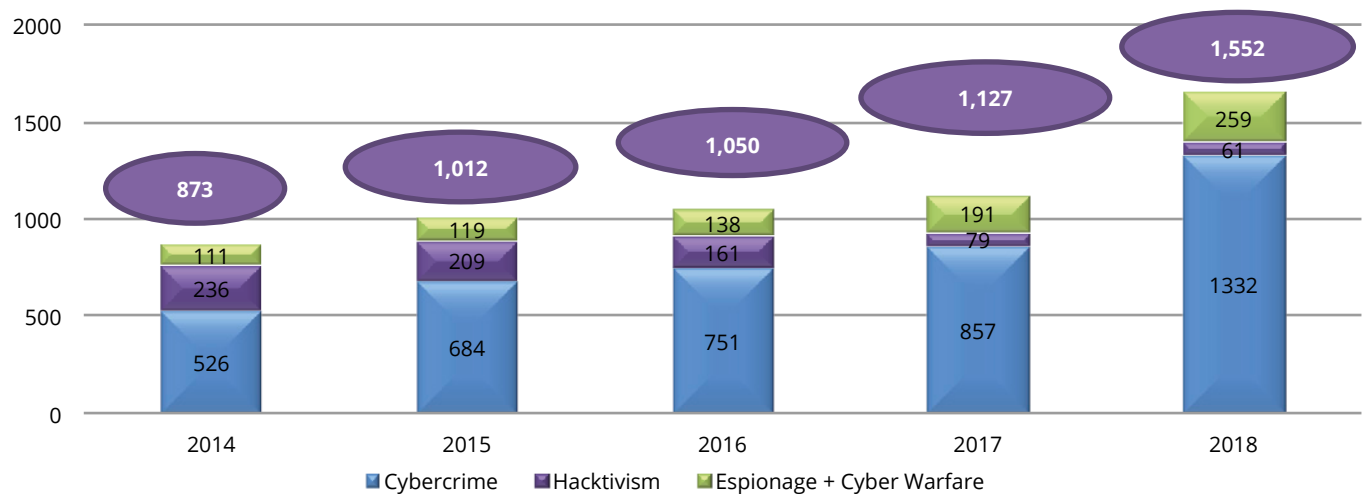
to 2017, while Cyber Espionage and Information Warfare increased by 35.6% in 2018 compared to 2017. On the contrary, Hacktivism decreased by 22.8% in 2018 compared to 2017. Cybercrime is the first cause of serious cyberattacks at a global level. It has gradually been increasing, from 60% of analysed cases in 2014 to 79% in 2018, showing an unequivocal trend.

Therefore, in an increasingly digitalised world, cybersecurity has jumped to the top of the company risk agenda after a number of high-profile data breaches, ransom demands, Distributed Denial of Service (DDoS) attacks and others, over the last years. Customer information, financial information and strategic plans make up the top three most valuable information areas that organisations would like to protect. In fact, for 17% of the organisations interviewed, the biggest fear is the loss of customer information, followed by the loss of financial information (12%) and strategic plan violations (12%) (Fig. 2.30).

Cyberattacks are having a significant and growing financial impact on businesses worldwide. According to the Cost of Cyber Crime Study published by Accenture and the Ponemon Institute (2019)[17], the global average cost of cybercrime, which includes the total of costs incurred to detect, recover, investigate

17 The Cost of Cyber Crime Study surveyed 2,647 security and IT professionals in 355 companies in 11 countries - Australia, Brazil, Canada, France, Germany, Italy, Japan, Singapore, Spain, the United Kingdom and the United States.

Fig. 2.30   Top 10 most valuable information to cyber criminals

Source: EY Global Information Security Survey, 2018-19

Information type	Percentage
Customer information	17%
Financial information	12%
Strategic plans	12%
Customer passwords	11%
Board member information	11%
R&D information	9%
M&A information	8%
Intellectual property	6%
Supplier information	5%
Non-patented IP	5%
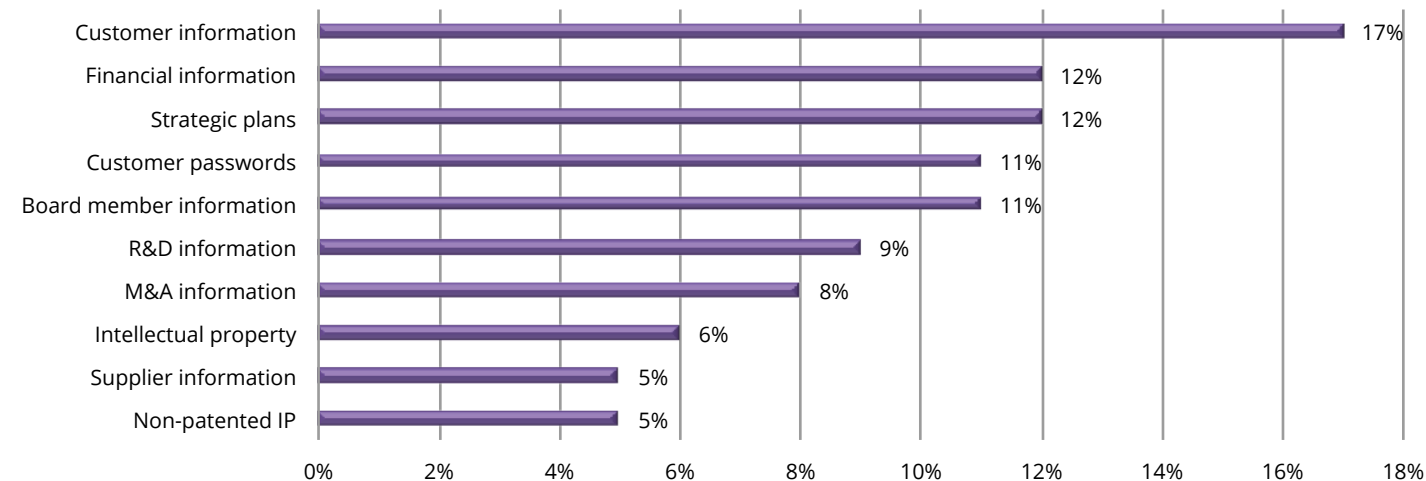
and manage the response to cyberattacks, climbed to $13 million in 2018, with an increase of 12% from $11.7 million reported in 2017, and 72% in the last five years. Malware is the most expensive attack type for organisations, followed by web-based attacks, however, the cost of ransomware and malicious insider attack types has grown the fastest over the last year (21% and 15%, respectively). Analyses show that banking and utilities industries continue to incur the highest costs for cybercrime, equal to $18.37 million and $17.84 million with an increase of 11% and 18%, respectively. In comparing different countries, US companies incurred the highest total average cost at $27.4 million, increasing by 29% in 2018 compared to 2017. But the highest increase of 31% was experienced by organisations in the UK growing to $11.5 million, closely followed by Japan increasing by 30% in 2018, reaching $13.6 mln on average for each organization. Finally, the main and most costly impacts on organisations that suffered cyberattacks are loss of information, business disruption, loss of revenue and damage to equipment.

Europe is playing an increasingly active role in addressing the multiple cyber threats and holds a leading position in the global context. According to the Global Cybersecurity Index 2018 (a composite index combining 25 indicators into one benchmark to monitor and compare the level of the cybersecurity commitment of Member States for

Fig. 2.31 Top 10 biggest cyber threats to organizations

Source: EY Global Information Security Survey, 2018-19

Threat	%
Phishing	22%
Malware	20%
Cyberattacks to disrupt	13%
Cyberattacks to steal money	12%
Fraud	10%
Cyberattacks to steal IP	8%
Spam	6%
Internal attacks	5%
Espionage	2%
Natural disasters	2%
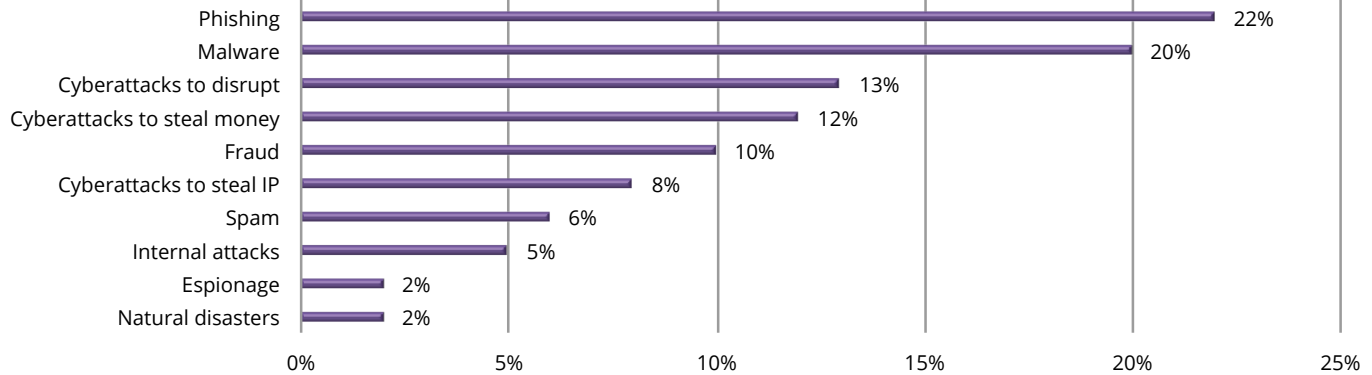
Fig. 2.32 Cost of cybercrime (2018)

Source: Accenture and Ponemon Institute, 2019

By industry

Industry	million $
Banking	~18.5
Utilities	~18
Softwear	~16
Automotive	~16
Insurance	~16
High tech	~15
Capital markets	~14
Energy	~14
US Federal	~14
Consumer goods	~12
Health	~12
Retail	~11.5
Life sciences	~11
Communications and Media	~9.5
Travel	~8.5
Public Sector	~8

By country

Country	million $
United States	~27
Japan	~13
Germany	~12.5
United Kingdom	~11
France	~9.5
Singapore	~9
Canada	~9
Spain	~8
Italy	~8
Brazil	~7
Australia	~7

the five pillars[18] of the Global Cybersecurity Agenda) published by the International Telecommunication Union (ITU), the UN Agency that deals with TLC and network policies, European countries have improved their rankings due to initiatives such as the EU certification framework for ICT security products, the implementation of the General Data Protection Regulation (GDPR) and the Directive on security of network and information systems (NIS Directive). In 2018, six European countries with the highest level of commitment to cybersecurity were in the top ten most committed countries globally. The UK dominated the global ranking, followed by France in third position, Lithuania (4th), Estonia (5th), Spain (7th) and Norway (9th). Finally, Europe stands out as having the highest number of Member States with national strategies with, out of a total of 45 European states, as many as 39 having a National Cybersecurity Strategy.

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18   The five pillars are: 1. Legal Measures based on the existence of legal institutions and frameworks dealing with cybersecurity and cybercrime; 2. Technical Measures based on the existence of technical institutions and frameworks dealing with cybersecurity; 3. Organizational Measures based on the existence of policy coordination institutions and strategies for cybersecurity development at the national level; 4. Capacity-building Measures based on the existence of research and development, education and training programs, certified professionals and public sector agencies fostering capacity building; 5. Cooperation Measures based on the existence of partnerships, cooperative frameworks and information sharing networks.

2.8. WAITING FOR THE AI WHITE PAPER: RECENT EU INITIATIVES

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 minimising 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 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 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 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 will issued a guidance document on the interpretation of the Product Liability Directive in light of technological developments by mid-2019 and published, by mid-2019, 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 of them by mid-2019. 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 ForTrustworthy 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 achieving 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).

PART 3

TAKING CARE OF EU HEALTH POLICY: COUPLING EUROPEAN INDUSTRIAL LEADERSHIP WITH A PATIENT-CENTRED APPROACH

3. TAKING CARE OF EU HEALTH POLICY: COUPLING EUROPEAN INDUSTRIAL LEADERSHIP WITH A PATIENT-CENTRED APPROACH
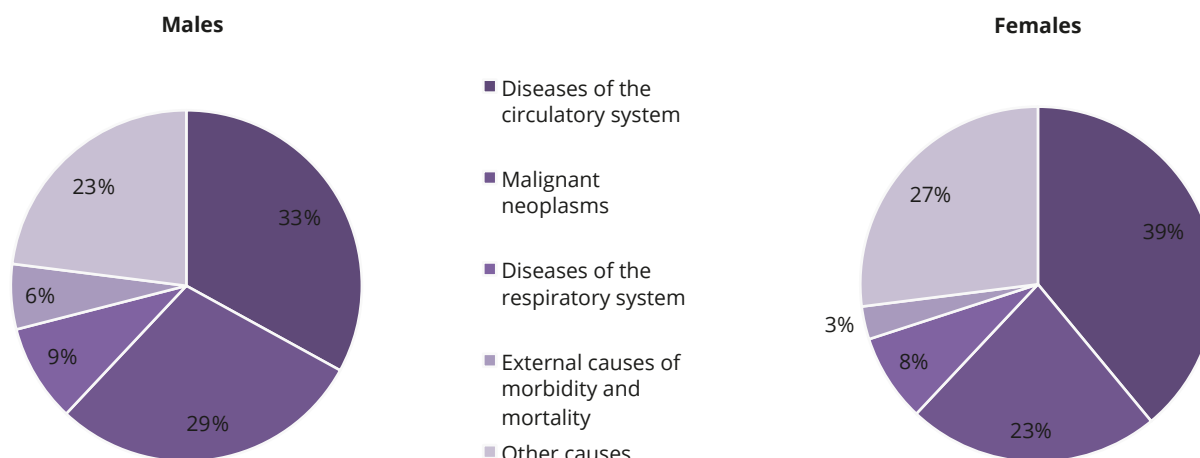
3.1. MAIN RISK FACTORS AMONG EUROPEAN COUNTRIES: THE ROLE OF HEALTH PROMOTION AND PREVENTION

The ageing population and chronic diseases, such as antimicrobial resistance and vaccination prejudice, together with 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 become 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 behaviour, diet and exercise, as well as to genetic predispositions. It is clear that this has increased the demand and availability of treatment and personalised lifelong care and will create an economic stress on health systems that will no longer be sustainable in the long term. Circulatory diseases (especially ischaemic heart disease and strokes) and malignant neoplasms, followed by respiratory diseases and external causes of death (accidents, suicides, homicides, etc.) are the main causes of death in EU countries. Circulatory diseases caused over 1,800,000 deaths in 2016, especially in

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Fig. 3.1   Main causes of mortality among women and men in the EU (2016)

Source: Eurostat, 2019

Males

33%
29%
9%
6%
23%

- Diseases of the circulatory system
- Malignant neoplasms
- Diseases of the respiratory system
- External causes of morbidity and mortality
- Other causes

Females

39%
23%
8%
3%
27%

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. 3.1).

One of the steps needed for a paradigm shift towards more sustainable healthcare systems concerns integrating patient care across the continuum of life, bridging the gap between acute, treatment-driven demand, and normal, healthy living. In this context health promotion, and prevention are essential channels to invest in. Health promotion allows people to increase control over and improve their health. It is an integral element of health systems, essential in helping them to become efficient and sustainable and improve health outcomes. For this reason, investing in health promotion is 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[19]. 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. "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"[20]. 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 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;

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19 European Commission, State of Health in the EU, Companion Report 2019
20 Breslow L. (1999), From Disease Prevention to Health Promotion, JAMA. 1999;281(11):1030-1033

coordinated action is also required by other sectors such as governments, non-governmental and voluntary organisations, local authorities, industry and the media.

Based on the latter, the Ottawa Charter recognises that improvement in health requires a solid foundation of prerequisites, such as education, food, decent income, stable eco-systems, 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. According to EuroHealthNet (European partnership for improving health outcomes and inequalities)[21], 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. Health outcomes and health inequalities are mainly

Fig. 3.2   Self perceived health in the EU (aged 16 or above, 2019)

Source: EuroHealthNet, 2019
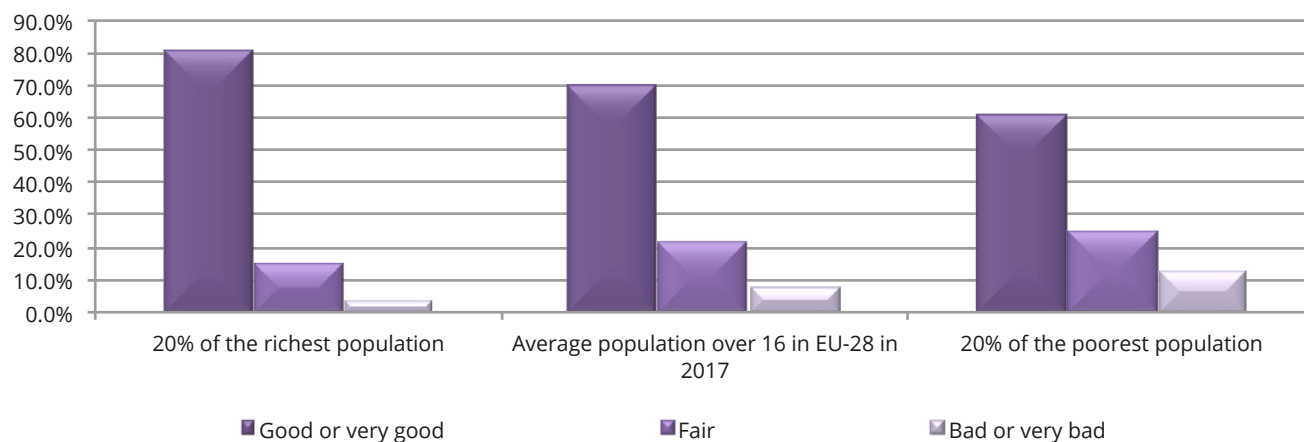
21 Health Inequalities in Europe, EuroHealthNet factsheet, October 2019.

affected by the social, economic, and environmental determinants of health, such as the conditions in which we are born, grow up, live, work, and age. The latter evidence is at a first glance observable by looking at the percentage of people in the EU that describe their health as "good" or "very good" according to their level of education and income (Fig. 3.2). Out of 20% of the richest of the population, 80.4% of the group declare to perceive their 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.

Together with health promotion, disease prevention is crucial in improving health outcomes, reducing health inequalities and rationalising economic resources.

Disease prevention commonly refers to intervention (either population or individual-based) which aims at minimising the burden of diseases and associated risk factors. It is frequently categorised 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 behavioural 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

Fig. 3.3   Health expenditure for preventive care (2017)

Source: OECD

■ € per-capita   ● % of GDP (dx)
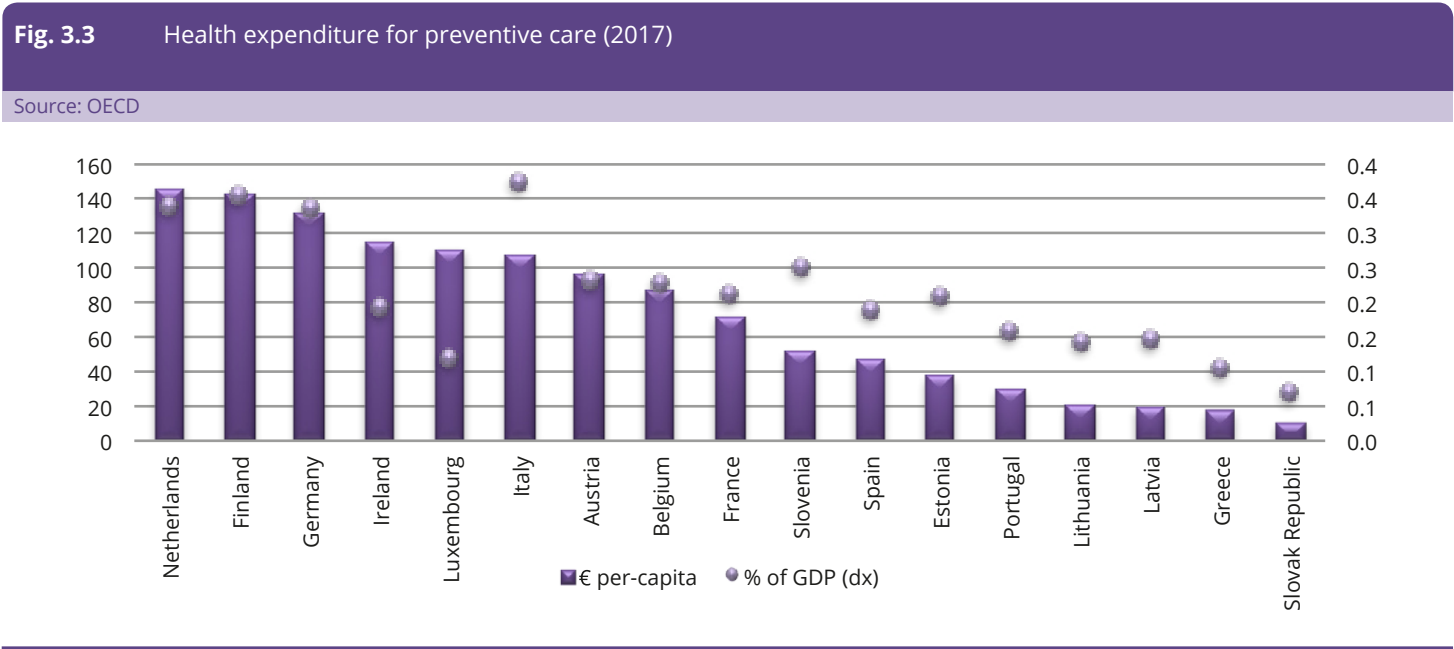
population-based screening programmes, including production and purchasing of screening tests for early disease detection. Tertiary prevention is associated with services that promote better quality of life for those living with a disease. It includes rehabilitation, disease management programmes and support for patients with an established disease to minimise residual disabilities and complications.

Quaternary prevention is related to avoiding over-medicalisation 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-centred care, chronic disease management and, more importantly, prevention measures. The State of Health in the EU's 2019 Companion Report[22] 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, programmes 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 3.3 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 Slovakia it amounts at €10.6.

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 for 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 3.4 highlights the preventable death rate for European countries.

The State of Health in the EU's 2019 Companion Report[23] recalls that after the financial crisis, the Commission drew up, through the European Pillar of Social Rights,

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22 State of Health in the EU Companion Report, Publications Office of the European Union, 2019.

23 Companion Report 2019, State of Health in the EU, ec.europa.eu/health/state

Fig. 3.4	Preventable standardised death rate per 100,000 inhabitants (2016)
Source: Eurostat	
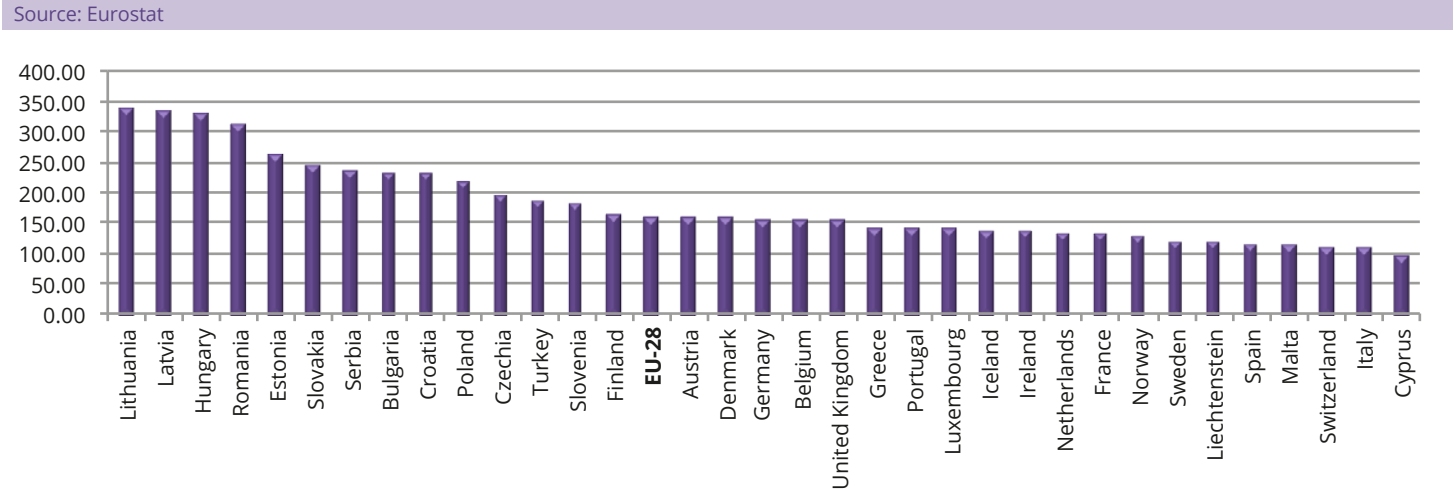
a set of principles to support EU citizen rights and safeguard social standards in a fast-changing world. One of these principles declares that everyone has the right to timely access to good quality, affordable, preventive and curative health care, accessibility being a vital and multi-dimensional aspect 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, organisational 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.

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.

3.2. BRINGING INNOVATION TO PATIENTS: EU VALUE-BASED HEALTHCARE

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 prioritise healthcare services, there is a need to factor in epidemiology, severity of needs, and outcome-based data. The latter requires a clear and mutually recognised 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. 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. Although the concept of "value-based healthcare (VBHC)" is seen as an idea to improve our healthcare systems, there is still no single agreed on definition of VBHC. Value in the context of healthcare has been often defined as "health outcomes relative to monetised 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-centred 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 emphasises 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 personalised 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 prioritises (i.e. the numerator) as the primary objective of any healthcare organisation, 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 organisations, transparently defining the process of continuous provider improvement committed to optimising 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 input, 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[24], 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 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 organisational 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. Over time, the approach followed by Porter

was recognised 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[25].

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"[26].

A decade later, the OECD published its report on *"Wasteful Spending in Health"*[27] 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

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

25 Gray J.A. Optimising the value of interventions for populations. BMJ 2012; 345:e6192

26 Gray, J.A. 2013; The shift to personalised and population medicine. The Lancet, 382(9888), 200-201

27 Organization for Economic Cooperation and Development (OECD), (2017), Tackling Wasteful Spending on Health.

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.

In this broader context, Porter's definition of VBHC and value-based pricing (VBP)[28] 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 optimise 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.

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28 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.

3.3. 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 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 collaboration among hospital groups.

The Commission Communication from 2014[29] **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 organising 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

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

components, together with strong leadership, sound accountability mechanisms and a clear organisational 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 minimise the length of hospitalisation;

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 organisational 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?

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 recognises that health systems today are under pressure to adapt and to modernise 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 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. In the opinion, the EXPH recognised 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 recognising 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 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 recognising that for eventual equally effective interventions the socially deprived may need to be prioritised.

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. 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, and 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 recognise 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.

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

An important challenge that 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 behaviours. 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 analysed 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.). Broadly speaking, digital innovation in the healthcare sector is indeed becoming increasingly important, 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[30], 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

Fig. 3.5   The biggest eHealth priorities for healthcare providers at the moment

Source: HIMSS Analytics Annual European eHealth Survey, 2019
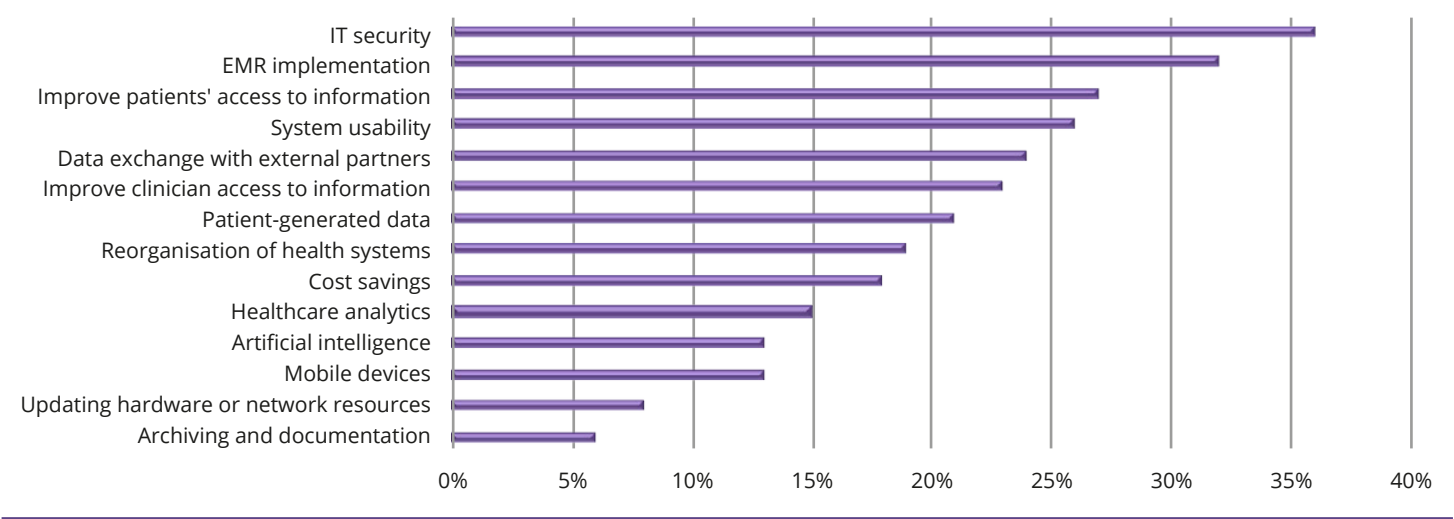
30 Eurobarometer, Special Eurobarometer 460: Attitudes towards the impact of digitization and automation on daily life, 2017

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
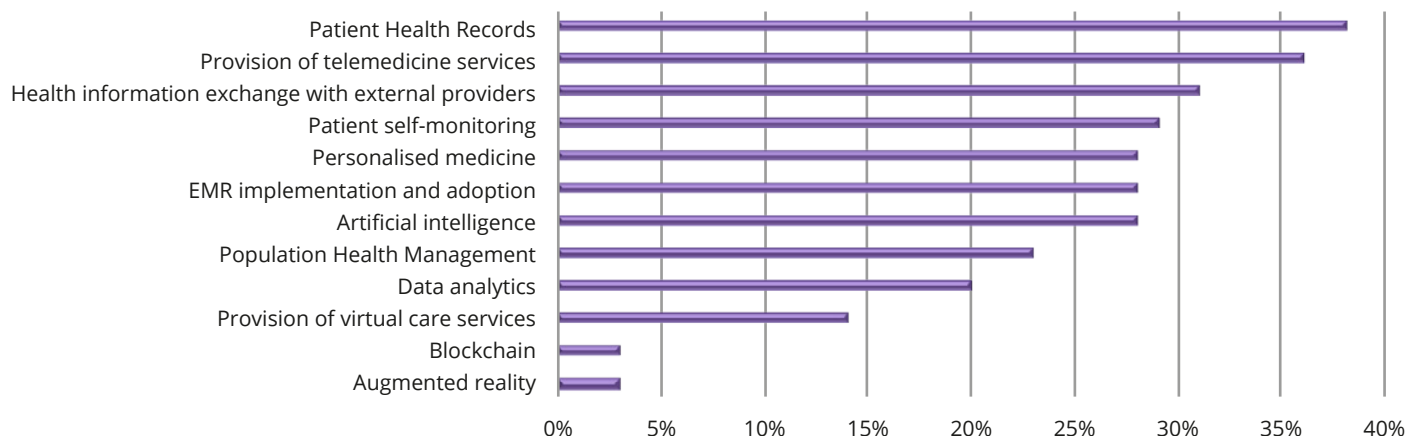
consent. According to an infographic on transformation of healthcare in the Digital Single Market[31], 80% of EU citizens agree to share their health data if privacy and security are ensured.

The new HIMSS Analytics Annual European eHealth Survey (2019)[32] provides an insight into top health IT priorities in Europe. The survey involved 537 respondents in Europe that operate in 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

Fig. 3.6   The biggest eHealth trend in Europe in the coming years

Source: HIMSS Analytics Annual European eHealth Survey, 2019

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31 https://ec.europa.eu/digital-single-market/en/news/infographic-digital-health-and-care-eu
32 https://europe.himssanalytics.org/europe/ehealth-barometer/ehealth-trend-barometer-annual-european-ehealth-survey-2019

importance has increased compared to last year. Electronic Medical Records (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. 3.5).

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, personalised medicine, EMR implementations and artificial intelligence projects. On the contrary, few blockchain-based solutions and augmented reality applications will be implemented (Fig. 3.6).

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. 3.7).

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. 3.8). 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;

Fig. 3.7   European countries with the best performance in terms of eHealth

Source HIMSS Analytics Annual European eHealth Survey, 2019
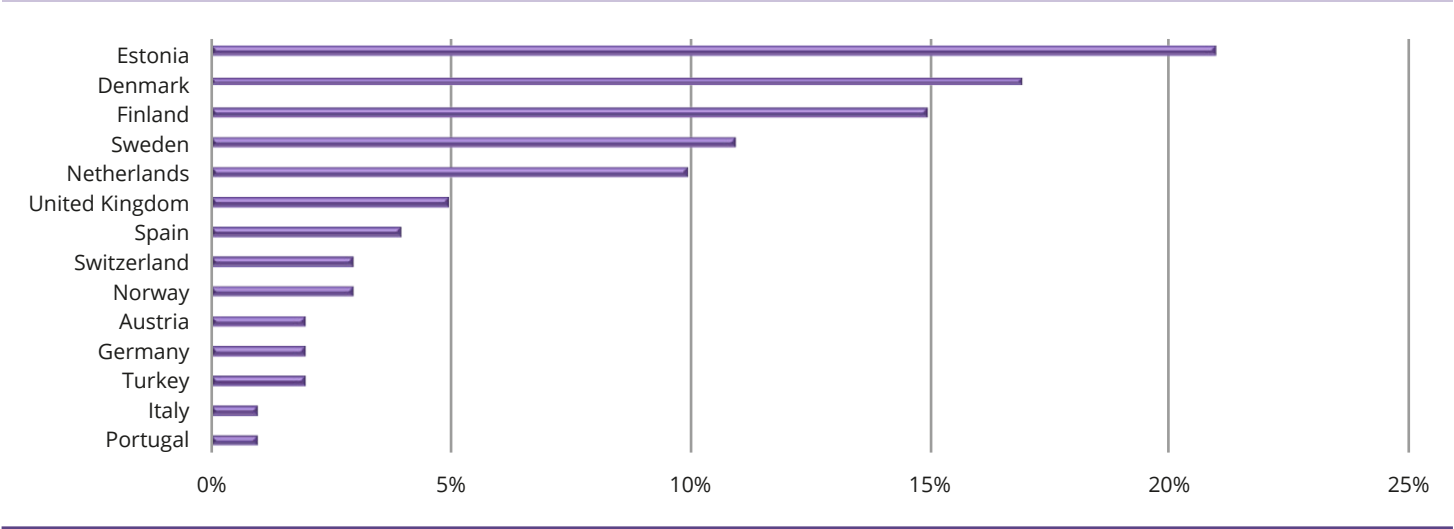
- GPs using electronic networks to transfer prescriptions to a pharmacist;
- GPs exchanging medical patient data with other healthcare providers and professionals;
- NGA broadband coverage;
- 4G coverage;

- 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

Fig. 3.8　　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
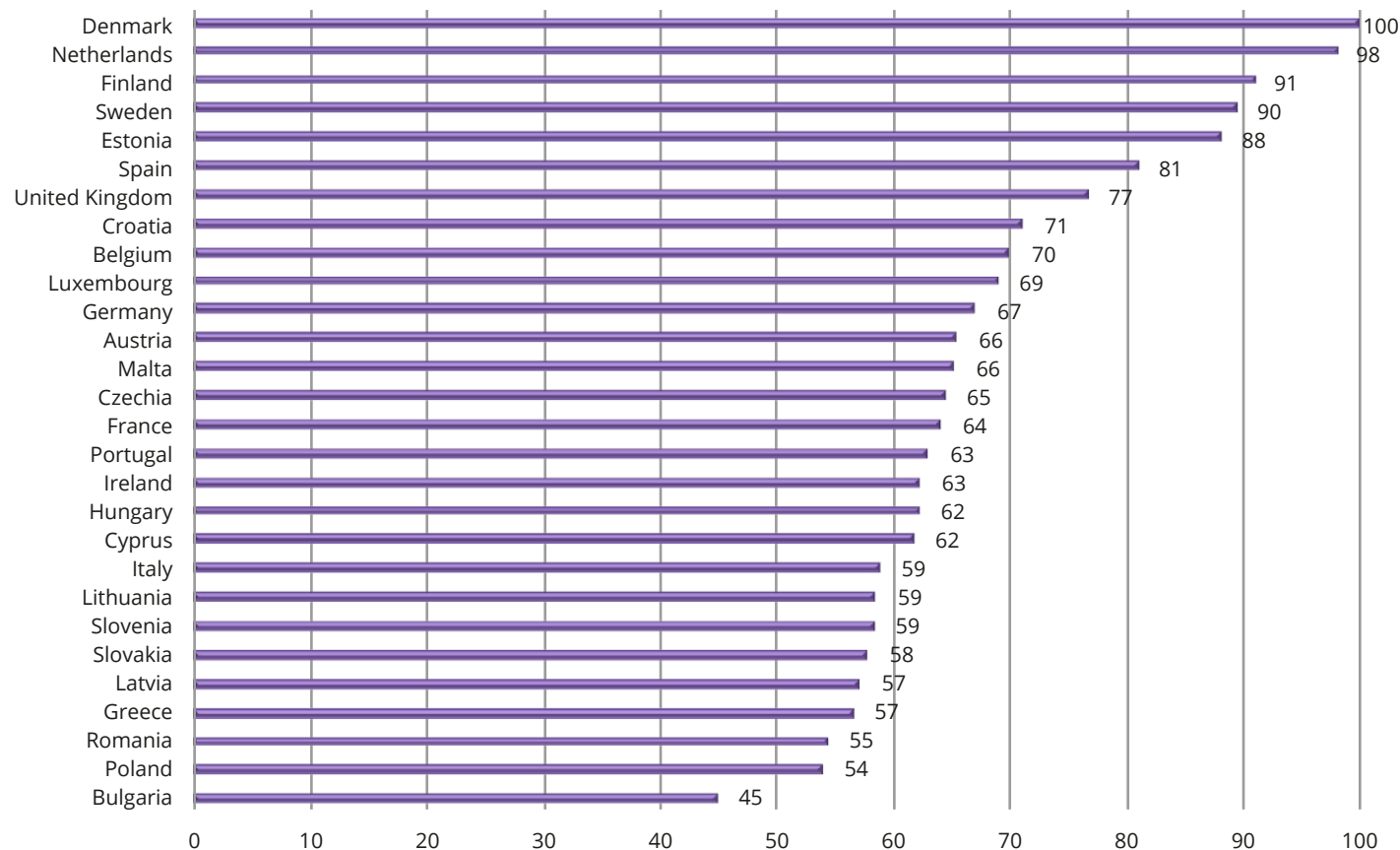
as identification procedure for online services;

■ 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 normalised relative to the best performer country, so as to establish a ranking from 0 to 100.

Top ranking 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.

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 organisations and public authorities enabling them to deliver more personalised 'citizen-centric' healthcare. This is more targeted, effective and efficient and helps reduce errors, as well as the length of hospitalisation, 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 maximise 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-specialised healthcare units from over 300 hospitals in 26 EU countries and aim to tackle complex or rare diseases and conditions that require highly specialised 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[33].

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[34].

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 standardised 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 immunisations, as well as radiology images and laboratory results[35].

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[36]:

- 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 clarity for health and well-being mobile applications and the lack

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33 European Commission, European Reference Networks, Conference Report, 2017.
34 European Commission, eHealth: connecting health systems in Europe, June 2016.

35 WHO, From innovation to implementation. eHealth in the WHO European Region, 2016.
36 Ingenico, e-Health in Europe, June 2012.

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 organisational 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.

The mid-term review of the Digital Single Market Strategy 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 personalised 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 analysing 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) mobilise funds. The second involves personalised 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 personalised 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 mobilise funds. Thirdly, citizen empowerment with digital tools for user feedback and person-centred 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, mobilising relevant EU programme 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 organisations 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.

The list of things that artificial intelligence 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 customise treatment. AI, combined with healthcare digitisation, 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[37]. 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 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 (anonymised, 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[38].

Therefore, the main benefits of AI in healthcare have been identified by HIMMS Analytics[39] in its survey on AI use in European healthcare, as improved quality of care (19%), improved medical decision-making (13%), improved diagnostics (10%) and the ability to process

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37 McKinsey Global Institute, Artificial Intelligence: the Next Digital Frontier?, 2017

38 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

39 HIMMS Analytics, eHealth Trend Barometer, May 2018

Fig. 3.9 The biggest benefits from using AI in healthcare

Source: Himss Analytics, eHealth Trend Barometer, May 2018
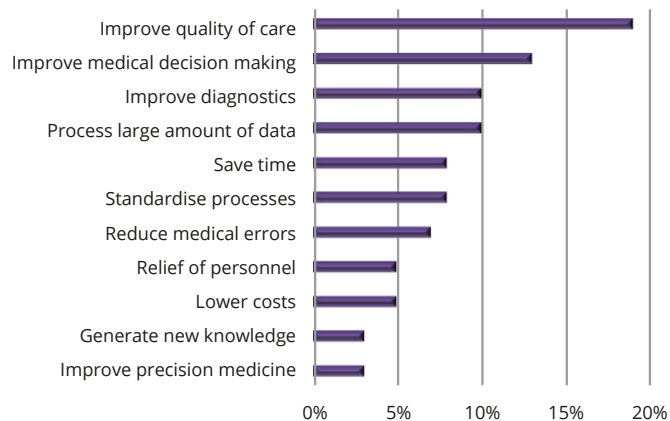
large amounts of data (10%) (Fig. 3.9).

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. 3.10).

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

Fig. 3.10 Fields where health facilities use or plan to implement AI tools

Source: Himss Analytics, eHealth Trend Barometer, May 2018

■ Available in health facility   ■ Planned in health facility
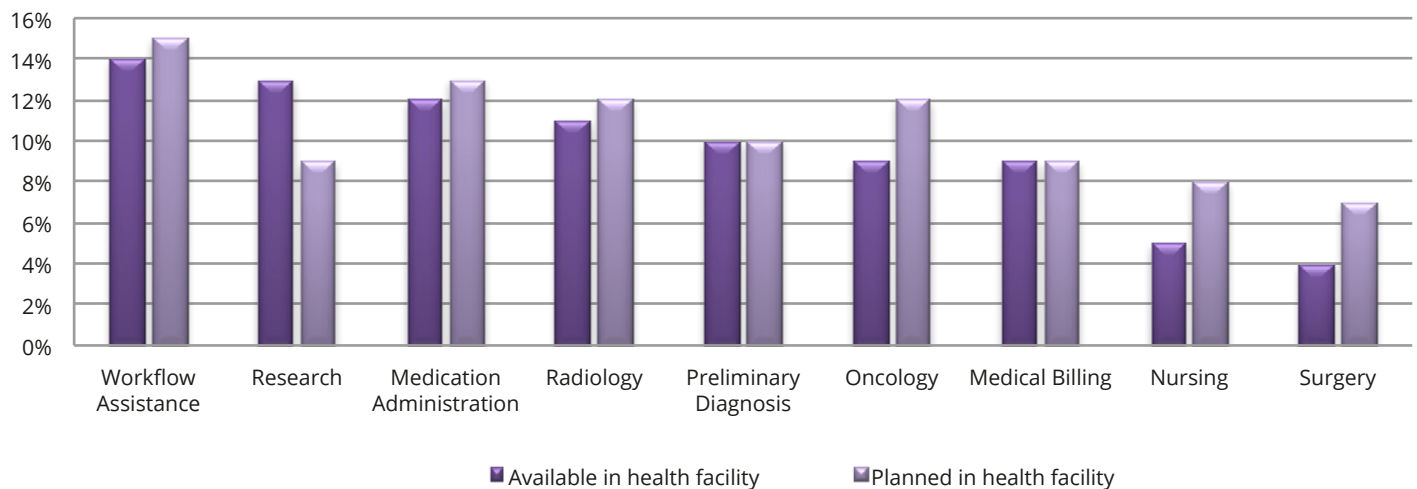
transparency in how results are achieved, as well as putting into place some best practices that increase transparency and the level of information provided to patients relative to their data processing, and avoid collecting an amount of data greater than required to use AI models. Moreover, there is 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.

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

Today, the healthcare industry looks very different from ten years ago. New technologies have revolutionised 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 organise 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.

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[40]. 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 harmonise.

Not only does the life science industry added value represent a significant share in the total added value of manufacturing in European countries, its R&D investments are crucial in driving medical progress and improving patient health and quality of life. Comparing the main European countries with the US and Japan, the gap between the R&D expenditure share out of the manufacturing total is worth mentioning. In the US, this share is 26.8%, followed by Spain (19.5%) and Japan (12.4%). Instead, in Germany, Italy, France and the UK it is below 10% (Fig. 3.11).

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. EU pharmaceutical production grew by an annual 4% in the 2000-2018

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40 European Council meeting (20 June 2019) – Conclusions

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. However, the pro-capita R&D expenditure in this sector shows huge differences among 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, globalised and fiscally interesting countries in the Eurozone.

If compared to the US, 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 US, it was at 8.6% (Fig. 3.12).

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

Fig. 3.11	Share of R&D expenditure out of manufacturing total (%, 2016)

Source: I-Com on OECD data
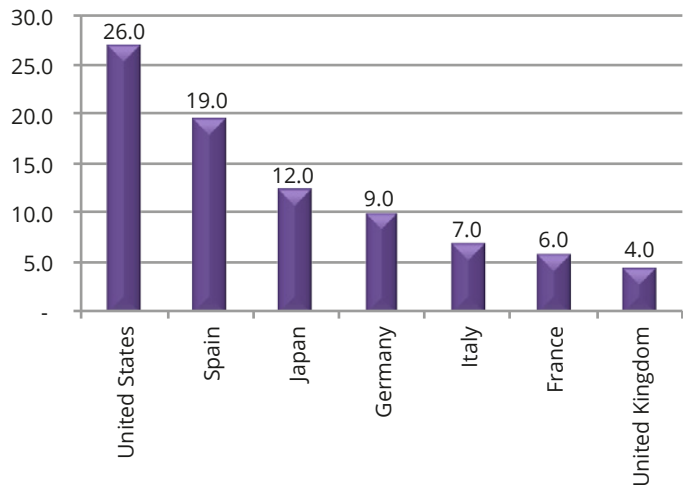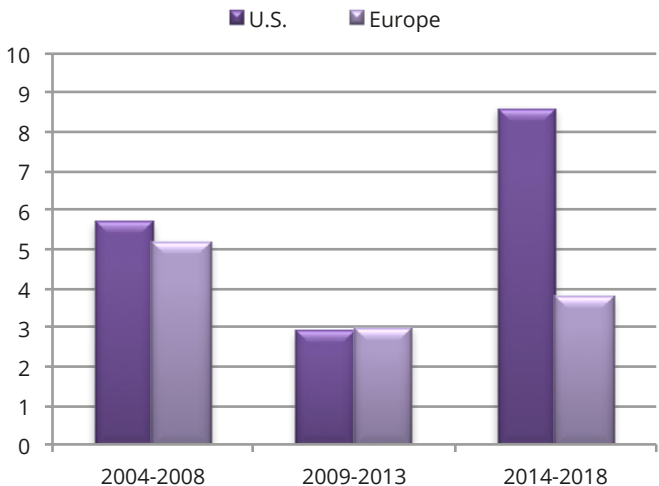

Fig. 3.12	Pharmaceutical R&D expenditure CAGR (%)

Source: EvaluatePharma, World Preview, 2019

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

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.

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.

Fig. 3.13   U.S. and European medical technology companies' R&D expenditure (2009=100)

Source: MedTech Europe, 2019

Legend: U.S. medical technology companies — European medical technology companies
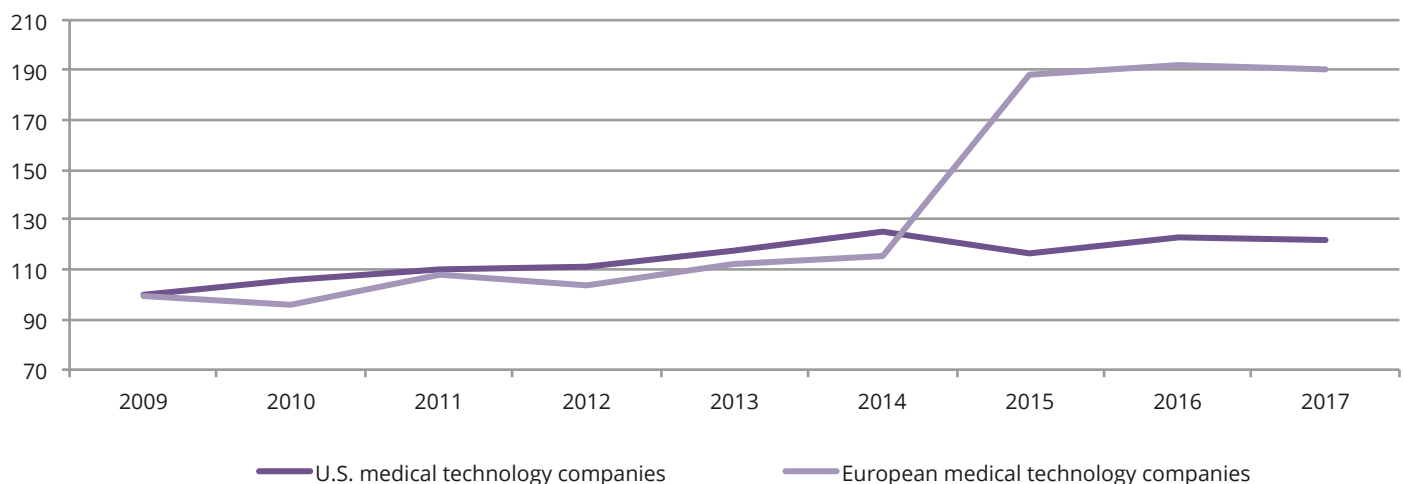
3.5.1. Attracting life science investments in Europe

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, globalisation, digitalisation 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 US and China. What results from this research is that, from a global perspective, the EU has a much larger internal market than the US and a wealthier internal market than China. The size and the wealth of the EU make it attractive to investors. However, in life science and healthcare, this internal European market has not fully materialised. Research funds, health policy and taxation systems remain national and Europe's attractiveness could increase by being less fragmented and by increasing harmonisation. 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.

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 authorisation for a medicinal product

in the EU is quite harmonised, EU Member State requirements vary considerably for local subsidiaries seeking authorisation to commercialise 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 modernise 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 personalised 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.

At a first glance, the data is already quite revealing in terms of clusters and innovation hotspots. Table 3.1 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.

As far as the financing of life science research in Europe is concerned, three main EU research and innovation programmes are listed. According to the EU's official website, Horizon 2020 is the biggest research and innovation programme, 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 organisations. 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.

Tab. 3.1   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
California (US)	1718	794	506	56

POLICY RECOMMENDATIONS – A MANIFESTO FOR AN INNOVATIVE EUROPE

POLICY RECOMMENDATIONS – A MANIFESTO FOR AN INNOVATIVE EUROPE

ENVISIONING A MORE COMPETITIVE EUROPE

- **A huge potential in the background.** Europe has an extraordinary potential in terms of talents, skills, diversity, culture and values that are awaiting to be tapped.
- **First of all, fighting against fragmentation.** Diversity too often translates into fragmentation, hindering the achievement of that critical mass that makes the difference in terms of innovation capabilities. A fragmented investment landscape produces duplication and mostly incremental innovation. A fragmented data market impairs artificial intelligence development and slows down new digital ventures. A fragmented financial market, as well as a fragmented regulation, is the main obstacle for startups and innovative SMEs trying to scale up.
- **Investing more, spending better.** Europe needs to significantly increase investments in key technologies (i.e. AI). At a European level, programmes, such as Horizon Europe and Digital Europe, need to be supported in the next Multiannual Financial Framework at the least in line with the budget proposed by the European Commission. Flexibility clauses concerning national budgets should focus on key investment areas related to EU main priorities such as the ecological transition and the digital transformation. However, investment coordination should be improved in order to make the overall spending more effective and impacting. The European Commission should be endowed with more sophisticated monitoring tools to evaluate the effectiveness of such investments, collaborating with Member States.
- **Fostering innovation by regulation.** Regulation, particularly concerning innovative sectors, should be as European wide as possible, while today it is more often national and sometimes sub-national. As well, regulatory sandboxes should become a standard tool, hopefully not only at national level, but especially at European level.
- **No public policy silos.** Horizontal priorities such as the ecological transition and digital transformation require a more coordinated and systemic approach to public policy. An upgraded governance relies on a holistic approach, able to connect the dots better and quicker than in the past. Here, the first milestone would be set by the industrial strategy that the European Commission is expected to publish in March.

ECOLOGICAL TRANSITION

- **The mobilisation of adequate investments.** In line with the commitments made in Paris under

the UN Framework Convention on Climate Change, decarbonisation is one of the main drivers of EU energy policies. Among all the world regions, the EU stands out for having undertaken demanding decarbonisation policies, through the promotion of renewable energy and energy efficiency. This result is clearly reflected in both past data and future projections on greenhouse gas emissions and energy demand. Furthermore, the EU has raised even further its ambition with the launch of the European Green Deal, fixing the goal of climate neutrality by 2050 and reaffirming European leadership on climate and environmental policies. Obviously, in order to achieve the ambitious goals, set by the European Green Deal, consistent and sustained investments are needed. The Commission itself has provided some estimates, however, and despite the presentation of the European Green Deal Investment Plan, the financial resources provided appear to be not adequate enough to meet the challenges of the Deal. The specified tools are still too vague and it is not clear where the expected amount of investments will come from, except, assuming an extremely consistent leverage effect. In addition, an important part of the co-financing comes from national budgets. it is therefore not clear whether, and how much, the planned funds are additional to current resources. Consequently, a huge mobilisation of both the public and private sector is required.

■ **A proper coordination between EU countries and EU institutions and among EU countries themselves.** The European Green Deal envisages the launch in the next two years of countless strategic and regulatory initiatives, which will span numerous areas of climate, energy, industrial, transport and environmental protection policies. The limitations of the lack of coordination and the diversity of national approaches has recently become evident when drawing up the National Energy and Climate Plans, submitted in draft form by the Member States to the Commission and aimed at defining, at individual country level, European energy / climate strategies to 2030. Despite the effort towards uniformity required by the Commission, it was clear that the plans were not balanced due to the different approaches adopted by the various Member States. Obviously, the specific base conditions of the individual countries underlie the differences in objectives and general approach. The Commission will therefore have to make an effort to clearly define a more balanced contribution expected by the States in the Green Deal transition process. The fulfilment and implementation of these provisions will require close coordination between the European institutions and the Member States and among the Member States themselves. Otherwise, the ongoing and wide-reaching transformation detailed in the Deal will be hindered or will proceed slowly and unevenly among European States.

■ **A common industrial strategy**. Despite the ambitious goals and the adopted policies, the EU will progressively lose its position in in world energy

consumption and related global emissions. In all the different scenarios hypothesised by the IEA, the EU will drop in the ranking of the main global geographic areas for energy consumption and related climate-altering gas emissions. However, any incremental improvement will also carry predictably higher and growing costs, and increasingly limited effects globally. In focusing on the industrial sector, currently accounting for more than 20% of EU GDP, it is clear that climate and energy policies will increasingly have to converge towards common global standards, in order to avoid EU products becoming less competitive, and the consequent industry delocalisation towards geographic areas with less restrictive energy and environmental policies. In this field, an EU industrial strategy should play an important role.

- **Energy policies for European competitiveness**. The EU has the lowest industrial CO2 emissions and industrial production ratio of the main regions of the world. Furthermore, this ratio is continuously improving. The EU registers an average end electricity price for industry as higher than in China, the USA and Russia (regarding the main international partners). As well, Europe is the only case, among those considered, that has seen an increase in average electricity costs for the industrial sector (although it must be remembered that, within the EU, prices for industry vary greatly from country to country and, within the same country, between different consumer groups). A more detailed analysis of the various manufacturing

sectors should be the starting point for identifying any competitive distortions both between the EU and the rest of the world and in the intra-European context. Obviously, the sectors with higher energy and carbon intensity and those with more integrated trade flows are those most exposed to possible competitive imbalances. All these factors should lead to focusing on the potential impacts that medium/long-term energy and environmental policies can have on the competitiveness of industrial sectors.

- **Policies for decarbonising the transport system**. European and national policies should ensure fair and efficient pricing in transport; promote multi-modality, such as inland waterways, short-sea shipping and rail; and encourage the deployment of a more technologically neutral efficient transport systems with low-emission alternative energy for transport and low- and zero-emission vehicles, interoperability and standardisation for electro-mobility in order to increase the use of low-emission alternative energy for transport, also providing incentives to the traditional operators to invest in low emission technologies. To support the long-term transition towards zero-emission mobility research, innovation and competitiveness should be encouraged as in the acquisition of new skills. In this revolutionary context, stronger social dialogue should be encouraged, as well as support mechanisms to help people make the best of the new opportunities, for example, those created by digital technologies.

- **Boost digitalisation in the energy sector**. Digitalisation may have a potentially disruptive effect in the world of energy. It greatly changes both the supply and demand sides and results in creating a safer, cheaper and more efficient system. The EU requires the right policies to accelerate a widespread digital technology uptake, and these should involve: improving access to energy-related data; providing adequate cybersecurity and protection from data privacy risks; strengthening trust in digital technologies; encouraging technology and business model innovation; investing in digital skills; assuring equitable access to digital technology and infrastructures.

- **Digitalisation and the transport system**. The development of digital technologies is revolutionising the transport sector. Digital connectivity is expected to markedly improve road safety, traffic efficiency and comfort of driving, by helping the driver to take the right decisions and adapt to traffic conditions. Communication between vehicles, infrastructures and with other road users is also important for increasing the safety of automated vehicles and their full integration into the overall transport system. Facilitating the convergence of investments and regulatory frameworks across the EU is a priority to encourage the deployment of Cooperative Intelligent Transport Systems (C-ITS), as well as ensuring continuity of service, privacy, data protection, interoperability and international standardisation at all levels, a clear regulation of liability, protecting the privacy of individuals and their personal data and cybersecurity, addressing legal aspects and enabling the coordination of research. But not only. The availability of high-performance TLC infrastructure is essential to guaranteeing technological progress in the transport sector. In this context, fibre and 5G deployment will play a very important in digital services development in the mobility sector. Encouraging investments and creating a clear, simple and investment-friendly regulatory framework is a priority for ensuring EU competitiveness.

- **EU citizens and the Green New Deal ownership**. The challenging goals of the European Green Deal must not only be supported by a strong political commitment and adequate financial investments, but must also link up citizens with local, regional, national and European institutions, civil society, industry and advisory bodies. Bolder policies will only work if citizens are fully convinced about and involved in their development, along with the active participation of NGOs and all stakeholders. This means creating a wide and strong public opinion consensus on the decarbonisation and the full acceptance of the resulting and inevitable changes in habits and behaviour and willingness to share the costs in this transition. For these reasons, the transition should take into account the principle of social equity, supporting those that are hit the most by the process, sharing information and encouraging the understanding of threats and challenges posed by energy and environmental issues, also through virtual channels. In so doing, trust in the transition will

be reinforced, and policies will be accepted and work better.

■ **Strengthening cooperation with developing countries and other advanced economies**. Decarbonising the EU economy and protecting the EU environment is only one part of the global challenge. The Green Deal transition principles must be applicable on a wider scale involving both developed and developing countries. In also considering the integration of industry at a global level, the entire value chain should be involved in reaching the objectives of decarbonisation, efficiency and promotion of the circular economy. The EU's international development and cooperation policy is essential here to achieve the global UN development targets and the Green New Deal objectives. In its proposal for a neighbourhood and international cooperation tool, the Commission has put forward the idea of allocating 25% of the financial envelope to climate objectives. This is an important first step in this direction, and should help mobilise the public and private funds necessary for the transition.

■ **The removal of barriers and the investment in innovation**. Moreover, the EU needs to engage further in the removal of technological and regulatory barriers among EU countries. The development and spreading of new technologies and sustainable solutions are essential to achieve the objectives of the European Green Deal, to create new European value chains in the sectors that are located at the technological frontiers and to support the

competitive advantages of the EU economic system. For this reason, all the measures the new framework programme for research and innovation, Horizon Europe, must be inspired by the ambitions of the Green New Deal, involving universities and research centrers and promoting data accessibility and interoperability. The new cutting-edge technologies in the field of AI, supercomputers, cloud computing and ultrafast networks are fundamental enablers, while batteries, clean hydrogen, the circular bio-industry and low carbon production are among the sectors of main interest.

DIGITAL TRANSFORMATION

■ In order to **foster the Digital Single Market strategy**, the existing gap between EU countries must be eliminated or, at least, greatly reduced. This is especially so in certain areas, such as skills and digital technology integration into businesses, as well as adapting data regulation, encouraging public and private partnerships and reshaping and upgrading the E-commerce Directive to include new developments, particularly regarding intermediary platforms and industrial IoTs.

■ **To boost connectivity**, an investment-friendly ecosystem and harmonised rules are necessary to attract massive capital, addressing the digital divide between and within Member States, also with the contribution of EU cohesion funds, encouraging

national governments to complete 5G auctions as soon as possible and allow for a fast roll-out of 5G networks, and setting specific financial measures to support connectivity demand and, thus, investment returns.

- The **spread of data-driven innovation and AI** requires setting up datasets and creating a suitable regulatory environment for adopting and fostering innovation. Removing barriers to the distribution and use of government data may be opportune and, at the same time, encouraging private entities to disclose data in order to improve market efficiency or solve fundamental market failures, as well as setting direct incentives (in the form of tax credits or other money-equivalent forms) to encourage companies to take the necessary steps to implement DDI. Investments in AI research and production by both public and private entities - boosting cooperation with the industrial sector – should be encouraged, tackling European fragmented AI ecosystems and retaining top talents.

- **Upskilling/reskilling in the data economy require education and training in AI**, as well as inter-disciplinary initiatives, promoting skills development, encouraging collaboration between humans and machines, to improve and increase current and future job opportunities.

- **To allow consumers to fully take advantage of the digital economy, price transparency should be improved and the enforcement of consumer rights** should be strengthened, as well

as the guidance necessary to clarify what qualifies as an unfair trading practice in the digital world. It is important here to ensure that digital comparison tools work effectively, contributing to lowering transaction costs and delivering better deals, as well as guaranteeing simple, efficient, fast and low-cost dispute resolution arising from the sale of goods or the supply of services online.

- **In the field of cybersecurity, a unified and coordinated approach to should be encouraged,** coordinating European cyber practices by increasing the capacity of all Member States to monitor, prevent and respond to cybercrime, as well as encouraging investments in startups to allow for the burgeoning of new technologies and practices, as well as a relevant procurement policy for EU-based companies.

HEALTHIER EUROPE

- **The digital healthcare transformation can become a major tool in enhancing healthcare system efficiency and integration**. 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. 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. 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 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.

■ **AI in healthcare must be more widespread 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.

■ **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 responding 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.

■ **Fragmentation among EU country healthcare systems must be overcome** in order to pursue modern, responsive and sustainable health systems, starting from the standardisation of quality of care assessment indicators among EU countries. Otherwise, value assessment risks will continue to be broadly based 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. Moreover, the interactions between quality and other performance aspects (e.g. efficiency, equity, access) should be further investigated by enhancing Member State and cross-institutional cooperation, essential for addressing disparities and sharpening levels of expertise. 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.

■ **Level of public investment in healthcare sector should be increased to guarantee efficiency and quality care.** 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. 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 overlooking 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.

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