

# Site Selection for life sciences companies in Europe

2024 edition

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## **Foreword**

#### Smart site selection for sustainable value chains

#### Dear readers,

As investor and government scrutiny grows, life sciences companies are under growing pressure to meet Environment, Social and Governance (ESG) requirements. This is particularly relevant in Europe, where the European Union (EU) has launched the European Green Deal (EGD) in its quest to become the first climateneutral continent by 2050 and to reduce net greenhouse gas emissions by at least 55% by 2030. Smart site selection can help companies choose locations for expansion that are both economically efficient and support their ESG goals.

We observe a trend in life sciences and more widely towards strategic location of key value drivers at sites across Europe that offer favorable infrastructure and regulatory, governance, social, economic and fiscal conditions that not only match overall business and innovation ambitions, but also support the transformation of value chains towards sustainability.

From a purely environmental perspective, key value drivers such as manufacturing (of active pharmaceutical ingredients or finished products), research and development, distribution or headquarters impact a company's ability to achieve decarbonization goals in different ways. For example, the production of complex biological ingredients or finished products presents a greater environmental challenge than the operation of centralized headquarters.

However, when social and governance issues are integrated into the site selection process, other key value drivers are also affected. Locating headquarters or distribution operations in countries where good governance models are less strictly enforced can create

reputational risk. Increasing the number of women in senior management may be challenging in a country where women are underrepresented in leadership or childcare is prohibitively expensive.

For this report, we have compiled data from a variety of sources to help life sciences companies considering a European location to gain an overview of the advantages that different options can offer in meeting ESG objectives.

As with previous reports, this edition of our Site Selection series, also contains information on other relevant developments for life sciences in Europe, such as national life sciences strategies and access to public funding for manufacturing and R&D.

We hope you will find this report useful and welcome your comments and questions.



Jon Haynes

EMA Head of
Life Sciences



André Guedel

Head Site Selection
Services

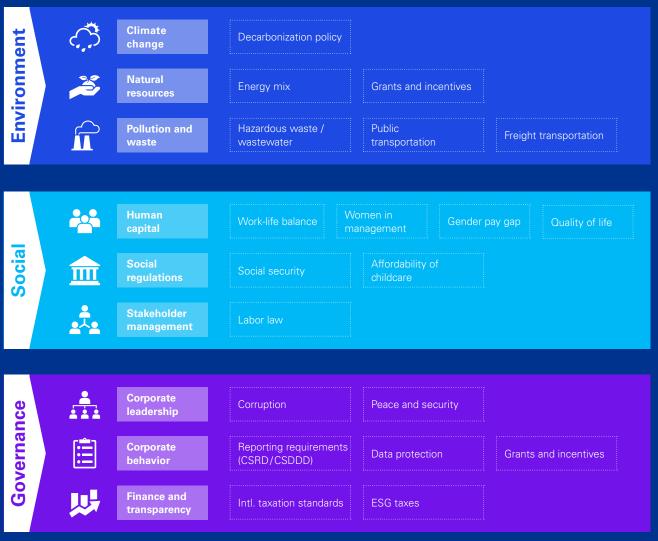
# Site selection factors that improve ESG ratings

ESG is a framework that helps companies track and promote sustainable and ethical standards in three key areas: environmental, social and governance. The environmental aspect focuses on how a company impacts the natural environment, for example by reducing emissions or practicing sustainable resource use. The social aspect looks at how a company interacts with its employees, suppliers and the community, including issues such as diversity and inclusion. Finally,

governance is about how the company is managed, including executive remuneration, compliance with laws and regulations and transparency to stakeholders.

In this section of the report, we look at how smart site selection can support social and environmental sustainability and governance by providing frameworks that allow or incentivize companies to strengthen their ESG performance.

#### Parameters related to ESG Factors



Source: KPMC

# **Environment**

Large European infrastructure projects, ranging from highways to rail freight systems, from public transport to energy infrastructure, from waste management to wastewater treatment, are still mostly organized and financed at the national level. Buying green energy across borders is very complex. If a company is trying to reduce its carbon footprint or ensure that waste and wastewater are properly treated at a new manufacturing site, it is important to understand what a target country or location can offer in this regard.



#### **Energy infrastructure**

The life sciences industry – characterized by its large energy requirements for complex manufacturing and R&D operations and the maintenance of controlled environments – faces high operating costs and needs to minimize its carbon footprint<sup>1,2,3,4</sup>. The life sciences industry is increasingly demanding renewable energy, but pricing and accessibility varies significantly among European countries.

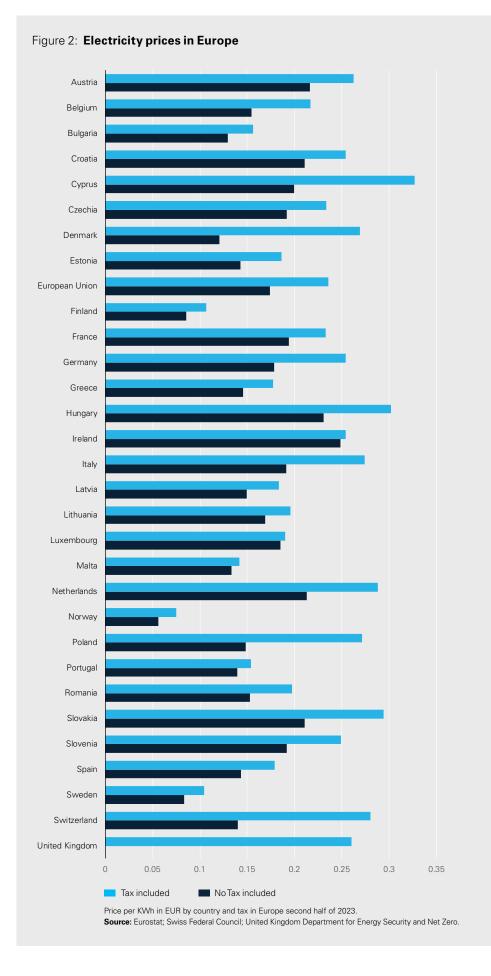
Europe's energy landscape is remarkably diverse, influenced by factors such as geography, weather patterns, political dynamics and economic developments.

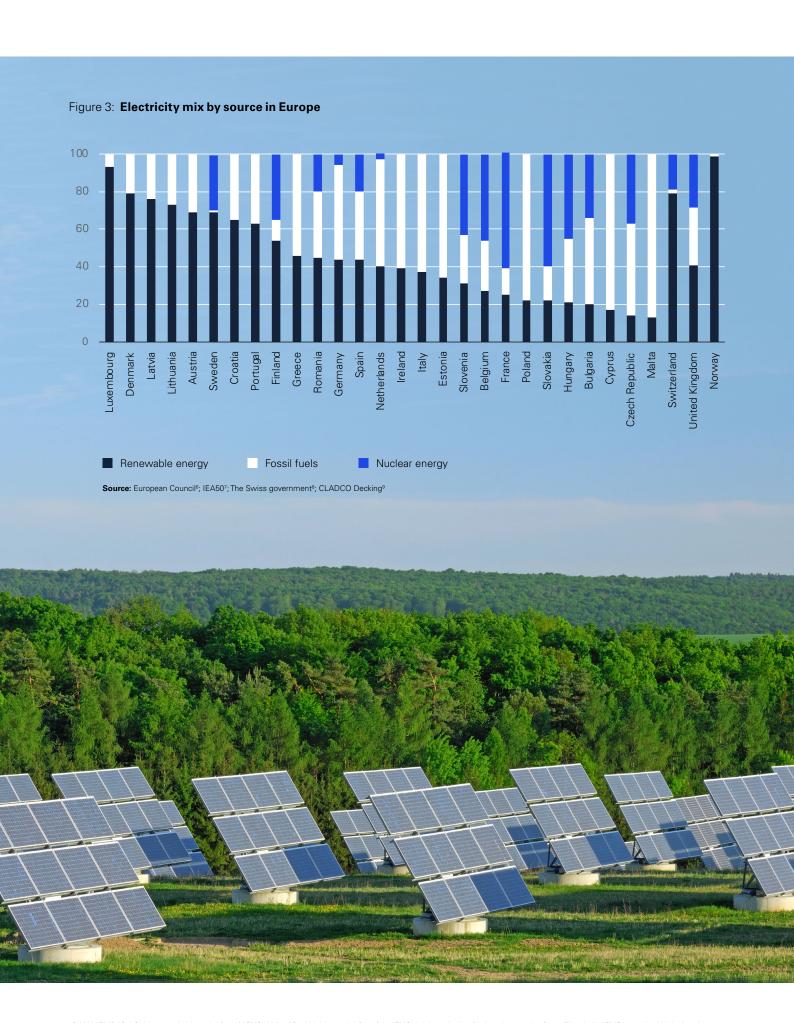
Countries rich in renewables, like Sweden with its wind and hydro or Spain with its solar power, have lower energy costs and lead the field for clean energy. Countries reliant on traditional sources face higher costs for renewable energy.

When evaluating new sites for energy intensive activities it is important that energy management of a company's new operations is aligned with its sustainability goals.

Besides differences in electricity prices between European countries, there is also variation in the composition of the energy that businesses and households can access directly from their outlets<sup>5,6,7,8,9</sup>.

One possible strategy to mitigate price and supply risks for green energy is the conclusion of power purchase agreements (PPAs). Prices for PPAs can vary significantly per country<sup>10</sup>. For details, see the appendix.





#### Hazardous waste management

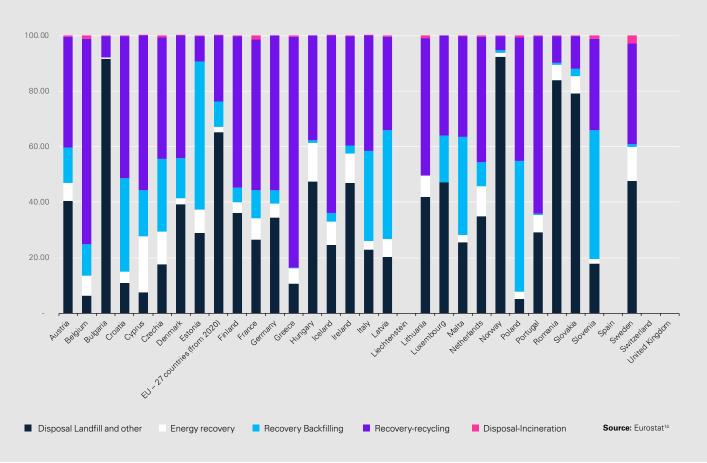
Effective management and treatment of medical, pharmaceutical and chemical waste is critical in the life sciences sector, particularly given the hazardous nature of such waste, which includes toxic drugs, radiological hazards and dangerous micro-organisms.

Approaches to managing this waste vary across Europe. Germany, for example, is a leader in the treatment of hazardous waste and has extensive waste-to-energy (WtE) infrastructure, demonstrating a robust approach to minimizing landfill and recovering energy from waste<sup>11,12,13</sup>. France joins Germany in its commitment to strategic investment in WtE facilities. This positive signal from two major economies demonstrates Europe's shift towards sustainable waste management and energy recovery<sup>15</sup>.

However, the variation in municipal waste recycling rates across Europe – with leaders such as Italy and Belgium setting high standards – points to disparities in waste management efficiency and the adoption of sustainable practices<sup>16</sup>.



Figure 4: Waste treatment by type of recovery and disposal





#### Industrial wastewater management

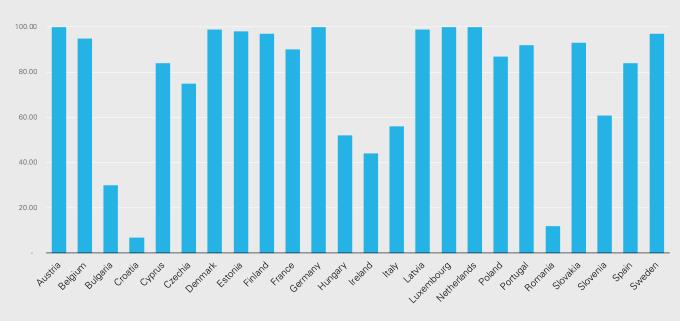
The management of industrial wastewater is a key issue for the life sciences sector in Europe in the context of managing the environmental impact of operations<sup>15</sup>. Wastewater management need to be tailored to allow a focus on compliance with local and EU regulations<sup>16</sup>.

At the EU level, the Urban Wastewater Treatment Directive (UWWTD) relevant for life sciences companies alongside various guidelines, including<sup>17</sup>:

- Chemicals management under REACH
- Emissions control under the Industrial Emissions Directive: Applying Best Available Techniques (BAT)
- Water management and reuse according to Regulation (EU) 2020/741
- Water Framework Directive
- Industrial Emissions Directive (IED)
- European Pollutant Release and Transfer Register (E-PRTR)<sup>18</sup>.

Figure 5: Proportion of urban waste water that meets all requirements of the UWWTD in urban areas in Europe

The graph shows the percentage of urban waste water in Europe that meets all standards of the UWWTD, including collection and biological treatment to eliminate nitrogen and/or phosphorus in complying urban areas<sup>19</sup>



Source: WISE-Freshwater<sup>20</sup>

## **Environmental risk management for life sciences companies**

Zurich Resilience Solutions (ZRS), the risk advisory unit of the Zurich Insurance Group, helps organizations to build resilience and long-term business value through their risk management expertise, data-driven insights and advisory services.

A key exponent of ZRS is their global Climate Resilience practice, comprised of climate data scientists and specialized risk consultants who work with customers to identify climate risks, adapt their physical assets and future-proof their operations.

Proactively managing climate change-related disruptions - as well as those triggered by current natural hazard events – throughout the whole supply chain is particularly important for the life sciences industry. Ideally, such

considerations are incorporated at the site selection phase of a project through a detailed and dedicated assessment.

Current natural hazard levels, and their evolution under different climate scenarios and at various time-horizons. are key components in site selection, not only from an exposure perspective, but also to ensure the necessary measures are in place; from site layout, to design of buildings and processes to selection of the supply chain.

The table below provides examples of how the outputs of these analyses can be used to consider climate risks throughout the value chain at the site selection phase of the due diligence process.

Figure 6: Environmental risk management for life sciences companies

Indu	stry-specific vulnerabilities	Suggested adaptation measures
	Buildings	<ul> <li>Enhance protection measures (engineering &amp; management) to reduce likelihood or impact of extreme events, especially at sites with high criticality processes or specialized equipment.</li> <li>Design buildings beyond building code requirements, considering local conditions, building function, and extended design life (typically 30 years).</li> </ul>
	Workforce	<ul> <li>Assess risk to workers under local heat or drought conditions and prepare requisite management actions or safety investments, such as improved building insulation, efficient cooling systems, or reviewing worker health and safety provisions.</li> </ul>
Manufacturing	Service interruptions	<ul> <li>Assess and adjust business continuity plans including considerations of the site and the local area. Consider working with the local authorities to assess and improve infrastructure, e.g. site access, energy availability. Triggers for such disruption can be any peril, from acute (wildfires, floods, windstorms, etc.) to chronic (sea level rise, coupled with increased windstorms, leading to higher inland flooding).</li> </ul>
	Water	<ul> <li>Assess and enhance site water risk management, by identifying water source dependencies (river, ground water, etc.), including water risk in business continuity plans for operations, working with local authorities and community for water access and management. Higher risk of water availability during drought and heatwave conditions.</li> </ul>
	Waste	<ul> <li>Include wastewater and water treatment plants in the site acquisition risk assessment process, specifically natural hazards and climate change-impacts. Increased heat or flood events can impact efficiency of such systems.</li> <li>Install early warning and monitoring systems for water quality.</li> </ul>

#### Figure 6 (continued):

#### Environmental risk management for life sciences companies

Indu	stry-specific vulnerabilities	Suggested adaptation measures
Manufacturing	Energy	<ul> <li>Increasing heat places excessive demand on energy supply. Identify type and locations of existing energy sources and include these in the risk assessment.         Consider their reliability and the potential impact of disruption at sites. Response (recovery time) to historical natural hazard events is a good source of information, as this is publicly available information.     </li> <li>Establish redundancies for energy supply, e.g. emergency generators</li> </ul>
Supply	Rawmaterials	<ul> <li>Assess extreme weather vulnerability of critical suppliers' sites and consider joint strategic planning for long-term resilience to climate change.</li> <li>Assess the impact of climate change on livestock and plant life (impact, e.g. on yield, or health)</li> </ul>
ıtion	Transport	<ul> <li>Plan for extreme-weather-related interruptions on transport routes, e.g. heat or flooding on land transport routes, sea level rise on ports, reduced water levels in rivers due to drought, etc.</li> </ul>
Distribution	Storage	<ul> <li>Increase traceability in the distribution chain to aid product tracking and assess potential damage in case of extreme events.</li> <li>Assess transport infrastructure and storage facilities for climate resilience and improve protection from possible disruptions.</li> </ul>
ımers	Industrial buyers	<ul> <li>Identify opportunities for closer engagement with customers in regions that are expected to be impacted by changing climate, or customers supplied by critical plants to better understand their own resilience.</li> </ul>
Consumers	End consumers	• Use insights gained from location-specific climate risk assessments to work with local consumer groups on changing preferences, e.g. considering potential product diversification.

Source: Zurich Resilience Solution, Zurich Insurance

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#### **Transportation**

The implementation of sustainable and innovative means of transport plays an important role in the EU's energy and climate objectives<sup>21</sup>. The focus is on the quality and expansion of the transport network and the importance of affordable pricing to encourage the use of public transport. Countries such as Luxembourg, Germany and Austria have introduced specific climate passes to make public transport more affordable.

Figure 7:

#### Affordability of public transport in Europe

The table ranks the affordability of public transport tickets and the availability of climate/network passes, considering climate/network passes, full-price season tickets, social discounts and VAT.

Country	Points per country according to Greenpeace	Ranking in Europe
Austria		
	81	3
Belgium	29	12
Bulgaria	0	30
Croatia	2	28
Cyprus	63	5
Czech Republic	40	11
Denmark	10	16
Estonia	45	10
Finland	5	21
France	5	21
Germany	69	4
Greece	2	28
Hungary	54	8
Ireland	21	13
Italy	5	21
Latvia	3	26
Lithuania	7	19
Luxembourg	100	1
Malta	88	2
Netherlands	46	9
Norway	3	26
Poland	7	19
Portugal	9	17
Romania	4.5	25
Slovakia	5	21
Slovenia	18	14
Spain	62	6
Sweden	9	17
Switzerland	58	7
United Kingdom	15	15

Source: Greenpeace<sup>22</sup>



Figure 8: **Quality of infrastructure in Europe** 

Country	Quality of overall infrastructure	Ranking in Europe	Distribution infrastructure of goods and services generally	Road infrastructure- density of network	Railroads- density of the network, km per square km	Quality of air transportation, number of passengers carried by main companies, thousands
Austria	76.1	8	8.28	1.65	0.06	18′901
Belgium	78.83	7	7.86	-	0.12	5′404
Bulgaria	29.22	29	5.40	0.18	0.04	41
Croatia	41	27	6.71	0.47	0.03	768
Cyprus	44.43	25	6.81	2.23	-	103
Czech Republic	66.99	12	7.83	1.66	0.12	1′418
Denmark	92.71	2	9.29	1.74	-	20′067
Estonia	61.77	16	7.00	1.30	0.03	532
Finland	87.6	3	8.61	0.23	0.02	2′806
France	74.5	9	8.20	2.03	0.05	32'001
Germany	66.99	12	8.48	1.80	0.09	33'073
Greece	47.95	23	6.53	0.89	0.02	8′726
Hungary	49.57	21	7.09	2.10	0.08	20′127
Ireland	73.25	10	7.65	1.44	0.03	74′065
Italy	58.81	17	6.79	0.45	0.06	2'449
Latvia	45.6	24	5.96	1.10	0.03	1′599
Lithuania	58.36	18	8.00	1.30	0.03	11
Luxembourg	66.76	14	8.03	1.13	0.11	1′081
Malta	-	-	-	-	-	-
Netherlands	86.19	5	9.05	3.35	0.07	19′349
Norway	80.25	6	7.76	-	0.01	20′067
Poland	48.46	22	6.71	1.38	0.06	3'676
Portugal	58.34	19	7.88	0.16	0.03	8′056
Romania	35.84	28	5.54	0.13	0.05	2′719
Slovakia	43.42	26	7.64	0.37	0.07	9
Slovenia	54.99	20	6.83	1.91	0.06	21
Spain	64.91	15	8.30	1.35	0.03	43'440
Sweden	86.71	4	8.19	-	0.02	20′067
Switzerland	92.99	1	9.22	-	0.10	10′989
United Kingdom	72.04	11	7.06	1.63	0.07	26′632

 $\textbf{Source:} \ \mathsf{IMD} \, \mathsf{World} \, \mathsf{Competitiveness} \, \mathsf{Yearbook} \, \mathsf{2023}^{23}$ 

#### Intermodal freight transport

Intermodal freight transport refers to the transportation of goods in a single loading unit (such as a container) using a

combination of road, rail, waterways or air. Intermodal transport terminals are crucial in efforts to shift more cargo from road to rail.

Figure 9:

Overview of intermodal terminals in Europe

Country	Number of Terminals
Austria	19
Belgium	26
Bulgaria	7
Croatia	7
Cyprus	0
Czech Republic	17
Denmark	4
Estonia	6
Finland	3
France	23

Country	Number of Terminals
Germany	144
Greece	1
Hungary	8
Ireland	6
Italy	24
Latvia	1
Lithuania	5
Luxembourg	2
Malta	2
Netherlands	24

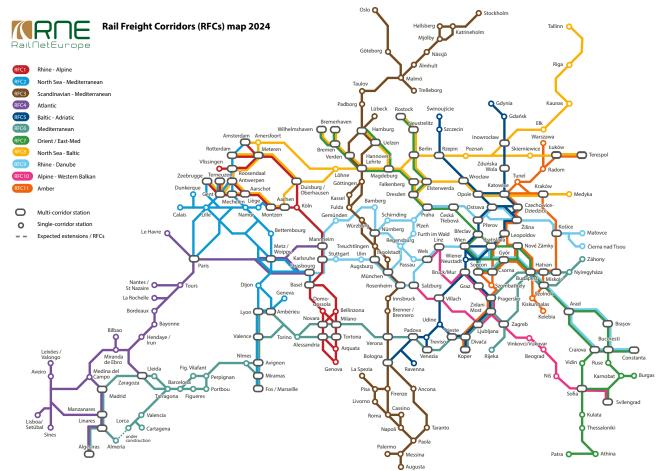
Country	Number of Terminals
Norway	5
Poland	28
Portugal	3
Romania	21
Slovakia	10
Slovenia	5
Spain	19
Sweden	19
Switzerland	16
United Kingdom	63

Source: KombiConsult GmbH 24

Figure 10:

#### Overview of the European railway system

The map shows the European rail network, highlighting the areas with the highest density of freight rail lines.



Author and holder of copyright: RNE. Source: RailNet Europe

For further Information - United Kingdom: https://www.nationalrail.co.uk; Ireland: https://www.irishrail.ie/en-ie/travel-information/station-and-route-maps and the state of the state of

# Social



#### **Work-life balance**

Achieving a healthy work-life balance is key to employee wellbeing in Europe, where on average 10% of employees work more than 50 hours a week. Italy, Denmark and Norway lead the way with favorable policies. Governments across Europe have an important role to play in promoting flexible working practices to support this balance, although differences between countries highlight the need for continued focus on the equitable distribution of work and leisure time<sup>30</sup>. The OECD work-life balance score shows the balance between work and leisure time in several OECD countries.

Figure 11:

Work-life balance in European countries

Country	OECD work-life balance score	Ranking in Europe
Austria	6	24
Belgium	7.7	9
Czech	7	18
Denmark	8.6	2
Estonia	7.3	15
Finland	7.3	15
France	8.1	6
Germany	8	8
Greece	7	18
Hungary	7.6	12
Ireland	6.2	23
Italy	9.4	1
Latvia	7.5	13
Lithuania	7.7	9
Luxembourg	7.4	14
Netherlands	8.3	5
Norway	8.5	3
Poland	6.5	22
Portugal	6.7	20
Slovakia	7.1	17
Slovenia	6.7	20
Spain	8.4	4
Sweden	8.1	6
Switzerland	7.7	9
United Kingdom	5.6	25

Source: OECD Better Life Index31



#### Women in management

Figure 12:

#### Woman in management

Country	% in 2022	Ranking in Europe
Austria	29.4	19
Belgium	30.2	15
Bosnia and Herzegovina	19.4	30
Bulgaria	40.9	4
Croatia	17.5	31
Cyprus	21.7	29
Czechia	25.1	27
Denmark	29.0	21
Estonia	46.0	2
EU – 27 countries*	31.1	13
Finland	36.5	7
France	35.7	9
Germany	26.1	24
Greece	30.1	16
Hungary	36.3	8
Iceland	34.9	10
Ireland	33.3	11
Italy	25.7	25
Latvia	49.7	1
Liechtenstein	n/a	n/a
Lithuania	44.2	3
Luxembourg	15.2	32
Malta	25.3	26
Netherlands	23.7	28
Norway	29.7	18
Poland	38.8	6
Portugal	29.4	19
Romania	29.0	21
Slovakia	30.1	16
Slovenia	31.7	12
Spain	30.8	14
Sweden	40.7	5
Switzerland	27.7	23

**Source:** Eurostat<sup>32</sup> \* from 2020

#### **Gender Pay Gap**

In terms of gender equality around the world, Europe ranks highest with a 76.3% parity rate across different categories. About one-third of European nations are in the global top 20 for gender parity, with 20 of 36 countries achieving at least 75% equality<sup>33</sup>. Iceland topped the list for the 14th year in a row with a score of 91.2 out of 100.

Figure 13: **Gender Pay Gap Index 2023** 

Austria Belgium Bosnia and Herzegovina	74.0 79.6 69.8	20 7
		7
Bosnia and Herzegovina	69.8	
200.11a arra ricizegovilla		25
Cyprus	67.8	30
Czechia	68.5	29
Denmark	78.0	14
Estonia	78.2	13
Finland	86.3	3
France	75.6	18
Germany	81.5	4
Greece	69.3	27
Hungary	68.9	28
Iceland	91.2	1
Ireland	79.5	8
Italy	70.5	24
Latvia	79.4	9
Lithuania	80.0	6
Luxembourg	74.7	19
Netherlands	77.7	15
Norway	87.9	2
Poland	72.2	21
Portugal	76.5	17
Romania	69.7	26
Slovak Republic	72.0	22
Slovakia	72.0	22
Slovenia	77.3	16
Spain	79.1	11
Sweden	81.5	4
Switzerland	78.3	12
United Kingdom	79.2	10

Source: World Economic Forum<sup>34</sup>

#### **Public healthcare system**

Per capita health expenditure in Europe varies considerably due to a number of factors. Germany, France, Austria and Switzerland are among the countries that spend the most on healthcare per person in 2022. On the other hand, Poland, Ireland and Luxembourg spend less than the EU average<sup>26</sup>.

Figure 14: Healthcare spending as percentage of GDP

Country	Healthcare spending	Ranking in
	as % of GDP	Europe
Austria	11.4	3
Belgium	10.9	6
Czechia	9.1	13
Denmark	9.5	12
Estonia	6.9	22
Finland	10.0	11
France	12.1	2
Germany	12.7	1
Greece	8.6	17
Hungary	6.7	23
Iceland	8.6	17
Ireland	6.1	25
Italy	9.0	14
Latvia	8.8	15
Lithuania	7.5	21
Luxembourg	5.5	26
Netherlands	10.2	10
Norway	7.9	19
Poland	6.7	23
Portugal	10.6	8
Slovak Republic	7.8	20
Slovenia	8.8	15
Spain	10.4	9
Sweden	10.7	7
Switzerland	11.3	4
United Kingdom	11.3	4

Source: OECD Data Explorer<sup>27</sup>

## Quality and affordability of the public healthcare system

The Global Health Security (GHS) Index is a comprehensive assessment and benchmark of health security. It indicates a country's readiness to respond to potentially catastrophic biological events such as epidemics or pandemics.

Figure 15:

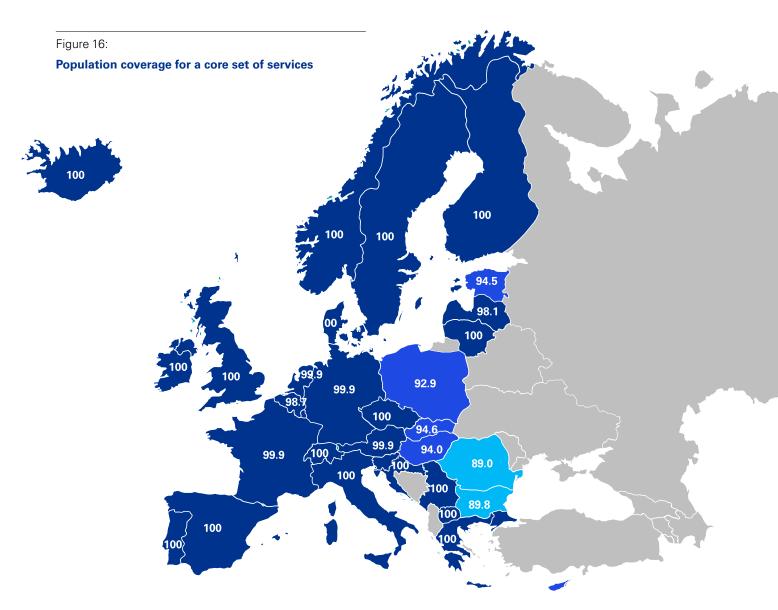
#### **GHS Index**

The GHS Index assesses countries' health security and capabilities using six categories and 37 indicators.

Country	GHS Index score	Ranking in Europe
Austria	56.9	16
Belgium	59.3	14
Bulgaria	59.9	12
Croatia	48.8	26
Cyprus	41.9	30
Czechia	52.8	23
Denmark	64.4	7
Estonia	55.5	18
Finland	70.9	1
France	61.9	8
Germany	65.5	4
Greece	51.5	25
Hungary	54.4	21
Iceland	48.5	27
Ireland	55.3	19
Italy	51.9	24
Latvia	61.9	8
Lithuania	59.5	13
Luxembourg	48.4	28
Malta	40.2	31
Netherlands	64.7	6
Norway	60.2	11
Poland	55.7	17
Portugal	54.7	20
Romania	45.7	29
Slovakia	54.4	21
Slovenia	67.8	2
Spain	60.9	10
Sweden	64.9	5
Switzerland	58.8	15
United Kingdom	67.2	3

**Source:** Johns Hopkins Center for Health Security, Nuclear Threat Initiative, Economist Impact

The quality of the public healthcare system in Europe is generally high. However, full health insurance coverage is not assured for the entire population in all countries.



Population coverage of core services, %, 2018 or nearest year

0 - 90

90 – 98

98 – 100

Source: OECD<sup>28</sup>

#### Affordability of childcare

Affordability of childcare is crucial for parents with young children to be able to participate in the labor market. In the EU, childcare subsidies significantly reduce the gross cost of childcare, making it more affordable for families. However, costs vary widely between countries. Most EU countries offer childcare support which particularly benefits single parents and couples on low to middle incomes<sup>35</sup>.

Figure 17:

#### **Net childcare costs**

The net childcare cost (NCC) indicator calculates the financial burden on families using full-time center-based childcare. It compares the net income of families who pay for childcare with those who do not, assuming they use free informal care. The lower the score, the less parents in that country pay for childcare.

Country	NCC score (2022)	Ranking in Europe
Austria	3.0	5
Belgium	12.0	21
Cyprus	27.0	27
Czechia	20.0	24
Denmark	11.0	19
Estonia	0.0	1
Finland	11.0	19
France	9.0	16
Germany	1.0	4
Greece	5.0	7
Hungary	7.0	11
Iceland	5.0	7
Ireland	28.0	28
Italy	0.0	1
Latvia	0.0	1
Lithuania	8.0	12
Luxembourg	3.0	5
Netherlands	16.0	23
Norway	8.0	12
Poland	8.0	12
Portugal	5.0	7
Romania	9.0	16
Slovak Republic	12.0	21
Slovenia	8.0	12
Spain	9.0	16
Sweden	5.0	7
Switzerland	23.0	25
United Kingdom	25.0	26

Source: OECD.Stat<sup>36</sup>

#### **Quality of life**

Finland, Denmark, Iceland and Sweden lead the global happiness rankings, reflecting the high levels of life satisfaction in these Nordic countries. In Europe, there is a notable convergence in happiness levels, with the Czech Republic, Lithuania and Slovenia moving close to the top 20, reflecting a wider positive trend across the continent<sup>37</sup>.

Figure 18:

#### World Happiness Report ranking 2024

Countries are ranked based on their self-assessed life evaluations. Finland, Denmark, Sweden and Iceland consistently come out on top in both the European and global rankings.

Country name	Score	Ranking in Europe
Austria	6.905	9
Belgium	6.894	10
Croatia	5.942	30
Cyprus	6.068	27
Czechia	6.822	12
Denmark	7.583	2
Estonia	6.448	20
Finland	7.741	1
France	6.609	17
Germany	6.719	16
Greece	5.934	31
Hungary	6.017	29
Iceland	7.525	3
Ireland	6.838	11
Italy	6.324	24
Kosovo	6.561	18
Latvia	6.234	26
Lithuania	6.818	13
Luxembourg	7.122	7
Malta	6.346	23
Netherlands	7.319	5
Norway	7.302	6
Poland	6.442	21
Portugal	6.03	28
Romania	6.491	19
Slovakia	6.257	25
Slovenia	6.743	15
Spain	6.421	22
Sweden	7.344	4
Switzerland	7.06	8
United Kingdom	6.749	14

Source: World Happiness Report 2024<sup>38</sup>

# Governance



#### **Corruption**

A high level of corruption is particularly problematic for life sciences companies as the sector operates in a highly regulated environment and has many touchpoints with governments and regulators. In addition, corruption can have a negative impact on a company's ESG goals.

Figure 19:

#### **Corruption Perception Index 2023**

The Corruption Perceptions Index measures levels of corruption. The higher the score, the lower the perceived corruption.

Country/Territory	CPI score 2023	Ranking in Europe
Austria	71	13
Belgium	73	11
Bulgaria	45	30
Croatia	50	27
Cyprus	53	25
Czechia	57	20
Denmark	90	1
Estonia	76	10
Finland	87	2
France	71	13
Germany	78	7
Greece	49	28
Hungary	42	31
Iceland	72	12
Ireland	77	9
Italy	56	21
Latvia	60	18
Lithuania	61	16
Luxembourg	78	7
Malta	51	26
Netherlands	79	6
Norway	84	3
Poland	54	23
Portugal	61	16
Romania	46	29
Slovakia	54	23
Slovenia	56	21
Spain	60	18
Sweden	82	4
Switzerland	82	4
United Kingdom	71	13

Source: Transparency International<sup>39</sup>

Figure 20:

#### Worldwide governance

The World Bank's Worldwide Governance Indicators include the dimension Rule of Law, which reflects perceptions of the extent to which agents trust and abide by the rules of society, particularly the quality of contract enforcement, property rights, police and courts and the likelihood of crime and violence.

Country	Worldwide	Ranking in
	governance	Europe
Austria	68.87	16
Belgium	65.57	20
Bulgaria	52.36	30
Croatia	66.98	19
Cyprus	58.96	26
Czechia	75	11
Denmark	77.36	8
Estonia	71.7	12
Finland	79.72	6
France	56.13	28
Germany	67.45	18
Greece	49.06	31
Hungary	67.92	17
Iceland	95.28	1
Ireland	78.77	7
Italy	58.49	27
Latvia	60.38	24
Lithuania	69.34	15
Luxembourg	86.32	3
Malta	80.66	4
Netherlands	71.23	13
Norway	76.42	9
Poland	61.79	22
Portugal	75.94	10
Romania	60.85	23
Slovakia	59.91	25
Slovenia	70.75	14
Spain	53.3	29
Sweden	80.19	5
Switzerland	92.45	2
United Kingdom	62.26	21

Source: The World Bank

#### **Peace and security**

Strengthening women's rights and general peace go hand in hand with ensuring safe working and living conditions. Countries with high social status for women also offer attractive and sustainable business conditions.

#### Figure 21:

## Country performance on the Women, Peace and Security Index

The Women, Peace and Security (WPS) Index is an aggregate indicator that reflects changes in the status of women across three dimensions: inclusion, justice and security.

Country	WPS Index score	Ranking in Europe
Austria	91.1	8
Belgium	90.2	10
Bulgaria	82.6	27
Croatia	86.2	19
Cyprus	73.9	31
Czechia	88.4	14
Denmark	93.2	1
Estonia	89.2	11
Finland	92.4	4
France	86.4	18
Germany	87.1	17
Greece	76.6	30
Hungary	83.5	25
Iceland	92.4	4
Ireland	89.2	11
Italy	82.7	26
Latvia	87.2	16
Lithuania	88.6	13
Luxembourg	92.4	4
Malta	84.6	24
Netherlands	90.8	9
Norway	92	7
Poland	85.9	21
Portugal	87.7	15
Romania	80	29
Slovakia	85.6	23
Slovenia	82.4	28
Spain	85.9	21
Sweden	92.6	3
Switzerland	92.8	2
United Kingdom	86	20

 $\textbf{Source} \colon \text{GIWPS} \, \text{Women, Peace, and Security Index 2023/24} \, ^{41}$ 

#### **General Data Protection Regulation**

The EU mandates strict adherence to the EU General Data Protection Regulation (GDPR)<sup>42</sup> and the EU Clinical Trials Regulation (CTR)<sup>43</sup> for patient data and clinical trial management. Data protection authorities (DPAs) in each EU country are responsible for monitoring and enforcing these regulations<sup>44</sup>.

#### Figure 22:

#### **GDPR** in Europe

Within the boundaries of GDPR, some countries have issued additional regulations regarding life science, as shown in the table.

## Countries which are compliant with the standard EU GDPR rules

Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Iceland, Latvia, Luxembourg, Poland, Romania, Slovakia, Slovenia

## Countries which adopted additional GDPR rules for the Health Sector

Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Malta, Netherlands, Portugal, Spain, Sweden, United Kingdom, Switzerland, Liechtenstein, Norway

**Source:** KPMG internal research based on publicly available information (as of January 2024).

# Incentives and taxes to support the green transition

When looking for support to achieve ESG goals through smart site selection, it is recommended to look for public funding at EU and national level.

The European Green Deal (EGD) serves as an overarching blueprint for Europe to become climate neutral. The EGD

is complemented by Fit for 55, a legislative package to make the EU's climate, energy, land and forest use, transportation and taxation policies fit to reduce net greenhouse gas emissions by at least 55% by 2030. To achieve the EGD and Fit for 55 goals, the EU has launched in 2023 the Green Deal Investment Plan (GDIP).

Figure 23:

#### Grants and incentive programs that are part of the GDIP

Several existing and new EU grants and incentive programs support companies in their transition to net zero and green practices.

		Investment themes	Budget
	Horizon Europe	Biggest EU research & innovation program to drive systemic changes to ensure a <b>sustainable</b> , innovative and prosperous EU. 35% of its expenditure will support climate objectives.	Budget of EUR 95.5 bn (2021-2027).
	InvestEU	Budgetary guarantee for riskier projects that are commercially viable and leverage private investments. Areas: <b>sustainable infrastructure</b> ; research, innovation and digitalization; SMEs and social investment skills	Private and public loan/equity financing is mobilized for a budget of EUR 26.2 bn and can grow to EUR 372 bn over 7 years.
	Modernisation Fund	Support 10 lower-income EU countries in <b>their transition to climate neutrality</b> by helping to modernize their energy systems and improve energy efficiency, storage, generation and use of renewable sources	The Modernisation Fund may amount to EUR 14 bn in 2021-30 (depending on revenues from EU ETS – 2% of total allowances value).
€	Innovation Fund	Bringing highly innovative <b>low-carbon industrial technologies</b> in need of additional CAPEX & OPEX support to reach break-even in the next decade	Budget of around EUR 20 bn (2020-2030).
	LIFE programme	The only EU funding program entirely dedicated to environmental, climate and energy objectives.	Budget of EUR 5,43 bn.
íίĺ	Just in Transition Fund	Supports investments for SMEs, research and innovation, <b>clean energy</b> , transformation of carbon- intensive installations	Grants of EUR 19.3 bn, and generation of EUR 30 bn from investments.
**** *EU * ****	Important Project of Common European Interest (IPCEI)	Support with investments in innovative and clean energy projects that pursue common European objectives.	Depending on the project, several billion euros per IPCEI: €5.4 bn Hydrogen; €6,1 bn Battery value chain

Source: KPMG

At the national and regional level, there are a large number of incentive programs aimed at encouraging companies to transform their value chains towards sustainability. Examples include:

- In the United Kingdom, the Industrial Energy Transformation Fund (IETF) helps high energy use industrial sites transition to a low carbon future.
- The **Dutch** energy investment deduction, also known as EIA (Energie-investeringsaftrek), is a tax incentive program that encourages businesses to invest in assets, technologies and measures that reduce energy consumption and CO<sub>2</sub> emissions.
- In Ireland, the SEAI program offers various business grants to reduce energy costs and help meet energy savings targets.
- In Austria, a special fund that provides financial support for the installation of efficient machinery.
- Other national support programs can be found in the KPMG ESG Tax Tracker.

Identification of EU or national funding programs is complex since calls are changing over time. Programs need to be evaluated on a regular basis and applications should start before the start of the projects for which public funding is required.

#### Relaxed state aid rules for strategic net-zero sectors

On 9 March 2023, following consultations with EU member states, the European Commission (Commission or the EC) adopted a new Temporary Crisis and Transition Framework (TCTF) as part of the broader Green Deal Industrial Plan for the Net-Zero Age. Under the new framework, applicable until 31 December 2025, member states are allowed to implement schemes to support new investments in production facilities in defined, strategic

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Senior Tax Manager KPMG International +31 88 909 1037 dejager.nicole@kpmg.com net-zero sectors, including through tax benefits. Individual aid would also be available for businesses in the green technology sectors that are at risk of relocating outside the EU<sup>45</sup>.

#### **Carbon and ESG-related taxes**

To accelerate the greening of certain industries, the EU and selected member states have introduced new mechanisms and taxes for carbon pricing and the environment

#### **CBAM**

The Carbon Border Adjustment Mechanism (CBAM) is intended to counteract the risk of carbon leakage to countries with little or no ambition to combat CO<sub>2</sub> emissions. Since 1 October 2023, affected companies have been subject to a statutory reporting duty without financial obligations. Foreign companies with branches in the EU are also affected by the reporting obligation.

Non-EU countries, which are integrated into the EU emissions trading system (ETS) or whose emissions trading systems are recognized as equivalent, can be excluded from the scope of application<sup>46</sup>. These are currently: Iceland, Norway, Liechtenstein, Switzerland and five other territories<sup>47</sup>.

The UK Government has confirmed that it will implement a UK CBAM by 2027<sup>48</sup>.

#### **ESG Tax Tracker**

To reduce the use of plastics, waste, coal and more, some EU countries have introduced national environmental taxes. The approach to environmental regulation varies considerably between member states in terms of application and requirements. Life sciences companies, particularly medical device manufacturers, may be affected by these taxes depending on the member state in which they sell their products.

The ESG Tax Tracker provides an overview of (in)direct taxes, carbon pricing, environmental taxes and incentives in European countries. It provides a comprehensive insight into the global regulatory landscape for environmental sustainability. The value of the tracker lies in its ability to keep life sciences companies informed of current and emerging tax legislation and incentives in over 70 countries, helping them to maintain compliance and optimize their strategic advantage in sustainability efforts.

For details and updates see: Updated ESG Tax Tracker -Global developments in ESG-related taxes, incentives and grants | Meijburg & Co Tax & Legal

Figure 24:

ESC	G Tax Tracker							Ē																					Ε
	Implemented Considered	Austria	Belgium	Cyprus	Czech Republic	Denmark	Estonia	European Union	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Netherlands	Norway	Poland	Portugal	Romania	Serbia	Slovakia	Spain	Sweden	Switzerland	United Kingdom
	Green power and CHP/photovoltaic installations	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	New innovative projects and environmentally friendly investments	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Incentives	Electric vehicles	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Sustainable energy (producers)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Renewable energy (consumers)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Vehicle tax (exemptions & concessions)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Air pollution tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Plastics tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
SS	Petroleum fuel tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
<b>Environmental taxes</b>	Tax on greenhouse gases	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•
nvironm	Air passenger tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
_	Water tax & water usage fee	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Coal tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Energy / Electricity tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Waste tax & landfill tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Carbon pricing	Carbon pricing	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Carbon	Carbon tax	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Wage tax & wage relief	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
xes	Excise duty (refunds/exemptions/ reductions)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
(In)direct taxes	VAT (exemptions & reductions)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
٤	Corporate income tax (deductions/ relief/ benefits)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Personal income tax (deductions/relief/ benefits)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

Source: KPMG

# Reporting requirements

# Corporate Sustainability Reporting Directive (CSRD)

An immediate action point for life sciences companies arising from the EGD and Fit for 55 is currently the Corporate Sustainability Reporting Directive (CSRD)<sup>49</sup>, which has been in force since January 2023.

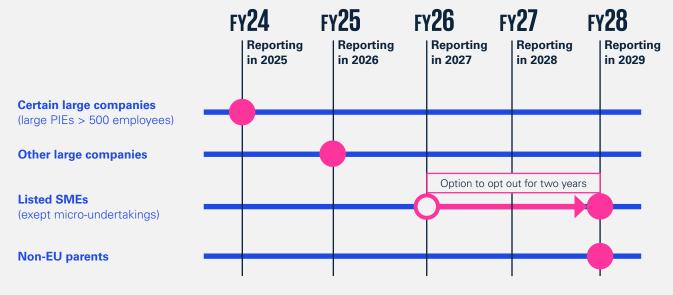
The CSRD sets out requirements for corporate reporting on environmental, social and governance issues<sup>50</sup>. Companies, including life sciences companies, have to provide transparent and comparable information on their sustainability performance and to disclose the environmental and social impacts of their operations, known as double materiality.

The first group of companies will be required to comply with the new regulations from FY2024, with reports due by 2025. Those in scope for CSRD will have to comply with the European Sustainability Reporting Standards (ESRS).

#### What is the impact of CSRD for non-EU companies

- Currently, US companies are required to comply with the mandatory SEC-ESG reporting standards.
   However, the CSRD requires more comprehensive disclosure than the US SEC rules. Importantly, the CSRD adopts a dual materiality perspective, requiring companies to not only disclose the influence of sustainability issues on their operations, but also to articulate the impact of their business activities on society and the environment<sup>51</sup>.
- 2. Differences in reporting requirements between EU countries are expected, leading to uncertainty as to whether companies operating in several EU countries will have to comply with each country's standards. The prevailing assumption is that the CSRD requirements of the EU-headquartered country should lead to consistent reporting across all subsidiaries.

Figure 25: Timeline for companies required to disclose under the CSRD



Source: KPMG

# Corporate Sustainability Due Diligence Directive (CSDDD)

On 24 April 2024, the European Council approved the Directive on Corporate Sustainability and Due Diligence (CSDDD)<sup>52</sup>. The CSDDD aims to ensure that companies implement responsible business practices and report transparently on their sustainability standards, environmental due diligence and measures to prevent human rights abuses.

The CSDDD will enter into force twenty days after it has been formally adopted by the Council, signed and published in the EU Official Journal, Member States will then have two years to transpose the new rules into national law. The new rules will be implemented gradually, with different deadlines for companies depending on their size and turnover. From 2027, the rules will apply to companies with more than 5,000 employees and a global turnover of more than 1,500 million euros. From 2028, it will apply to companies with more than 3000 employees and a global turnover of €900 million. And from 2029, it will apply to all other companies within the scope of the Directive, including those with more than 1000 employees and a global turnover of more than €450 million<sup>53</sup>.

The exact nature of these differences, as well as whether the reporting requirements of the CSDDD will be merged with those of the CSRD or whether there will be two separate sets of reporting requirements, remains uncertain at this stage.

Similarly to the CSRD, the CSDDD functions as a directive, which means that differences at national level are to be expected. As the CSDDD incorporates elements of the regulations of the French and German supply chain acts, companies can expect the corresponding national supply chain laws to be tightened. Once the CSDDD comes into force, EU law will take precedence over national law. This means that companies will have to comply with the requirements of the CSDDD – even if they are already complying with national supply chain laws.

#### **Sustainability rankings**

Various sustainability rankings provide an overview of the status of sustainability in European countries.

Figure 26:

## **Environmental Performance Index and Sustainable Development Goals**

The 2022 Environmental Performance Index (EPI) ranks 180 countries on climate change, environmental health and ecosystem vitality. The SDG Index assesses the performance of UN member states on the Sustainable Development Goals (SDGs). Governments and civil society use the Sustainable Development Report to prioritize actions, identify challenges, track progress, ensure accountability and identify gaps.

Country	EPI score	Ranking in Europe	SGD Score	Ranking in Europe
Austria	66.5	8	77.71	3
Belgium	58.2	20	71.03	14
Bulgaria	51.9	29	59.48	31
Croatia	60.2	16	69.96	17
Cyprus	58	21	61.02	30
Czech Republic	59.9	18	74.36	6
Denmark	77.9	1	80.04	2
Estonia	61.4	14	73.03	9
Finland	76.5	3	80.64	1
France	62.5	12	72.86	11
Germany	62.4	13	75.43	5
Greece	56.2	24	65.21	26
Hungary	55.1	28	68.96	22
Iceland	62.8	10	73.71	8
Ireland	57.4	23	71.35	13
Italy	57.7	22	69.93	19
Latvia	61.1	15	69.45	21
Lithuania	55.9	27	67.66	24
Luxembourg	72.3	6	67.83	23
Malta	75.2	4	65.88	25
Netherlands	62.6	11	70.09	16
Norway	59.3	19	62.19	29
Poland	50.6	30	77	4
Portugal	50.4	31	72.82	12
Romania	56	25	69.95	18
Slovakia	60	17	62.61	27
Slovenia	67.3	7	62.45	28
Spain	56	25	70.12	15
Sweden	72.7	5	73.74	7
Switzerland	65.9	9	69.58	20
United Kingdom	77.7	2	72.94	10

Source: Yale University<sup>54</sup>, Europe Sustainable Development Report 2023/24

# Further site selection factors impacting productivity, profitability and innovation

#### **Innovation**

For companies looking for a new R&D or manufacturing location, the level of innovation in a country becomes particularly important. Factors such as the presence of centers of excellence in specific therapeutic areas, clinical research capabilities and the level of collaboration between academia and industry are important considerations. A country with a high number of scientific co-publications per million inhabitants indicates that it is well positioned as an innovation hub<sup>56</sup>.



Figure 27:

#### **European Innovation Scoreboard 2023**

The European Innovation Scoreboard assesses and compares the innovation performance of EU countries, other European countries and neighboring regions. The EU's innovation performance is steadily improving, thanks to improvements in human resources, an innovation-friendly environment and an attractive R&D system.

Country	Score	Rank
Austria	130.00	7
Belgium	136.44	6
Bulgaria	50.63	29
Croatia	75.44	25
Cyprus	114.29	13
Czech Republic	102.73	17
Denmark	149.24	2
Estonia	107.00	15
Finland	145.63	4
France	114.21	14
Germany	127.79	9
Greece	86.22	23
Hungary	76.31	24
Ireland	125.60	11
Italy	97.99	18
Latvia	56.97	28
Lithuania	90.92	22
Luxembourg	127.15	10
Malta	93.11	20
Netherlands	139.55	5
Norway	129.55	8
Poland	68.09	27
Portugal	92.88	21
Romania	35.85	30
Slovakia	71.20	26
Slovenia	103.10	16
Spain	96.79	19
Sweden	145.92	3
Switzerland	151.39	1
United Kingdom	124.53	12

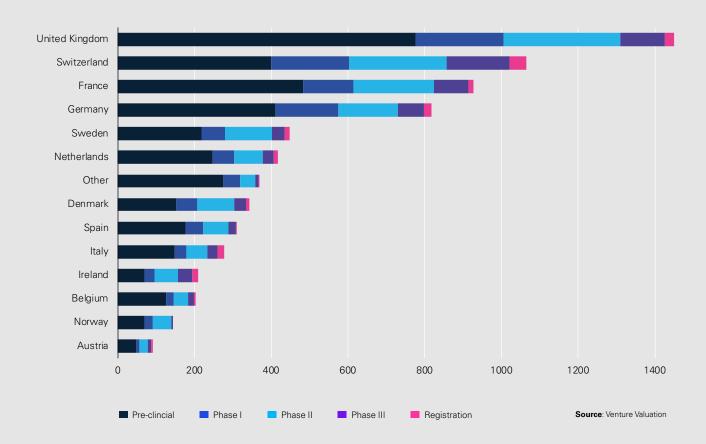
Source: European Commission<sup>57</sup>

#### **Products under development**

Figure 28:

#### Product pipeline and stage of development

An analysis of product pipelines provides a good understanding of the strength of a life sciences cluster. The UK remains to have the strongest product pipeline in Europe, followed by Switzerland. A review of Phase III products places Switzerland ahead of the UK, though. France has the second strongest pre-clinical pipeline. It should be taken into account that certain products are owned by a company in one country while development takes place in another country.



#### **Contact**

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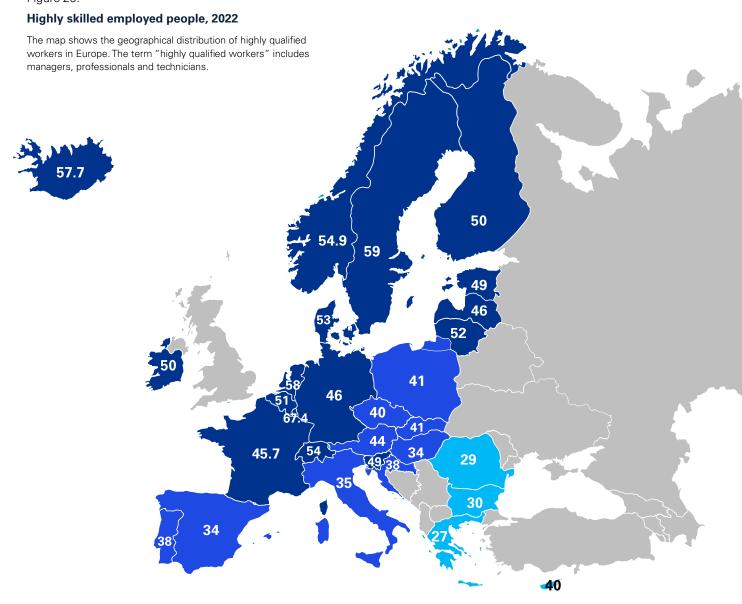
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#### **Talent development and attractiveness**

In 2022, the EU had around 80 million skilled workers, representing 44.2% of the labor force aged 25-64. Regions such as Stockholm, Utrecht and Luxembourg had the highest rates of highly qualified employment<sup>58</sup>. In terms of university degrees, the United Kingdom led

in science, health and social work, while Germany excelled in ICT graduates<sup>59</sup>. Switzerland, Denmark and the Netherlands ranked highest in attracting skilled workers from abroad <sup>60</sup>.

Figure 29:



Highly qualified employment 2022 as % of 25-64 year olds in employment by NUTS 2 regions

0 – 30

31 – 45

46 – 70

Source: Eurostat<sup>61</sup>

#### Figure 30:

#### **INSEAD Global Talent Competitiveness Index 2023**

The Global Talent Competitiveness Index assesses how well countries and major cities compete in attracting diverse talent and evaluates the impact of policies on productivity through the attraction, development and retention of human capital.

Country	Score	Ranking
Austria	69.05	12
Belgium	69.12	11
Bulgaria	49.05	29
Croatia	50.38	28
Cyprus	59.46	20
Czech Republic	62.43	16
Denmark	76.54	2
Estonia	64.29	14
Finland	74.35	4
France	66.91	13
Germany	69.88	10
Greece	52.75	27
Hungary	53.91	26
Ireland	70.45	9
Italy	58.07	22
Latvia	56.78	23
Lithuania	58.73	21
Luxembourg	72.88	8
Malta	62.66	15
Netherlands	74.76	3
Norway	73.96	5
Poland	54.10	25
Portugal	61.60	17
Romania	47.39	30
Slovakia	54.24	24
Slovenia	60.62	18
Spain	60.36	19
Sweden	73.86	6
Switzerland	78.96	1
United Kingdom	73.75	7

Source: INSEAD62

#### Life sciences clusters

Unlike the US, where the life sciences industry is clustered mainly in the Boston and Bay Area, clustering is less pronounced in Europe, where R&D and manufacturing activities are more evenly distributed across countries. Nevertheless, certain life sciences hotspots can be identified, including Barcelona and Madrid in Spain; Paris or Lyon in France; London, Cambridge and Oxford in the UK; Greater Dublin in Ireland; Greater Brussels in Belgium; the Greater Amsterdam area in the Netherlands; Munich and Berlin in Germany; the Copenhagen and Stockholm region in the Nordics; the Milan area in Northern Italy; and Basel, Zug and Geneva in Switzerland.



Figure 31:

#### Life sciences plants in Europe

There are about 2,400 pharmaceutical manufacturing sites in Europe, of which 398 specialize in active pharmaceutical ingredient (API) production, 583 in contract services, 118 in packaging, 885 in finished dosage form production and 416 in R&D facilities, illustrating the sector's extensive presence in Europe.

Country	Regions	API	Contract services	Packaging	Manufacturing	R&D facilities	Total
Austria	Vienna	2	6	0	14	7	29
	Rest of Austria	6	11	4	29	0	50
Belgium	Brussels	0	2	1	13	2	18
	Greater Liege	0	4	2	4	5	15
	Greater Puurs	0	1	1	2	1	5
	Flemish	5	14	3	22	13	57
	French	6	7	0	9	2	24
Cyprus	Cyprus	2	1	0	4	2	9
Denmark	Copenhagen	5	1	0	11	13	30
	Rest of Denmark	6	14	2	30	9	61
Finland	Finland	5	8	0	9	3	25
France	North	18	9	4	10	7	48
	Paris	2	6	1	8	5	22
	Center	4	5	1	9	2	21
	South	14	6	4	7	4	35
	Lyon	3	12	0	6	5	26
Germany	North	15	11	7	21	16	70
	Berlin	1	11	0	17	6	35
	South	11	78	26	91	45	251
	Munich	1	4	1	10	1	17
United Kingdom	Scotland	5	8	0	10	5	28
	Wales	2	2	1	2	0	7
	North England	19	11	7	9	4	50
	Northern Ireland	2	2	0	0	0	4
	South England	4	12	9	6	5	36
	London	0	1	0	2	3	6
	Oxford/Cambridge	0	1	0	3	4	8
Greece	Greece	1	13	0	25	7	46
Iceland	Iceland	0	3	0	4	0	7
Ireland	Cork	11	0	0	13	0	24
	Dublin	4	5	0	16	11	36
	Rest of Ireland	6	14	2	44	3	69
Italy	North	40	36	3	17	2	98
	Milan	11	8	0	20	3	42
	Center	14	4	1	19	9	47
	South	2	3	1	31	9	46
Liechtenstein	Liechtenstein	1	1	0	0	1	3

Source: Latenemaps.com<sup>63</sup>

Figure 31 (continued):

#### Life sciences plants in Europe

Country	Regions	API	Contract services	Packaging	Manufacturing	R&D facilities	Total
Luxembourg	Luxembourg	0	0	1	0	1	2
Malta	Malta	2	5	1	6	1	15
Netherlands	North	7	5	3	15	10	40
	Amsterdam	7	2	1	2	9	21
	South	3	11	8	10	27	59
Norway	Norway	8	7	0	10	1	26
Portugal	Lisbon	0	0	0	0	2	2
	Rest of Portugal	2	7	0	17	6	32
Spain	Barcelona	15	11	1	6	3	36
	Madrid	8	12	0	14	8	42
	Rest of Spain	37	32	0	40	24	133
Sweden	Stockholm	3	1	0	3	3	10
	Uppsala	3	5	1	1	1	11
	Rest of Sweden	7	11	0	10	4	32
Switzerland	Western Switzerland	11	15	3	9	8	46
	Basel	4	12	1	6	8	31
	Eastern Switzerland	3	9	3	5	5	25
	Zurich	5	5	1	5	3	19
	Southern Switzerland	1	5	1	10	4	21
Bosnia	Bosnia	0	0	0	4	1	5
Bulgaria	Bulgaria	2	2	0	21	3	28
Croatia	Croatia	1	1	0	10	0	12
Czech Republic	Czech Republic	4	14	6	26	23	73
Estonia	Estonia	2	2	0	3	1	8
Hungary	Hungary	10	14	2	11	11	48
Kosovo	Kosovo	0	0	0	1	0	1
Lithuania	Lithuania	0	6	2	1	0	9
Latvia	Latvia	4	4	0	5	2	15
Macedonia	Macedonia	0	0	0	7	0	7
Moldova	Moldova	0	0	0	2	0	2
Poland	Poland	7	19	1	51	18	96
Romania	Romania	3	10	0	6	5	24
Serbia	Serbia	0	6	1	9	0	16
Slovakia	Slovakia	7	5	0	3	2	17
Slovenia	Slovenia	3	8	0	3	8	22
Total		397	581	118	879	416	2391

Source: Latenemaps.com<sup>63</sup>

Figure 32:

#### **High Security Labs in Europe**

The table shows the number of BSL4 laboratories per country across  $\ensuremath{\mathsf{Europe}}.$ 

Country	BSL-4 labs
Czech Republic	2
France	3
Germany	4
Hungary	2
Italy	2
Sweden	1
Switzerland	1
United Kingdom	6
Other countries	4

Source: Globalbiolabs.org<sup>65,66</sup>; George Mason University

#### **High-security labs**

High-security facilities are vital infrastructure for conducting research on highly hazardous pathogens. Currently, Europe has 25 operational biosafety level (BSL) 4 facilities serving this purpose<sup>64</sup>.



### **Labor law and productivity**

Multinational corporations (MNCs) have to adapt to stakeholder needs, market changes and new technologies through business transformation. Choosing locations with the necessary flexibility is critical and is significantly influenced by employment restrictions. These restrictions, including laws on firing permanent employees and hiring temporary workers, are measured by the OECD Employment Protection Indicators, which consider both individual and collective dismissals.



Figure 33:

### **Employment Protection**

Multinationals need agile operations to adapt to change. One critical factor is the stringency of employment protection legislation, which measures the rigidity of regulations governing the hiring and firing of workers. The OECD indicators assess these regulations for both individual and collective dismissals, as well as for permanent and temporary contracts.

Country	Labor freedom	Ranking in Europe
Austria	2.39	12
Belgium	3.02	24
Bulgaria	n/a	n/a
Croatia	2.30	10
Cyprus	n/a	n/a
Czech Republic	2.90	23
Denmark	1.84	2
Estonia	2.07	6
Finland	2.06	5
France	2.83	22
Germany	2.78	21
Greece	2.49	15
Hungary	2.07	6
Ireland	1.95	3
Italy	2.61	16
Latvia	3.10	25
Lithuania	2.25	8
Luxembourg	2.66	18
Malta	n/a	n/a
Netherlands	3.51	26
Norway	2.31	11
Poland	2.43	14
Portugal	2.67	19
Romania	n/a	n/a
Slovakia	2.68	20
Slovenia	2.41	13
Spain	2.25	8
Sweden	2.62	17
Switzerland	1.98	4
United Kingdom	1.60	1

Source: OECD

Figure 34:

### Labor productivity forecast

Labor productivity is a key indicator of the strength of an economy. The forecast shows that countries in Europe are growing at different pace.

Country	Labor productivity forecast in %	Ranking in Europe
Austria	1.007	24
Belgium	1.024	20
Bulgaria	1.253	4
Croatia	1.156	6
Czech Republic	1.095	12
Denmark	1.084	13
Estonia	1.107	10
Finland	1.018	21
France	0.989	26
Germany	1.018	21
Greece	0.948	29
Hungary	1.148	8
Iceland	1.073	14
Ireland	1.346	2
Italy	1.013	23
Latvia	1.218	5
Lithuania	1.15	7
Luxembourg	0.949	28
Netherlands	1.003	25
Norway	1.031	19
Poland	1.276	3
Portugal	1.066	16
Romania	1.398	1
Slovakia	1.114	9
Slovenia	1.099	11
Spain	0.985	27
Sweden	1.053	17
Switzerland	1.068	15
United Kingdom	1.051	18

Source: OECD 2024 68

#### **Labor costs**

Comparing nominal salaries across countries and industries is challenging. An alternative to net salary comparison is to look at employer contributions beyond net salary, which provide a clearer picture of total payroll costs. Employer and employee contributions vary widely across Europe.

The table includes employee and employer contributions on separate tabs. It focuses on social security contributions for an assumed base salary of EUR 75,000 and EUR 150,000. Only compulsory pension contributions at standard rates are included. No income tax, wealth tax or similar taxes are calculated. Voluntary deductions are not included, only standard/statutory deductions and country default positions are used. Calculations are based on a single person with no dependents. Current social security rates are applied. Data is based on publicly available information from the IBFD and KPMG databases. In the case of Hungary, third-country nationals employed by foreign companies are exempt from certain contributions if the assignment lasts less than two years. Therefore, the calculation assumes that the assignee is treated as a local.

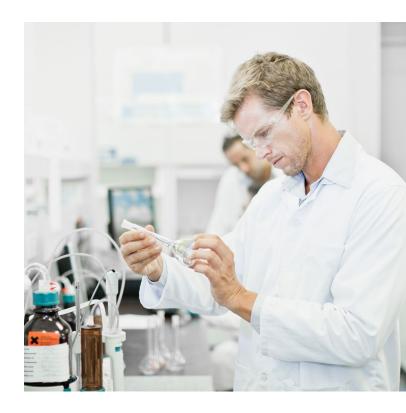


Figure 35: **Employer and employee social security contribution** 

Country	Employer Social Security - EUR 75k	Employer Social Security - EUR 150k	Employee Social Security - EUR 75k	Employee Social Security - EUR 150k
Austria	19′605	25′583	13′445	15′209
Belgium	20′288	40′575	9′803	19'605
Bulgaria	3'968	3′968	2′875	2′875
Croatia	12′375	24′750	15′000	19'687
Cyprus	15′681	25′356	6′973	8′960
Czech Republic	25′350	32'894	8′250	11′833
Denmark	1′500	1′500	152	152
Estonia	25′350	50′700	1′200	2′400
Finland	14′551	29′100	6′888	13′953
France	34′067	68'090	15′413	30'274
Germany	14′067	15′721	14′439	16′093
Greece	16′718	22'240	10′403	13′839
Hungary	9′750	19′500	13′875	27′750
Iceland	13′388	26′775	3′000	6′000
Ireland	8'288	16′575	3′019	6′150
Italy	22′171	35′764	7′346	11′386
Latvia	17'693	30'855	7′875	13′737
Liechtenstein	5′550	11′000	3′900	7′700
Lithuania	1′328	2′655	14′626	23′127
Luxembourg	9'927	19'853	9′233	18′570
Malta	2'826	2′826	2′826	2′826
Netherlands	13′230	13′230	1′792	1′792
Norway	10'666	24'991	5′850	11′700
Poland	13′371	17′909	7′955	9′793
Portugal	17′813	35'625	8′250	16′500
Romania	1′688	3′375	26′250	52′500
Slovakia	26'401	42'928	10′050	16′297
Slovenia	12′076	24′150	16′575	33′150
Spain	16′939	16′939	3'480	3'480
Sweden	23′565	47′130	3′767	3′767
Switzerland	9′324	15′914	9'324	15′914
United Kingdom	8′879	19'228	4′739	6′239

Source: KPMG

### **Access to markets in Europe**

The EU, with its 27 member states, and the much smaller European Free Trade Association (EFTA, consisting of Switzerland, Norway, Liechtenstein and Iceland) are the two European organizations facilitating pan-European business.

### Access to the EU single market

The single market refers to the EU as one territory without any internal borders or other regulatory obstacles to the free movement of goods and services. For details see: https://ec.europa.eu/growth/single-market\_en69

EFTA members have access to the EU's single market through bilateral agreements with the EU (Switzerland) or through the European Economic Area (EEA) Agreement (Iceland, Liechtenstein and Norway).

The UK is part of neither the EU nor EFTA but has instead concluded a Trade and Cooperation Agreement (TCA) with the EU. This sets out preferential arrangements in areas including but not limited to trade in goods and services, digital trade and intellectual property.

### Collaboration between Switzerland and the UK

Switzerland negotiated nine new bilateral agreements with the UK as part of the "Mind the Gap" strategy, which aims at deepening the relations with the UK (Mind the Gap+). Discussions are currently ongoing regarding possible areas for enhanced cooperation in areas of common interest for both countries such as research and development<sup>70</sup>.

### Schengen Area

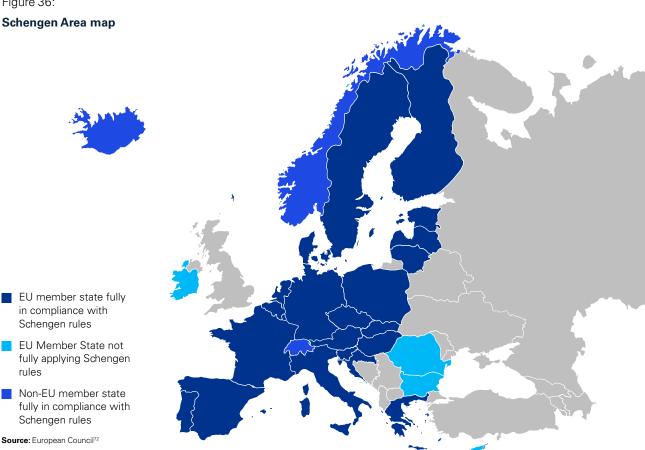
The Schengen Area<sup>71</sup> allows people to travel freely between member countries without going through border controls. Today, the Schengen Area covers a population of almost 420 million people and includes 27 countries: 23 of the 27 EU member states and all EFTA members.

Ireland and the UK are not part of the Schengen Area, meaning that travelers arriving in the Schengen Area from those countries are required to pass through an immigration checkpoint.

#### Free movement of workers

Free movement of workers is a fundamental principle of the EU and is essential for multinational companies seeking to hire international staff. The freedom to move to





another EU country to work without a work permit is a right for EU nationals.

Although Iceland, Liechtenstein and Norway are not members of the EU, their nationals can work in the EU on the same basis as EU nationals because they are part of the EEA.

Under the EU-Switzerland Agreement on the Free Movement of Persons, Swiss nationals are free to live and work in the EU and vice versa.

The free movement of workers allows companies to employ workers from across the EU and EFTA without a lengthy work permit application process and is an

Figure 37:

Overview of access to markets in Europe

Country	Schengen Area <sup>6</sup>	Access to EU single market <sup>7</sup>	EU member state	Eurozone member state
Austria	Yes	Yes	Yes	Yes
Belgium	Yes	Yes	Yes	Yes
Bulgaria	Yes	Yes	Yes	No
Croatia	Yes	Yes	Yes	Yes
Cyprus	No	Yes	Yes	Yes
Czech Republic	Yes	Yes	Yes	No
Denmark	Yes	Yes	Yes	No
Estonia	Yes	Yes	Yes	Yes
Finland	Yes	Yes	Yes	Yes
France	Yes	Yes	Yes	Yes
Germany	Yes	Yes	Yes	Yes
Greece	Yes	Yes	Yes	Yes
Hungary	Yes	Yes	Yes	No
Ireland	No	Yes	Yes	Yes
Italy	Yes	Yes	Yes	Yes
Latvia	Yes	Yes	Yes	Yes
Lithuania	Yes	Yes	Yes	Yes
Luxembourg	Yes	Yes	Yes	Yes
Malta	Yes	Yes	Yes	Yes
Netherlands	Yes	Yes	Yes	Yes
Norway	Yes	Yes	No	No
Poland	Yes	Yes	Yes	No
Portugal	Yes	Yes	Yes	Yes
Romania	Yes	Yes	Yes	No
Slovakia	Yes	Yes	Yes	Yes
Slovenia	Yes	Yes	Yes	Yes
Spain	Yes	Yes	Yes	Yes
Sweden	Yes	Yes	Yes	No
Switzerland	Yes	Yes	No	No
United Kingdom	No	Limited	No	No

Source: European Parliament<sup>73</sup>

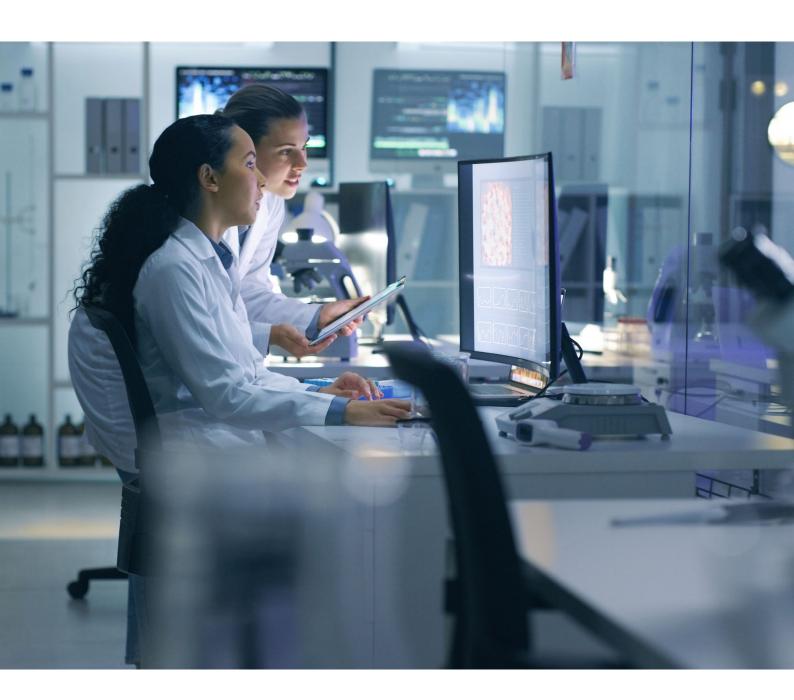
important factor to consider when choosing a location in Europe.

Brexit has put an end to the free movement of people for British citizens. They no longer have the freedom to work, study, start a business or live in the EU. Likewise, EU citizens or their employees in the UK will need to apply for a work permit if they wish to work in the UK or plan to hire workers from EU or EFTA countries.

#### **Eurozone**

The euro is the official currency of 20 EU countries that together make up the euro area, also known as the eurozone.

The euro is the most tangible evidence of European integration: some 341 million people use it every day, making it the second most widely used currency in the world. Establishing operations in a eurozone country can significantly reduce currency risks and currency conversion costs.



### EU and national industrial strategies

The EU has launched the Pharmaceutical Strategy 2020 for Europe to strengthen the competitiveness, innovation and resilience of its pharmaceutical sector. Key initiatives include the reform of pharmaceutical legislation and the creation of a public health emergency agency.

Many EU member states and other European countries have launched national life sciences or pharmaceutical strategies. Countries with a well-defined industrial policy or strategy, including taxes and incentives, are attractive locations for life sciences projects, as investors and promoters rely on government support for their existing and planned activities.

Figure 38:

### Life sciences strategy plans in Europe

Country	Туре	
EU	Life sciences and biotechnology strategy	
Austria	General life sciences industry strategy	
Bulgaria	General research strategy including biotechnology	
Cyprus	General research strategy including biotechnology	
Czech Republic	General research strategy including biotechnology	
Denmark	General life sciences industry strategy	
Finland	Bioeconomy strategy including biotechnology	
France	General life sciences industry strategy	
Hungary	Biotech and life sciences industry strategy	
Iceland	General research strategy including biotechnology	
Ireland	General life sciences strategy	
Italy	Pharma manufacturing strategy	
Latvia	Biotech industry strategy	
Lithuania	Life sciences sector roadmap	
Netherlands	International strategy for life sciences and health	
Norway	Norwegian roadmap for research infrastructure	
Luxembourg	General research strategy including biotechnology	
Malta	General research strategy including biotechnology	
Poland	General research strategy including biotechnology	
Portugal	General life sciences strategy	
Slovakia	General research strategy including biotechnology	
Slovenia	General research strategy including biotechnology	
Spain	Bioeconomy strategy including biotechnology	
Sweden	General life sciences industry strategy	
Switzerland	Life sciences research and innovation strategy & general life sciences industry strategy	
United Kingdom	General life sciences industry strategy	

Source: KPMG

### **Taxes and incentives**

European countries have begun to implement a global minimum tax framework (BEPS Pillar Two). Companies with global revenues exceeding EUR 750 million will be subject to a minimum effective tax rate of 15%. Certain exceptions to these rules apply in the case of significant substance in the respective countries.

The EUR 750 million threshold significantly limits the ability of countries to offer tax holidays or tax breaks to large companies. One of the remaining tax incentives still available under the OECD/G20 framework is the Qualified Refundable Tax Credit (QRTC), which is considered a cash subsidy rather than a tax incentive.

Figure 39: Corporate income tax rates in Europe

Country	Year 2024	Ranking in Europe
Austria	23.00	19
Belgium	25.00	22
Bulgaria	10.00	2
Croatia	18.00	7
Cyprus	12.50	3
Czech Republic	19.00	8
Denmark	22.00	16
Estonia	20.00	12
Finland	20.00	12
France	25.00	22
Germany	30.00	27
Greece	22.00	16
Hungary	9.00	1
Ireland	12.50	3
Italy	24.00	20
Lithuania	15.00	5
Luxembourg	24.94	21
Malta	35.00	29
Netherlands	25.80	26
Norway	22.00	16
Poland	19.00	8
Portugal	31.50	28
Romania	16.00	6
Slovakia	21.00	15
Slovenia	19.00	8
Spain	25.00	22
Sweden	20.60	14
Switzerland average	19.70	11
United Kingdom	25.00	22

Source: KPMG

While the 15% minimum tax rate limits tax competition among European countries, there are still significant differences in ordinary tax rates that are worth exploring when looking to relocate key value drivers.

#### **Grants and incentives**

Many European governments are now trying to incentivize foreign direct investment through loans or grants rather than tax breaks. EU member states often work with EU funding facilities. Typical EU funding facilities for capital-intensive projects include the LIFE program and the Just Transition Fund.

A mix of EU and national funding programs is available for research and development activities. At the EU level, Horizon Europe and the Innovative Health Initiative (IHI) are of particular interest to life sciences companies. Horizon Europe is the EU's key funding program for research and innovation. It is designed to tackle climate change, support achievement of the SDGs and foster competitiveness and growth in the EU. The IHI is a public-private partnership for the funding of health research and innovation and aims to contribute to the creation of an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations.

### Incentives at the national level

There are a variety of both, tax and non tax incentives available at the national and regional level in Europe for capital and R&D investments.

When selecting a location in Europe, it is advisable to contact local KPMG offices or national economic development agencies to find out what incentives are available.

Additional information on grants and incentives is listed below. We also refer to the following pages for further details of specific topics:

- → European Funding and Tender Portal
- → Access to EU Finance portal
- → Horizon Europe
- → LIFE Programme
- → Just Transition Fund
- → Innovative Health Initiative

**An overview of R&D tax credits** in Europe can be found in the KPMG Global R&D Incentives Guide 2023: https://kpmg.com/kpmg-us/content/dam/kpmg/pdf/2021/global-rd-incentives-guide.pdf?

### **EU Foreign Subsidies Regulation**

The Foreign Subsidies Regulation (FSR) is a new EU law concerning subsidies granted by non-EU states to companies active in the EU. The FSR enables the European Commission to investigate financial contributions granted by non-EU states to companies active in the EU. Particularly the reporting of tax incentives is likely to cause significant challenges. Tax measures have historically presented unique challenges within the state aid rules and, in principle, many of them, including R&D credits or equivalent tax measures, could fall within the meaning of "financial contribution".

For details see: Legislation - European Commission (europa.eu)

### **General competitiveness comparisons**

Various organizations issue global rankings of countries based on competitiveness aspects. To analyze trends, it is advisable to compare countries over time rather than relying on snapshots of a single year or ranking.

The Heritage Foundation's Index of Economic Freedom measures a country's economic freedom based on factors such as trade, business, investment and property rights.

Meanwhile, the IMD World Competitiveness Yearbook assesses a country's ability to manage its resources and competences to create long-term value.

Figure 40: Comparison of European countries' competitiveness

Data from	Ranking [1] Economic Freedom 2024	Ranking in Europe	Ranking [2] World competitiveness Index 2023	Ranking in Europe
Austria	68.4	18	78.16	12
Belgium	65.6	23	89.69	7
Bulgaria	68.5	17	46.83	29
Croatia	67.2	20	54.93	26
Cyprus	72.2	11	60.21	22
Czech Republic	70.2	14	83.48	9
Denmark	77.8	4	100	1
Estonia	77.8	4	76.84	13
Finland	76.3	9	89.73	6
France	62.5	27	71.05	16
Germany	72.1	12	80.47	11
Greece	55.1	30	55.12	25
Hungary	61.2	28	59.85	23
Ireland	82.6	2	99.71	2
Italy	60.1	29	63.32	19
Latvia	71.5	13	54.7	27
Lithuania	72.9	10	71.67	15
Luxembourg	79.2	3	82.46	10
Malta	64.5	24	n/a	n/a
Netherlands	77.3	8	95.58	4
Norway	77.5	6	88.43	8
Poland	66	21	60.48	21
Portugal	68.7	16	65.54	18
Romania	64.4	25	55.34	24
Slovakia	68.1	19	53.84	28
Slovenia	65.9	22	62.82	20
Spain	63.3	26	67.22	17
Sweden	77.5	6	91.86	5
Switzerland	83	1	99.13	3
United Kingdom	68.8	15	75.48	14

Source: The Heritage Foundation<sup>74</sup>; IMD<sup>75</sup>

## Market access authorization in Europe

### **EU and EEA countries**

The centralized authorization procedure in the EU allows pharmaceutical companies to submit a single marketing authorization application to the European Medicines Agency (EMA). The EMA's scientific committees assess the application and make a recommendation to the European Commission, which takes the final decision. Once granted, the marketing authorization is valid in all EU member states and EEA countries (Norway, Iceland and Liechtenstein).

On the other hand, most generic and over-the-counter medicines in the EU are evaluated and authorized at national level. Each EU member state has its own national marketing authorization procedures.

For medicines outside the scope of the centralized procedure, companies can choose between the mutual recognition procedure, where an authorization granted in one member state is recognized in others, or the decentralized procedure, which allows simultaneous authorization in several member states for a medicine not yet authorized in the EU<sup>76</sup>.

For details see: EMA Authorization of medicines | European Medicines Agency (europa.eu)

### **Access Consortium**

Through their participation in the Access Consortium, the UK and Switzerland offer attractive new opportunities to pharmaceutical and biotech companies seeking commercialization of their products on an international scale.

The Access Consortium is a collaboration between Australia's Therapeutic Goods Administration (TGA), Health Canada, Singapore's Health Sciences Authority (HSA), Swissmedic and the UK's Medicines and Healthcare products Agency (MHRA). The consortium aims to strengthen international regulatory cooperation, reduce duplication of efforts and speed up access to safe and effective medicines for a combined population of 150 million in these countries<sup>77</sup>.

For details see: https://www.swissmedic.ch/swissmedic/en/home/about-us/international-collaboration/multilateral-co-operation-with-international-organisations—ini/multilateral-co-operation-with-international-organisations—ini.html



# EU strategies, initiatives and legislative projects relevant to life sciences

## EU Pharmaceutical Strategy for Europe and revision of EU pharmaceutical legislation

The EU launched its Pharmaceutical Strategy in 2020 to strengthen the competitiveness, innovation and crisis resilience of its pharmaceutical sector. The strategy focuses on ensuring patients access to affordable and innovative medicines, supporting the industry's global competitiveness and improving crisis preparedness. The strategy aims to address pressing health challenges such as antimicrobial resistance and cancer, while promoting sustainable and high-quality medicines. Key initiatives include the revision of pharmaceutical legislation and the creation of a public health emergency authority<sup>78</sup>.

For details see: Pharmaceutical Strategy for Europe (europa.eu)

### Revision of EU pharmaceutical legislation

In April 2023, the European Commission launched a major overhaul of its pharmaceutical legislation, marking a pivotal moment for the life sciences sector in Europe. The review is driven by the objectives of ensuring timely access to medicines for EU patients, improving security of supply, supporting innovation, enhancing environmental sustainability and tackling antimicrobial resistance<sup>79</sup>. The revision is seen as a step towards creating a more resilient and innovative pharmaceutical sector in Europe<sup>80</sup>. Critics fear that the proposed changes, particularly in the areas of data protection and market exclusivity, could harm the sector's competitiveness, stifle innovation and fail to address the underlying problems of access to medicines and supply shortages<sup>81,82</sup>.

For details see: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation\_en

### European Commission's Health Emergency Preparedness and Response Authority (HERA) and HERA Invest

The mission of HERA is to prevent, detect and rapidly respond to health emergencies. HERA Invest is a financing mechanism to promote advanced research and development of medical countermeasures and related technologies for tackling priority cross-border health threats. HERA Invest is one of the five flagship initiatives outlined in the HERA Work Plan 2023.

For details see: https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/funding-and-opportunities\_en

## Accelerating Clinical Trials in the EU (ACT EU) initiative

An average of 2,800 clinical trials are authorized annually in the EU/EEA. The ACT EU initiative aims to strengthen the EU's position as a leading center for innovative clinical research. It builds on the Clinical Trials Regulation (CTR) and the launch of the Clinical Trials Information System (CTIS) in January 2022. ACT EU is a joint initiative of the European Commission, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA). The CTR harmonizes the assessment and monitoring of clinical trials across the EU and requires trial sponsors to register all new clinical trial applications in the CTIS.

### For details see:

- ACT EU: https://www.ema.europa.eu/en/humanregulatory-overview/research-development/clinical-trialshuman-medicines/accelerating-clinical-trials-eu-act-eu
- Clinical Trials Regulation: https://www.ema.europa.eu/ en/human-regulatory-overview/research-development/ clinical-trials-human-medicines/clinical-trials-regulation
- Clinical trials in human medicines: https://www.ema. europa.eu/en/human-regulatory-overview/researchdevelopment/clinical-trials-human-medicines

## Further legislative projects and initiatives in the EU of relevance to life sciences

Several other regulatory projects at the EU level have an impact on the life sciences industry, particularly medical devices. Examples include:

### Regulations on medical devices/in vitro diagnostics

New regulations came into force in 2017. They regulate the Directive on active implantable medical devices and in vitro diagnostic medical devices (98/79/EC).

For details see: https://www.medical-device-regulation.eu/download-mdr

### **Representative Actions Directive (RAD)**

This new EU-wide legal structure, which came into force in 2020, is particularly relevant for medical device companies. RAD is relevant for the medical device sector since it might increase the risk of exposure to consumerled class actions in a wide range of areas.

For details see: https://commission.europa.eu/law/law-topic/consumer-protection-law/representative-actions-directive\_en

### **Artificial Intelligence (AI) Liability Directive (AILD)**

AILD ensures that individuals affected by AI technologies receive the same protection as for other technologies and introduces a rebuttable presumption of causation to reduce the burden of proof on victims. The medical device sector is particularly affected by this new directive<sup>83</sup>.

For details see: https://commission.europa.eu/business-economy-euro/doing-business-eu/contract-rules/digital-contracts/liability-rules-artificial-intelligence\_en

### **Critical Medicines Alliance**

The Commission plans to set up a Critical Medicines Alliance with all stakeholders by the beginning of 2024 to expand the supply of essential medicines and to stimulate and update their production. This Alliance aims to introduce an industrial policy component to the European Health Union, enabling coordination between national authorities, industry, civil society representatives, the Commission and EU agencies. This collaborative effort at EU level aims to tackle drug shortages and address issues related to supply chain vulnerabilities<sup>84</sup>. The Commission is currently conducting a vulnerability analysis for a first sub-set of substances listed on the Union list of critical medicines that was first published by EMA in December 2023.

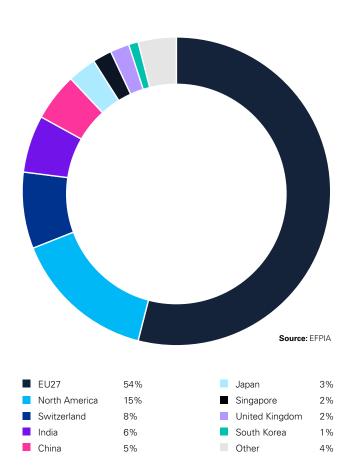
For details see: https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance\_en

### **Critical Medicines Act**

The proposed Critical Medicines Act is envisaged as a comprehensive EU mechanism, presented in the form of a regulation, to actively support the production of active pharmaceutical ingredients and finished medicinal products within the European Union. This mechanism would provide funding for research and development, infrastructure development and operational costs.

For details see: https://www.eesc.europa.eu/en/news-media/news/critical-medicines-act-secure-europes-pharmaceutical-independence

Figure 41: **API manufacturers worldwide** 



### **European Health Union**

The European Commission is building a strong European Health Union, in which all EU countries prepare and respond together to health crises. Medical supplies should be available, affordable and innovative, and countries should collaborate to improve prevention, treatment and aftercare for diseases such as cancer.

For details see: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union\_en

## Initiatives in the UK, Switzerland and Norway

Like the EU with its EU Life sciences strategy and many EU member states with their life sciences strategies, non-EU countries have also adopted programs focusing on life sciences, R&D and innovation.

The **UK's** strategy to boost its life sciences sector includes significant investment in R&D, with a target to spend 2.4% of GDP in this area by 2027. The UK is a leader in genetic research and precision medicine and is home to the world's largest genomics project, among others. The country also improves access to health data through initiatives such as the Digital Innovation Hub<sup>85</sup>.

For details see: Life Sciences Industrial Strategy Update (publishing.service.gov.uk)

**Switzerland** is strengthening its life sciences sector through the "Federal measures to promote biomedical research and technology 2022-2026" master plan, which focuses on innovation, clinical research, innovative therapies and digitalization. Key initiatives include creating a national platform for clinical research, improving the regulatory framework to encourage innovation in the pharmaceutical industry, particularly for innovative therapies, and promoting e-medicine. These strategic efforts are in line with the broader Health 2030 strategy, which aims to maintain Switzerland's competitiveness in biomedical research and technology for the benefit of the economy and the healthcare system<sup>86</sup>.

Switzerland has specifically set up international research cooperation agreements with countries such as the UK, Brazil, Canada, Germany, Israel, South Korea and Sweden.

For details see: https://www.innosuisse.ch/inno/en/home/promotion-of-international-projects/bilateral-cooperation.html

**Norway's** Research Infrastructure Roadmap 2023, led by the Research Council of Norway, focuses on clear funding guidelines, strategic priorities and detailing of essential research infrastructure. It emphasizes the need to align with global and European research priorities, such as the European Open Science Cloud and EuroHPC, while taking into account the geopolitical context. The roadmap emphasizes collaboration in international projects, in line with the government's long-term research and education goals<sup>87</sup>.

For details see: Norwegian Roadmap for Research Infrastructure 2023 (forskningsradet.no)

## Pharmaceutical Mutual Recognition Agreements (MRA)

The Mutual Recognition Agreements (MRAs) between the FDA and the EU increase efficiency by allowing both agencies to rely on each other's inspections of pharmaceutical manufacturing practices, saving valuable regulatory resources. However, certain products such as Advanced Therapy Medicinal Products (ATMPs), human blood and blood components and veterinary immunologicals are not covered by these agreements. The inclusion of vaccines and plasma-derived drugs will be reviewed by the FDA in July 2025<sup>88</sup>. In addition, the FDA has similar agreements with Switzerland and the UK<sup>89</sup>. Conversely, countries such as Norway, Iceland and Liechtenstein do not have MRAs with either the FDA or the EU<sup>90</sup>.



## **Appendix**

## European Green Deal and sector-specific regulations for life sciences

In its quest to make Europe the first climate-neutral continent by 2050, the European Union (EU) has positioned itself as a climate leader and driver of the global environmental agenda. To achieve its ambitious goal, the EU presented the European Green Deal (EGD) in December 2019. The EGD represents the EU's core strategy to combat climate change and achieve climate neutrality, and consists of specific regulations, policies and financing mechanisms covering eight key policy areas. Targets under the EGD include a milestone 55% reduction in greenhouse gas emissions by 2030, a share of over 32% renewable energy in the energy mix and an improvement in energy efficiency of at least 32.5%.

In 2021, the European Commission presented a series of legislative proposals to align EU climate, transport, land use, energy and taxation policies with the 2030 milestone target under the Fit for 55 package.

In 2022, the EU launched the REPowerEU plan, which aims to make the EU independent of Russian fossil fuels and accelerate the green energy transition through more ambitious renewable energy and energy efficiency targets.

To achieve the goals set by the EGD and to ensure that the transition to a climate-neutral economy is equitable and leaves no one behind, the EU has also launched the EGD Investment Plan (GDIP), which is the investment pillar of the EGD. Through this plan, the EU aims to mobilize at least EUR 1 trillion in sustainable investments over 10 years and to support the regions and communities most exposed to the impacts of the EU's climate ambitions.

The EDG, which includes the Fit for 55 package, consists of a wide range of regulations, directives and laws, policies and plans that are constantly evolving, with new proposals and revisions emerging regularly.

The following policies and regulations may be relevant to life sciences companies, in addition to those mentioned previously such as CBAM, CSRD, ESG taxes and CSDDD:

### EGD policies and plans relevant to life sciences companies

- Circular Economy Action Plan
- Chemicals Strategy
- Zero Pollution Action Plan
- European Green Deal Industrial Plan

### Fit for 55 regulations and directives relevant to life sciences companies

- European Climate Law
- Regulations on Batteries and waste Batteries
- Nature Restoration Law
- Amendment to the Energy Efficiency Directive
- EU Emissions Trading System

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### **Power purchase agreements (PPAs)**

PPAs are bilateral, usually long-term electricity supply contracts concluded between energy buyers and sellers that provide a stable and predictable framework for energy procurement. The contract regulates the supply of a quantity of electricity (often) at a fixed price or equivalent financial compensation. PPAs are therefore particularly beneficial as they allow companies to secure long-term energy supplies at fixed prices. This reduces exposure to market price volatility, helps with financial planning and budgeting, and aligns with industry sustainability goals, providing a clear path to reduce carbon emissions and support a company's own decarbonization targets.

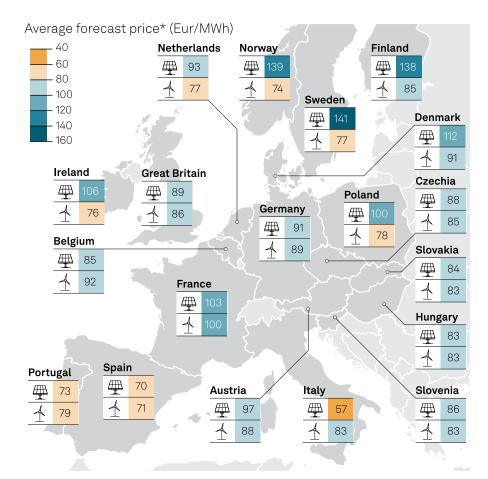
Alongside contractual protection against rising electricity prices, the contracting parties typically also conclude agreements on the transfer of guarantees of origin (GoOs or renewable energy certificates (RECs) for the electricity generated by the plant operator.

There are significant price differences in PPAs between EU countries<sup>91</sup> and energy sources like wind and solar<sup>92</sup>. In addition, cross-border PPAs are complex because of the above-mentioned barriers<sup>93</sup>. In EU member states such as Sweden or Spain, larger areas with higher wind speeds or more hours of sunshine are available compared with other EU countries such as Germany, for example. Projects in locations with favorable conditions for renewable energy often generate several hundred GWh/a. This means a life sciences company can achieve much more with a single green PPA in such a location and reduce transaction costs.

RECs or GoOs serve as a tool for companies to demonstrate their commitment to the use of renewable energy. They provide transparent and verifiable evidence that the energy consumed comes from renewable energy projects. This is critical for regulatory compliance and brand reputation as consumers and stakeholders increasingly value environmental responsibility<sup>94</sup>.

Figure 42: PPA price forecast

The projected average price in EUR/MWh for standard pay-as-produced PPAs between 2025 and 2034, considering the midpoint of the capacity factor sensitivity range, which includes costs related to new construction, operation and financing.



Source: S&P global 98

Figure 43: **European Union support for renewable energy** 

### Region Project or grant name For details see:

	GET.invest	Home - GET.invest (get-invest.eu)	
(etip-pv.eu)		ETIP PVThe European Technology and Innovation Platform for Photovoltaics – ETIP PV (etip-pv.eu)	
		Resilex – Resilient Enhancement for the Silicon Industry Leveraging the European Matrix (resilex-project.eu)	
	TRUST PV	TRUST PV – SOLAR PV, performance and reliability (trust-pv.eu)	
	EVERPV	Home - EVERPV	

Source: in table

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## The generic medicines industry in Europe

The generics industry plays a key role in providing affordable healthcare solutions. However, the industry has faced years of cost containment policies across Europe that have driven manufacturers to consolidate and globalize manufacturing supply chains, particularly to Asia. Concerned about geopolitical risks in Asia, and as part of the lessons learned from Covid-19, where many countries introduced de facto or de jure export restrictions on components or ingredients for manufacturing, the EU Council (representing member states) asked the Commission to create a Critical Medicines Act - similar to the Chips Act for microchips or the Critical Raw Materials Act for high-tech metals. The European Commission has started its work in this area with a new communication on tackling drug shortages, which sets out a future policy to encourage more investment in generic and active pharmaceutical ingredient manufacturing in Europe. The communication focuses on:

- Coordinating public procurement practices at EU level
- Exploring how to diversify global supply chains through strategic partnerships
- Strengthening Europe's capacity to produce and innovate in a coordinated way in the manufacture of key medicines and ingredients
- Developing a common strategic approach to stockpiling medicines in the EU
- Helping to leverage and align EU and national funding

Based on a newly adopted list of critical medicines, the Commission will assess the EU's dependence on foreign supply chains and consider ways to reinvest in EU production of these medicines. This approach is similar to what has been done in Japan and India to reduce dependence on China for certain active ingredients and medicines.

A number of key issues remain unaddressed in the EU investment policy for generic medicines and API manufacturing. EU state aid rules prevent EU funds or member states from investing significantly in manufacturing. To invest in pharmaceutical manufacturing, the EU would need to adopt legislation similar to the Chips Act for pharmaceuticals.

While this financial support could certainly help, to maintain investment in manufacturing the EU would need to reform the markets for generic medicines for critical medicines, as Japan has done. So far, the Commission has only initiated a reform of the pharmaceutical

procurement rules to include security of supply as a key purchasing criterion. This reform will have a positive impact on hospital markets. However, there has been no attempt to reform pharmaceutical reimbursement policies, as many of the medicines on the EU's list of critical medicines, such as antibiotics, are dispensed through community pharmacies.

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Figure 44: Industry associations and healthcare organizations

Name	Link	Location	Description
EBE – European Biopharmaceutical Enterprises	http://ebe-biopharma.eu	Brussels	EBE represents European biopharmaceutica companies and was established as an EFPIA subgroup based in Brussels. It is open to all biotech companies bringing new medicines to the market.
EFPIA – European Federation of Pharmaceutical Industries and Associations	https://efpia.eu	Brussels	EFPIA represents the European biopharmaceutical industry, promoting innovation and contributing to the economy through the collaboration of 37 national associations and 40 leading pharmaceutical companies.
EMA – European Medicines Agency	https://ema.europa.eu/en	Amsterdam	The EMA, a decentralized EU agency, evaluates, supervises and monitors the safety and scientific aspects of medicines.
EPHA – European Public Health Alliance	https://epha.org	Brussels	EPHA is Europe's largest civil society platform advocating for public health through diverse member engagement and policy contributions.
EuropaBio	www.europabio.org	Brussels	EuropaBio is Europe's largest biotech industry group, influencing legislation and representing the healthcare and industrial biotech sectors in dialogue with EU institutions.
European Medtech Association	https://medtech europe.org	Brussels	MedTech Europe promotes innovative medical technologies for accessible healthcare, advocates policies that meet Europe's needs and emphasizes value creation through innovation, research and stakeholder engagement.
FDA Europe Office	https://www.fda.gov/ about-fda/office-global- operations/europe-office	Brussels	Established in May 2009, the European Office represents the FDA's interests in Europe, ensuring the safety and quality of European medical devices and foods exported to the United States.
GIRP – European Healthcare Distribution Association	https://girp.eu	Brussels	GIRP represents more than 750 pharmaceutical wholesalers across Europe, distributing 15 billion packs of medicines each year and committed to improving patient health through innovative healthcare services.
Medicines for Europe – representing generic, biosimilar and value added industries	https://www.medicines foreurope.com/	Brussels	Medicines for Europe, formerly EGA, initially focused on generics and later expanded to include biosimilars, adapting to changes in the pharmaceutical industry and healthcare landscape over the past 20 years.

Source: in table

Figure 44 (continued): Industry associations and healthcare organizations

Industry associations and healthcare organizations			
Name	Link	Location	Description
PGEU – Pharmaceutical Group of European Union	https://pgeu.eu	Brussels	The Pharmaceutical Group of the European Union (PGEU) represents community pharmacy in Brussels, advocating for a stronger role for pharmacists in European healthcare systems and patient care.
WHO – World Health Organization	https://who.int	Geneva	The World Health Organization (WHO) is the United Nations agency that fosters global connections among nations, partners and individuals to improve health, ensure global security and help those in need.
IFPMA – International Federation of Pharmaceutical Manufacturers and Associations	https://ifpma.org	Geneva	IFPMA represents the innovative pharmaceutical industry at the international level and in official relations with the United Nations.

Source: in table



## How to launch a pharmaceutical product for the first time in Europe

By working with first-time launchers, KPMG has defined **six work streams to support** companies in building a compliant, efficient, sustainable and scalable operating model for successful launch in Europe.

Direct market entry does not preclude outsourcing of business functions such as logistics, regulatory, quality control, pricing and reimbursement. In fact, developing a tailored outsourcing concept and identifying outsourcing partners early in the process can be a key factor in achieving a successful launch.

### **Planning and timing**

Planning, timing and balancing the strategy of each workstream against the overall company benefit is crucial when it comes to European market entry; delays in the launch phase significantly reducing a firm's ability to recover its investment in the development of the product. Wasting time in a product's patent life can leave the door open for competitors. Most importantly, a launch delay also means that the (quality of) life of patients is at stake.

### **Project management office**

Based on KPMG experience, the most efficient way for a first-time launcher to achieve success is to work with an experienced service provider offering a project management office (PMO). The PMO coordinates internal resources on the company side with external service providers to ensure that the various workstreams are aligned and that the product can be launched within the planed timeline.

#### Workstreams

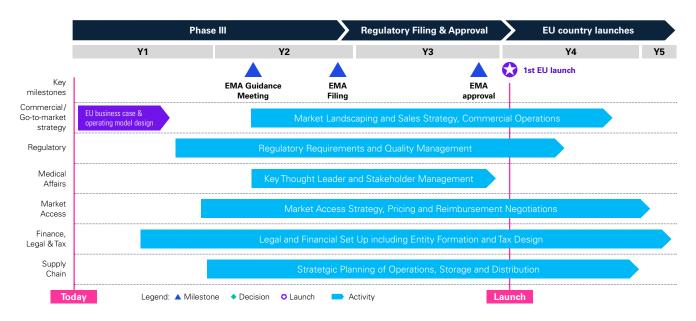
### Commercial / go-to-market strategy

The process of deciding whether to enter the European markets and, if so, whether to launch or license should start as early as the beginning of phase 3 clinical trials. The first step is the development of a business case for Europe drawing on commercial studies in different European key markets. If a decision is taken in favor of launch, the operating model should be defined. A key element of this model is the design of transaction flows for goods, finances and titles. It also includes where to set up European headquarters and subsidiaries. Later on in the process, sales strategies need to be defined, commercial operations implemented per country and a sales force recruited.

#### Regulatory

EMA dossier development and submission for marketing authorization is a key element of this workstream. In addition, applications need to be made for manufacturing and import authorizations (MIAs) and for wholesale and distribution licenses (WDL). This is also where quality management systems, processes and training need to be considered.

Figure 45: Workstreams and Timeline for launch in Europe



Source: KPMG

### **Medical affairs**

This workstream includes profiling of Key Opinion Leaders (KOLs), identification of early access programs and training of the sales force.

### **Market access**

Designing the market access strategy for the key markets (launch sequencing) is the first step in this workstream. Since in Europe every country and in certain cases even individual provinces can set the price of a pharmaceutical product individually, it is vital to conduct a comprehensive pricing strategy in order to secure commercial success in Europe.

Almost every country in Europe uses international reference pricing (IRP). The IRP formula varies from one country to another, however, with some using the lowest prices observed in the reference countries and others applying an average of the reference prices. The reference sets are made up of an increasing number of countries over time, which typically induces convergence in international drug prices.

Other important elements of this workstream include reimbursement dossier development and submission.

### Finance, legal and tax

Based on the operational and transactional model and the location of the regional headquarters, there are series of steps to be taken such as implementation of finance and IT infrastructure, incorporation of legal entities and analysis of VAT, trade and customs as well as other indirect taxes. Direct tax model design and implementation also falls under this workstream.

### Supply chain

Design of the supply chain follows the transactional model and should start early in the process. In most cases, companies work with logistics service providers (3PL and 4PL). Questions regarding labeling and packaging also fall under this workstream along with defining the location of the warehouses.



## Sources

- <sup>1</sup> World Economic Forum
- <sup>2</sup> STAT News
- <sup>3</sup> Axpo
- <sup>4</sup> International Monetary Fund
- <sup>5</sup> Swiss Federal Office of Energy
- <sup>6</sup> European Council
- <sup>7</sup> IEA50
- <sup>8</sup> Swiss Government
- <sup>9</sup> CLADCO Decking
- <sup>10</sup> International Monetary Fund
- <sup>11</sup> The Pharma Journal
- <sup>12</sup> The Pharma Journal
- <sup>13</sup> Eurostat
- <sup>14</sup> Eurostat
- <sup>15</sup> European Environment Agency
- <sup>16</sup> European Environment Agency
- <sup>17</sup> European Commission
- <sup>18</sup> European Environment Agency
- <sup>19</sup> Freshwater Information System For Europe
- <sup>20</sup> Freshwater Information System For Europe
- <sup>21</sup> European Union
- <sup>22</sup> Greenpeace
- <sup>23</sup> IMD World Competitiveness Ranking
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- 33 World Economic Forum
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- <sup>40</sup> The World Bank
- <sup>41</sup> Georgetown Institute for Women, Peace and Security
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- <sup>47</sup> Dentos
- <sup>48</sup> Government of United Kingdom

- 49 EUR-Lex
- <sup>50</sup> EUR-Lex
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- 52 European Parliament
- 53 European Parliament
- 54 Yale University
- 55 Sustainable development Solutions Network
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- 59 OECD
- 60 Eurostat
- <sup>61</sup> Eurostat
- 62 INSEAD Global Talend Competitiveness Index
- 63 La Tene Maps
- 64 Global Biolabs
- 65 Global Biolabs
- 66 George Mason University
- <sup>67</sup> The Heritage Foundation: Index of Economic Freedom
- 68 OECD
- <sup>69</sup> European Commission
- <sup>70</sup> Swiss Federal Department of Foreign Affairs
- <sup>71</sup> European Council
- <sup>72</sup> European Council
- <sup>73</sup> European Parliament
- <sup>74</sup> Index of Economic Freedom
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- <sup>76</sup> European Medicines Agency
- 77 Government of United Kingdom
- <sup>78</sup> European Commission
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- 80 EFPIA
- 81 EFPIA
- 82 EFPIA
- 83 MedTech Europe
- 84 European Commission
- 85 Government of United Kingdom
- <sup>86</sup> Swiss Federal Office of Public Health
- 87 The Research Council of Norway
- 88 U.S. Food & Drug Administration
- 89 Government of the Netherlands
- <sup>90</sup> U.S. Food and Drug Administration
- 91 PV-magazine.com92 BloombergNEF
- 93 World Business Council for Sustainable Development
- <sup>94</sup> Energy Certificate Association, Deutsche Energie-Agentur
- 95 S&P Global

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