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FAST TRACK TO EU STRATEGIC AUTONOMY

SPEED CHECK FOR DIGITAL, GREEN AND HEALTH

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EXECUTIVE SUMMARY

In recent years, geopolitical competition has shifted from military grounds to **technological supremacy**. As dominance is being played out in this way, recent phenomena – such as the Covid crisis and geopolitical tensions – have pushed towards the decrease in the dependence of supply chains on other actors. For these reasons, the trend towards EU strategic autonomy is becoming increasingly important, and is involving more and more technological domains and their related policies. The study focuses on how technological competition, industrial expertise and supply chains - from raw materials to final goods - interact, affecting European strategic autonomy in the three key areas of digital, health and energy.

In the **first part of Chapter 1**, dealing with digital, **telecommunication networks and 5G** are analysed as one of the main areas of the competition for technological supremacy and as a lynchpin for economic and societal development. In 2021, **mobile technologies and services contributed to generating 5% of global GDP**, an economic value of **$4.5 trillion** that is expected to increase to $5 trillion by 2025. 5G alone is expected to generate $960 billion in economic benefits globally by 2030.

It is clear from the above data that the race to develop new telco networks is a priority issue for all major global economies. Currently, however, at an industrial level, the development of this technology is the prerogative of a very few countries. The **largest global holder of patents** in the field of **5G** technology is **China,** followed closely by the **US**, while the EU only counts two representatives among the world's top players in the sector. In total, **more than 41% of 5G patents are held by Chinese companies and this number doubled in the period 2015-2020**, while those of the US, Japan, South Korea and the EU saw a slight decline.

The technology gap can also be seen in the **volume of investments** made by mobile network operators, broken down by geographical area. **North American** operators, few in number but large in size, allocate 66% more resources (over $78 billion) to investments than their European competitors.

The Communication "***2030 Digital Compass: the European way for the Digital Decade***" (2021) has set an ambitious goal for 2030 - all European households should be covered by a gigabit network, with all populated areas covered by 5G. Lastly, the **European Declaration on Digital Rights and Principles for the Digital Decade** (2022) has stated that everyone, everywhere in the EU, should have access to affordable and high-speed digital connectivity.

Previously, in 2020, the Commission adopted **Recommendation n. 2020/1307 on a common Union toolbox for reducing the cost of deploying very high-capacity networks** and ensuring timely and investment-friendly access to 5G radio spectrum, and to foster connectivity in support of economic recovery from the

Covid-19 crisis in the Union. In March 2021, Member States agreed on a Connectivity Toolbox containing 39 best practices covering the areas of reductions in network deployment costs and efficient access to the 5G radio spectrum. In July 2022, an overview on the progress achieved by the Member States in implementing the best practices of the Connectivity Toolbox – and accelerating the deployment of high-capacity networks - was published. As well as measures and initiatives aimed at accelerating the development of 5G networks, the Commission has repeatedly launched initiatives aimed at ensuring their security.

In December 2020, the Commission launched the "**Cybersecurity package**", including the "***EU Cybersecurity Strategy for the Digital Decade***", a **new directive on the resilience of critical entities** (on 28 June 2022, the European Parliament and the Council reached an agreement on this proposal), and a proposal for a directive on the measures necessary to achieve a high common level of cybersecurity throughout the Union – NIS2 (on 13 May 2022, the European Parliament and Council reached an agreement on the approval of NIS2).

In February 2021, the European Commission tasked ENISA, the EU Cybersecurity Agency, with developing a 5G certification system while on 18 October 2022, a proposal for a **Council recommendation on a coordinated Union approach to strengthen the resilience of critical infrastructure** was published. For 5G, it encourages MSs to urgently implement the measures recommended in the EU toolbox on cybersecurity of 5G networks without further delay and strengthen the physical and non-physical protection of critical and sensitive parts of 5G networks, including through strict access controls.

The **second part of the chapter** focuses on **artificial intelligence**, a crucial macro-area in which tomorrow's technological and economic development is being played out.

IT development is dominated by the two largest global economies, **the US and China**, the latter recently overtaking the former. China saw the number of patents registered annually by its organisations increase by 326% between 2015 and 2020.

In the global race for IT research and development, **the European Union appears to be significantly lagging behind** other major global economies, both for the number of patents registered and the number of scientific publications.

The **US** maintains supremacy in **AI research,** due to the attractiveness of working for US organisations, while the EU seems unable to retain its top talent, despite being the area of origin of 18% of the top-level researchers. The concentration of so much high-level expertise in the field has made the US particularly fertile ground for innovations that exploit AI solutions.

The European Commission has launched several initiatives to accelerate the development of AI and create a regulatory framework to guarantee the effective protection of fundamental rights.

In April 2021, the Commission presented the "**AI Package**" made up of three documents - the Communication on

Fostering a European Approach to Artificial Intelligence, the 2021 update to the Coordinated Plan with Member States and a proposal for an AI Regulation laying down harmonised rules for the EU (AI Act). Methodologically, the AI Act, still under consideration by the co-legislators, identifies diversified obligations that follow a risk-based approach, distinguishing between uses of AI that create unacceptable risk, high risk, and low or minimal risk. Different consequences clearly follow these with the adoption of appropriate risk management measures to be taken according to a set of detailed criteria and principles enumerated and following specific tests directed at measuring their appropriateness. Finally, on September 2022, the European Commission adopted a **proposal to revise the Product Liability Directive** and **a proposal for a Directive on Artificial Intelligence Liability.** The first, specifically, aims at modernising existing rules on strict liability of manufacturers for defective products (from smart technologies to pharmaceuticals) updating an outdated set of rules. It also introduces the right of a consumer harmed by an unsafe product imported from third countries to be compensated by the importer or the manufacturer's representative in the EU and the businesses disclosure of evidential information that a claimant would need to prove their case in court (but including a safeguard for the protection of trade secrets). The second, on the other hand, pursues the harmonisation of national rules on AI liability, making it easier for those who have suffered AI-related damages to obtain compensation through the introduction of a **presumption of causation.** This occurs when the claimant can prove both that there is fault (someone failed to comply with a certain obligation related to the injury) and that a causal link with AI benefits is reasonably probable and the provision of the right of victims to access evidence from companies and suppliers, in cases where high-risk AI is involved.

In the **third part of the chapter**, **cloud computing** is analysed as one of the domains where technological sovereignty has become the centre of political debates. EU Member States seem to suffer from a clear dependence on non-EU suppliers, especially from those in the US and East Asia.

This sector is growing significantly across the globe. Geographically, the **US appears to be the largest market for this technology**, with reported **revenues of $171 billion in 2021**. Although still very far from the US figures, the public cloud market in the **EU** also appears to be growing strongly, with revenues of **$54 billion** in 2021.

About 80% of the world market for cloud computing services is in the hands of only eight companies, six from the **US** and two from **China.** In order to foster the development of an internal market and reduce dependency on foreign providers, the European Commission has supported the creation of the **'Gaia-X' project**, an initiative that envisages the creation of a new pan-European platform that brings together different cloud service providers.

The Gaia-X platform should operate mainly in the areas related to the establishment of **trust mechanisms** and

intervene on the supply side through the creation of federated catalogues and the definition of **certifications and mandatory standards**. On the other hand, some concerns may regard the Gaia-X governance, as it is opening its doors to big tech (and foreign influences) and to a wider number of members, which risks giving rise to difficulties in defining common objectives.

In 2020, the Communication "**A European Strategy for Data**" outlined the European strategy consisting of a series of measures and investments to enable the data economy over the next five years. This communication has identified several critical issues needed to be overcome concerning the availability of data, imbalances in market power, data interoperability and quality, data governance, data infrastructures and technologies, and empowering individuals to exercise their rights, skills and data literacy and cybersecurity.

As part of the strategy, the Commission announced for the period 2021-2027 investments in a High Impact Project on European data spaces and federated cloud infrastructures. Specifically, the Commission intends to fund the establishment of EU-wide common, interoperable **data spaces in strategic sectors,** that are manufacturing, green deal, mobility, health, financial, energy, agriculture, skills, and public administrations.

The importance of ensuring the development and usage of cloud services is also underlined in the Communication "**2030 Digital Compass: the European way for the Digital Decade**", stressing that EU-based cloud providers have only a small share of the cloud market and sets an ambitious goal on usage by 2030.

Implementing the strategy, Regulation n. 2022/868 (**Data Governance Act**) was adopted. This regulation establishes a mechanism for the reuse of certain categories of protected data held by public bodies, sets out a number of requirements that data sharing service providers must meet, and provides a notification regime for data sharing service providers. It also regulates **data altruism** and, thus, the possibility for individuals or companies to make their data available on a voluntary basis for the common good.

On **governance** and **enforcement**, the Member States are required to designate one or more competent bodies and to establish a **one-stop shop** responsible for receiving requests for information and requests for reuse.

In 2022, the Commission launched the **Data Act** proposal, which aims to remove, through the establishment of a harmonised EU-wide set of rules, barriers to data access for both consumers and businesses.

In the **fourth part of the chapter**, a similar context is observed where the EU's position on dependence on foreign suppliers for the procurement of **semiconductors** is concerned. The semiconductor supply chain is extremely complicated and segmented amongst several countries, so no one can consider itself as completely autonomous and independent. However, **some countries play an especially crucial role in certain segments**, making the extreme global dependence on the semiconductor value chain in the current geopolitical situation more evident.

Global semiconductor turnover stood at $555.9 billion in 2021, with Asia as the main market for these materials

accounting for $343 billion, while in Europe, companies traded semiconductors for a volume of $47.8 billion.

One of the main semiconductor materials used in electronic components is **silicon**. The main producer of semi-finished silicon products is **China**, with about 6 million tonnes annually. The second largest global producer is **Russia**.

The largest exporter of electronic integrated circuits globally **is Hong Kong**, with over $211 billion in value, followed by **Taiwan**, with $155.9 billion, and **China** with a further $155.3 billion.

The EU appears to be lagging far behind the other major world economies in terms of both market and technological progress. This trend emerges quite clearly from the analysis of **WIPO semiconductor patent data**, which sees Japan leading the way this time, and the **EU in last place also in this sector**.

In order to overcome the current situation in which the EU plays a marginal role in microprocessor production (only 10% of global production), and with the ultimate goal of fostering the EU's achievement of digital sovereignty, the **Digital Compass,** published in March 2021, set a very ambitious goal for 2030 - to raise European production of semiconductors to **at least 20% of the value of global production.**

To this end, in 2022, the Commission launched the **"Chips Package"** including a recommendation defining tools for monitoring the chip ecosystem with immediate actions suggested for MSs, and a **Proposal for a Regulation to build a Resilient European Ecosystem and Strengthen Europe's Technology Leadership** (**Chips Act**).

The **European chips strategy** aims to strengthen European leadership in research and technology, build and strengthen European capacity for innovation in the design, fabrication and packaging of advanced chips and their transformation into commercial products, establish an appropriate framework to substantially increase European manufacturing capacity by 2030 through investment in new advanced manufacturing facilities, overcome the lack of skills and develop an in-depth understanding of global semiconductor supply chains.

The Chips Act proposal, instead, identifies the operational tools, procedures and rules aimed at strengthening the semiconductor sector at the Union level, focusing on three pillars - the "Chip for Europe" initiative (the 2021-2027 multiannual financial framework with total resources of €3.3 billion), the establishment of criteria to recognise and support EU integrated manufacturing facilities and open foundries that promote the security of semiconductor supply in the Union and the definition of a coordination mechanism between MSs and the Commission to monitor semiconductor supply and crisis response to semiconductor shortages.

Chapter 2 focuses on the relevance of the pandemic towards building a strong European and national health system and pharmaceutical industry. The past years have indeed revealed the risks of having an intricate system of global interdependence**.**

The first part deals with the competitiveness of the pharmaceutical industry in Europe in order to pinpoint

its strengths and weaknesses**.** In 2021, total European pharmaceutical market value at ex-factory prices increased from €89.4 billion in 2000 to €255 billion in 2021. Moreover, the value of production for the research-based European pharmaceutical industry grew from €127.5 billion in 2000 to €300 billion in 2021. The growth of European pharmaceutical exports was even greater, from €90.9 billion to €565 billion over the same period, with 2021 ending in a positive trade balance of €175 billion. **This international advantage is explained by the typically European R&D intensity of the pharmaceutical sector.** Following this pattern of specialisation, **pharmaceutical R&D expenditure in Europe has increased by about 400% from 1990. However, it is still experiencing lower growth rates than the US and China**. In Europe, the pharmaceutical industry is one of the leading sectors in terms of number of patents and, globally, **15% of pharmaceutical patents have been granted to European-resident inventors.** Despite this marked growth, **many challenges are still to be faced to allow the European pharmaceutical industry to maintain and even strengthen its role as a primary hub of innovation**.

The second part focuses on the meaning of strategic autonomy for the pharmaceutical sector within both the health and industrial EU landscape. It offers an overview of the role of the pharmaceutical strategy for Europe in regaining strategic autonomy. **Indeed, the time has come for Europe to take its own strategic interests in hand**. This is the only way to ensure that European citizens' interests are properly represented and protected before the future challenges. Consequently, the concept of **technological sovereignty** comes into play, and **it is crucial for Europe to take on a central role in promoting international cooperation on technological projects**. This will rely on **technological, regulatory and economic preparedness**. As a result, Europe must tackle **three critical deficits - a lack of resources and raw materials, of digital skills and of an adequate regulatory framework to encourage commercialisation of resources.**

First and foremost, **European longstanding structural problems in the domain of supply of generic medicines and essential active ingredients** must be addressed. In fact, the European supply chain still relies heavily on non-EU raw material subcontractors, which benefit from lower labour costs and less strict environmental standards. As a result, between 60% and 80% of active chemical ingredients are produced outside the Union, mainly in China and India. **Even so, European manufacturers retain specialisation in high-end APIs with low production volumes and complex production processes**. Europe accounts for more than 23% of global sales of prescription medicines and is the largest exporter of medicines in the world with a positive trade balance. This result is achieved due to the **unique first-mover advantages connected with European high-quality R&D activities**. On the other hand, **Europe's positioning in the global pharmaceutical landscape cannot be taken for granted**. Evidence of this comes from the data on clinical trials. From 2010 to 2015, Europe

was the leading world region for clinical trials initiated per year. **From 2016 onward**, however, **the Western Pacific region has taken the lead**. As a response to the increased competition on the global markets, **on 25 November 2020, the European Commission adopted the Pharmaceutical Strategy for Europe**. The text constitutes a far-reaching framework for pharmaceutical policy, **envisioning a more responsive, innovative and resilient pharmaceutical sector**, able to keep up with international competitors. The plan will act in synergy with other initiatives, such as the Green Deal, Europe's Beating Cancer Plan and the new Industrial Strategy. The Commission is expected to propose an update of EU pharmaceutical legislation by the end of 2022.

The third part of the chapter focuses on the controverted role of Intellectual Property Rights (IPRs) in supporting the competitiveness and attractiveness of the pharmaceutical industry in the EU, and in the wider objective to reinforce EU strategic autonomy. As EU innovators still hold a relatively strong international position in pharmaceuticals compared to other high technology sectors, **EU institutions have recognised the need to improve the ability to attract and preserve new investments**. Here, the issues of access to medicines and intellectual property rights (IPRs) have become highly contested. In the pharmaceutical industry, **the role of Intellectual Property Rights is indeed generally recognised as a disincentive for product development**. IPRs attempt to balance long-run incentives for innovation and short-run access to innovation. **The existence of IPRs makes a market more attractive for innovators, leading to country-specific investments in marketing and distribution**. A clear example is the case of **orphan drugs** for rare diseases, which require complex scientific and clinical research which cannot always be compensated through market mechanisms. The European discipline on orphan drugs, carried out since 1999, has focused on **correcting market failures through tax reduction schemes, a 10-year period of market exclusivity and various other research incentives.** This framework has encouraged investment in the development of orphan drugs by pharmaceutical companies and has significantly transformed the lives of patients and their families, proving to be **fundamental in developing treatment options for previously untreatable conditions**. The regulatory framework and the initiatives applied in the field of rare diseases represent **a virtuous example of regulatory agility in favour of the needs of care** in areas of research and development that would otherwise risk remaining unexplored.

Chapter 3 covers the energy transition challenges and its implications for the EU autonomy.

At the beginning, the chapter focuses on the energy crisis that the world and, particularly, Europe has slipped into over the past year. Amongst the major reasons for **European energy vulnerability,** we find the dependence of its energy system on natural gas. Natural gas occupies second place in gross available energy accounting for 23.7% of the total sources used in the EU in 2020. In

addition, the EU is overwhelmingly dependent on foreign suppliers, with **EU import dependency on natural gas from outside Europe being 83.6%.**

The **Russian invasion of Ukraine** has been by far the main cause for the disproportionate energy price growth. As well known, Russia has always been a major supplier of fossil fuels to the EU. In 2020, **24.4% of all energy products consumed within the EU came from Russia**. The reduction in inflows from Russia, the sanctions imposed by Europe and the fear of a total shutdown of the natural gas supply sent markets into crisis. The incorrect management of natural gas storage facilities, the increase in global demand (especially from Asian countries), coinciding with the end of the acute phase of the pandemic crisis, a very cold spring in Northern Europe, lower hydroelectric production in Brazil and lower extraction from gas fields in Norway and Russia played a supporting role in influencing the price crisis in the early stages at the end of last year. All these factors have resulted in gas hitting an historical high. **At the end of August 2022, the gas price for the winter contract on the Dutch trading point TTF touched €350/MWh**.

To tackle the energy crisis, both the European Union and the individual Member States have adopted measures aimed at both controlling price increases and guaranteeing their own energy security. The reduction in gas supplies due to the Russian invasion of Ukraine has also put a strain on the energy stability of the Union. Since the outbreak of the war, 13 EU states have been affected by partial interruptions in supply from Russia, while 5 no longer actually receive any supply at all. The accidents that occurred on the Nord Stream 1 and 2 gas pipelines were yet another alarm signal regarding the reliability of the Russian supply.

To free itself from dependence on the Russian gas pipelines, the European Union has tried to maximise the supply of LNG ships. After the implementation of the REPowerEU Plan, the decline in Russian supply since the beginning of the war has been offset by an increase in LNG supplies from the US and Qatar. Moreover, the European Commission has decided to intervene on storage so as to increase the Union's energy security.

Although the implemented measures seem to have secured the European energy supply for this winter, important problems could emerge for the following one. According to IEA projections, if there is no reduction in demand, **in order to fill the storage before the winter of 2023, an increase of 24.6 billion cubic metres will be required compared to this year, a 36% increase.**

To counter this hypothesis, the EU has adopted some voluntary and compulsory measures to push the MSs to reduce their energy consumption in the coming months. These interventions should lead to a reduction in consumption which the IEA estimates to be around 11%. If the reduction in consumption were to be between 9 and 13%, the commitment that the MSs would make to fill the storage should be in line with what occurred in 2022.

The **emergency measures** undertaken by the MSs have not only been limited to the diversification of supplies and the filling of stocks. Numerous and important measures have also been adopted to limit the impact deriving from

the extra costs of energy expenditure for households and businesses. According to an analysis carried out by Bruegel**, from September 2021 to October 2022, a total of €573 billion were allocated by the MSs**. Specifically, the measures adopted by governments are of various kinds, including the reduction of VAT and energy taxes, the regulation of retail and wholesale prices, monetary transfers to the most vulnerable sections of the population, support for businesses, taxation of windfall profits from energy companies, interventions on publicly owned energy companies, etc.

In addition to those already described, several other extraordinary measures are being studied. At the time of writing (mid-November 2022), negotiations are underway involving the European Commission, the European Council and Member States on what actions are to be implemented and how. Among these, we can mention joint purchases of natural gas, a complementary gas price index that would act as a more accurate benchmark in reflecting market conditions and a "dynamic cap" on the price of gas.

The second part of the chapter analyses the state of the art in relation to **energy efficiency** and **the promotion of renewable sources** and the major EU policies in this area. In 2021, global primary energy consumption was about 595.35 EJ, 10.1% was required by Europe. **EU energy intensity has been steadily declining** as can be seen **between 2000 and 2020** when there was **a decrease of 27.1%**. In 2020, **the total installed electrical capacity in Europe stood at 962,900 MW**, +1.7% compared with 2019 and +57% compared with 2000. **The main sources feeding this electrical capacity were fossil fuels**, however, renewable energies have been gaining ground due to the continuous expansion of electrical capacity powered by wind and solar energies. **Renewable energies, in 2020, made up about 33% of the total installed electrical capacity**.

The **total gross consumption of energy used in Europe in 2020 was 32.6% from oil and petroleum products, 24.4% from natural gas, 10.5% from fossil fuels, 13.1% from nuclear sources, and 17.9% from renewable sources and biofuels**. Much of this energy was used by the transportation sector (252 Mtoe) and the residential sector (248.2 Mtoe).

In 2013, renewable energy became the leading energy source to produce electricity, surpassing nuclear power and solid fossil fuels. In 2020, renewables produced more than one million GWh, compared with 680,000 from nuclear power, 560,00 from natural gas, and 350,000 from solid fossil fuels. The total electricity production from renewable sources was made up of 37.2% wind power, 35.1% hydropower, 13.5% solar power, 7.8% primary solid biofuels and 5.2% biogas.

The main energy source that is used in heat generation is natural gas. However, the share of renewables both in electricity and heat generation is growing. **In 2020, 37.5% of the total electricity generated came from renewable sources**, +3.4% over the 2019 figure, **while 23.1% of the energy for heating and cooling was produced from renewable sources**, +0.7% over the previous year.

On the contrary, the role of renewable energy is still

marginal in the **transportation sector**. The main energy sources supporting this sector are diesel and gasoline, while biofuels play a secondary role, although the latter have experienced significant growth in absolute terms.

Regarding recent policies and targets, the European Union has succeeded in reaching the target of 22% of the renewable share in total gross final energy consumption, set by the 2009 **Renewable Energy Directive (RED)**. The average figure shows a considerable heterogeneity among European countries, with only 13 out of 27 European countries having a value of 22% or more. There are also some countries that have already exceeded the 32% target for 2030 set by the 2019 RED II, such as Sweden, Latvia, Finland and Austria.

The **Fit for 55 package** proposes a broad range of actions aimed at achieving a 55% drop in greenhouse gas emissions (compared to the 1990 value) by 2030, and putting the EU on the path to achieving climate neutrality by 2050. The achievement of these objectives requires an upward revision of the targets set by the main directives, such as the RED and the **Energy Efficiency Directive (EED)**. In the paragraph, the reform process underway and the most important policy measures envisaged are presented. Lastly, the Commission, through a communication published in May 2022, outlined the REPowerEU programme. With this plan, the Commission aims to accelerate the green energy transition and increase energy independence from foreign imports, particularly from Russia. The plan proposes to increase the target share of renewables in final energy consumption to 45%. Through its **EU Solar Strategy**, **it aims to bring more than 320 GW of solar PV into the grid by 2025 and increase this to nearly 600 GW by 2030**. To achieve this goal, the strategy includes four initiatives: 1) increase the presence of PV panels on the roofs of buildings; 2) encourage shorter and simpler bureaucratic procedures; 3) establish an EU skills partnership; and 4) launch a European solar PV industry alliance.

The third and final part of the chapter focuses on **green supply chains** and Europe's efforts towards **strategic autonomy**. It analyses the role of **raw materials** and minerals in the production of technologies required for the green transition, such as **batteries, solar panels or wind turbines**. Different clean energy technologies require different types of materials for their construction. Lithium, cobalt and nickel are indispensable for electric vehicles (EVs) and battery storage. Rare earth elements also play an essential role in the manufacturing of wind turbines and EVs. Copper is used in most electricity related technologies. As the demand for batteries, solar panels and wind turbines rises, so does the demand for many raw materials and minerals. According to the 2022 World Energy Outlook Announced Pledges Scenario, **demand for critical minerals employed in clean energy technology production will be 2.5 times higher by 2030 and will quadruple by 2050**. The IEA Special Report on the role of critical minerals in clean energy transitions also comes to a similar conclusion. By 2040, mineral demand from clean energy technologies is set to double in their Stated Policies Scenario and quadruple in their Sustainable Development Scenario.

Since the dependence of the energy sector on raw materials and minerals is intensifying, assuring the stability and security of supply is of crucial importance for the green transition and for industrial resilience. Unfortunately, **critical mineral extraction and processing is highly concentrated**. According to the 2021 IEA Report, in 2019 China produced 60% of the world's supply of rare earth elements and almost 70% of the world's graphite, the Democratic Republic of Congo produced 70% of the global supply of cobalt, South Africa over 70% of platinum, and Australia was responsible for the production of 55% of the world's lithium. This high degree of concentration poses concerns for companies that produce clean energy technologies, as their supply chains could very easily be affected by changes in regulations, trade policies, political instability and other events happening in the few producing countries. Moreover, supply chains for clean energy technologies are complex and may also give rise to risks associated with the environmental, social and governance impacts of production processes and activities.

The European industrial sector is highly dependent on international markets. For example, **almost the entire EU supply of rare earth elements (98%) is provided by China. The EU imports 98% of its borate supply from Turkey, 85% of its niobium from Brazil and 71% of its platinum consumption from South Africa**. To strengthen European industrial competitiveness, promote critical materials' production, and increase supply risk awareness, the European Union periodically publishes a **list of Critical Raw Materials** (CRMs). The fourth and most recent list of CRMs for the EU contains **30 materials**. The Commission has also established the **European Raw Materials Alliance**. Other industrial alliances have been launched by the European Union and they include the **Renewable and Low-Carbon Fuels Value Chain Industrial Alliance**, the **European Clean Hydrogen Alliance**, and the **European Battery Alliance (EBA).** Important Projects of Common European Interest (IPCEIs) can also play an important role in strengthening competition and industrial policies in the EU. As of February 2022, the Commission had approved **three IPCEIs**. One on **microelectronics**, worth up to €1.89 billion (between 2018 and 2024) involving five Member States, and another **two projects on batteries -** the first run by seven Member States and worth up to €3.2 billion (2019-2031), the second run by 12 Member States and worth €12.9 billion (2021-2028).

PART 1

THE EU IN THE GLOBAL DIGITAL COMPETITION

1. THE EU IN THE GLOBAL DIGITAL COMPETITION

In the geopolitical competition between different countries and areas of the world, **technological supremacy** is now more than ever an indispensable lever. While, in the past, this predominantly took place on military grounds – also regarding the technological side –, today, it involves product and service innovations that seems to have taken on a highly important economic significance. If the **transition to 5G** has enabled the **Internet of Things** revolution to occur, thanks to the possibility of connecting objects and services in mobility with a very low latency and dedicated frequency slices, **artificial intelligence** applications provide multiple uses in terms of improving the functioning of moving objects (e.g., self-driving vehicles, industrial robots, advanced mobile devices), while **cloud computing** allows for the use of new generation applications, also by SMEs.

In this context, given the increasing digitisation of a large number of goods and services, the supply chain of **chips**, which are increasingly spreading to all devices with processing and connection capabilities (from supercomputers to personal devices, to household appliances, cars or even same car remote controls), is also becoming more and more central.

In this (almost) invisible war, and in the related technologies, the competition for 21st century dominance is being played out. Moreover, in the view of recent phenomena such as the Covid crisis and geopolitical tensions, new trends such as a **decoupling from China and reshoring** are aiming at reducing the dependence of supply chains on non-European players, subject to contexts and regulations outside the Union's control. For these reasons, the trend towards EU strategic autonomy, decreasing this dependence on non-European players, is becoming increasingly important, and is involving more and more technological domains and their related policies.

1.1 5G DEPLOYMENT AT GLOBAL LEVEL

The competition for technological supremacy is being played out on many fronts, and one of the most important is certainly the development of new telecommunication networks and 5G. Throughout human history, communication networks have always been the lynchpin for economic and societal development, and the new fifth-generation standard is set to be yet another important opportunity for development and growth on a planetary level. This is especially so for its ability to enable new services and new advanced applications for the Internet of Things. According to the latest data released by the GSMA, **in 2021, mobile technologies and services contributed to generating 5% of global GDP**, which translates into an economic value of $4.5 trillion that is expected to increase, by 2025, by more than $400 billion, close to $5 trillion. **5G alone is expected to bring $960 billion in economic benefits globally by 2030.**

It is clear from the above data that the race to develop new telco networks is a priority issue for all major global economies. Currently, however, at an industrial level, the

development of this technology is the prerogative of a very few companies based in seven different countries. Analysing the data contained in the report *Who leads the 5G patent race November 2021?* drawn up by IPlytics, we can observe that the largest holder of **patents in the field of 5G technology** at global level is the Chinese multinational Huawei (5,604), followed by the US company Qualcomm (4,133) and the Korean Samsung (4,119). In general, **China, with 10 exponents, is the most represented country in this pool of companies**, followed closely by the US with 6, **while the EU only counts two representatives –** Finland's Nokia and Sweden's Ericsson – among the world's top players in the sector (Fig. 1.1).

By looking at the number of patents of each company

Fig. 1.1 Main patent holders of 5G family technologies (Sept. 2021)

Source: Who leads the 5G patent race November 2021? – IPlytics

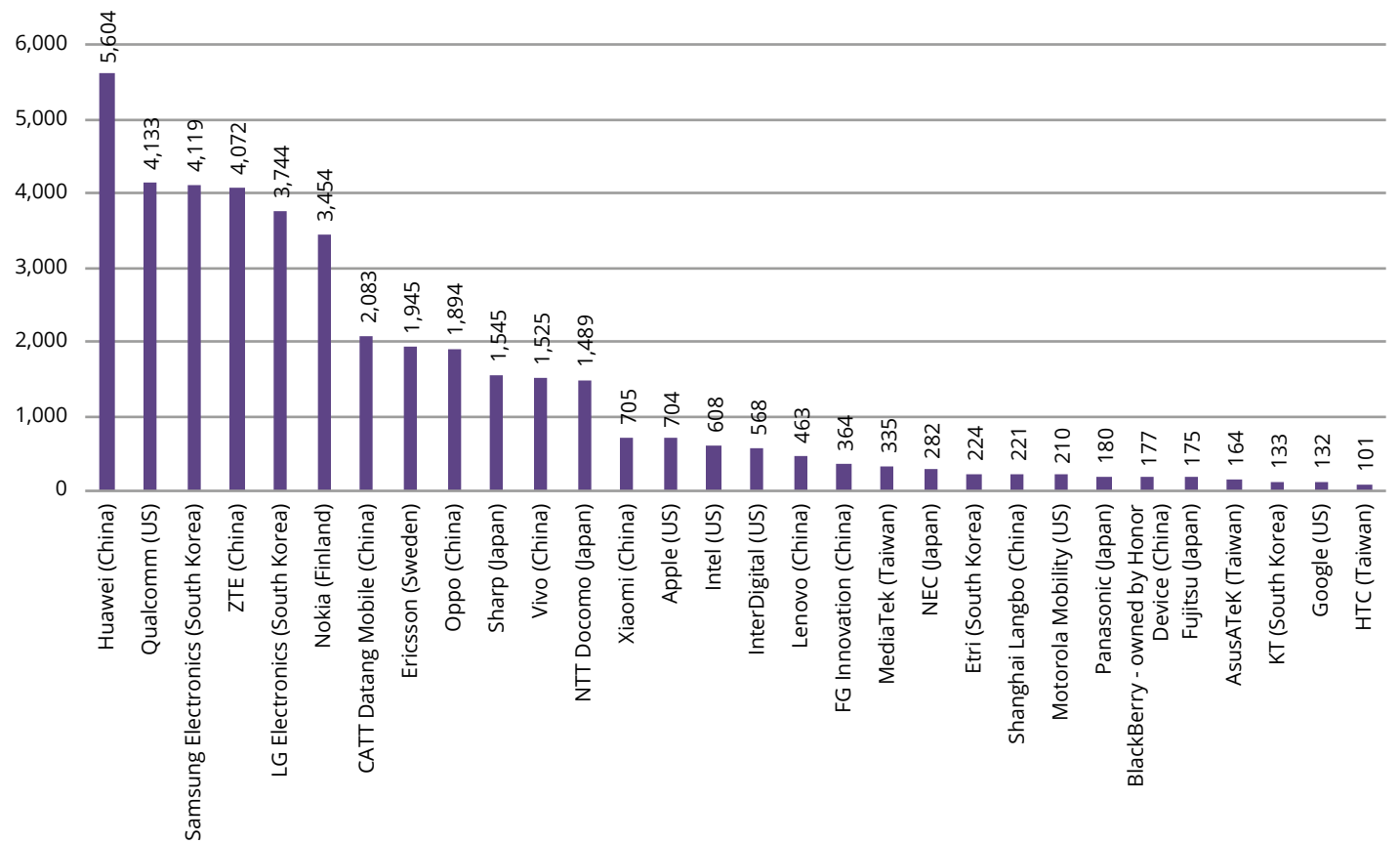
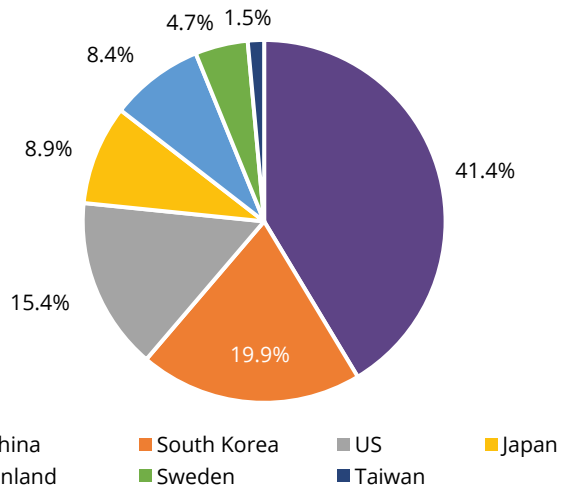


Fig. 1.2 Patents of 5G family technologies by country of owner (Sept. 2021)

Source: I-Com elaborations on IPlytics data

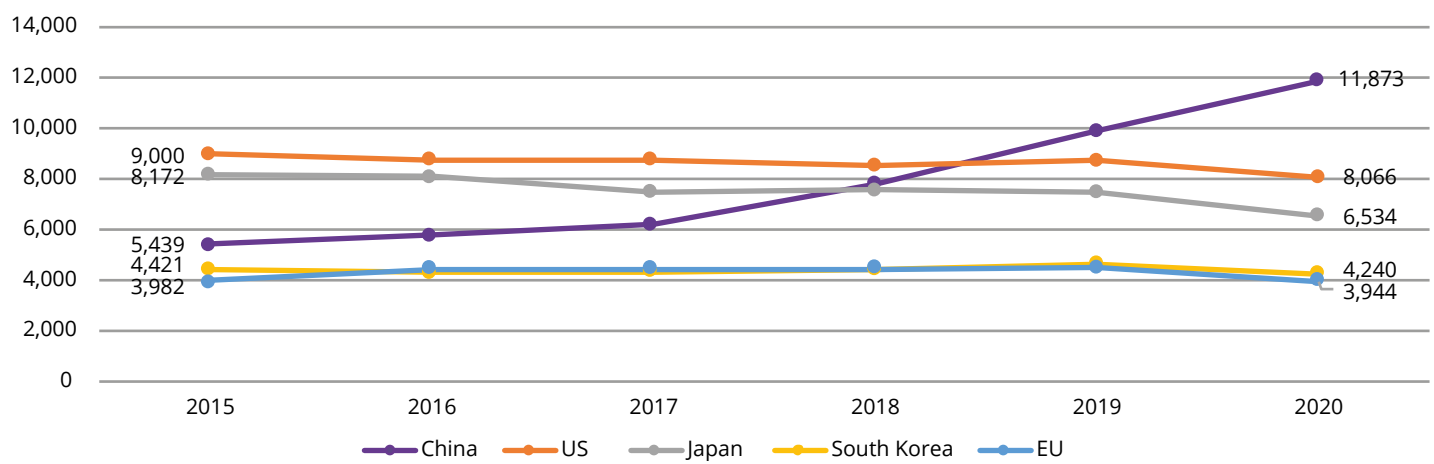


per host country, we can observe that **China still plays a pivotal role, with more than 41% of the 5G patents held by its companies** (Fig. 1.2). With regard to Europe, it can be observed how, despite having only two exponents in the ranking, it **holds 13.6% of patents for 5G-related technologies, just behind South Korea and the US with 19.9% and 15.4%, respectively**.

Extending the research to the entire telecommunications domain, the analysis of data from the WIPO database shows that China has embarked on a powerful growth trajectory in recent years, resulting in it overtaking the US in 2019 for the number of registered patents (Fig. 1.3). In the five-year period 2015-2020, **patents registered by organisations based in China more than doubled (+112%), while those of the US, Japan, South Korea and the EU saw a slight decline.** With around 4,000

Fig. 1.3 Patents registered in the field of 'telecommunications' by geographical area of applicant

Source: I-Com elaborations on WIPO database (Data extracted on 11-10-22)



patents registered annually, the EU competed with South Korea for last position of the geographical areas considered, falling well behind in the numbers registered by Chinese and US competitors.

While this is the situation on the technological development side, from the deployment point of view, the picture looks somewhat different. Despite the fact that **China clearly outstrips everyone in terms of the number of base stations installed**, with more than 1.85 million parametrising the data to the size of the population – a useful measure for an indicative understanding of the number of devices needed to ensure coverage of the territory – we can observe that **China, the EU and the US are quite well balanced, with the first standing at 132 units per 100,000 inhabitants and the second and the third following with 57 and 30 devices** (Fig. 1.4). This normalisation also highlights the performance of another Asian country, South Korea, which, with 162,000 installed base stations, can count on 415 installed devices per 100,000 inhabitants.

Looking at indicative 5G subscribers normalised per 100,000 inhabitants, we notice that the highest value among the areas considered is for South Korea, followed by China and the US which present closer values. Data on subscriber numbers was collected from different sources including regulator announcements (Fig. 1.5).

Fig. 1.4 Estimated installed base stations in absolute value and per 100,000 inhabitants

Source: 5G Observatory, Quarterly Report (October 2022)

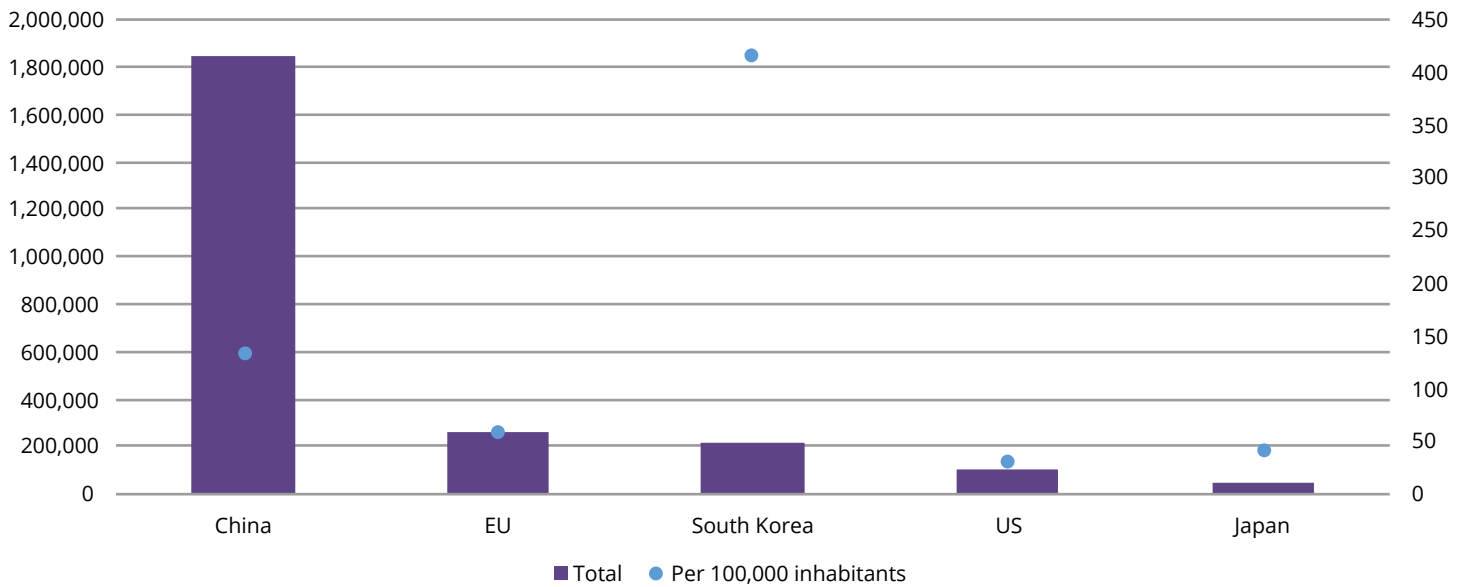


Fig. 1.5 Indicative 5G subscribers, normalised per 100,000 inhabitants

Source: 5G Observatory, Quarterly Report (October 2022)

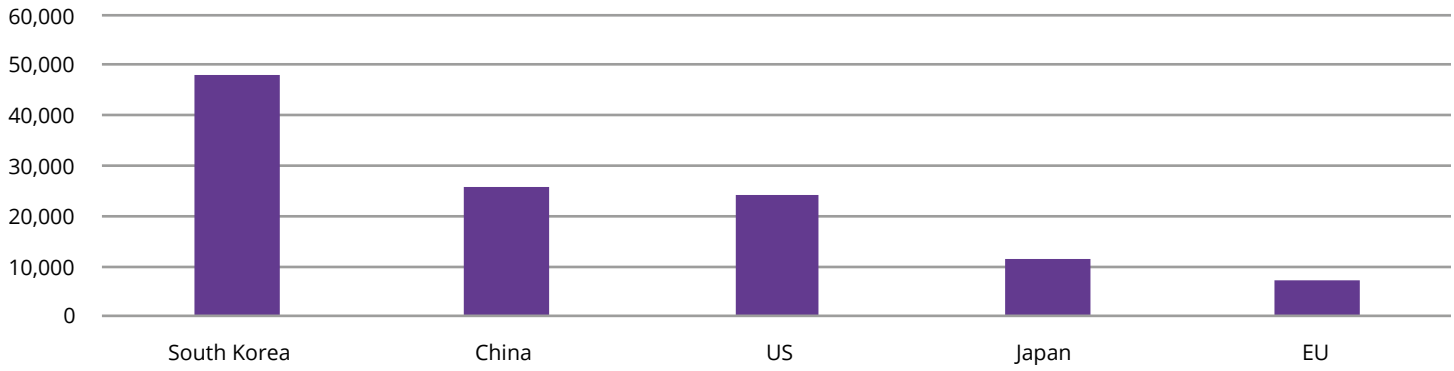
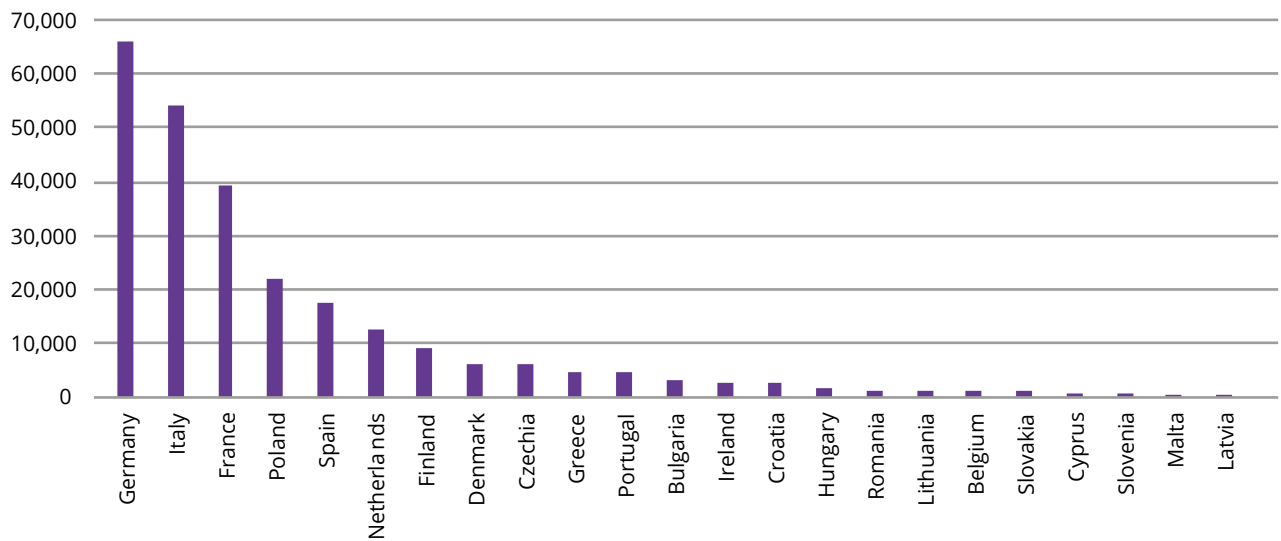


Fig. 1.6 Number of operating 5G base stations in Europe

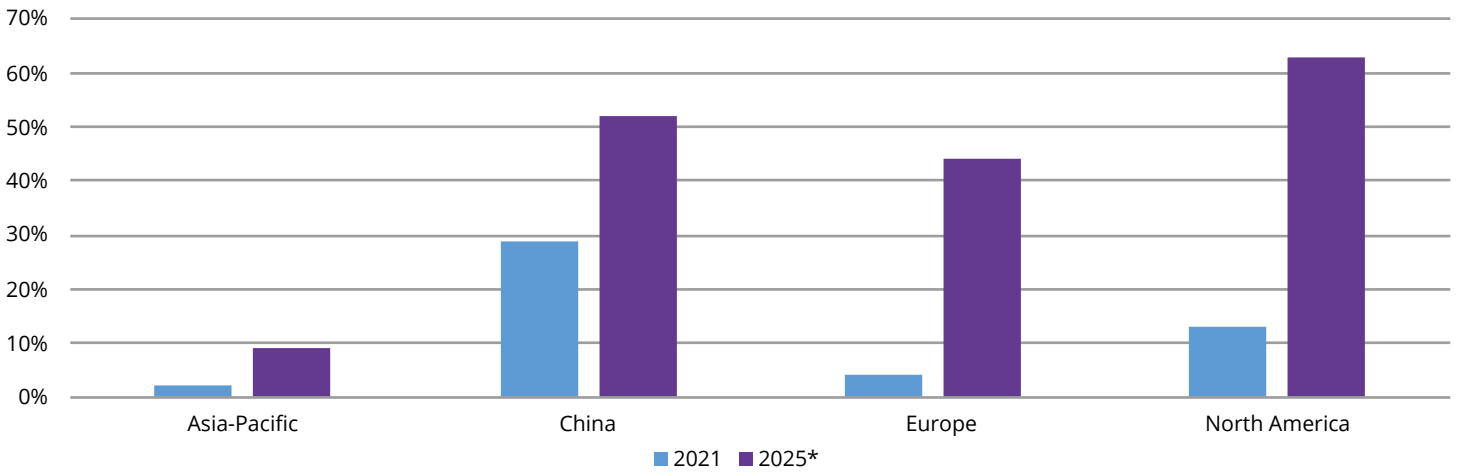
Source: 5G Observatory, Quarterly Report (October 2022)



Note: For Austria, Estonia, Luxembourg and Sweden no recent updated numbers are available.

Fig. 1.7 Share of 5G in the mobile telephony technology mix in 2021 and 2025 by geographical area

Source: The Mobile Economy 2022, GSMA



* Forecast

Note: The geographic breakdown reflects that reported by the GSMA, where China's figures also include Hong Kong and Taiwan, North America's figures include Canada and the US, Asia Pacific's figures include Afghanistan, Australia, Bhutan, Cambodia, South Korea, the Philippines, Japan, India, Indonesia, Laos, Malaysia, Myanmar, Mongolia, New Zealand, Pakistan, Thailand and Vietnam, and Europe's figures include the EU, Albania, Bosnia and Herzegovina, Montenegro, Norway, Kosovo, Serbia, Switzerland and the UK.

We can observe the most recent data[1] for the end of August 2022 on the number of **base stations per Member State** (Fig. 1.6). **Germany leads with almost 70,000 customers, followed by Italy (54,000) and France (40,000),** according to the 5G Observatory estimates dated October 2022.

In general, 5G networks today still only play a marginal role in the technological mix of mobile telephony, particularly in Europe (Fig. 1.7). A clear picture of this situation can be seen in the latest projections of the GSMA, which show that **in Europe, in 2021, the weight of fifth-generation networks on the entire mobile network apparatus was barely 4%,** compared to 13% in North America (US and Canada) and 29% in China[2].

However, the outlook for 2025 appears less pessimistic. Even if lagging behind North America and China, **Europe is expected to increase 5G networks to 44%.** Moreover, by 2025 in Europe, fast mobile networks (5G and 4G) should reach 95% of the mobile technological mix, which is slightly higher than for North America (94%) and China (90%).

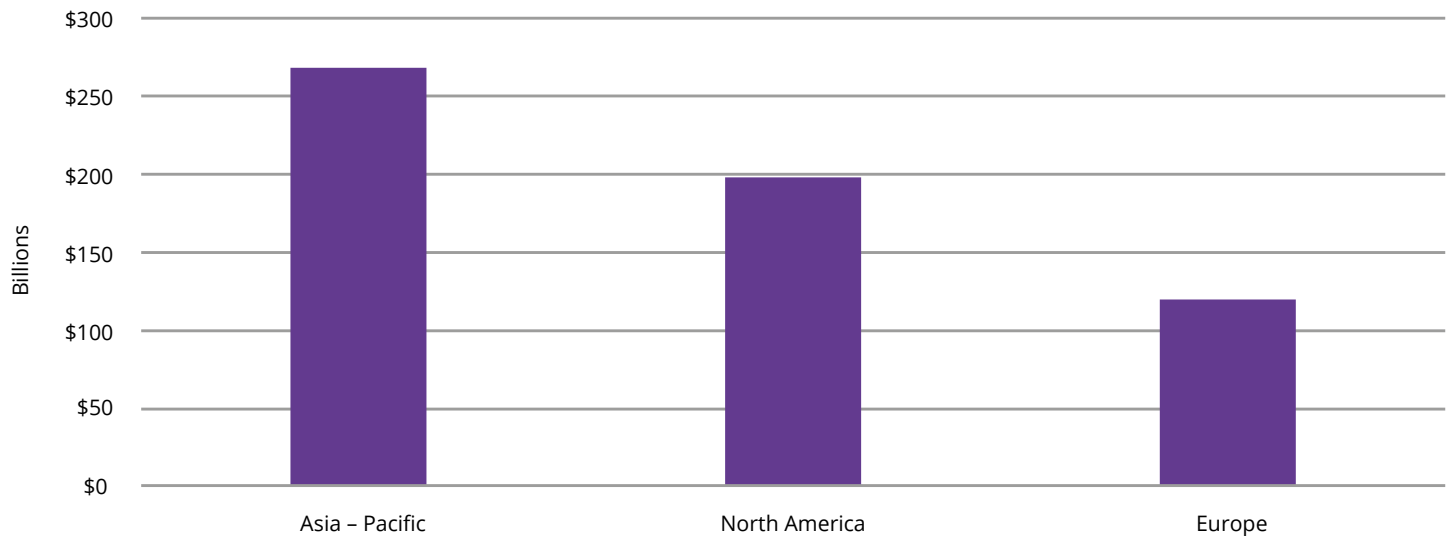
1 The figures are indicative.

2 The figure for China includes all territories administered by China (including Hong Kong and Macao) plus those administered by Taiwan.

The technology gap mentioned above can also be seen in the volume of investments made by mobile network operators, broken down by geographical area. In the current phase of transition to the new networks, the volume of resources that companies in the sector intend to invest is a possible indicator of what the situation will be in the near future. On the one hand, we can observe the evident expansion of the Asia Pacific area, which also takes into account the physical and demographic extension of the area considered. On the other, it is interesting to highlight the **comparison between North America and Europe which, according to GSMA's forecasts, sees North American operators, few in number but large in size, allocate 66% more resources (over $78 billion) to investments than their European competitors**, who amount to several dozens of subjects but are also much more fragmented (Fig. 1.8). Against this backdrop, the classic economic policy question related to the direction to take at European level seems to be coming back into vogue, i.e. choosing between encouraging competition and the existence of a larger number of players, or allowing the emergence of larger players who are able to compete, particularly in terms of investments, with the overseas giants. In between, we find the option of encouraging as much as possible the signing of co-investment agreements between operators or other modes that favour infrastructural development and the spreading of technology.

Fig. 1.8 Mobile network operators' investments planned for 2022-2025 by geographical area

Source: The Mobile Economy 2022, GSMA



1.1.1. The initiatives to encourage development and security of 5G networks in Europe

5G is one of the most important factors for ensuring the evolution of digital services and EU competitiveness. Several initiatives Have been launched by the Commission to encourage and accelerate the development and security of connectivity infrastructures, in general, and 5G, in particular. Specifically, the European policy framework related to 5G and 5G security involves both hard law, i.e., normative acts that are legally binding and have executive force (e.g., regulations), and soft law, i.e., non-binding rules (e.g., Commission communications).

Specifically, for 5G development and connectivity targets, the Commission published in September 2016 the Communication "***5G for Europe: an Action Plan***", to boost EU efforts for the deployment of 5G infrastructures and services across Europe, setting out a clear roadmap for public and private investments in 5G infrastructures in the EU. On a technical level, Member States were required to identify a list of "pioneer" frequencies for the initial rollout of 5G services, to adopt an agreement on the full set of frequencies, and to monitor the progress of small cells, encouraging their development. On the organisational level, states were encouraged to adopt national roadmaps, to promote preliminary trials (from 2017) and commercial trials (from 2018), to make an initial global 5G standard available (end of 2019), and to identify at least one city to become "5G enabled" (by end of 2020). With the Communication ***"Connectivity for a Competitive Digital Single Market – Towards a European Gigabit Society"*** (14 September 2016), the European Commission announced the goals to ensure gigabit connectivity for places driving socio-economic development, 5G coverage for all urban areas and all major terrestrial transport paths and access for all European households to Internet connectivity offering at least 100 Mbps, while the Communication ***"Shaping Europe's digital future***" set three macro-pillars to be pursued – implementing technologies that serve individuals, creating a transparent and competitive market, and achieving an open, democratic and sustainable society – highlighting the tremendous importance of investing in innovation and the various enablers of digital service deployment (including skills and networks) and accelerating the deployment of ultrafast broadband in private homes, schools and hospitals across the EU. Finally, the Communication ***"2030 Digital Compass: the European way for the Digital Decade"*** (9 March 2021) has set a more ambitious goal for 2030 – all European households will be covered by a gigabit network, with all populated areas covered by 5G. Lastly, the **European Declaration on Digital Rights and Principles for the Digital Decade** (January 2022) has stated that everyone, everywhere in the EU, should have access to affordable and high-speed digital connectivity.

To achieve the connectivity targets, the **2018 European Electronic Communications Code** has updated the rules for radio spectrum management across the EU, calling for creating a stable and harmonised regulatory environment and facilitating innovation, particularly through 5G networks. In particular, the Code calls for long licence durations, coupled with clear rules on

license renewals and more stringent requirements to use spectrum effectively and efficiently, fixes strict deadlines for the use of pioneer spectrum bands for 5G as well as for spectrum harmonised for wireless broadband networks and services, seeks to ensure better coordination of spectrum policies and assignment conditions across the EU, with a peer review mechanism, facilitates the deployment of 5G networks, provides more means for national authorities to support competition and creates an improved spectrum coordination mechanism. In view of a better implementation of 5G networks, the Code invites Member States and European institutions to cooperate in order to implement policies of strategic planning, coordination and harmonisation of the use of radio spectrum. More specifically, the Member States must ensure its effective management by ensuring that its allocation, as well as the granting of the relative general authorisations and individual rights of use by the competent authorities, are based on objective, transparent, non-discriminatory and proportional criteria. As well, the granting of individual rights of use must be limited to situations where such rights are necessary to maximise the efficient use of spectrum in light of demand, and their duration must not be less than 20 years, which should ensure legal certainty and stimulate long-term investment.

In July 2020, the European Council agreed on the **Recovery and Resilience Facility**, the centrepiece of NextGenerationEU, a temporary recovery instrument that allows the Commission to raise funds to help repair the immediate economic and social damage brought about by the coronavirus pandemic. In order to receive funds from the Facility, Member States have had to prepare and submit national recovery and resilience plans, with at least 20% being allocated in support of digital transformation. Amongst flagship areas for investments and reforms, the roll-out of rapid broadband services is one of the most important.

In the same year, in September, the Commission adopted a **Recommendation n. 2020/1307 on a common Union toolbox for reducing the cost of deploying very high-capacity networks** and ensuring timely and investment-friendly access to 5G radio spectrum, and to foster connectivity in support of economic recovery from the Covid-19 crisis in the Union. The aim of the recommendation is for Member States to develop a toolbox of best practices for reducing the cost of deploying electronic communications networks and for efficient access to the 5G radio spectrum. This recommendation set a deadline of 20 December 2020 for Member States to identify and share best practices and a deadline of 30 March 2021 for Member States to finalise an agreement on the toolkit. Finally, the Commission set a deadline of 30 April 2021 for each Member State to submit a roadmap for the implementation of the toolkit and a deadline of 30 April 2022 for Member States to report on the implementation of the toolkit. In line with the roadmap set out in the recommendation, Member States, in close cooperation with the Commission, agreed on 25 March 2021 on a **Connectivity Toolbox** containing 39 best practices covering the areas of reductions in network deployment costs and efficient access to the 5G

radio spectrum, outlining a set of best practices to reduce these costs, promote access to physical infrastructure and streamline authorisation procedures for civil works. Specifically, the toolbox: a) encourages the availability of information on existing physical infrastructure, planned civil works, and authorisation procedures through Single Information Points or equivalent platforms, as well as to promote the electronic management of all authorisation application procedures; b) simplifies procedures for the deployment of network elements, particularly relevant to 5G, by providing for the mechanism of silence-consent and offering operators broader access to public infrastructure (in line with what is already provided in the European Electronic Communications Code for small cells); c) makes dispute resolution mechanisms between the actors involved more transparent and efficient; d) undertakes initiatives to limit adverse environmental effects and improve the sustainability of networks; e) prescribes regular reviews of national spectrum management strategies, the conclusion of procedures for the allocation of bands for 5G and the promotion of measures that incentivise the use of spectrum and the rollout of 5G; f) adopts coordinated measures that support wireless connectivity for industrial use cases, including those with a cross-border dimension; g) promotes flexible licensing regimes in the 26 GHz band with a focus on local licensing and infrastructure sharing; h) combines financial incentives with coverage obligations in consideration of the specific needs of the MS and the relevant market situation; i) promotes national and EU level scientific research and information campaigns in order to counteract social resistance to the deployment of 5G networks; l) implements the measures contained in the toolbox (to this end, a deadline of 30 April 2021 is set for the submission of the roadmap for the implementation of these measures and a deadline of 30 April 2022 for the submission of a report on the progress of the implementation itself).

In line with this roadmap, on 20 July 2022, an **overview on the progress achieved by the Member States in implementing the best practices of the Connectivity Toolbox – and accelerating the deployment of high-capacity networks** (adopted on 29 June 2022) was published.

As well as measures and initiatives aimed at accelerating the development of 5G networks, the Commission has repeatedly launched initiatives aimed at ensuring their security.

Specifically, in 2016, the NIS Directive (Directive n. 2016/1148) was adopted. It is the first step to to setting organic measures in the area of cybersecurity and implementing a system of cooperation between the EU and MSs in this area.

In 2019, **Reg. n. 2019/881** gave a permanent mandate to ENISA, the EU's cybersecurity agency, through the allocation of more resources and the assignment of new tasks, to play a key role in establishing and maintaining the European cybersecurity certification framework, to provide the framework for the adoption of specific certification schemes and inform the public about certification schemes and certificates issued through a dedicated website, as well as to increase operational

cooperation at the EU level, supporting EU MSs that request it in managing their own cybersecurity incidents and supporting EU coordination in the event of large-scale cyberattacks and cross-border crises.

In the same year, on 26 March, the Commission adopted **Recommendation 2019/534** on the cybersecurity of 5G networks, highlighting the risks for these networks and suggesting risk-analysis and management methods at the national level to be implemented within a coherent European context. For 5G networks, it identifies a clear roadmap that the MSs must follow to evaluate risks, updating the requirements for firms that provide public communication networks or public communication services. In order to achieve an effective prevention of and fight against threats, the document points out the importance of a **European coordination of the evaluation systems** and encourages **information sharing between MSs and the European institutions**, in order to reach a common awareness of the cybersecurity risks connected to 5G networks.

Hence, consistent with the recommendation, the **NIS Cooperation Group** has published an **EU-wide coordinated risk assessment of 5G network security**. This is a report that, starting from the respective MS's evaluations, identifies the most important threats and most dangerous agents, the sensitive resources, the main vulnerabilities and the different strategic dangers. The report also focuses on the innovations brought about by these networks and, as well, the role of providers in setting up and using 5G networks, and the degree of dependence on the single provider.

On 29 January 2020, the Commission published the Communication ***"Secure 5G deployment in the EU – Implementing the EU toolbox"*** which has identified the most relevant threats and the main perpetrators of those threats, the most sensitive resources, and the main vulnerabilities (technical and other) affecting 5G networks. On the same date, the NIS Cooperation Group published the **EU toolbox on 5G**, including risk mitigation measures, which addresses all the risks identified in the coordinated report on their assessment, identifying and describing a number of policy and technical measures, as well as corresponding supporting actions aimed at enhancing their effectiveness and that can be implemented to mitigate them. In particular, it is recommended that Member States strengthen security requirements for mobile network operators, assess the risk profile of suppliers and, therefore, apply relevant restrictions on suppliers deemed to be high risk for key assets defined as critical and sensitive in the EU coordinated risk assessment, ensure that each operator has an appropriate multi-supplier strategy to avoid or limit any heavy reliance on a single supplier (or suppliers with a similar risk profile), ensure an appropriate balance of suppliers at the national level, and avoid reliance on suppliers deemed to be high risk. The Commission, in expressing its willingness to continue to provide full support and take all relevant actions within its competencies to support the implementation of the toolbox by member states and to strengthen its impact, has outlined a roadmap for the MSs to follow for the implementation of this toolbox. On 24 July 2021, the NIS

Cooperation Group, with support from the Commission and ENISA, published a **report on the progress of MSs in implementing the 5G security toolbox** which describes the level of maturity achieved by them in implementing the toolbox measures. In general, the report points out that the three main risks identified are that of misconfiguration of networks, lack of access control, and state interference through the 5G supply chain. For the latter, it also highlights the widespread belief among states that there is a lack of adequate existing measures.

In February 2021, the European Commission tasked ENISA, the EU cybersecurity agency, with developing a **5G certification system** that will help address risks related to technical vulnerabilities in networks. To this end, ENISA launched a call for tenders (closed on 30 June 2021) to set up a working group to prepare a new 5G certification scheme.

On 11 May 2022, EU Member States, with the support of the European Commission and ENISA, published a **report on the cybersecurity of Open RAN**, a new type of 5G network architecture which will in the coming years provide an alternative way of deploying the radio access part of 5G networks based on open interfaces. This report underlines that through greater interoperability among RAN components from different suppliers, Open RAN could allow greater diversification of suppliers within networks in the same geographical area contributing to achieving the EU 5G Toolbox recommendation that each operator should have an appropriate multi-vendor strategy to avoid or limit any major dependency on a single supplier. The report highlights that Open RAN could also help increase visibility of the network thanks to the use of open interfaces and standards, enhance automation so reducing human errors, and increase flexibility through the use of virtualisation and cloud-based solutions even if cybersecurity, due to the complexity of the network, remains a significant challenge, especially in the short term.

In December 2020, the Commission launched the "**Cybersecurity package**", including the "***EU Cybersecurity Strategy for the Digital Decade***", a **new directive on the resilience of critical entities**, and a proposal for a directive on the measures necessary to achieve a high common level of cybersecurity throughout the Union (**NIS2 Directive**).

The strategy, in particular, contained concrete proposals for policy, regulatory and investment initiatives in three areas of EU action: 1) resilience, technological sovereignty and leadership; 2) development of operational capabilities for prevention, deterrence, and response; 3) promotion of a global and open cyberspace. Under the first pillar, there was a goal to ensure secure next-generation mobile networks through the completion of the implementation of the 5G toolbox by the second quarter of 2021, prepare new horizontal standards aimed at improving cybersecurity of all related products and associated services in the internal market and promote European leadership in digital technologies and cybersecurity along the digital supply chain (including data and cloud, next-generation processor technologies, ultra-secure connectivity, and 6G networks), in line with European values and priorities.

On 28 June 2022, the European Parliament and the Council reached an agreement on the approval of the **Critical Infrastructure Resilience (CER) Directive**, aiming to strengthen the level of preparedness of critical infrastructure in the face of a range of threats, including natural hazards, terrorist attacks, insider threats or sabotage, as well as health emergencies such as the recent Covid-19 pandemic. This directive, in particular, sets obligations for Member States to take certain measures aimed at ensuring the provision in the internal market of services essential for the maintenance of vital societal functions or economic activities (to identify critical entities and entities to be treated as equivalent in certain respects and to enable them to meet their obligations), establishes obligations for critical entities aimed at enhancing their resilience and improving their ability to provide those services in the internal market and, finally, sets rules on supervision and enforcement of critical entities and specific overseeing of critical entities considered to be of particular European importance.

On 18 October 2022, a proposal for a **Council recommendation on a coordinated Union approach to strengthen the resilience of critical infrastructure** was published. For 5G, it encourages MSs to urgently implement the measures recommended in the EU toolbox on cybersecurity of 5G networks without further delay and strengthen the physical and non-physical protection of critical and sensitive parts of 5G networks, including through strict access controls. In addition, MSs, in cooperation with the Commission, should assess the need for complementary actions, including legally binding requirements at the Union level, to ensure a consistent level of security and resilience of 5G networks.

On 13 May 2022, the European Parliament and Council reached an agreement on the approval of the **NIS2 Directive** introducing many changes to the proposal published by the Commission. In order to overcome the current regulatory fragmentation, it: introduces the distinction between important and essential subjects that is based on the criticality of the services provided and from which different supervisory regimes are derived; sets regulations of reporting and notification requirements and defining the concept of "significant incident"; expands the content of the national strategy providing for the adoption by MSs of a national plan for responding to large-scale cybersecurity incidents and crises; strengthens the technical and organisational measures to be taken by important and essential parties (digital infrastructures are defined essential), also introducing a multi-risk approach; provides for coordinated EU-wide risk assessments of critical supply chains and coordinated disclosure of vulnerabilities (and also the preparation of a vulnerability register); institutes the European Network of Cyber Crisis Liaison Organisations (EU-CyCLONe); and establishes a peer learning system. The directive also provides Member States with the possibility to require entities to use particular ICT products, services and processes certified under specific European cybersecurity certification schemes: This is accompanied by an assessment of the impact of the measures on the manufacturers or suppliers of such ICT products, services or processes and users in terms of their costs, as well as the social or economic

benefits of the expected increase in the level of security for the ICT products, services or processes in question, and the availability of their alternatives in the market.

To boost 5G deployment and foster Europe's technology sovereignty in 6G, in November 2021, **Council Regulation n. 2021/2085 established the Smart Networks and Services Joint Undertaking** (SNS JU) as a legal and funding entity as part of the 10 European Partnerships **to step up the green and digital transition. The SNS JU enables the pooling of EU and industrial resources in Smart Networks and Services, fosters alignment with Member States for 6G Research and Innovation, and deployment of advanced 5G networks setting out an ambitious mission**, and with an EU budget of €900 million for the period 2021-2027.

In October 2022, the Smart Networks and Services Joint Undertaking selected the first 35 research, innovation and testing projects to enable the evolution of 5G ecosystems and promote research on 6G in Europe.

In the same month, the Commission launched the **second set of calls for proposals under the Connecting Europe Facility Digital Programme** (deadline 23 February 2023), with a planned budget of €277 million, in order to support projects for secure, fast and high-capacity networks, backbone infrastructures, including quantum communication, cloud federation and submarine cables, strengthen the networks that connect rural, remote and overseas areas, as well as increasingly digitalise transport and energy networks. The calls are open to businesses, public administrations and entities from EU Member States, and overseas territories and countries associated with the programme.

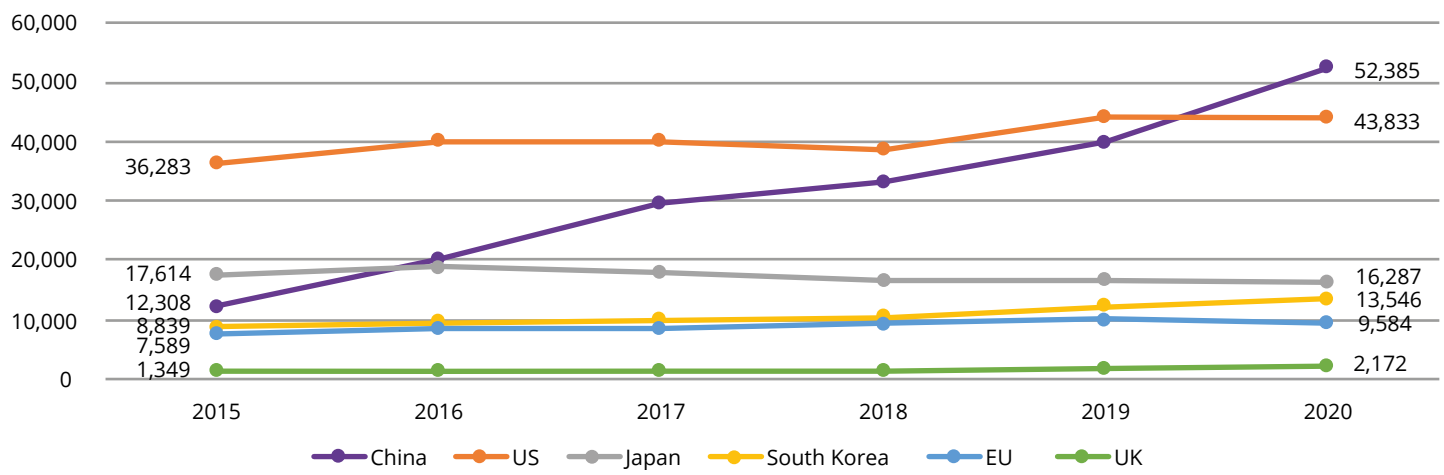
1.2 THE PATH OF MAJOR GLOBAL ECONOMIES TOWARDS AI

Another macro-area in which, starting from today, tomorrow's technological and economic development is being played out, concerns the domain of all those technologies and applications that, for some years now, have been penetrating all economic sectors, and that fall under the umbrella term **artificial intelligence (AI).** Some of them, such as natural language understanding, image recognition, decision support systems, machine learning and robotics, have reached levels of maturity that have allowed them to be already applied to most consumer products and services. The implementation of intelligent systems is enabling and will enable increasingly sophisticated capabilities in machines. Therefore, **it seems likely that those who will dominate the development of AI will largely dictate global technology standards in the coming years**.

As things stand, **IT development is dominated by the two largest global economies, the US and China**, competing to become the most advanced country in terms of investment in innovation. Here, the already mentioned WIPO data on annual patents, registered by country of origin of the applicant, can provide a picture for understanding the forces at play and the direction this competition seems to be taking. Firstly, it is interesting to note that, **in IT as in telecommunications, China has recently managed to overtake the US. China has seen the number of patents registered annually by**

Fig. 1.9 Patents registered in 'information technology' by geographical area

Source: I-Com elaboration on WIPO database (Data as of 11.10.2022)



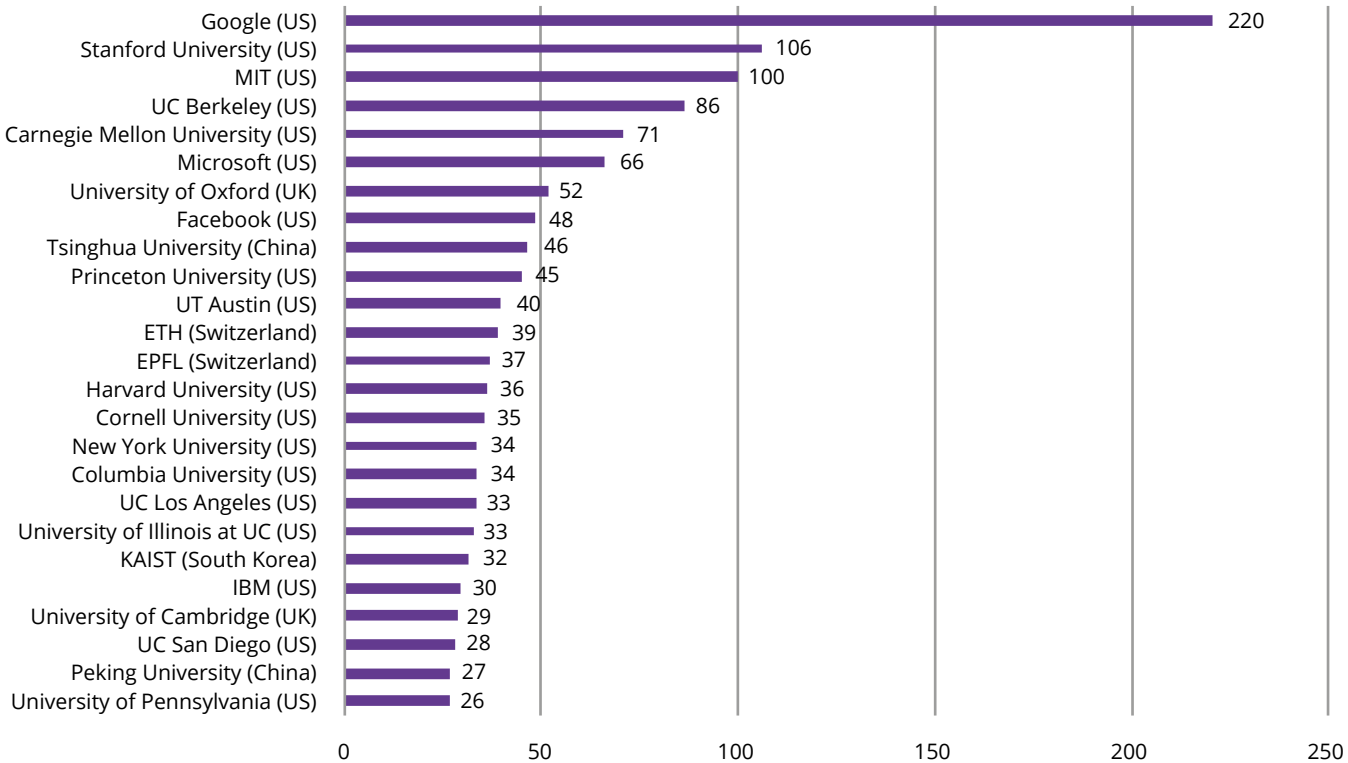
its organisations increase by 326% between 2015 and 2020 and, although the US also experienced significant growth during the observation period (+20.4%), it failed to keep up with the disruptive pace of the Asian giant (Fig. 1.9).

In the global race for IT research and development, the EU appears to be significantly lagging behind other major global economies. The 9,584 patents registered in 2020 by organisations registered in the Union make up only 18% of those in China and 22% of those in the US, placing it even behind Japan (16,287) and South Korea (13,546).

The EU's backwardness concerning patents in this field is also confirmed by the analysis of the main organisations involved in advanced research on AI by a number of scientific publications produced globally, contained

Fig. 1.10 Top 25 organisations involved in advanced AI research by number of scientific publications (2020)

Source: Digital Economy Report 2021, UNCTAD



in UNCTAD's 'Digital Economy Report 2021'. In fact, looking at the data on the top 25, no public or private organisation residing in the EU appears, with the only representatives of the area being the two leading British universities, Oxford and Cambridge, and the Swiss ETH and EPFL (Fig. 1.10).

Another very interesting factor that emerges from the analysis of the data on **scientific publications on AI** is the high prevalence that the US can boast in the top 25 most prolific organisations. In detail, there are 18 US exponents between universities and private companies, for an overall total of over a thousand research works, almost fifteen times the figure recorded by China. Parametrising these figures with those expressed earlier on information technology in general, it is clear that, **despite China's strong growth in the field, the US continues to maintain its hegemony in AI research**.

The US supremacy in AI is certainly due to a polarisation of high-level skills serving the country's public and private organisations. This can be certified by the data on **high-level AI researchers** released by UNCTAD and from "The Global AI Talent Tracker". **While the countries of origin of researchers appear to be quite varied**, with China in the lead at 29%, the US second at 20% and Europe third at 18%, **the place of work of the vast majority of them is the US (59%)**. This means that US organisations are highly attractive to AI experts from all parts of the world. On the other hand, this figure reveals the **EU's inability to retain its top talent**. Indeed, **despite being the area of origin of 18% of top-level researchers,**

Fig. 1.11 Where high-level AI researchers come from and where they work (2019)

Source: The Global AI Talent Tracker (2019)

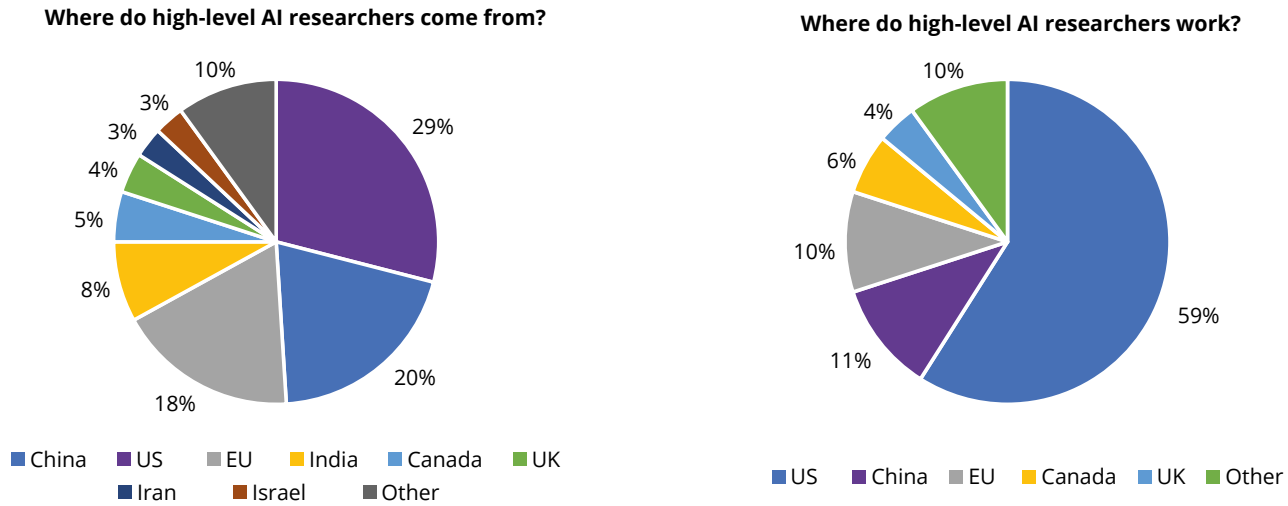
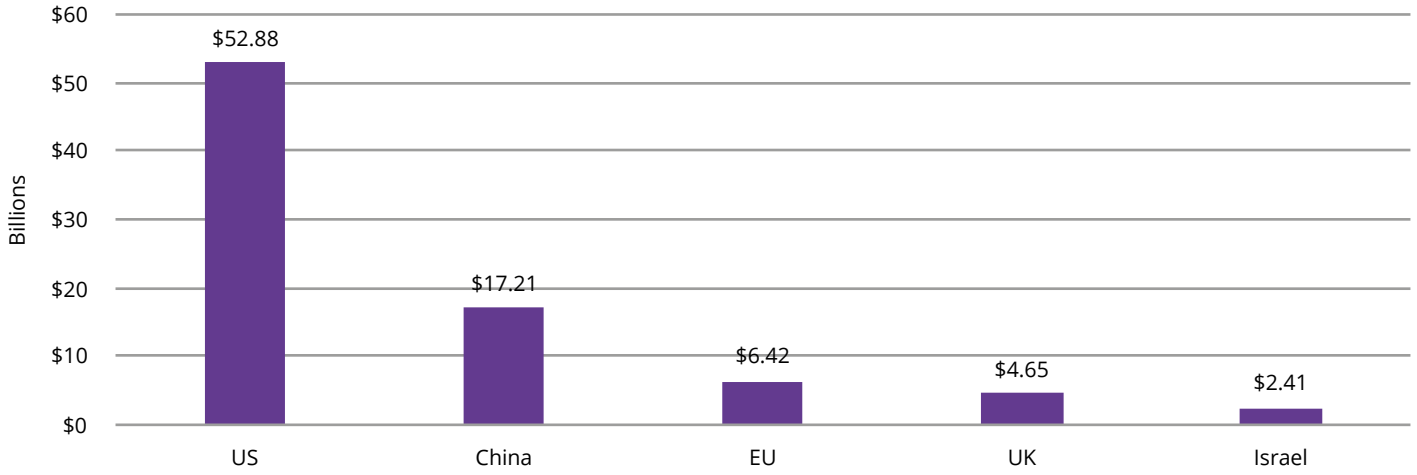


Fig. 1.12 Private Investment in AI by geographical Area (2021)

Source: Artificial Intelligence Index Report 2022, Stanford University



professionally speaking Europe hosts only 10% of them (Fig. 1.11).

The concentration of so much high-level expertise in the field has made the US particularly fertile ground for innovations that exploit AI solutions. Thanks to such a large pool of talent at their disposal, US organisations, and especially private companies, have become true development hubs, effectively driving global technological advancement in the area of AI. This scenario has become possible thanks to the deployment of a huge amount of resources devoted to Artificial Intelligence, resulting in American companies becoming much more attractive than their competitors in other parts of the world.

According to data from Stanford University contained in the *Artificial Intelligence Index Report 2022*, in 2020, **private investment in AI in the United States reached $52.88 billion, more than the total amount spent by the four geographical areas following it (China, the EU, the UK and Israel)** (Fig. 1.12). Looking at the EU figure it can be seen that, with only $6.42 billion invested, **the Old Continent puts into play less than half of China's resources ($17.21 billion) and about 1/8 of those of the US**.

1.2.1. The European framework on Artificial Intelligence

Considering that AI is a set of enabling technologies able to revolutionise the lives of citizens, businesses and public administrations, the European Commission has launched several initiatives to accelerate the development of AI and create a regulatory framework to guarantee the effective protection of fundamental rights.

Despite the fact that the EU's interest and actions in the field of AI have been longer, the start of the EU's pro-active approach to AI regulation can be set on 25 April 2018, when the European Commission presented the Communication "***AI for Europe***", the official kick-off of the EU's actions in this field. It was based on three main pillars: a) placing the EU at the cutting-edge of technological developments, encouraging the uptake of AI by both the public and private sectors, increasing the EC annual investments in AI by 70% under the Horizon 2020 Research and Innovation Programme, strengthening AI research centres across Europe and supporting the development of AI applications in key sectors; b) preparing the EU for socio-economic changes brought about by AI, supporting business-education partnerships to attract and keep more AI talent in Europe and implementing training and retraining schemes for professionals; c) ensuring an appropriate ethical and legal framework.

In 2019, the High-Level Expert Group on Artificial Intelligence (AI HLEG), set up in June 2018, presented the "***Ethics Guidelines for Trustworthy AI***" to provide guidance to all stakeholders and set a framework for achieving trustworthy AI. According to the guidelines, trustworthy AI should be lawful by complying with all applicable laws and regulations, ethical by ensuring adherence to ethical principles and values and robust, both from a technical and social perspective, since, even with good intentions, AI systems can cause unintentional harm.

In February 2020, along with the Communication "Shaping Europe's digital future" and "A European Strategy for Data", the Commission published the White Paper "**Artificial Intelligence: a European Approach to Excellence and Trust**" to create an "ecosystem of excellence" and an "ecosystem of trust" for AI. According to the white paper, AI applications must be deemed as high-risk when the AI technology is employed in a sector where, given the characteristics of the activities typically undertaken, significant risks can be expected to occur (for instance, healthcare, transport, energy and parts of the public sector) and the AI application in the sensitive sector is used in such a manner that significant risks are likely to arise, being clear that the use of AI applications for employment processes, biometric identification and other intrusive surveillance purposes would always be considered as high-risk. Where an AI application falls under the category of "high-risk", some mandatory requirements were established by the white paper.

In April 2021, the European Commission presented the "**AI Package**" made up of three documents: the Communication on Fostering a European Approach to Artificial Intelligence, the 2021 update to the Coordinated Plan with Member States and a **proposal for an AI Regulation laying down harmonised rules for the EU** (**AI Act**). The aim was to establish the world's first AI all-encompassing regulatory framework, set leverage in exporting 'trustworthy AI' around the world and create a set of international AI standards based on European values.

The aim of the Coordinated Plan is to use funding to create enabling conditions for AI development and uptake through the exchange of policy insights, data sharing and investments in critical computing capacities, foster AI

excellence 'from the lab to the market' (by setting up a public-private partnership, building and mobilising research, development and innovation capacities, and making testing and experimentation facilities as well as digital innovation hubs available to SMEs and public administrations), ensure that AI works for people and build strategic leadership in high-impact sectors and technologies.

The key part of this package is the proposal of an Artificial Intelligence Act. This proposal, in particular, targets suppliers who market AI systems in the EU, regardless of their place of establishment, users of AI systems located in the EU and suppliers and users of AI systems located in a third country where the output produced by the system is used in the EU, and aims to increase European citizens' confidence in AI. Methodologically, the proposed regulation declines diversified obligations that follow a **risk-based approach**, distinguishing between uses of AI that create **unacceptable risk, high risk, and low or minimal risk**, from which different consequences clearly follow. Specifically, there is a ban on practices that are considered unacceptable because they are contrary to the values of the Union, for example, where they violate fundamental rights (e.g., manipulative practices of minors or the disabled or involving the use of subliminal techniques that exploit the unawareness of individuals etc.). Instead, for high-risk AI systems, the regulation distinguishes the main types of systems that fall into this category, identifies the criteria to be followed in assessing whether an AI system poses high risks and sets out a number of mandatory requirements in addition to making access to the European market for such systems subject to an ***ex ante*** **conformity assessment** in accordance with detailed procedures.

In this regard the regulation requires the establishment, maintenance, and demonstration of a **risk management system** that is the result of a process of constant and systematic updating throughout the life cycle of the system, and the adoption of **appropriate risk management measures** to be taken according to a set of detailed criteria and principles enumerated and following specific tests directed at measuring their appropriateness. It also prescribes the preparation and maintenance of supporting technical documentation, a design aimed at ensuring an adequate level of accuracy, robustness and cybersecurity, obligations for post-market monitoring and reporting of serious incidents or malfunctions and guarantees of collaboration with the competent authorities. Specific obligations are placed on importers and distributors of high-risk AI systems. The proposed regulation also takes care to define obligations on users of high-risk AI systems by highlighting the need to use such systems in accordance with the instructions for use.

In addition to the obligations imposed on the development, deployment, and use of AI systems, the AI Act contains several measures to support innovation in this area. In fact, it encourages national competent authorities to create regulatory sandboxes and establishes a basic framework in terms of governance, supervision and accountability, as well as measures to reduce the burden on SMEs and start-ups.

The regulation also encourages the adoption of **Codes of**

Conduct drawn up by individual AI system providers or organisations representing them or both. It also includes the participation of users and all other stakeholders and their representative organisations aimed at promoting the voluntary application to AI systems of requirements relating, for example, to environmental sustainability, accessibility for people with disabilities, etc..

On **governance,** the proposal calls for a European Artificial Intelligence Committee made up of the national supervisory authorities, represented by the head of that authority or a senior official of equivalent level, and the European Data Protection Supervisor and chaired by the Commission. Its task is to collect and share knowledge and best practices amongst Member States and contributing to the uniformity of their administrative practices. It can also formulate opinions, recommendations or written contributions on issues related to the implementation of the regulation. Instead, it is left to each Member State to designate a competent authority in order to ensure the application and implementation of the regulation (with the task, also, of providing guidance and advice on the implementation of the regulation itself) and to draw up an annual report to be forwarded to the Commission.

Concerning compliance with the discipline contained in the regulation, the proposal identifies a set of **penalties** regarding the various possible violations by deferring to the MSs the establishment of the rules on sanctions prescribing that they are effective, proportionate and dissuasive, and take into account the particular interests of small and start-up providers and their economic sustainability.

However, the process of adopting the AI Act is proving to be quite complex. Since its presentation, it has sparked off a wide-ranging international debate, which, while appreciating the choice to establish a harmonised framework for AI and adhere to a risk-based approach focused on protecting the rights and interests of individuals, has also expressed concerns. These involve the insufficient determinacy of some obligations, the need to pay more attention to the possible applications and uses of AI technologies (rather than the technologies themselves), and assess the magnitude of the costs burdening especially SMEs and start-ups and their impact on competition and innovation.

The proposal is still under consideration by the co-legislators. In the Council, negotiations have begun to find a common position amongst MSs and a progress report was presented by the French Presidency last June. In the Parliament, where debates are being led by the Committee on the Internal Market and Consumer Protection (IMCO) and the Committee on Civil Liberties, Justice and Home Affairs (LIBE), a draft report was presented in April 2022 that has received more than 3,000 amendments currently under consideration. The joint IMCO-LIBE report is scheduled to be voted on in the Parliament by the end of 2022.

In the **Report on Artificial Intelligence Liability** (February 2020), the Commission identified the specific challenges posed by AI to existing liability rules and, in October 2020, the European Parliament adopted a **legislative own-initiative resolution on civil liability for AI** requesting the Commission to propose legislation. Consequently, in order to adapt liability rules to the

green and digital transition, on 28 September 2022, the European Commission adopted a **proposal to revise the Product Liability Directive** and a **proposal for a Directive on Artificial Intelligence Liability**.

The first, specifically, aims to modernise existing rules on strict liability of manufacturers for defective products (from smart technologies to pharmaceuticals) updating an outdated set of rules by **extending the possibility of obtaining compensation** for damage caused by products such as robots, drones or home automation systems. The same proposal also sets an important principle, namely the right of a consumer harmed by an unsafe product imported from third countries to be compensated by the importer or the **manufacturer's representative in the EU**. As well, in a logic of favouring consumers, the proposal introduces more flexibility in the deadlines for filing claims and lightens the burden of proof for injured parties in complex cases, such as those involving AI. In fact, to guarantee the effective protection and exercise of consumers' rights, the proposal provides that **businesses disclose evidential information that a claimant would need to prove their case in court,** however, including a safeguard for the protection of trade secrets.

With the proposed **Directive on AI Liability**, on the other hand, the Commission aims to harmonise national rules on liability for AI, making it easier for those who have suffered AI-related damages to obtain compensation. The proposal sets common rules on the disclosure of evidence on high-risk AI systems to enable a claimant to substantiate a non-contractual fault-based civil law claim for damages and the burden of proof in the case of non-contractual fault-based civil law claims brought before national courts for damages caused by an AI system. One of the objectives is to simplify access to compensation for damages. Art. 3, in particular, prescribes that the potential claimant must present facts and evidence **sufficient to support the plausibility** of a claim for damages and national courts must limit the disclosure of evidence to that which is **necessary and proportionate** to support a potential claim or a claim for damages and the preservation to that which is necessary and proportionate to support such a claim for damages. Starting from the idea that proving causation is very complex for AI, the same proposal also introduces a **presumption of causation**, when the claimant can prove both that there is fault (someone failed to comply with a certain obligation related to the injury) and that a causal link with AI benefits is reasonably probable and sets the right of victims to **access evidence from companies and suppliers**, in cases where high-risk AI is involved. The Commission has been called to evaluate, five years after the entry into force of the AI Liability Directive, the appropriateness of no-fault liability rules for claims against the operators of certain AI systems, as long as not already covered by other Union liability rules, and the need for insurance coverage, while taking into account the effect and impact on the roll-out and uptake of AI systems, especially for SMEs.

1.3 CLOUD COMPUTING AND DATA SOVEREIGNTY BETWEEN GLOBAL PLAYERS AND EUROPEAN STRATEGIES

In recent years, also due to a growing awareness of the technological gap between the EU and the world's superpowers, the discussion on European digital and technological sovereignty has often been at the centre of political debates. For most of the emerging technologies, indeed, **EU Member States seem to suffer from a clear dependence on non-EU suppliers, especially from those in the US and East Asia**. **Cloud computing is one of the domains where Europe appears to be most dependent on foreign providers**.

At a technical level, NIST defines cloud computing as "a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction."[3]

Since the volume of global data is increasing quickly, the availability of cloud computing is becoming fundamental in guaranteeing an efficient processing of data. Technically, cloud computing enables the spread of advanced services such AI, machine learning, Big Data analysis, and Internet of Things, also among SMEs and local public administration bodies, which cannot afford to invest a huge capital in IT hardware.

At the same time, while the advantages of cloud computing – especially the "public cloud[4]"– involves accessing services at the required time and performance scale, and thus reducing the impact of investments and peak load management, the policies concerning the geographical allocation of processors and data, as well as their protection, depend on the provider, and this particular aspect has raised the question of cloud provider nationality and localisation.

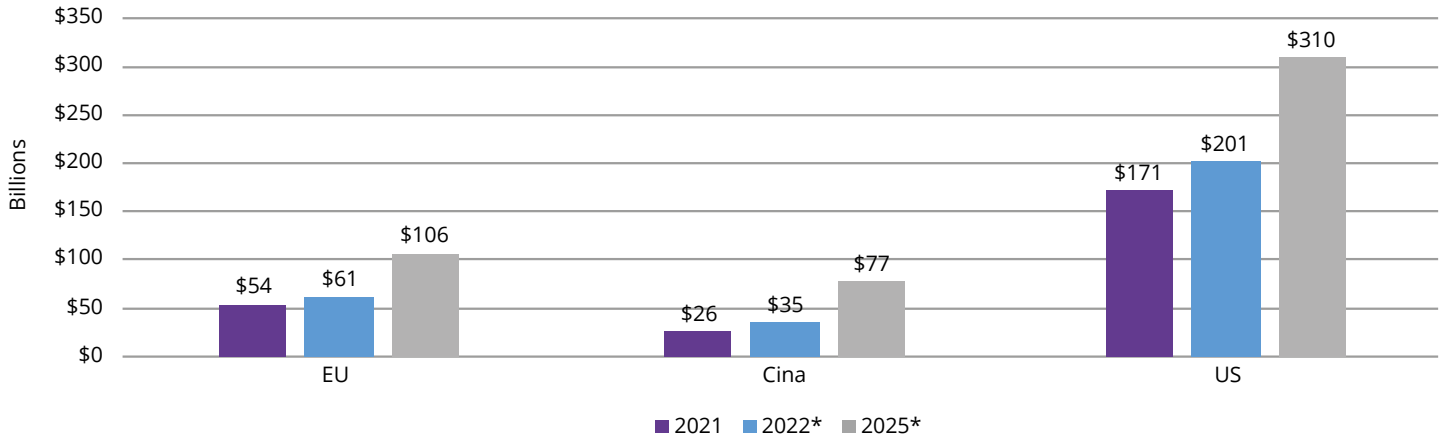
Looking at the latest data in the 'Statista Technology Market Outlook', updated to June 2022, relating to the public cloud, it can be seen that this sector is growing significantly across the globe. Geographically, the **US appears to be the largest market for this technology, with reported revenues of $171 billion in 2021** and estimates for growth reaching $201 billion by the end of this year and $310 billion by 2025. Although still very far from the US figures, the public cloud market in the EU also appears to be growing strongly. According to the same analysis, **revenues generated in the EU stood at $54 billion in 2021**, and could surpass the $60 billion cap this year, and almost double by 2025. The European

3 The NIST Definition of Cloud Computing. Recommendations of the National Institute of Standards and Technology, September 2011.

4 In the public cloud architecture, infrastructure and services are made available by a provider (a company or a governmental or academic organisation, or a combination thereof) to a wider public. The same server system is used within a public network, while multiple customers are allowed access to the same virtualised machines. Where the "private cloud" model by definition restricts access to users outside the provider, the public cloud shares resources to offer a unified (and optimised) level of service. In particular, public cloud users can only access their own information, while access to that of other users is prevented. The advantages for public cloud users consist in being able to use services at the required time and performance scale, thus reducing the impact of investments and peak load management, while the policies concerning the geographical allocation of processors and data, as well as their protection, depend on the provider.

Fig. 1.13 Public cloud revenues by geographical area

Source: Statista Technology Market Outlook



* Forecast

turnover currently appears to be significantly higher than that of China, whose revenues, at around $26 billion in 2021, are expected to reach $35 billion by the end of the year, and around $77 billion by 2025.

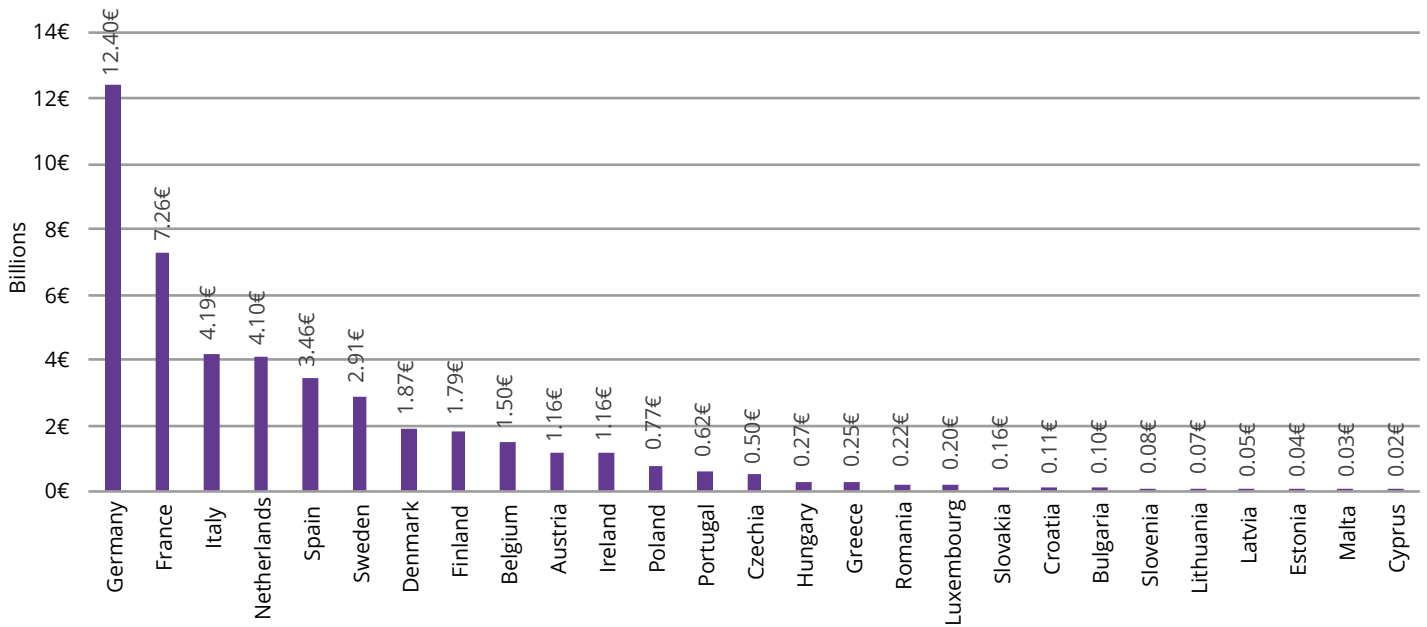
By observing the EU internal market (Fig. 1.14), we can see that, among the MSs, **Germany generates the highest amount of revenues ($12.4 billion), followed by France ($7.3 billion) and Italy ($4.2 billion).** In general, what is worrying about European competitiveness is related to the lower part of the ranking, which sees 15 MSs recording less than €1 billion in revenues from cloud computing. These also include medium-sized economies such as Poland ($774 million), Portugal ($616 million), Czechia ($501 million), Hungary ($271 million), Greece ($250 million) and Romania ($224 million).

On the other hand, while the European Union is today the world's second largest market for cloud computing (in 'public' mode[5]), an analysis of the market distribution of the main global providers shows that it does not have a single global provider among its ranks. **About 80% of the world market for cloud computing services is in**

5 In the public cloud architecture, infrastructure and services are made available by a provider (a company or a governmental or academic organisation, or a combination thereof) to a wider public. The same server system is used within a public network, while multiple customers are allowed access to the same virtualised machines. Where the private cloud model by definition restricts access to users outside the provider, the public cloud shares resources to offer a unified (and optimised) level of service. In particular, public cloud users can only access their own information, while access to that of other users is prevented. The advantages for public cloud users consist in being able to use services at the required time and performance scale, thus reducing the impact of investments and peak load management, while the policies concerning the geographical allocation of processors and data, as well as their protection, depend on the provider.

Fig. 1.14 Public cloud revenues by Member State (2021)

Source: Statista Technology Market Outlook

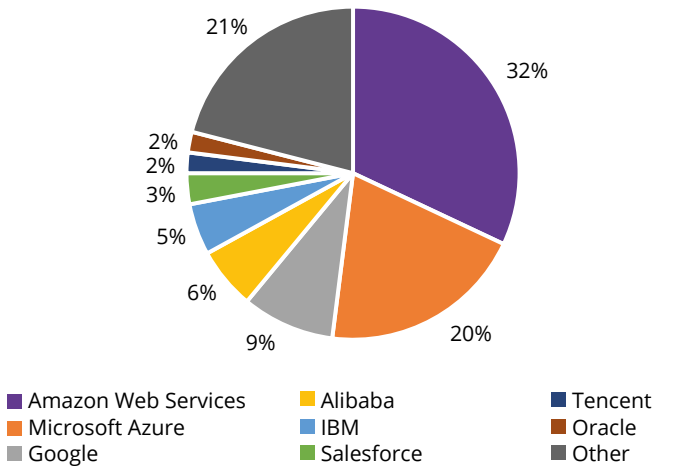


the hands of only eight companies, six from the US and two from China (Fig. 1.15). At present, the market leadership is held by three US companies – namely Amazon Web Services (32%), Microsoft (20%) and Alphabet-Google (9%).

In order to foster the development of an internal market and reduce dependency on foreign providers, the European Commission has supported the creation of the **'Gaia-X' project**, an initiative that envisages the **creation of a new pan-European platform that brings together different cloud service providers, also from outside Europe, as long as they accept the set of requirements, standards and values promoted at EU level**. Gaia-X is part of a wider strategy under the von der Leyen Commission's European strategic autonomy. The project was revealed at the Digital Summit 2019 in Dortmund (Germany) and has been constantly evolving since. It was founded by 22 companies including firms providing cloud services, infrastructure and telecommunications, but also research companies active in the fields of innovation. Among the objectives, along with increasing the level of protection of data belonging to European citizens,

Fig. 1.15 Global cloud services sales market share distribution (Q4 2020)

Source: Digital Economy Report 2021, UNCTAD



businesses and public administrations, there is also the goal of exploiting the broader expertise of providers of global dimensions which, thanks to greater investment and experience, can count on recognised service quality, speed, usability and lower costs. **The Gaia-X platform should operate mainly in the areas related to the establishment of trust mechanisms** to guarantee the identity of sources and recipients, access and usage rights, and should work on the harmonisation of the existing standards for interoperability and portability between infrastructures, applications, data and terms of use. **Furthermore, it should intervene on the supply side through the creation of federated catalogues and the definition of certifications and mandatory standards at the European level to support operators in offering secure and interoperable services.**

At the same time, the initiative intends to ensure interoperability and security standards aimed at promoting an open and transparent digital ecosystem – where data and services can be made available, collected and shared in a secure environment – also guaranteeing to users the sovereignty of their data. Indeed, each user should be able to determine for themselves where to store their personal data, as well as the level of accessing and processing it.

On the base of standardisation rules and different management and control options, data could then be subsequently exchanged and processed between companies, and eventually monetised in "value-creating" networks capable of exploiting the synergies and the greater efficiency produced by the aggregated and interoperable system.

As of October 2022, Gaia-X has moved from a founder base of 22 members to 357 members[6], with an associated growth rate of 32% per year. Moreover, the association has currently 15 national hubs, 5 international hubs, 3 committees, 19 working groups and over 2,000 contributors across different vertical systems, such as mobility, healthcare, energy, manufacturing, finance, tourism, agriculture, aerospace, and public service. Twelve important partners[7] have recently been

6 This information was extracted from a press release of 24 October 2022, https://gaia-x.eu

7 BDVA, Big Data Value Association, Capgemini Belgium NV, FIWARE Foundation, Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e.V., Gaia-X the European Association for Data and Cloud AISBL, IDSA, International Data Spaces e. V., National University of Ireland Galway, Katholieke Universiteit Leuven (KU Leuven), MyData Global,NederlandseOrganisatievoorToegepastNatuurwetenschappelijk Oonderzoek TNO, Sitra, Teknologian tutkimuskeskus VTT Oy. Press release of 13 October 2022, https://gaia-x.eu

tasked to set-up and operate the Data Spaces Support Centre, which has the target to facilitate common data spaces in diverse sectors that will collectively create an interoperable data sharing environment[8].

There is a compelling need, for Europe and beyond, for a new generation of reliable digital services, controllable by the data subjects and data controllers. To achieve this, a common governance framework for the free and secure flow of data in the digital space is required. The Gaia-X project entails the development of a digital governance based on regulatory, industry standards and requirements from its members to allow them establish the rules and characteristics necessary to satisfy real market expectations. **The novelty introduced by the project is that these rules are not only being defined in written specifications, but also a technology framework is being implemented – i.e. source code – to achieve what is called 'Gaia-X Compliance'**.

The approach to keep the adoption of the Gaia-X Compliance easy and effort and time effective involves implementing it as a software. Previously defined as "regulation by automation", this is progressing into the subsequent phase of "Compliance as Code".

Today Gaia-X has a simple central deployment of through a container compliance code. This option allows for rapidly deploying the project's first software version with little management effort and minimal cost. Nevertheless, this is not a deployment scenario sustainable in the long run, since it burdens the association itself with the responsibility of the service, creates a singularity and cannot scale in a geo-distributed setting with non-homogenous network transport layers.

Hence, several models are imagined for the future[9]. The first is the **licensed model**. In order to maintain a tight supervision, the Gaia-X association licenses a release of the Compliance source code of Gaia-X to some Gaia-X members. This model foresees contractual legal binding agreements between the Gaia-X Association and each chosen Gaia-X member to cover liability, RTO, MTD, SLA, updates/upgrades, maintenance, and operations. It implies improved scalability and resilience compared to the current one. Nevertheless, it is not the best solution regarding transparency and openness, assigning the control of the Gaia-X Compliance to specific market subjects. Moreover, it will obligate the Gaia-X Association to check all contracts.

The second model envisioned is the **private decentralised model**. The development of the preceding model with a better scalability and recognition of possible rule breakers, would be the implementation of a Gaia-X Consortium blockchain to enact the Gaia-X Compliance service. This model is more governable, implies high transaction speed and would open a playground for *tokenomics*. Nevertheless, this only entails privacy of the service and participant descriptions within the scope of the Consortium.

The third model envisioned is the **secure private model**. This is similar to the preceding model with various

8 Press release of October 13th, 2022, https://gaia-x.eu

9 Source: Gaia-X Compliance Service deployment scenario, September 2nd, 2022 available at https://gaia-x.eu/news/latest-news/gaia-x-compliance-service-deployment -scenario/

deployment instances, but to cancel the requirement of a manual legal binding agreement and allow instances of the service to be enacted in environments without prior knowledge on their ownership or their security level, the Gaia-X Association demands particular verifications for the exactitude of the execution.

The final model envisioned is the **public decentralised model**. Notwithstanding the general fame of Web3, not many services are successfully remaining decentralised. Therefore, more studies and analyses should be carried out. This model would execute the Gaia-X Compliance software as a smart-contract on one or more public blockchain networks.

To conclude, all the models mentioned above have their benefits and drawbacks and are not mutually exclusive. Before being submitted for confirmation to the Gaia-X Technical Committee, all models will require technical validation.

On the other hand, some concerns may regard the Gaia-X governance. In November 2021, the French cloud provider Scaleway, one of the founders of Gaia-X, withdrew from the project, due to diverging opinions about how to achieve the objective of constructing an open, federated data infrastructure for European firms to host their cloud workloads. More specifically, concerns emerged regarding Gaia-X opening its doors to big tech (and foreign influences) to shape the European project. Indeed, Gaia-X has increased its members to include big-tech companies such as Microsoft, Google, Amazon and IBM. This has led to internal disputes with companies and digital activists afraid that Europe could lose its control over its project. Moreover, **some concerns have been raised in relation to the wide number of members, which risks giving rise to difficulties in defining common objectives, also because of the broad range of views and interests**, some of which seeming to be diametrically opposed. In addition, the critical points of Gaia-X would not be limited to foreign influence. Another element that may play a role in this context would be the restrictive membership conditions which would risk preventing transparency, openness and valuable criticism[10]. For these reasons, it seems important, for the further development of the project, to focus on producing value-creating use cases and platforms that can concretely be used by companies, as well as guaranteeing this important initiative with the funding originally planned.

1.3.1. Cloud and data regulation

Services and new digital technologies feed on data and produce huge amounts of data. To accelerate the digital revolution without sacrificing the protection of fundamental rights, the European institutions have for a time been focusing on two different aspects – the protection of personal data and the creation of an ecosystem enabling data circulation and use.

After adopting Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, Directive 97/66/EC concerning the processing of personal data and the

10 For example, the membership agreement reports that "a member can be expulsed if it acts against the interests of the Association," which does not seem to exclude public criticism of Gaia-X.

protection of privacy in the telecommunications sector, Regulation n. 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, and Directive 2002/58/EC **– E-Privacy Directive, with the adoption of the Regulation n. 2016/679**, the European Union has become the global model for personal data protection. This is a very important regulatory intervention that has fixed the principle concerning the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not and to the processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union. This applies when the processing activities are related to: (a) the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or (b) the monitoring of their behaviour as far as their behaviour takes place within the Union. It has laid down the foundations of lawfulness of data processing, indicated in an exhaustive manner the timing, content and modalities of the information notice, defined the rights of data subjects (access, cancellation-oblivion, limitation of processing, objection, portability), identified the subjective characteristics and responsibilities of data controllers and data processors (introducing, among the various criteria, that of 'data protection by default and by design' and of risk) and regulated international data transfers.

Successively, on 23 October 2018, **Regulation n. 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) n. 45/2001 and Decision n. 1247/2002/EC** was adopted. It lays down rules on how EU institutions, bodies, offices and agencies should treat the personal data they hold on individuals, upholds an individual's fundamental rights and freedoms, especially the right to protection of personal data and the right to privacy and aligns the rules for EU institutions, bodies, offices and agencies with those of the General Data Protection Regulation (GDPR) and of Directive (EU) 2016/680.

Along with the need to ensure effective protection of personal data, the intention of the institutions to guarantee that individuals, businesses and public administrations can benefit from the enormous opportunities associated with the use of data is also a priority. In fact, after adopting **Regulation n. 2018/1807 on a framework for the free flow of non-personal data in the European Union** aiming at ensuring the free flow of data other than personal data within the Union by laying down rules relating to data localisation requirements, the availability of data to competent authorities and the porting of data for professional users and **Directive n. 2019/1024 on open data and the re-use of public sector information (Open Data Directive)** setting timelines, procedures to process the request for re-use and the conditions for re-use identifying available formats and principles governing charging and conditions (specific rules are set for high-value datasets), in February 2020, the Communication "***A European Strategy for Data***"

outlined the European strategy consisting of a series of measures and investments to enable the data economy over the next five years. This communication, in detail, has identified several critical issues needed to be overcome concerning the availability of data, imbalances in market power, data interoperability and quality, data governance, data infrastructures and technologies, and empowering individuals to exercise their rights, skills and data literacy and cybersecurity. Considering these issues, the Commission has outlined a strategy focused on four pillars and several key actions to encourage a cross-sectoral governance framework for data access and use, to strengthen Europe's capabilities and infrastructures for hosting, processing and using data, interoperability to reinforce competences and skills and to create common **European data spaces in strategic sectors** and domains of public interest (specifically, manufacturing, green deal, mobility, health, finance, energy, agriculture, public administrations and skills).

Implementing the strategy, on 30 May 2022, Regulation n. 2022/868 (**Data Governance Act**) was adopted. This regulation establishes a mechanism for the reuse of certain categories of protected data held by public bodies. We refer, in particular, to a reuse subject to respect for the rights of third parties (especially for reasons of personal data protection, but also for the protection of intellectual property rights, statistical confidentiality, and commercial confidentiality) where a set of harmonised basic conditions are identified to enable its effective implementation. The regulation prohibits exclusive arrangements having the object or effect of preventing or limiting the availability of data for reuse by entities other than the parties to the agreement, and regulates the concrete modalities of reuse, requiring public entities that allow it, on the one hand, to equip themselves in a manner that ensures full protection of data protection, privacy, and confidentiality through anonymisation of personal data and aggregation of confidential business data and information, and,; on the other hand, to set up a secure physical or digital (in the case of remote access) processing environment provided or controlled by the public entity. Public entities that allow reuse may, by regulation, impose fees – the amount of which must take into account a range of necessary costs identified by the same regulation – which must be transparent, non-discriminatory, proportionate, objectively justified, and not restricting competition, without prejudice, however, to the possibility for the same entities to provide for a reduced or zero fee, particularly for SMEs and start-ups, civil society, and educational institutions to incentivise the reuse of data for non-commercial purposes. The deadline for processing requests for reuse is set at 20 days that can be extended to a maximum of 30 days in the case of exceptionally large and complex requests (the right to appeal for the requesting party is enshrined).

The same regulation sets out, in Chapter III, a number of **requirements that data sharing service providers must meet** and provides a **notification regime for data sharing service providers.**

It also regulates **data altruism** and, thus, the possibility for individuals or companies to make their data available on a voluntary basis for the common good,

setting the possibility for organisations that wish to practice it to be registered, if they meet certain requirements, on public registries provided at the national and European level. Member States, are responsible for designating competent authorities for the registration of organisations for altruistic data and compliance monitoring activities. On the other hand, the Commission is required to adopt implementing acts for the establishment and development of a European data altruism consent form (after consultation with the European Data Protection Board, taking into account the opinion of the European Data Innovation Board and involving relevant stakeholders as appropriate) in order to facilitate data collection on these bases.

On **governance** and **enforcement**, the Member States are required to designate one or more competent bodies (new or existing) responsible for assisting public bodies that grant or deny access to reuse and to establish, for a new or existing body, a **one-stop shop** – which may be linked to sectoral, regional, or local desks -that is responsible for receiving requests for information and requests for reuse. This one-stop shop, specifically, must make available, electronically, a searchable list of available data resources, including, as appropriate, those available from sectoral, regional, and local one-stop shops, containing relevant information describing the available data. This must include at least the format and size of the data and the conditions for their reuse with the possibility of providing a separate, simplified, and well-documented information channel for SMEs and start-ups. The regulation has also established a formal group of experts, the "**European Data Innovation Board**," with its composition and functioning described, to provide support and advice to the Commission and to facilitate the development of best practices by MS authorities.

The European Parliament resolution of 25 March 2021 on a European Strategy for Data urged the Commission to present a data act to encourage and enable greater and fairer flows of data in all sectors, from business-to-business, business-to-government, government-to-business and government-to-government: Instead, in its resolution of 25 March 2021, the European Parliament also highlighted the need to create common European data spaces for the free flow of non-personal data across borders and sectors and between businesses, academia, relevant stakeholders and the public sector.

Consequently, complementing the Data Governance Act, on 23 February 2022, the Commission launched the **Data Act** proposal, which aims to remove, through the establishment of a harmonised EU-wide set of rules, barriers to data access for both consumers and businesses. Specifically, the proposal pursues the following goals: 1) facilitate access to and the use of data by consumers and businesses while preserving incentives to invest in ways of generating value through data; 2) provide for the use by public sector bodies and Union institutions, agencies or bodies of data held by enterprises in certain situations where there is an exceptional data need; 3)

facilitate switching between cloud and edge services; 4) introduce safeguards against unlawful data transfer without notification by cloud service providers; 5) provide for the development of interoperability standards for

data to be reused between sectors.

To achieve these goals, the regulation establishes common rules to regulate the sharing of data generated by the use of related products or services (e.g., IoT, industrial machines), ensure fairness in data sharing contracts, and allow public entities to use data held by businesses in case of exceptional need (e.g., public emergency). The proposed data law also introduces new rules to facilitate switching between cloud service providers and other data processing services and puts in place safeguards against illegal international data transfer by cloud service providers.

This proposal, in particular, to foster data circulation, in Chapter II regulates **business-to-consumer and business-to-business data sharing** by requiring that the design and manufacture make data generated accessible in an easy and secure (and where appropriate, direct) manner. Related to this obligation is that to provide to the user – prior to the conclusion of a contract for the purchase, rental or lease of a product or related service – information in a clear and comprehensible manner, on terms of relevance and indications concerning the means by which the user may request that data be shared with third parties. The right of users to access and use the data generated by the use of related products or services is punctually spelled out in Article 4, which, among other things, requires the data controller to **make the data produced available to the user promptly and free of charge** (and continuously and in real time where applicable) and makes the data controller's **use of personal data subject to the prior conclusion of a contractual agreement with the user**.

The proposal also regulates in detail the right to share data with third parties (Art. 5), setting specific prohibitions on providers of basic platform services designated gatekeepers under the DMA in the logic of averting risks of conditioning or altering user choices. On the other hand, it prescribes processing the data made available only for the purposes and under the conditions agreed with the user and without prejudice to the rights of the data subject with regard to personal data, and to delete the data when it is no longer necessary for the agreed purpose. In addition, there is a prohibition on conditioning or manipulating the user's autonomy, using the data for profiling individuals, making the data available to third parties (unless it is necessary to offer the service to the user), providing the data it receives to a company that provides basic platform services for which one or more of these services has been designated as a gatekeeper, use the data to develop a product that competes with the product from which the accessed data came (nor share the data with another third party for that purpose), and prevent the user, including through contractual commitments, from making the data it receives available to other parties.

Chapter V, instead, establishes a harmonised framework for the **use by public bodies and Union institutions, agencies and bodies** of data held by businesses in situations where there is an exceptional need for the requested data.

Chapter VI introduces minimum regulatory requirements of a contractual, commercial and technical nature,

imposed on **cloud providers**, edge and other data processing services, to enable switching between such services. In particular, the proposal ensures that customers maintain functional equivalence (a minimum level of functionality) of the service after they have switched to another service provider. The proposal does not mandate specific technical standards or interfaces but requires services to be compatible with European standards or open interoperability technical specifications where these exist.

In order to ensure compliance and foster European cooperation, Member States are required to identify one or more new or existing national competent authorities.

The legislative procedure is still in its early stages. The rapporteur to the Parliament, MEP Pilar Del Castillo Vera, presented her own draft report last September underlining the necessity to better define the scope of the regulation and specify how it should be applied where the various actors are concerned, to strengthen the protection of trade secrets, extend the exemption for SMEs, clarify the implementation and enforcement rules and provide for fair remuneration for making data available to public bodies in exceptional circumstances.

By the deadline of 9 November 2022, over 1,000 amendments were submitted, ranging from scope and type of data to be covered by the regulation to data monetisation, public access to private data, governance and interoperability.

In the Council, on the other hand, following the progress report presented by the French Presidency in May 2022, the first compromise texts were presented by the Czech Presidency last September showing that the discussion is currently focused on the scope of the proposal, the conditions under which data should be provided exceptionally to public sector entities, restrictions on gatekeepers, and exemptions in favour of SMEs.

Focusing on **cloud services,** they are very important digital infrastructures that the European Commission considers critical given that the most important cloud service providers are non-EU companies.

In the European strategy for data analysed above, the Commission announced for the period 2021-2027, investments in a High Impact Project on European data spaces and federated cloud infrastructures. The project will fund infrastructures, data-sharing tools, architecture and governance mechanisms for thriving data-sharing and AI ecosystems. It will be based on the European federation (i.e., interconnection) of energy-efficient and trustworthy edge and cloud infrastructures (Infrastructure-as-a-Service, Platform-as-a-Service and Software-as-a Service). Specifically, the Commission intends to fund the establishment of EU-wide common, interoperable **data spaces in strategic sectors,** that are manufacturing, green deal, mobility, health, financial, energy, agriculture, skills, and for public administration data spaces. These spaces aim at overcoming legal and technical barriers to data sharing across organisations, by combining the necessary tools and infrastructures and addressing issues of trust. The spaces will include the deployment of data-sharing tools and platforms, the creation of data governance frameworks and improving the availability, quality and interoperability of data – both

in domain-specific settings and across sectors. Funding will also support authorities in the MSs in making high value data sets available for reuse in the different common data spaces. The support for data spaces will also cover data processing and computing capacities that comply with essential requirements in terms of environmental performance, security, data protection, interoperability and scalability.

In this context, the Commission will foster synergies between the work on the European cloud federation and MS initiatives such as the "**Gaia-X"** cloud project, a federated data infrastructure to enable the management, access and control of data belonging to EU citizens and businesses (discussed in the previous paragraph).

In addition to the commitment to the creation of the European Federal Cloud within the framework of the Gaia X project, on December 2020, the European Commission launched a **European Alliance on Industrial Data, Edge and Cloud**, made up of MS representatives, cloud computing providers and industrial cloud users. It will develop several work streams, related to key EU policy goals: 1) joint Investment in cross-border cloud infrastructures and services to build the next generation cloud supply, including to enable Common European Data Spaces; 2) EU Cloud Rulebook for cloud services, which will provide a single European framework of rules, transparency on their compliance and best practices for cloud use in Europe; 3) a European marketplace for cloud services, where users will have a single portal to cloud services meeting key EU standards and rules. It is expected to lead the implementation of the pan-European cloud with a budget of up to €10 billion.

The importance of ensuring the development and usage of cloud services is also underlined in the Communication "***2030 Digital Compass: the European way for the Digital Decade***" (9 March 2021) stressing that EU-based cloud providers have only a small share of the cloud market and sets an ambitious goal on usage by 2030. 75% of European enterprises have taken up cloud computing services, Big Data and AI.

1.4 TECHNOLOGICAL SUPPLY CHAIN: THE CHALLENGE OF SEMICONDUCTORS

A context similar to the one of the cloud is also observed where the **EU's position on dependence on foreign suppliers for the procurement of semiconductors is concerned**. Semiconductors play a pivotal role in our modern economy and represent a strategic resource for global value chains. In particular, **semiconductors are the backbone of the digital revolution**, as they are fundamental for the spread of emerging technology applications such as those related to AI, quantum computing, Industry 4.0, 5G networks, Internet of Things and many others.

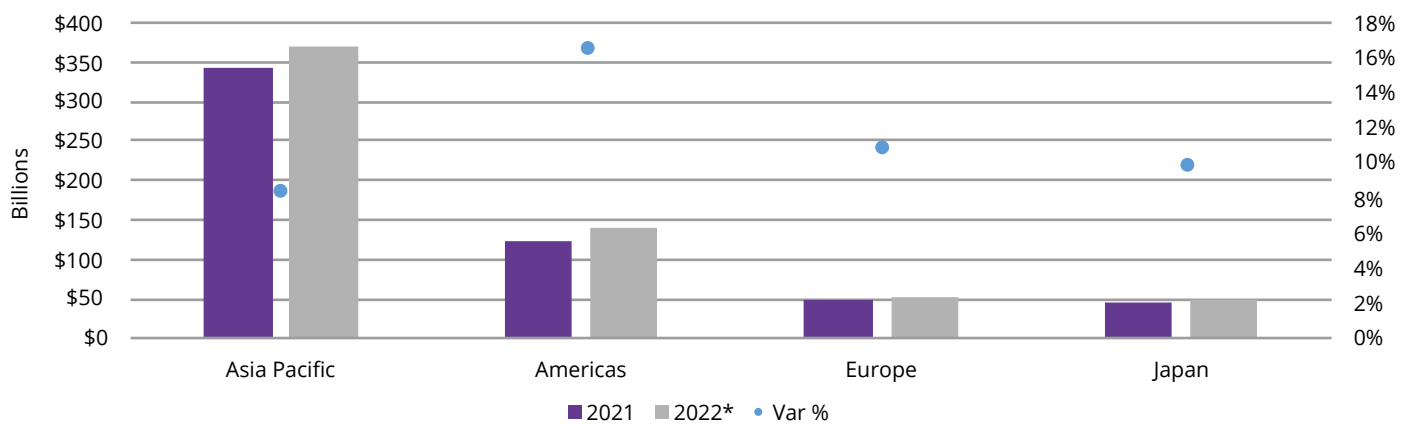
For these reasons, the global semiconductor shortage is an issue that affects not only individual companies, but Europe as a whole in political and economic terms.

Moreover, it is worth noting that **the semiconductor supply chain is extremely complicated and segmented amongst several countries, so no one can consider itself as completely autonomous and independent.** However, **some countries play an especially crucial role in certain segments**, making the **extreme global dependence on the semiconductor value chain in the current geopolitical situation more evident**.

The semiconductor supply chain has become an important strategic asset in geopolitical manoeuvres, and not only in China and the West. This year, Russia restricted exports of noble gases, including neon, a key ingredient for chip production. This followed Japan's 2019 restriction of

Fig. 1.16 World semiconductor market

Source: World Semiconductor Trade Statistics, March 2022



* Forecast

exports to South Korea of high-purity hydrogen fluoride, a cutting gas used in semiconductor production.

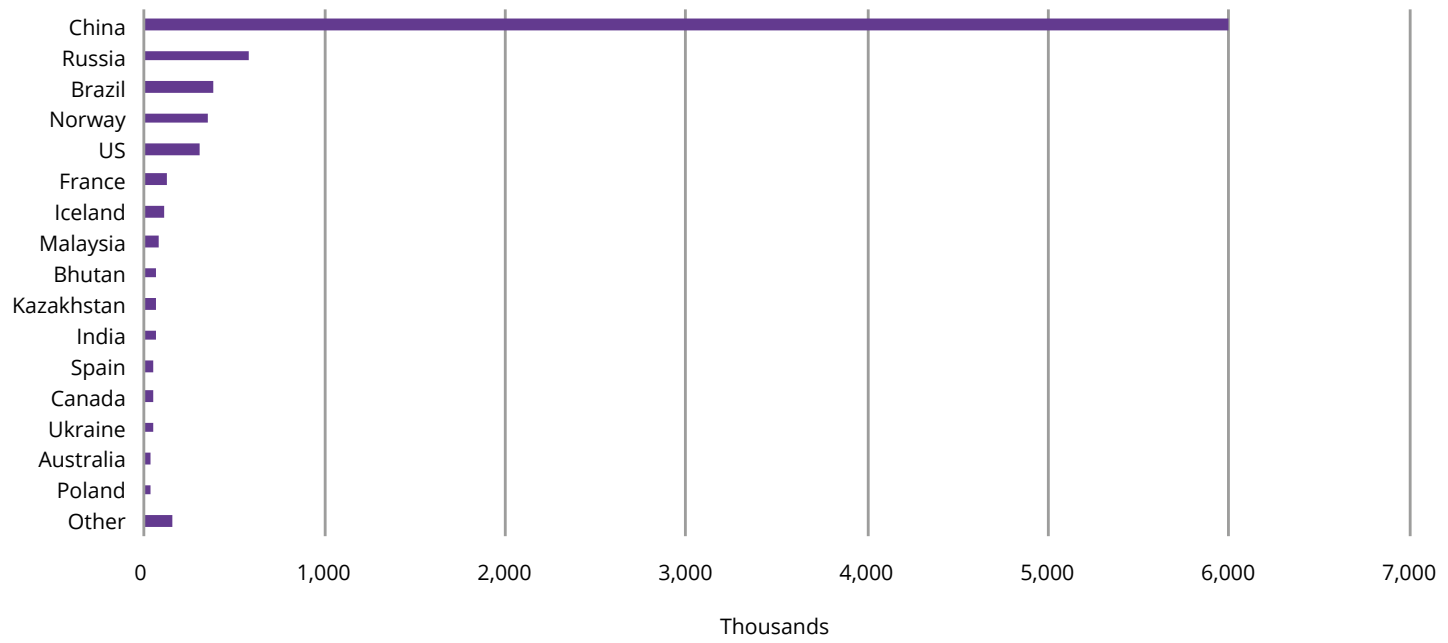
Growing tensions between China and the US threaten further fragmentation of global technology ecosystems. The US has already cut China off from receiving advanced tools, and 'domestic-first' policies in China could make it difficult for Western companies to access cutting-edge chips from China, where there is a concentration of cutting-edge wafer production centres. These are just some of the reasons why semiconductor consumers will increasingly have to take geopolitical risks into account when sourcing chips and why the **European Union is pushing to reconsider its current technological dependence to avoid falling into the same dependence on China as it did with oil and gas from Russia.**

The importance of these materials lies in their special physical characteristics, which make them central to the production of numerous electronic components that are crucial for our companies, including microchips.

To understand this for the global industry, one only has to look at the latest available market data released by the World Semiconductor Trade Statistics last March (Fig. 1.16**). Global semiconductor turnover stood at**

Fig. 1.17 Main silicon producing countries globally (tonnes per year, 2021)

Source: Mineral Commodity Summaries 2022, U.S. Department of the Interior & U.S. Geological Survey



$555.9 billion in 2021, and is expected to reach $613.5 billion by the end of this year (+10.4%).

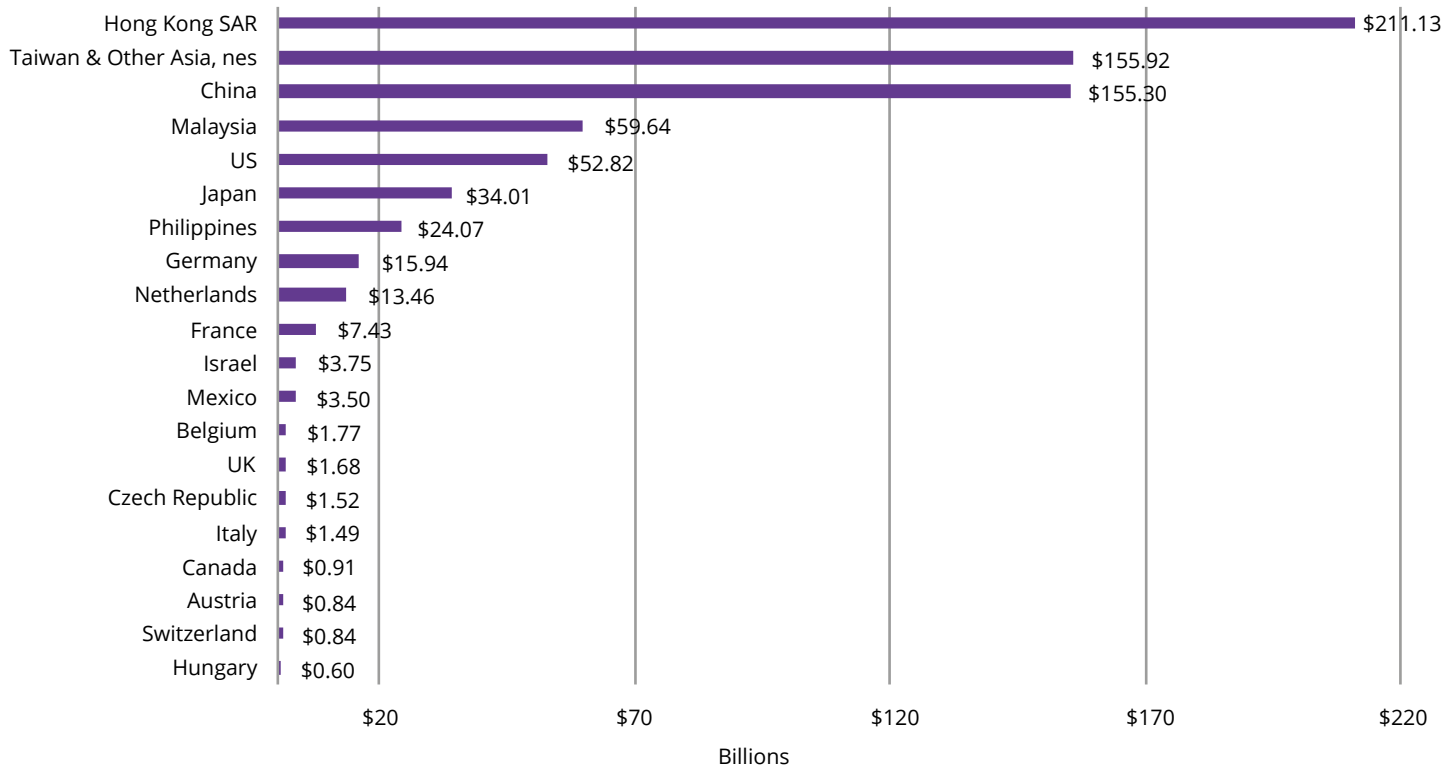
Asia is the main market for these materials accounting for $343 billion in 2021, and is estimated to reach the $371 billion threshold by the end of 2022, showing YoY growth of around 8.3%. In the Americas, sales of these goods stood at $121.5 billion last year and are expected to reach $141.4 billion in 2022, while in Europe, companies **traded semiconductors for a volume of $47.8 billion in 2021** and the market is expected to reach $52.9 billion by the end of the year (+10.8%).

One of the main semiconductor materials used in electronic components is **silicon**. This element, which is not difficult to find in nature, requires a long and complex process to be transformed into wafers, i.e. in thin slices on which electronic chips are made.

The 2022 Mineral Commodity Summaries report by the U.S. Department of the Interior and the U.S. Geological

Fig. 1.18 Top 20 countries with the largest exports of electronic integrated circuits by economic value (2021)

Source: UN Comtrade Database, data extracted on 19/09/2022



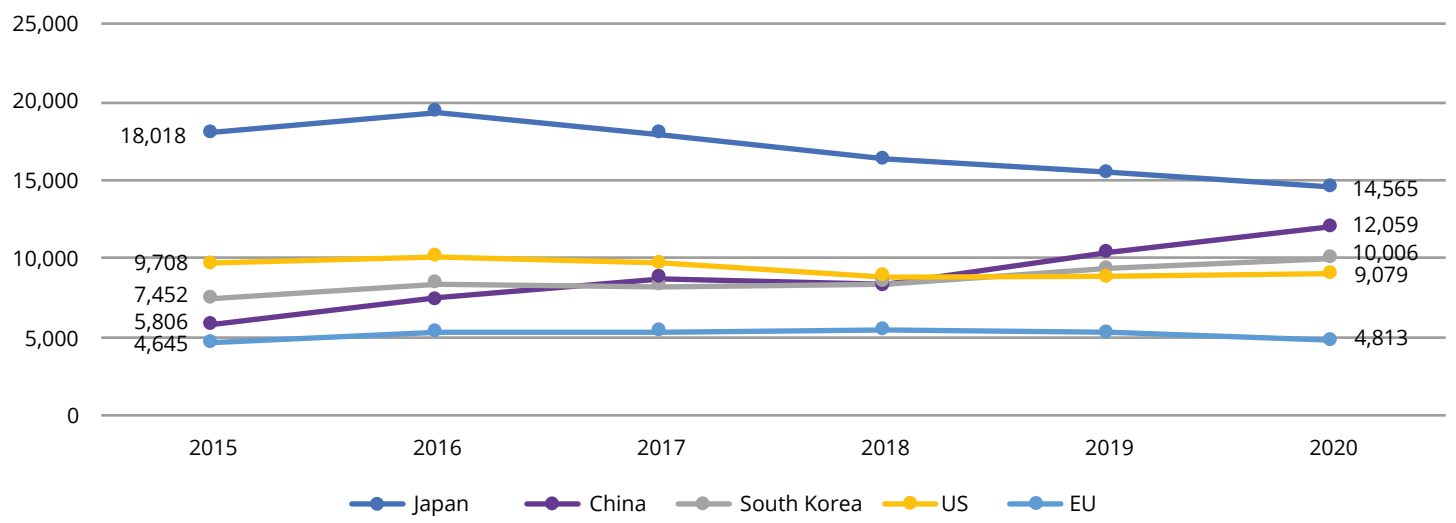
Survey shows that **the main producer of semi-finished silicon products is China, with about 6 million tonnes annually** (Fig. 1.17). The **second largest global producer is Russia**, whose trade relations with Europe came to an abrupt halt following the outbreak of the war with **Ukraine** (the latter also appeared among the main producers with 49,000 tonnes annually). Among EU producers, a modest quantity of silicon is processed in France (120,000 tonnes), Spain (58,000 tonnes) and Poland (42,000 tonnes), volumes that do not seem sufficient to meet the ever-increasing needs of Europe's industries, especially in the automotive sector.

Another snapshot showing how preponderant China is in this market is provided by data on exports of electronic integrated circuits, i.e. microchips (the main finished product made from silicon wafers) collected in the UN Comtrade database (Fig. 1.18). **The largest exporter of electronic integrated circuits globally is Hong Kong**, which recently came under the strict influence of the Chinese government, **with over $211 billion in value, followed by Taiwan, with $155.9 billion, and China with a further $155.3 billion**. In general, China, Hong Kong and Taiwan together generate a chip turnover equivalent to over $522 billion.

The EU appears to be lagging far behind the other major world economies in terms of both market and technological advancement. This trend emerges quite clearly from the analysis of **WIPO semiconductor patent data**,

Fig. 1.19 Registered semiconductor patents by geographical area

Source: I-Com elaborations on WIPO database (Data extracted on 11-10-22)



which sees Japan leading the way this time, with 14,565 registrations in 2020, albeit slightly down over the last five years (Fig. 1.19). Over the period under consideration, the values recorded by the world's largest economies show that Japan's leadership may soon be challenged by China, which has experienced impressive growth also in this domain (+108%). The **EU**, on the other hand, **is in last place also in this sector**, and has shown a fairly stable trend over the last five years, with a decline in 2020.

To tackle the rise of Asian technological powers or international turmoil, the European Union has recently decided to take action to reduce its dependence on foreign players and strengthen its position in the global arena.

1.4.1. The Chips Act proposal

The increasing prevalence of digital and digitised products, from smartphones to automobiles to critical infrastructure and industrial automation, the surge in demand for computing equipment in the last three years, as well as the development and operation of AI, Edge computing and 5G/6G, have placed semiconductor chips at the centre of strong geostrategic interests and the global technology race. In order to overcome the current situation in which the EU plays a marginal role in microprocessor production (only 10% of global production) and with the ultimate goal of fostering the EU's achievement of digital sovereignty, the **Digital Compass** published in March 2021, set a very ambitious goal for 2030 – to raise European production of semiconductors to **at least 20% of the value of global production.**

To this end, on 8 February 2022, the Commission launched the "**Chips Package**," including a **recommendation** defining tools for monitoring the chip ecosystem with immediate actions suggested for MSs, the Communication "**A Chips Regulation for Europe**" outlining the European strategy and rationale behind the initiative, a **Proposal for a Regulation to build a Resilient European Ecosystem and Strengthen Europe's Technology Leadership (Chips Act), and finally a proposal for a Council Regulation amending Council Regulation 2021/2085 establishing Joint Undertakings under Horizon Europe.**

The **European chip strategy** is structured around five strategic goals: 1) **to strengthen European leadership in research and technology**, with a focus on technologies to achieve sub-2nm transistors, breakthrough technologies for AI, ultra-low-power processors, new materials, and heterogeneous and 3D integration of different materials, as well as emerging design solutions, such as those based on the open source RISC-V computing architecture; 2) **to build and strengthen European capacity for innovation in the design, fabrication and packaging of advanced chips and their transformation into commercial products.** The establishment of a large-scale design infrastructure for integrated semiconductor technologies through a virtual platform available throughout Europe, accessible to stakeholders including innovative SMEs, and the development of new pilot lines, e.g., one for FDSOI technology (10 nm and below), one for leading edge nodes (below 2 nm), and one for 3D heterogeneous systems integration and advanced packaging, and the establishment of reference certification procedures for

specific critical technologies and sectors with a possible high societal impact, will be crucial; 3) **to establish an appropriate framework to substantially increase European manufacturing capacity by 2030 through investment in new advanced manufacturing facilities**, with the possibility for the Commission to justify coverage by up to 100% of public resources if such facilities would not otherwise be built in Europe; 4) to **overcome the lack of skills**, attracting new talent and supporting the emergence of a skilled workforce through the "Chip for Europe" initiative that will support education, training, skills and retraining interventions, the strengthening of MS national microelectronics skills strategies and the input of the European Industrial Processor Alliance; 5) to **develop an in-depth understanding of global semiconductor supply chains** through coordinated risk assessment by MSs, which will identify early warning indicators and anticipate key supply chain risks.

The proposed regulation identifies the operational tools, procedures and rules aimed at strengthening the semiconductor sector at the Union level, focusing on three pillars:

a. the "**Chip for Europe**" initiative, for the duration of the 2021-2027 multiannual financial framework with total resources of €3.3 billion (provided by Horizon Europe and Digital Europe). This initiative identifies 5 distinct operational objectives that are the development of advanced large-scale design capabilities for integrated semiconductor technologies, the upgrading of existing advanced pilot lines and the development of new lines, the development of advanced technological and engineering capabilities to accelerate the innovative development of quantum chips, the creation of a network of competence centres throughout the Union and the implementation of activities to facilitate access to debt and equity financing by start-ups, scale-ups and SMEs and other companies in the semiconductor value chain. Institutionally, there are plans to establish a European Chips Infrastructure Consortium-ECIC and a European network of semiconductor competence centres;

b. the establishment of criteria to **recognise and support EU integrated manufacturing facilities and open foundries** that promote the security of semiconductor supply in the Union. The proposal indicates the criteria that EU integrated production facilities and open foundries must meet and specifies the elements for evaluating applications for approval of facilities submitted by companies or consortia. The Commission is called to monitor the activities of plants and foundries, which are declared to be in the public interest. As for national permit procedures, the proposed regulation requires MSs to establish fast-track national permit procedures and to give EU integrated production facilities and open smelters the most important status possible, with corresponding treatment reserved in permit procedures, including those concerning environmental assessments and, where applicable, also concerning land use planning. For each integrated production facility and open smelter in the EU, the MS is required to appoint an

authority to facilitate and coordinate administrative applications concerning design, construction and operation. This authority is entrusted with the appointment of a coordinator to act as a single point of contact for the EU integrated production facility or open smelter and is called on to establish a working group made up of all authorities dealing with administrative applications in order to draw up a permit granting programme and to monitor and coordinate its implementation.;

c. the definition of a **coordination mechanism** between MSs and the Commission to monitor semiconductor supply and crisis response to semiconductor shortages. The proposed regulation requires MSs to conduct regular monitoring of the semiconductor value chain by inviting major semiconductor users and other relevant stakeholders to provide information regarding significant demand fluctuations and known disruptions and to provide relevant findings to the European Semiconductor Council in the form of periodic updates as well as to inform the Commission without delay in the event that a potential semiconductor crisis or risk factors related to semiconductors become known. In the case of a potential crisis situation, the Commission is called, on the one hand, to convene an extraordinary meeting of the European Semiconductor Council to assess the situation and decide if it is appropriate, necessary, and proportionate for MSs to jointly procure semiconductors, intermediate products, or raw materials that have been affected, or are likely to be affected, by a potential semiconductor crisis. On the other hand, to engage in consultations or cooperation, on behalf of the Union, with relevant third countries in order to seek cooperative solutions to address supply chain disruptions, while respecting international obligations. In the event of a crisis, the Commission may, where necessary and proportionate to ensure the operation of all or certain critical sectors, require EU integrated production facilities and open smelters to accept and prioritise a crisis-relevant product order even if an enterprise is subject to a third country measure related to orders classified as priority. In such a case, it is the Commission's responsibility to assess the legitimate purposes of the enterprise concerned, the costs and efforts required for any change in the production sequence by indicating in its decision the time limit within which the order must be carried out and, where appropriate, specifying the product and quantity, as well as the penalties for failure to comply with the obligation.

In terms of **governance,** the proposal establishes the **European Semiconductor Council**, chaired by a representative of the Commission and made up of representatives of the Member States, with tasks of monitoring and analysis and providing advice and assistance to the Commission. To ensure implementation and enforcement of this regulation at the national level, each MS is required to designate one or more national competent authorities and a single national point of contact responsible for exercising

a liaison function in order to ensure cross-border cooperation with the competent national authorities of other MSs, the Commission and the European Semiconductor Council.

On this proposal, the **European Economic and Social Committee** issued its opinion, published in the EU Journal on September 23, which, while welcoming the Commission's initiative to strengthen the European semiconductor industry and increase the transparency of the semiconductor chain in the logic of gaining greater EU independence, noted a number of critical issues to be addressed. At a general level, it is suggested more attention on and the preparation of specific measures, for semiconductor segments actually needed by the industry today rather than on those that will be important in the industry in the future, a specific focus on the energy efficiency of chips and the type of materials used for production, and specific forecasts on storage. The opinion also underlines the need to go beyond design and production by including sections in the regulation specifically on packaging, testing and assembly, which are areas of vulnerability that need to be acted upon. Where the information MSs are required to collect is concerned, the Committee suggests the implementation of a single template to be submitted to all EU companies that takes due account of the need to ensure its confidentiality. For skills, while appreciating the focus on skills, the Committee points out that the focus is only on high-level skills and training while it would be appropriate to extend this to lower level skills as well.

In the plenary session on October 10-12, the **European Committee of the Regions** issued its opinion. This opinion, specifically, has noted the crucial nature of the European chip regulation and proposed a number of actions including the establishment of a Knowledge and Innovation Community (KIC) for semiconductors and the founding of a "Semiconductor Academy" along the lines of the "Battery Academy.,". It would involve the participation of industry and research institutes and the inclusion of local and regional authorities in the "semiconductor coordination mechanism" in order to benefit from their specific knowledge of semiconductor research, business and production clusters. It has also proposed to establish a "prevention toolbox" rather than an "emergency toolbox," in view of the fact that short-term interventions in semiconductor manufacturing are not possible due to the complexity of the different circuits embedded in the final products and the extensive international supply chain, as well as the desirability of providing new funds, ensuring adequate European and national funding with consequent modification of the multi-year financial framework.

PART 2

PROMOTING LONG-TERM COMPETITIVENESS IN THE EU: A FOCUS ON THE PHARMACEUTICAL INDUSTRY

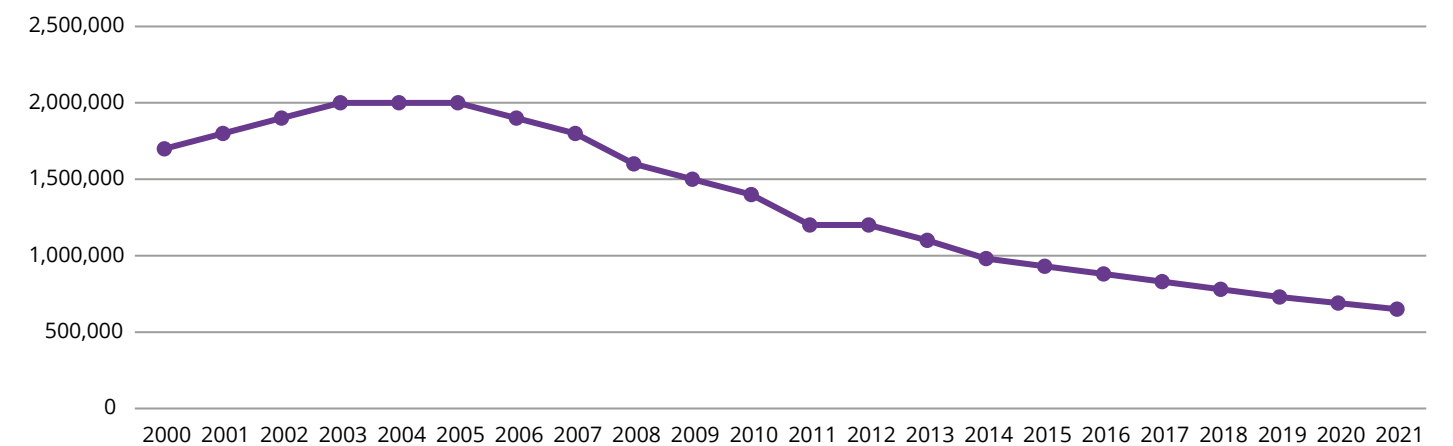
2. PROMOTING LONG-TERM COMPETITIVENESS IN THE EU: A FOCUS ON THE PHARMACEUTICAL INDUSTRY

The pandemic has demonstrated **the importance of having a strong European and national health system and pharmaceutical industry,** and has revealed the **risks of having an intricate system of global interdependence**. The length of the supply chains, together with the reduction, over time, in manufacturing competences have contributed **to weakening EU responsiveness during the health emergency.** It has thus become clear that **we need to support our internal production** and investment capacities so as to contribute to the health and wealth of European patients and citizens.

This is **a strategic asset as far as social and economic sustainability** in the long run are concerned. In all its forms, **access to innovation remains a crucial and delicate issue for public health.** The development of new technologies and drugs can represent an extremely significant turning point in patient care but, at the same time, increasingly sophisticated and targeted therapies have high costs that reflect the efforts in terms of investments in research and development and production. When the pandemic broke out in 2020, **pharmaceutical supply chains showed signs of potential failure** across the continent, underlining the weaknesses of the current system and **stressing the need to support European manufacturing as part of a comprehensive strategy** to guarantee the security of supply of medicines for all European patients.

Fig. 2.1 Total worldwide number of AIDS-related deaths (all ages)

Source: https://aidsinfo.unaids.org/ (Last Access: November 2022)



2.1 HOW COMPETITIVE IS THE PHARMACEUTICAL INDUSTRY IN EUROPE

The pharmaceutical industry plays a unique role in improving patient well-being. Indeed, thanks to important advances in medicine and drug discoveries, nowadays, worldwide citizens can expect to live longer than they had done a century ago and enjoy a better quality of life. In addition, some major steps in biopharmaceutical research have allowed for the reduction in mortality of some diseases, for example, that related to HIV/AIDS (Fig. 2.1) and several cancers.

Moreover, the pharmaceutical industry has become an important pillar of global economy. In 2021, the **world pharmaceutical market** was worth an estimated $ 1,256,863 million at ex-factory prices[11]. The North American market (US and Canada) remained the world's largest with a 49.1% share (Fig. 2.2), well ahead of Europe (23.4%), China (9.4%) and Japan (6.1%)[12]. However, **the total European pharmaceutical market value at ex-factory prices increased from €89.4 billion in 2000 to €255 billion in 2021** (Fig. 2.3). Germany was the top-ranking pharmaceutical market in Europe with a value of some €43 billion in 2020, followed by France and Italy.

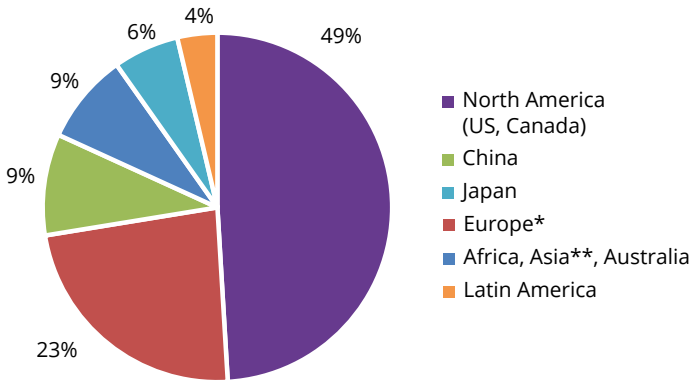
Moreover, **the value of production for the research-based European pharmaceutical industry grew from €127.5 billion in 2000 to €300 billion in 2021,** with Italy still being the main pharmaceutical producer of the

11 Data relates to the 2021 global retail and hospital pharmaceutical market (prescription only) at ex-factory prices.

12 EFPIA, The Pharmaceutical Industry in Figure, 2022.

Fig. 2.2 The world pharmaceutical market (sales 2021, in %)

Source: EFPIA 2022

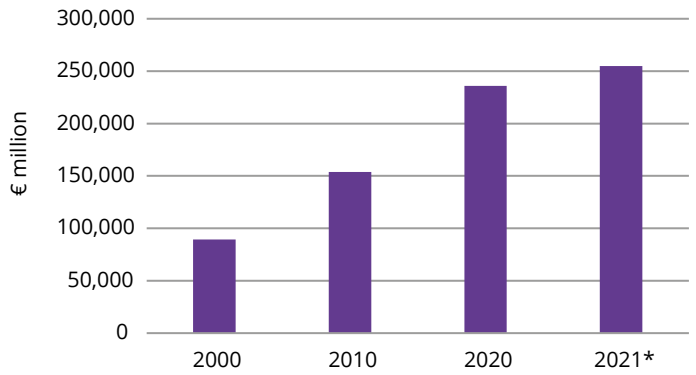


* When referring to "Europe" data include both EU and non-EU countries of the European continent

** Excluding China and Japan

Fig. 2.3 Total European pharmaceutical market value at ex-factory prices

Source: EFPIA 2022

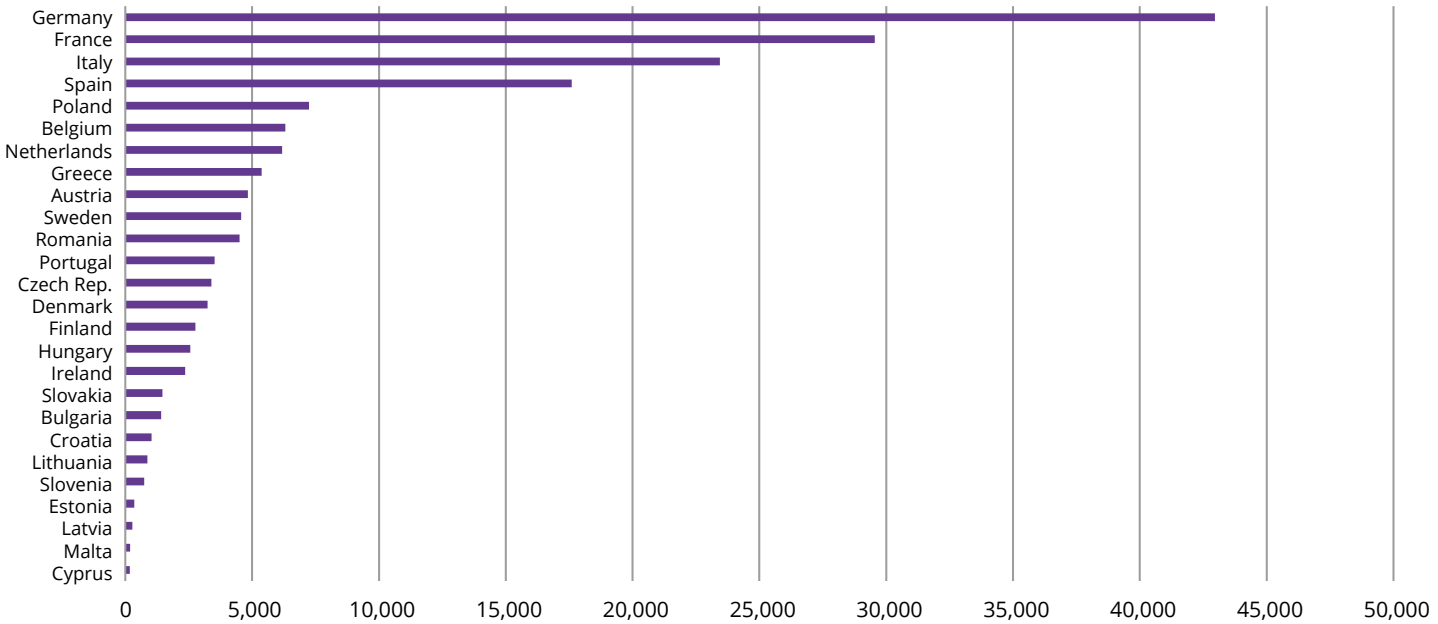


* Estimate

Note: The figures above are for pharmaceutical sales, at ex-factory prices, through all distribution channels (pharmacies, hospitals, dispensing doctors, supermarkets, etc.), whether dispensed on prescription or at the patient's request. Sales of veterinary medicines are excluded.

Fig. 2.4 Market value of pharmaceutical industry by Member State (million €, 2020)

Source: EFPIA 2022



Note: The figures above are for pharmaceutical sales, at ex-factory prices, through all distribution channels (pharmacies, hospitals, dispensing doctors, supermarkets, etc.), whether dispensed on prescription or at the patient's request. Sales of veterinary medicines are excluded.

European countries, followed by Germany and France. **Even more important is the growth of European pharmaceutical exports, increasing from €90.9 billion to €565 billion over the same period**. In 2021, imports accounted for €390 billion, **with a positive trade balance of €175 billion** (Fig. 2.5).

Exports to the US (32%) are almost a third of all EU exports and are followed at some distance by Switzerland (12%), the UK (7%) and China (6%). Imports to the EU are dominated by Switzerland (37%) and the US (30%), followed by China and the UK (both 8%)[13] (Fig. 2.6).

The share of intra-EU imports in total (intra + extra) imports of medicinal and pharmaceutical products varied among Member States in 2021. For Lithuania, Estonia and Luxembourg, it was above 94%, while for Slovenia and Malta it fell below 40%. The EU average was 68%. The share of intra-EU exports in total (intra + extra) exports of medicinal and pharmaceutical products also varied greatly among Member States in 2021. For

13 International trade in medicinal and pharmaceutical products – Statistics Explained (europa.eu) (Last access: November 2022).

Fig. 2.5 Production and international trade in the European pharmaceutical industry

Source: EFPIA 2022

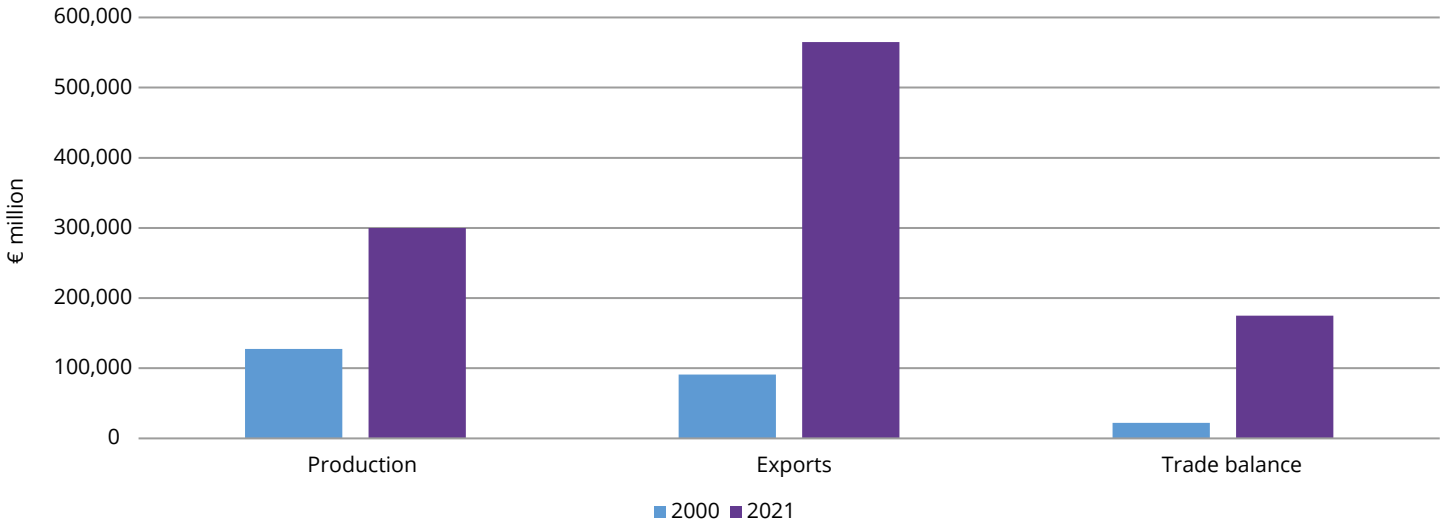
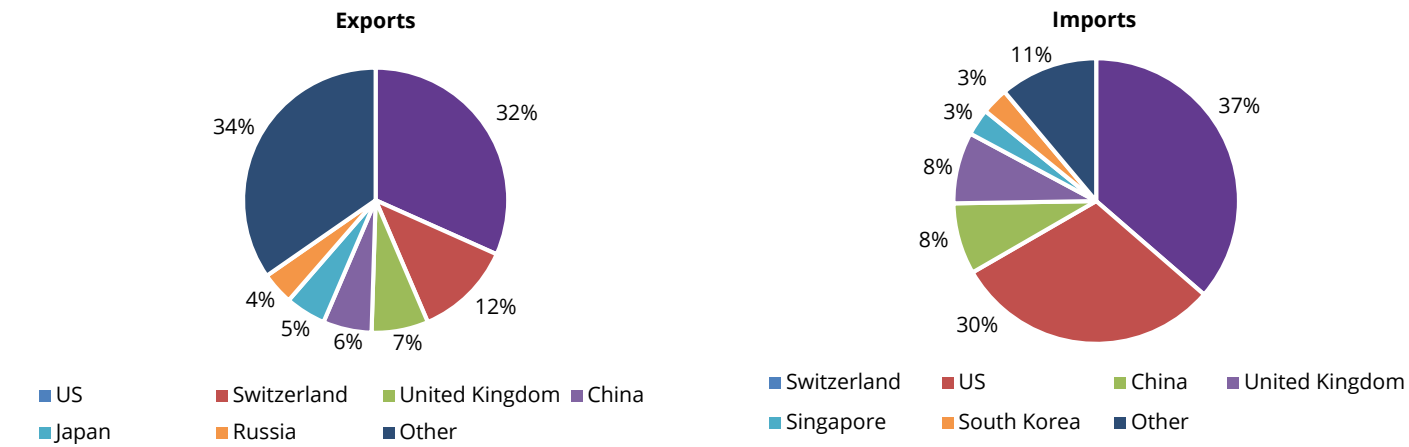


Fig. 2.6 Main EU partners for trade of medicinal and pharmaceutical products (2021)

Source: Eurostat 2022



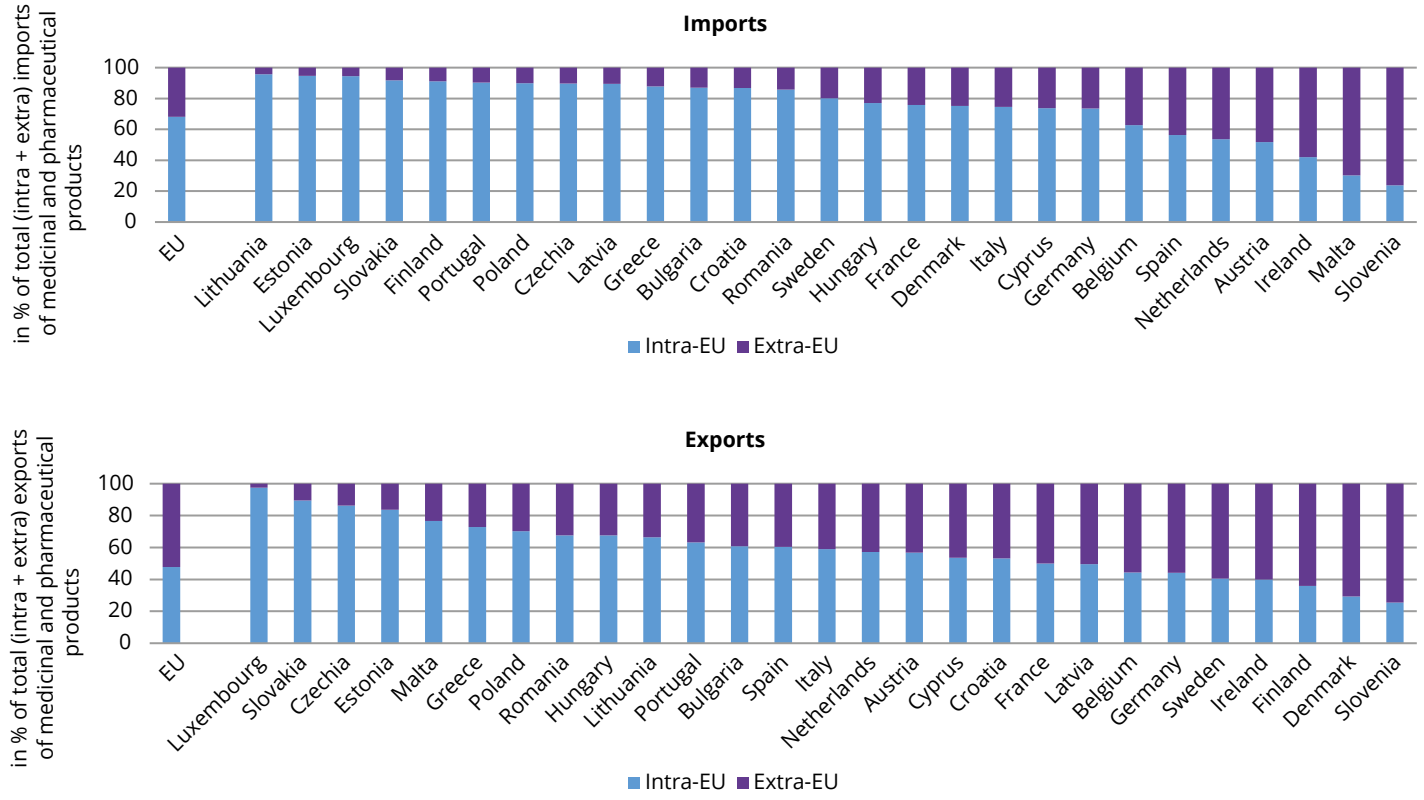
Luxembourg, Slovakia and Czechia it was above 85%, while for Ireland, Finland, Denmark and Slovenia it fell to below 40%. The EU average was 48%.

Looking at only to extra-EU trade, Germany had the highest exports (€56 billion) followed by Belgium (€46 billion), Ireland (€38 billion), the Netherlands (€19 billion) and France (€17 billion). Moreover, Germany (€38 billion), Ireland (€32 billion) and Belgium (€28 billion) had the largest trade surpluses for medicinal and pharmaceutical products in 2021, while Spain (- €2 billion) had the largest trade deficit (Fig. 2.8).

In addition to the remarkable performance on international markets, **the European pharmaceutical industry is recognised as a highly R&D intensive industrial sector**.

Fig. 2.7 Trade in medicinal and pharmaceutical products by Member State

Source: Eurostat 2022



In 2021, it invested an estimated €41,500 million in R&D and employed 125,000 employees in R&D activities. Compared to the past, **pharmaceutical R&D expenditure** in Europe has increased considerably (Fig. 2.9), growing from 1990 by about 400%. However, it is still experiencing lower growth rates than the US and China (Fig. 2.10).

The European pharmaceutical industry is also one of the leading European sectors in terms of number of patents (Fig. 2.11). According to the EPO, in 2021, the number of European patent applications in the pharmaceutical field was 9,026, up compared to the previous year by 6.9% (Fig. 2.12). However, Europe (15%) is still lags behind the US (33%) and China (18%) in the number of pharmaceutical patents (Fig. 2.13).

Fig. 2.8 Extra-EU trade in medicinal and pharmaceutical products by Member State (2021)

Source: Eurostat 2022

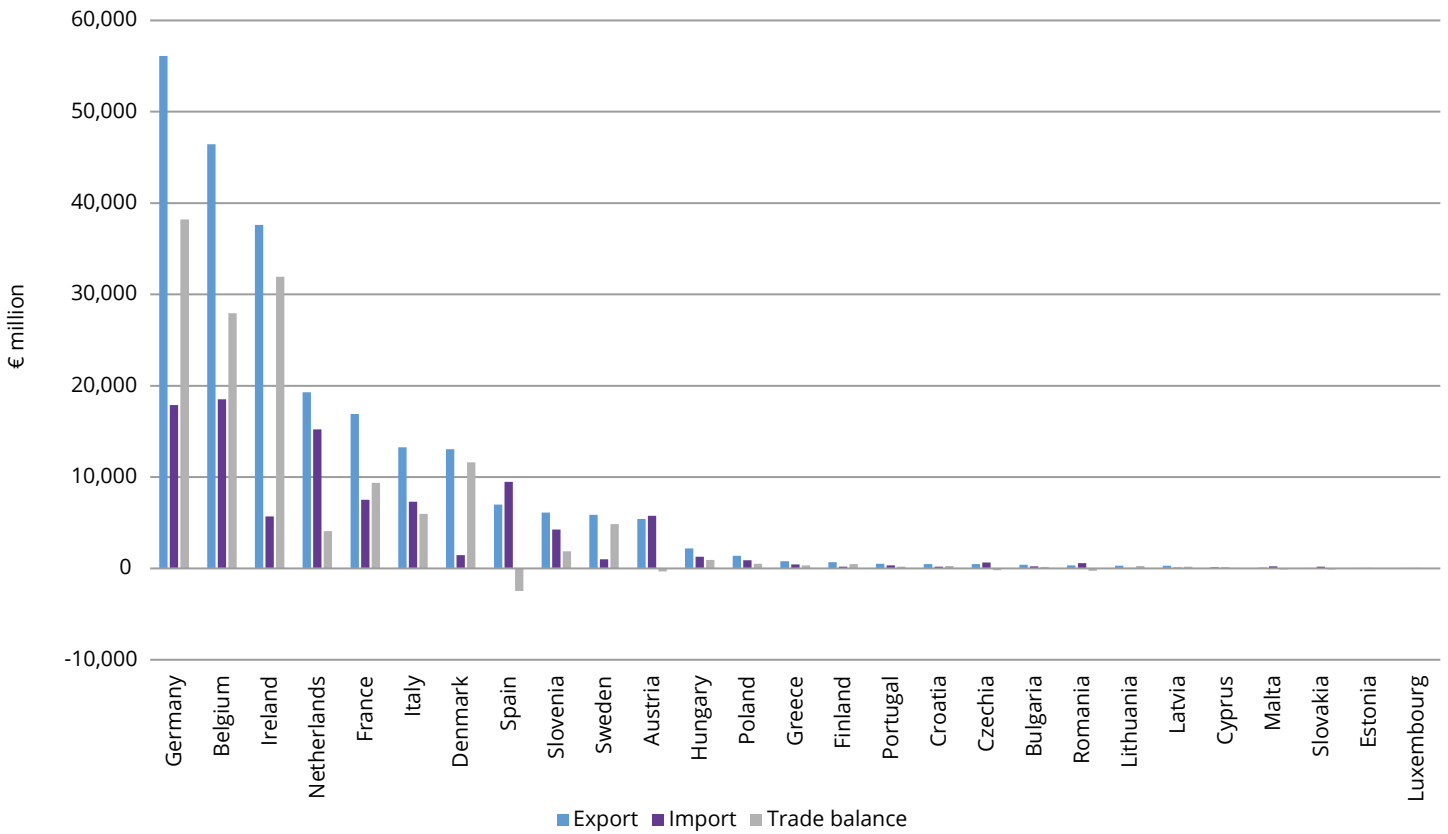


Fig. 2.9 Pharmaceutical R&D expenditure in Europe

Source: EFPIA 2022

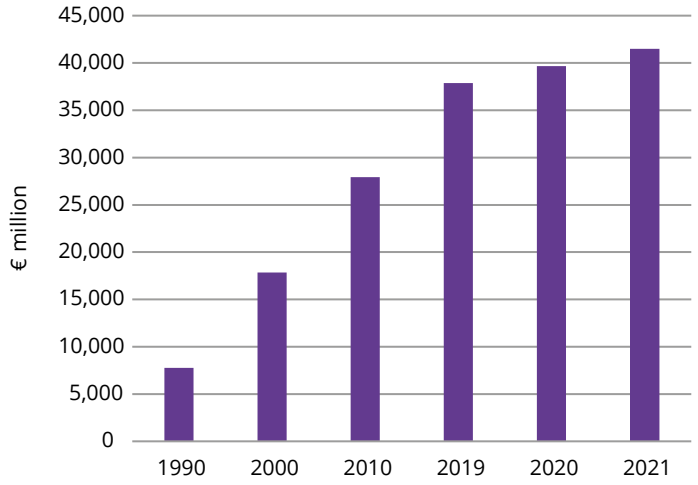


Fig. 2.10 Pharmaceutical R&D expenditure (annual growth rate)

Source: EFPIA 2022

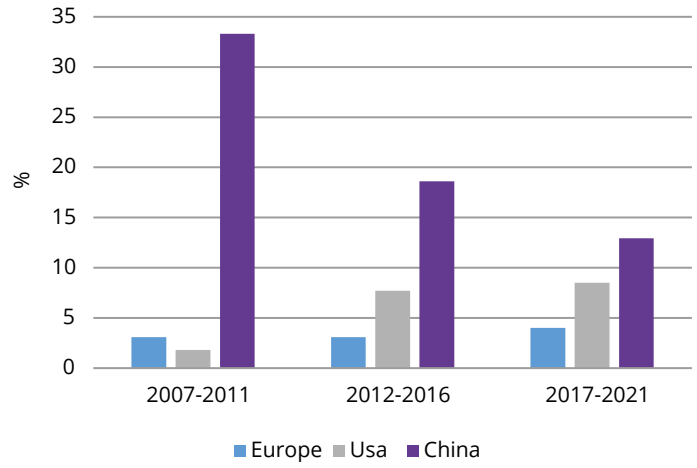
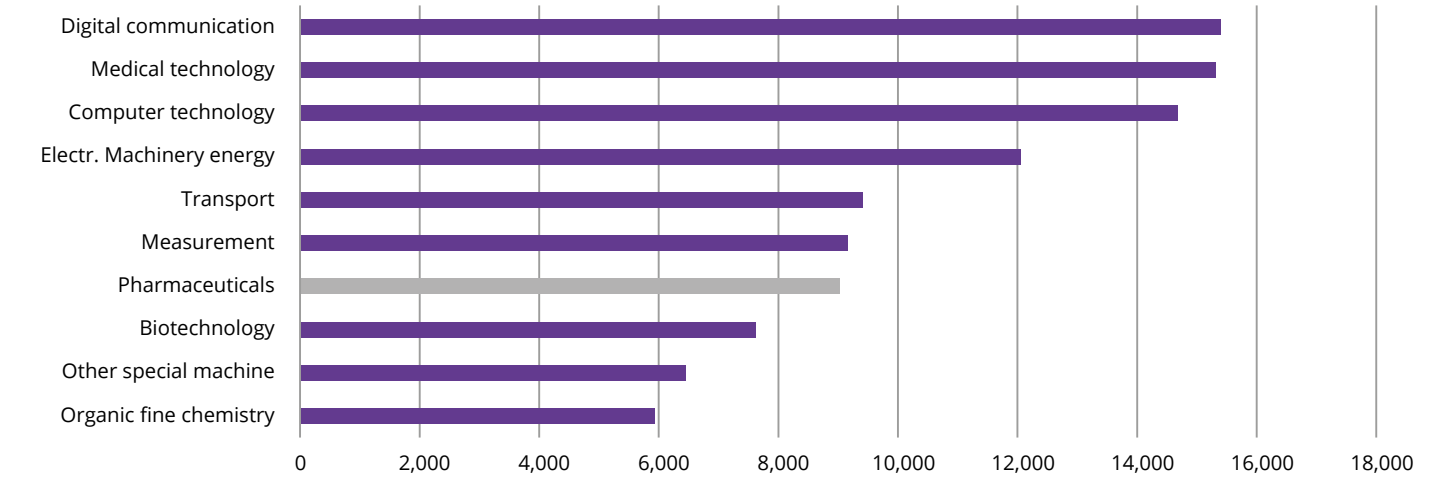


Fig. 2.11 Top ten technology fields with applications for patents in Europe*

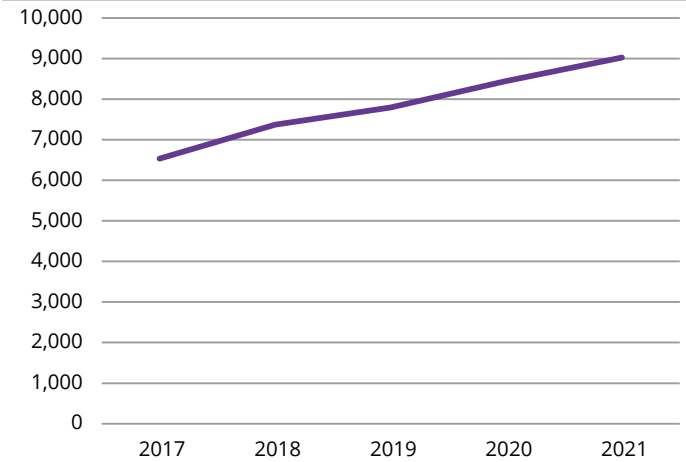
Source: EPO 2022



* Europe refers to the 38 member states of the European Patent Organisation, which includes the 27 states of the EU

Fig. 2.12 Applications for patents in the European* pharmaceutical industry (2017-2021)

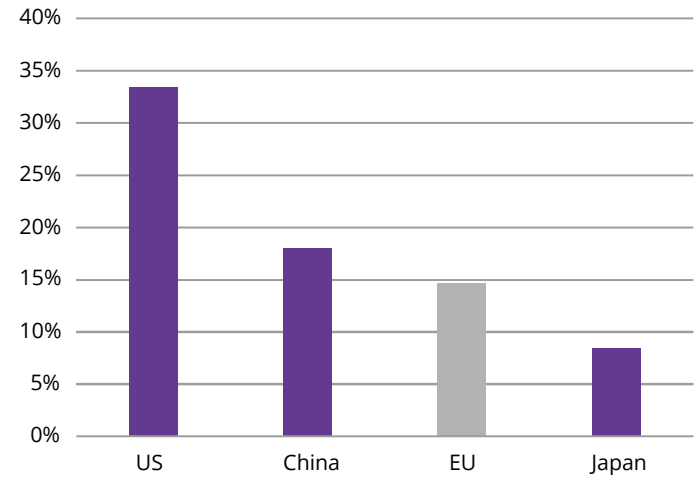
Source: EPO 2022



* European refers to the 38 member states of the European Patent Organisation, which includes the 27 states of the EU

Fig. 2.13 Number of pharmaceutical patents by inventor's country of residence (% of total pharmaceutical patents in the world, 2019)

Source: I-Com elaboration on OECD data



Despite this marked growth, many challenges must still be faced to allow the European pharmaceutical industry to maintain and even strengthen its role **as a primary hub of innovation**, and thus contributing to the overall success of the EU's economy.

It is crucial to maintain and develop a predictable, **robust regulatory framework**, embrace the power of **digitalisation** and ensure **innovation-supportive incentives** and **IP ecosystems,** as well as **strengthening raw material supply chains**[14].

14 https://eipg.eu/tag/annual-report-2022/ (last access: November 2022).

2.2 TOWARDS STRATEGIC AUTONOMY? THE AMBITION OF THE PHARMACEUTICAL STRATEGY FOR EUROPE

As a technological war becomes tougher between blocks, and namely between the US and China, Europe is struggling to find its dimension of self-definition within an increasingly conflictual international landscape.

The pandemic has revealed the European dependence on several strategic goods and technologies. The emergency made it evident that the time has come for Europe to take its own strategic interests into its hands as it is the only way to **ensure that European citizens' interests are properly represented and protected in the face of future challenges**.

Technological sovereignty is key to this process, yet it is not an easy concept to define. In fact, it is tempting to decline it as a form of protectionism and isolationism. Nevertheless, this interpretation is contrary to EU values and identity, and it is simplistic.

A much more suitable interpretation sees **Europe taking on a central role in promoting international cooperation in technological projects, aimed at developing European alternatives to major innovations and products.** By encouraging common initiatives and international partnerships, the Union can become a technological leader on the world stage.

In a paper issued by the European Parliament Research Service, the definition of technological sovereignty encompasses three dimensions:

- a **technological dimension** considering the development of European research and development (R&D) competencies, by maintaining a strong knowledge base, industry and networks in the critical technologies;
- a **regulatory dimension**, at the heart of the development of policies and standards to reflect European identity and to influence global regulations;
- an **economic dimension** involving the achievement and preservation of a position of leadership in Key Enabling Technologies (KETs)[15], the ability to turn R&D into market products, and access to a diversity of resources along the value chain with the aim of reducing dependence on third countries[16].

Therefore, an appropriate synonym for technological sovereignty is the concept of **strategic autonomy**.

In order to achieve the goals of autonomy and sovereignty, **Europe must tackle three critical deficits – a lack of resources and raw materials, of digital skills and of an adequate regulatory framework to encourage the commercialisation of resources**. Therefore, four actions need to be taken:

- **develop R&D competencies and knowledge** through private-public partnerships;
- provide the capacity to **turn R&D into market products**;

15 The Key Enabling Technologies identified by the European Commission are six – advanced manufacturing, advanced (nano) materials, life science technologies, micro/nano electronics and photonics, AI, security and connectivity technologies.

16 European Parliament Research Service (2021), Key Enabling Technologies for Europe's technological sovereignty. https://www.europarl.europa.eu/RegData/etudes/STUD/2021/697184/EPRS_STU(2021)697184_EN.pdf

- protect and favour the delivery of innovation through **patenting and co-inventions**;
- **retain competencies and knowledge**.

For the **pharmaceutical market**, the challenge of technological sovereignty comes with a peculiar complexity. The recent health emergency has highlighted and exacerbated **longstanding structural problems in the EU related to the supply of medicines**, particularly generic medicines, and dependence on third-country imports for certain pharmaceuticals and essential active ingredients.

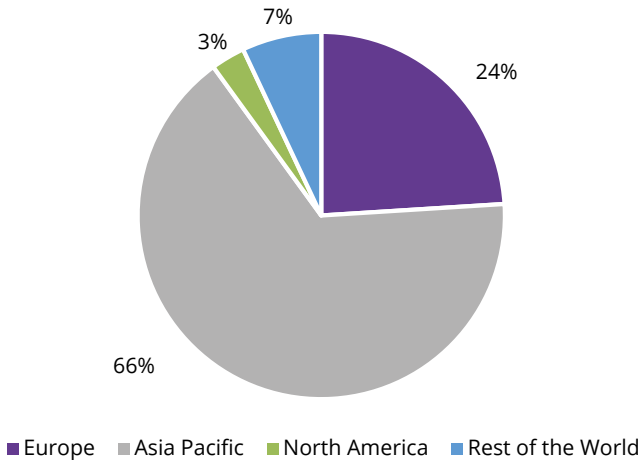
Although Europe is an established manufacturing power, **its supply chain still heavily relies on extra-EU raw material subcontractors**, which benefit from lower labour costs and less strict environmental standards. As a result, **between 60% and 80% of active chemical ingredients are produced outside the Union, mainly in China and India**. According to some estimates, these two countries produce 60% of the world's paracetamol, 90% of penicillin and 50% of ibuprofen[17].

As previously mentioned, **autonomy should not be confused with isolation**. Indeed, strategical autonomy does not have to do with autarchy as much as with the diversification of suppliers. It needs to be kept in mind that there are market reasons for the choice of purchasing raw materials from abroad, and that **exposing the EU to significant price increases, even for basic generic medicines, is not a desirable scenario**.

17 European Parliament (2020), Report on the shortage of medicines – how to address an emerging problem. https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.html

Fig. 2.14 Shares of APIs production

Source: Chemical Pharmaceutical Generic Association Report (2015)



Certainly, there is evidence of a regional concentration in generic API production. The EU accounts for 24% of the world's value of API production, while 66% is produced in Asia Pacific (India and China), 3% in North America and 7% in the rest of the world[18] (Fig. 2.14).

Even so, a clarification is necessary. While **China and India are the world's key producers of generic APIs**, thanks to their undisputed cost advantages, **European manufacturers are specialised in high-end APIs with low production volumes and complex production**

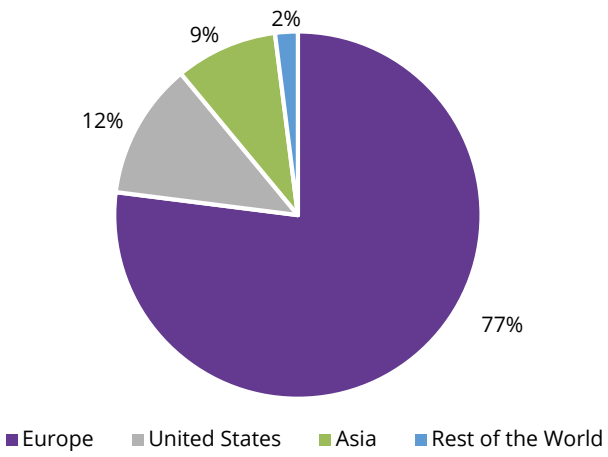
18 European Commission (2020), Strategic dependencies and capacities accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021SC0352&from=FR These statistics exclude APIs for biological products.

processes. Italy accounts for the highest number of APIs manufacturing sites (185), followed by France (149), Germany (92), Spain (87) and Poland (84). Italy and Spain are also the largest producers of generic APIs in Europe, and export more than 95% of their production. According to an EFPIA-survey, 77% of all APIs needed for innovative medicine production in the EU come from within the Union, 12% come from the US and only 9% from Asia[19] (Fig. 2.15). This seems to disprove the hypothesis that Europe is dependent on Asian countries in its pharmaceutical production, at least for now.

As already mentioned in the previous paragraph, **Europe retains more than 23% of global sales of prescription medicines**. **The EU alone is the largest exporter of medicines in the world** and has a positive trade balance. This result is achieved due to the unique **first-mover advantages connected with European high-quality R&D activities**[20]. Even so, this advantageous positioning within the global value chains cannot be taken for granted and needs to be protected. In fact, EU's growing dependency on imports of medicines and APIs manufactured outside the EU may soon become a concern for the EU's strategic autonomy, especially in the event of a health crisis.

Fig. 2.15 Origin of APIs used for innovative medicines in the EU (2020)

Source: European Federation of Pharmaceutical Industries and Associations



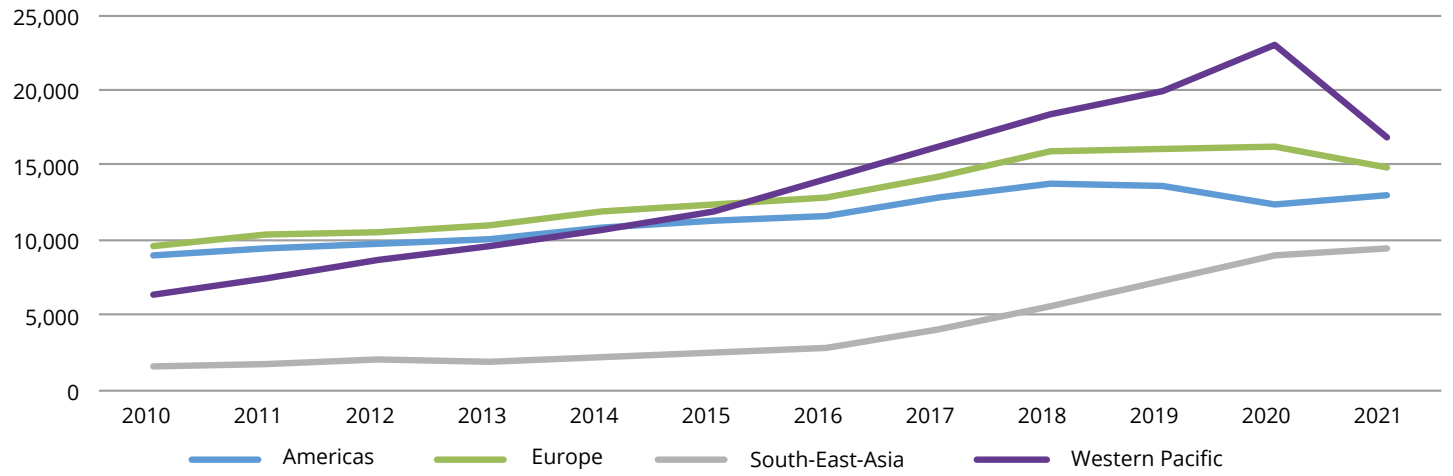
The fact that Europe's positioning in the global scenario cannot be considered as taken for granted is **confirmed by the data about clinical trials** (Fig. 2.16). From 2010 to 2015, **Europe was the leading world region for clinical trials initiated** per year, closely followed by the Americas – which means it attracted the most investment in the field. From 2016 onward, other regions' performances improved and **the Western Pacific strongly took the lead**. At the same time, **South-East Asia made its way into the market rising** from 2,521 trials started in 2015 to almost 10,000 in 2021. In 2020, the Western Pacific reached its clinical trial peak with 23,040 trials, mainly because of Covid-19. In the same year, 16,256 and 12,288 trials were launched respectively in Europe and in the Americas.

19 EFPIA (2020), EU strategic resilience in pharmaceuticals: global value chains and innovation. https://www.efpia.eu/news-events/the-efpia-view/blog-articles/eu-strategic-resilience-in-pharmaceuticals-global-value-chains-and-innovation/

20 European Commission (2020), Strategic dependencies and capacities accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021SC0352&from=FR

Fig. 2.16 Number of clinical trials by region and year

Source: WHO International Clinical Trial Registry Platform



Following the aim of reinforcing the EU positioning in the global landscape, on 25 November 2020, the European Commission adopted the **Pharmaceutical Strategy for Europe**[21]. Its goal is to give the EU's pharmaceutical policy a long-term vision, ensuring it is crisis-resilient and sustainable, and reinforcing the EU's position in the global scenario while, at the same time, guaranteeing access to affordable medicines for patients. According to the Commission, the strategy will also support innovations and facilitate digital and technological change to:

1. ensure patients' access to **affordable medicines** and address unmet **medical needs**;
2. promote the **competitiveness, innovation capacity, and sustainability of the EU pharmaceutical sector** and the production of high-quality, safe, effective and environmentally friendly medicines;
3. **strengthen emergency preparedness** and response mechanisms and address the issue of security of supply;
4. **assert EU leadership on the global stage** by promoting high standards of quality, efficacy, and safety.

In detail, the strategy consists of **55 legislative and non-legislative actions covering the entire drug life cycle** from R&D to clinical trials, to commercialisation, to HTA processes, and pricing. The strategy's main initiatives include:

21 European Commission (2020), European Pharmaceutical Strategy. https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

- **a revision of the basic pharmaceutical legislation** (Directive 2001/83/EC and Regulation (EC) No 726/2004);
- the creation of an **EU Health Emergency Response Authority** (HERA);
- a revision of the **legislation on medicines for children and for people with rare diseases** (Regulations (EC) No 1901/2006 and 141/2000);
- the initiation of an **open and constructive dialogue among all stakeholders in pharmaceutical production and public authorities**, to identify weaknesses in the global supply chain of essential medicines and define strategies to strengthen the continuity and security of supply;
- encouraging **cooperation on pricing, payment and procurement** among national authorities, to make medicines more cost-effective and increase the sustainability of health systems;
- the creation of a **robust digital infrastructure**, including a proposal for a **European health data space**;
- **support for research and innovation**;
- actions to **promote innovative approaches in the European R&D and procurement sectors regarding antimicrobials** and their alternatives[22].

The strategy will create synergies with other initiatives, such as the **Green Deal**, **Europe's Beating Cancer Plan** and the **new Industrial Strategy**, which will be further explored below. The new strategy puts into effect both Parliament's requests to step up efforts to tackle medicine shortages and to move towards a more sensible use and disposal of pharmaceuticals so as to prevent risks to the environment and public health.

On 26 February 2021, the Commission launched a structured dialogue with the actors in the pharmaceutical manufacturing chain. According to the Commission, the initiative will put forward **policy recommendations to address vulnerabilities in the chain, with the aim of strengthening the EU's resilience.** On 24 November 2021, the European Parliament adopted an own-initiative resolution on a pharmaceutical strategy for Europe, and **the European Commission is expected to propose an update of EU pharmaceutical legislation at the end of 2022**.

For the EU, a major importer and exporter, **openness to trade and investment is a strength and source of growth**. However, as previously mentioned, Covid-19 has shown disruptions in global supply chains and led to shortages of many products in Europe, including pharmaceuticals and medical devices. The need to further improve Europe's open strategic autonomy in various areas was already set out in the EU's 2020 Industrial Strategy[23]. However, on 5 May 2021, **the Commission updated the Industrial Strategy to further include the needs that emerged during the pandemic crisis.** This update points to the need to strengthen the resistance of the Single Market to disruptions and to ensure continuity in the free movement of persons, goods, services and capital, the need to analyse and address

22 *Idem*.

23 https://single-market-economy.ec.europa.eu/industry/strategy_en

strategic dependencies, and the need to accelerate the green and digital transition. The updated strategy puts forward a number of additional actions that have to be implemented to tackle these challenges and, specifically, a legislative proposal on a Single Market Emergency Instrument to ensure the free movement of persons, goods and services in future crises. Furthermore, **the Commission will implement a range of actions to reduce and prevent strategic dependencies, for instance, the further development of industrial alliances**.

The **proposal for a regulation on foreign subsidies distorting the internal market**, also presented on 5 May, aims to contribute to ensuring the EU's strategic autonomy by addressing potential distortions in the internal market caused by subsidies granted by foreign governments to undertakings wishing to acquire an EU company or bid in public procurement. **The report[24] related to the Industrial Strategy identifies 137 products in sensitive ecosystems where the EU is highly dependent on foreign sources. These include active pharmaceutical ingredients.**

24 Commission Staff Working Document, "Strategic dependencies and capacities" (2021) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021SC0352&from=FR

2.3 THE ROLE OF INTELLECTUAL PROPERTY RIGHTS

The pandemic has demonstrated the importance of having a strong European and national health system and pharmaceutical industry, and has revealed the risks of having an intricate system of global interdependence. The length of the supply chains, together with the reduction in manufacturing competences have contributed to weakening the EU responsiveness during the health emergency. It has thus become clear that we need to support our internal production and investment capacities so as to contribute to the health and wealth of European patients and citizens. This represents a strategic asset as far as social and economic sustainability in the long run are concerned. **We saw that the European pharmaceutical sector uses more than 60% of raw materials from China and India to produce medicines and, furthermore, 30% of the generic medicines used in Europe come from Asia.** Moreover, **the share of patent applications originating from EU innovators in total patent applications has steadily decreased over the past 20 years**. In 2000, patent applications in the pharmaceutical industry originating in EU Member States accounted for 26% of all patent applications in the sector, while it **gradually declined to 21% in 2019**. At the same time, the data shows that EU innovators **still hold a relatively strong international position compared to other high technology sectors such as macromolecular chemistry and polymers (20% in 2019), biotechnology (17%), digital communication technologies (13%) and computer technologies (8%)**[25]. So far, the European Union institutions have recognised the importance of strengthening European sovereignty in the manufacturing of active substances and medicines, **counting on the well – developed pharmaceutical industry, but also improving on the ability to attract, and preserve, new investments**. This included in a range of documents that call for and draft actions in this area. It includes the Recovery Plan for Europe, the European Parliament resolution of 17 September 2020 on the shortage of medicines, the regulation of the European Parliament and of the Council on the establishment of a programme of Union action in the field of health for 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU Health Programme") and last, but not least, the Pharmaceutical Strategy for the European Union. More recently, in a statement adopted in March 2022 at the informal meeting of EU Heads of State in Versailles on Russian military aggression against Ukraine[26], EU leaders acknowledged that **it is necessary to take further decisive steps towards building European sovereignty, reducing dependence, and developing a new model for growth and investment.** The EU leaders also focused on supporting the **sustainable production of affordable medicines,** funding research and development and building the capacity for critical products to respond to health crises.

25 WIPO data.
26 https://www.consilium.europa.eu/en/press/press-releases/2022/03/11/statement-of-the-heads-of-state-or-government-on-the-russian-aggression-against-ukraine-10-03-2022/

This is also needed from the perspective of developing the EU and national pharmaceutical industries and building strategic autonomy in the field of medicines.

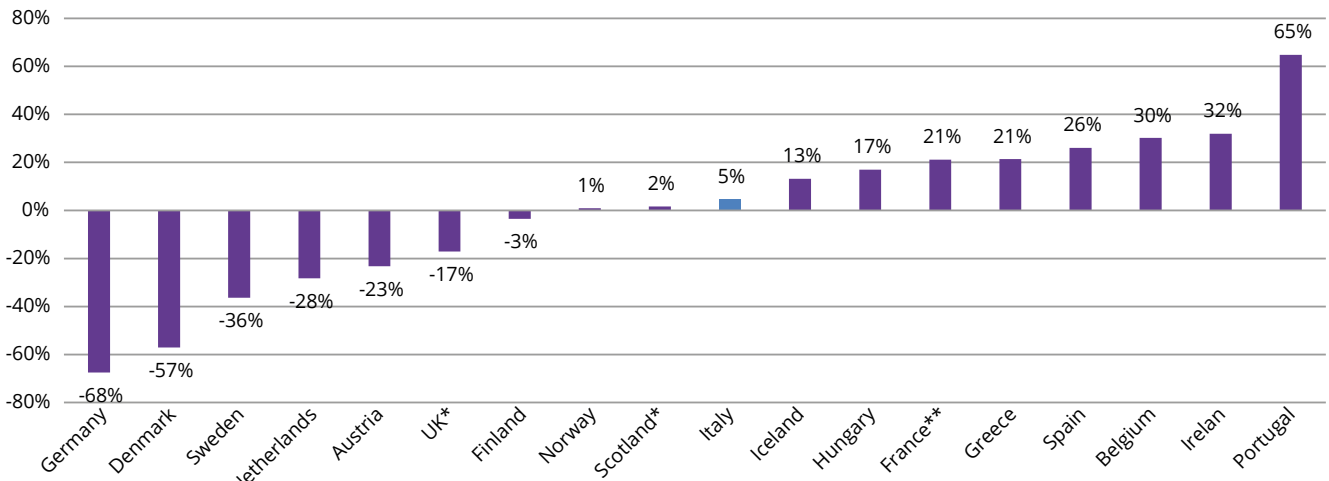
However, **understanding the main causes of unavailability or delays in patient access to medicines among European countries is fundamental for an adequate intervention through reforms that also include national intervention on the regulation on market access conditions**, including the role of Health Technology Assessments (HTA) and national reimbursement practices. It is a fact that **access to medicines among EU countries is still unequal,** as can be seen in Figure 2.17 below. According to our elaboration on EFPIA data, the time that elapses between the central authorisation for placing a drug on the market and the actual accessibility in European countries strongly deviates from the average if we consider the period 2017-2020. The best performer is Germany at 68% lower than the mean, while the worst performer is Portugal where the time is 65% higher than the mean.

In this context – and against the general increase in health expenditure related to demographic factors and to the pace of scientific innovation in biotechnological fields – **the issues of access to medicines and Intellectual Property Rights (IPRs) has become a highly contested topic**.

The nexus between innovation and patents has been

Fig. 2.17 Time elapsed between the central authorisation for placing a drug on the market and actual accessibility in the selected EU countries (deviation from the average, % values, 2017-2020)

Source: I-Com processing of EFPIA Patients WAIT indicator survey 2021 – IQVIA data



* In the UK the MHRA's Early Access to Medicines Scheme allows the access to some medicinal products before the MA-these cases are excluded from the analysis.
** In France, data include products from the ATU system, for which the process is generally longer. If these products were considered directly available on the market (0 days) the mean time to availability would be 240 days.

politically contentious since TRIPS[27] took effect in 1995, **yet acknowledging that IPRs is a driver of innovation**. In the pharmaceutical industry, **the role of Intellectual Property Rights is indeed generally recognised as a deterrent incentive for product developmen**t. In particular, there are a few distinguishing factors that make the pharmaceutical sector riskier than other industries, including the lengthy market access process, and the high rates of attrition and failure, when compared to other sectors[28]. Furthermore, the evidence of safety and efficacy confidentially submitted could be used by follow-on applicants, within the same jurisdiction or in other jurisdictions, unless appropriate protections are in place. **Intellectual property rights attempt to balance long-run incentives for innovation and short-run access to innovation** and though some studies recognise that the market power granted by IPRs allows innovators to charge higher prices[29], potentially reducing access to patented products, the existence of IPRs make a market more attractive for innovators, leading to country-specific investments in marketing and distribution**. Such investments may result in a quicker launch of new products, increased marketing of older products, and greater availability of treatments.**

The need for strong international and EU IPR protection to encourage product development appears to be greater than ever given recent developments, connected to the Covid-19 pandemic. Covid has shown to have been a great shock to our health and economic system, and the legal and policy discussions will determine **the extent to which IPRs will be confirmed and maintained as a driver for new product development and, of course, the extent to which the EU will remain attractive as a basis for R&D.** Various sources show different reasons why a strong international and European IPR protection is necessary to encourage product development and maintain the role of Europe as an innovative platform in the future. Among them we can list[30]:

1. the high costs of drug and manufacturing capacity development, confirmed by the race to develop Covid-19 vaccines (it is estimated that the public sector alone spent €93 billion on vaccine development in the course of 2020);
2. the risks of failure, that require investing in different technological approaches to maximise the chances to obtain safe and effective products to be brought to market.

For some market segments, it has been recognised that current incentives have been a determinant in supporting research and development investments. This is the case of orphan drugs, in the field of rare diseases. The European regulatory framework has undoubtedly encouraged investments in the development of orphan

27 https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm

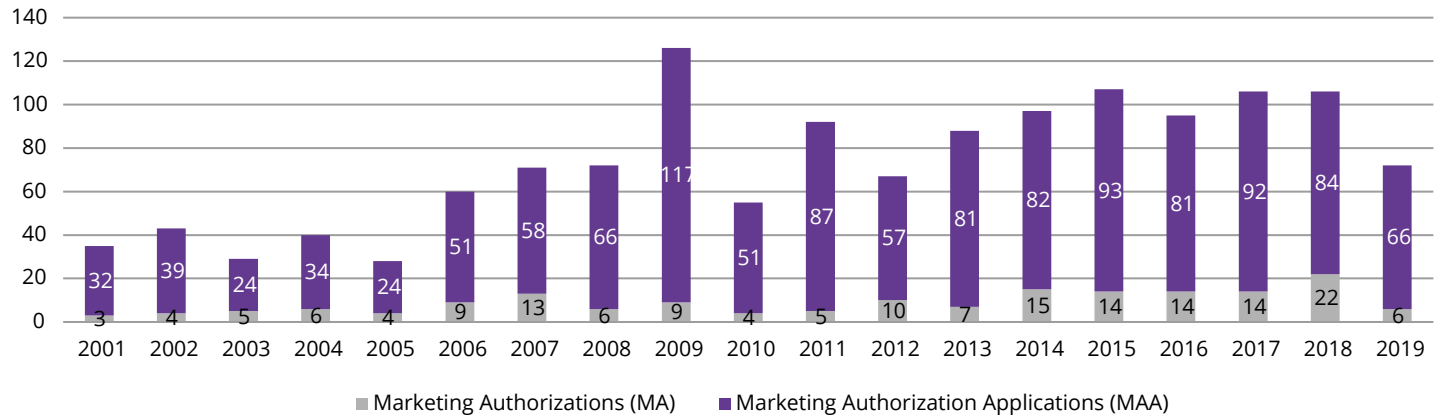
28 J. Jacobs et al, The cost of opportunity, A study on pharmaceutical R&D costs, available at https://gupta-strategists.nl/studies/the-cost-of-opportunity

29 https://www.ifpma.org/wp-content/uploads/2022/09/2022_The-role-of-IP-in-the-biopharmaceutical-sector.pdf

30 ECIPE, European Centre for International Political Economy,"The Relevance of Intellectual Property for Pharmaceutical Innovation", June 2022.

Fig. 2.18 Orphan drug applications and marketing authorisations (MA) in the EU

Source: European Medicines Agency



drugs by pharmaceutical companies. From 2001 to 2019, 170 authorisations were granted for the marketing of medicines for the treatment of rare diseases. Before the introduction of Regulation 141/2000[31], the total number of authorisations amounted to only 8. According to EMA data, the marketing authorisations for orphan drugs between 2001 and 2018 grew by 13% each year reaching 170 at the end of 2019 (Fig. 2.18).

However, despite the adoption of the EU Orphan Medicinal Products Regulation in 2000, 95% of the thousands of rare diseases still have no authorised treatment option, as underlined in the proposal for an EP and Council Regulation on orphan and paediatric medicinal products (2020)[32]. Moreover, only one-tenth of products that have received an orphan drug designation manage to achieve a MA.

Despite during the Covid-19 emergency many called for temporary IP waivers or compulsory licensing[33], other factors typically influence and eventually hinder market entry. These include national regulatory and legislatiive frameworks, national budget contraints and pricing models often difficult to be adapted to the growing scientific and multifaceted innovation in the pharmaceutical field. **Meanwhile it is, instead, a realistic risk that conditional market exclusivity rights could undermine universal incentives for innovation in the EU and contribute to discouraging the innovation process.**

Most of the national and European instruments dedicated to early access have been created to facilitate patients'

31 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32000R0141

32 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=pi_com%3AAres%282020%297081640

33 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True

access to treatment in the field of rare diseases. Because of the characteristics of these diseases, **patients with rare diseases experience significant unmet health needs and lack of available therapies. And not only,** orphan drugs would not be developed under normal market conditions because of their limited commercial attractiveness as each **rare** disease involves a small though epidemiologically relevant population group. Moreover, **these diseases are highly complex and subject to limited scientific and clinical knowledge**, resulting in the high complexity **of their research and development.** In view of this important demand for health, the European[34] Union has allocated scientific and economic resources to address the exceptional needs of these citizens. Already in 1999, Europe, following the US example, prepared a unified policy for orphan drugs for all Member States, adopting Regulation EC 141/2000 and, subsequently, Regulation EC 847/2000. Regulation 141/2000 established a community procedure and criteria for the qualification of orphan medicinal products by providing incentives for the research, development and marketing of these medicinal products, which include a specific period of market exclusivity:

- **tax reductions/exemptions from the** regulatory assessment procedure;
- **scientific assistance and protocol** through early dialogue with the regulatory body;
- a 10-year period **of market** exclusivity after authorisation for products designated as orphans;
- other incentives where medicinal products qualified as orphans may benefit from incentives made available by the Community and the MSs to promote research, the development and placing on the market of orphan medicinal products and, in particular, the **research** aid measures for small and medium-sized enterprises provided for in the framework programmes for research and technological development.

With Regulation 847/2000, the European Commission, on the other hand, explained the criteria needed to qualify as an orphan medicinal product. Subsequently, Regulation (EC) 726/2004 established that the CHMP (Committee for Medicinal Products for Human Use) could issue guidelines on compassionate use programmes. Regulation (EC) 507/2006 then identified the procedure for placing on the market defined as conditional, which was also extended to orphan drugs in accordance with Regulation 141/2000.

In 2009, the Commission and the Council of the European Union indicated to the Member States the need to adopt a National Plan for Rare Diseases by 2013. In 2010, the European **Union Committee of Experts on Rare Diseases (EUCERD**) was established by European Commission Decision 2009/872/EC. 2021 was a particularly important year in this area and the objective was set to assist the Commission in the preparation and implementation of Community actions on rare diseases, in cooperation *with* the Member States, European public health and research authorities and other relevant actors. The United Nations with the consent of 193 member states also passed the Resolution "Addressing

34 See paragraph 19.

the Challenges of Persons Living with a Rare Disease and their Families", the first that recognises the rights of more than 300 million people worldwide living with a rare disease. At the same time, in Italy, in November, Law 10 n.175 "Provisions for the treatment of rare diseases and for the support of research and production of orphan drugs", also known as "Single Text on Rare Diseases", was published in the Official Gazette. The text represents a turning point resulting from more than three years of work, which lays the foundations for a major change for patients suffering from such diseases.

This regulatory framework has undoubtedly encouraged investment in the development of orphan drugs by pharmaceutical companies and, since the adoption of the European Regulation, 23 MSs have established at least one national plan for rare diseases[35]. It can therefore be said that the **regulatory** framework **has significantly transformed the lives of patients and their families, their health and quality of life outcomes, and proving to be fundamental in developing treatment options for previously untreatable conditions.** The introduction of regulatory and economic incentives has also led to further developments in medical knowledge and has promoted an ecosystem conducive to research, innovation and investment in Europe. Rare diseases and the European and national initiatives that affect them represent a **paradigm of regulatory flexibility and capacity to develop new payment models and market access.** Since the unsatisfied therapeutic needs and areas of research and development for new drugs are increasing, and new technologies, in different ways, develop therapeutic solutions at an increasingly high rate, **the regulatory framework and the initiatives applied in the field of rare diseases are a reference point and a virtuous example of regulatory agility in favour of care needs in R&D areas that would otherwise risk remaining unexplored.**

35 http://www.europlanproject.eu/NationalPlans?idMap=1

PART 3

TACKLING THE CRISIS AND ENSURING ENERGY SECURITY IN THE EU

3. TACKLING THE CRISIS AND ENSURING ENERGY SECURITY IN THE EU

3.1 THE ENERGY CRISIS: EFFECTS AND MEASURES TO REDUCE THE EU'S VULNERABILITIES

3.1.1. Causes and effects of EU energy crisis

Over the past year, the world and particularly Europe has slipped into an energy crisis that is unprecedented in recent decades. This situation is severely impacting the economic situation of businesses and households in the EU, and if not resolved very quickly risks driving the European Union's economy into recession. The causes are numerous and the outbreak of the war in Ukraine has played a decisive role. Nonetheless, a notable role is also played by the weight that natural gas has in the EU energy system. Looking at the latest available data on the European energy mix, we see t**hat natural gas occupies second place in the "gross available energy" mix accounting for 23.7%** of the total sources used in the European Union in 2020 (Fig. 3.1).

Natural gas thus accounts for about a quarter of the energy products that are used within the European Union. Despite this, Europe is overwhelmingly dependent on foreign suppliers, with **EU import dependency on natural gas from outside Europe being 83.6%** (Fig. 3.2). As is well known, Russia has always been a major supplier of fossil fuels to the EU. In **2020, 24.4% of all energy products consumed within the EU came from Russia**.

Fig. 3.1 EU gross available energy mix by source (2020)

Source: Eurostat

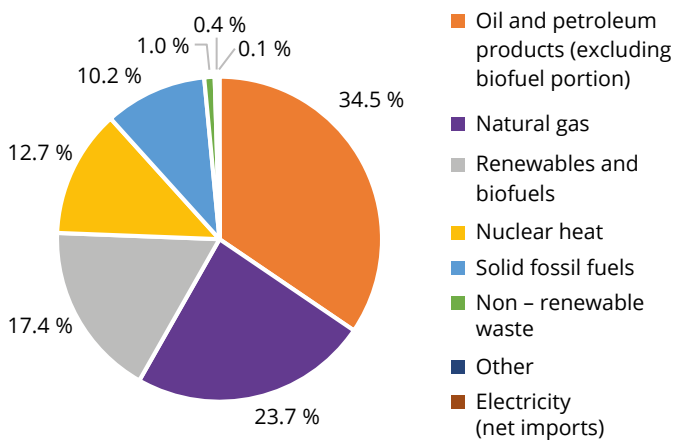


Fig. 3.2 Import dependency as the share of net imports in the gross available energy by energy product (2020)

Source: Eurostat

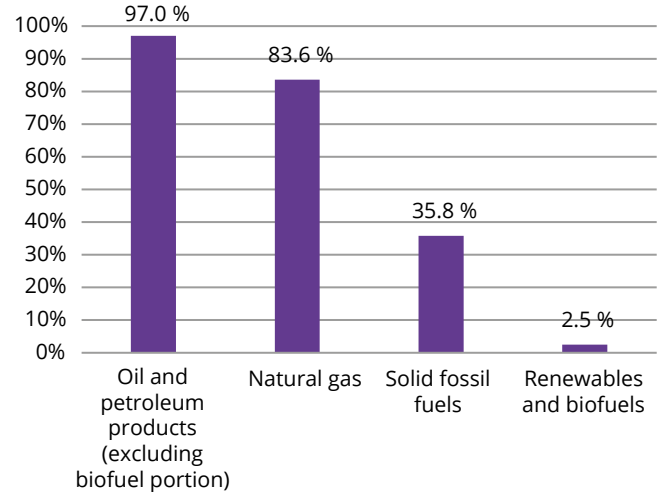
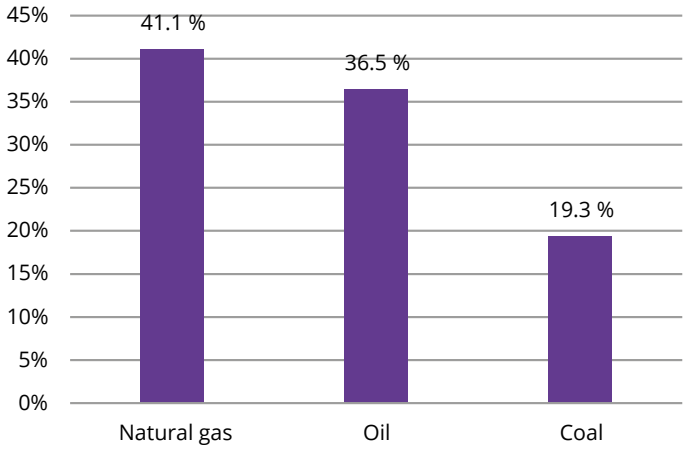


Fig. 3.3 Share of imports from Russia in gross available energy by energy product in 2020

Source: Eurostat

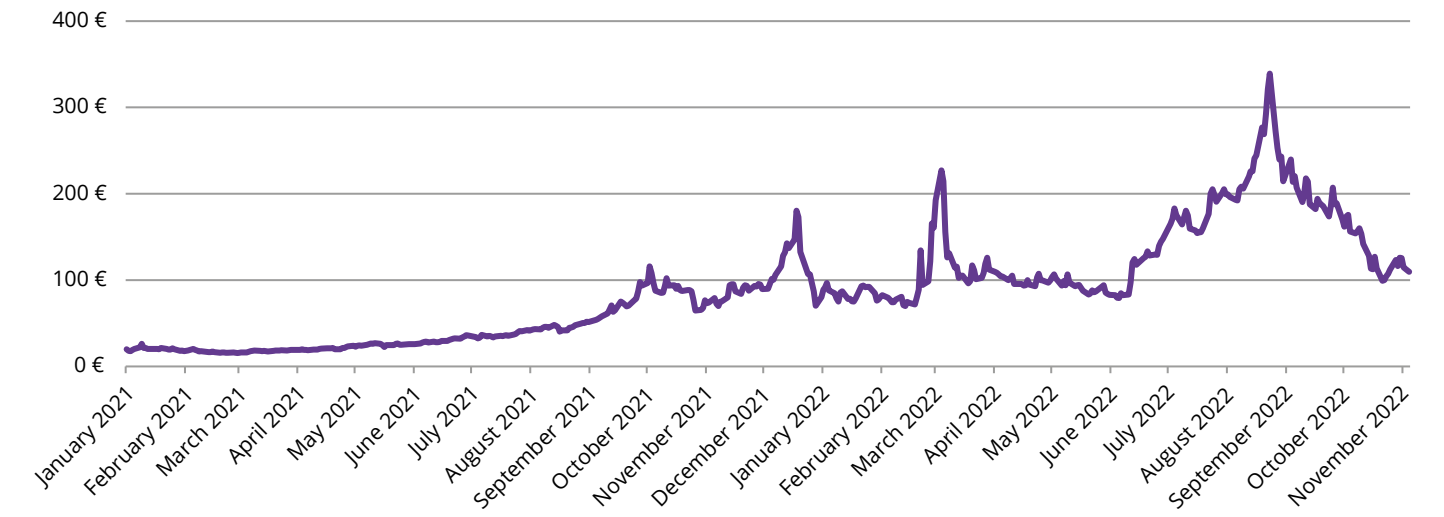


The relationship between the EU and Russia has been particularly important in the natural gas market. The huge investments made over the decades in pipeline construction have made this country the leading supplier of natural gas in the EU. **In 2020, Russia supplied 41.1% of all the natural gas consumed in the EU** (Fig. 3.3). For these reasons, Russia's invasion of Ukraine has disrupted a very close energy dependence link. The sanctions imposed by Europe on Russia and the fear of a total shutdown of natural gas supply sent markets into crisis.

As mentioned above, although the Russian invasion of Ukraine was the main factor influencing the increase in natural gas prices, it has not been the only one. They had already begun rising from autumn 2021 with the beginnings of the economic recovery after the Covid-19

Fig. 3.4 Dutch TTF Natural Gas Futures (dec22 contract, €/MWh)

Source: Investing.com



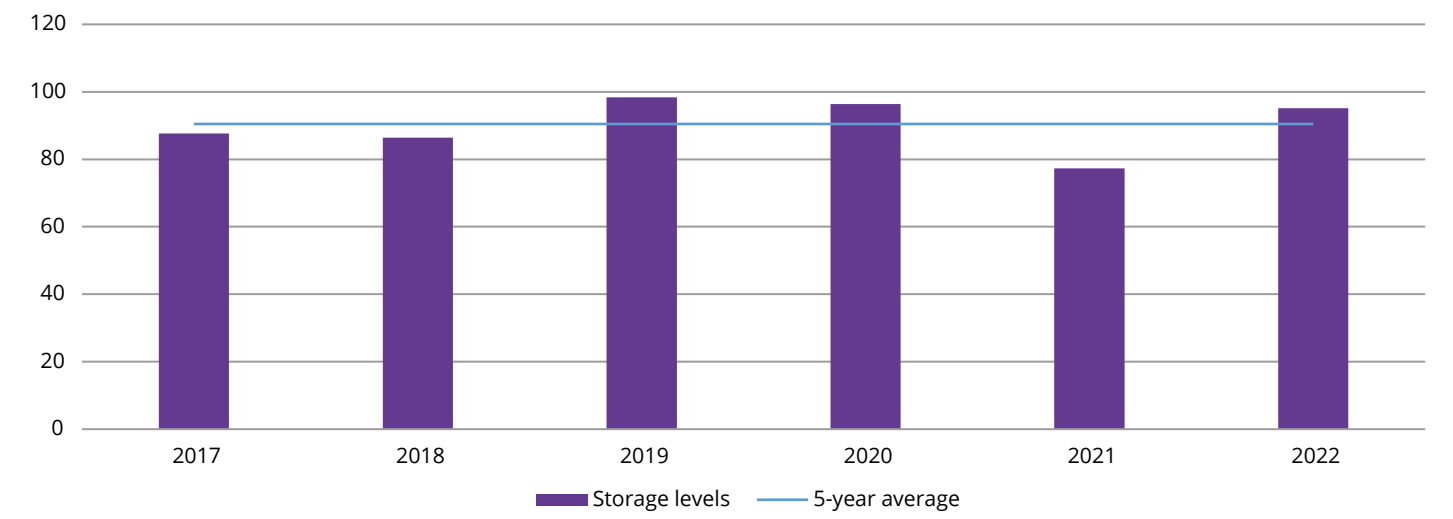
pandemic, but bottlenecks in global supply chains caused inflationary pressures. Already in December last year, the Dutch TTF, the Europe-wide natural gas price benchmark, had reached a record of €180 per MWh, or approximately 1,060% more than the minimum price recorded in 2021 which was €15.53 per MWh (Fig. 3.4).

Another factor that influenced the price crisis in the early stages at the end of last year was the management of natural **gas storage facilities**. According to data contained in the IEA report "Never Too Early to Prepare for Next Winter: Europe's Gas Balance for 2023-2024," the level of European natural gas storage in 2021 was significantly lower than it has been in recent years. In 2021, EU natural gas storages took in about 77.3 billion cubic metres (bcm), 19.8% less than the previous year and 14.6% less than the average of the past five years (Fig. 3.5). Amongst the reasons for this lower storage capacity during the summer months there is probably also the growth in the price of natural gas, which after the lowest point reached in the summer of 2020, the minimum peak of about €3.5 per megawatt hour on the Amsterdam exchange, had experienced a significant upswing with the restart of the global economy. Therefore, near the end of last year, in order to avoid a supply shortage, European MSs began to make more gas purchases to make up for the gap that had arisen in storage causing the price to rise further.

In addition to the storage facilities issue, the increase in global demand, especially from Asian countries, coinciding with the end of the acute phase of the pandemic crisis and the subsequent economic recovery, played a major role

Fig. 3.5 EU gas storage levels (1 November 2017- 1 November 2022, bcm)

Source: IEA



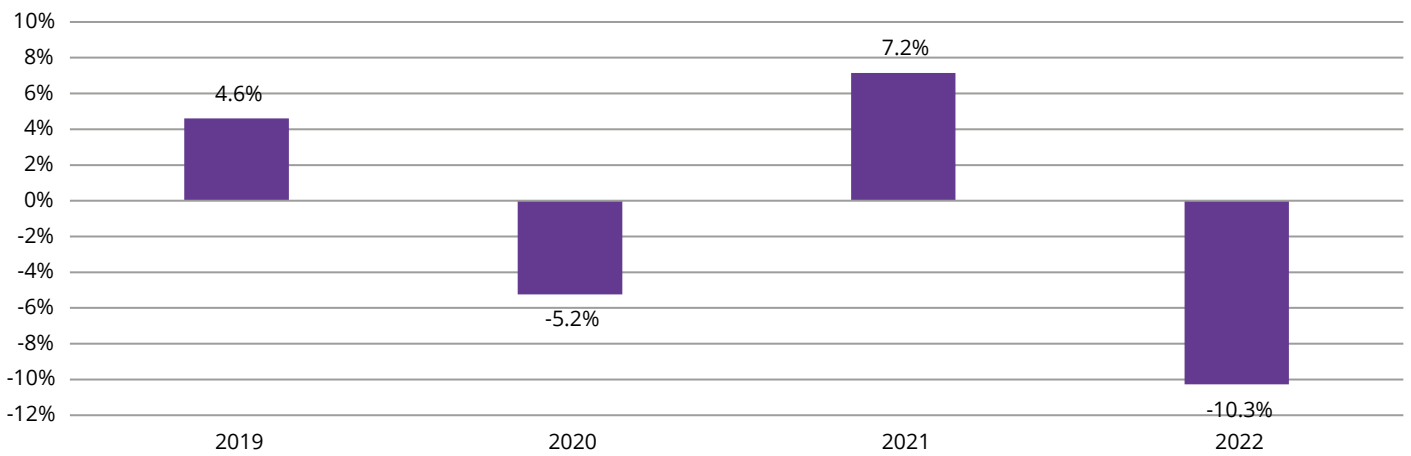
in the crisis. Moreover, during 2021, northern European countries experienced a very cold spring resulting in an increased demand for energy. This was compounded by lower hydroelectric production in Brazil and lower extraction from gas fields in Norway and Russia.

All these regional imbalances have been aggravated by insufficient investment in gas supply. Indeed, since 2015, investments in the exploration and development of hydrocarbon deposits have plummeted. The Paris Agreements brought about a marked slowdown in investments by fossil fuel companies, which, in order to avoid ending up with stranded assets, diverted available resources to operations that could guarantee profits for a longer period of time. The European Investment Bank (EIB) itself has fully espoused the energy transition and is gradually excluding fossil fuel-related investments from its portfolio. At the same time, however, investments in renewable energy have not been sufficient to meet the energy demand globally and in Europe.

All these reasons have resulted in gas hitting an historical record. **At the end of August 2022, the gas price for the winter contract on the Dutch trading point TTF touched €350/MWh** (Fig. 3.4). The surge in prices obviously caused gas consumption to drop significantly. Looking at year-on-year changes in natural gas consumption in the EU, we can see that gas use decreased by 10.3% in 2022 compared to the previous period (Fig. 3.6). It is particularly interesting to note that the drop in consumption between 2021 and 2022 was about double of what occurred between 2019 and 2020 when many economic activities had to temporarily suspend their activities due to the pandemic restrictions.

Fig. 3.6 Year-on-year change in EU gas consumption in the first 8 months of each year (January - August)

Source: Eurostat



The rise in the price of gas has a direct impact on all other energy products and, especially, on electricity. **Natural gas has a share of 19.6% in the EU electricity generation mix** (Fig. 3.7). Among the Member States, there are some that are much more dependent on natural gas for electricity generation, such as **Malta (88.7%), the Netherlands (58.6%), Ireland (51.4%), Latvia (50.4%) and Italy (48.3%)**. Consequently, in addition to the price of gas, the cost of the wholesale price of electricity has also increased dramatically. In July of this year, it was more than four times higher than that recorded in the same period of the previous year, while **retail electricity prices have increased by about 35%** (Fig. 3.8).

Fig. 3.8 Wholesale and retail gas and electricity prices and carbon prices in the EU

Source: Platts and VaasaETT

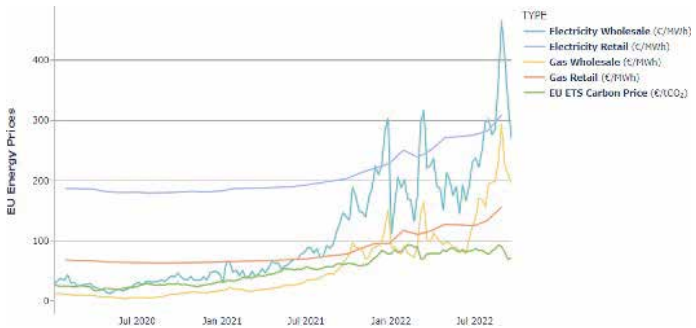
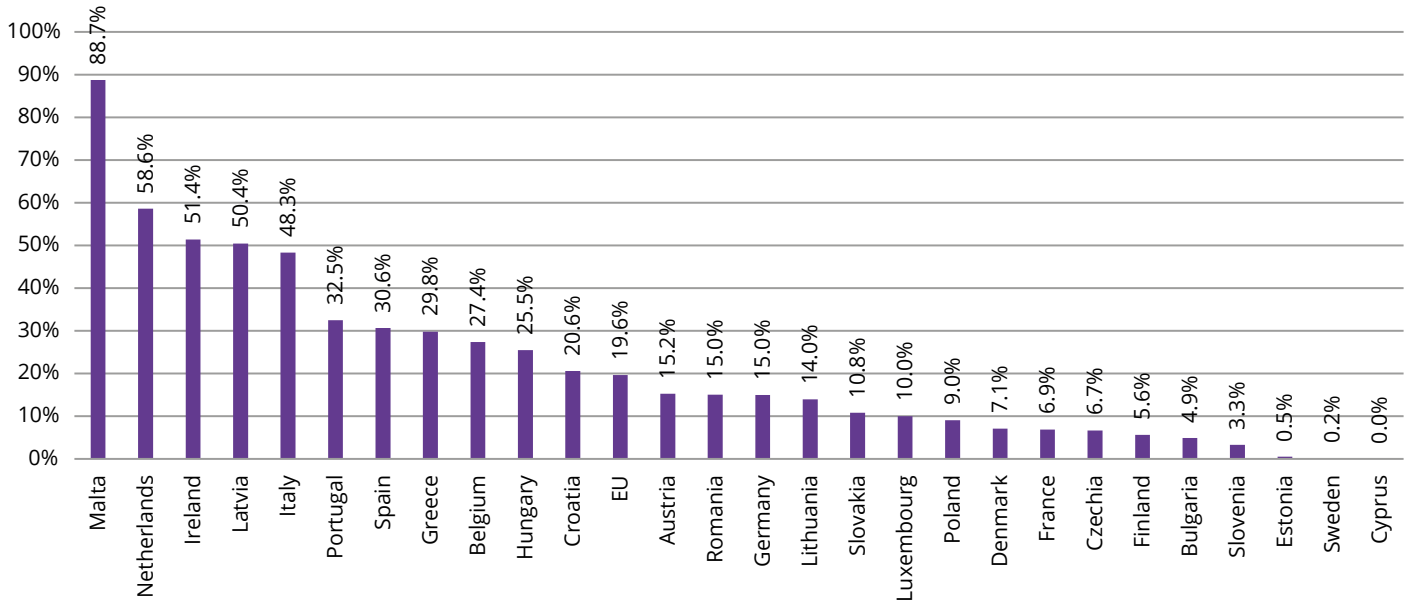


Fig. 3.7 Share of natural gas in gross electricity production (2019)

Source: Eurostat



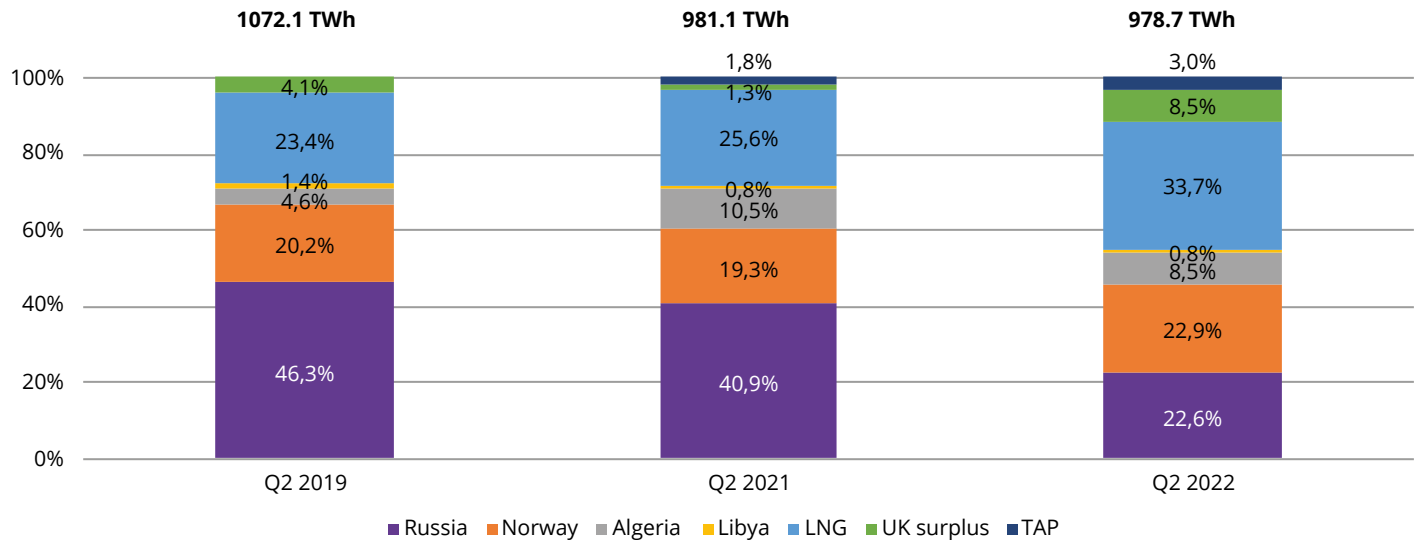
3.1.2. EU and the Member States response to the energy crisis and a look at the coming winter

To tackle the energy crisis, both the European Union and the individual Member States have adopted measures aimed at both controlling price increases and guaranteeing their own energy security. The reduction in gas supplies due to the Russian invasion of Ukraine has also put a strain on the energy stability of the Union. Since the outbreak of the war, 13 EU states have been affected by partial interruptions in supply from Russia, while 5 no longer actually receive any supply. The accidents that occurred on the Nord Stream 1 and 2 gas pipelines were yet another alarm signal regarding the reliability of the Russian supply.

One of the first moves made by the European Union was the implementation of the "Strategy for an EU external energy engagement" in May 2022 as part of the EU RePower Plan. The strategy aims to reduce overall energy demand, ensure fair competition for resources, improve energy efficiency and the development of renewables, and prepare for an integration of the EU energy market by paving the way for a future partnership for 'green hydrogen'. After the implementation of the REPowerEU Plan and the Strategy, the dependence on Russia for the supply of natural gas, as previously highlighted, dropped significantly in 2022. **The Russian share of EU natural gas import went down from 46.3% in 2019 to 22.6% estimated for this year** (Fig. 3.9).

Fig. 3.9 Share of EU imports of natural gas by source (%)

Source: I-Com elaboration on data from the ENTSO-G Transparency Platform, data as of 6 September 2022



To free itself from dependence on the Russian gas pipelines, the European Union has tried to maximise the supply of LNG ships. After the implementation of the REPowerEU Plan and the Strategy, the decline in Russian supply since the beginning of the war was offset by an increase in LNG supplies from the United States and Qatar. According to the data contained in the "Quarterly report on European gas markets" published by the European Commission, in the second quarter of 2022, **the US was the main supplier of LNG to the Union with 16 billion cubic meters, representing about 45% of total imports**. Compared to the previous year, imports of LNG from the US to the EU increased by 117%. Unfortunately, despite the tensions generated by the war, **Russia is still the second largest supplier of LNG to the EU with an 18% share**. The third largest supplier of LNG to the EU is Qatar with a market share of 13%, followed by Nigeria which accounts for 8% (Fig. 3.10).

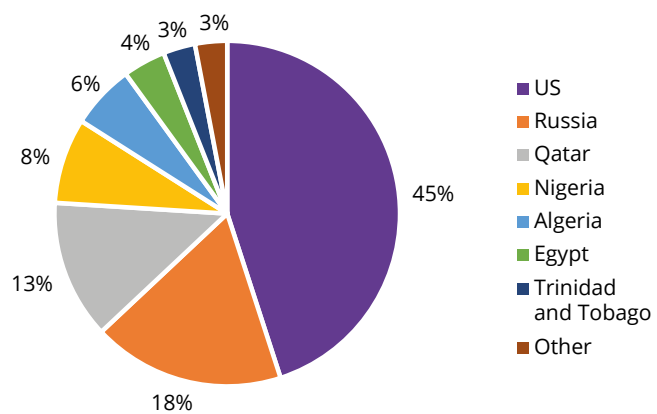
An important help in the diversification of supply and the containment of prices should also come from the **EU Energy Platform**. This is a voluntary coordination tool which aims to pool demand, coordinate the use of infrastructure, negotiate with international partners and prepare for joint gas and hydrogen purchases. The platform was established last April and will work through regional groups. Action plans of all regional groups are currently being implemented.

Moreover, the European Commission has decided to intervene on storage so as to increase the Union's energy security. With a **Storage Regulation, it has set the target of at least 80% of the gas in storage to be achieved by November 2022**. **This target has been largely exceeded**, and according to the latest data released by the Commission dating back to the end of October, EU storage facilities were already over 91% fill. This being the case, thanks to a coordinated effort, the MSs have managed to secure their gas supply for the coming winter. However, important problems could emerge for the following winter. According to IEA projections, if there is no reduction in demand, **in order to fill the storage before the winter of 2023, an increase of 24.6 billion cubic meters will be required compared to this year, an increase of 36%** (Fig. 3.11).

However, this hypothesis could be countered by the high prices, which discourage consumption, and by the

Fig. 3.10 Share of EU imports of LNG in second quarter of 2022 by country (%)

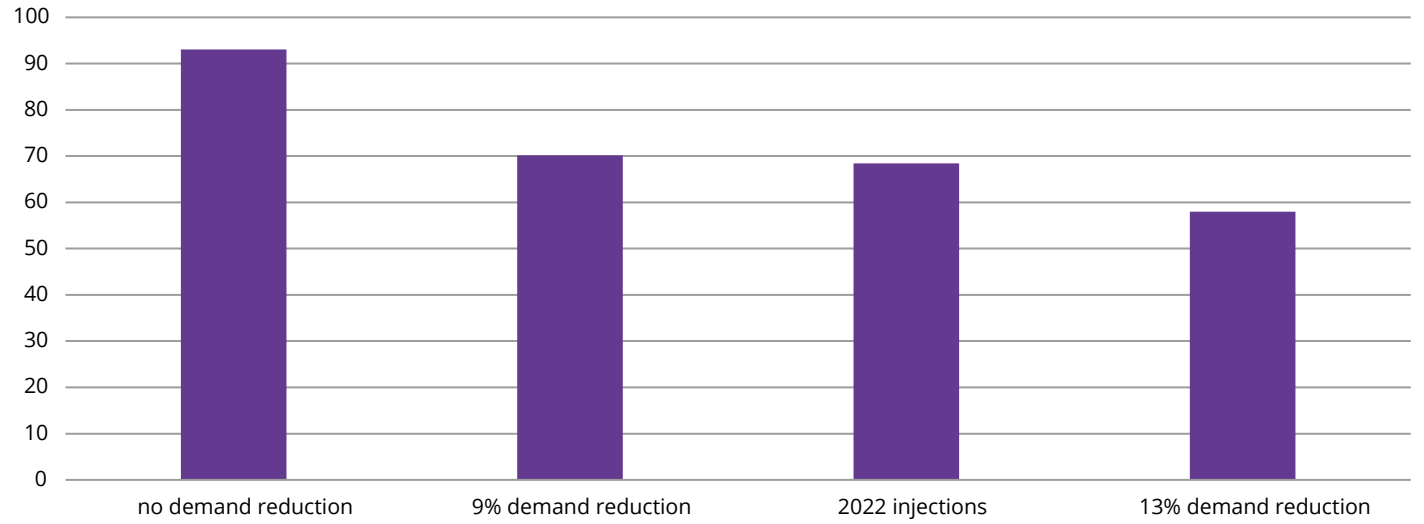
Source: Commission calculations based on tanker movements reported by Refinitiv



Note: "Other" includes Finland, Malta and Croatia

Fig. 3.11 Resulting injection needs in EU and UK storage in summer 2023 to reach 95% fill level (bmc)

Source: IEA



measures to reduce the demand for gas imposed by the European institutions and the MSs. In August, the **European Council adopted a voluntary reduction of natural gas demand by 15% this winter**. Specifically, MSs agreed to reduce their gas demand by 15% compared to their average consumption in the past five years, between 1 August 2022 and 31 March 2023, with measures of their own choice. However, there are several exemptions and possibilities to apply a partial or, in some cases, a full derogation from the mandatory reduction target, to take into account the particular situations of MSs. The regulation also provides for the possibility for the Council to activate a "Union Alert" that would make the reduction mandatory if the EU's energy security is in danger.

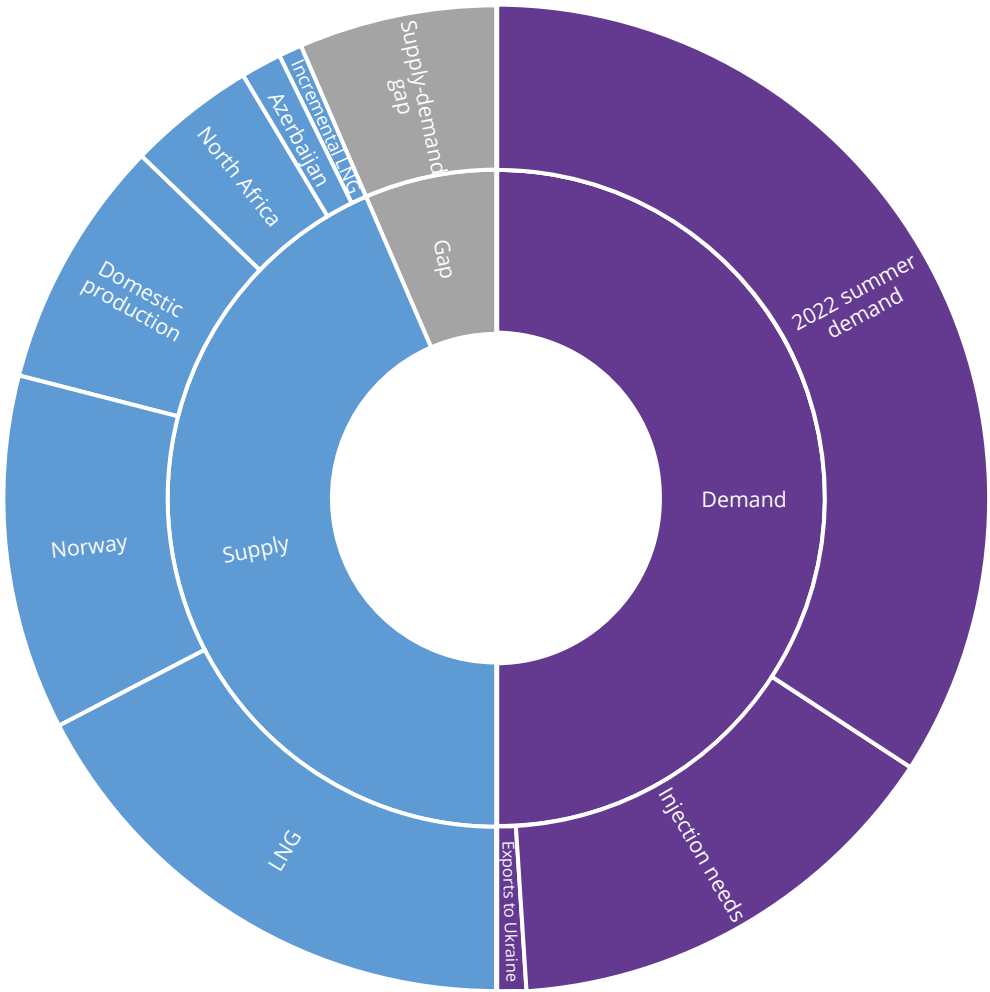
Included in the interventions planned to counter the crisis, the EU has also asked countries to voluntarily reduce their overall electricity demand by 10%, and has imposed an obligation to reduce consumption by at least 5% during peak hours, considered 10% of hours with the highest expected price.

These interventions should lead to a reduction in consumption which the IEA estimates to be around 11%. If the reduction in consumption were to be between 9-13%, the commitment that the MSs would make to fill the storage should be in line with what occurred in 2022. Despite all the measures put in place by the Union up to now and the important effort towards the diversification of gas suppliers, the gap to be recovered in the event of

a complete stop of Russian supply is still very large. In fact, according to IEA projections, **in the summer of 2023 the gap between supply and demand in the absence of Russia would amount to 15%** (Fig. 3.12).

Fig. 3.12 Breakdown of the summer 2023 natural gas balance of the EU and the UK in case of full cessation of Russian flows and limited LNG availability, April – September 2023

Source: I-Com elaboration on IEA data



The emergency measures undertaken by the MSs have not only been limited to the diversification of supplies and the filling of stocks. Numerous and substantial interventions have also been adopted to limit the impact deriving from the extra costs of energy expenditure for households and businesses. According to an analysis carried out by Bruegel, **from September 2021 to October 2022 a total of €573 billion were allocated by the MSs** (Fig. 3.1). Specifically, **the measures adopted by governments are of various kinds, including the reduction of VAT and energy taxes, the regulation of retail and wholesale prices, monetary transfers to the most vulnerable sections of the population, support for businesses, taxation of windfall profits from energy companies, interventions on publicly owned energy companies**, etc.

Tab. 3.1 Measures taken by MSs to mitigate the impact of the energy crisis

Source: Bruegel

	Reduced energy tax / VAT	Retail price regulation	Wholesale price regulation	Transfers to vulnerable groups	Mandate to State-owned firms	Windfall profits tax / regulation	Business support	Other
Austria	Implemented	Implemented		Implemented			Implemented	Implemented
Belgium	Implemented	Implemented		Implemented		Proposed	Implemented	Implemented
Bulgaria	Implemented	Implemented		Implemented		Implemented	Implemented	
Croatia	Implemented			Implemented			Implemented	Proposed
Cyprus	Implemented			Implemented	Implemented			
Czech Republic	Implemented	Implemented		Implemented	Proposed	Proposed	Implemented	Implemented
Denmark	Implemented	Implemented		Implemented				Proposed
Estonia	Implemented	Implemented		Implemented			Implemented	
Finland	Implemented			Implemented			Implemented	Implemented
France	Implemented	Implemented	Implemented	Implemented	Implemented		Implemented	Implemented
Germany	Implemented	Implemented		Implemented		Proposed	Implemented	Proposed
Greece	Implemented			Implemented	Implemented	Proposed	Implemented	
Hungary	Implemented	Implemented				Implemented	Implemented	
Ireland	Implemented			Implemented			Implemented	Implemented

	Reduced energy tax / VAT	Retail price regulation	Wholesale price regulation	Transfers to vulnerable groups	Mandate to State-owned firms	Windfall profits tax / regulation	Business support	Other
Italy	Implemented			Implemented		Implemented	Implemented	
Latvia	Implemented			Implemented			Implemented	
Lithuania		Proposed		Implemented			Implemented	Implemented
Luxembourg	Implemented	Implemented		Implemented			Implemented	
Malta			Implemented		Implemented			
Netherlands	Implemented	Implemented		Implemented		Proposed		
Poland	Implemented	Implemented		Implemented		Implemented		
Portugal	Implemented		Implemented	Implemented	Implemented	Proposed	Implemented	
Romania	Implemented	Implemented		Implemented		Implemented	Implemented	
Slovakia	Implemented	Implemented		Implemented	Implemented			
Slovenia	Implemented			Implemented			Implemented	
Spain	Implemented	Implemented	Implemented	Implemented		Implemented	Implemented	
Sweden	Implemented			Implemented				Implemented

It emerges that there are important differences in the measures taken by the various governments to respond to the emergency. In addition, there are considerable differences in the amount of funds given to support households and businesses (Fig. 3.13). Looking at the data, we see that the first Member State by share of GDP destined to mitigate the crisis is Malta with 7.7%, followed by Germany (7.4%) and Lithuania (6.6%).

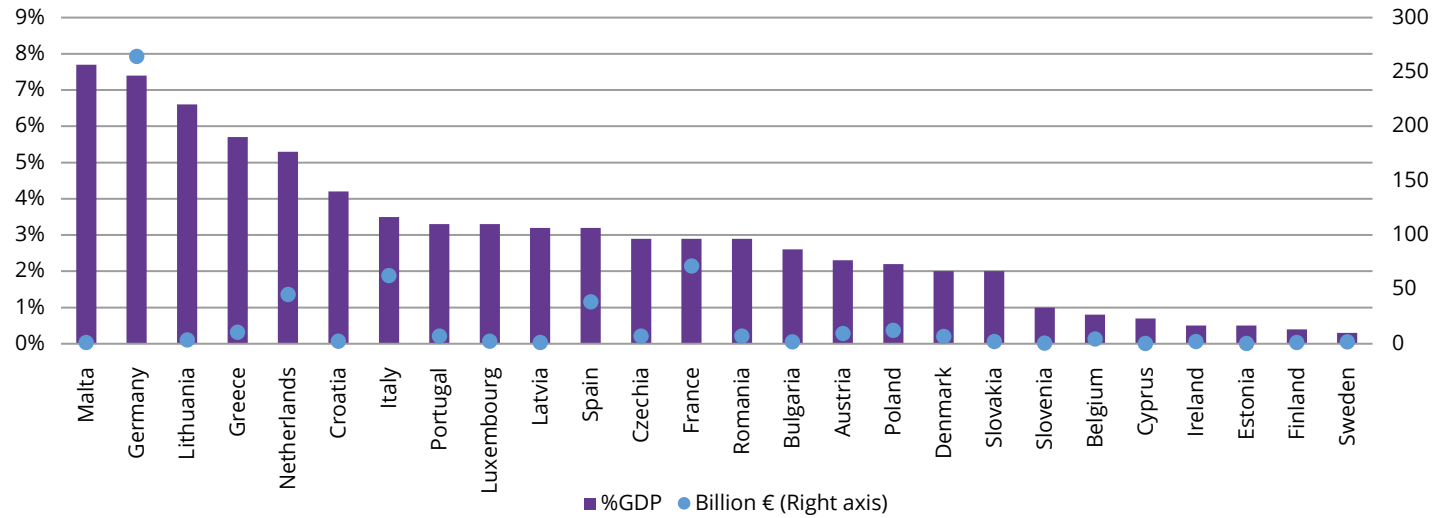
After the peak at the end of August, the price of gas underwent a very significant drop. Currently, it is equal to one third of the levels recorded at the time. Several factors have influenced this trend. Amongst these, undoubtedly, the full achievement of storage targets, the considerable drop in gas consumption, especially in European industry, and the mild weather in October which reduced the demand for heating. In addition, the fact that gas imports continued at high volumes despite the drastic cut in Russian supplies has certainly had a positive impact.

Nonetheless, the sharp decline in prices must not side step that long-term prices will continue to be at much higher levels than in previous years.

For this, in addition to the measures already described, several other extraordinary measures are being studied.

Fig. 3.13 Governments earmarked and allocated funding to shield households and businesses from the energy crisis (Sep 2021 - Oct 2022)

Source: Bruegel



At the time of writing, negotiations are underway involving the European Commission, the European Council and Member States on what actions are to be implemented and how. Among these, we can mention **joint purchases of natural gas, which would be binding for 15% of the filling needs**. The goal is to avoid internal competition in procurement and aggregate EU demand (which in this case would be at least 13.5 bcm of gas) in order to strengthen its market power on the global stage. In addition, ACER was asked to develop by next March a **complementary gas price index** that would act as a more accurate benchmark in reflecting market conditions.

At the same time, the Commission is working to provide more details on the application of a dynamic cap to the price of gas, a tenuous variant of the price cap and an exceptional (and, therefore, subject to different conditions) and temporary instrument, but applicable in the short term. It is the most controversial issue in the discussion on the interventions to be adopted, which has seen opposition from those MSs that most fear that the imposition of a price ceiling could lead to difficulties in finding supplies, and those that, instead, manifest the need to contain expenditure for the energy that has reached exorbitant levels.

The Commission will also, as requested by the Council, better examine the proposal for a cap on gas used in electricity generation, borrowed from the "tope" Iberian model, where a cap of €40/MWh has been imposed which

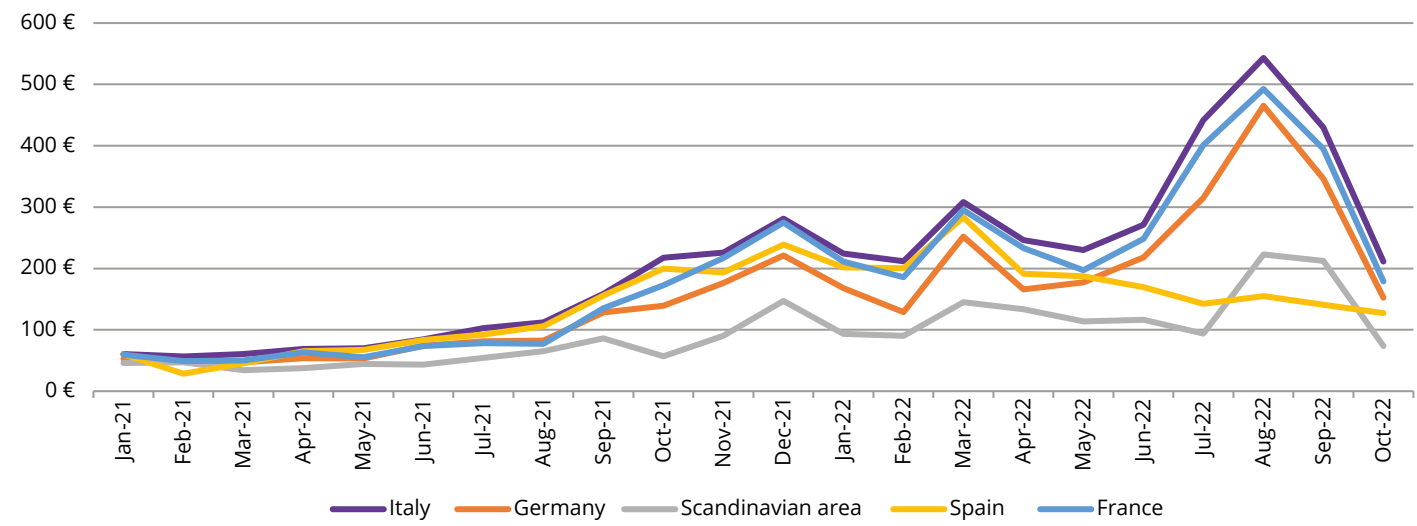
increases by €5/MWh per month to reach €70/MWh in May 2023. Looking at the Refinitiv data relating to the monthly trading prices of some of the main electricity exchanges in Europe, we see that the performance of the Spanish exchange before the introduction of the price cap followed that of the other countries. After the introduction of the cap, the price of electricity on the Spanish stock exchange experienced a significant drop. This is precisely in the months in which other large economies such as Italy, France and Germany recorded price peaks (Fig. 3.14).

However, it must be added that the Spanish price data reported is not comprehensive. In fact, the amount of the subsidy that is paid, as compensation for the higher generation costs, to thermal producers (CCGTs, coal and cogeneration) should be added. For this reason, the real gap compared to other European countries is smaller and, at the time of writing, the Iberian Peninsula has overall higher prices than Germany. In any case, due to the distortions that this measure causes in exchanges between countries, by encouraging net exports of electricity to interconnected neighbours, a measure of this type could be implemented only in countries with very limited interconnections or uniformally throughout the European Union.

The package is completed by measures of solidarity between the EU states in the event of severe supply disruptions, intervention mechanisms on intra-day

Fig. 3.14 Electricity price trends on some of the main European exchanges

Source: Refinitiv



trading of derivatives (the elaboration of which has been entrusted to ESMA) and further measures to simplify the development of renewable sources and electricity grids, including through emergency measures (see par. 3.3). Although an agreement on this point still seems a long way off, the potential positive effect of setting a ceiling on the price of energy can be seen in the data of the electricity market in Spain. Spain and Portugal have seen their "energy island"[36] status and have received approval from the European Commission to set a ceiling on the price of electricity at €50 per MWh for 12 months.

36 The electricity interconnection of Spain and Portugal with the rest of Europe is only 2.8%.

3.2 AGAINST ENERGY DEPENDENCY: PROMOTING RENEWABLE ENERGY SOURCES AND IMPROVING ENERGY EFFICIENCY

3.2.1. An overview of the EU energy system

Main trends in energy demand and production

In 2021, **global primary energy consumption** was 595.35 EJ, with **Europe accounting for 10.1%** and the rest of the world 89.9%. According to data from the BP "*Statistical Review of World Energy 2022*", **2021 registered the largest increase in primary energy consumption in history**, fully offsetting the sharp decline that was recorded in 2020. In fact, the 2021 primary energy consumption, was only 8 EJ above the 2019 level. This strong growth was mainly driven by renewable energy, with the level of fossil fuel energy remaining unchanged between 2019 and 2021, and the decrease in demand for oil (-8 EJ) being offset by an increase in consumption of natural gas (5 EJ) and coal (3 EJ) (Fig. 3.16). Returning to the primary energy consumed in 2021, 6.7% of this comes from renewable energy, 19.8% in the European Union.

Shifting the focus to the European continent, in order to have a better understanding of energy use, an in-depth analysis of the energy intensity indicator and per capita consumption may be a good starting point. **Energy intensity** is one of the indicators for measuring the energy needs of an economy and is often used as an approximation of energy efficiency. Eurostat data on European energy intensity shows that its evolution

Fig. 3.15 Final energy consumption (%, 2021)

Source: BP Statistical Review of World Energy 2022

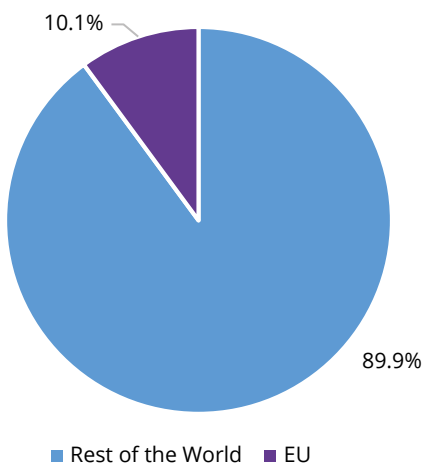
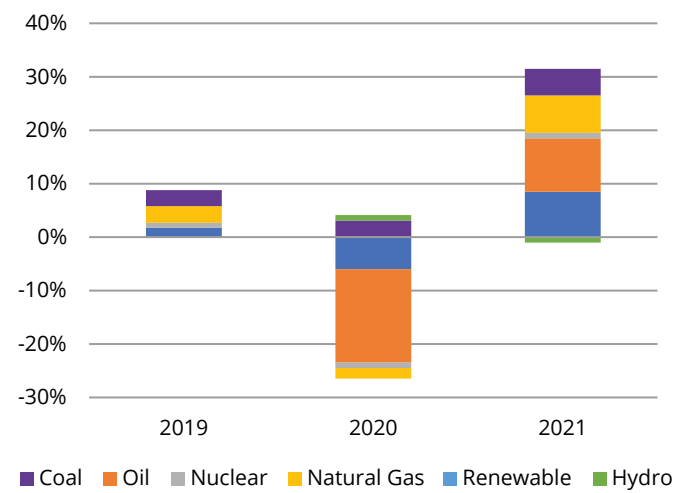


Fig. 3.16 Primary energy consumption in the world (rate of growth, %)

Source: BP Statistical Review of World Energy 2022



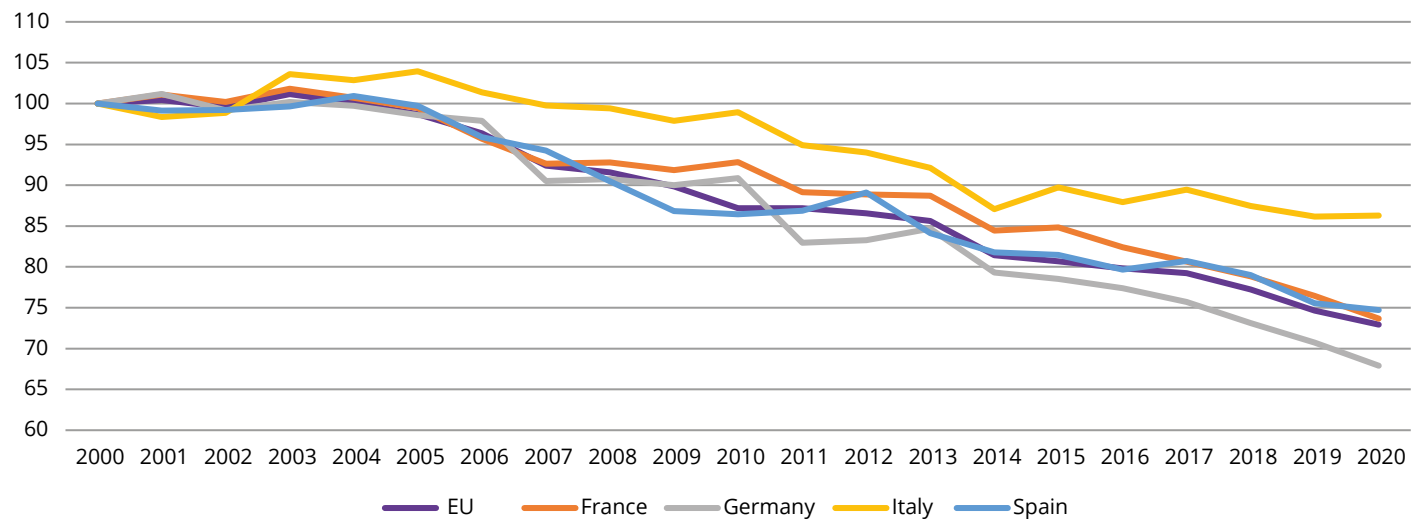
since 2000 has been declining, reaching a value of **110.1 Kgoe/T€ in 2020, compared to the 151 Kgoe/T€ in 2000**. Taking the year 2000 as a point of reference, the European trend in 2020 recorded **a decline of 27.1%,** a figure similar to that noted by Spain (-25.3%) and France (-26.3%) (Fig. 3.17). The main European countries that had the lowest energy intensity in 2020 and, therefore, showed a higher efficiency were Ireland (39.21), Denmark (55.62), Luxembourg (66.52) and Italy (91.56). The most energy-consuming countries were Hungary (206.7), Czechia (219.5), Malta (249.5) and Bulgaria (361.7) (Fig. 3.18)

Regarding per capita consumption, 2019 data will be considered since those referring to the 2020 data may be distorted due to the extraordinary reduction in energy demand for that year (-8% in final energy consumption in 2020 compared to 2019). According to Eurostat data, the northern countries consume the most energy (without considering Luxembourg), and Finland, along with Belgium and Sweden, are the top three countries with the highest per capita energy consumption values, with 6201 Kgoe/cap, 4896 Kgoe/cap and 4860 Kgoe/cap, respectively. These figures far exceed the EU average of 3,374 Kgoe/cap. Instead, at the lower end of the ranking we find Hungary, Romania and Malta, with values of 2156, 1826 and 1710 Kgoe/cap, respectively (Fig. 3.19).

Before delving into the physiognomy of European energy, additional data allowing us to be aware of the magnitude of energy production is that related to installed electrical

Fig. 3.17 Energy intensity (Kgoe/T€)

Source: Eurostat



capacity. According to Eurostat data, **in 2020, the total installed electrical capacity on European territory stood at about 962,600 MW, registering an increase of about 1.7% compared to 2019 and 57% compared to 2000**. In general, the evolutionary trend of installed electrical capacity since 2000 has experienced a continuous growth, with a CAGR of 2.2%. In 2020, the European countries with the highest values of installed capacity were in order Germany, France, Italy and Spain, with values of 233,747, 136,637, 116,383 and 108,421 MW, respectively. The main energy sources feeding this electrical capacity were **combustible fuels** (Fig. 3.20), **powering about 40% of the total electrical capacity**. However, it should be noted that since 2012, the evolutionary trend of the

Fig. 3.19 Energy consumption per capita (2019)

Source: Eurostat

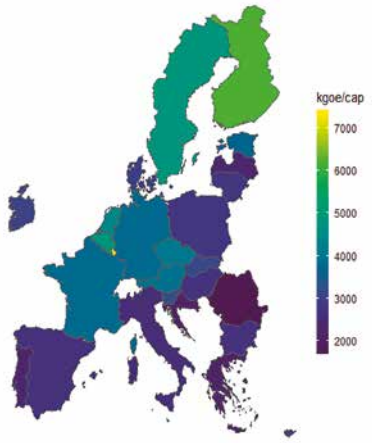
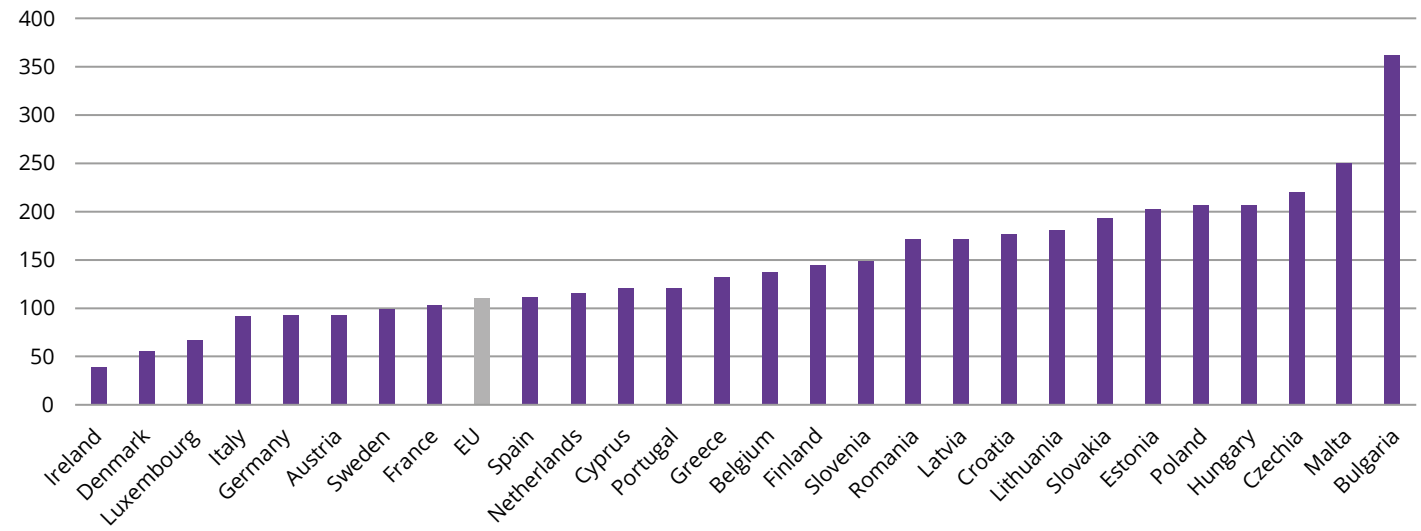


Fig. 3.18 Energy intensity by country (Kgoe/T€, 2020)

Source: Eurostat



latter has been decreasing, with a CAGR of -1%. On the other hand, if **renewable energies** (hydro, solar, wind, geothermal, etc.) are considered, these **made up about 33% of the total installed electrical capacity in 2020**. Going into more detail (Fig. 3.21), we can see that the increase in the importance of the renewable component is due to the continuous enlargement of installed electrical capacity powered by wind and solar energies. For these, wind energy has experienced a CAGR of 13.5%, while solar energy a rate of 37.4%.

Energy consumption in Europe is based on the use of a quite heterogeneous mix of energy sources, however, it still heavily relies on non-renewable energy sources. Considering the total gross energy consumption in Europe in 2020, **32.6% of the energy consumed was produced from oil and petroleum products, 24.4% from natural gas, 10.5% from fossil fuels,** while only 1.1% from non-renewable waste. Instead, **13.1% of the energy consumed was produced from nuclear sources and 17.9% from renewable sources together with biofuels**. Therefore, renewable sources still have less weight in the energy mix, with non-renewable energy sources still dominating (Fig. 3.22).

In terms of economic sectors, energy is mainly used in

Fig. 3.20 Electricity production capacities in the EU (MW)

Source: Eurostat

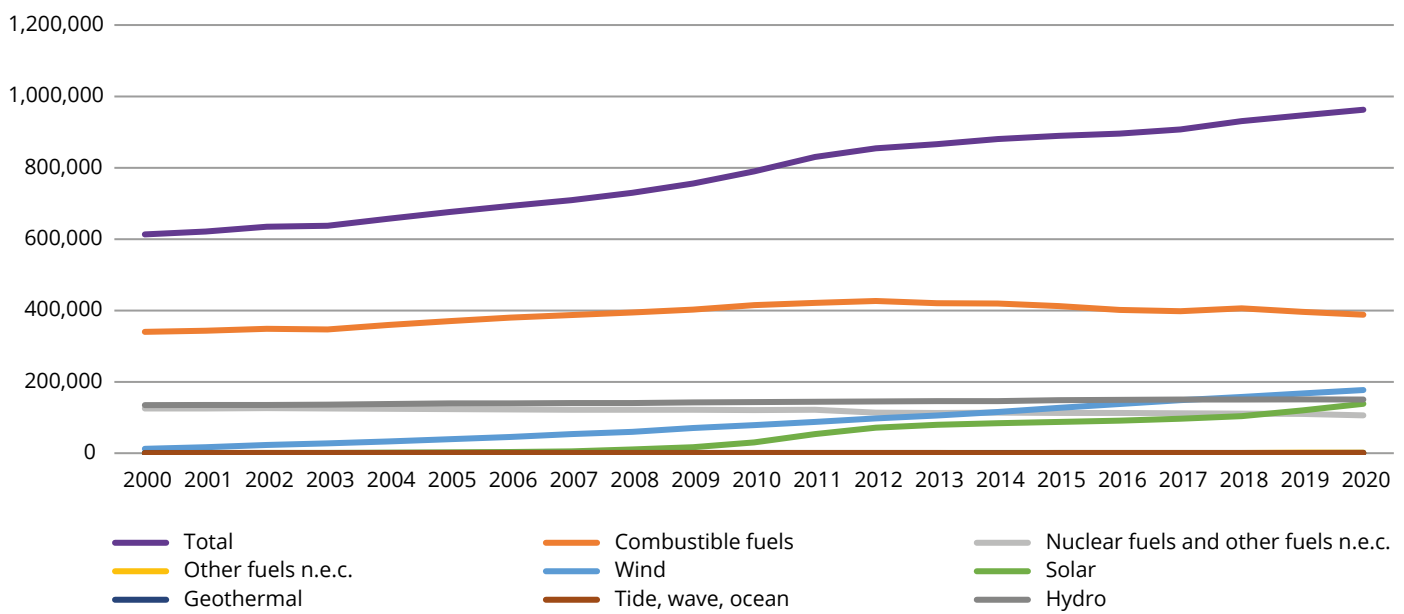


Fig. 3.21 Wind and solar energy in electricity production capacities (MW)

Source: Eurostat

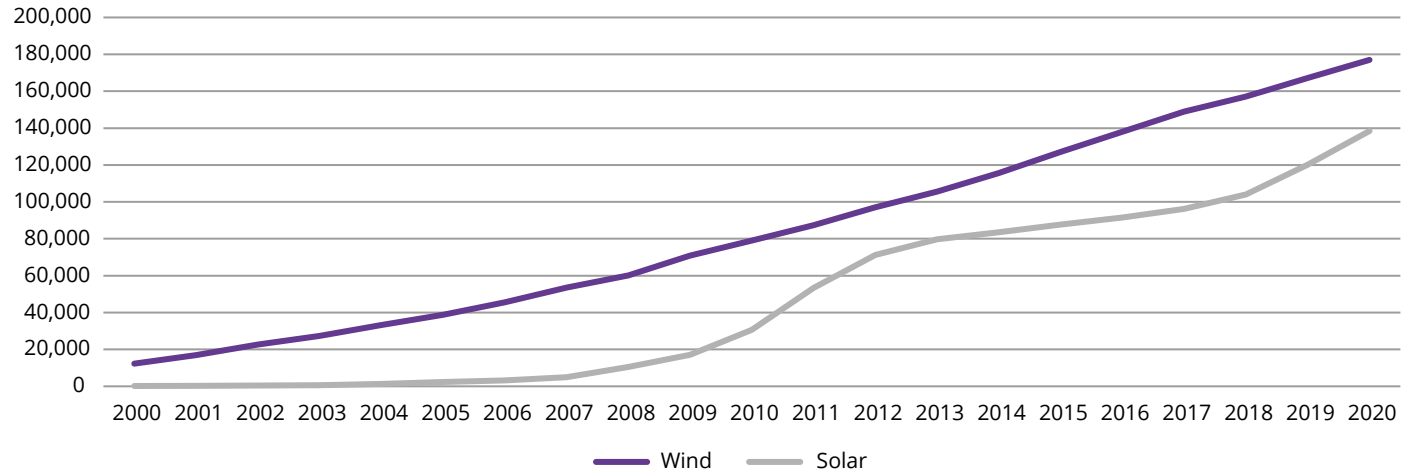


Fig. 3.22 Gross inland consumption by fuel (%, 2020)

Source: Eurostat

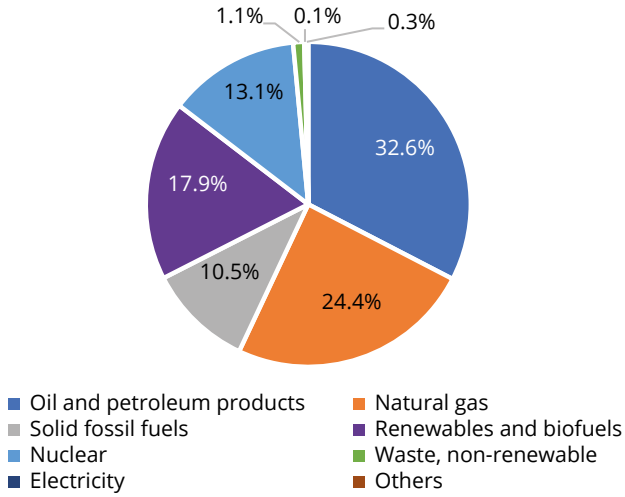
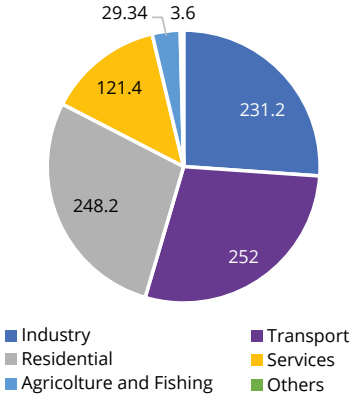


Fig. 3.23 Final energy consumption by sector (Mtoe, 2020)

Source: Eurostat



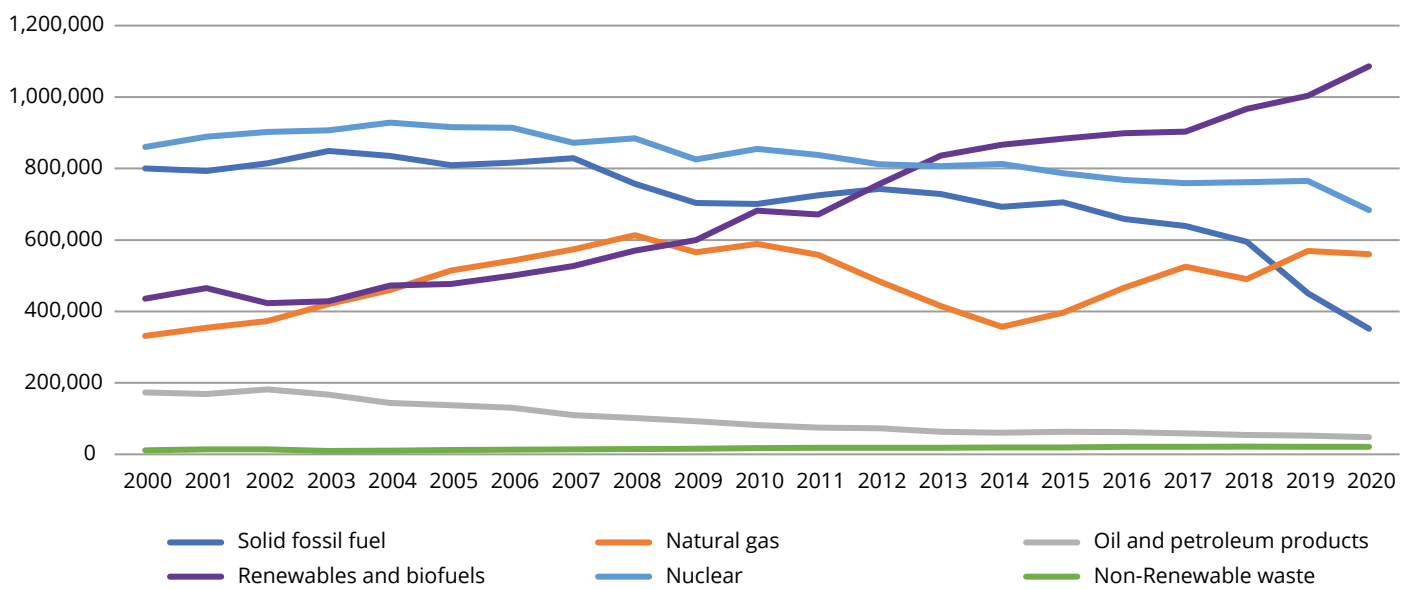
the transportation sector. In 2020, the **transportation sector used about 252 Mtoe of energy, similar to the residential sector which consumed 248.2 Mtoe of energy, while the industrial sector accounted for 231.2 Mtoe**. The sectors, on the other hand, that use a lower amount of energy are the service sector and the agricultural and fisheries sector, which consumed 121.4 Mtoe and 29.3 Mtoe of energy, respectively (Fig. 3.23).

A focus on renewable energy sources

One of the main final energies is electricity. It will represent an increasingly significant share, driven by electrification policies. In the first decade of the 2000s, the most important energy sources that were used for electricity generation were fossil fuels and nuclear energy. On the fossil fuel side, the main producers of electricity were Poland, Spain and Italy. On the nuclear energy side, on the other hand, the main producers were France, Germany, Sweden and Belgium. However, these two energy sources underwent a gradual decline during this decade, while in the background, renewable energies and fossil biofuels continued to advance gradually. Only in 2013, did a turnaround occur, with renewables becoming a major player in power generation, and their upward trend does not seem to be stopping. **In 2020, renewables produced about more than 1 million**

Fig. 3.24 Gross electricity production (GWh)

Source: Eurostat



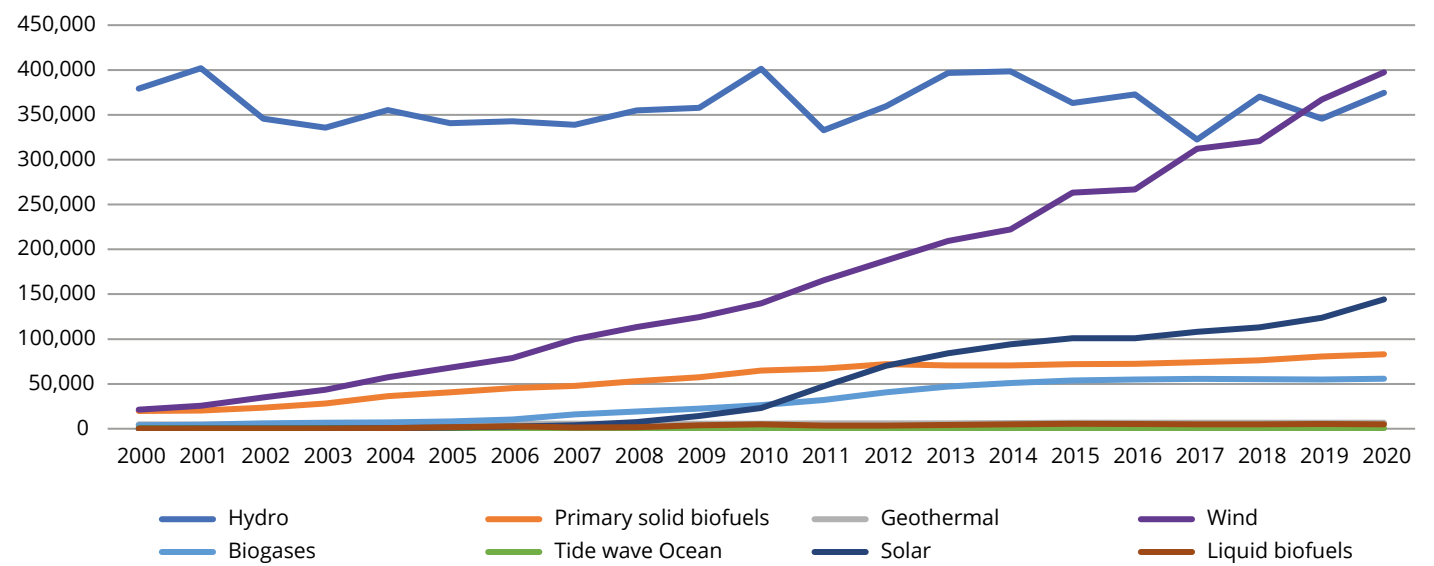
gigawatts per hour, compared with about 680,000 of nuclear power, 560,000 of natural gas, and about 350,000 of fossil fuels. To confirm this, the CAGR of the renewable sources and biofuels channel was 4.4%, while nuclear power and fossil fuels recorded -1.1% and -3.8%, respectively. **The main countries producing electricity through the renewable energy channel are Germany, Norway, Italy and Spain** (Fig. 3.24).

On the other hand, if we look in detail at the main renewable technologies used for energy production, over the past two decades**, hydropower has been the main renewable technology used to produce electricity**. **Only from 2018, has wind energy become the main technology for electricity production**. From 2010, solar energy has increasingly been used, but still remains at a low level in relation to the main technologies. In 2020, compared to total gross electricity generation, 37.2% consists of wind power, 35.1% hydro power, 13.5% solar power, 7.8% from solid primary biofuels, 5.2% from biogas, while figures of less than 1% involve geothermal power, liquid biofuels and tidal power (Fig. 3.25).

According to an E3G-EMBER analysis**,** when compared with total installed electrical capacity in 2021 (1,479 TWh), the increase in wind and solar helped to mitigate the impacts caused by drought (21% reduction in hydro-electric generation) and the

Fig. 3.25 Renewable electricity generation by source (GWh, 2020)

Source: Eurostat

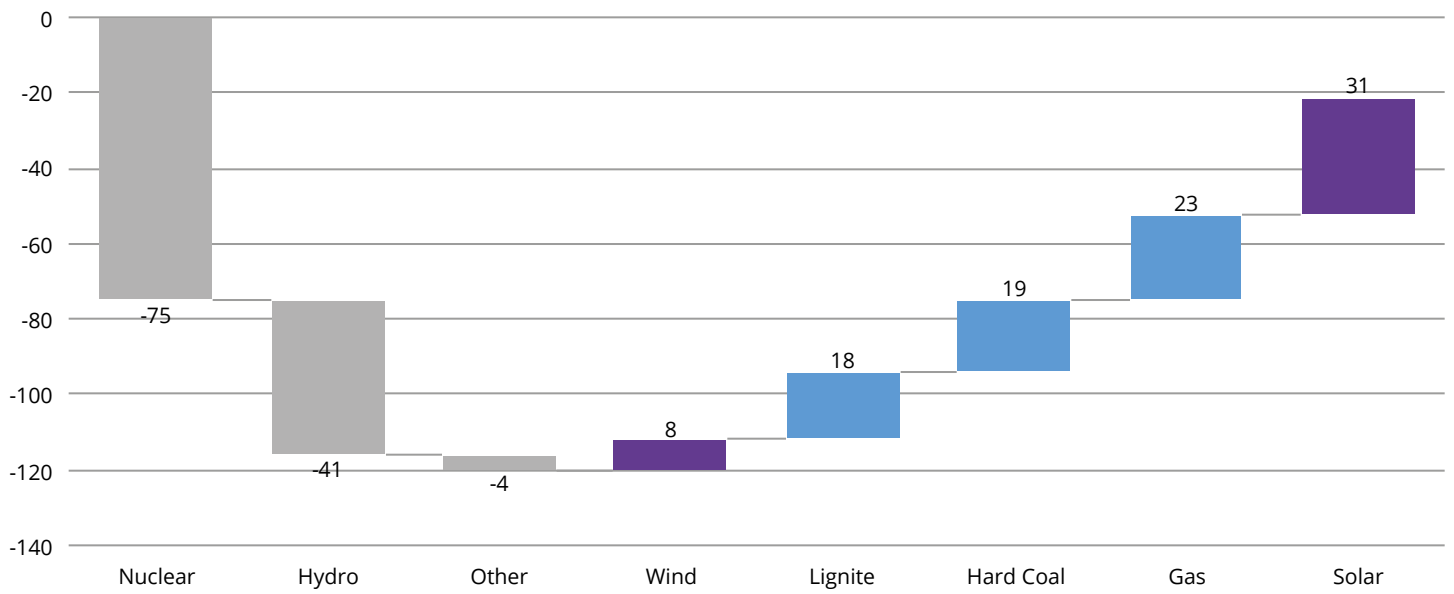


unavailability of nuclear capacity (19% reduction in nuclear electricity generation). In total, in the period from March to September of this year, wind and solar energies produced 345 TWh of electricity – 192 TWh and 153 TWh, respectively –, a 13% increase over the previous year (Fig. 3.26). **Without this wind and solar production, therefore, the European Union would have needed an additional 70 bcm of natural gas imports** to produce electricity from gas. It is estimated that **this additional gas would have cost €99 billion**, based on the average EU benchmark TTF Day price for the March-September period.

The main energy resources used for heat production, also in this case, are heterogeneous and include renewable and non-renewable sources. Looking at the time period from 2000 to 2020, it can be seen that the main energy source used for heat production was natural gas. In second position, until 2015, there were solid fossil fuels, to be surpassed by renewable and biofuels. In second place, on the other hand, there are oil and petroleum products, non-renewable waste and nuclear energy. Renewable sources and biofuels are worth noting with a CAGR of 6.3%, while the figure for natural gas is 0.3% and that for petroleum -5.7%. As has been the case with electricity production, there has also been an important development in renewable energy in heat production,

Fig. 3.26 Change in EU electricity generation (TWh, March-September 2022)

Source: E3G – Ember



which now takes a leading role in this area as well. **In 2020, total heat production amounted to about 2 million TJ, of which 37.8% was produced by natural gas, 32.6% by renewable energy and biofuels, 20.1% by solid fossil fuels**, 6.2% by non-renewable waste, 3.2% by petroleum and petroleum products, while only 0.2% was produced by nuclear energy (Fig. 3.27).

Therefore, the **shares of renewable energy** have been steadily growing. In 2020, in the European Union **37.5% of electricity generated came from renewable sources**, with a percentage increase of 3.4% compared to the previous figure of 31.1% recorded in 2019 and, in general, from 2004 to 2020, the CAGR was 12.2%. In 2020, **energy was produced from renewable sources in the form of heating and cooling for 23.1%**, a figure slightly higher than the previous year's value of 22.4%. In this case, the CAGR is moderate, standing at about 4.1% (Fig. 3.28).

Transport holds a significant share in final energy. If we look at the period from 2000 to 2020, it can be seen that there are two main energy sources that support energy demand in the transportation sector. These are gas oil and diesel oil, along with gasoline, while liquefied petroleum gas and biofuels, such as bio-gasoline and biodiesel, play a minor role (Fig. 3.29). However, if we set aside the comparison with the main energy sources and conduct a single study,

Fig. 3.27 Gross heat production (TJ, 2000-2020)

Source: Eurostat

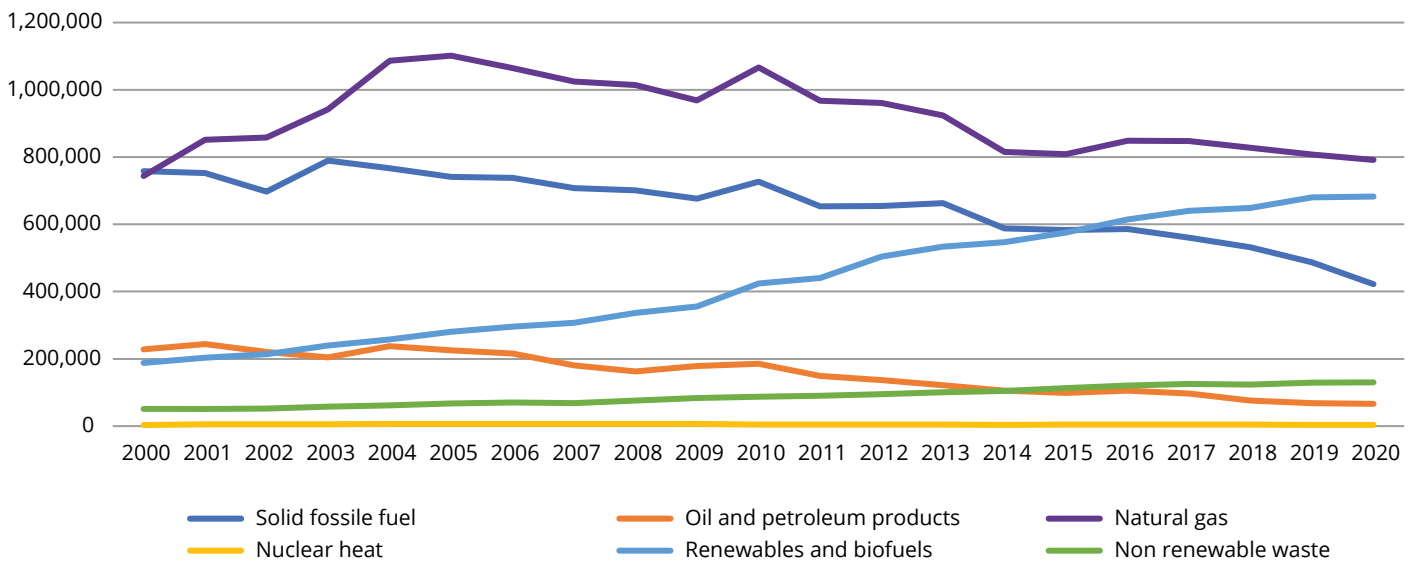


Fig. 3.28 Renewable energy shares in gross final energy consumption (%)

Source: Eurostat

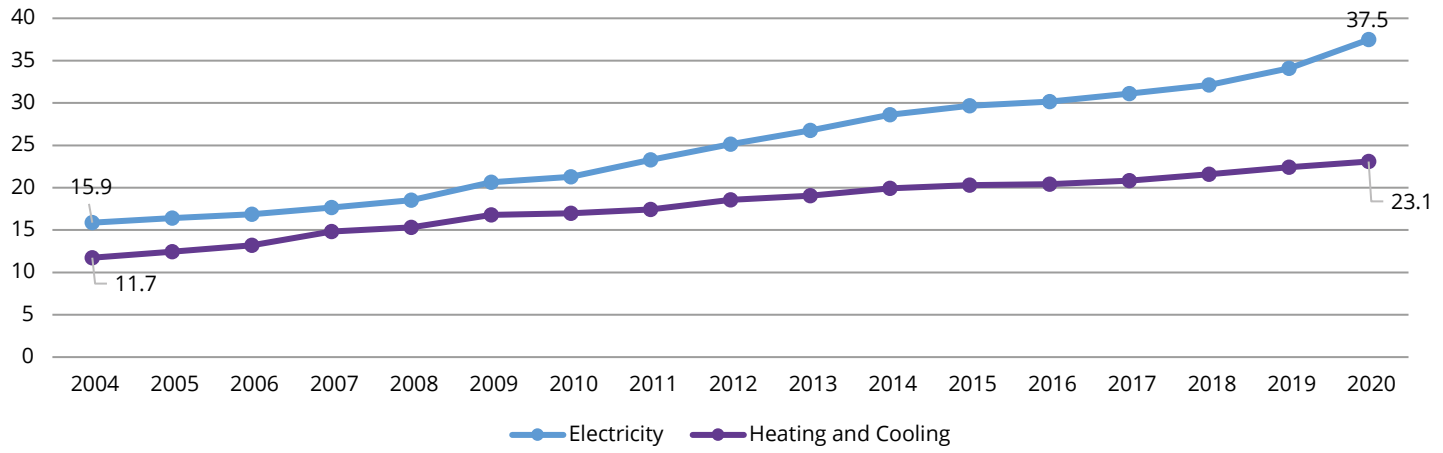
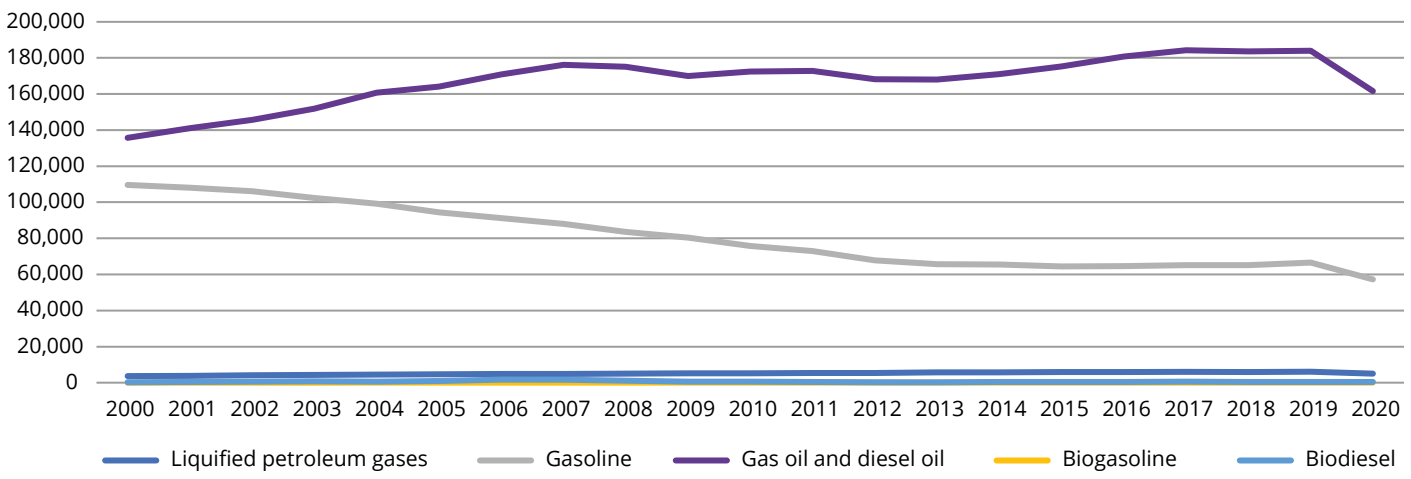


Fig. 3.29 Final consumption in the transport sector (Ktoe)

Source: Eurostat



biofuels have had an important growth since 2000. If we consider bio gasoline production, it has increased from 58.7 Toe in 2000 to about 2,809 Toe in 2020, while for biodiesel, from 400 Toe in 2000 peaking at about 13,294 Toe in 2020. The former has experienced a CAGR of 20.2% while, on the other hand, the figure for the latter is 18.5%. Thus, although the main energy sources supporting this sector are still non-renewable sources, biofuels have experienced a significant growth. It remains to be emphasised, however, that the transportation sector still lags behind in terms of penetration of renewable sources. **In 2020, only 10.2% of the energy supplying transportation was produced from renewable sources**, again with a moderate CAGR of 5.1% between 2004 and 2020 (Fig. 3.30).

Negligible, on the other hand, is the electricity generated from renewable sources that supports electric mobility. In fact, according to Eurostat data, **in 2019, only 0.6% of electricity from renewable sources was used for mobility**, with **about 82.7% used for rail transport, 12.6% for road transport, and 4.7% for the remaining transport modes**.

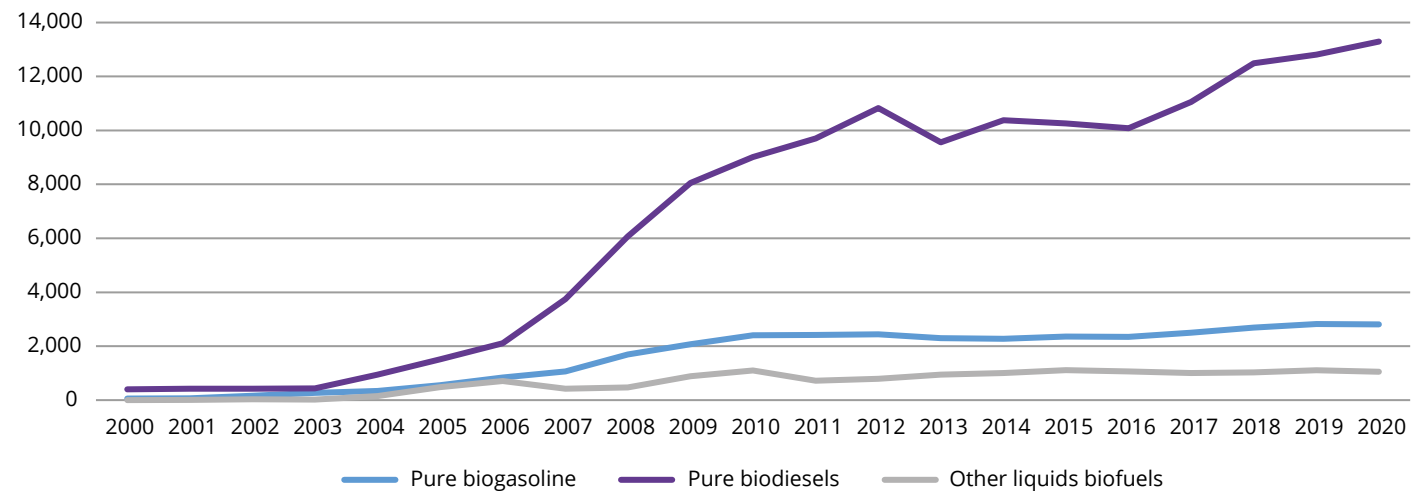
3.2.2 Recent policies and objectives

The starting point for renewables and energy efficiency

Currently, the European average of the share of renewable energy in total gross final energy consumption is 22.1%. The target set by the 2009 Renewable Energy Directive has been achieved. The achievement is of considerable importance, however, it has some negative notes. In fact, the average figure masks the high heterogeneity

Fig. 3.30 Production of biofuels (Ktoe)

Source: Eurostat



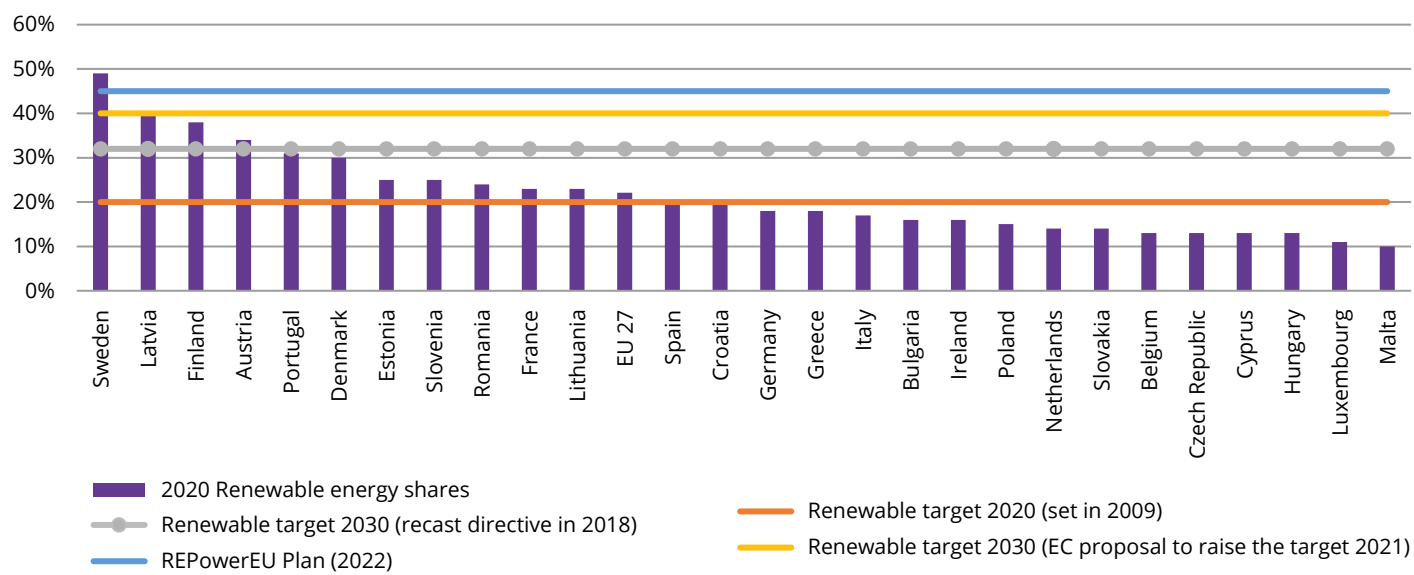
that characterises the distribution of renewable energy across Europe. **Only 13 countries out of 27 have a value at or above 22%**. For example, **Sweden, Latvia and Finland at 49%, 40%, 38%, respectively** (Fig. 3.31). On the 20% threshold, on the other hand, there are Spain and Croatia. Italy is among those countries that did not reach the target with a figure of 17% and, finally, in the last positions we find Hungary, Luxembourg and Malta at 13%, 11% and 10%, respectively.

Looking at Fig. 3.31, the green line shows the EU target set by the 2018 Renewable Energy Directive, an amendment of the 2009 directive. The target is set for 2030, but there are already some European countries that have fully complied, such as Sweden, Latvia, Finland and Austria (34%). Sweden is the only country that, with its 49%, already goes beyond the 45% target set in the recent REPowerEU plan (purple line).

As mentioned earlier, renewable energies enable the production of clean energy and, thus, reduce greenhouse gas emissions. The goal set by the "2030 Climate Target Plan", later strengthened with the set of proposals offered by the "Fit for 55" package, is to reduce net greenhouse gas emissions by at least 55% by 2030, taking 1990 greenhouse gas emissions as the baseline. The ultimate goal is to achieve climate neutrality by 2050. Compared to 1990, **2020 found a 31.6% reduction**

Fig. 3.31 Renewable energy shares and target by Member State (%, 2020)

Source: Eurostat



in greenhouse gas emissions (Fig. 3.32). Meeting the target is still a long way off, but the significant decrease that is affecting the trend of greenhouse gas emissions is encouraging.

Another indicator that European institutions keep track of to protect the environment and mitigate climate change is **energy efficiency**. It must be improved across the entire energy chain, from production to final consumption. Not surprisingly, the two main variables used to control this phenomenon are primary and final energy consumption. Starting with primary **energy consumption**, it can be seen (Fig. 3.33) that in 2020 this stood at about 1,236 Mtoe, about 117 Mtoe less than the 2019 figure. Compared to 2011, the CAGR was -1.3%. The target set by the 2012 Energy Efficiency Directive, which is equivalent to a primary energy consumption of 1,312 Mtoe, has been reached. However, the **drop in demand caused by the Covid-19 pandemic has been fundamental in this result**. To effectively achieve the energy efficiency target, a more substantial reduction in energy consumption is required compared to pre-pandemic levels. The 2018 Energy Efficiency Directive target is even further away. Regarding final energy consumption, this amounted to about 906 Mtoe in 2020, and considering the same time frame taken

Fig. 3.32 Greenhouse gas emissions (Mtoe, Δ %)

Source: Eurostat

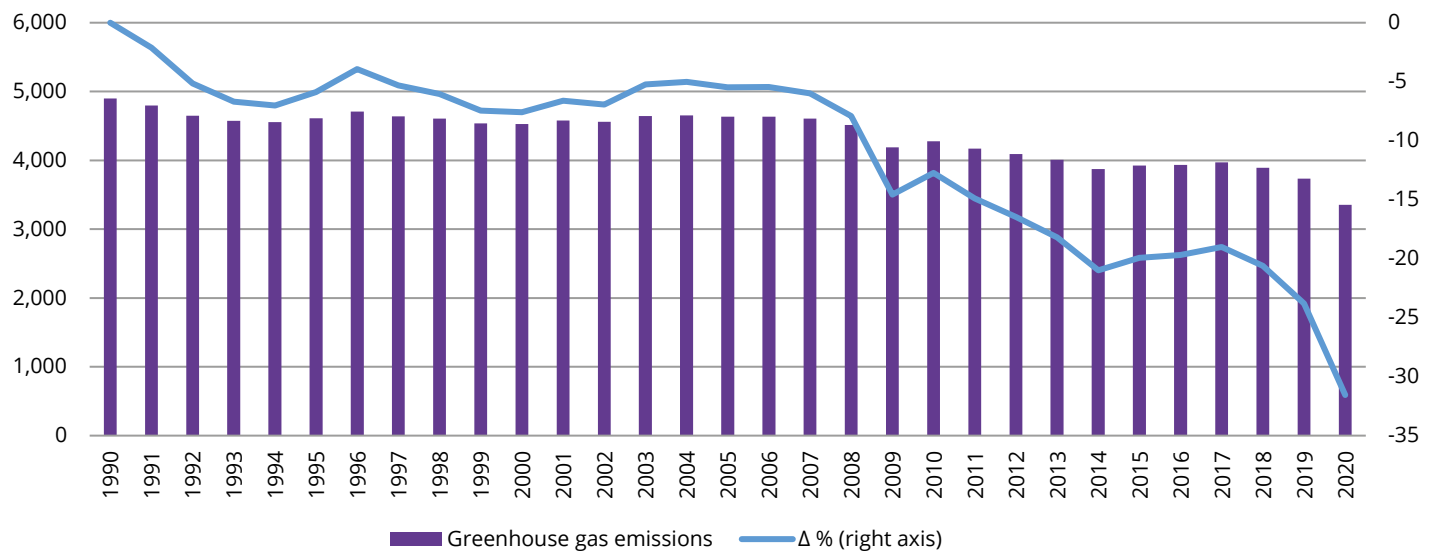


Fig. 3.33 Primary energy consumption and targets (Mtoe)

Source: Eurostat

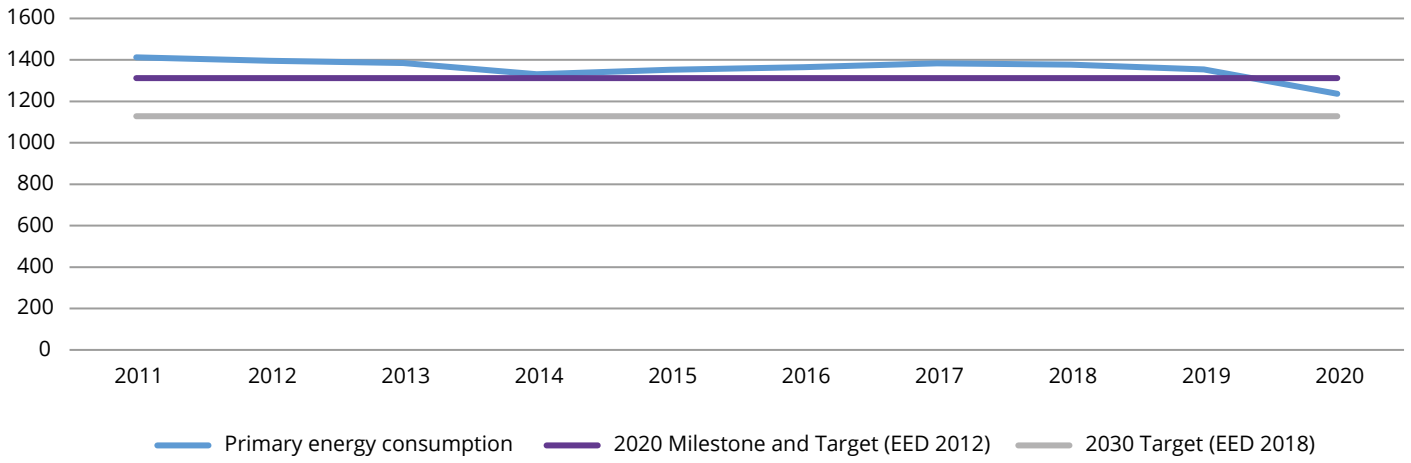
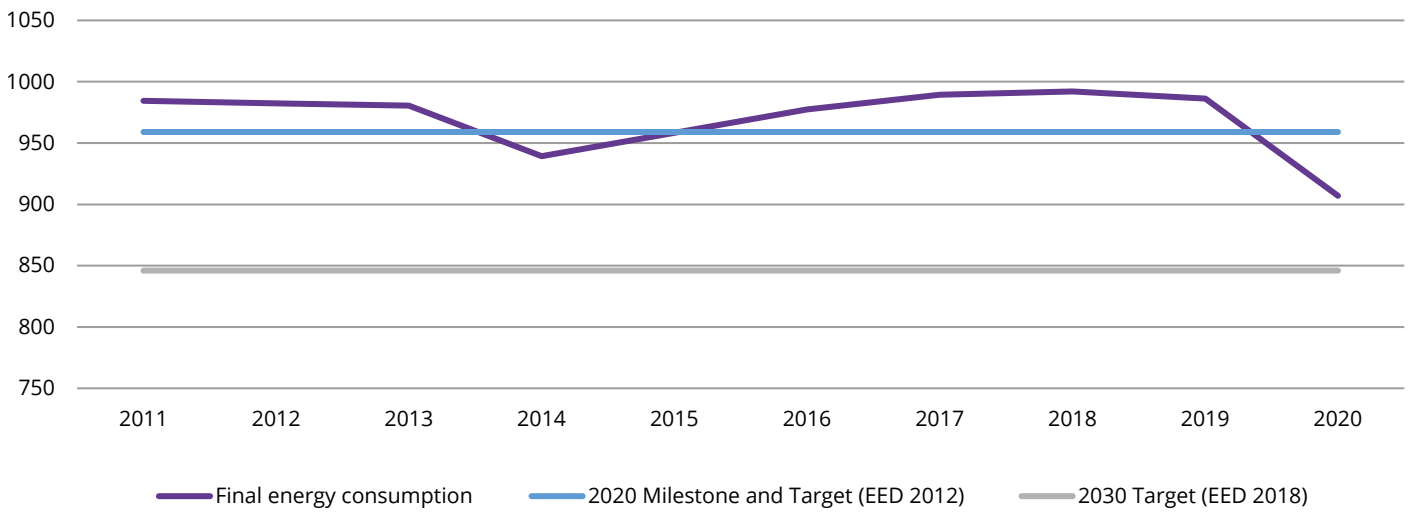


Fig. 3.34 Final energy consumption and targets (Mtoe)

Source: Eurostat



above, its downward trend was slightly weaker than primary energy consumption, with a CAGR of -0.8%. Again, the target imposed by the 2012 Energy Efficiency Directive has been met (959 Mtoe). Also in this case, the collapse in energy consumption caused by the pandemic has been essential for achieving the goal. Further improvements are therefore required. A reduction of about 61 Mtoe is lacking to reach the 2030 target (846 Mtoe) (Fig. 3.34).

RED and EED revisions in the Fit for 55 package

The European Union has for many years placed the policies of decarbonisation and the promotion of renewable sources at the top of its agenda. The European Green Deal and the ambitious Fit for 55 package, which aims to reduce net greenhouse gas emissions by at least 55% by 2030, are two milestones and the revision of the **Renewable Energy Directive (RED)** represents a fundamental point.

The RED was adopted in 2009 with the main objective of ensuring a minimum share of 20% in final energy consumption by 2020. Then, in 2018, it was amended to raise the minimum share of renewables in final energy consumption to 32% by 2030. After the entry into force of the "European Climate Law", approved in May 2021 by the European Council and the Commission, a 55% reduction in greenhouse gas emissions by 2030 (compared to the 1990 value) and the achievement of climate neutrality by 2050 were made binding. Both targets are taken from the European Green Deal and from the "Fit for 55" plan contained therein. According to the Commission's Impact Assessment[37], underpinning the plan for the 2030 climate goals, the new 55% target will require a 38-40% share of renewable energy in final energy consumption by 2030, which has made the EU's revision of RED II and related climate and energy legislation necessary, as these are only geared toward providing a minimum Renewable Energy source (RES) share of 32%.

In July 2021, the Commission published a nearly 400-page impact assessment[38] report in support of the legislative proposal to revise RED II. The impact assessment evaluated a number of key policy options for aligning RED II with the EU's new climate objective. Below are the main ones:

i. a 40% RES target by 2030
ii. increased ambition for RES in heating and cooling and in the transport sector, with the introduction of higher sub-targets
iii. new measures to improve energy system integration (sectoral coupling)
iv. more promotion of renewable fuels of nonbiological

37 European Commission, Impact Assessment accompanying the document Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions, Stepping up Europe's 2030 climate ambition, 17/09/2020, SWD/2020/176 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020SC0176 [accessed 15/11/2022].

38 European Commission, Impact Assessment Report, accompanying the Proposals for a Directive of the European Parliament and the Council amending Directive (EU) 2018/2011 of the European Parliament and of the Council, Regulation (EU) 2018/1999 of the European Parliament and of the Council and Directive 98/79/EC of the European Parliament and of the Council as regards the promotion of energy from renewable sources, and repealing Council Directive (EU) 2015/652, 14/07/2021, SWD/2021/621 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0621 [accessed 15/11/2022].

origin (RFNBO), particularly hydrogen, to be achieved through new targets

v. extension of agricultural biomass areas
vi. extensions of greenhouse gas and biofuel sustainability criteria to cover all existing RES installations
vii. increase cross-border cooperation
viii. various measures to promote RES uptake in industry.

In preparing the legislative proposal, the committee also organised consultations with stakeholders and the general public. The Initial Impact Assessment (IIA) received a total of 374 responses from 21 MSs and 7 non-European countries, with the vast majority of submissions in favour of RED II revision. Subsequently, the Commission organised a broad public consultation based on a detailed questionnaire containing open-ended and multiple-choice questions on issues related to the RED II review, also holding a series of policy and technical workshops.

The final legislative proposal contains numerous changes that have, as their main legal basis, Article 194 of the TFEU, which is dedicated to energy and gives the European Union a specific mandate to adopt policies related to the development of new and renewable forms of energy. Regarding the form, the Commission opted for an amending directive (not a complete recast) due to the relatively short time elapsed since the adoption of RED II (December 2018) and its transposition by MSs. In short, the proposed revision focuses on achieving the EU's new 2030 climate targets. Below are the main changes:

1. Article 1 – "Definitions" is amended to include new definitions of RES technologies;
2. Article 3 – "Binding overall Union target for 2030" is amended to set a new EU target on the minimum share of RES energy in final consumption, raising the previous target of 32% to 40%;
3. Article 9 – "Joint projects between Member States" is amended to introduce an obligation for MSs to carry out a cross-border pilot project within three years, which should be useful for cooperation on the amount of off-shore renewable energy production by 2050;
4. Article 15 on "Administrative procedures, regulations and codes" is amended to strengthen existing provisions on renewable power purchase agreements;
5. Article 15, on the integration of renewable energy on buildings, is amended to set a binding 49% share of renewable energy in heating and cooling of buildings by 2030.

Furthermore, in brief, the proposal sets an indicative target of increasing the use of renewable energy in industry by 1.1% each year, makes the target of 1.1% annual growth of renewable energy in the heating and cooling sector binding and also providing a series of financial measures to help the most vulnerable consumers. It also plans to increase the RES target in the transport sector by setting the target of reducing greenhouse gas intensity to 13%.

However, The Commission, along with the communication published in May 2022 which sets out the **REPowerEU Plan**, adopted an additional legislative proposal that aims to amend RED II. This proposal would increase the binding share of RES in the EU's final energy consumption to 45% by 2030 (higher than the 40% seen in the previous

legislative proposal of 2021) and introduce a number of strengthened measures. These aim at speeding up the permit procedures for new RES power plants and for the adaptation of existing RES installations. Member States will also be required to designate "Renewables go-to areas", which are particularly suitable areas for RES plants and are immune to any legal objections. Trilogue negotiations between the Parliament, the Council and the Commission on RED revision are still ongoing as of date.

We saw earlier that in 2020, the European Union managed to comply with the 2020 energy efficiency target imposed by the **Energy Efficiency Directive (EED)**. The EED was originally adopted in 2012 to help the EU and its MSs to improve energy efficiency by at least 20% by 2020 (compared to the 2005 value), which means having a primary energy consumption of 1,313 Mtoe or less and a final energy consumption of 959 Mtoe or less. In 2018, the EED was revised and reinforced through the update of the target to improve energy efficiency by at least 32.5% by 2030 (1,128 Mtoe for primary energy consumption and 846 Mtoe for final energy consumption), and each MS is required to meet higher annual energy saving obligations of +0.8% on final energy consumption.

Subsequently, with the enactment of the new European climate law in June 2021, through which the European Union made the target of -55% greenhouse gas emissions by 2030 and the achievement of climate neutrality by 2050 legally binding, in order to achieve these climate goals, the EED required substantial modifications.

The European Commission, thus, acted through the "Fit for 55" legislative package, which includes a substantial "recast" of the EED. The Commission's proposal to revise the EED includes higher targets for reducing the EU's primary (-39%) and final (-36%) energy consumption by 2030, setting an upper limit of 1023 Mtoe for primary energy consumption and 787 Mtoe for final energy consumption (compared to 1128 and 846 Mtoe, respectively, in the 2018 EED). This means reducing energy consumption by 9% by 2030, compared to projections made in 2020.

The new proposal aims to significantly increase energy efficiency in EU MSs, focusing on sectors with high potential for energy savings (heating and cooling, industry and energy services). The Commission's proposal includes several measures such as increasing building renovation rates, increasing the uptake of energy efficiency investments, addressing energy poverty, and empowering and protecting consumers.

The Commission's proposal would nearly double the annual energy savings obligations (+1.5%) that MSs would have to meet over the 2024-2030 period (compared to +0.8% in the 2018 EED).

There are also several actions to promote energy efficiency in the heating and cooling sector, which accounts for 80% of energy consumption in buildings. The public sector, as a whole, should reduce annual energy consumption by 1.7% each year, should ensure that 3% of the floor area of public buildings is renovated annually (until now, this requirement only applied to central government buildings), and include more systematic energy efficiency requirements in public procurement procedures.

In conclusion, the Commission's proposal introduces a new obligation for MSs to take measures to implement energy efficiency improvements for people affected by or at risk of energy poverty, vulnerable customers and those living in social housing. It will also establish a clear legal basis for the application of the "energy efficiency first" principle (introduced in the 2018 EED) and ensure its practical implementation.

REPowerEU and EU Solar Strategy actions

On 18 May 2022, a European Commission Communication introduced an updated plan on Europe's ecological transition. In response to the disruption of the world energy market and the high energy prices caused by the Russian invasion of Ukraine, European institutions reacted by focusing on accelerating the transformation of the European energy system. With the aim of increasing Europe's energy independence from unreliable suppliers and volatile fossil fuels and with the aim of speeding up the transition to clean energy. The plan has the following main objectives:

1. diversifying energy supplies by cooperating with various international partners;
2. saving energy to cope with emergencies such as supply disruptions;
3. accelerating towards clean energy by increasing renewable energy.

The plan sees the expansion of renewable energy as one of many tools needed to end dependence on Russian fossil fuels and, generally, reduce dependence on foreign imports. As can be seen (Fig. 3.35), the **European energy dependency rate** (energy imports over gross available energy) **since 2013 has been on an upward trend until it peaked in 2019, when 60.4% of Europe's gross available energy came from foreign imports**. In 2020, this figure dropped to 57%, but this should not suggest an improvement, in fact this decrease is most likely due to the decrease in energy demand that characterised the 2020s. From Figure 3.36, we can see the main energy importers of the European Union , and the European Union's high energy dependence on Russian energy supply (see par. 3.1). More precisely, in 2020, for example, in relation to total coal imports, 53.9% came from Russia, while only 16.7% came from the United States and 14.9% from Australia. On the other hand, regarding crude oil and natural liquid gas imports, out of the total, 25.7% came from Russia, while for natural gas imports, 43.3% from Russia.

Fig. 3.35 Energy imports dependency (%)

Source: Eurostat

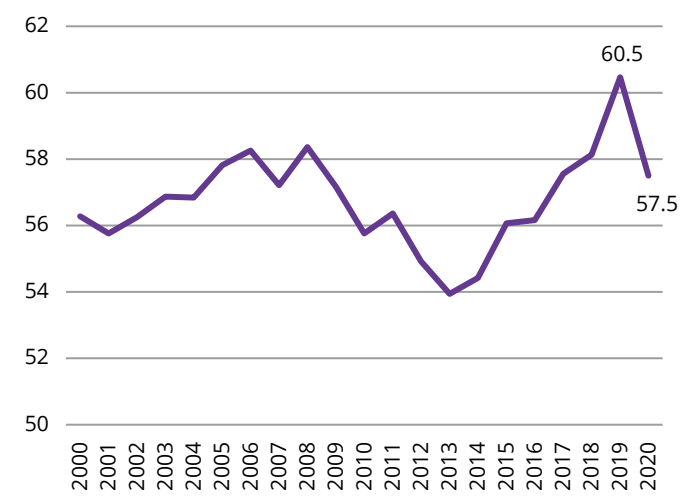
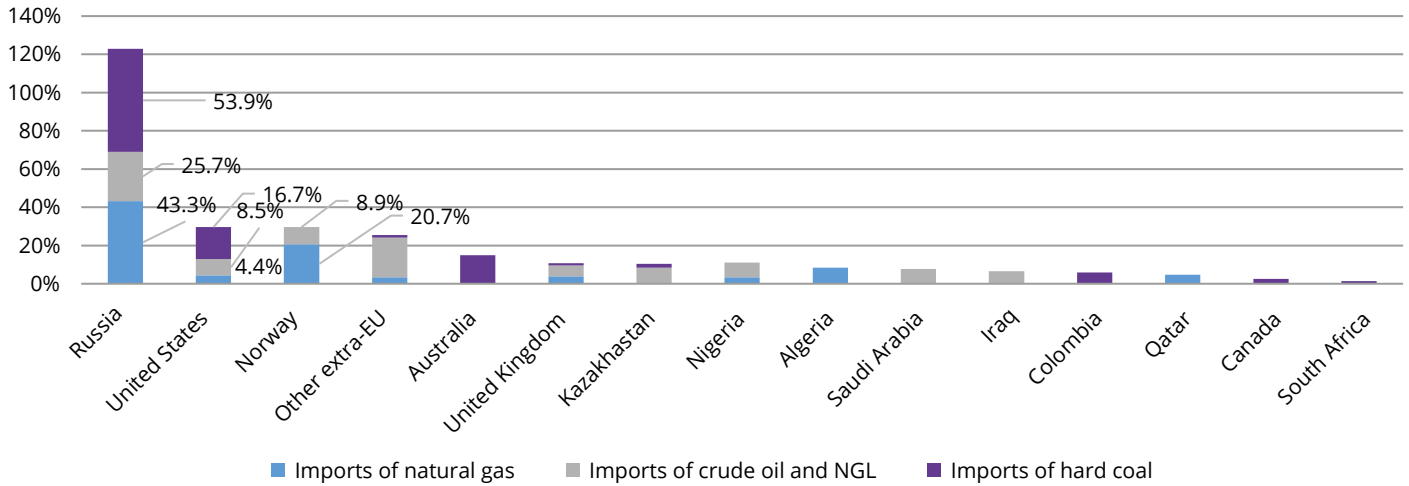


Fig. 3.36 Imports by country of origin (%, 2020)

Source: Eurostat



With a view to reducing the rate of energy dependence, particularly on Russia, the European Commission sees the spread of renewable energy as an essential tool for reducing the need to import energy. Therefore, renewable energy is beginning to assume a dual role; The first is to generate clean energy by fostering the green transition, and the second is to decrease energy dependence on imports.

This is why the European Commission, through the REPowerEU, is proposing to increase the EU's 2030 target for renewables.

The **main forecasts of the plan** are as follows:

1. the plan is expected to increase total renewable energy capacity to 1,236 GW by 2030, compared to the 1,067 GW envisioned in the "Fit for 55" package;
2. it is also expected to increase the deployment of photovoltaic power by connecting more than 320 GW of newly installed solar PV to the grid by 2025 and nearly 600 GW by 2030, reducing consumption of 9 billion m^3 of natural gas;
3. on the industrial side, electrification, energy efficiency and renewable energy deployment could save 35 billion m^3 of natural gas by 2030;
4. it is also expected that by 2030 about 30% of EU primary steel production will be decarbonised through the use of renewable hydrogen.

Overall, thanks to these measures, the RES target rises from 40% to 45%. From the perspective of project funding for the plan implementation, the Recovery and Resilience Facility (RRF) is the core for the implementation

of the plan and MSs will need to add a REPowerEU chapter to their recovery and resilience plans in order to allocate investments to REPowerEU priorities and, thus, implement needed reforms.

One policy supporting renewables that deserves further analysis in the REPowerEU plan is the section on solar energy. As mentioned earlier, by encouraging acceleration towards clean energy, the plan envisions putting more than 320 GW of solar PV on the grid by 2025 and increasing it to nearly 600 GW by 2030. Taking again Eurostat data (Fig. 3.20), the total installed electrical capacity from solar PV is 136 GW, which is still far from the target. The rapid and large-scale deployment of solar energy is considered critical because PV-based technologies are relatively inexpensive and they can be deployed quickly, features that reduce dependence on fossil fuels and foreign energy imports.

To achieve the goal of 600 GW of solar PV in the grid, the **EU Solar strategy**, within the REPowerEU, contains 4 initiatives:

1. European solar rooftops initiative
2. shorter and simple bureaucratic procedures
3. establish an EU large-scale skills partnership
4. launching a European Solar PV Industry Alliance

The first initiative aims to unlock the vast underutilised potential of rooftop solar power generation. To accomplish this, the EU has drafted a series of proposals, the most important of which are as follows:

- increase the share of renewables to 45%, to be achieved by 2030;
- limit the duration of the permit process for rooftop solar installations to a maximum of 3 months;
- adopt provisions to ensure that all new buildings are "solar-ready";
- make the installation of rooftop solar systems mandatory for all existing public and commercial buildings with a useful area greater than 250 m^2 by 2027, and make it mandatory for all new residential buildings by 2029.

The European Commission estimates that if the strategy is fully implemented, **the propagation of rooftop installations will provide 19 TWh of additional electricity after the first year of implementation (36% more from those projected in the "Fit for 55 percent" package)**. This means that **by 2025, additional electricity will amount to 58TWh (more than double the projections of the "Fit for 55" package)**.

In addition to rooftops, there are also plans to encourage moves towards innovative forms of solar energy deployment, such as the use of farmland (agrivoltaics), exploitation of the surface of water (floating photovoltaics), the surface of artificial lakes, and transportation infrastructure such as highways, railroad tracks and electric cars.

Concerning the establishment of a European Skills Partnership, the European Commission intends to implement a coordination among key stakeholders (cooperation among business, social partners, training providers and regional authorities) in the renewable energy sector in order to improve skills and promote retraining. The problem to be countered, in this case, is the already present shortage of qualified personnel, in a

sector that continues to generate new jobs.

Finally, the last point, has the aim to mitigate the supply risks associated with the need for widespread deployment of solar energy in the EU. An alliance between industry players, research institutes, consumer groups, and other PV stakeholders would enable coordination of investment to enhance EU manufacturing of innovative and sustainable products and promote supply diversification by encouraging heterogeneous importation (see par. 3.3).

As well, in order to accelerate the development of renewables, the European Commission has recently put forward a proposal for a **new temporary emergency regulation** which introduces the presumption that RES plants are of over-riding public interest. This would allow the new authorisation procedures to benefit, with immediate effect, from a simplified assessment for specific derogations provided for by EU environmental legislation. The Commission also proposes a maximum deadline of one month for the authorisation of PV systems on buildings and related accumulations and connections to the grid. These plants, in addition, are exempted from the need to carry out certain environmental assessments.

To support the spread of small-scale plants, the concept of "positive administrative silence" is introduced in the permit granting procedures.

Permitting for repowering interventions is also streamlined. Environmental assessments must be limited to any impacts resulting from the modification or expansion of the original project and be completed within 6 months. In the event that the increase in power does not exceed 15%, a simplified procedure is provided for connections to the network. Three months, on the other hand, would be the maximum limit to be able to authorise heat pumps, whose connection to the network would be simplified for smaller technologies.

The REPowerEU, in an effort to improve energy savings, also devotes a section on energy efficiency and, in short, aims to strengthen long-term energy efficiency measures by raising the energy efficiency target within the "Fit for 55" package of the European green deal, from 9% to 13%. In other words, the plan proposes to further lower energy consumption of at least 13% by 2030, compared to the Reference Scenario (750 Mtoe in final and 980 Mtoe in primary energy consumption, respectively).

3.3 EFFORTS TOWARDS GREEN SUPPLY CHAINS AND THE UNION'S STRATEGIC AUTONOMY

3.3.1. Raw materials and their role in clean energy transitions

Raw materials are essential for the European economy. They are used in the manufacturing processes of a broad range of goods and are at the basis of numerous strategic industrial value chains across Europe. **Specific raw materials are key inputs in the production of technologies required for the green transition**, such as batteries, solar panels or wind turbines. Moreover, as innovation pushes down the overall production costs of such technologies, raw materials become an important element in their cost structuring. For instance, raw materials account for about 50-70% of total battery costs. The increase in demand for critical materials due to energy transition requirements and to the industrialisation of major economies has been raising concerns on the reliability of supply. As well, recent geopolitical developments have been fueling these concerns.

While the Covid-19 crisis took a heavy toll on fuel consumption, green technologies have shown some resilience. **Investments in clean energy reached $755 billion in 2021 according to Bloomberg.** However, as described in the *World Energy Outlook* Sustainable Development Scenario (SDS), putting emissions on a path in line with the Paris Agreement will require a significant boost in clean energy technology deployment. As already mentioned, specific raw materials play a fundamental role in the production of such technologies. Indeed, while many clean technologies, such as solar PV plants and wind farms, do not require fuel to operate, they do require a high quantity of raw materials for their construction. Thus, **the green transition involves a change of paradigm from a fuel-intensive to a material-intensive system.**

The IEA Report, "*The Role of Critical World Energy Outlook Special Report Minerals in Clean Energy Transitions*", specifically focuses on minerals and their role in the transition to a clean energy system. As stated in the Report, during the last decade, **due to the deployment of renewables**, **the average amount of minerals needed for a new unit of power generation capacity has increased by 50%.** Different clean energy technologies require different types of minerals for their construction (Tab. 3.2). **Lithium, cobalt** and **nickel** are indispensable for electric vehicles (EVs) and battery storage. **Rare earth elements** also play an essential role in the manufacturing of wind turbines and EVs. **Copper** is used in most electricity related technologies. All this implies a strong, clear link between clean energy and minerals, **as the demand for batteries, solar panels and wind turbines rises, so does the demand for many minerals.**

The dependency of the energy sector on minerals is set to intensify with the deployment of clean technologies, driven by the ambitious target of reaching net-zero emissions by 2050. The 2022 *World Energy Outlook* has analysed three possible scenarios: the Stated Policies Scenarios (STEPS) reflects the trajectory

Tab. 3.2 Critical mineral needs for clean energy technologies

Source: The Role of Critical Minerals in Clean Energy Transitions, IEA (2022)

	Copper	Cobalt	Nickel	Lithium	REEs	Chromium	Zinc	PGMs	Aluminium
Solar PV	●	●	●	●	●	●	●	●	●
Wind	●	●	●	●	●	●	●	●	●
Hydro	●	●	●	●	●	●	●	●	●
CSP	●	●	●	●	●	●	●	●	●
Bioenergy	●	●	●	●	●	●	●	●	●
Geothermal	●	●	●	●	●	●	●	●	●
Nuclear	●	●	●	●	●	●	●	●	●
Electricity networks	●	●	●	●	●	●	●	●	●
EVs and battery storage	●	●	●	●	●	●	●	●	●
Hydrogen	●	●	●	●	●	●	●	●	●

Relative importance of minerals for a particolar clean energy technology ● High ● Moderate ● Low

implicit in the current policy setting; the Announced Pledges Scenario (APS) supposes that government announcements and targets are fulfilled completely and on time, including the long-term net zero objective; and the Net Zero Emissions by 2050 Scenario (NZE) assumes that by 2030 a 1.5 °C stabilisation in the increase in global average temperatures will be achieved, along with widespread access to modern technology. **Looking at the demand for critical minerals employed in clean energy technology production, in the APS Scenario this demand will be 2.5 times higher by 2030 and will quadruple by 2050.** The NZE Scenario involves an even faster deployment of green technologies and, therefore, a demand for critical minerals four-times higher in 2030 and 2050 compared to 2021. In the NZE Scenario, lithium sees the fastest growth, while demand for cobalt, nickel and graphite also increases quite rapidly.

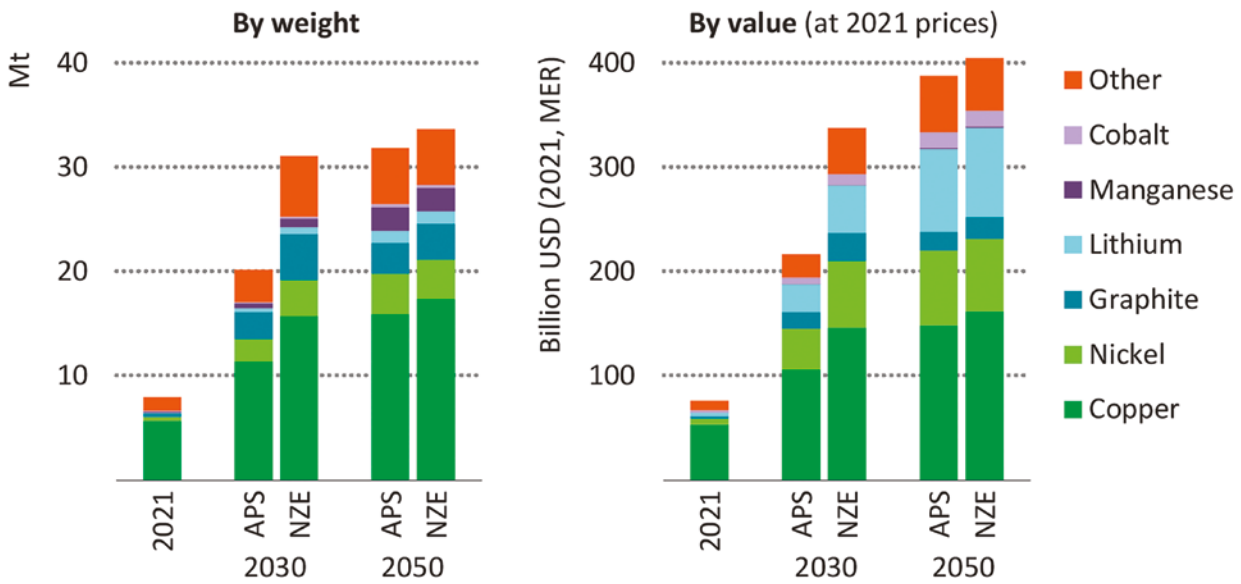
Sometimes assessments based on weights fail to fully capture the importance of certain minerals, so it may be useful to also consider their monetary value. Based on

the WEO 2022 analysis, **the value of critical minerals at 2021 prices will reach about $400 billion by 2050 in the NZE Scenario and slightly less in the APS.** It is worth keeping in mind that, as of today, coal is by far the largest source of revenue for mining companies, accounting for revenues which are ten times larger than those obtained from mineral production. However, according to IEA, energy transitions and phase-out policies are bound to reverse this situation.

The IEA Special Report on the role of critical minerals in clean energy transitions also assesses critical mineral demand under two main scenarios – the Stated Policies Scenario (STEPS) and the Sustainable Development Scenario (SDS) – which indicate the path consistent with the Paris Agreement targets. According to their analysis, **mineral demand from clean energy technologies is set to double in the STEPS scenario and quadruple in the SDS scenario by 2040**. About **half of this growth will be driven by the deployment of EVs and battery storage.** Over the period to 2040, mineral demand for production of EVs and battery storage increases by ten times in the STEPS scenario and by about 30 times in the SDS scenario. Once again, it is lithium experiencing the fastest growth. **Another major driving force of mineral demand are electricity networks, which account for about 70% of today's demand from energy technologies.** Demand

Fig. 3.38 Critical mineral demand by weight and value for clean energy technologies by scenario

Source: World Energy Outlook 2022



from low-carbon power generation shows a rapid growth in both scenarios as by 2040 it will double in the STEPS scenario and almost triple in the SDS Scenario. Wind and solar power also play a leading role in driving demand.

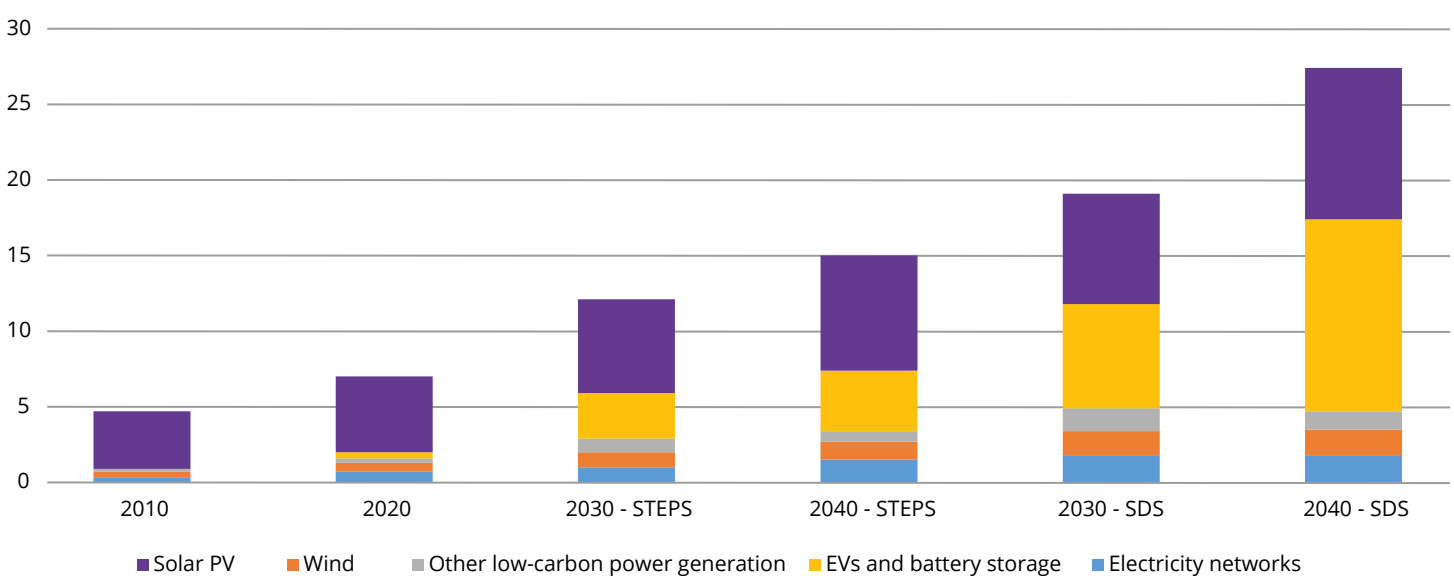
Until the mid-2010s, clean energy technologies accounted for a very small portion of total mineral demand. This scenario has rapidly changed in recent years and will continue to evolve due to energy transitions. In 2015, EVs and battery storage became the major consumers of lithium, surpassing consumer electronics and accounting for about 30% of total current demand. Clean technologies are rapidly becoming the fastest-growing component of mineral demand. In the 2040 SDS scenario, their share of total demand reaches up to over 40% for copper and rare earths, up to 60-70% for nickel and cobalt and almost 90% for lithium.

3.3.2. Stability and security of supply chains

It is clear how the dependence of the energy sector on raw materials and minerals is intensifying. In this scenario, **assuring the stability and security of supply is of crucial importance for the green transition** and for industrial resilience. Unfortunately, critical mineral extraction and processing is highly concentrated, even more so than for fossils fuels. It is not uncommon for a single country to account for more than half of the global

Fig. 3.39 Total mineral demand from clean energy technologies by scenario

Source: The Role of Critical Minerals in Clean Energy Transitions, IEA (2022)

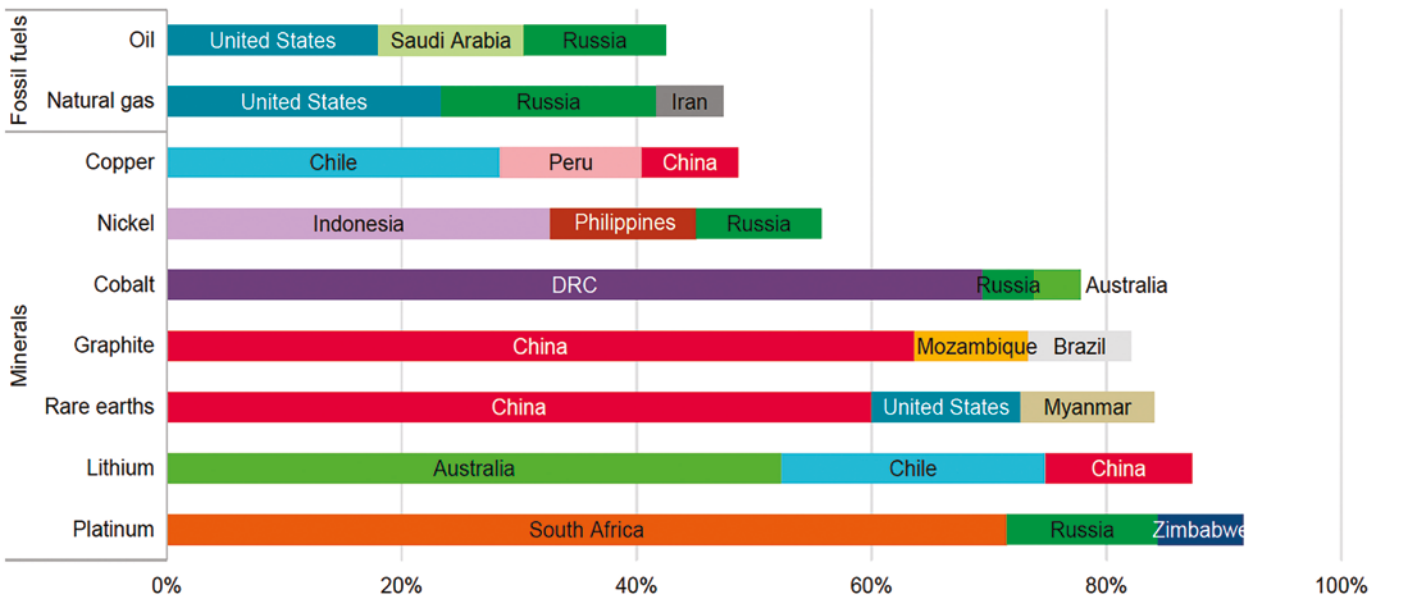


production of some key minerals. For example, according to the 2021 IEA Report, in 2019 **China produced 60% of the world's supply of rare earth elements and almost 70% of the world's graphite; the Democratic Republic of Congo produced 70% of the global supply of cobalt; South Africa over 70% of platinum; and Australia was responsible for the production of 55% of the world's lithium.** The production of copper and nickel is a little more diversified compared to the other key minerals, nonetheless, about 50% of the world's total supply is accounted for by three producing nations. China holds a near-monopoly also over the processing of several critical minerals, refining around 35% of the global supply of nickel, 50-70% of lithium, and cobalt, and 90% of rare earth elements (REEs).

This high degree of concentration poses concerns for companies that produce clean energy technologies, as their supply chains could very easily be affected by changes in regulations, trade policies, political instability and other events happening in the few producing countries. **A European Parliamentary study on the EU's supply of critical raw materials published in 2022, points out Europe's vulnerability related to REE supply shortages.** The reasons for such vulnerability are twofold. On the one hand, there are market forces at play, where demand for some minerals (neodymium and

Fig. 3.40 Share of top three producing countries in total production for selected minerals and fossil fuels (2019)

Source: The Role of Critical Minerals in Clean Energy Transitions, IEA (2022)

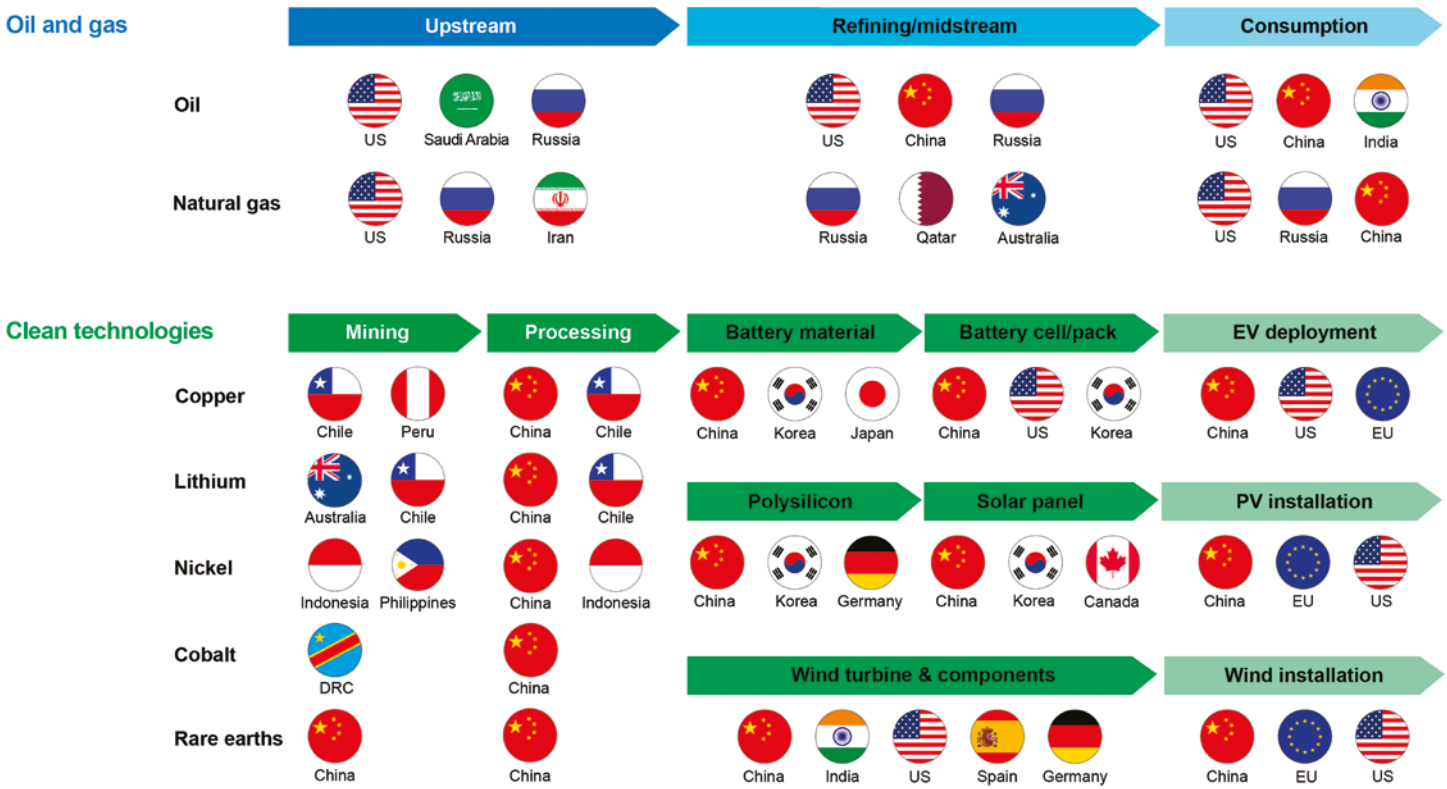


dysprosium, in particular) is expected to exceed supply by 2030. On the other, as already mentioned, China has almost complete dominance over the market of REEs. In 2010, following Japan's capture of a Chinese fishing boat, China imposed a two-month embargo on REE exports to Japan. In the same year, China imposed export quotas on REEs (quotas which were later declared illegal by the WTO), causing some prices to rise by 1000%.

Price volatility and supply chain disruption issues are not the only risks associated with critical materials and

Fig. 3.41 Indicative supply chains of oil and gas and selected clean energy technologies

Source: The Role of Critical Minerals in Clean Energy Transitions, IEA (2022)



clean technology production**. Supply chains for clean energy technologies are complex and may give rise to risks associated with the environmental, social and governance impacts of production processes and activities.** Efforts are required to align clean energy transition objectives to the public request for ethically and sustainably produced materials. Human rights' violations, corruption, child labour and loss of biodiversity are just some of the devastating impacts associated with mining and mineral processing. For example, in the Democratic Republic of Congo, which accounts for 70% of the global supply of cobalt, the surge in demand is fuelling artisanal mining and child labour by armed groups. In addition to the unacceptable ethical problems, incidents of corruption or human rights' abuses may cause governments to pause production, giving rise to supply risks.

3.3.3. European initiatives for the development of green supply chains and strengthening of strategic autonomy

Coordinated efforts are needed to further develop and **secure clean energy supply chains, making them resilient and ethically sustainable.** Looking specifically at the European Union, several initiatives are in place. The aim is to secure strategic supply chains which are key for energy transitions, foster research and innovation for material substitution, identify new opportunities and encourage efficient use of resources and recycling.

We have seen that some materials, more than others, can be considered of key importance for the deployment of clean technologies, but their production is highly concentrated. **To access many critical materials and minerals the EU relies on imports from non-EU countries.** Aside from a few limited cases of domestic production (such as France which provides 84% of the EU supply of hafnium), the European industrial sector is highly dependent on international markets. For example, **almost the entire EU's supply of rare earth elements (98%) is provided by China. The EU imports 98% of its borate supply from Turkey, 85% of its niobium from Brazil and 71% of its platinum supply from South Africa.** In addition, Europe is dependent on single EU companies for its supply of hafnium and strontium. Concentration of supply involves all kinds of risks which could potentially have devastating consequences on Europe's industrial sector. The risks are even higher considering that many of these materials have low substitution rates and are not easily recycled. To build resilience and secure access to critical raw materials, the EU is undertaking actions to diversify supply and ensure that markets are not distorted.

In 2011, the European Commission first published a **list of critical raw materials (CRMs) for the EU**. Since then, the Commission has updated the list periodically, reflecting both market and technological developments. According to the Commission, the importance of CRMs lies in **three key factors**: their link to all industries across all supply chain stages; their ability to foster technological progress and improve quality of life; and their role in the production of clean technologies. To determine whether a material is "critical" for the EU or

not, the Commission relies on different parameters. Two main parameters considered in the criticality assessment are economic importance and supply risk. The first aims at understanding the value of a material with regard to end-use applications and the value added (VA) of European manufacturing sectors. The second provides insight on the risk of a halt in the EU supply of the material.

The 2011 list of CRMs contained 14 materials. That number rose to 20 in 2014 and 27 in 2017. **The fourth and most recent list of CRMs for the EU contains 30 materials**. As compared to 2017, 26 materials remained on the critical list, and four materials – bauxite, lithium, titanium and strontium – were added for the first time (Tab. 3.3). Helium was taken off the list due to its decline in economic importance. According to the Commission, the list should help strengthen European industrial competitiveness, promote CRM production, its efficient use and recycling, increase supply risk awareness among EU countries, companies, and investors, negotiate trade agreements and foster research and innovation.

To efficiently address the many challenges linked to the procurement of raw materials, the Commission has also established the **European Raw Materials Alliance**. Its main objective is to improve resilience and increase strategic autonomy for the EU's rare earths and magnet

Tab. 3.3 Critical raw materials list (2020)

Source: European Commission

Antimony	Hafnium	Phosphorus
Baryte	Heavy Rare Earth Elements	Scandium
Beryllium	Light Rare Earth Elements	Silicon metal
Bismuth	Indium	Tantalum
Borate	Magnesium	Tungsten
Cobalt	Natural graphite	Vanadium
Coking coal	Natural rubber	**Bauxite**
Fluorspar	Niobium	**Lithium**
Gallium	Platinum Group Metals	**Titanium**
Germanium	Phosphate rock	**Strontium**

supply chains. More specifically, the alliance's activities aim at supporting the creation of sustainable innovation and infrastructure, promoting industrial production and strategic investment across specific value chains, implementing a Circular Economy of complex products, such as clean energy technologies, and supporting raw material industry capability. The alliance is open to EU countries, investors, research and technology organisations and any relevant stakeholders.

Apart from the one concerning raw materials, other industrial alliances have also been launched by the European Union. As a part of the **EU Solar Energy Strategy** (see chapt. 3.2) adopted in May 2022, the **EU Solar PV Industry Alliance** aims at supporting Europe's PV manufacturing industry to promote a massive deployment of solar energy and end EU's dependance on fossils fuels. Among other things, the alliance will foster the development of efficient and sustainable technologies and facilitate higher recycling efficiencies and circularity. It will work to attract private investments, analyse the availability of financial support, and promote dialogue among stakeholders and provide advice to Member States. European industry has already positioned itself along various parts of the solar PV value chain. It is particularly strong in the downstream segment of the chain, which concerns manufacturing of inverters and solar trackers and monitoring and control activities. However, efforts are needed to gain positioning in the upstream segment, which includes important manufacturing and assembly steps. Indeed, the fact that Europe contributes only minimally to the manufacturing and assembly steps of the chain, together with the near-monopolistic role played by one country at the component stage, puts Europe in a position of risk in the case of supply chain disruptions.

The **Renewable and Low-Carbon Fuels Value Chain Industrial Alliance** was set up on 6 April 2022 and focuses on increasing the production and supply of renewable and low-carbon fuels specifically in the aviation and waterborne transport sectors. Its main objective is to make sure that such sectors have sufficient access to renewable and low-carbon fuels, as to reduce their greenhouse gas emissions by 90% by 2050.

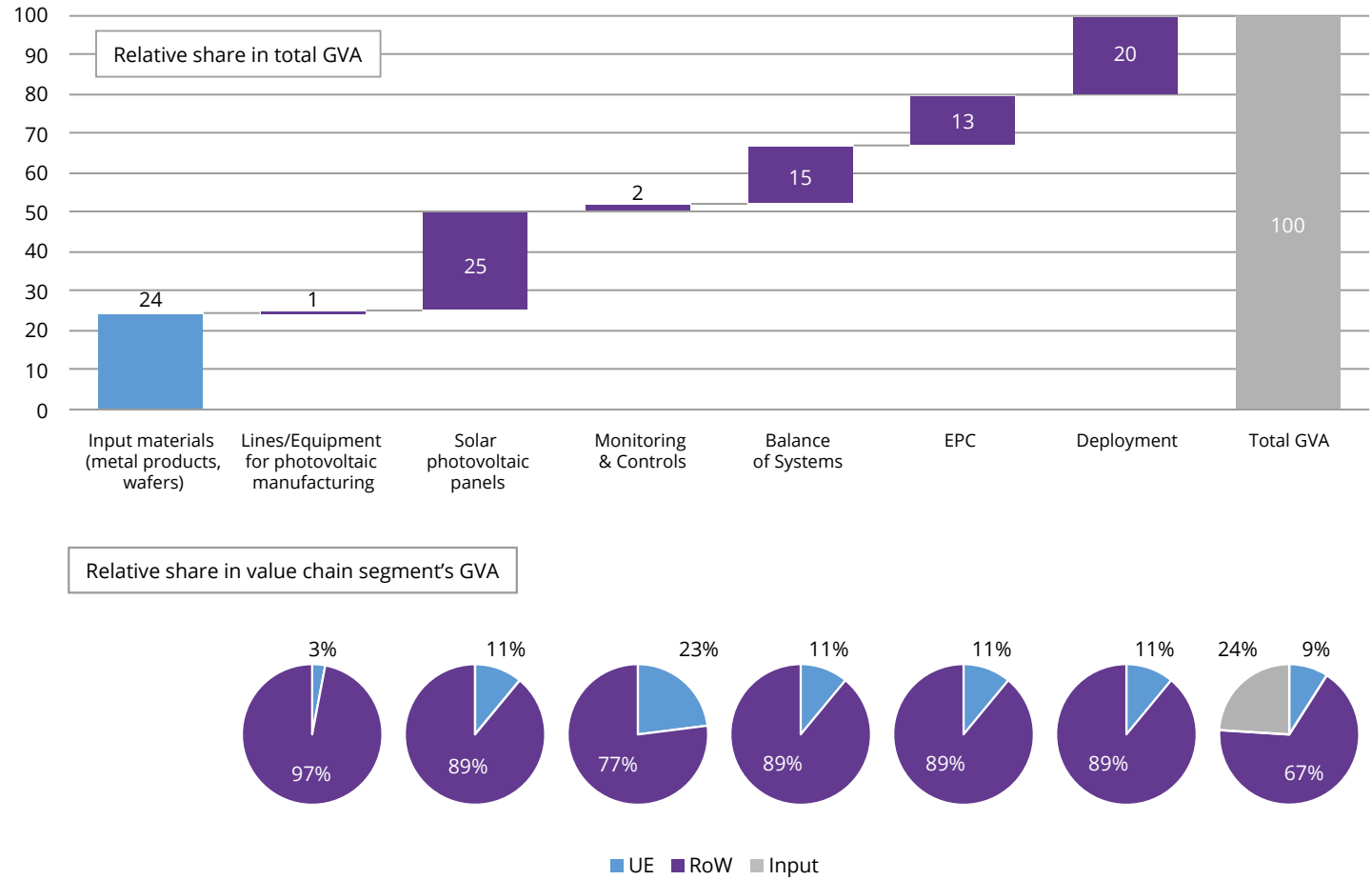
The **European Clean Hydrogen Alliance** was launched in July 2020 to support the deployment of clean hydrogen technologies and accelerate the decarbonisation of industry and heavy transport. Green hydrogen is expected to play a major role in the reduction of global emissions by 2030. It can serve as a replacement for fossil-based hydrogen in industrial processes and transport, and it can also be used to create new industrial products, such as green steel and fossil-free green fertiliser. With the REPowerEU strategy, the European Union has quadrupled its green hydrogen targets for 2030, to 10 million metric tons (MMt). The European Clean Hydrogen Alliance brings together public and private stakeholders and focuses on the requirements and main barriers to large-scale deployment of clean hydrogen technologies. In this context, the alliance has also published a pipeline of viable projects to facilitate investments and integrate hydrogen value chains. The pipeline includes more than 750 projects that touch all segments of the value chain, from hydrogen

production and distribution to its application in industry, transport and building sectors, and energy systems.

Another strategic industrial alliance is the **European Battery Alliance (EBA),** launched in 2017 with the purpose of transforming Europe into a global leader in the production and use of batteries, which serve as key enablers of clean technologies and are thus crucial for the green transition. To this end, the alliance promotes the development of a competitive and innovative battery value chains in Europe. As stated in Europe's strategic

Fig. 3.43 Breakdown of Gross Value Added throughout solar PV value chain

Source: Guidehouse Insights, 2020



action plan for batteries, the EU has identified six value chain priority areas:

- ensure secure and reliable access to raw materials needed for battery production;
- support, through the EIB or the state aid IPCEIs, battery cell manufacturing and other investments;
- foster research and innovation with the aim of strengthening industrial leadership;
- secure a highly skilled workforce along the entire value chain;
- support the sustainability of the battery cell industry;
- ensure framework consistency.

Where state aid schemes are concerned, the concept of **important projects of common European interest (IPCEIs)** allows Member States to intervene with the implementation of national investments in case of systematic market failures or societal challenges. The first guidelines for supporting and assessing collaborative projects which promote common European interests – that is IPCEIs – were first published by the European Commission in 2014. The guidelines were updated in 2021 through the adoption of a communication which aimed at better aligning IPCEI criteria to Europe's political priorities, especially considering the new challenges posed by the twin digital and green transition and the acquirement of strategic autonomy. According to the Commission, IPCEIs should demonstrate a common European interest, contributing to the achievement of one or more EU political priorities. The competition bias caused by IPCEIs should be outweighed by their positive impact, with spillovers reaching beyond the specific sector or enterprise that is being supported. Starting from 2021, IPCEIs projects have had to include at least four Member States and be characterised by breakthrough research and innovation.

IPCEIs can play a significant role in strengthening competition and industrial policies in the EU. The 2021 communication has amplified the reach of initiatives, facilitating the participation of more Member States and industrial players. As of February 2022, the Commission had approved three IPCEIs. One on **microelectronics**, worth up to €1.89 billion (between 2018 and 2024) involving five Member States, and another **two projects on batteries –** the first run by seven Member States and worth up to €3.2 billion (2019-2031), the second run by 12 Member States and worth 12.9 billion (2021-2028).

Looking at the former of the two battery IPCEIs, this seeks to develop a full battery value chain, enhancing Europe's strategic advantage through the development of new technologies and processes. The seven MSs involved and that will provide the funding for the project are Belgium, Finland, France, Germany, Italy, Poland and Sweden. The project involves 17 direct participants, including small and medium-sized enterprises (SMEs). Specifically, this IPCEI supports the development of particularly **innovative technologies for lithium-ion batteries** that last longer and are more efficient, safer and sustainable than those currently available. Research and activities will concern all segments of the battery value chain, starting from mining and processing to the recycling of used batteries. Project

participants will specifically focus on four areas: 1) raw and advanced materials; 2) cells and modules; 3) battery systems; 4) repurposing, recycling and refining.

The second IPCEI on batteries – the **European Battery Innovation (EuBatIn)** – can be considered complementary to the first. It involves Austria, Belgium, Croatia, Finland, France, Germany, Greece, Italy, Poland, Slovakia, Spain and Sweden. The project has 42 direct participants, including SMEs and start-ups. In addition, other IPCEIs on clean hydrogen, cloud and health are currently being explored.

CONCLUSIONS AND POLICY RECOMMENDATIONS

CONCLUSIONS AND POLICY RECOMMENDATIONS

Technological supremacy has become the key issue on which geopolitical competition across states of the world is being played out. Product and service innovations are becoming increasingly crucial for countries in order to maintain their dominance in the global arena.

The main areas where the technological competition is taking place in the **digital realm** are in **the transition to 5G**, enabling Internet of Things technologies, **artificial intelligence** applications, **cloud computing and the semiconductor supply chain**. In these fields, some common trends can be highlighted. In particular, dependence from non-European actors is an issue that requires to be promptly tackled, as new crises arise and innovative technological domains emerge. Indeed, in a fierce global competition, according to current data and trends, **the European Union is running the serious risk of lagging behind the other major world economies in terms of both technological development and industrial competitiveness**.

Much of the EU's current and future competitiveness depends on the capacity and speed of the development of **5G networks,** the enabler of the most sophisticated and revolutionary digital services and technologies.

5G technologies seem to play a marginal role in the technological mix of mobile telephony in Europe, with stark differences to North America, but is expected to markedly increase by 2025. However, investments by mobile network operators are quite unbalanced, as North America allocates 66% more resources than European competitors.

The **European regulatory framework on 5G is very articulated and focused on two objectives - on one hand, accelerating the development of networks and, on the other, ensuring maximum cybersecurity.** Considering the complexity of the regulatory framework and the existence of numerous regulatory acts and Commission proposals, one of the main challenges is to ensure a harmonised, clear ecosystem that does not represent an obstacle to innovation and investment but, on the contrary, favours the rapid deployment of 5G networks.

Against this backdrop, the classic economic policy question related to the direction to take at European level seems to be coming back into vogue. This involves choosing between encouraging competition and the existence of a larger number of players, or allowing the emergence of larger players who are able to compete, especially in terms of investments, with the overseas giants. Finding a sustainable compromise between these two alternative scenarios could be crucial for the development of the field in the EU.

For what concerns **artificial intelligence (AI)**, it seems likely that those who will dominate its development will largely dictate global technology standards in the coming years.

The **AI Act** is vital in supporting the development and deployment of AI systems, which are so important in global competition.

The European Union also seems unable to retain its top

talent and, despite being the area of origin of 18% of top-level researchers, actually employs only 10% of them, while the US attracts the majority. This means that the US has become fertile ground for AI-based innovation.

While Europe continues to lag behind China and especially the United States on the **investment front**, on the **regulatory front** it aims to be a global model, as well as for personal data protection. The risk-based approach is certainly reasonable but it is necessary to carefully define and limit the perimeter of high-risk applications to avoid the **risk of discouraging investment in Europe**.

Moreover, in order to scale up innovation in the area of AI, the EU should undertake stronger efforts to ensure attractiveness of its organisations and retain higher-level expertise within the area. This could be done by increasing investments and resources in research but also pooling them through impactful European-wide projects and deploying more efforts to encourage EU companies to adopt AI.

The **Data Act**, whose adoption procedure is still in its initial stages, aims to remove, through the harmonised set of rules at EU level, barriers to accessing data for both consumers and businesses. To achieve this goal, the proposal for a regulation establishes common rules to regulate the sharing of data generated by the use of related products or services (e.g., IoT, industrial machines), to ensure fairness in data sharing contracts and to allow public bodies to use data held by businesses in case of exceptional need (e.g., public emergency). The proposal also introduces new rules to facilitate switching between cloud service providers and other data processing services and puts in place safeguards against the unauthorised international transfer of data by cloud service providers. This is a highly complex proposal that requires a series of reflections on the **scope of the application of the proposal, the conditions under which data should exceptionally be provided to public sector entities, restrictions on gatekeepers, and exemptions in favour of SMEs**.

Given the crucial need for semiconductors for technological development and the global production chain, the geopolitical relations among states takes on a fundamental importance.

The proposed **Chips Act** aims to strengthen the European semiconductor industry and increase the transparency of the semiconductor chain in the logic of gaining greater EU independence. It is a multi-faceted proposal revolving around the **Chips for Europe initiative** which enhances and encourages the development of integrated production facilities and open EU foundries, and outlines a major coordination mechanism between Member States and the Commission imposing a balance between the need to enhance the European role and that of guaranteeing the flow of competitive and commercial dynamics.

Given the present market scenario and supply chain, the **European Union, although already making an effort to increase its role, cannot help but depend on non-European players**.

In view of the delicate relations amongst states, more attention should be given to the **relations with controversial countries** and finding a decent

compromise between respecting European values and guaranteeing the grounds for a functioning supply chain. In this regard, further reflection could be useful to understand the level of effective competitiveness that the European industry could reach in the chips market, for two reasons. Firstly, given the mandatory integration of the chips supply chain, it will be important to accurately select those key partners even in times of geopolitical crisis and, secondly, it will be necessary to create an EU industry which can effectively compete with international competitors, even when public funding comes to an end The generous public support schemes envisaged by the EU, but also some important countries, such as the US, could result in **overcapacity risks in the long term**, at least in parts of the value chain.

Technological sovereignty in the **pharmaceutical sector** is not only a matter of competitiveness. A resilient and innovative pharmaceutical production **is key to providing European citizens with appropriate health assistance**, even during times of emergency, and by addressing previously unmet medical needs.

Up to now, Europe has been well positioned in international pharmaceutical competition. Data shows that the volume of European exports of high-value medical products has no equal worldwide. At the same time, this is being currently threatened by the rise of the Asian economies, which are able to be more cost-effective and increasingly involved in innovation. Far from proposing that the EU should be totally self-reliant and absent from global value chains, aiming at strategic autonomy within the international markets is a priority. In so doing, Europe should set the pace for a worldwide highly innovative research environment for pharmaceutical products.

By retaining knowledge and investment in R&D activities, **Europe can take on a leading role in fields where scarce scientific and clinical knowledge can finally addressed**. However, such a far-reaching goal cannot be achieved without **a proper regulatory framework** guaranteeing, at the same time, affordability of healthcare and the encouragement of private investments.

The **EU Pharmaceutical Strategy** paves the way for the transformations to come, by confronting the most pressing challenges of our time. **Incentivising investment in research areas suffering from market failures is key to safeguarding public health**. Therefore, support for research and development could **boost the number and quality of clinical trials**, as well as **guarantee private involvement in fighting rare diseases**. At the same time, careful consideration of ongoing health trends should translate into **proper planning and foster meaningful research and innovation efforts**, and in doing so, Europe will be better equipped to deal with any future emergencies.

Continuing to protect **Intellectual Property Rights (IPRs)** globally would also be pivotal. The EU has historically led in shaping global IPR policy and best practices, while providing a model to countries looking to boost their innovation ecosystems. Most recently, the EU has had a strong voice at the World Trade Organisation for IPR rights in the **development and production of Covid vaccines**, challenging countries seeking to put

narrow industrial policy before IPR enforcement.

However, the EU could soon turn away from its IPR leadership role. In a bid to increase access to innovative medicines, the Pharmaceutical Strategy is considering **changes that could erode many of the regulatory protection measures and exclusivities regarding patents** necessary for a thriving innovative biopharmaceutical sector.

Energy is at the heart of the crisis which is severely impacting families and businesses. The start of the war in Ukraine and the confrontation between Russia and the EU, long linked by solid supply relationships, has shown **the vulnerability of the European energy system** where Russian supplies are concerned. **Gas prices have reached historic highs**, at ten times higher than pre-crisis levels, placing extremely heavy energy spending burdens on the European economic system. The volatility of prices, faced with the progressive drop in flows from Russia, has given rise to the concern of being able to adequately satisfy the demand for energy in the winter months. Faced with this state of affairs, the European institutions and the Member States have adopted **extraordinary measures**, giving support to the population and businesses with a very wide range of interventions and for several hundred billion euros. At the same time, **considerable efforts have been made to diversify supplies, trying to maximise LNG input and supplies through the remaining pipelines, and to fill storage facilities**.

When writing (midNovember 2022), the fact that gas imports continued at high volumes despite the drastic cut in Russian supplies, the full achievement of storage targets, the considerable drop in gas consumption, especially in European industry, and the mild weather which reduced the demand for heating has led to a drastic drop in prices after the peaks in August. However, the introduction of **further extraordinary measures is necessary to return to a situation of normality, face new possible crisis situations and strengthen the resilience of the EU energy system.** In several respects, they represent an important evolution compared to the policy lines on which the energy union has been built in recent decades. The **use of joint purchasing, more stringent energy demand containment objectives, gas price correction mechanisms and the market design reform** are among the main regulatory developments that will require a considerable effort for more in-depth study, to be discussed and implemented in the coming months.

The **reform of the electricity market design** is a useful way to decouple the price of electricity from that of gas and ensure that consumers benefit more from the growing share of renewable generation. The RES, in fact, on the basis of increasingly ambitious climate policies, are undergoing a continual development throughout Europe. However, achieving the **Fit for 55 and climate neutrality goals** still requires much more effort. There is a wide gap between the trends, albeit positive ones, based on current policies and the targets set for the development of renewable capacity, the penetration of RES in the electricity mix and final consumption, the reduction of energy

consumption, etc. They require considerable skills in the implementation in the Member States in a short time of the policies undertaken with the Fit for 55 package and with **REPowerEU.** For this, it is necessary to act on numerous fronts. Investments in new renewable capacity, both for electricity and for renewable and synthetic gases, must be accompanied by **market interventions** (as well as the reform of the electricity market, there are, for example, the further development of Contracts for Difference, the spread of Power Purchases Agreements, the enhancement of demand-side flexibility). Furthermore, **extraordinary simplification measures** must be introduced, tools for punctual identification of the 'go-to areas' and **incentives** for the dissemination of electrification and decarbonisation technologies for final consumption.

In addition, there is a need to create and strengthen **European industrial partnerships and alliances in green supply chains.** The energy transition underlies creation of the European open strategic autonomy. The **high concentration of critical mineral extraction and processing** in other areas of the world, as well as the heavy dependence on international markets for technologies required for the green transition, such as solar panels, represent a factor of vulnerability for European industry which runs the risk of becoming even more pronounced in the future. The global demand for raw materials and green technologies will be subjected to severe stress in the coming years and the post-Covid economic recovery has already highlighted evident **bottlenecks along the supply chains**. This is why it is essential for the European Union to equip itself with its own cutting-edge **production capacity** in these industries. Expanding European alliances in crucial sectors such as raw materials, batteries, hydrogen and Renewable and Low-Carbon Fuels, as well as approved IPCEIs, bode well for building and strengthening competition and industrial policies in the EU. European industry, which has always been at the forefront in the world, has all it takes to win this challenge.

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