KPMG

Site Selection for Life Sciences Companies in Europe

2021 edition

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Introduction

Site Selection for Life Sciences Companies in Europe 2021

When the COVID-19 pandemic began to take hold, there was a great fear that it would disrupt supply chains in Life Sciences manufacturing. Ultimately, the opposite proved to be true. New vaccines were developed in record time and manufacturing capacities were built up rapidly. The pandemic tested the agility and resilience of the global Life Sciences industry – and the industry passed the test.

As we look to the aftermath of the initial shocks, many governments have begun stimulus programs to support economic recovery. These include a USD 1.7 trillion COVID-19 Stimulus Package in the US, and in the EU an additional EUR 870 billion for the NextGeneration EU program. A significant proportion of the EU money is aimed at strengthening the healthcare and Life Sciences sector.

In terms of how the Life Sciences industry itself responded to the crisis, the success of mRNA technology has generated increased interest in Biologics, in particular cell and gene therapy. This is triggering a strengthening of production capacity with originators and contract manufacturers. The favorable business environment for Life Sciences projects has also emboldened many companies to launch their first product themselves rather than licensing to a large pharma group.

We also observe key developments on taxation and climate change-related matters:

- In the OECD, 130 countries approved a minimum tax rate of 15 percent and the taxing of profits of the biggest multinationals in countries where the profits are earned. This will limit countries' potential to attract investments through competitive tax planning opportunities
- The European Commission unveiled its Green Deal in July 2021, at the heart of which is the transition of national economies toward lower carbon emitting production. We expect this to intensify competition among members states to attract Life Sciences investments, which are generally low-carbon emitting and high added value.
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For these reasons and more, now is a good time to look at new Life Sciences operations or expand existing ones across Europe. The continent has many outstanding locations to bring research and production closer together. In addition, leading edge biotech innovation clusters, highly qualified workforce and excellent infrastructure are key ingredients. Europe is ready to support the entire Life Sciences value chain, from drug development or medical device design to manufacturing – encouraging investments that strengthen the healthcare system.

Thomas Hillek
Partner
Head EMA Life Sciences

André Guedel
Director
Head Site Selection Services

KPMG

Part 1:

Life Sciences in Europe – developments and trends

KPMG's Site Selection solutions

Choosing the right location in Europe for a headquarters, shared services center, manufacturing plant, warehousing facility or R&D operation is a challenge.

Having grown to cover the EU27 plus Norway, the UK and Switzerland, this report is the fifth in our series covering the European business environment for Life Sciences.

It is designed for all types of companies from fully integrated pharmaceutical companies (Fipcois) to mid-size pharmaceutical or virtual biotech businesses to CDMOs or CROs.

It also provides governments and investment promotion agencies across Europe with a benchmark on how they are positioned in terms of attractiveness to Life Sciences investments and where there is room for improvement.

KPMG has extensive experience in helping Life Sciences companies' site selection processes in Europe. We offer services either on a stand-alone basis or as an integrated part of our comprehensive launch support package, which helps companies commercialize their products in Europe.

The importance of Life Sciences in Europe

The Life Sciences industry (pharma, biotech and medtech) contributes significantly to the creation of high value adding jobs and R&D investment in Europe.

According to the European Federation on Pharmaceutical Industries and Associations (EFPIA), pharma invested around EUR 39 billion in R&D in Europe in 2020 and directly employs 830,000 people[1].

MedTech Europe, the European trade association representing the medical technology industries, states, medtech is a major contributor to the EU economy, employing over 730,000 people in high quality jobs[2].

Medicines for Europe, the industry association for generics, biosimilar and value added medicines estimates that its members operate over 400 manufacturing plants and 126 R&D centers in Europe and that the companies it represents provide over 190,000 skilled, high value direct jobs and more than 500,000 indirect jobs in Europe[3].

Europe's biotech, pharma and medtech market

At a CAGR of 8 percent, the global pharmaceutical market is expected to grow from USD 1,228 billion in 2020 to USD 1,701 billion in 2025[4], with Europe accounting for 24 percent of the world's pharmaceutical sales in 2020[5]. The European market is dominated by the UK, Germany, France, Italy and Spain ("Europe 5" countries), which are estimated to have a market share of around 70 percent and are expected to grow at a CAGR of 4.5 percent between 2017 and 2022[6]. The EU market for medical devices was estimated to be EUR 140 billion in 2020, which is 27.6 percent of the global market and is the largest market after the US[7].

[1] https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf
[2] https://www.medtecheurope.org/
[3] https://www.medicinesforeurope.com/
[4] https://www.statista.com/statistics/266470/pharmaceutical-market-forecast-2008-to-2013/
[5] EFPIA https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf
[6] https://info.evaluategroup.com/rs/607-YGS-364/images/Evaluate-European-Drug-Forecasts-Infographic-IG.pdf
[7] https://www.medtecheurope.org


IOT

Health spending total, % of GDP, 2020

	Health spending total as % of GDP in 2020
Austria	11.5
Belgium	10.7
Bulgaria	7.1
Croatia	7.0
Cyprus	7.0
Czech Republic	7.8
Denmark	10.0
Estonia	8.1
Finland	9.2
France	11.1
Germany	12.5
Greece	7.8
Hungary	6.4
Ireland	7.2
Italy	9.7
Latvia	6.7
Lithuania	7.6
Luxembourg	5.4
Malta	8.8
Netherlands	11.2
Norway	11.3
Poland	7.2
Portugal	10.1
Romania	5.7
Slovakia	7.0
Slovenia	10.1
Spain	9.1
Sweden	11.4
Switzerland	11.3
United Kingdom	12.8

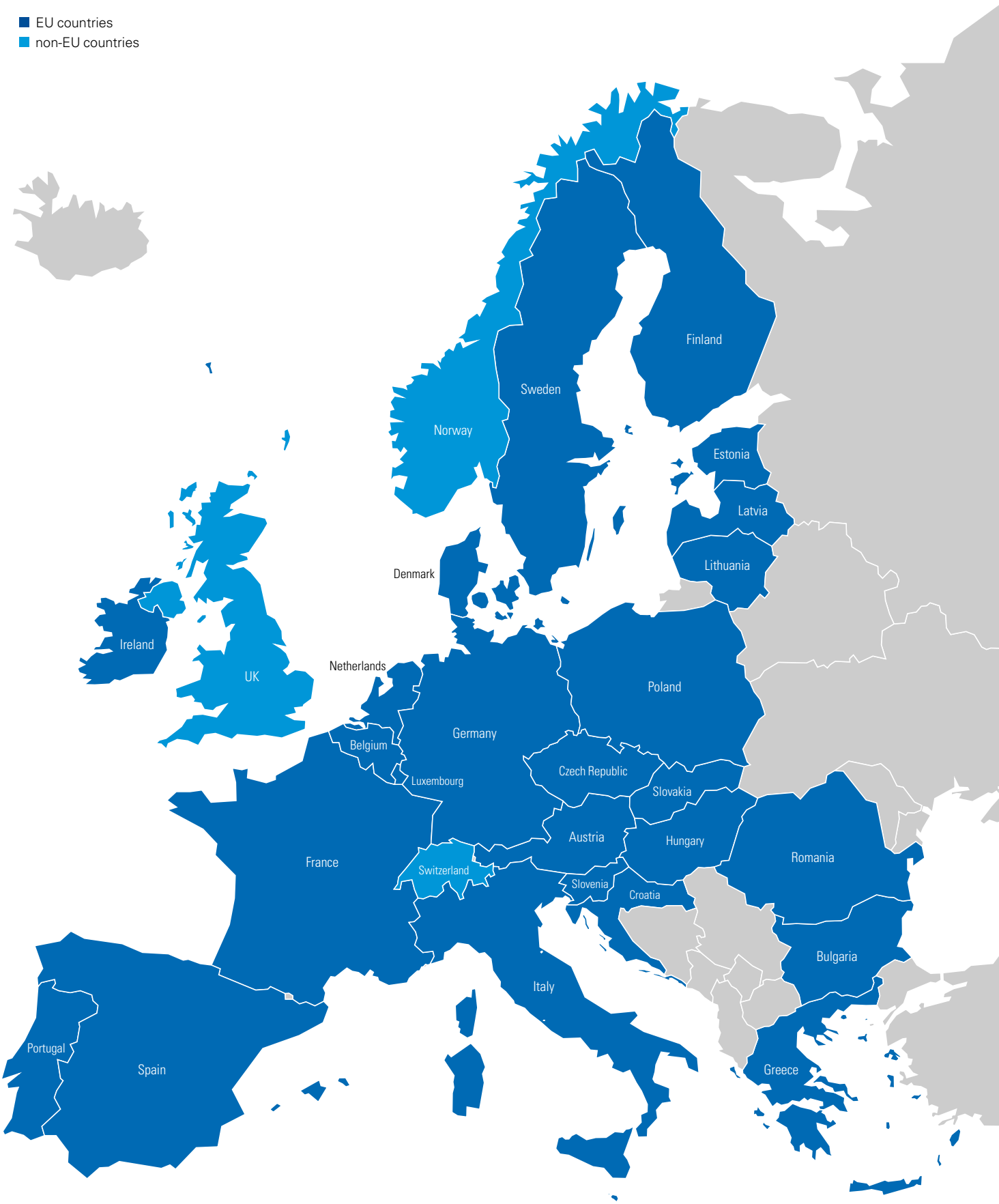
Source: https://data.oecd.org/healthres/health-spending.htm

Health spending as a percentage of GDP[8]

Health spending as a percentage of GDP varies significantly between European countries. To determine which European markets to enter first, further parameters such as epidemiologic data or the different pricing models also need to be understood. While most European countries with the exception of the UK and Sweden use international reference pricing (IRP) or external reference pricing (ERP), the IPR/ERP formula varies from one country to another. Some use the lowest price observed in the reference countries while others apply an average of the reference prices.

[8] https://data.oecd.org/healthres/health-spending.htm

Countries covered in this report



Latest trends affecting Life Sciences direct investments in Europe

The return of industrial strategies – this time with a green touch

Following a period of reluctance to implement industrial strategies, there is a now a readiness by the EU and its member states and other European countries to develop environmental, digital, and industrial strategies to navigate the industrial landscape towards sustainability and climate neutrality.

To achieve this goal, the EU has made available EUR 1,500 billion in grants and loans for 2021 to 2027 to stimulate the economy, reduce economic and social differences between member states, support industrial projects, and foster scientific research and innovation in the EU.

You may find more detail in the Spotlight on EU funding section.

Europe's Green Deal

Europe aims to become the world's first climate-neutral continent by 2050, with a more sustainable and innovation-driven economy. On 14 July 2021, the European Commission adopted a package of proposals, the Green Deal, to make the EU's climate, energy, land use, transport and taxation policies ready to reduce net greenhouse gas emissions by at least 55 percent by 2030.

The Green Deal includes national targets and binding regulations on pollution or production processes. These regulations will impact Life Sciences through:

- Requirements to increase the use of renewable energy sources
- Reducing pollution from micro-plastics and pharma
- Mobilizing industry for a clean and circular economy by 2030.

The Green Deal also foresees substantial incentives for investments in clean and innovative technologies in carbon intensive areas (the Just Transition Mechanism). With its high value adding but low carbon emission processes, Life Sciences is likely to be a main beneficiary of these incentives[9].

Newcomers arriving in Europe

Biotech companies about to achieve market authorization for their first product are increasingly considering bringing their products to market themselves rather than licensing it to large pharma groups. Due to its sizeable market for biopharmaceutical products, Europe is a particularly attractive destination for first-time launchers from the US as well as home-grown businesses.

First time launchers from outside or within Europe have become an important feature of Europe's Life Sciences landscape. They bring a welcome boost to the Life Sciences ecosystems of the countries in which they operate through job creation and the transfer of knowledge. Several countries in Europe have emerged as hubs for regional HQs of such companies, while other countries offer attractive distribution and logistics services to them.

You can see our insights into what a successful launch pathway looks like in Annex 1.

BEPS 2.0 – Global minimum profit tax and taxation rights to market jurisdictions

The OECD began working on a BEPS 2.0 agreement to deal with tax issues arising from the increasing digitalization and globalization of business models and counter what some governments consider to be harmful tax competition.

The multilateral agreement envisaged under BEPS 2.0 moved forward in July 2021 with a statement on a two pillar solution to address the tax challenges arising from the digitalization of the economy[10]. An implementation plan is envisaged by October 2021, with enactment into law by 2022, anticipated to be effective in 2023.

What is the potential impact on Life Sciences?

BEPS 2.0 consists of two pillars:

- Pillar 1 relates to the taxation of large multinational enterprises (MNEs) by shifting taxation rights to countries where the products are marketed
- Pillar 2 relates to the introduction of a global minimum profit tax.

Pillar 1 might affect pharma businesses with global revenues in excess of EUR 20 billion by shifting taxation rights to the countries where they sell their products (market jurisdictions). In such circumstances, 20-30 percent of the residual profit (profit in excess of 10 percent of revenue) will be re-allocated, for example, from the profitable principal company to relevant market jurisdictions. Pillar 1 foresees a revenue-based allocation key to the extent that such residual profits are not already taxed in the respective market jurisdictions, e.g. due to the presence of a distribution company.

[9] A European Green Deal | European Commission (europa.eu). https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

[10] www.oecd.org

Pillar II affects Life Sciences companies with global revenues in excess of EUR 750 million. The most impactful change is the fact that the minimum tax mechanisms will be applied irrespective of whether a company that is taxed at a rate below 15 percent carries out an active business with appropriate substance or merely earns passive income with limited or no substance. Certain reliefs on these rules are applicable in case of significant substance in the respective countries.

Can companies still benefit from competitive tax rates and tax holidays?

Several jurisdictions in Europe have comparatively low statutory corporate tax rates. Others offer tax breaks and holidays for investment projects in Life Sciences.

Many Life Sciences companies have structured their operational and tax model to benefit from such low taxes or tax holidays. Such tax planning models will no longer be possible or worthwhile if they push the effective tax rate below 15 percent. This is because host countries will likely raise their tax rates to a minimum of 15 percent for companies with revenues above a certain threshold and / or abolish tax holiday schemes.

Are IP Box models still possible?

Many Life Sciences companies that currently benefit from advantageous treatments on expenses and revenues from IP might be affected by the 15 percent minimum taxation. If their relevant effective tax rate is below 15 percent due to IP Boxes or other R&D tax incentives, they might be affected by Income Inclusion Rules or Undertaxed Payment Rules of other countries than the one where they benefit from IP Box regimes[11].

Supporting resilient supply chains and manufacturing

The EU's Pharmaceutical Strategy for Europe sets out reforms of pharmaceutical laws, including a new focus on a strong and competitive pharmaceutical manufacturing sector in Europe. In parallel, the EU's Industrial Strategy for Europe aims to reduce Europe's dependence in some strategic areas, including pharmaceutical production.

Pharmaceutical supply chains are complex and not always sufficiently diversified. This is exacerbated by the fact that EU Member State reimbursement policies for medicines aim for extreme price commoditization. This promotes consolidation in the supply chain, especially for generic medicines.

Cost pressures on the industry means a growing reliance on outsourcing primary and secondary manufacturing. Yet, this comes with political concerns that the EU is becoming dependent on manufacturers in other regions of the world. The EU has therefore launched a structured dialogue with the pharmaceutical industry, EU Member States, healthcare practitioners and payers to encourage more investment in manufacturing and resilient supply chains.

This dialogue aims to map out EU production capabilities and vulnerabilities and consider sectoral reforms.

To map manufacturing capabilities, the EU may look at two scenarios:

1. Assess the balance of supply and demand across Europe during crisis situations, enabling the EU to know if it faces an acute imbalance during times of a likely demand surge
2. Create a methodology to calculate the rough productive capacity in Europe to compare annual consumption and see if the EU is dependent on imports.

The EU will then look at policy options to support greater manufacturing capacity for certain critical medicines. This is likely to include changes to:

- The pharmaceutical regulatory framework to encourage more investment in European sourcing of API (or at least multi-sourcing) and medicines production
- Procurement and reimbursement for critical medicines to encourage multi-winner outcomes and to reward manufacturers that invest in more robust supply chains
- EU funding for investments in manufacturing technology where the EU has lost the technical capability to manufacture or technology for more modern manufacturing processes.

Encouraging more investment in pharmaceutical manufacturing in Europe is a significant challenge given the higher costs involved, particularly while maintaining patients' access to medicines and ensuring Europe remains a competitive region.

Contributed by Medicines for Europe
info@medicinesforeurope.com

Are grants or loans still available?
In the absence of many tax-related tools to attract investments, governments may seek to incentivize foreign direct investments through loans or grants rather than tax reliefs, though such moves might be limited by international state aid and anti-subsidy rules.

What can companies do to prepare?
The biggest unknowns are how individual jurisdictions will choose to implement BEPS 2.0, including potentially securing the minimum tax level in the domestic territory, as well as specifics on implementation and approach. Up-to-date information can be obtained through the KPMG factsheet[11].

Companies should also begin to investigate the many subsidies and grants available, further explained in our Spotlight on EU funding. For more details on R&D incentives, please refer to Annex 2.

Changes in the regulatory environment

Annex 21
A particularly important regulatory change is the EU GMP Annex 21. With the potential to disrupt operating models across Europe, it aims to provide a long-term solution to guarantee the highest standards of efficacy, quality and safety in any process involving the manufacturing of health products. It covers the whole manufacturing process, from API through to the finished product.

Annex 21 is aimed at holders of Manufacturing and Import Authorizations (MIAs) within the EU who import human or veterinary medicinal products directly from countries outside the EU. It does not cover products that do not have a marketing authorization in the EU and are re-exported immediately.

Annex 21 is particularly relevant for Life Sciences companies that have their European headquarters in a non-EU country and subsidiaries in different EU countries. In many cases, the non-EU headquarters are in the UK or Switzerland and host key functions and assets (IP) as well as managing contractual risks. In this case one option is to use a subsidiary in an EU country which (e.g the Netherlands) acts as a master distributor holding the EU marketing authorization (MA) and the Manufacturing and Import Authorization (MIA).

The master distributor works with local subsidiaries in different EU countries to distribute the products on a buy and sell basis. In certain cases, the local subsidiaries, also called limited risk distributors (LRDs), receive the shipments directly from the non-EU headquarters instead of from the master distributor. In this case, going forward under Annex 21 each legal entity will need a separate MIA if they receive shipments via the non-EU entity instead of via the EU entity which holds the MIA.

While it is unclear when Annex 21 will enter into force, many EU member states have already started to request that LRDs apply for MIAs if they import directly from outside the EU.

Brexit
The UK formally left the EU on 31 January 2020. As a result, the European Medicines Agency, EMA, moved from London and the UK no longer participates in EMA scientific committees or working party meetings, nor in the agency's Management Board. Brexit has an impact on MAs and the recognition of GMP inspections.

Marketing Authorizations (MAs)
Since 1 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) assumed the functions of the EMA and is the only medicines and medical devices regulator regarding products being marketed in the UK. It is possible for companies to convert existing Centralized Marketing Authorizations issued by the EMA into UK MAs ('grandfathering').

Conversely, the EMA does not recognize UK MAs. Companies wishing to sell pharma products in the EU will have to apply for an MA through either a Decentralized Procedure, Mutual Recognition Process (MRP) or Centralized Marketing Authorization (CMA).

Holders of MAs for EU markets must be located in an EU member state. The legal entity that has the authorization to market a medicine in one, several or all EU Members States[12] for centrally authorized medicines issued by the EMA previously based in the UK had to move to an EU member state by November 2020.

Good Manufacturing Practice (GMP)
The UK trade and cooperation agreement[13] between the EU and the UK applies provisionally since 1 January 2021, pending the completion of ratification procedures. It contains an annex[14] on the treatment of a substance or a combination of substances that is intended to treat, prevent or diagnose a disease or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action ('Annex TBT 2[15] - '). This means the EU and the UK will recognize the outcomes of GMP inspections carried out by the other party in their territories. This applies to the manufacture of medicines for human and veterinary use, including biological and immunological products[16], for human and investigational medicinal products.

The agreement also foresees the possibility of EU recognition of inspections carried out by the UK authorities

Opportunities for CDMOs in Europe

In Europe, more than 30% of all healthcare spending in 2018 was on biological medicines[18]. This share is growing. Biosimilars are available in more than 100 countries worldwide, and the EU has authorized 65 biosimilars for use. Biosimilars in Europe had already captured 9% of the total biologics market in 2020 and experienced dramatic growth over the last five years at 58% CAGR[19]. Contract Development and Manufacturing Organizations (CDMOs) are likely to benefit most from the increasing use of biosimilars, as many of these products are outsourced to CDMOs to reduce costs. With over 1,000 biosimilars in development or marketed worldwide and over 800 companies worldwide involved in follow-on products, the demand for mammalian production capacity at CDMOs will only grow.

The accelerating growth of the cell and gene therapy market – projected to grow from USD 1 billion in 2018 to over USD 14 billion by 2025[20] – creates a tailwind for microbial manufacturing. As the industry moves rapidly towards the commercial phase, there is growing need for GMP-grade bacterial plasmid DNA (pDNA). This is a key component in cell and gene therapy (CGT) manufacturing that is produced using microbial systems. Most of today's pDNA manufacturing is outsourced to specialized manufacturers and CDMOs which are struggling to keep up with growing demand; they have built up long waiting lists and substantial backlogs.

The COVID-19 pandemic has exacerbated the problem, as mRNA and DNA vaccines both rely on pDNA in their manufacturing process. Manufacturing mRNA and DNA vaccines require significant quantities of pDNA.

Adding to this growing demand for CGTs, the pDNA supply has become the bottleneck. This poses a significant commercial opportunity for CDMOs that are able to offer GMP quality pDNA supply.

Viral vector manufacturing is another area where CDMOs could meet growing demand. There were 1,220 cell and gene therapies clinical trials ongoing at the end of 2020, with 152 of those trials in Phase 3[21]. In Europe, 378 ongoing clinical trials have 82 trials in phase 3; this supports the FDA and EMA's predictions that they will each be approving 10-20 cell and gene therapies each year by 2025.

Bottlenecks in viral vector manufacturing will limit the widescale commercial manufacturing of cell and gene therapies. This capacity crunch will lead to significant demand for related services from CDMOs, especially for late-stage projects. This is because commercialization or advancing multiple early-stage projects both require considerable manufacturing capacity.

Another factor driving demand for microbial capacity is a potentially disruptive new class of medicines for which the active substance is a living microorganism - Live Biotherapeutic Products (LBPs). LBPs are currently being developed for multiple indications, from gastrointestinal diseases to oncology and diabetes. The lack of outsourcing capacity for process development and commercial manufacturing of LBPs is becoming clear as bacteria-based product candidates progress though phase 2/3 clinical trials.

The first commercial product likely to come to the market within the next few years (most likely in the US) should fuel the demand for manufacturing of LBPs and CDMOs services.

Contributed by Laimutis Abeciunas, MD, MBA
Business Development for Life Sciences Companies
+001 310 923 2565
la2113@caa.columbia.edu

in third countries. Applicants and holders may submit UK-issued GMP certificates for sites located in third countries as supporting information for regulatory submissions in the EU, for consideration as part of the evaluation, as appropriate[17].

For details of the regulatory environment in Europe see Annex 3.

[11] https://assets.kpmg/content/dam/kpmg/xx/pdf/2020/12/beps-2-0-assessing-the-impact-on-your-organization.pdf
[12] www.ema.europa.eu/en/glossary/marketing-authorisation-holder
[13] https://ec.europa.eu/info/relations-united-kingdom/eu-uk-trade-and-cooperation-agreement_en
[14] https://www.ema.europa.eu/en/glossary/medicinal-product
[15] https://www.ema.europa.eu/en/glossary/medicinal-product" \t "_blank" \o "A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.
[16] https://www.ema.europa.eu/en/glossary/advanced-therapy-medicinal-product
[17] https://www.ema.europa.eu/en/glossary/marketing-authorisation" \t "_blank" \o "The approval to market a medicine in one, several or all European Union Member States.
[18] IQVIA: The impact of biosimilar competetion in Europe, 2019.
[19] IQVIA MIDAS® June MAT 2020.
[20] Cell & Gene Therapy Market – Global Outlook and Forecast 2020-2025.
[21] Alliance for Regenerative Medicine's (ARM) 2020 Annual Report.

Spotlight on EU strategies and funding for Life Sciences

The EU has launched various strategies and specific measures to support the Life Sciences Industry. These include May 2021's update on its industrial strategy to support the transition to a green and digital economy, make EU industry more competitive globally, and enhance Europe's strategic autonomy.

In parallel, the European Commission launched a European Pharmaceutical Strategy in 2020, details of which are currently being developed[22].

Certain other initiatives are also relevant to Life Sciences. These include Europe's Beating Cancer Plan, launched in February 2020, which represents a political commitment to leave no stone unturned in the fight against cancer. It is structured around four key action areas: prevention, early detection, diagnosis and treatment, and quality of life. The plan will focus on research and innovation, tapping into the potential offered by digitalization and new technologies[23].

Non-EU countries are also developing strategies that are specific to Life Sciences. The UK is investing heavily to maintain is leading role in Life Sciences R&D. It presented its UK Life Sciences Vision in July 2021, which includes the launch of a Life Sciences Investment Program. The amount of funding available to UK's most promising Life Sciences companies stands at GBP 1 billion.

For details see: Bold new life sciences vision sets path for UK to build on pandemic response and deliver life-changing innovations to patients – GOV.UK (www.gov.uk)

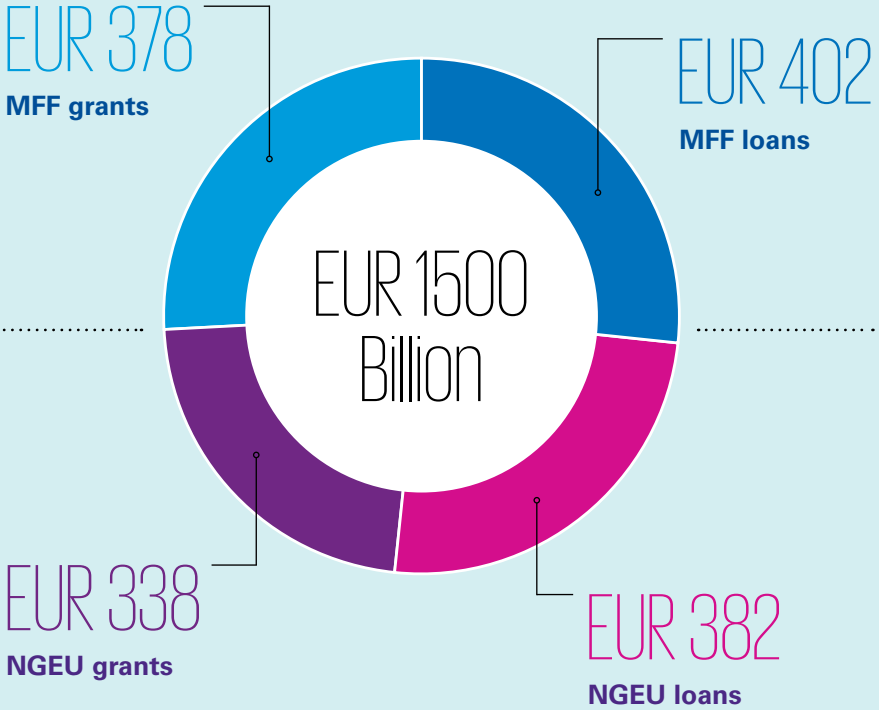
What funding is available?

The MFF and NGEU

In 2020, the EU provided an unprecedented response to the coronavirus crisis. At its heart is a package worth EUR 2.1 trillion in current prices.

MFF grants and loans for innovation, regional development and green transition
EUR 780 billion

The NGEU's Recovery and Resilience Facility to support green transition, digital transformation, job growth, social and regional cohesion and resilience of the health system
EUR 720 billion



The EU's long-term Budget Multiannual Financial Framework (MFF) 2021-2027 of EUR 1.2 trillion is at the core of the funding for the strategic priorities. Around EUR 780 billion of the MFF budget is available to support regional development projects, investment into manufacturing, to finance research and innovation, or to finance the transition towards a greener and more digital economy.

The European Commission also launched a temporary recovery plan for Europe, called NextGeneration (nEU) with a budget of EUR 807 billion to help repair the economic and social damage caused by the coronavirus pandemic.

Around EUR 720 billion of the NGEU budget goes to the Recovery and Resilience Facility (RRF) which supports a green transition, digital transformation, job growth, social and regional cohesion, and the resilience of the health system. This is particularly interesting to Life Sciences projects in the context of green and digital transformation, healthcare, R&D and innovation, education, and resilience.

Other sources of funding

In addition to the EU funding is funding from the European Investment Bank's (EIB) through its investment arm the European Investment Fund (EIF). It provides direct funding through debt and equity instruments, or indirectly via funding for private equity and other funds which then invest in innovative companies in the EU.

The European Bank for Reconstruction and Development (EBRD) also plays an important role in developing the manufacturing sector in Europe by supporting corporate clients with both debt and equity financing.

Programs and funds funded by MFF

Around EUR 780 bn of the EU MFF budget is available in the form of grants and loans, from which Life Sciences companies can benefit. The EU budget is split into various categories (Headings), with each containing different programs with different funds. The following page provides an overview of the different funding facilities.

How can Life Sciences companies benefit from funding and grants from the RRF?

The European Commission is currently reviewing the National Recovery and Resilience Programs submitted by the member states, who shall implement them by the end of 2021[24]. Certain national programs have a focus on support for research and development and for health-related projects. For further details please refer to Annex 4.

[22] https://ec.europa.eu/health/human-use/strategy_en
[23] https://www.europeancancer.org/policy/1:the-europe-s-beating-cancer-plan.html
[24] An up-dated list on the on the programs of the member states can be found on the recovery and resilience website Recovery and Resilience Facility | European Commission (europa.eu)

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Programs and Funds funded by MFF which are accessible for Life Sciences Projects

Owner	Program	Funds	Program
European Commission	Research and Innovation	Horizon Europe	Grants, Prices
European Commission	Research and Innovation	Digital Europe Program	Grants
EC/EIB/EIF	European Strategic Investments	Invest EU	Loan guarantees to implementing partners
European Commission	Regional Development and Cohesion	European Regional Development + Cohesion Fund	Grants
European Commission	Recovery and Resilience Facility	EU4Health	Grants
European Commission	Environment and Climate Action	Just Transition Fund	Grants, loans and financial guarantees

Headings: Single Market, Innovation and Digital | Cohesion, Resilience and Values | Natural Resources and Environment

Overview	Target Beneficiary	Budget 2021 - 2026
Largest research and innovation funding program in the world and the most ambitious such program in the history of the EU. Focus on fundamental research, applied research and support for start-ups	Companies of any size, Universities, NGOs. One focus is on Health and Bioeconomics	EUR 95.5 bn
The Digital Europe Program provides strategic funding in five key capacity areas: supercomputing, artificial intelligence, cybersecurity, advanced digital skills and application of digital technologies across the economy and society	Companies of any size (i.e. active in digital health), universities, NGOs, etc	EUR 7.6 bn
EU loan guarantees of EUR15.2 bn to implementing partners such as the European Investment Bank (EIB) Group and other financial institutions and national banks with the aim to mobilize EUR 372 bn in loans	Companies of any size can apply via implementing partners	Up to EUR 372 bn
Largest EU program to support economic growth and social cohesion. Accessible to regions which have a GDP per capita which is below 90 percent of the average GDP of the EU-27	Project of any size; typically large FDI projects. Accessible via national or regional managing organizations	EUR 274 bn
EU4Health's objective is to strengthen the EU-wide healthcare system resilience through a variety of measures such as digital tools & services or improvement of access to medical products and devices	Program under development: companies, hospitals, NGOs, governments which can provide support, services or products related to key objectives of the program	EUR 5.3 bn
Just Transition Mechanism (JTM) is a complementary financial instrument, created to support decarbonization of 31 European coal regions in 11 member states with funding by the Just Transition Fund (JTF).	JTF supports companies which are investing in low carbon technologies and sustainable job creation in coal regions.	EUR 19.3 bn

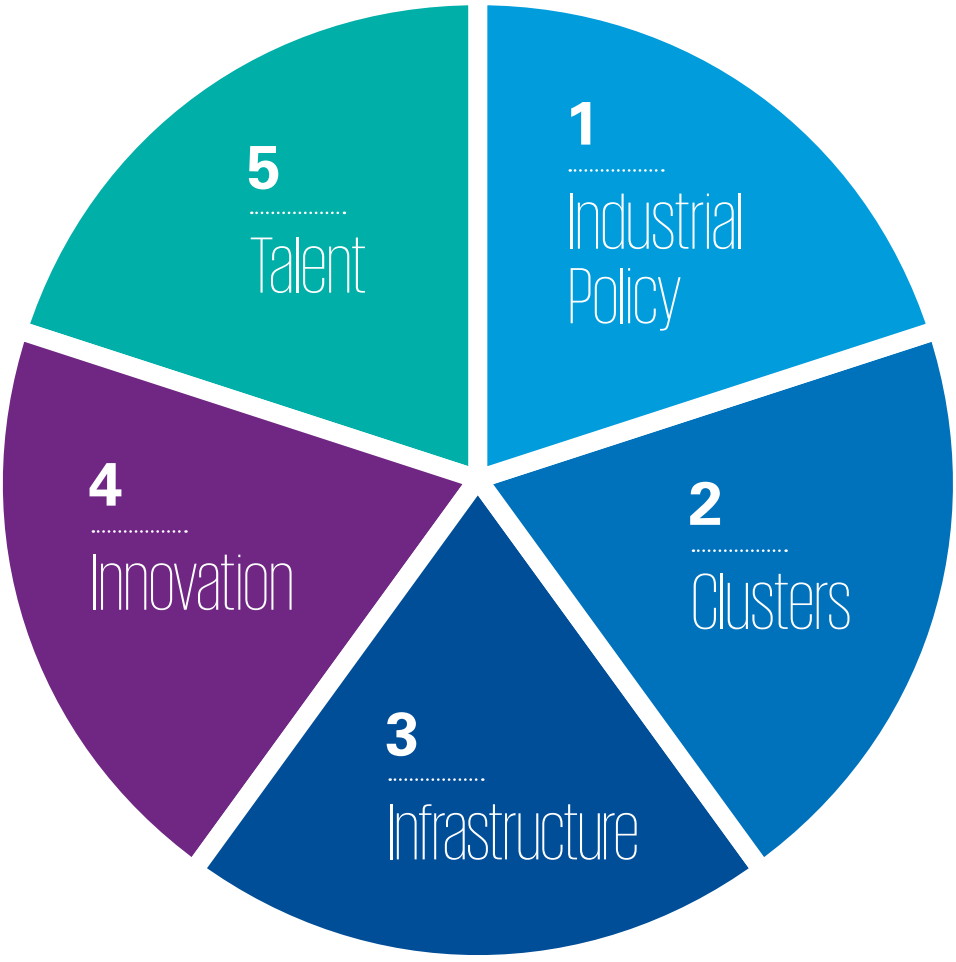
Part 2:

Site Selection

The European Medicines Agency is one of the most important EU institutions relevant to Life Sciences. It has a huge impact on making a large part of Europe more easily manageable for Life Sciences. Despite great efforts and achievements, Europe remains complex and fragmented in many respects, however. Brexit has further complicated the European business landscape, resulting in two of Europe's leading Life Sciences countries – Switzerland and the UK – not being part of the European single market, the world's second largest market for pharma products and medical devices.

Given this complexity it is important that Life Sciences companies understand the European landscape in depth when planning to start or expand operations in Europe. This includes a detailed view of the advantages and disadvantages of the various locations – and how the various countries are embedded in pan-national systems such as the EU single market or the Schengen system. The networks of bilateral tax treaties and investment protection agreements are also major factors relevant when selecting a location in Europe.

There are five commonly used site selection criteria: criteria: industrial policy, clusters, infrastructure, innovation, and talent.



Industrial policy

The industrial policy criteria include industrial strategy, tax strategy and incentives to attract investments in Life Sciences. Countries with a clearly defined industrial policy or Life Sciences strategy, including taxes and incentives, are attractive as companies can expect a commitment for specific support for existing and planned activities.

Examples of countries in Europe which have a clearly defined national Life Sciences and/or industrial strategy can be found below:

Country	Year	Type
Austria	2014	General Life Sciences Industry Strategy
Denmark	2021	General Life Sciences Industry Strategy
France	2021	General Life Sciences Industry Strategy
Ireland	2019-2023	General Life Sciences Strategy
Italy	2019	Pharma Manufacturing Strategy
Latvia	2018	Biotech Industry Strategy
Lithuania		General Research and Innovation Strategy
Netherlands	2020-2023	General Life Sciences Strategy
Norway	2011-2020	Biotech Industry Strategy
Portugal	2020	General Life Sciences Industry Strategy
Sweden	2020	General Life Sciences Industry Strategy
Switzerland	2018, 2030	Life Sciences Research and Innovation Strategy – General Life Sciences Industry Strategy
United Kingdom	2020	General Life Sciences Industry Strategy

Source: KPMG intern

When deciding where to locate key value drivers, an attractive tax and incentive environment should include competitive ordinary corporate tax rates. International tax treaties with leading trading partners are also important. The table on the next page shows the ordinary corporate tax rates for 2021.

It should be noted that BEPS 2.0 will put a halt to certain tax planning opportunities and make grants and loans even more relevant to companies seeking governmental support.

For details on taxes and incentives, refer to Annex 2.

Corporate Profit Tax Rates

	2021
Austria	25.00%
Belgium	25.00%
Bulgaria	10.00%
Croatia	18.00%
Cyprus	12.50%
Czech Republic	19.00%
Denmark	22.00%
Estonia	20.00%
Finland	20.00%
France	26.50%
Germany	30.00%
Greece	24.00%
Hungary	9.00%
Ireland	12.50%
Italy	24.00%
Lathvia	20.00%
Lithuania	15.00%
Luxembourg	24.94%
Netherlands	25.00%
Norway	22.00%
Poland	19.00%
Portugal	21.00%
Romania	16.00%
Serbia	15.00%
Slovakia	21.00%
Slovenia	19.00%
Spain	25.00%
Sweden	20.60%
Switzerland average	14.87%
United Kingdom	19.00%

Source: KPMG intern

Clusters

Comparing cluster sizes and pipelines is a good indicator of a location's attractiveness. A strong cluster creates a local pool of talent, expertise and know-how that supports profitable pipelines. The positive impact of clusters is particularly pronounced when it comes to innovation, as clusters may enable drug discovery and development specialists to benefit from the creative environment around a strong academic ecosystem.

Clusters can, however, become victims of their own success when salary levels for specialists spike due to increased demand, or land prices and office rents increase. They lead to a higher staff turnover rate and increased retention costs. In Life Sciences, this is felt especially in manufacturing where technical employees are often trained in-house but then move on to new roles with competitors.

Depending on the type of activities for which a location is being scouted, a company might decide to be at the core of a Life Sciences cluster, e.g. for R&D where proximity to top academia or international HQ operations is required. For manufacturing operations, a location on the fringe of a Life Sciences cluster would be more suitable, due to the better availability of a qualified workforce.

The list on the left shows the number of companies in different segments per country. A definition of the segements can be found at http://www.biotechgate.com/web/cms/index.php/covered_industry_sectors.html.

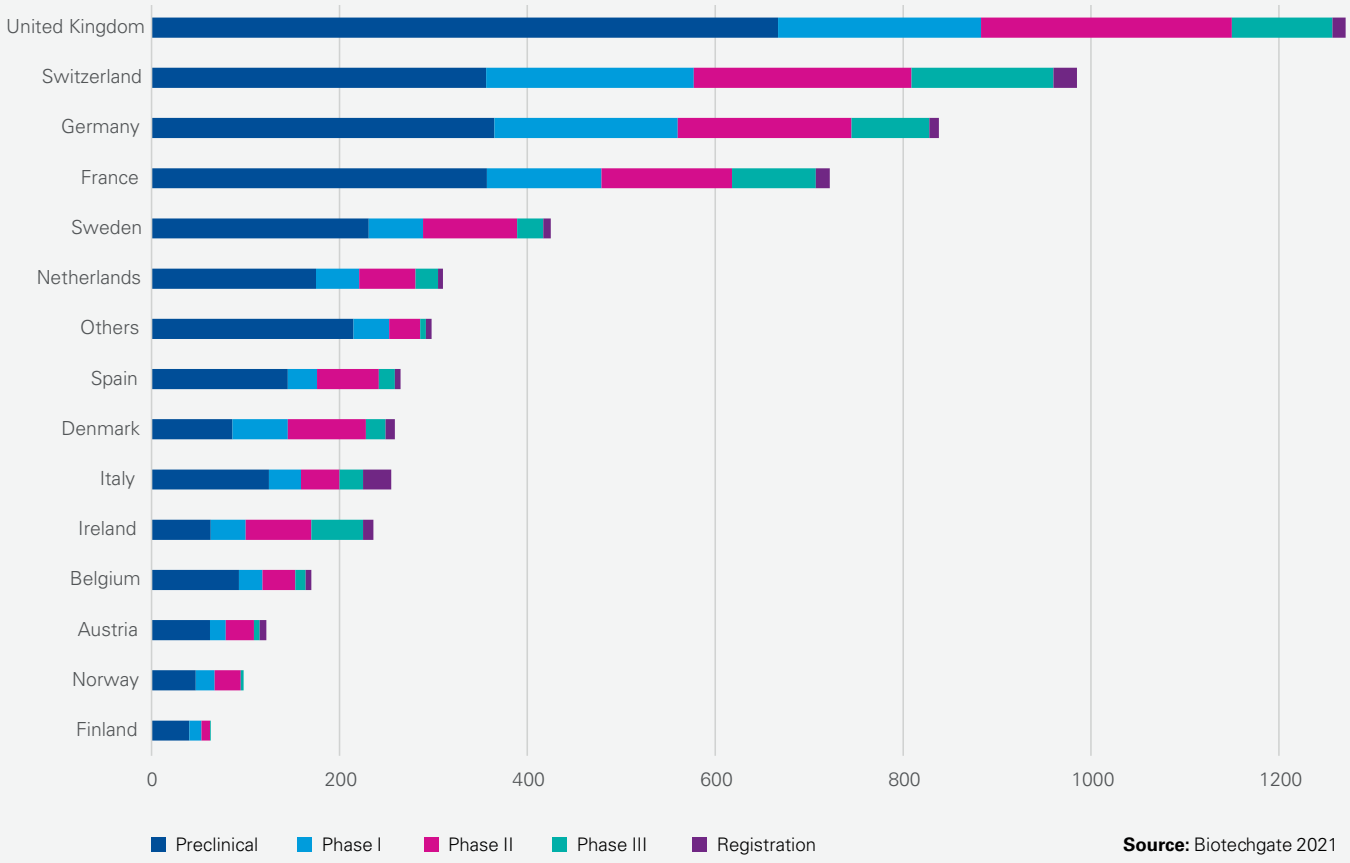
KPMG

Number of companies in the Life Sciences industry per country

Country	Bio-technology – Other	Bio-technology – R&D Services	Biotechnology – Therapeutics and Diagnostics	Digital Health	Medical Technology	Pharma (fully integrated)	Total
Austria	15	64	49	6	21	20	175
Belgium	76	147	80	15	54	38	410
Bulgaria	4	13		11		3	31
Croatia	1	10			1	6	18
Cyprus		4	2	3	1	2	12
Czech Republic	12	46	5	5	10	6	84
Denmark	32	89	78	26	96	12	333
Estonia	1	14	1	5	3	1	25
Finland	16	52	20	29	43	9	169
France	187	468	261	189	262	81	1'448
Germany	193	786	220	74	552	121	1'946
Greece	5	20	3	12	5	20	65
Hungary	16	62	9	15	28	10	140
Iceland	2	2	3		2	2	11
Ireland	36	58	48	26	76	64	308
Italy	159	221	65	23	100	80	648
Latvia	11	6	1	13	6	7	44
Lithuania	21	33	7	16	29	4	110
Luxembourg		1	5	1	1		8
Malta	1	2	1	1		1	6
Netherlands	135	217	139	63	133	42	729
Norway	76	47	45	33	38	9	248
Poland	36	64	13	25	37	26	201
Portugal	10	20	11	15	9	9	74
Romania	3	3		10	1	8	25
Slovakia	5	11		7		4	27
Slovenia	5	3	1	2	6	3	20
Spain	197	298	120	233	131	96	1'075
Sweden	99	214	171	97	287	44	912
Switzerland	100	243	250	90	283	72	1'038
United Kingdom	200	681	423	108	313	126	1'851
Total	**1'674**	**3'939**	**2'054**	**1'159**	**2'546**	**984**	**12'356**

Source: Biotechgate 2021

Product pipeline and stage of development



Source: Biotechgate 2021

An analysis of product pipelines provides a good understanding of the strength of a Life Sciences cluster. The UK has the strongest product pipeline in Europe, followed by Switzerland. A review of Phase III products places Switzerland ahead of the UK, though.

It should be taken into account that certain products are owned by a company in one country while development takes place in another country.

Economic fundamentals

Economic fundamentals are important when choosing where to locate valuable assets such as manufacturing plants or IP.

Government debt as a percentage of GDP is a key indicator of economic stability. Deficit spending is not indefinitely sustainable; it impacts a country's credit rating and consequently its refinancing costs. COVID-19 has changed the government debt landscape dramatically, with debt levels increasing in many countries. It remains to be seen how sustainable those levels are going forward in some national economies that have weak economic fundamentals.

Another indicator is the current account balance, which shows how much a country is importing or exporting in relation to its GDP. Governmental spending in percentage of the GDP indicates how strong the governmental sector is compared to the private sector.

Economic fundamentals

Country	GDP (USDbn) 2020	"GDP (PPP) per capita in (current international) USD 2019/2020"	Current account balance in % of GDP 2020	Government debt as % of GDP	Government expenditure as % of GDP
Austria	428,965.40	58,649.70	2.50	83.9	57.90
Belgium	515,332.50	54,693.40	-0.20	114	60.00
Bulgaria	69,105.10	24,579.20	-0.80	24.2	42.90
Croatia	55,966.58	30,246.00	-1.00	88.7	55.40
Cyprus	23,804.34	38,458.20	-12.00	118	46.30
Czech Republic	243,530.38	43,004.50	3.60	38.1	46.30
Denmark	355,184.02	60,334.80	7.30	42.2	54.00
Estonia	31,029.97	38,819.30	-1.30	18.2	45.10
Finland	271,233.88	51,619.80	-0.20	69.2	56.70
France	2,603,004.40	49,377.10	-1.9	116	62.10
Germany	3,806,060.14	55,891.20	7.00	69.8	51.10
Greece	189,410.11	30,869.20	-6.70	206	60.70
Hungary	155,012.93	33,949.60	0.10	80.4	51.60
Ireland	418,621.82	87,212.00	-11.30	59.5	28.40
Italy	1,886,445.27	44,821.00	3.70	156	57.30
Latvia	33,505.19	32,047.30	3.00	43.5	43.60
Lithuania	55,887.27	38,756.10	8.40	47.3	43.50
Luxembourg	73,263.98	120,962.20	4.10	24.9	47.80
Malta	14,647.38	46,071.20	-3.90	54.3	46.60
Netherlands	912,242.34	59,469.10	7.80	54.5	48.10
Norway	362,008.96	67,978.70	1.90	40.3	58.40
Poland	594,164.69	34,151.80	3.50	57.5	48.70
Portugal	231,255.59	36,760.10	-1.10	134	48.40
Romania	248,715.55	32,349.20	-5.30	47.3	42.40
Slovakia	104,574.15	32,545.00	-0.30	60.6	48.00
Slovenia	52,880.47	41,193.80	7.10	80.8	52.00
Spain	1,281,199.09	42,185.60	0.70	120	52.30
Sweden	537,609.87	55,027.40	5.20	39.9	52.90
Switzerland	747,968.64	70,276.60	3.80	42.9	36.20
United Kingdom	2,707,743.78	48,438.60	-3.50	97.4	52.20

Source:	http://data.worldbank.org/indicator/NY.GDP.MKTP.CD	https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD	http://data.worldbank.org/indicator/BN.CAB.XOKA.GD.ZS	https://tradingeconomics.com/country-list/government-debt-to-gdp	https://tradingeconomics.com/country-list/government-spending-to-gdp

General competitiveness comparisons

Rising competitiveness leads to rising prosperity. Competitive economies are likely to grow more sustainably and inclusively, meaning that everyone in society benefits. Various organizations issue global rankings of countries based on certain competitiveness aspects. As countries' rankings can vary significantly over time and between reports, it is advisable to analyze trends by country rather than observing only snapshots for a given year or ranking.

The **Index of Economic Freedom by the Heritage Foundation** measures economic freedom of countries based on freedom of trade, business freedom, investment freedom and property rights.

The **IMD World Competitiveness Yearbook** measures how well countries manage their resources and competencies to facilitate long-term value creation.

Country	Ranking 2020*	Ranking 2021**
Austria	25	19
Belgium	37	24
Bulgaria	35	53
Croatia	79	59
Cyprus	33	33
Czech Republic	27	34
Denmark	10	3
Estonia	8	26
Finland	17	11
France	64	29
Germany	29	15
Greece	96	46
Hungary	55	42
Ireland	5	13
Italy	68	41
Latvia	30	38
Lithuania	15	30
Luxembourg	18	12
Malta	36	na
Netherlands	16	4
Norway	28	6
Poland	41	47
Portugal	52	36
Romania	43	48
Slovakia	61	50
Slovenia	48	40
Spain	39	39
Sweden	21	2
Switzerland	4	1
United Kingdom	7	18

*Source: https://www.heritage.org/index/

**Source: https://www.imd.org/centers/world-competitiveness-center/rankings/world-competitiveness/

Political stability and corruption

The World Bank's Worldwide Governance Indicators (WGI) project reports aggregate and individual governance indicators for various dimensions of governance relevant to doing business. European countries generally rank very favorably compared to many others worldwide. However, as the IMD Competitiveness Report states, there is still a risk of political instability, especially in eastern Europe.

Country	Rank*	Risk of political instability 2020**
Austria	82.86	6
Belgium	61.90	48
Bulgaria	66.19	47
Croatia	71.90	43
Cyprus	63.33	21
Czech Republic	80.48	37
Denmark	83.81	1
Estonia	68.10	33
Finland	79.05	7
France	58.57	19
Germany	66.67	11
Greece	57.14	28
Hungary	71.43	29
Ireland	82.38	22
Italy	60.95	56
Latvia	60.00	31
Lithuania	75.24	32
Luxembourg	95.71	3
Malta	89.05	na
Netherlands	75.71	5
Norway	92.38	15
Poland	64.29	51
Portugal	90.95	20
Romania	65.24	57
Slovakia	72.38	59
Slovenia	73.81	36
Spain	59.05	53
Sweden	86.67	12
Switzerland	94.76	2
United Kingdom	63.81	23

*Source: http://info.worldbank.org/governance/wgi/index.aspx#reports

**Source: IMD Worldbook 2020, risk of instability. Ranking: 1 being the lowest, 63 being the highest risk

Corruption Perception Index

Country	Index/Rank (of 180)	Score (of 100)
Austria	15	76
Belgium	15	76
Bulgaria	69	44
Croatia	63	47
Cyprus	42	57
Czech Republic	49	54
Denmark	1	88
Estonia	17	75
Finland	3	85
France	23	69
Germany	9	80
Greece	59	50
Hungary	69	44
Ireland	20	72
Italy	52	53
Latvia	42	57
Lithuania	35	60
Luxembourg	9	80
Malta	52	53
Netherlands	8	82
Norway	7	84
Poland	45	56
Portugal	33	61
Romania	69	44
Slovakia	60	49
Spain	32	62
Slovenia	35	60
Sweden	3	85
Switzerland	3	85
United Kingdom	11	77

Source: https://www.transparency.org/country

A high level of corruption is particularly problematic for Life Sciences companies as they operate in a highly regulated environment, including having many touchpoints with governments and regulators.

The Nordics and Switzerland lead the table, while eastern European countries are generally less transparent.

Resilience

Catastrophic events can impact businesses dramatically. Resilience is defined as the capacity to recover from challenging events in uncertain times.

The FM Global Resilience Index is the first data-driven tool that ranks the resilience of 130 countries and territories according to their enterprise resilience to disruptive events.

Denmark tops the table for overall resilience, followed by a cluster of very high scorers: Norway, Luxembourg, Germany, Switzerland, and Finland.

Access to the EU market and international treaty network

Productivity and efficiency are critically impacted by how well a location is embedded in the wider network. Countries participate in international trade through free trade agreements, investment protection treaties and double taxation treaties, social security treaties, and agreements on the free movement of people. A strong framework of treaties facilitates and accelerates international growth.

Free movement of goods and people

While most countries covered in this report belong to the EU, Switzerland, Norway and the UK are not part of it (the UK left effective 31 January 2020).

The Schengen Area comprises most EU countries, except for Bulgaria, Croatia, Cyprus, Ireland and Romania. Non-EU States Iceland, Norway and Switzerland have also joined the Schengen area, which operates as a single jurisdiction for international travel purposes with a common visa policy.

The UK is the only country in this report that is neither a member of the EU nor the Schengen area[25] – it was not a member of Schengen even when it was part of the EU.

A functioning single market stimulates competition and trade, improves efficiency, raises quality and helps cut prices. 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[26]. Norway and Switzerland have access to the EU single market[27].

The EU and the UK have concluded a Trade and Cooperation agreement which entered into force on 1 May 2021[28].

Global Resilience Index

Country	Ranking	Index/ Overall Score
Austria	8	94.2
Belgium	15	90.1
Bulgaria	45	64.6
Croatia	40	67.4
Cyprus	43	64.7
Czech Republic	20	87.2
Denmark	1	100
Estonia	28	76.5
Finland	6	95.3
France	19	89.3
Germany	4	96.2
Greece	51	57.2
Hungary	35	72.8
Ireland	11	91.4
Italy	33	74
Latvia	39	68.5
Lithuania	30	76
Luxembourg	3	96.7
Malta	46	62.8
Netherlands	16	90
Norway	2	98.1
Poland	24	84.1
Portugal	27	76.8
Romania	38	70.4
Slovakia	31	75.3
Slovenia	41	67.1
Spain	21	86.8
Sweden	7	95
Switzerland	5	96.2
United Kingdom	10	91.5

Source: https://www.fmglobal.com/research-and-resources/tools-and-resources/resilienceindex/explore-the-data/?&vd=1

[25] https://ec.europa.eu/home-affairs/what-we-do/policies/borders-and-visas/visa-policy/schengen_visa_en
[26] www.ec.europa.eu
[27] https://ec.europa.eu/growth/single-market_en
[28] https://ec.europa.eu/info/relations-united-kingdom/eu-uk-trade-and-cooperation-agreement_en

All EU member states are part of the Economic and Monetary Union (EMU) and coordinate their economic policymaking to support the EU's economic aims.

The Euro is the most tangible proof of European integration: around 341 million people use it every day, making it the second most-used currency worldwide. The benefits of the common currency are immediately obvious to anyone travelling abroad or shopping online on websites based in another EU country.

Bulgaria, Croatia, the Czech Republic, Denmark, Hungary, Poland, Romania and Sweden are the EU member states that are not part of the Eurozone.

Country	Schengen Area	Access to EU single market	EMU member	Eurozone member state
Austria	Yes	Yes	Yes	Yes
Belgium	Yes	Yes	Yes	Yes
Bulgaria	No	Yes	Yes	No
Croatia	No	Yes	Yes	No
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	No	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	No*	No	No

Source: https://www.schengenvisainfo.com/de/ https://www.efta.int/free-trade/fta-map https://europa.eu/european-union/about-eu/countries_en https://ec.europa.eu/info/business-economy-euro/euro-area/what-euro-area_en

International Investment Agreements

The value chains of larger Life Sciences businesses traditionally spread over various jurisdictions. Governments are eager to attract the most valuable parts of these value chains such as R&D or manufacturing and will provide generous tax breaks, grants and loans for investments. Investors must be aware, however, that investment in a foreign jurisdiction can bear risks: governments may introduce exchange control mechanisms, withdraw tax-free status or cancel tax rulings, introduce out-of-proportion tax collection measures, or in certain cases even expropriate assets (including patents) belonging to the investor.

Around 3,000 International Investment Agreements (IIA) are in force, most of which are bilateral, helping protect investors that have investments in foreign jurisdictions.

By entering into IIAs, states commit inter alia to refrain from implementing expropriation measure and to provide fair and equitable treatment to foreign investors.

Life Sciences companies with valuable tangible and intangible assets should take into account the network of IIAs in place when deciding how to organize. It can be advisable to hold certain investments via an entity in a jurisdiction with a dense IIA network, for instance. As with tax planning models, however, substance requirements may also apply to IIA, when deciding if an IIA applies.

European countries with the largest network of IIAs include Germany, Switzerland, the UK, France, the Netherlands and Luxembourg.

An overview of the IIAs currently in place can be found on the Unctad Investment Policy Website[29].

Investors who wish to maintain the option of bringing a case before an independent panel of arbitrators (rather than local courts) for an investment in an EU country need to invest via an entity outside of the EU with an IIA in place with the respective target country.

[29] https://investmentpolicy.unctad.org/international-investment-agreements

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Physical infrastructure

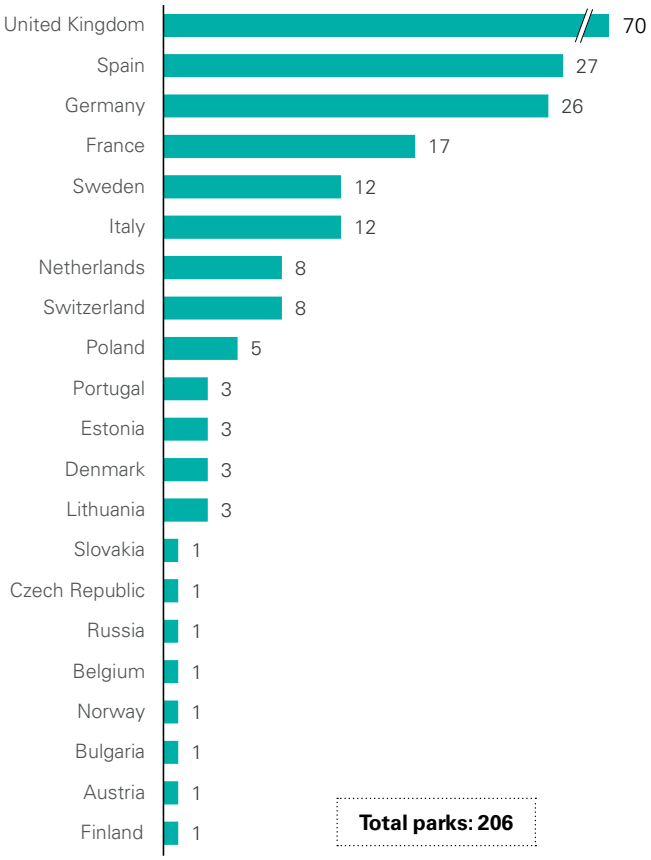
Infrastructure quality is of great importance in Life Sciences, where disruptions to manufacturing or logistics can have a significant impact on supply chains.

Quality of infrastructure (ranking)

Country	Quality of overall infrastructure	Distribution infra-structure of goods and services generally	Road infrastructure-density of network	Railroads-density of the network	Quality of air transportation
Austria	10	7	14	14	18
Belgium	19	22	na	4	24
Bulgaria	50	52	45	24	46
Croatia	48	45	36	22	57
Cyprus	38	27	5	61	41
Czech Republic	32	37	12	3	42
Denmark	2	1	10	20	4
Estonia	33	35	19	31	59
Finland	4	5	43	35	8
France	13	9	7	18	19
Germany	11	11	9	7	9
Greece	39	36	29	36	34
Hungary	41	41	6	8	37
Ireland	23	40	16	30	33
Italy	30	42	38	16	43
Latvia	37	34	26	28	27
Lithuania	34	19	21	27	40
Luxembourg	24	20	24	5	29
Malta	n/a	n/a	n/a	n/a	n/a
Netherlands	9	3	4	11	5
Norway	6	24	33	46	20
Poland	35	39	18	13	39
Portugal	27	10	47	29	32
Romania	47	56	39	23	52
Slovakia	46	51	27	9	58
Slovenia	29	38	8	15	62
Spain	26	16	17	26	14
Sweden	1	8	20	32	12
Switzerland	3	2	11	6	3
United Kingdom	12	26	15	12	23

Note: Ranking from 1 to 63; **Source:** IMD, the World Competitiveness Yearbook 2020

Number of science and technology parks per country



Source: Biotechgate

There is a dense network of science or pharma/biotech parks across Europe. Often set up as public private partnerships, the aim is to attract investment or support growth. Unlike incubators these parks focus mostly on tenants with commercial products on the market. Such parks have recently become targets of specialized investors focusing on Life Sciences real estate.

These parks offer an attractive solution for Life Sciences companies that are looking for ready to operate locations for their R&D and manufacturing activities.

In contrast to the US where market data for the leading Life Sciences hubs are readily available, this is not case for Europe. Market data such as rents, yields and vacancy rates is not available through the usual sources of broker reports or databases. One reason for this is the fragmented market in Europe. While in the US, the Life Sciences industry is concentrated in 5-10 hubs, the industry in Europe is much more spread out. There is a split between privately managed parks and parks that are largely operated by public entities.Incubators are different from science or pharma/biotech parks as they support precommercial companies. An incubator is an institution to support technology-oriented, preferably innovative start-ups and young companies that are designed to grow. Technology and start-up centers are also intended to contribute to regional economic development and networking.

CEIV Pharma

The pharmaceutical and air cargo industry faces many challenges that lie ahead. There is a growing number of global, regional, and local regulations and compliance requirements to comply with for airlines, ground handlers, warehouse operators, trucking companies and forwarders. This growing trend makes it is essential for all players handling pharmaceuticals to align themselves around a global certification standard. Cold chain management requires a holistic approach and process to maintain integrity of pharmaceuticals, but some shippers, operators and facilities are not properly equipped and prepared to manage it effectively.

Working alongside aviation industry stakeholders and regulators, IATA has created the Center of Excellence for Independent Validators in Pharmaceutical Logistics (CEIV Pharma) to help organizations and the air cargo supply chain get on the right track for pharma handling excellence. CEIV Pharma addresses industry's need for greater safety, security, compliance, and efficiency, through the creation of a globally consistent and recognized pharma product handling certification.

By establishing a common baseline from existing regulations and standards, this certification ensures international and national compliance to safeguard product integrity while addressing specific air cargo needs.
CEIV Pharma encompasses, or even supersedes, many existing standards and guidelines such as:

- IATA Temperature Control Regulations (TCR)
- European Union Good Distribution Practices (EU GDP)
- World Health Organization Annex 5 (pdf)
- United States Pharmacopeia Standards

All certified companies will also be registered on IATA's newest platform ONE Source. IATA ONE Source is an online industry platform for validated aviation capability and infrastructure information. ONE Source only lists information verified through the different IATA validation programs.

This is particularly timely amid the COVID-19 crisis when shippers of medical supplies and pharma need accurate information for time and temperature-sensitive shipments. ONE Source lists the latest operational information on airlines, airports, cargo handling facilities, freight forwarders, ground handlers, shippers, and trucking companies. IATA ONE Source is free for all service providers across the air cargo supply chain.

More information on IATA's website: https://customer-portal-iata.force.com/onesource/s/

Contributed by: Ronald Schaefer, Senior Principal
IATA Consulting, schaeferr@iata.org

Certification approach and methodology

IATA will certify companies in several steps

1 Preparation

- Assemble team
- Prepare project logistics
- Send data and information request
- Send interview request sheet for first visit

3 Assessment

- On-site (remote) assessment by Independent validator
- Assessment versus minimum IATA CEIV Pharma Checklist
- Comparison against best practice
- Establish findings and offer recommendations for change
- Develop implementation plan and secure resources

4 Validation

- On-site (remote) visit by an Independent Validator to ensure full compliance with the IATA CEIV Pharma checklist and also review the progress made against recommendations during the assessment phase
- Drafting of report

5 Certification

2 Training required for certification

6 Additional training

Safety and security

Covid19 has shown the vulnerability of globals supply chains to biological risks. For Life sciences companies it advisable to take such considerations into account when looking for locations to place key value drivers and assets. The Global Health Security (GHS) Index is a comprehensive assessment and benchmarking of health security and related capabilities across 195 countries. It indicates a country's readiness to respond to potentially catastrophic biological events such as epidemics or pandemics.

Country	GHS overall score
Austria	26
Belgium	19
Bulgaria	61
Croatia	38
Cyprus	77
Czech Republic	42
Denmark	8
Estonia	29
Finland	10
France	11
Germany	14
Greece	37
Hungary	35
Ireland	23
Italy	31
Latvia	17
Lithuania	33
Luxembourg	67
Malta	98
Netherlands	3
Norway	16
Poland	32
Portugal	20
Romania	60
Slovakia	52
Slovenia	12
Spain	15
Sweden	7
Switzerland	13
United Kingdom	2

Source: www.ghsindex.org

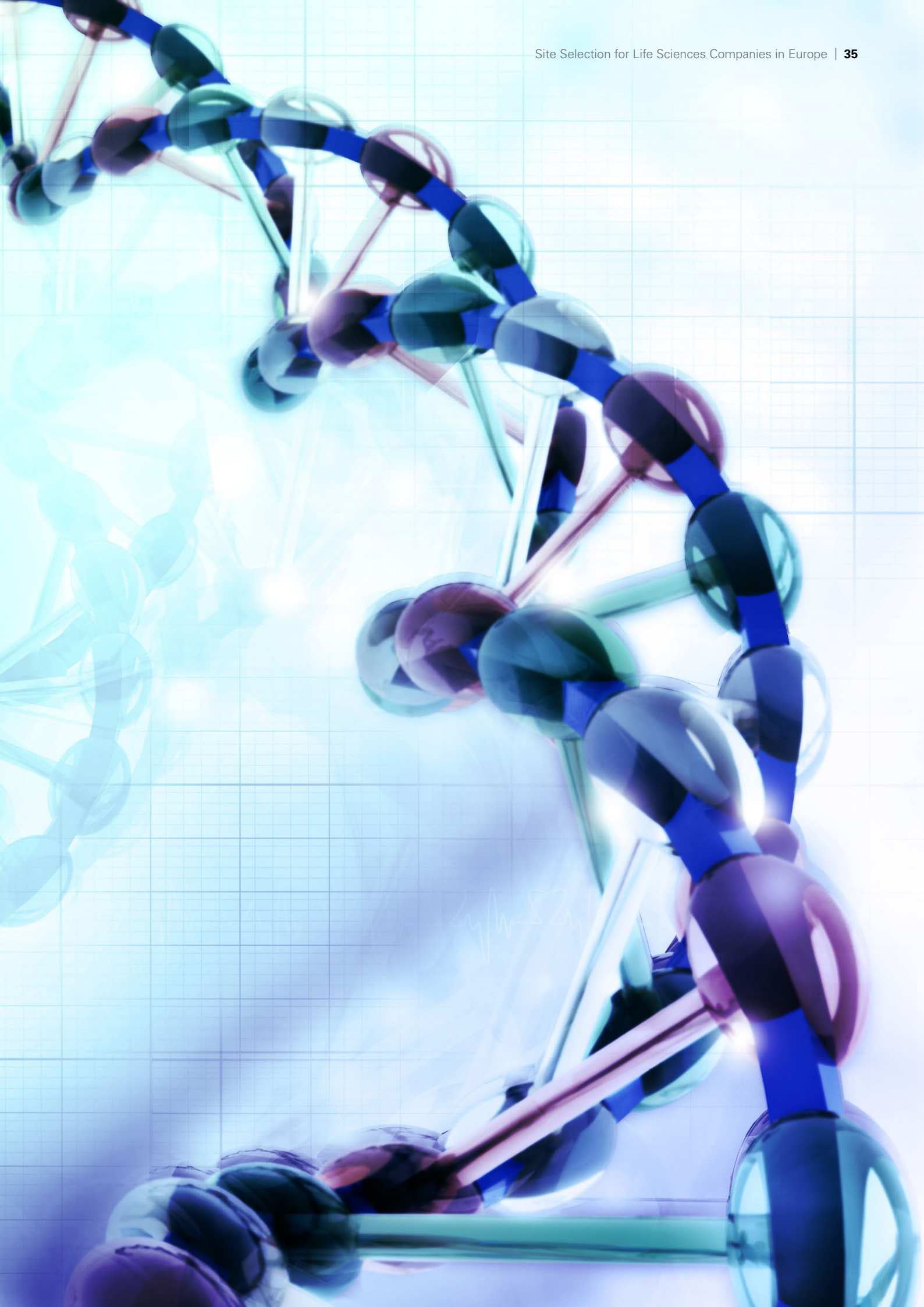
Maximum containment facilities are crucial infrastructure for research with dangerousness pathogens. There are currently 22 such BSL 4 facilities in operation in Europe.

Country	BSL-4 labs
Czech Republic	2
France	3
Germany	4
Hungary	2
Italy	2
Sweden	1
Switzerland	1
United Kingdom	7

Source: www.globalbiolabs.org

Important organizations in Europe

Name	link
EBE – European Biopharmaceutical Enterprises	https://www.efpia.eu/
EFPIA – European Federation of Pharmaceutical Industries and Associations	https://www.efpia.eu/
EMA – European Medicines Agency	https://www.ema.europa.eu/en
EPHA – European Public Health Alliance	https://epha.org/
Europa Bio	www.europabio.org
FDA Europe Office	www.fda.gov/about-fda/office-global-operations/europe-office
GIRP – European Healthcare Distribution Association	http://girp.eu/
Medicines for Europe – representing generic, biosimilar and value added industries	https://www.medicinesforeurope.com/
PGEU – Pharmaceutical Group of European Union	https://www.pgeu.eu/



Spotlight on FDA-regulated pharma manufacturing plants

The FDA has a physical presence in Europe. Facilitating progress on joint European-US projects that span the full spectrum of FDA-regulated products, it covers the EU and individual non-EU countries such as the UK, Switzerland and Norway. The FDA Europe Office's mission is to strengthen the safety, quality and effectiveness of medical products and food produced in Europe for export to the US.

One focus is Pharmaceutical Mutual Recognition Agreements (MRA). The FDA, EU and individual member states may rely on each other's GMP inspections, freeing up valuable regulatory resources. The Europe Office has a critical role in conducting capability assessments and facilitating other steps necessary to establish and implement MRA processes.

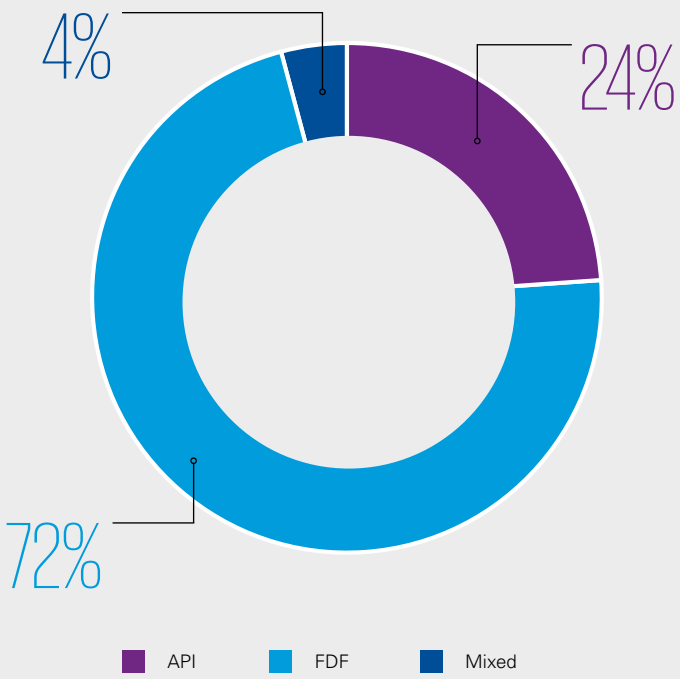
Europe has a total of 999 FDA-regulated pharma manufacturing plants. Of these, 240 produce only active pharmaceutical ingredients (APIs), 722 focus only on finished dosage form (FDF) production, and 37 are mixed plants. The difference between western and eastern Europe is quite pronounced. In western Europe, 882 plants comprise 214 API, 634 FDF and 34 mixed. The 117 plants in eastern Europe are 26 API, 88 FDF and three mixed.

There is a tendency to create specialized plants rather than mixed sites. European pharma manufacturing focuses primarily on FDFs rather than APIs.

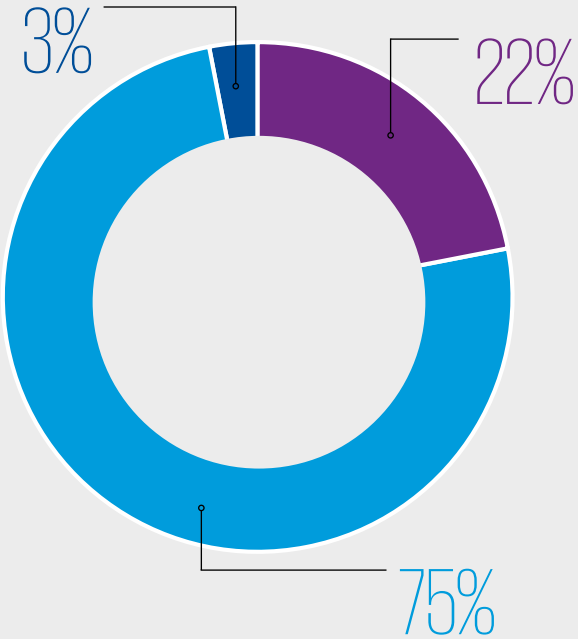
Further information: https://www.fda.gov/about-fda/office-global-operations/europe-office

Distribution of manufacturing facilities for operating business units in western and eastern Europe

Facilities in western Europe



Facilities in eastern Europe



FDA approved manufacturing plants per country

Country	Regions	API	FDF	Mixed	Total facilities
Austria [A]	Vienna	0	4	4	19
	Rest of Austria	3	7	1	
Belgium [A]	Brussels	1	3	0	36
	Greater Liege	1	4	0	
	Greater Puurs	0	4	1	
	Flemish	2	6	0	
	French	5	9	0	
Bulgaria [B]	Bulgaria	0	6	0	6
Cyprus [B]	Cyprus	0	2	0	2
Croatia [B]	Croatia	0	4	0	4
Czech Republic [B]	Czech Republic	6	4	1	11
Denmark [A]	Copenhagen	2	12	3	25
	Rest of Denmark	3	3	2	
Estonia [B]	Estonia	0	0	0	0
Finland [A]	Finland	2	6	0	8
France [A]	North	8	25	0	127
	Paris	3	16	0	
	Center	10	29	1	
	South	4	19	0	
	Lyon	3	9	0	
Germany [A]	North	21	33	3	168
	Berlin	3	5	0	
	South	23	65	1	
	Munich	1	3	0	
UK [A]	Scotland	6	10	0	119
	Wales	0	7	0	
	North England	8	28	1	
	Northern Ireland	1	5	0	
	South England	3	35	1	
	London	0	9	1	
	Oxbridge	1	3	0	
Greece [A]	Greece	0	9	0	9
Hungary [B]	Hungary	3	9	0	12
Ireland [A]	Cork	0	7	0	20
	Dublin	1	8	1	
	Rest of Ireland	0	3	0	
Italy [A]	North	13	29	3	137
	Milan	11	25	2	
	Center	10	34	1	
	South	1	8	0	

Country	Regions	API	FDF	Mixed	Total facilities
Lithuania [B]	Lithuania	0	3	0	3
Luxembourg [A]	Luxembourg	0	0	0	0
Latvia [B]	Latvia	2	1	0	3
Malta [A]	Malta	2	3	0	5
Netherlands [A]	North	2	14	0	34
	Amsterdam	0	2	1	
	South	8	6	1	
Norway [A]	Norway	4	4	0	8
Poland [B]	Poland	5	14	1	20
Portugal [A]	Lisbon	1	4	0	8
	Rest of Portugal	0	3	0	
Romania [B]	Romania	1	6	0	7
Slovakia [B]	Slovakia	3	0	0	3
Slovenia [B]	Slovenia	0	4	0	4
Spain [A]	Barcelona	24	19	1	90
	Madrid	3	11	0	
	Rest of Spain	12	20	0	
Sweden [A]	Stockholm	0	3	1	18
	Uppsala	0	1	1	
	Rest of Sweden	1	11	0	
Switzerland [A]	Western Switzerland	4	18	0	66
	Basel	1	8	1	
	Eastern Switzerland	4	18	1	
	Zürich	0	3	0	
	Southern Switzerland	0	7	1	

[A] Western Europe
[B] Eastern Europe

API and FDF locations

Germany has the highest number of API facilities, followed by Italy and Spain. API sites are relatively equally distributed between northern and southern Germany. In Italy, most API plants are in the north with a hotspot in Milan. In Spain, the highest concentration of APIs is in Barcelona.

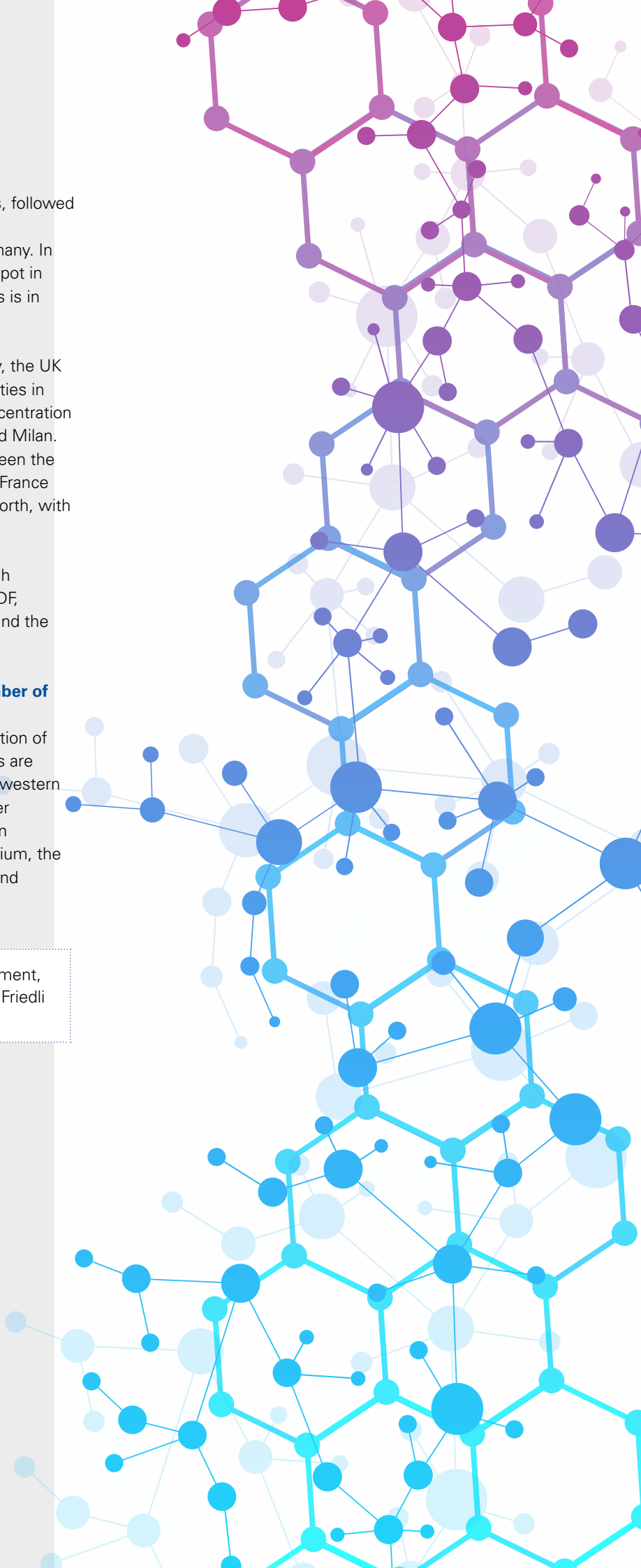
FDF facilities are mainly located in Germany, Italy, the UK and France. In contrast to API facilities, FDF facilities in Germany are mostly in the south. Italy has a concentration of FDF in the north, with a particular focus around Milan. In the UK, FDF facilities are equally divided between the north and the south of England with no hotspot. France has a higher concentration of FDF plants in the north, with a hotspot in Paris.

Germany and Italy are the two countries with high numbers of production plants for both API and FDF, whereas Spain is more API focused and France and the UK lean towards FDF plants.

Small countries with comparatively high number of FDF facilities

Switzerland has an extraordinarily high concentration of FDF facilities relative to its size. Swiss FDF plants are equally distributed between the eastern and the western parts of the country, with a hotspot in Basel. Oher countries with a comparatively high concentration compared to their small populations include Belgium, the Netherlands, Ireland, Lithuania, Slovenia, Malta and Portugal.

Contributed by Institute of Technology Management, University St.Gallen (Contact: Prof. Dr. Thomas Friedli & Matteo Bernasconi)



Innovation

European Innovation Scoreboard

The level of innovation in country is particularly relevant when a company is looking for a new R&D or manufacturing location. Aspects such as the presence of centers of excellence in certain therapeutic areas, clinical research capabilities, and the level of collaboration between academia and industry are important. Having an elevated level of scientific co-publications per million inhabitants indicates that a country is well positioned as an innovation hub (EU Innovation Scoreboard, 2020).

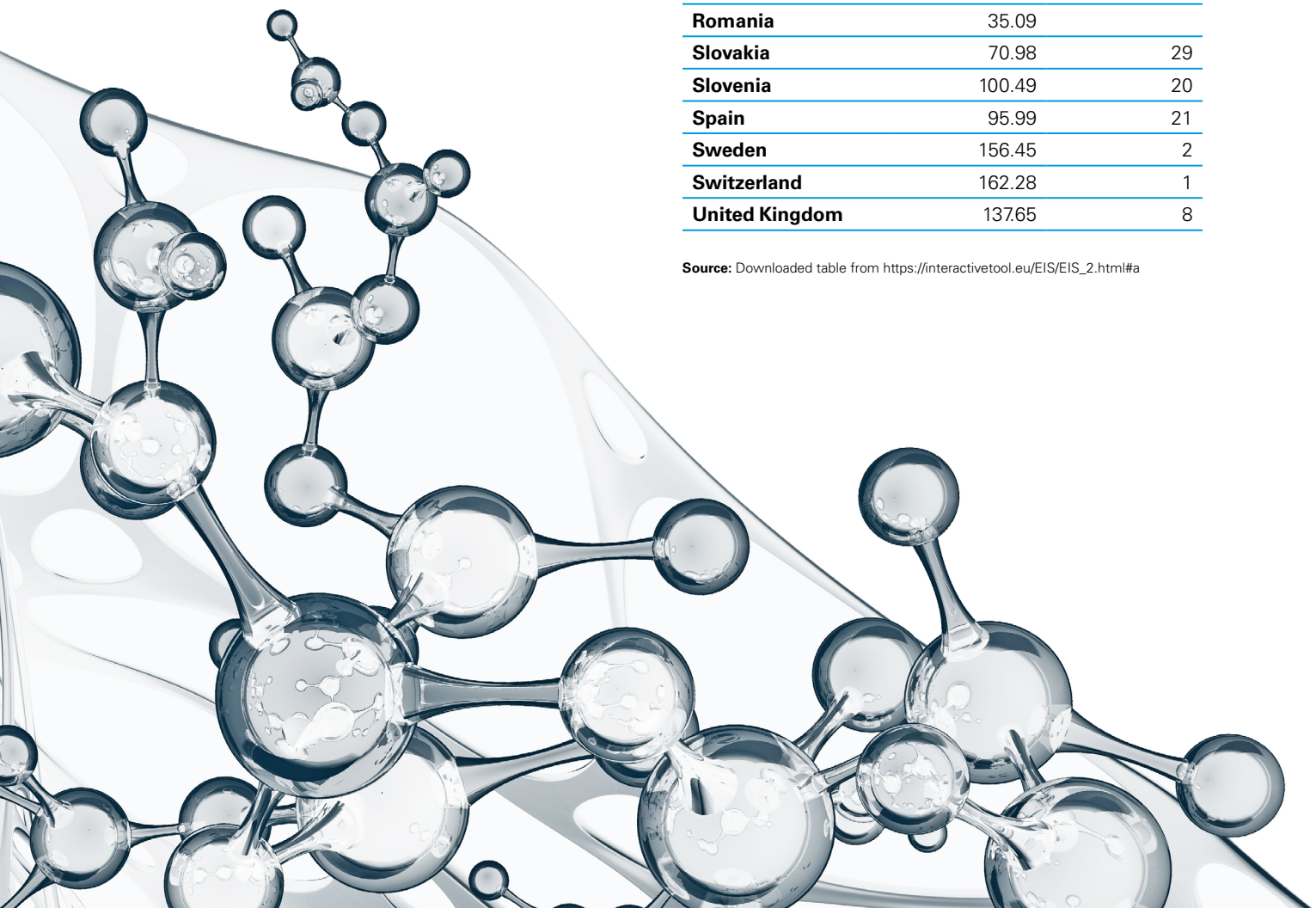
Innovation scoreboard

The European Innovation Scoreboard compares innovation in various European countries. The assessment reflects the relative strengths and weaknesses of national innovation systems and is a valuable resource for countries wishing to improve performance. Switzerland stands out as the clear innovation leader, followed by Sweden, Finland and Denmark.

European Innovation Scoreboard 2021

Country	Score	Ranking
Austria	133.62	10
Belgium	143.52	5
Bulgaria	50.06	34
Croatia	78.22	26
Cyprus	106.48	18
Czech Republic	94.41	22
Denmark	147.51	4
Estonia	128.29	12
Finland	151.38	3
France	122.30	14
Germany	137.92	7
Greece	88.49	25
Hungary	76.42	27
Ireland	121.27	16
Italy	108.08	17
Latvia	55.87	31
Lithuania	92.08	23
Luxembourg	136.53	9
Malta	101.76	19
Netherlands	138.50	6
Norway	132.82	11
Poland	65.88	30
Portugal	90.26	24
Romania	35.09	
Slovakia	70.98	29
Slovenia	100.49	20
Spain	95.99	21
Sweden	156.45	2
Switzerland	162.28	1
United Kingdom	137.65	8

Source: Downloaded table from https://interactivetool.eu/EIS/EIS_2.html#a



R&D expenditure

Gross domestic spending on R&D is defined as the total expenditure (current and capital) on R&D carried out by all resident companies, research institutes, university and government laboratories, etc. in a country. It includes R&D funded from abroad but excludes domestic funds for R&D performed outside the domestic economy. This indicator is measured in USD constant prices using 2010 base year and Purchasing Power Parities (PPPs) and as percentage of GDP.

R&D expenditure as percentage of GDP

Country	% of GDP
Austria	3.2
Belgium	2.9
Bulgaria	2.9
Croatia	n/a
Cyprus	n/a
Czech Republic	n/a
Denmark	3
Estonia	1.6
Finland	2.8
France	2.2
Germany	3.2
Greece	1.3
Hungary	1.5
Ireland	1.2
Italy	1.4
Latvia	0.6
Lithuania	1
Luxembourg	1.2
Malta	n/a
Netherlands	2.2
Norway	2.2
Poland	1.3
Portugal	1.4
Romania	0.5
Slovakia	0.8
Slovenia	2
Spain	1.3
Sweden	3.4
Switzerland	3.2
United Kingdom	1.8

Source: https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm

Talent

Life Sciences companies are highly dependent on access to talent. Leading Life Sciences clusters are capable of attracting top workforce from business, R&D and manufacturing from around the world, which makes them so attractive to Life Sciences investments.

Global Talent Competitiveness Index

The Global Talent Competitiveness Index ranks countries and major cities on their ability to compete for diverse talent. It looks at how policies can drive productivity by attracting, developing, and retaining human capital.
Source: https://knowledge.insead.edu/talent-management/global-talent-competitiveness-index-2932

Global Talent Competitiveness Index 2020

Country	Score	Ranking
Austria	68.87	17
Belgium	68.87	18
Bulgaria	45.76	55
Croatia	43.53	59
Cyprus	57.47	30
Czech Republic	60.91	25
Denmark	75.18	5
Estonia	61.97	24
Finland	74.47	7
France	64.83	21
Germany	72.34	11
Greece	47.51	47
Hungary	46.62	52
Ireland	70.45	15
Italy	52.91	36
Latvia	54.40	33
Lithuania	53.32	35
Luxembourg	73.94	8
Malta	62.02	23
Netherlands	74.99	6
Norway	72.91	9
Poland	49.48	44
Portugal	57.80	28
Romania	62.14	64
Slovakia	52.08	39
Slovenia	57.42	31
Spain	55.70	32
Sweden	75.82	4
Switzerland	81.26	1
United Kingdom	72.27	12

Note: Score from 1 to 100; Ranking from 1 to 132; **Source:** https://www.insead.edu/sites/default/files/assets/dept/globalindices/docs/GTCI-2020-report.pdf

University ranking

The Times Higher Education World University Rankings 2021 include more than 1,500 universities across 93 countries and regions, making it the largest and most diverse university ranking. Below is the number of universities in the top 100 in Life Sciences & Medicine and Natural Sciences.

Top universities ranking – Number of universities in Top Universities ranking for Life Sciences & Medicine or Natural Sciences top 100, 2021

Country	Number of universities in top 100 in Life Sciences & medicine sources*	Number of universities in top 100 in natural sciences**
Austria	1	0
Belgium	2	0
Bulgaria	0	0
Croatia	0	0
Cyprus	0	0
Czech Republic	0	0
Denmark	2	1
Estonia	0	0
Finland	1	0
France	2	5
Germany	3	6
Greece	0	0
Hungary	0	0
Ireland	0	0
Italy	2	1
Latvia	0	0
Lithuania	0	0
Luxembourg	0	0
Malta	0	0
Netherlands	6	2
Norway	0	0
Poland	0	0
Portugal	0	0
Romania	0	0
Slovakia	0	0
Slovenia	0	0
Spain	1	2
Sweden	4	2
Switzerland	5	2
United Kingdom	14	9

Source: * https://www.topuniversities.com/university-rankings/university-subject-rankings/2021/life-sciences-medicine; ** https://www.topuniversities.com/university-rankings/university-subject-rankings/2021/natural-sciences

Date: 2021

Quality of life and environmental performance

Quality of life is vital to attract the best of the international talent pool. Some factors are subjective and will vary depending on the target group. Senior executives with families in tow will be influenced by different push and pull factors than young, single start-up employees.

Work-life balance

The right balance between work, leisure and other commitments is a universal challenge. Governments can help to address the issue by encouraging supportive and flexible working practices, benefitting parents in particular as they juggle work and home life.

Quality of life and environmental performance

Country	Quality of living ranking (Note 1)*	Environmental Performance Ranking (Note 2)**
Austria (Vienna)	1	6
Belgium (Brussels)	28	15
Bulgaria	n/a	41
Croatia	n/a	34
Cyprus	n/a	31
Czech Republic	n/a	20
Denmark (Copenhagen)	8	1
Estonia	n/a	30
Finland (Helsinki)	31	7
France (Paris)	39	5
France (Lyon)	40	5
Germany (Munich)	3	10
Germany (Dusseldorf)	6	10
Germany (Frankfurt)	7	10
Germany (Berlin)	13	10
Germany (Hamburg)	19	10
Germany (Nuremberg)	23	10
Germany (Stuttgart)	27	10
Greece	n/a	25
Hungary	n/a	33
Ireland (Dublin)	33	16
Italy (Milan)	41	20
Latvia	n/a	36
Lithuania	n/a	35
Luxembourg (Luxembourg)	18	2
Malta	n/a	23
Netherlands (Amsterdam)	11	11
Norway (Oslo)	25	9
Poland	n/a	37
Portugal (Lisbon)	37	27
Romania	n/a	32
Slovakia	n/a	26
Slovenia	n/a	18
Spain (Barcelona)	43	14
Spain Madrid)	46	14
Sweden (Stockholm)	23	8
Switzerland (Zürich)	2	3
Switzerland (Geneva)	9	3
Switzerland (Basel)	10	3
Switzerland (Bern)	14	3
United Kingdom (London)	41	4
United Kingdom (Edinburgh)	45	4
United Kingdom (Glasgow)	48	4

Work-life balance

Country	Ranking
Austria	24
Belgium	19
Bulgaria	n/a
Croatia	n/a
Cyprus	n/a
Czech Republic	21
Denmark	7
Estonia	8
Finland	12
France	26
Germany	17
Greece	23
Hungary	10
Ireland	20
Italy	15
Latvia	6
Lithuania	n/a
Luxembourg	13
Malta	n/a
Netherlands	3
Norway	9
Poland	22
Portugal	27
Romania	n/a
Slovakia	16
Slovenia	18
Spain	14
Sweden	5
Switzerland	2
United Kingdom	30

Source: OECD better life index

Source: * Mercer Quality of Living Index 2019, https://mobilityexchange.mercer.com/Portals/0/Content/Rankings/rankings/qol2017e784512/index.html;
Date: 2019; Rank from 1-231

** https://epi.yale.edu/epi-results/2020/component/epi;
Date: 2020; Rank from 1-180

Labor laws and regulations

Multinational companies are permanently in business transformation mode in order to respond to changing stakeholder requirements, changing market environments or disruptive technologies. To ensure that they can transform their business when required, they should look for business locations with the necessary agility.

One indication is the strictness of employment protection, which measures on an aggregated level how strict employment protections are on a collective and individual level. The OECD indicators of employment protection legislation evaluate the regulations on the dismissal of workers on regular contracts and the hiring of workers on temporary contracts. They cover both individual and collective dismissals.

Employment protection

Country	Strictness of employment protection - individual and collective dismissals (regular contract) - Index
Austria	1.66
Belgium	2.72
Bulgaria	n/a
Croatia	n/a
Cyprus	n/a
Czech Republic	3.02
Denmark	1.84
Estonia	1.89
Finland	2.37
France	2.45
Germany	2.22
Greece	2.54
Hungary	1.78
Ireland	1.98
Italy	2.72
Latvia	2.64
Lithuania	2.25
Luxembourg	2.5
Malta	n/a
Netherlands	2.85
Norway	2.27
Poland	2.4
Portugal	2.85
Romania	n/a
Slovakia	2.28
Slovenia	2.18
Spain	2.43
Sweden	2.48
Switzerland	1.57
United Kingdom	1.74

Source: https://stats.oecd.org/Index.aspx?DataSetCode=EPL_OV#

Labour productivity and utilization

Country	Labour productivity, annual growth rate (%)	Labour utilization, annual growth rate (%)
Austria	2.8	-9.2
Belgium	0.4	0.8
Bulgaria	0.6	-4.1
Croatia	-6.7	-1.0
Cyprus	n/a	n/a
Czech Republic	0.3	-6.1
Denmark	0.5	-3.5
Estonia	3.2	-6.3
Finland	-0.8	-2.1
France	0.4	-8.4
Germany	0	-4.8
Greece	3.3	-11.1
Hungary	0.8	-5.5
Ireland	9.2	-4.1
Italy	2.4	-10.5
Latvia	2.1	-5.0
Lithuania	5.1	-5.7
Luxembourg	2.1	-4.8
Malta	n/a	n/a
Netherlands	-1.1	-3.2
Norway	n/a	n/a
Poland	-1.9	-0.7
Portugal	1.8	-9.3
Romania	-1.4	-2.3
Slovakia	4.5	-9.0
Slovenia	0.9	-7.0
Spain	-0.5	-10.9
Sweden	0.4	-3.9
Switzerland	0.6	-0.2
United Kingdom	1.9	-12.0

Source: https://data.oecd.org/chart/6qLb

Labor productivity and utilization

Labor productivity growth is a key dimension of economic performance and an essential driver of changes in living standards. Labor productivity is measured as growth in GDP per hour worked. An increasing labor utilization rate, defined as hours worked per capita, is a sign that people are working more hours or that more people, who previously did not work, are entering the workforce. A high labor force utilization is an indication of the strength of an economy to absorb a large part of the potential workforce, including less qualified persons.

Labor costs

When choosing a location, salaries play an important part in the decision-making process, both for companies wanting to invest as well as for workforce looking for a job in a certain location abroad. While highly skilled specialists earn similar wages across Europe, employee and employer contributions vary.

Nominal salaries per employee for certain positions are difficult to collect and compare. A useful alternative is to look at employer contributions on top of gross salaries. This view gives an understanding of total salary costs, which in many cases are significantly higher than net salaries. Employees have to consider how much is deducted from their gross salary for social security contributions, when selecting a country to work in.

The tables have been put together with employee (EE) and employer (ER) contributions. It considers social security contributions from an employer and employee perspective based on employment income of EUR 75,000 and EUR 150,000[31].

Employer contribution[30]

Country	Social Security – EUR 75k	Social Security – EUR 150k
Austria	19'942	24'584
Belgium	20'318	40'635
Bulgaria	3'501	3'501
Croatian	12'375	24'750
Cyprus	15'416	25'091
Czech Republic	23'325	30'075
Denmark	1'335	1'335
Estonia	25'350	50'700
Finland	14'806	29'610
France	33'620	67'202
Germany	13'375	14'446
Greece	16'905	22'140
Hungary	12'750	25'500
Iceland	4'575	9'150
Ireland	8'288	16'575
Italy	22'171	33'303
Latvia	17'693	35'385
Liechtenstein	5'843	11'687
Lithuania	1'328	1'437
Luxembourg	9'800	17'261
Malta	7'601	15'101
Netherlands	10'840	10'840
Norway	10'574	21'149
Poland	10'248	14'786
Portugal	17'813	35'625
Romania	1'688	3'375
Slovakia	26'401	36'963
Slovenia	12'076	24'150
Spain	15'091	15'091
Sweden	23'565	47'130
Switzerland	9'766	14'754
United Kingdom	8'932	19'282

Source: https://data.oecd.org/chart/6qLb; **Date:** 2020

[30] Pension fund: Pensions have only been considered if mandatory, with standard rates currently in force. Individual taxes: No income tax, personal wealth tax or other similar tax have been calculated.
No voluntary deductions have been considered. Only standard/ statutory deductions have been considered and country default positions have been selected for each country calculated in the cost projection tool, i.e. only mandatory tax positions and social security for these countries have been used in the calculations.

[31] The individual is single without children or other dependents.
The calculations have been done only considering a base salary of EUR 75'000 and EUR 150'000
Only country default positions have been used, i.e. only mandatory positions have been considered with no voluntary contributions.
Only standard and statutory deductions have been used.
Social security rates used are those currently in force.
For countries where a voluntary pension contribution is possible, this has not been considered.
All calculations have been made using publicly available data from the IBFD and KPMG database.
Hungary – If the assignment is under 2 years - a third country national employed by a foreign firm are exempted from paying social security contributions (employee) and social tax (employer). Therefore, calculation has been done with the assumption of assignee being treated as a local.

Employee contribution[32]

Country	Social Security - EUR 75k	Social Security - EUR 150k
Austria	19’942	24’584
Belgium	20’318	40’635
Bulgaria	3’501	3’501
Croatian	12’375	24’750
Cyprus	15’416	25’091
Czech Republic	23’325	30’075
Denmark	1’335	1’335
Estonia	25’350	50’700
Finland	14’806	29’610
France	33’620	67’202
Germany	13’375	14’446
Greece	16’905	22’140
Hungary	12’750	25’500
Iceland	4’575	9’150
Ireland	8’288	16’575
Italy	22’171	33’303
Latvia	17’693	35’385
Liechtenstein	5’843	11’687
Lithuania	1’328	1’437
Luxembourg	9’800	17’261
Malta	7’601	15’101
Netherlands	10’840	10’840
Norway	10’574	21’149
Poland	10’248	14’786
Portugal	17’813	35’625
Romania	1’688	3’375
Slovakia	26’401	36’963
Slovenia	12’076	24’150
Spain	15’091	15’091
Sweden	23’565	47’130
Switzerland	9’766	14’754
United Kingdom	8’932	19’282

Source: https://data.oecd.org/chart/6qLb; **Date:** 2020

[32] Assumptions & notes:
- single, no kids
- only standard/ statuary deductions
- no company pension plan has been considered
- For countries where a voluntary pension contribution are possible, these % has not been considered
- For Hungary - If the assignment is under 2 years - a third country national employed by a foreign firm are exempted from paying social security contributions (employee) and social tax (employer). Therefore calculation has been done with the assumption of assignee being treated as a local


01

KPMG

Annex 1

How to launch a pharma product for the first time in Europe

Based on our extensive experience of working with first time launchers, KPMG has defined six workstreams to help companies build a compliant, efficient, sustainable and expandable operating model for a successful European launch.

Finding the right partner

When launching directly into the market entry, businesses should also remember that outsourcing of certain business functions may be desirable, such as logistics, regulatory, quality control, pricing, and reimbursement. An important part of a successful launch is developing a tailored outsourcing concept and identifying an outsourcing partner early in the process.

Planning and timing

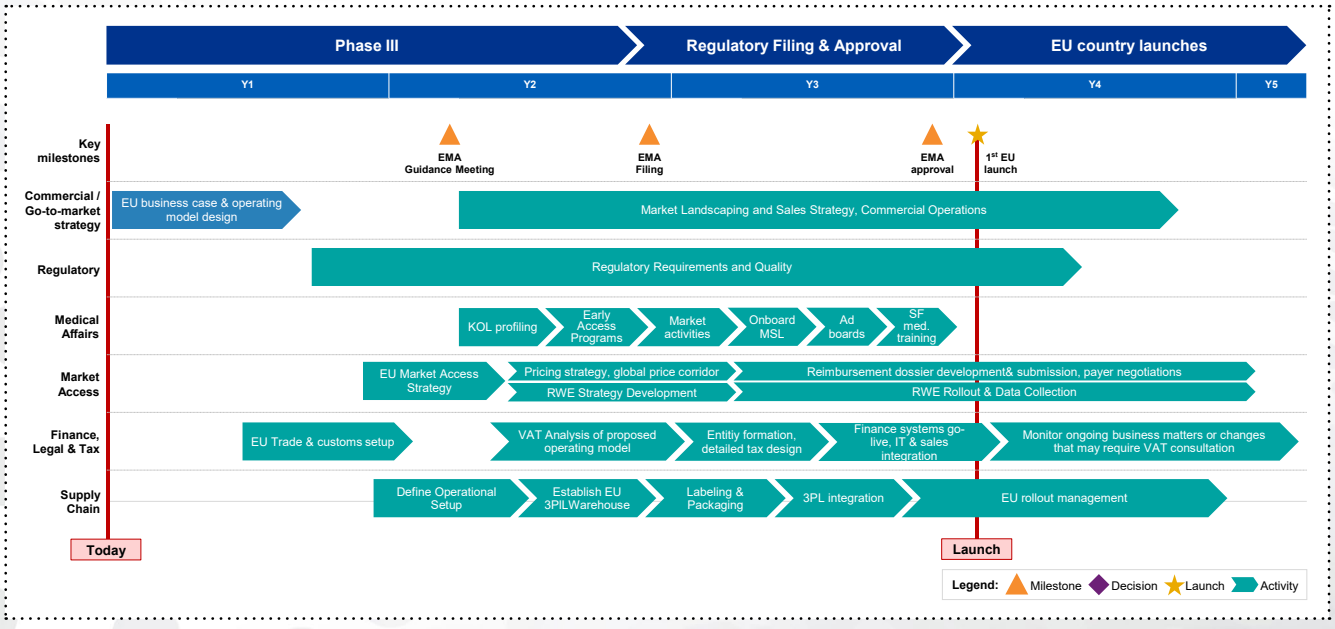
Delays in the launch phase can significantly reduce a firm's ability to recover its investment in developing the product.

Wasting time in a product's patent life can also leave the door open to competitors. More importantly, launch delays also mean patients' quality of life is at stake.

Introducing a Project Management Office (PMO)

The most efficient way is to work with an experienced service provider who offers PMO. The PMO will coordinate the company's internal resources with external service providers to ensure the various workstreams are aligned and the product can be launched within the planned timeline.

Typical timeline for expansion



Workstreams

Commercial/go to market strategy

The decision whether to enter the European market and whether to launch or license should start as early as the beginning of phase 3 clinical trials. Once the decision has been taken to launch, the operating model should be defined. A key element of this model is the design of transaction flows for goods, finances and titles, as well as where to establish the European HQ and subsidiaries. Later on in the process sales strategies need to be defined, commercial operations implemented by country, and sales force hired.

Regulatory

EMA dossier development and submission to obtain marketing authorization is a key element, together with applications for Manufacturing and Import Authorizations (MIAs) and Wholesale and Distribution Licenses (WDL). Quality Management Systems, processes and training also fall under this workstream.

Medical affairs

This workstream includes profiling Key Opinion Leaders (KOLs), identifying early access programs, and training sales forces.

Market access

This workstream should start with designing the market access strategy for key markets (launch sequencing). As every country, and in some cases even individual provinces, in Europe can set the price of a pharma product, it is critical to conduct a comprehensive pricing strategy.

While almost every country in Europe uses international reference pricing (IRP), the IRP formula varies between countries. Some use the lowest price observed in the reference countries while others apply an average of the reference prices.

Other important elements include the development and submission of a reimbursement dossier.

Finance, legal and tax

Based on the operational and transactional model and the location of the regional HQ, a series of steps must be taken such as: implementing a Finance and IT infrastructure, incorporating legal entities, and analyzing VAT, Trade and Customs and other indirect taxes. This includes designing and implementing a direct tax model.

Supply chain

The design of the supply chain follows the transactional model and should start early in the process. Companies typically work with logistics service providers (3PL and 4PL). Questions regarding labeling and packaging also come under this workstream, as does defining warehousing locations.

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Annex 2

R&D incentives

R&D tax incentives schemes are widely adopted in advanced economies. As more countries recognize the importance of research and innovation for economic growth, they have introduced incentives and increased support through the use of grants and other forms of funding.

Over 50 jurisdictions currently have some form of R&D incentive, and some countries offer multiple incentives.

Details, see https://home.kpmg/xx/en/home/insights/2021/05/global-minimum-tax-an-easy-fix.html

Summary of R&D Incentives in Europe

Jurisdiction	R&D tax credit	R&D deduction/	Accelerated depreciation on R&D assets	R&D grants	Patent-related incentives	Payroll-related incentives	Other R&D incentives, including loan
Austria	■			■			■
Belgium	■	■	■	■	■	■	■
Croatia		■		■			■
Czech Republic		■		■			■
Denmark	■	■					■
Finland		■	■	■		■	
France	■		■	■	■	■	■
Germany	■			■			
Greece		■		■	■		
Hungary	■	■		■	■	■	■
Ireland	■		■	■	■	■	■
Italy	■			■	■	■	■
Lithuania	■	■	■				■
Luxembourg	■		■	■	■		■
Netherlands	■	■	■	■	■	■	■
Norway	■			■			■
Poland		■		■	■		■
Portugal	■	■		■	■		■
Romania	■	■	■			■	
Slovakia		■		■	■		■
Spain	■		■	■	■	■	■
Sweden				■		■	■
Switzerland	■	■	■	■	■		
UK	■	■	■	■	■		

Source: KPMG study, 2018

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Annex 3

Regulatory and quality

Obtaining marketing authorization (MA) for a medicinal product (drug)

No medicinal product (drug) may be commercialized or distributed in the EU unless the EMA or relevant local health authority has issued an MA. The only exceptions to this are named patient programs, drugs delivered for experimental use, or for compassionate use[33].

In the EU has four, sometimes linked, procedures for obtaining an MA:

(1) Centralized procedure – in all EU member states. This procedure is mandatory for some medicinal products such as medicines containing a new active substance to treat HIV, cancer, diabetes and other auto-immune and viral diseases, advanced-therapy medicines, medicines derived from biotechnology processes and orphan drugs (for rare diseases)
(2) Decentralized procedure – in one or more EU member states
(3) Mutual recognition procedure – in one or more EU member states, if one member state has already approved MA
(4) National procedure – in one EU member state only. This procedure is rarely used.

An MA declares the drug to be safe, effective and approved to be marketed. It imposes a number of requirements on the Market Authorization Holder (MAH), such as the assurance of good pharmacovigilance practice (GVP).

An MA does not authorize pharma companies to commercialize their drug. Additional licenses are required are that, which are granted by the local health authority. The local licenses authorize the subsidiary to manufacture, import, and commercialize the product and assume responsibility for the safe handling of the product.

The compilation of a dossier and submission to the EMA or a local health authority is usually outsourced to a regulatory service provider located in the EU. The EMA's approval forms the basis of the European Commission's decision on whether a medicine can be authorized for marketing throughout the EU.

Manufacturing and Importation Authorization (MIA)

The importing subsidiary in the EU, i.e. the company that takes receipt of goods when they enter the EU for the first time, also needs a Manufacturing and Importation Authorization (MIA). Granted by the state where the activity takes place, the MIA imposes certain requirements to assure compliance with good manufacturing practice (GMP) regarding the imported finished goods. Similar requirements apply to imported API and to operate manufacturing operations in the EEA.

Depending on the configuration of the physical distribution pathway of the product, the pathway of invoicing and the extent of promotional activities, countries impose different requirements on local subsidiaries to commercialize a product. In most EU countries, the subsidiary intending to invoice the product to the end-customer, known as the buy-and-sell subsidiary, must first obtain authorization to do so from the local health authority.

Wholesale Distribution Authorization (WDA)

A Wholsale Distribution Authorization (WDA) is required to hold, procure, supply, or export medicinal products, unless the subsidiary already holds a MIA. A WDA is granted to the local subsidiary provided the entity can demonstrate that it has a system and a responsible person (or enough outsourcing solutions backed by quality agreements) to assure compliance with good distribution practice (GDP), which includes verification of GDP compliance of suppliers and customers. These practices are governed by EMA guidelines and are, in theory, applicable to all EU countries to the same extent. In practice, their interpretation and implementation in national regulations vary considerably from one EU country to another. This may also result in the need for appointing additional responsible persons / officers by the local affiliate, depending on the country where it sits.

Preparing the quality assurance system, securing qualified capacity (in-house or through an outsourcing provider), and establishing operations in compliance with GMP, GDP and GVP, is time-consuming. It needs to be planned according to the launch sequence and budgeted well ahead of time.

Pharma and biotech companies benefit from a high level of reciprocal recognition or shared standards between the EU member states. The subsidiary holding the MA, MIA, and WDA must be located in the EU. The EU headquarters with other functions, assets and risks can be located in any non-EU country such as Switzerland, Norway, UK, however.

Typical time line for expansion

Type	EU	Issuer	Validity	Timeline [34]
Marketing Authorization Similar to the new drug application in the US, the MA confirms that a product meets efficacy and safety criteria.	**MA**	**EMA** National authorities	**EU/EEA or individual countries** Accelerated process in Switzerland possible	**12 to 24 months**
Wholesale Dealers License/ Wholesale Distribution Authorization Pharmaceutical companies need a WDL in almost all EU countries for subsidiaries planning to operate under a buy-and-sell model in that jurisdiction. Th WDA confirms that an organization has effective quality assurance in place for GDP, and that it is monitored by a responsible person for wholesale.	**WDL/WDA**	**National authorities**	**Individual countries**	**6 to 9 months**
Manufacturing and Import Authorization The MIA confirms that the organization has a quality system in place at least for releasing the product to the market (QP batch certification) in line with good manufacturing practice (GMP). Only one subsidiary will need this license, i.e. the subsidiary of the country in which the product first physically enters the EU.	**MIA**	**National authorities**	**EU/EEA-wide** Accelerated process in Switzerland possible	**6 to 12 months** Often granted along with WDA
Good practices	**cGxP**	**EU directives, issued by national authorities**	**Enforced by national authorities**	**n/a**

Medical devices

The EU Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) came into effect in May 2017 to replace the EU's Medical Device Directive (93/42/EEC), Active Implantable Medical Devices Directive (90/385/EEC) and In Vitro Diagnostic Device Directive (98/79/EC).

The regulations have a transitional period of three (MDR) and five (IVDR) years. Switzerland plans to adopt these changes to ensure that Swiss companies remain competitive in the European market and elsewhere. A key goal of the initiative is to improve patient safety by enhancing the quality and safety of medical devices and harmonizing legislation within the EU. It affects clinical trials and performance tests but even such basic aspects as the identification and traceability of products.

Compliance with the new MDR/IVDR regulation is likely to mean an increased workload for affected companies. Established organizations must evaluate their product portfolio based on the new regulations and conduct a Fit/Gap-Analysis. Companies currently evaluating expansion to Europe should incorporate the changes in their planning, and factor in the additional cost and effort in the device registration and approval process, as well as for coordination and communication with the regulatory bodies. The main activities to be completed are bundled in quality management, regulatory affairs and data management within IT systems. Further, supply chain networks and contracts need to be reviewed to ensure a smooth delivery to the client base.

[33] Exceptions exist in the following cases, however:
- named patient programs
- drugs delivered for experimental purpose
- compassionate use

[34] The timeline is based purely on the Authorities timelines only. It does not include document creation (eg qms system), facillity set-up, vendor qualification, etc)

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Annex 4

EU grants and loans and further programs

EU grants and loans can be made available for investment and research and innovation projects in different ways. Some EU funding programs are administrated directly by the EU, such as Horizon Europe which is available directly to companies or research institutions. Others are indirect, stimulating similar investments by implementation partners such as financial intermediaries. A large part of the EU funds is made available to member states, which have authority to administer them directly under strict EU guidelines.

The following section discusses some of most import funding vehicles on EU level for investment and research and innovation projects.

Horizon Europe

Horizon Europe is the EU's 9th Framework Program, and runs from 2021 to 2027. It is the largest research and innovation funding program in the world and the most ambitious in the history of the EU so far, with a budget of EUR 95.5 billion.

An important element of the Horizon program is the emphasis on pan-European collaboration. To be successful, applicants must demonstrate that their projects are conducted with teams on a pan-EU scale involving different countries. Associated countries (see the link below under Pillar 1) and even non-European countries can be part of these projects.

The program is structured into three pillars and clusters referring to different sectors and thematic scopes.

Pillar I is designed to support fundamental research through funding via the European Research Council (ERC). The ERC is funded by EUR 16 billion. Researchers can apply for funding as long as they are located in an EU member state or Associated Countries.

Further information: ERC: European Research Council | https://erc.europa.eu/

Pillar II supports applied R&D. Life Sciences R&D is mainly covered in Pillar II in the clusters Health, Food, Bioeconomy, Natural Resources, Agriculture and Environment. Pillar II is the most important part of Horizon and has funding of EUR 70 billion.

Pillar III is aimed at enhancing Europe's innovation potential by bringing together key actors from research, education and business. The main organization within Pillar III is the European Innovation Council (EIC), which has a budget of EUR 10.1 billion. A unique feature of the EIC is that it provides funding for individual companies (mainly startups and SMEs) through grants and investments. Investments currently take the form of direct equity or quasi-equity investments and are managed by the EIC Fund.

The EIC Fund is owned by the European Commission and established to make direct equity investments in

Direct state aid versus regional state aid

Direct state aid for individual companies by member states is generally prohibited unless justified on the grounds of general economic development. By contrast, regional state aid which aims to develop entire regions is generally permitted. The European Commission has adopted revised guidelines which will enter into force in January 2022 for the period to 2027 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1825 . One notable change in these revised guidelines is the increase in the maximum aid to support the European Green Deal and Digital Strategy objectives by enabling additional incentives for investments in disadvantaged areas of the EU.

Companies and foreign direct investors may visit the following site for an updated aid intensity map: https://ec.europa.eu/competition-policy/state-aid/legislation/modernisation/regional-aid_en

companies. It provides equity from EUR 0.5 million to EUR 15 million to breakthrough innovation companies selected for EIC Accelerator- blended finance support (grant and equity).

Further information: Investment opportunities: https://ec.europa.eu/info/join-investment-plan_en

Applying for a Horizon Europe grant

Horizon Europe provides funds in the form of grants by creating specific calls on its portal. Upcoming calls for proposals are accessible through the Funding and Tenders Portal. Participants have six months to create and submit their proposals. The European Commission will make a decision in the following six months regarding how many and which projects will be funded.

Who may apply?

Companies, research organizations, universities, non-governmental organizations may apply. Any type of Life Sciences companies may apply if it is established in an EU member state or an eligible non-EU country.

Finding a partner

As most Horizon Europe calls require collaboration between researchers and companies in different EU member states or associated countries, it is critical to find project partners. Participation by non-European partners is possible if they are part of a research partnership with European partners. Companies with R&D activities in different EU countries and associated countries can form partnerships among their own groups of companies but need at least two non-related parties as additional partners to be able to submit a project.

Each participating country has a National Contact Point (NCP) which helps local companies and researchers with guidance, practical information and assistance on all aspects of participation in Horizon Europe. A list of NCPs can be found at Funding & tenders (europa.eu).

Digital Europe Program

The Digital Europe Program (DIGITAL) is a new EU funding program focused on bringing digital technology to businesses, citizens and public administrations. It has a budget of EUR 7.6 billion. The program focuses on five key capacity areas: supercomputing, artificial intelligence, cybersecurity, advanced digital skills, and ensuring a wide use of digital technologies across the economy and society, including through Digital Innovation Hubs.

The program's funding and tender opportunities web page provides an overview of the calls for proposals that are up-coming or already open. The program is open to companies of any size which are active in one of the above-mentioned key areas, i.e. in digital health or in AI-enhanced drug development.

Further information: https://digital-strategy.ec.europa.eu/en/activities/digital-programme

InvestEU Program

The EU aims to trigger more than EUR 372 billion in additional investment between 2021 and 2027 via loan guarantees to implementing partners.

Companies wishing to benefit from this program should investigate with their local commercial or public banks if their financial products are covered by the EU guarantee in their country or region.

Further information: How to get financing | InvestEU (europa.eu), https://europa.eu/investeu/investeu-fund/how-get-financing_en

European Regional Development and Cohesion Fund

The European Regional Development Fund is aimed at member states whose Gross National Income (GNI) per inhabitant is less than 90% of the EU average. The total budget is EUR 272 billion.

Companies wishing to benefit from such funds should apply directly via national Managing authorities which can be found here Managing authorities - Regional Policy - European Commission (europa.eu)

Further information: https://ec.europa.eu/regional_policy/en/2021_2027/

The ERDF shares responsibility between the European Commission and national and regional authorities in member states. The member states' administrations choose which projects to finance and take responsibility for day-to-day management.

Further information: Cohesion Fund – Regional Policy – European Commission (europa.eu), https://ec.europa.eu/regional_policy/en/funding/cohesion-fund/

EU4Health program

EU4Health is the EU's response to COVID-19. It provides funding to eligible entities, health organizations and NGOs from EU countries, or non-EU countries associated with the program. The budget is EUR 5.3 billion.

The program is still under development. Funding or collaboration opportunities are therefore not yet clearly defined. Companies which can provide support, services or products related to key objectives of the program should investigate with EU4Health directly via the website.

https://ec.europa.eu/health/funding/eu4health_en

Just Transition Fund

The Just Transition Mechanism (JTM) is a complementary financial instrument, created for the purpose of decarbonizing 31 European coal regions in 11 member

states. The Just Transition Fund (JTF) has a budget of EUR 17.5 billion to provide grants, loans and financial guarantees to companies and projects that will help this transition process.

JTM is currently under development. Companies considering supporting the transition to low-carbon technologies and economic diversification should approach JTM. The Just Transition Mechanism: making sure no one is left behind | European Commission (europa.eu)

"Access to finance"

Official site of EU which provides an overview of loans and venture capital supported by the EU. Access to finance – Your Europe (europa.eu) modernisation/regional-aid_en

Other financing sources

European Investment Bank and European Investment Fund
The European Investment Bank (EIB) is the world's biggest multilateral financial institution and one of the largest providers of climate finance. It supports projects that promote the EU's priorities and objectives.

While EIB direct funding to companies focuses on large corporates and mid-caps, the European Investment Fund (EIF) is a specialist provider of risk finance to SMEs across Europe.

Further information can be found on the EIB website https://www.eib.org/

European European Bank for Reconstruction and evelopment (EBRD)
The EBRD plays an important role in developing Europe's manufacturing sector by supporting corporate clients through debt and equity financing. EBRD loans to the private sector projects usually start from a minimum of EUR 3 million and go up to EUR 250 million. The average amount is EUR 25 million. EBRD invests equity ranging from EUR 2 million to EUR 100 million in private sector projects.
Further information: https://www.ebrd.com

Other projects – Private Public Partnerships

The Innovative Health Initiative (IHI)
The IHI's goal is to help create an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations. The EU will contribute up to EUR 1.2 billion to IHI, to match contributions of industry partners and contributing partners. Industry partners will contribute at least EUR 1 billion.

Further information can be found on the IMI Website Innovative Health Initiative | IMI Innovative Medicines Initiative (europa.eu)

Eureka / Eurostars Program
Eurostars is a joint program between EUREKA and the EU. Funding is available for large companies, SMEs and research institutions to support the development and commercialization of innovative products.

Registration on the Eurostars website is necessary for an application https://www.eurekanetwork.org/. Questions regarding the submission of applications and the applicable national funding conditions can be answered by the national contact person in the partner country.

Active Assisted Living (AAL)
AAL is a funding program that aims to create a better quality of life for older people and strengthen industrial opportunities in the field of healthy aging technology and innovation. AAL funds projects that work towards creating market-ready products and services for older people.

Further information: http://www.aal-europe.eu/about/

International research infrastructure and further sources of funding

European Molecular Biology Laboratory Ventures (EMBL Ventures)
Based in Heidelberg, Germany, EMBL Ventures invests throughout Europe to build companies that create significant commercial opportunities based on new therapeutic-treatment modalities and pharma, next-generation enabling-technology platforms, or innovations in the diagnostics and medical device area.

Further information: Industry relations | EMBL.org

European Synchrotron Radiation Facility
With a brand-new generation of high-energy synchrotron, the ESRF is the world's brightest X-ray source and a center of excellence for fundamental and innovation-driven research in condensed and living matter science. Located in Grenoble, France, the ESRF is based on international cooperation between 22 partner nations.

Further information: Industry (esrf.fr)

European Investment Bank / European Investment Fund

Owner	Funds	Program type	Realization of incentive	Target beneficiary
EIB/EIF	EIB direct investments EIF	Loans, guarantees and equity-type funding	The EIB offers loans, equity investments directly for the private sector or via the EIF which is a specialized investment fund for SMEs or venture capital investment	Large corporates or groups, mid-caps, SMEs, Special Purpose Vehicles for project finance (including PPPs and Concessions), PE, VC funds
European Bank for Reconstruction and Development	EBRD	Loans, guarantees and equity-type funding	The EBRD plays an important role in developing the manufacturing sector in Europe by supporting corporate in the manufacturing sector with both debt and equity financing	Companies planning to set up large size manufacturing operations in selected European countries

Other Projects – Public Private Partnerships

Owner	Program	Program type	Realization of incentive	Target beneficiary	Budget 2021-26
European Commission, private partners	Innovative Health Initiative IMI	Loans, guarantees and equity-type funding	Funding of cross-sectoral projects involving biotechnology and medical technology sectors, including companies active in the digital area	Companies and projects active in Life Sciences	EUR 2.2
Eureka	Eurostar-2	Grants	Eurostars is a joint program of EUREKA and the European Union. Funding is available for large companies, SMEs and Research Institutions for support development and commercialization of innovative products	Large corporates, mid-caps, SMEs planning to commercialize innovative products	
Selected EU countries	Active Assisted Living	Grants	Active Assisted Living (AAL) is a funding program that aims to create better quality of life for older people and to strengthen industrial opportunities in the field of healthy ageing technology and innovation	Technology and medtech companies	

International research infrastructure and further sources of funding

Owner	Program	Program type	Realization of incentive	Target beneficiary
27 member states	European Molecular Biology Laboratory (EMBL)	Venture Funding	EMBL Ventures invest throughout Europe to build companies that create significant commercial opportunities	Companies with projects in molecular biology
22 partner states	European Synchrotron Radiation Facility	Access to research infrastructure	ESRF is the world's brightest X-ray source and a center of excellence for fundamental and innovation-driven research in condensed and living matter science	Companies conducting research matter sciences

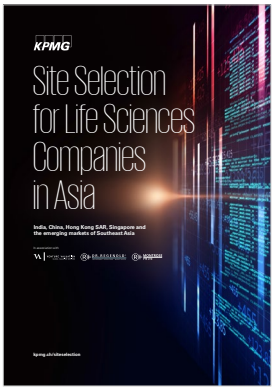
About us

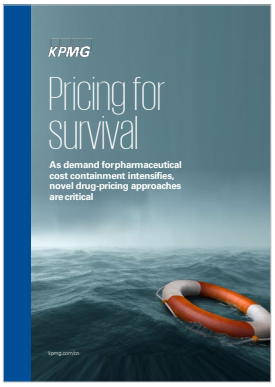
KPMG is a global network of independent member firms providing Audit, Tax and Advisory services. We operate in 147 countries and territories, collectively employing more than 219,000 people, to serve the needs of business, governments, public-sector agencies, non-profits and – through member firms' audit and assurance practices – the capital markets. We lead with a commitment to quality and consistency across our global network. In a world where rapid change and unprecedented disruption are the new normal, we inspire confidence and empower change in all we do.

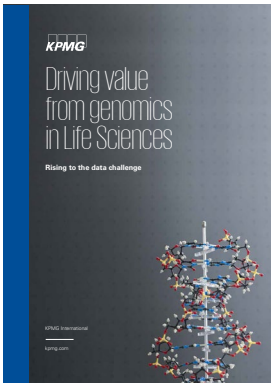
KPMG has a dedicated practice for the Healthcare & Life Sciences industry, and the variety of public-private partnerships therein. We support payers/providers with reform programs, ranging from care system redesign to connected health, operational excellence, and workforce capacity development. We support pharma, biotech and medtech companies in achieving organic and inorganic growth ambitions, streamlining operational structures, and ensuring regulatory compliance. We believe in the mission of improving population health and, utilizing a global network model, follow the "something to teach, something to learn" philosophy of sharing best practices from around the world.

Other KPMG publications

A series of publications from KPMG provides insights, analysis and studies from the featured countries in this report. All publications are available online. For more information, please click on the links below







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Contacts

André Guedel
Director
Head Site Selection Services
KPMG Switzerland
+41 58 249 28 24
aguedel@kpmg.com

Thomas Hillek
Global Lead Partner
Head of Life Sciences EMA
KPMG Germany
+49 89 9282-1409
thillek@kpmg.com

Mercedes Sanchez Varela
Partner KPMG Advisory
KPMG EU Office
+32 (0)476 49 08 88
msanchezvarela@kpmg.com

Daniela Dietz
Head of Regulatory
regenold GmbH
Badenweiler, Germany
+49 (7632) 8226 300
daniela.dietz@regenold.com

Dr. Patrik Frei
CEO
Venture Valuation
Zurich, Switzerland
+41 43 321 86 60
p.frei@venturevaluation.com

Publisher
KPMG AG
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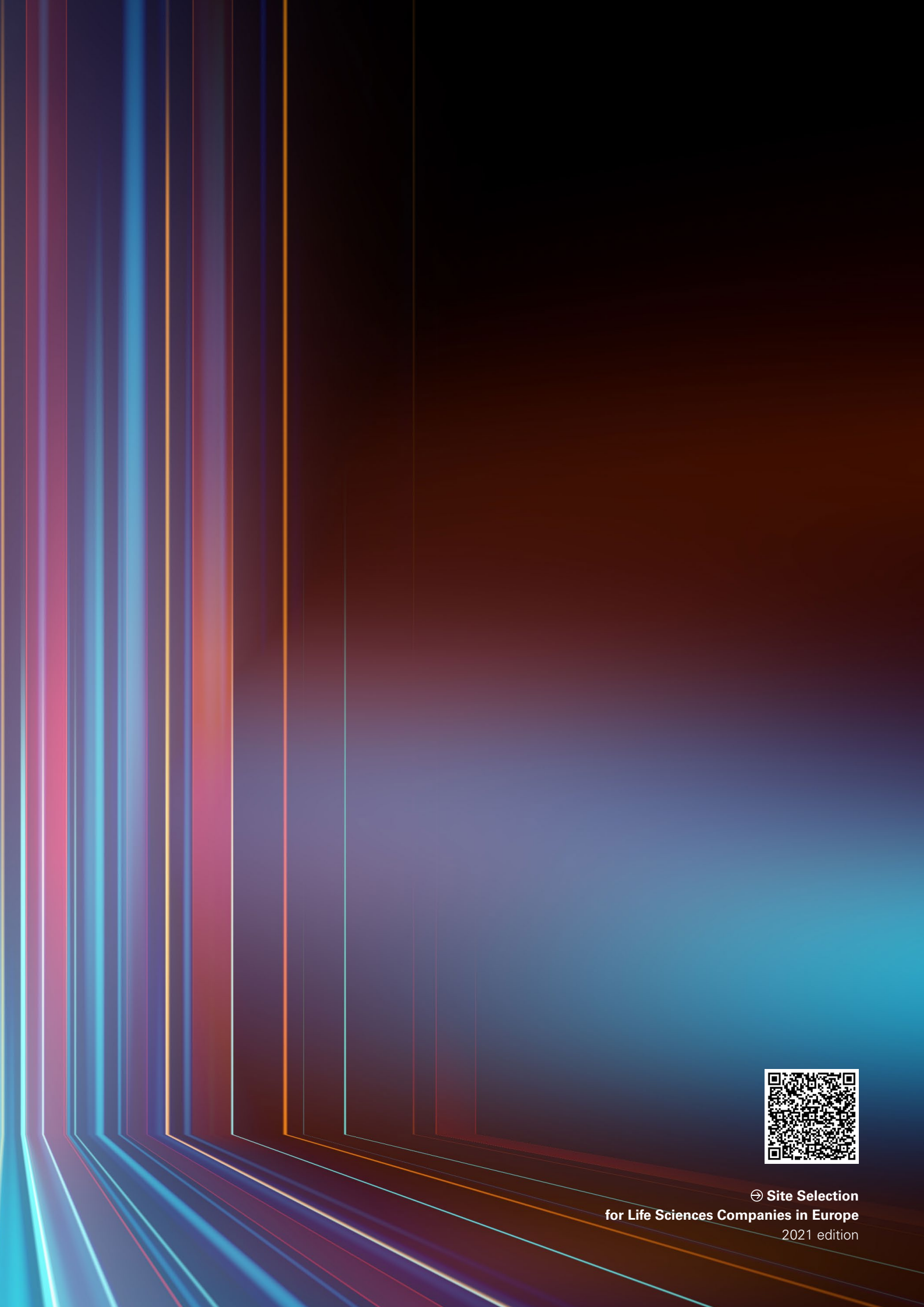
PO Box
CH-8036 Zurich

Concept, editing and design
André Guedel, KPMG AG
Christina Laubbacher Stewart, KPMG AG
ohcomms.co, London
sport media //design, Dietlikon

Coordination and project management
Christina Laubbacher Stewart, KPMG AG

Illustrations, pictures
Shutterstock

Additional Contributors
Hugues Salomé, KPMG Switzerland
Pawel Grzegorzewicz, KPMG EU Office
David Gelb, KPMG Australia
Dr. Arthur Krause, KPMG Switzerland



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