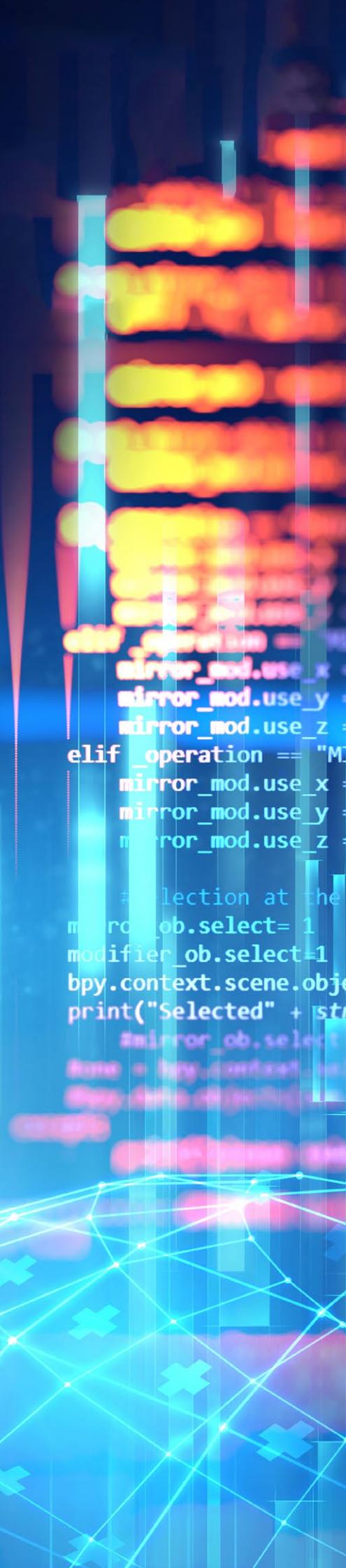




Site Selection

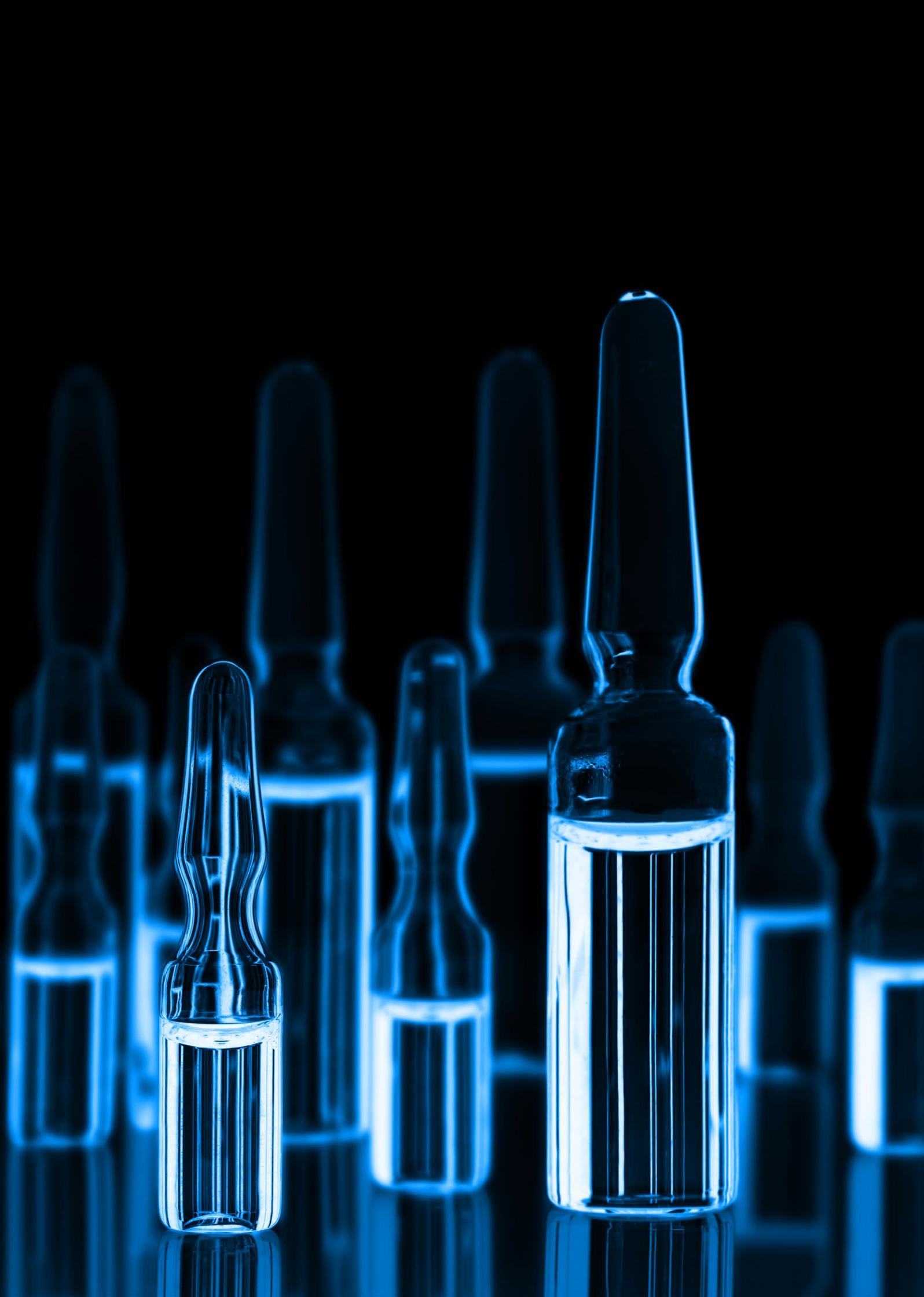
for Life Sciences Companies
in Europe, 2018 edition

In association with



```
elif_operation == "M
mirror_mod.use_x =
mirror_mod.use_y =
mirror_mod.use_z =
elif_operation == "M
mirror_mod.use_x =
mirror_mod.use_y =
mirror_mod.use_z =

# selection at the
mirror_ob.select= 1
modifier_ob.select=1
bpy.context.scene.objects
print("Selected" + str
    mirror_ob.select
    bone = bpy.context.o
    bpy.data.objects[ob
except
```



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Foreword

Site Selection for Life Sciences Companies in Europe – Expanding right into Europe

Welcome to the fifth edition of KPMG's popular Site Selection Report for Life Sciences Companies in Europe. Our 2018 report looks beyond site selection to include novel aspects of the various work streams involved in successfully commercializing pharmaceutical products in Europe.

The second-largest market for medicines in the world after the US, Europe is an attractive prospect for Life Sciences companies. There is a lot to think about when analyzing which European country or countries will enhance expansion plans. What is the best route to market? Which country should apply for marketing authorization? Which country will import the product, requiring a manufacturing and import authorization, and what about the wholesale dealer's license?

A detailed discussion of the different commercialization approaches kicks off this report. We examine the aspects to consider in deciding whether to enter the European market directly, via out-licensing or by applying a combined approach. We then explore the operational steps involved in launching through direct market entry. In our spotlight on Brexit, we raise some of the issues facing pharmaceutical companies in the transitional phase and beyond.

Christopher Stirling

Partner and Global Chair, Life Sciences
KPMG UK

When deciding where to locate their key value drivers such as regional headquarters and R&D centers, pharmaceutical companies consider factors including ease of academic collaboration, existence of clusters, quality of life for the workforce, and many more. Our popular site selection analysis compares the attractiveness of different countries' jurisdictions based on empirical data.

KPMG has extensive experience supporting Life Sciences companies on their European journey. This report offers a generic overview of the various steps to be considered by pharmaceutical executives and advisors. Our insights help interested parties understand what to expect in terms of process, costs and time involved. They also facilitate effective evaluation of potential sites for the various key value drivers to be located in Europe.

KPMG's Life Sciences teams across the global KPMG network are ready to discuss and provide assistance if your company is planning to start operations in Europe.

André Guedel

Head of International Headquarters
KPMG Switzerland



Part 1:

Successful commercialization of pharmaceutical products in Europe

Introduction

Europe is a highly attractive pharmaceutical market with a total population of over 500 million and annual expenditures of USD 145 billion.

In 2017, healthcare expenditure – including but not limited to medicine spend – remained the second largest item of general government expenditure in the European Union (EU), second only to the outlay on social protection. Healthcare spending is projected to increase in the coming years as the population ages and new diagnostic and therapeutic technologies become more widespread, further increasing pressure on governments to reduce costs.

The EU5 countries (United Kingdom, Germany, France, Italy and Spain) account for a combined share of around 20% of the branded global pharmaceutical market, behind only North America (about 44%). More importantly, EU5 per capita healthcare spending remains high and supportive of innovative therapies with demonstrated safety and efficacy.

1.1 Market entry – but how?

In the highly regulated pharmaceutical market, authorizations and licenses are fundamental business enablers. An upfront analysis will help companies decide on the critical strategic question: Should they out-license, enter the EU market directly or apply a combined approach?

A pharmaceutical company with one or more existing product licenses can choose from several options. There is empirical evidence suggesting that a **direct product launch** leads to better stock price performances. This might be the right path for an aspiring company with an innovative product as it develops into a fully integrated pharmaceutical company. It is also interesting for companies wishing to increase their valuation in view of a future acquisition or merger.

Working with the right partner organization in Europe, **out-licensing** may be an attractive prospect. Given the

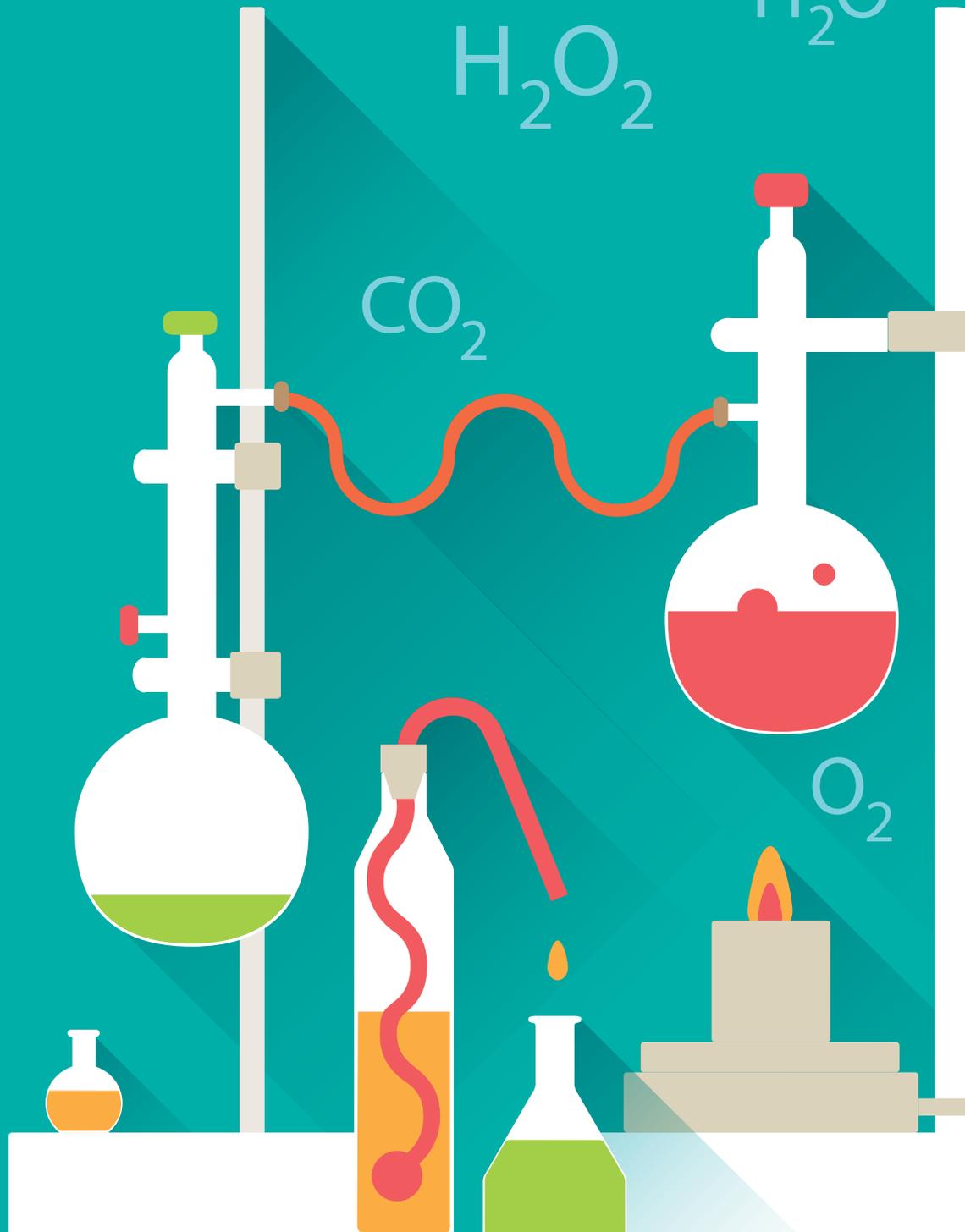
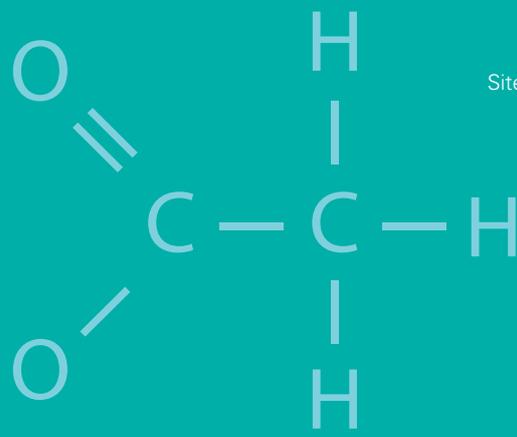
For novel drug developers, this is critical for the success of premium-priced therapies aimed at niche patient populations.

With its 28 member states, the European marketplace also presents a variety of general challenges, from numerous official languages to a complex regulatory framework. For certain industries, such as Life Sciences, the EU has made considerable progress in introducing common standards and regulations. Member states benefit from central regulatory bodies such as the European Medicines Agency (EMA), currently located in London but moving to Amsterdam soon.

Not all countries with an important healthcare market are part of the EU, however. Switzerland, Norway and – post-Brexit – the United Kingdom define their own regulations related to marketing of healthcare products. Nevertheless, it is in the interests of these countries to overlap with EU rules in many respects.

complexity of the legal, regulatory and healthcare landscape as well as pricing and reimbursement frameworks, out-licensing models often appeal to non-EU biotech and small pharmaceutical companies. As the seemingly easier option, this approach can save problems on the backend and shed sizable chunks of risk from the business model. In addition, license fee revenues from Europe might help to finance the development in the country where the biopharmaceutical company is headquartered. Negotiating an attractive license deal is complicated, however, and companies should seek sound legal advice to avoid the many pitfalls.

The picture is not always black and white, and Life Sciences companies are often best off applying a **mixed approach**.



1.2 Strategies

Direct market entry – invest and control

Entering the European market directly is cost- and time-intensive. The lengthy and complex process is often best mastered through strategic planning and delegated project management. Hiring experienced senior executives with a track record in Europe and seeking out the right outsourcing partners are key success factors. Another particularly important consideration is the fact that the company itself (or its outsourcing partners) needs to engage in pricing discussions for each country.

If a company decides to launch its own product through direct market entry, it needs to obtain a marketing authorization (MA) and set up its own network of subsidiaries in the European countries in which it plans to sell first.

The MA application for the countries within the EU can be submitted to the **European Medicines Agency (EMA)** – responsible for scientific evaluation, supervision and safety monitoring of medicines in the EU – by any regulatory services provider in the EU on behalf of the head office of the company. Companies planning a small-scale expansion may also consider a decentralized procedure, mutual-recognition procedure or purely national authorization procedures in any European (EU or non-EU) country.

The subsidiary selected to become the future marketing authorization holder (MAH) for Europe will carry responsibility for all activities related to the safety of the product in the entire EEA. Some of these activities can however be outsourced to other countries or to service providers.

Which EU subsidiary will **import the product**? Companies should set up their importing subsidiary at an early stage in order to start the application process for a manufacturing and import license (MIA). The “manufacturing” part of the MIA includes activities involved in testing and EU release. The subsidiary selected to become the future EU headquarters will carry the substance (i.e. the significant business part such as finance, R&D, IT, sales and marketing), so it is important to select the most appropriate country for these activities. Many companies choose to locate their European headquarters **outside the EU, in countries such as Norway, Switzerland and soon the UK**, because of their strong Life Science clusters.

Effective planning further includes defining a detailed **launch sequence**. Determining in advance the order in which subsidiaries should be established and applications for commercial and quality activity submitted is a chance to influence the pricing structure in Europe. It is also extremely important to choose the most appropriate location for each

of the three subsidiaries described above depending on their function.

Companies should be aware that a commercial and quality license is required for any subsidiary that invoices the product. This license referred to as the wholesale distribution authorization (WDA), or dealer’s license (WDL) in some European countries, and pharmaceutical establishment license (PEL) in Switzerland. If invoicing is delegated to one central site, the subsidiary needs only to register as a broker with the local health authority.

Finally, the company needs to decide how many and which functions it prefers to outsource to service providers and which functions to **set up and develop** with its own employees. Outsourcing can take place on a pan-European scale or in selected countries only. There are providers for all sorts of outsourcing services but typical arrangements include logistics, distribution and order-to-cash management, pricing negotiations per country and quality control.

Out-licensing – harvest and entrust

In an out-license market entry approach, the IP owner of the pharmaceutical product partners up with a large pharmaceutical company that already has well-developed structures, a qualified workforce and established functions. The licensee commercializes the in-licensed product according to its own strategies and priorities. This option may seem easy and attractive at first glance. However, data shows that companies entering the EU market themselves tend to achieve higher value creation than those choosing to out-license their product to a big pharmaceutical company.

Combined approach – prioritize and expand

A combined approach enables pharmaceutical companies to tailor their strategy to different markets. They operate with their own subsidiaries in certain countries, selecting the out-sourcing options that suit them, but out-license and collaborate with big pharmaceutical companies in others. For example, a company may launch its product directly in Western Europe, with a few outsourced functions, but partner with a well-established pharmaceutical company in Eastern Europe.

A fourth option?

Finally, there is a fourth option. European product license acquisition brings opportunities to Life Sciences companies – drug and non-drug patent owners – that are evaluating consolidation options for their product portfolio. Acquiring rights to commercialize a drug in the European market opens opportunities for Life Sciences companies looking to do business in Europe but lacking the necessary product licenses.

1.3 High-level roadmap on strategic decision-making and KPMG services

Planning a market entry strategy for Europe requires a long-term view, preferably starting early in the clinical phase with a market entry analysis. The decision on direct launch or out-licensing will ideally be made by the time phase III clinical trials are under way. Strategy implementation should be initiated alongside the marketing authorization application, and effective tracking system should be in place to keep on top of progress across work streams.

KPMG draws on Life Sciences expertise and experience across its global network to guide companies through the process.

In a first step (**market sizing**) KPMG helps companies to determining reimbursement price models in target markets

along with the pricing strategy. As part of market sizing, we help companies identify key competitors and the number of patients in European target markets.

Step two (**launch strategy and plan**) consists of identifying key drivers and barriers for the launch strategy. KPMG then focuses on providing management support to ensure a smooth **launch and execution phase**, including risk mitigation. A launch maturity assessment will be conducted just before the product is launched.

Finally, KPMG works with its partners to provide support in developing product dashboards to **track the launch** through analysis of product results by geography and customer segment.

Healthcare expenditure

Country	Total in EUR million	EUR per inhabitat	% of GDP
Austria	35,077	4,269	10.3
Belgium	42,982	3,812	10.5
Bulgaria	3,715	518	8.2
Denmark	28,065	4,938	10.3
Finland	19,790	3,612	9.5
France	241,366	3,623	11
Germany	338,207	4,140	11.2
Greece	14,732	1,361	8.4
Ireland	19,855	4,273	7.8
Italy	148,029	2,437	9
Luxembourg	3,165	5,557	6.1
Netherlands	72,323	4,269	10.6
Norway	34,749	6,697	10
Portugal	16,105	1,555	9
Spain	98,586	2,123	9.2
Switzerland	60,276	7,361	11.4
UK	254,827	3,913	9.9
Australia	170,400	\$7,096	10.3
US	\$3,300,000	\$10,348	17.9
Canada	\$242,000	\$6,604	11.5
Singapore	\$8,610	\$2,752	2.1
Taiwan	NT\$ 1,087	NT\$46,219	6.3
Israel	\$19,000,000	\$2,428	7.5

Source: eurostat 2018

Healthcare expenditure in Europe

With different organizational approaches and funding for healthcare within Europe, it can be difficult to compare countries. Figures on total expenditure, spend per capita and amount as a percentage of gross domestic product help indicate how well healthcare systems are responding to the challenge of universal access to affordable, quality healthcare. Eurostat, the statistical office of the European Union, publishes official data that can be used to track and compare EU and non-EU countries' spending on healthcare.

2. Operationalize to commercialize

Once the decision to commercialize pharmaceutical products in Europe has been made, careful planning is essential to drive implementation and get the desired results in a complex and competitive market. This section focuses on step two of the commercialization process (launch strategy and plan).

Whether a company opts for full or partial direct market entry, the process is best managed via clearly defined work streams. Companies may also benefit from partnering with experienced organizations for certain aspects of commercialization and (partial) out-licensing of products. Direct market entry does not preclude outsourcing of business functions such as logistics, regulatory, quality control, price and reimbursement.

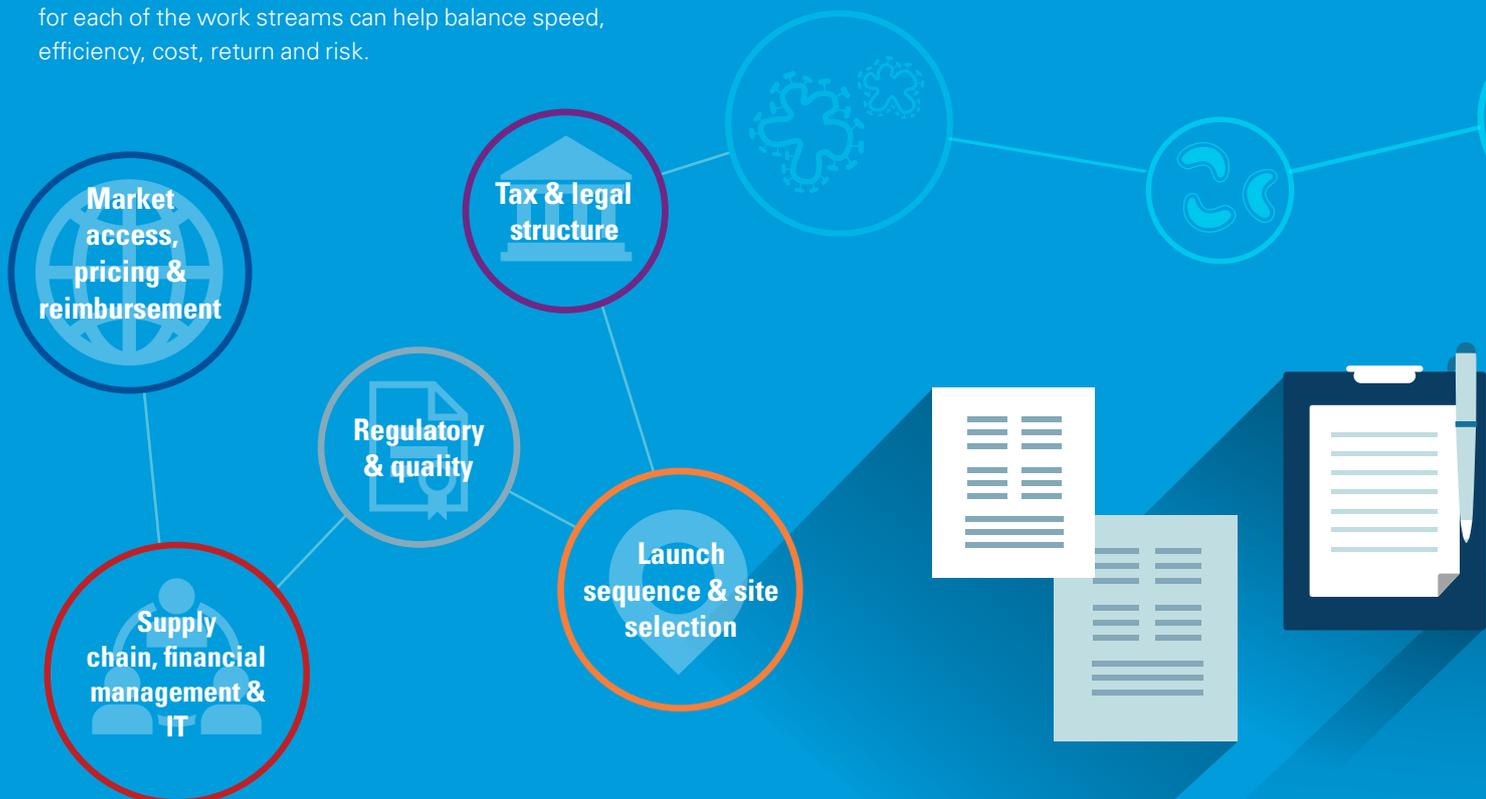
2.1 Operating model: Five key work streams

KPMG has identified five key work streams to build a successful operating model. They are interdependent and need to be worked on concurrently at times to ensure a timely launch. Developing a tailored outsourcing concept for each of the work streams can help balance speed, efficiency, cost, return and risk.

Market access, pricing and reimbursement

When selecting which European countries to operate in, pharmaceutical companies should bear in mind that national authorities (of both EU and non-EU countries) are free to set the prices of medicinal products and to designate the treatments they wish to reimburse under their social security systems. A market access and reimbursement analysis will establish which markets best match a company's specific product or products.

Although national authorities have freedom in terms of pricing and reimbursement, their systems are closely linked to the realization of European policy objectives such as the internal market, pharmaceutical competitiveness, sustainable research and development, and the protection of human health. The variety of healthcare and social security systems in the EU has an impact on the pharmaceutical industry, wholesalers, pharmacists, doctors, health insurers, and patients.



European health technology assessments (HTAs), which depend on the different European governments, are becoming more rigorous when recommending new products for the reimbursable drug lists. The agencies are also including cost containment measures that affect the reimbursement price.

The price level in some markets such as Switzerland and the Scandinavian countries is very high, while in others such as Spain and France it is much lower. Developing a strategy of which markets to approach first can help a company optimize pricing. In general, it is best to start with the most expensive markets. Starting with lower value markets will reduce prices and affects the amount that can be commanded in the more lucrative markets.

Supply chain, financial management and IT

Expanding to Europe for the first time is an opportunity to set up an efficient distribution and supply chain. This work stream focuses on developing the most appropriate logistics solution to deliver the product to the end-customer in a cost-efficient way.

The company needs to decide if it wants to use a direct delivery model or employ a network of different

wholesalers. In the direct delivery model, customer orders go to one EU central store, which delivers the product directly to the customer, be it a physician, pharmacy, hospital or a wholesaler. In a pre-wholesale chain, on the other hand, the product is stored separately in each country as consignment stock or as sold stock. This decision is usually made in alignment with the tax and legal work stream, taking financial management aspects into account.

Once the fundamental approach is defined, the supply chain work stream sets about securing the best logistic partners, arranging contracts and finalizing details in line with expected demand, transport conditions, volume and frequency of deliveries.

Thorough groundwork, balanced advice and alignment with other work streams are rewarded with smooth implementation and launch.

In parallel, the company has to set up a financial management plan and a related IT system. Since this is a very complex task, companies often rely on specialized pharma logistics companies to provide fully developed order-to-cash services.



Regulatory and quality

The pharmaceutical industry is heavily regulated, with the entire lifecycle of products subject to various rules and regulations. While the process of obtaining marketing authorization for a medicinal product in EU is well harmonized, EU member states' requirements vary considerably for local subsidiaries seeking authorization to commercialize and distribute a drug. Here we look at some of the main aspects to be considered in the regulatory and quality work stream.

Obtaining marketing authorization for a medicinal product (drug)

No medicinal product (drug) may be commercialized or distributed in the EU unless the European Medicines Agency (EMA) or relevant local health authority has issued marketing authorization (MA).

Exceptions exist in the following cases, however:

- named patient programs
- drugs delivered for experimental purpose
- compassionate use

In the EU, there are essentially four, sometimes linked, procedures for obtaining marketing authorization:

- (1) centralized procedure – in all EU member states; this procedure is mandatory for some medicinal products, such as orphan drugs
- (2) decentralized procedure – in one or more EU member state
- (3) mutual recognition procedure – in one or more EU member state, if one member state has already approved MA
- (4) the national procedure – in one EU member state only; rarely used

Companies expanding to Europe from abroad should preferably apply for the MA through the centralized procedure.

For an MA to be granted, the regulator must reach a favorable decision regarding the benefits of the medicinal product versus its risks, therapeutic efficacy and composition of the product. The assessment is based on a technical dossier submitted by the applicant. This requires careful articulation of the product profile and its benefits through the market access, pricing and reimbursement workstream.

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

Marketing authorization declares the drug to be safe, effective and approved to be marketed. The MA imposes a number of requirements on the MAH, for example the assurance of good pharmacovigilance practice (GVP).

An MA does not authorize pharmaceutical companies to commercialize their drug in European countries, however. For that, additional licences are required, which are granted by the local health authority. The local licenses authorize the subsidiary to manufacture, import, and commercialize a pharmaceutical product and assume responsibility for the safe handling of the product.

Obtaining local authorization

The importing subsidiary in the EU, i.e. the company that takes receipt of goods when they enter Europe for the first time, also needs a manufacturing and importation authorization (MIA). The MIA is granted by the state where this activity takes place and imposes certain requirements to assure compliance with good manufacturing practice (GMP) regarding the imported finished goods. Similar requirements apply to imported active pharmaceutical ingredients (API) as well as 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.

A wholesale distribution authorization (WDA) is required to hold, procure, supply, or export medicinal products, except if the subsidiary already holds an MIA³. 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 upstream suppliers. These practices are governed by guidelines issued by EMA and are, in theory, applicable to all EU countries to the same extent. In practice, their interpretation and implementation varies considerably from one EU country to the other.

Preparing the quality assurance system, securing qualified capacity (in-house or through an outsourcing provider), and establishing operations in compliance with GMP and GVP is a time-consuming undertaking and needs to be planned

³ Source: Article 77.3 of Directive 2001/83/EC: "possession of a manufacturing authorization shall include authorization to distribute by wholesale the medicinal products covered by the authorization."

New regulatory landscape for medical devices – MDR/IVDR

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 years (IVDR). Switzerland plans to adopt these changes as well to ensure that Swiss companies remain competitive in the European market and elsewhere.

One of the key goals of the initiative is to increase patient safety by improving the quality and safety of the medical devices and harmonizing the legislation within the EU.

It affects clinical trials and performance tests but even such basic aspects as the identification and traceability of products.

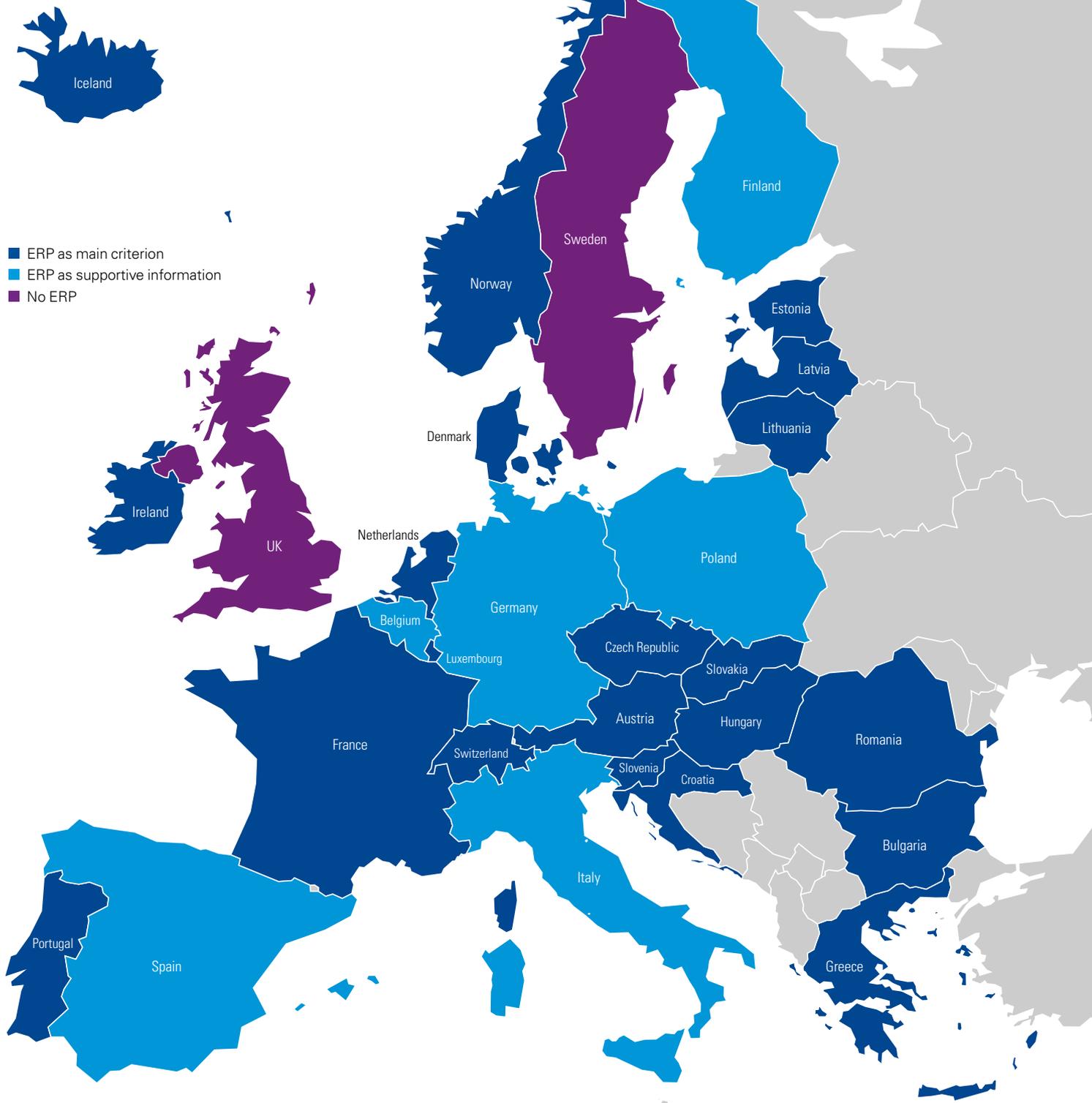
Compliance with the new MDR/IVDR regulation is likely to mean an increased workload for affected companies. Established organizations must evaluate their product portfolio based on the new regulations and conduct a risk and priority assessment. Companies currently evaluating expansion to Europe should 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.

according to the launch sequence and budgeted well ahead of time.

For setups other than "buy and sell," registration as a broker is sufficient. However, the subsidiary operating as a broker (or "commissionaire") must also have an effective vigilance and recall system in place, either of its own or outsourced. The subsidiary holding the marketing authorization carries overall responsibility for local pharmacovigilance and recall systems.

Foreign pharmaceutical investors expanding into Europe for the first time benefit from a high level of reciprocal recognition or shared standards between the EU member states. The subsidiary holding the marketing authorization (MA) must be located in the EU; the EU headquarters with other functions, assets and risks can be located in any non-EU country (Switzerland, Norway, soon UK), however, and this can have certain advantages.





Launch sequence and site selection

A company can only start commercializing its product(s) once certain steps have been taken. First, one subsidiary needs to have obtained marketing authorization for the product. Then another (or the same) subsidiary has to get the manufacturing and import authorization, and the European headquarters need to be set up. The company also requires a local license and a wholesale distribution license, in the country of first launch. A company should start planning its launch sequence, i.e. the order in which country launches take place, well in advance in order to maximize pricing potential.

Almost every country in Europe uses international reference pricing (IRP) or external reference pricing (ERP). The IRP formula varies from one country to another, with some using the lowest price observed in the reference countries and others applying an average of the reference prices. The reference sets are made up of an increasing number of countries over time, which typically induces convergence between international drug prices. Launch sequence has considerable overlap with the other work streams and has to be agreed and aligned with them too.

Tax model and legal structure

Diligent tax planning can significantly leverage the target operating model. Careful planning from the outset enables the company to remain flexible, scalable and sustainable as the business develops and grows. In the post-BEPS tax landscape, the alignment of taxing rights with economic substance is essential. BEPS Action 5 in particular aims to counter harmful tax practices more effectively, taking into account transparency and substance.

Companies need to identify the value drivers within a business and the parties responsible for those activities and look beyond two transacting parties, at all contributions that lead to the generation of profit for a business. It is critical that substance is located where profits are taxed – and this can make good business sense too. Companies need to keep the entire supply chain in mind to ensure that their key value drivers are located in the most suitable tax jurisdiction.

Against this background, the operational structure must be defined first without focusing on tax or legal aspects at all.

Once the basic operational decisions are made, it is time to optimize the tax and legal structure.

The subsidiary holding marketing authorization and the importing subsidiary must both be located in the EU. Headquarters (also referred to as the principal office) can be located in a non-EU country, and many companies have discovered the benefits of locating key value drivers in Switzerland or Norway, for example.

Model (example) for EU operations with headquarters in a non-EU country

An efficient and frequently employed EU model puts the headquarters – home to the functions, assets and risks of the business – in a non-EU country (such as Switzerland or Norway) while the subsidiary in an EU country, e.g. the Netherlands, holds marketing authorization, imports the drug and acts as master distributor. The marketing authorization holder is supported in its responsibilities by local subsidiaries operating either on a “buy and sell” basis (known as “limited risk distributors” (LRDs)) or as a broker (known as “commissionaire”).

2.2 European license environment: costs and timelines

Obtaining the relevant licenses and authorizations is the most important task in commercializing a product in Europe. Responsibility for applying for or holding the relevant permits

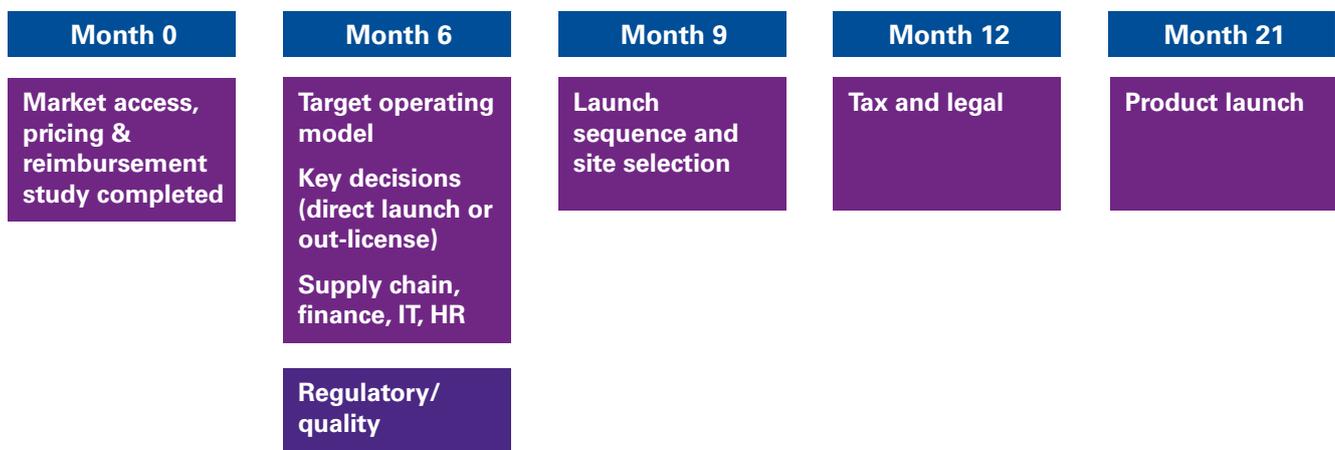
will depend on the operating model selected. This overview summarizes key considerations for the main licenses required in the EU and the EEA.

Type	EU	Issuer	Validity	Timeline	Costs
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	6 to 24 months	One-off EMA registration fee: EUR 300,000 additional data preparation fee: ca. EUR 100,000
Wholesale dealer's license/Wholesale distribution authorization Pharmaceutical companies need a WDA in almost all EU countries for subsidiaries planning to operate under a buy-and-sell model in that jurisdiction.	WDL / WDA / PEL	National authorities	Individual countries	6 to 8 months	ca. EUR 50,000 per country
Manufacturing and import authorization The MIA confirms that the organization has a system in place for testing and labeling the product in line with good manufacturing practice.	MIA / PEL	National authorities	EU/EEA-wide	6 to 12 months Often granted along with WDA	ca. EUR 20,000 in EU
Good practices: - Good manufacturing practice - Good pharmacovigilance practice - Good distribution practice	cGxP	EU directives	Enforced by national authorities	n/a	n/a

2.3 Efficient execution – what to expect

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

If planned and executed efficiently, the entire process can be completed in just under two years, with expenses in the region of EUR 1 million for a product’s marketing authorization and – depending on the company setup – EUR 0.4 to 0.8 million for the subsidiaries’ local licenses.



24 months

It can take less than 24 months to launch a Life Sciences product in Europe.



Spotlight on Brexit

It is now roughly two years since the British electorate voted to leave the EU. While the initial Brexit shock has faded, politicians are still debating definitions, deals and deadlines. Stranded in a sea of uncertainty, all branches of industry are struggling to make firm plans as they seek to adjust to challenges posed by the new environment. The recently announced two-year transition gives businesses a useful grace period to get prepared. However, the eventual post-Brexit model remains uncertain.

One particularly impacted sector is pharmaceuticals. The UK is a traditional hub for drug companies, the most popular EU country for phase I trials and a key location for other clinical phases. The full impact of Brexit on the pharmaceutical industry remains to be seen. In the meantime, most industry players are actively planning for a “hard Brexit” with some following the lead of the European Medicines Agency (EMA) in establishing regulatory functions outside the UK.

KPMG has identified six critical challenges for the pharmaceutical industry as they navigate rising complexity in the European business environment and new assumptions about a post-Brexit world.

1. Supply chain

- One of the most obvious issues posed by Brexit is the risk of significant supply chain delays on movement of goods between manufacturers in the UK and the EU
- Assuming no deal on customs union, severe border delays – and high costs – would be inevitable. Whilst this scenario looks less likely than it did a few months ago, suppliers of critically important medicines cannot afford to be complacent
- Although many companies are planning to build buffer stocks in the months leading to Brexit, short shelf lives or strict temperature requirements make it impossible to mitigate supply risks entirely

2. Indirect tax

- Currently, shipments from the EU are treated as intra-EU supplies with no VAT payable upfront
- Post-Brexit, companies will need to assess and pay VAT on import and claim it back later
- One large pharma group has already calculated the cash flow hit to be GBP 200 million p.a.
- Companies are making use of customs simplifications and accreditations such as SIVA and AEO to mitigate the worst cashflow impacts

3. R&D and clinical trials

- Uncertainty over future immigration restrictions in the UK is a major concern for companies looking to access international talent directly and through collaboration with the academic sector
- With the labor market already squeezed, companies face continued challenges in recruiting and retaining the right people
- There is an ongoing introduction of new clinical trials regulations and associated requirements which leads to an insecure future

4. Licenses and regulation

- Various EU licenses and associated regulatory activities will need to be moved or duplicated for the UK
- Under the current rules, for instance, marketing authorizations, wholesale distribution authorization and manufacturing and import authorization must be held in an EU member state along with associated regulatory and quality functions
- Companies are using the experience of Swiss-based pharmaceutical businesses to design their post-Brexit licensing and quality/regulatory structures
- The UK might need to duplicate activities that are currently performed by the EMA and local regulators may face capacity constraints limiting approval speed

5. Intellectual property

- Whilst uncertainty regarding the geographical validity of patents is likely over-played (the EPO is a non-EU organization and has confirmed that its activities are unaffected by Brexit) the future of some other areas of IP such as trademarks and SPCs remain in doubt
- Similarly, licensing and some procedures for intellectual property will most likely have to be duplicated as well

6. GDPR

- Effective as of May 2018, the General Data Protection Regulation (GDPR) applies in the UK until Brexit takes place. Unless the UK is granted mutual recognition/ equivalence of its data privacy laws by the EU, there may be additional hurdles for companies that hold or process personal data for EU patients (for example in clinical trials) or employees in the UK, even if UK entities are for all intents and purposes compliant with the GDPR
- For some pharmaceutical companies undertaking major trial activity in the UK this is a potentially expensive and complex issue.

In summary, there is a lot for pharmaceutical companies to focus on in the period up to Brexit, across many separate disciplines, professions and areas of expertise, including R&D, logistics, financial planning, regulatory requirements, human resources, intellectual property, data protection as well as taxation.

Brexit outlook

To transfer or re-register for authorization to operate inside the EU after Brexit, companies must choose to either use a new or existing subsidiary, or alternatively establish a branch of the UK company. Several companies have opted for the branch option. It gives companies flexibility, and Swiss companies have a track record of using this approach to tackle the issue of sitting outside the EU.

KPMG's experience shows that UK entities with a supply chain footprint in the EU should factor in at least nine months – and sometimes as long as 18 – for planning and execution. Restructuring inevitably has implications for tax, financing and operating systems, which management need to consider up-front.

It is also important to note that while the UK has secured a stand-still transitional deal with the EU giving companies until 2021 to prepare for these changes (with full regulatory equivalence and single market membership), "nothing is agreed until everything is agreed", and the risk of no deal remains for the time being.



Part 2:

Site selection

Despite significant efforts – and considerable progress – in bringing Europe closer together to offer a more unified business environment, the continent remains complex and fragmented in many respects. The right location is particularly crucial in Life Sciences; companies that operate in this industry must understand the various location advantages and disadvantages for their specific needs. The right site supports sustainable success through talent, tax and business incentives and innovation potential.



3. Key site selection aspects

We now turn our attention to the Life Sciences landscape across Europe, discussing the advantages and disadvantages of different jurisdictions as potential hosts for overseas Life Sciences players looking to start, expand or reorganize their European operations. Our analysis examines Life Sciences clusters from across Europe (14 EU and non-EU countries), and compares them with those in Australia, Israel, Singapore, Taiwan, the US (California) and Canada. We focus on the following factors that KPMG has found to be particularly relevant for Life Sciences companies in the process of site selection in Europe:

- Innovation, size and specialization of the Life Sciences industry
- Financing environment in the Life Sciences industry
- Business and political environment
- Infrastructure and connectivity
- Workforce and productivity
- Families and quality of life
- Taxes and incentives

Innovation – the life source of Life Sciences – often works best in collaboration with peers, universities and suppliers.

That is why Life Sciences clusters are so valuable. KPMG's analysis provides insights into the number, size, specialization and pipelines of companies per country. Our list of biotech incubators is essential reading for small companies and start-ups seeking support from more established peers.

The ability to attract financing is a good indicator of a Life Sciences cluster's strength and potential. Our overview of private and the public financing in the life sciences industry provides insights into the dynamics of potential locations in Europe.

This report also assesses general business environment, focusing on the availability of workforce, flexibility of labor law, legal requirements, infrastructure and quality of life.

Finally, countries' tax planning and incentive models are highly relevant factors in site selection. This is especially true for intellectual property – a key value driver in industries such as Life Sciences. Our high-level overview of incentives provides insights at a glance.

3.1 Size and specialization of the Life Sciences industry

Innovative Life Sciences companies benefit from the presence of peers in the bio, pharma or medtech field as well as proximity to producers and service companies, investors and universities. A strong cluster creates a local pool of talent, expertise and know-how to support profitable pipelines. Comparing the cluster size and pipelines is a valuable indication of the attractiveness of a location.

Life Sciences clusters

An initial glance at the data is already revealing in terms of clusters and innovation hotspots. The UK, Germany and France are popular locations for biotechs in terms of numbers. The percentage of therapeutic companies – a good indicator of innovation strength – is particularly high in Sweden and Switzerland (both 34%) or Australia (48%) and Denmark (37%).

With regard to medtech companies in Europe, Germany leads the field, followed by Sweden and Switzerland. The UK, Germany, Spain, France and Italy are popular locations for pharma companies, hosting many mid-size pharma companies' base for regional markets.

Number of companies in the Life Sciences industry

Country	Biotechnology	Biotech – therapeutics	Medtech	Pharmaceutical
Austria	119	44	23	18
Belgium	260	47	60	40
Denmark	171	68	93	12
Finland	83	21	41	6
France	802	180	182	85
Germany	1,073	178	531	102
Ireland	119	28	59	49
Italy	437	58	97	83
Netherlands	459	112	114	41
Norway	151	32	43	7
Spain	525	89	113	94
Sweden	500	170	282	46
Switzerland	463	159	264	76
UK	1,180	328	319	121
<hr/>				
Australia	219	106	65	31
Canada	940	248	370	111
Israel	275	134	449	28
Singapore	75	19	27	25
Taiwan	194	55	85	41
US - CA	1,718	794	506	56

Source: www.biotechgate.com 2018

Main activities of Life Sciences companies

Comparing the different activities of Life Sciences companies in different European countries shows that manufacturing is a particularly important aspect of the Life Sciences industry in Italy, Germany, Belgium and Ireland. R&D dominates in Spain, Ireland, Switzerland, France, Finland, Denmark, and Austria.

R&D on a contract basis appears to be a less popular business model overall but is nevertheless a significant activity for companies in the UK, France and Finland. The chart below sets out the percentage and absolute number of companies involved in manufacturing, R&D and contract R&D.

Main activities of Life Sciences companies

Country	R&D (% of all)	Manufacturing (% of all)	Research on contract basis (% of all)
Austria	120 (75%)	69 (43%)	23 (14%)
Belgium	180 (50%)	193 (54%)	49 (14%)
Canada	778 (55%)	738 (52%)	142 (10%)
Denmark	170 (62%)	136 (49%)	34 (12%)
Finland	80 (62%)	68 (52%)	21 (16%)
France	661 (62%)	520 (49%)	168 (16%)
Germany	780 (46%)	1,006 (59%)	201 (12%)
Ireland	136 (60%)	138 (61%)	14 (6%)
Italy	348 (56%)	381 (62%)	52 (8%)
Netherlands	357 (58%)	284 (46%)	82 (13%)
Norway	107 (53%)	97 (48%)	10 (5%)
Spain	500 (68%)	381 (52%)	58 (8%)
Sweden	489 (59%)	434 (52%)	83 (10%)
Switzerland	466 (58%)	416 (52%)	64 (8%)
UK	919 (57%)	695 (43%)	237 (15%)
<hr/>			
Australia	204 (65%)	137 (43%)	22 (7%)
Canada	738 (52%)	778 (55%)	142 (10%)
Israel	498 (66%)	430 (57%)	18 (2%)
Singapore	72 (57%)	74 (58%)	13 (10%)
Taiwan	256 (80%)	214 (67%)	38 (12%)
US - CA	1,656 (73%)	820 (36%)	175 (8%)

Source: www.biotechgate.com 2018. Note: figures do not add up to 100%, multiple counts are possible.

56%

of all companies are engaged in R&D and 46% in manufacturing.

European Innovation Scorebord

Country	Score
Austria	121.5
Belgium	120.9
Denmark	136.7
Finland	130.9
France	109.2
Germany	123.4
Ireland	115.7
Italy	75.1
Luxembourg	121.4
Netherland	129.5
Norway	115.8
Portugal	83
Spain	78.3
Sweden	143.6
Switzerland	164.6
UK	125.3
Israel	111

Source: EU Innovation Scoreboard 2017

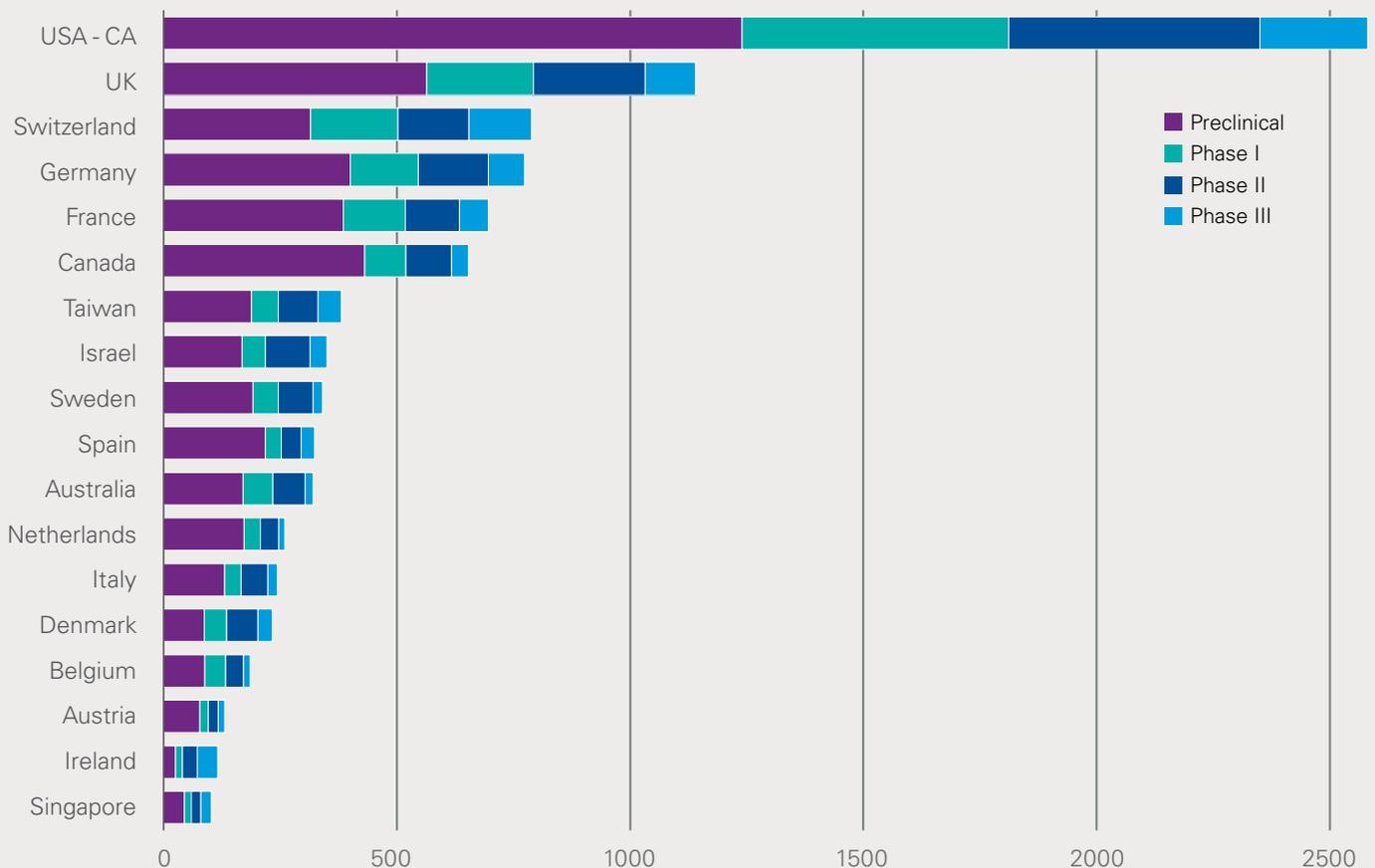
Leadership in innovation

The European Innovation Scoreboard compares innovation in EU countries, other European countries and regional neighbors. 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, Denmark and Finland. Overall, the EU's innovative performance continues to increase, mainly thanks to improvements in HR, an innovation-friendly environment and attractive R&D conditions.

Product pipeline and stage of development

Biotech companies in California have about the same number of products in the pipeline as the three strongest countries in Europe combined: UK, Switzerland and Germany. The UK has the strongest product pipeline in Europe. A review of phase III products places Switzerland ahead of the UK and Germany. Within Europe, Switzerland is joined by France and Germany in having a strong phase III pipeline as a percentage of the total number of products in development.

Product pipeline and stage of development



Source: Biotechgate.com, 2018

Influence of universities and innovation

Due to their dependence on a highly qualified workforce, players in the Life Sciences industry are increasingly seeking strong relationships with universities – and access to their students and graduates. This trend is reflected in the numerous programs, initiatives and networks designed to foster exchange. The results of collaboration are often tangible, with numerous spin-offs created each year in the field of life sciences.

The Academic Ranking of World Universities (ARWU) uses objective indicators including the number of alumni and staff that have won Nobel Prizes and Fields Medals, the number highly cited, the number of articles published in journals of nature and science, the number of articles indexed in the Science Citation Index - Expanded and Social Sciences Citation Index, and a university's per capita performance.

Shanghai Ranking – number of universities in top 100

Country	Number of universities in top 100	Number of universities in top 200
Austria	0	2
Belgium	2	4
Denmark	2	3
Finland	1	1
France	3	9
Germany	3	15
Ireland	0	1
Italy	0	2
Luxembourg	0	0
Norway	1	2
Portugal	0	1
Spain	0	1
Sweden	3	5
Switzerland	5	7
UK	9	20
Israel	1	4
Australia	6	10
Canada	4	8
Singapore	1	2
US	48	70

Source: Shanghai Ranking 2017, <http://www.shanghairanking.com/ARWU-Statistics-2016.html#2>

Collaboration with universities is a win-win situation. Students benefit from state-of-the-art laboratories funded or provided by the industry, while Life Sciences companies address the notorious challenge of talent acquisition and retention at an early stage.

Incubators

Incubators – organizations that support start-ups and smaller Life Sciences companies with facilities, mentoring and connections – make the ideal partner to nurture fragile businesses before their products reach launch maturity.

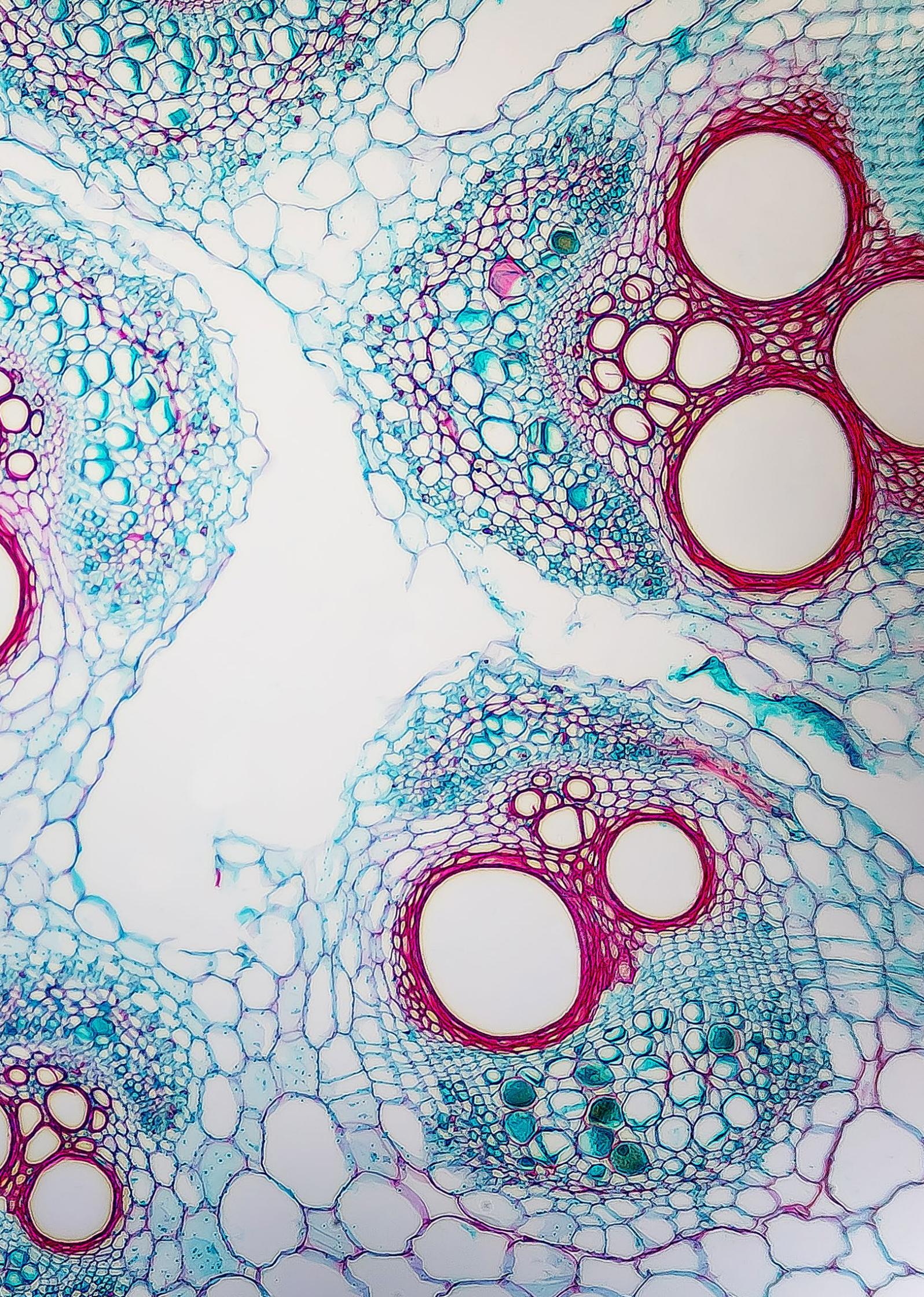
Since biotech is well established in Europe, there are plenty of incubators in various

countries. Companies interested in benefiting from the support and expertise of an incubator should do their research to find an incubator specializing in most relevant Life Sciences field.

The list below shows some examples of established European incubators only and is **not intended to be exhaustive**.

Name	Location	Founded	Focus
BioVille	Belgium, Diepenbeek	2012	Healthcare
Bio-incubator Leuven	Belgium, Leuven	2008	Biotechnology
Copenhagen Bio Science Park (COBIS)	Denmark, Copenhagen	2009	Biotechnology
Genopole	France, Evry	1998	Biomedicine and synthetic biology
Eurasanté Bio-Incubator	France, Lille	2000	Healthcare and food technology
Bayer HealthCare CoLaborator	Germany, Berlin	2014	Healthcare
Bio City Leipzig	Germany, Leipzig	2002	Biomedicine
Innovation and Startup Center for Biotechnology (IZB)	Germany, Munich	1995	Biomedicine
Toscana Life Sciences Bioincubator (TLS)	Italy, Siena	2004	Biomedicine
Oslo Cancer Cluster Incubator	Norway, Oslo	2007	Oncology
Genetrix	Spain, Tres Cantos	2001	Healthcare and diagnostics
BioVenture Hub	Sweden, Gothenburg	2014	Biotechnology and medtech
Umeå Biotech Incubator (UBI)	Sweden, Umea	2004	Biomedicine
Baselaunch	Switzerland, Basel	2017	Healthcare, Biotechnology, Biomedecine
Fongit	Switzerland, Geneva	1991	Medtech
EPFL Innovation Park	Switzerland, Lausanne	1991	Biotechnology, biochemistry
Technopark	Switzerland, Zurich	1993	Biotechnology, medtech
The Babraham Bioincubator Concept	UK, Cambridge	1998	Healthcare
BioCity	UK, Nottingham	2003	Biotechnology

Sources: <https://labiotech.eu/15-best-biotech-incubator-europe/>, <https://www.bioalps.org/biotechnology/incubators-technological-parks-76.html>



3.2 Financing environment in the Life Sciences industry

Financing is the foundation on which innovation is built. Funding volume and cluster strength go hand in hand, making the financing environment an important consideration even for companies not looking to raise capital. A closer look at the funding patterns, especially private financing rounds, for Life Sciences companies across Europe reveals a lot about the dynamic of a regional or national Life Sciences cluster.

In California, companies raised an average USD 22 million per financing round over the period 2010 to 2017 – that is twice the average for Europe (USD 11 million). With a higher total number and average volume of financing rounds, private Californian Life Sciences companies raised more money in 2017 (USD 6.8 billion) than all European companies combined (USD 2.8 billion). California, Israel, Switzerland and Canada saw a record total financing volume in 2017 in a comparison of the last seven years.

Most countries were able to increase financing for Life Sciences companies in the period 2014 to 2017

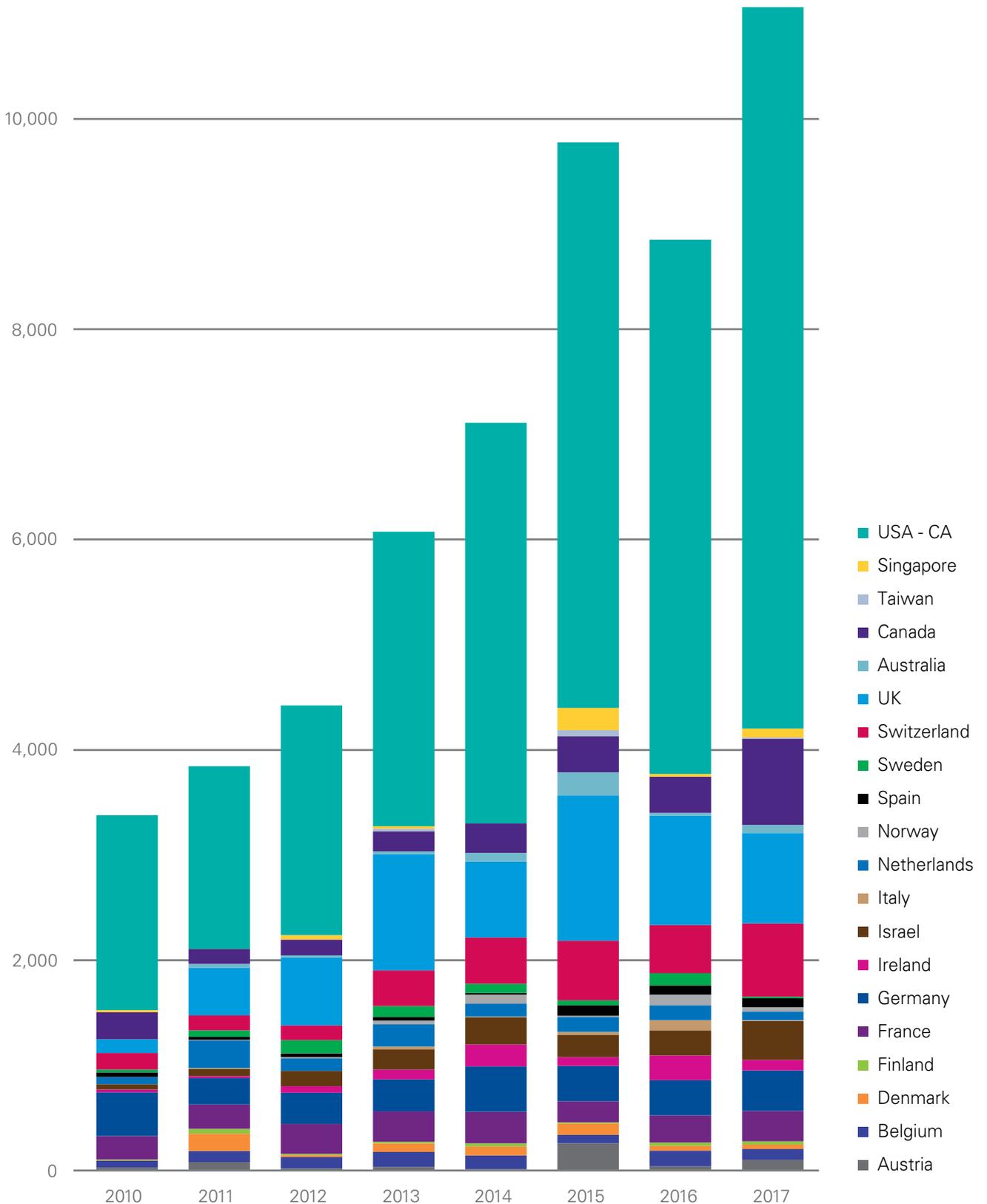
compared to 2010 to 2014, with the exception of the Netherlands and Sweden. Australia, Norway, Italy, Singapore and Ireland even achieved a substantial increase of over 200% between the two comparative periods.

In Europe overall, financing of private Life Sciences companies peaked in 2015 (USD 3.4 billion), dropping slightly since to USD 3.1 billion in 2016 and USD 2.8 billion in 2017. The number of financing rounds in Europe has been relatively stable since 2014, fluctuating between 246 and 279.



Financing of privately owned Life Sciences companies (medtech, biotech, pharma)

in USD million



Source: Biotechgate.com, 2018

Overall financing (public and private) of Life Sciences companies by country

Life Sciences companies in the UK receive the most public and private financing in Europe, followed by France and Switzerland. Germany, Ireland, Belgium and the Netherlands are also successful fundraisers. Beyond Europe, California once again outperforms Europe by some margin. Only in 2010 did the combined amount raised by European Life Sciences companies match the level of funds flowing to Californian companies; since then Europe has only raised between 37% and 79% of the total achieved by its Californian peers. A closer look at the figures reveals that one company, Gilead Sciences, Inc., raised USD 19 billion – a significant chunk of the overall amount – between 2014 and 2016, accounting for the spike around these dates.

Financing of pharmaceutical research in Europe

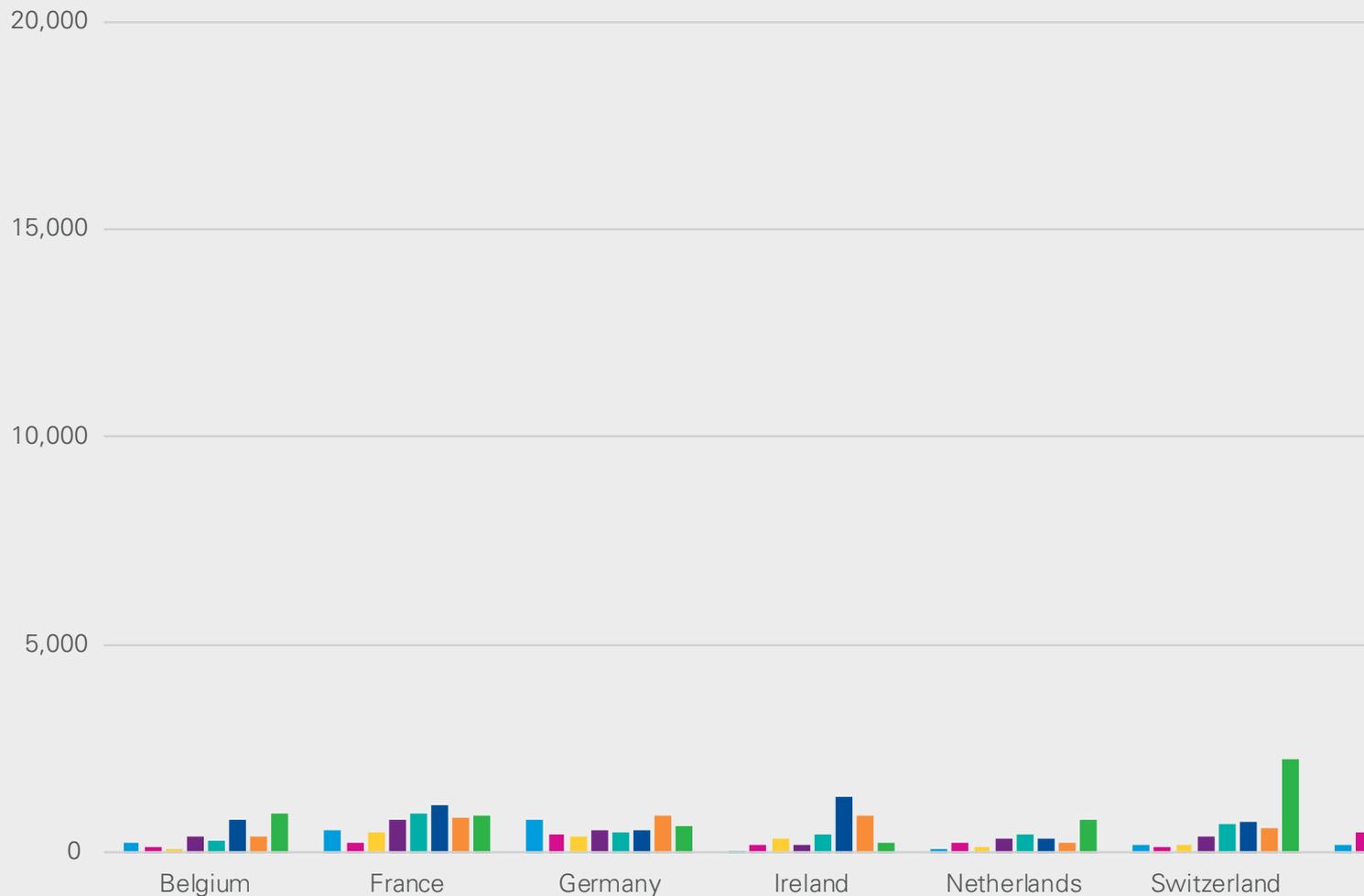
Horizon 2020

According to the EU's official website, Horizon 2020 is the biggest EU research and innovation program ever, with nearly EUR 80 billion of funding available over seven years (2014 to 2020) – in addition to the private investment that this money will attract. It promises more breakthroughs, discoveries and world-firsts by taking great ideas from the lab to the market.

A biotech company interested in participating would have to register under the Horizon2020 website. Biotechnology falls under the second section "Industrial Leadership" and has a total budget of EUR 17 billion over the seven years. There

Overall financing (public and private) of Life Sciences companies by country

in USD million



is also an option in the same section for promising SMEs to apply for funding.

European Investment Bank (EIB)

The EIB offers research and innovation loans to private and public sector organizations. Depending on the country of origin and nature of the entity, the loan may be supported by the European Fund for Strategic Investments (EFSI), InnovFin or other mandates managed by the EIB.

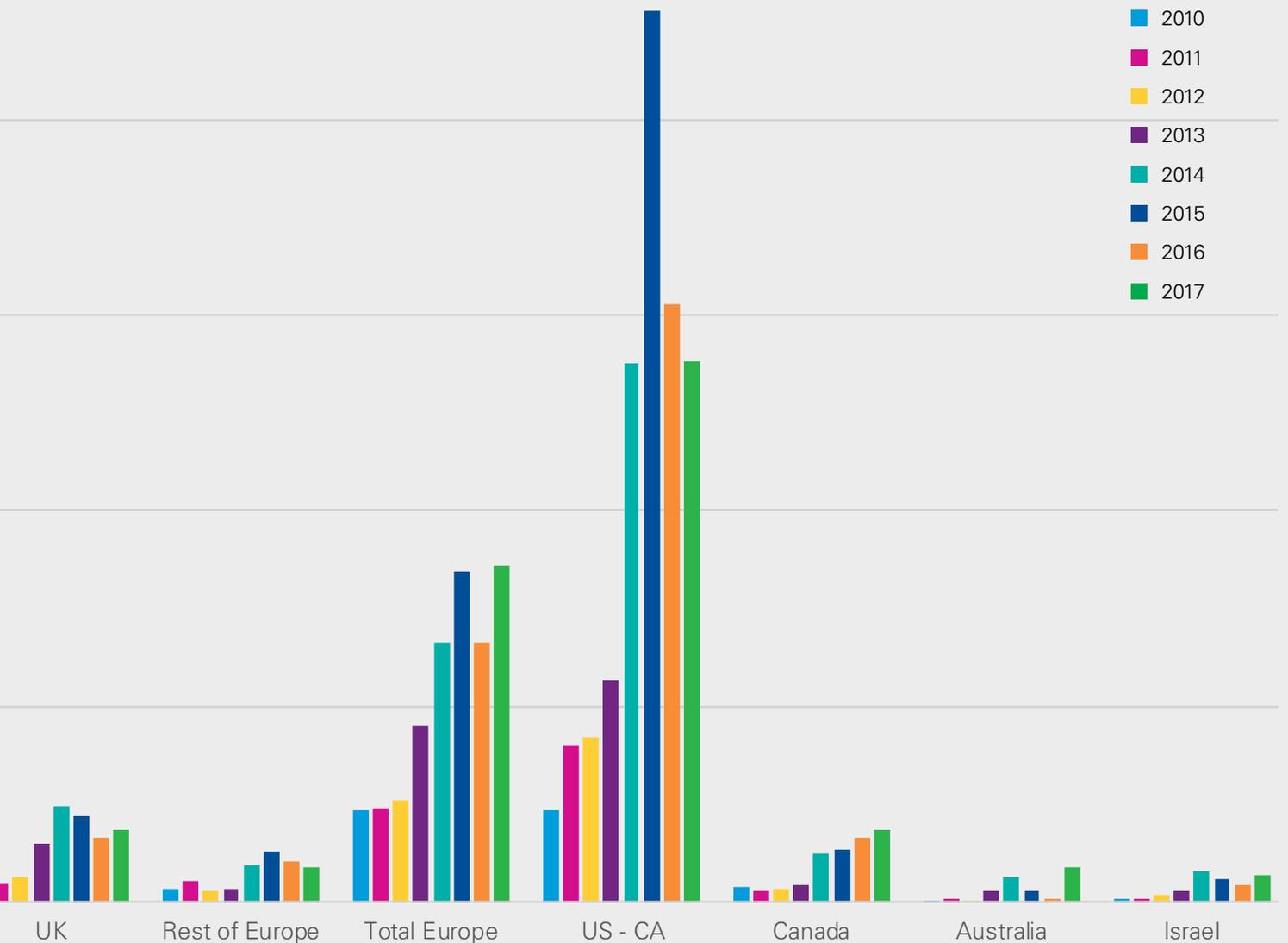
InnovFin

InnovFin is a package of financing tools from loans and guarantees to equity-type funding. Financing can be tailored to innovators’ needs and either provided directly or via a financial intermediary. InnovFin is available across all eligible

sectors in EU member states and associated countries under Horizon 2020.

European Investment Fund (EIF)

EIF works with a wide range of financial intermediaries (banks, guarantee institutions, private equity and venture capital funds, etc.) to enhance access to financing for SMEs and small mid-caps across Europe.



3.3 General business environment

Companies seeking fast and sustainable growth flourish in a business environment that affords agility, resilience, stability and the freedom to optimize their organizational setup and structure.

The countries covered in this report facilitate productivity and sustainability to differing degrees depending on a variety of factors that influence flexibility. The right site selection decision hinges on a careful assessment of each prospective location's merits and disadvantages in the context of a given company's specific circumstances and objectives.

Ideally, companies are looking for the security of a stable business environment and the opportunities of a

dynamic one. We examine potential site locations from this perspective, focusing on speed and sustainability, workforce and flexibility of labor law as well as quality of life factors.

The **sustainability of a business environment** is closely connected to key macroeconomic factors. An analysis of these helps predict whether a country can provide sufficient stability over time to attract and retain foreign direct investment.

General business environment

Country	GDP (USDbn)	GDP (PPP) per capita in USD	Current account balance in % of GDP	Government debt as % of GDP	Government expenditure as % of GDP	Real GDP growth forecast
Austria	387	47,742	1.61	83.9%	51.0%	2.00%
Belgium	467	45,011	-0.40	105.5%	53.5%	1.40%
Denmark	306	47,988	8.11	40.0%	53.6%	1.60%
Finland	237	42,044	-1.32	63.6%	56.1%	1.70%
France	2,462	40,969	-1.09	96.7%	56.5%	1.40%
Germany	3,465	48,401	8.49	67.7%	44.3%	1.60%
Ireland	294	68,230	4.72	76.3%	28.0%	3.40%
Italy	1,850	36,833	2.58	132.6%	49.6%	0.80%
Luxembourg	60	104,049	4.26	22.4%	41.2%	4.20%
Netherlands	771	51,037	9.63	62.5%	43.6%	2.10%
Norway	371	69,263	4.60	33.2%	51.1%	1.20%
Portugal	205	28,985	0.02	130.3%	45.0%	1.60%
Spain	1,232	36,302	2.00	99.3%	42.4%	2.50%
Sweden	511	50,123	4.66	41.7%	50.0%	2.70%
Switzerland	660	59,571	11.96	45.4%	33.9%	14.00%
UK	2,620	42,714	-4.37	89.1%	42.1%	2.00%
Australia	1,258	49,211	-2.67	41.1%	37.3%	3.10%
Canada	1,529	46,472	-3.34	92.3%	40.8%	1.90%
Israel	318	34,830	3.89	62.2%	26.7%	3.10%
Singapore	297	87,856	19.03	112.9%	17.4%	2.00%
Taiwan	530	48,094	13.40	35.3%	16.5%	1.90%
US	18,566	57,272	-2.59	107.4%	35.2%	2.30%

Source: IMD Yearbook 2017

Changes in GDP can be revealing, with economic growth typically a stabilizing factor. Developments need to be assessed carefully, however, as currency fluctuations can have a quick and significant impact on nominal GDP. There is also a risk that GDP does not adequately reflect an economy's strength. As the sum of private sector investments, government spending and household consumption (plus exports, minus imports), GDP growth reflects these drivers as much as the real strength and stability of an economy. For instance, lower rates of

government expenditure as a percentage of GDP are known to indicate an economy that is oriented more towards the free market.

Government debt as a percentage of GDP is a key indicator of economic stability. Deficit spending is not interminably sustainable; it impacts a country's credit rating and consequently its refinancing cost. As with many macroeconomic indicators, it is vital to consider movements in the context of an overall analysis rather than taking absolute figures at face value.

General competitiveness comparisons

Various organizations issue global rankings of countries based on certain competitiveness aspects. The Heritage Foundation's **Index of Economic Freedom**, the IMD's **World Competitiveness Yearbook** and the World Economic Forum's **Global Competitiveness Report** are widely regarded as being particularly useful. 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** [1] measures economic freedom of countries based on freedom of trade, business freedom, investment freedom and property rights.

The **IMD World Competitiveness Yearbook** [2] measures how well countries manage their resources and competencies to facilitate long-term value creation. The overall ranking reflects more than 300 criteria, approximately two-thirds of which are based on statistical indicators and one-third on an exclusive IMD survey of over 6,000 international executives.

The **Global Competitiveness Report** [3] ranks countries according to twelve different pillars including innovation, macro-economic environment and labor market efficiency.

Country	Ranking [1]	Ranking [2]	Ranking [3]
Austria	30	19	25
Belgium	49	17	23
Denmark	18	12	7
Finland	24	10	15
France	72	21	31
Germany	26	5	13
Ireland	9	23	6
Italy	79	44	44
Luxembourg	14	20	8
Netherlands	15	4	5
Norway	25	11	11
Portugal	77	46	39
Spain	69	32	34
Sweden	19	6	9
Switzerland	4	1	2
UK	12	7	19
Australia	5	22	21
Canada	7	15	12
Israel	36	24	22
Singapore	2	2	3
Taiwan	11	14	14
US	17	3	4

[1] **Note:** Ranking from 1 to 178
Source: 2017 Index of Economic Freedom by The Heritage Foundation

[2] **Note:** Ranking from 1 to 144
Source: World Economic Forum, The Global Competitiveness Report 2015-16

[3] **Note:** Ranking from 1 to 63
Source: 2017 IMD, The World Competitiveness Yearbook 2017

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. While all European countries covered in this report have a strong network of such agreements,

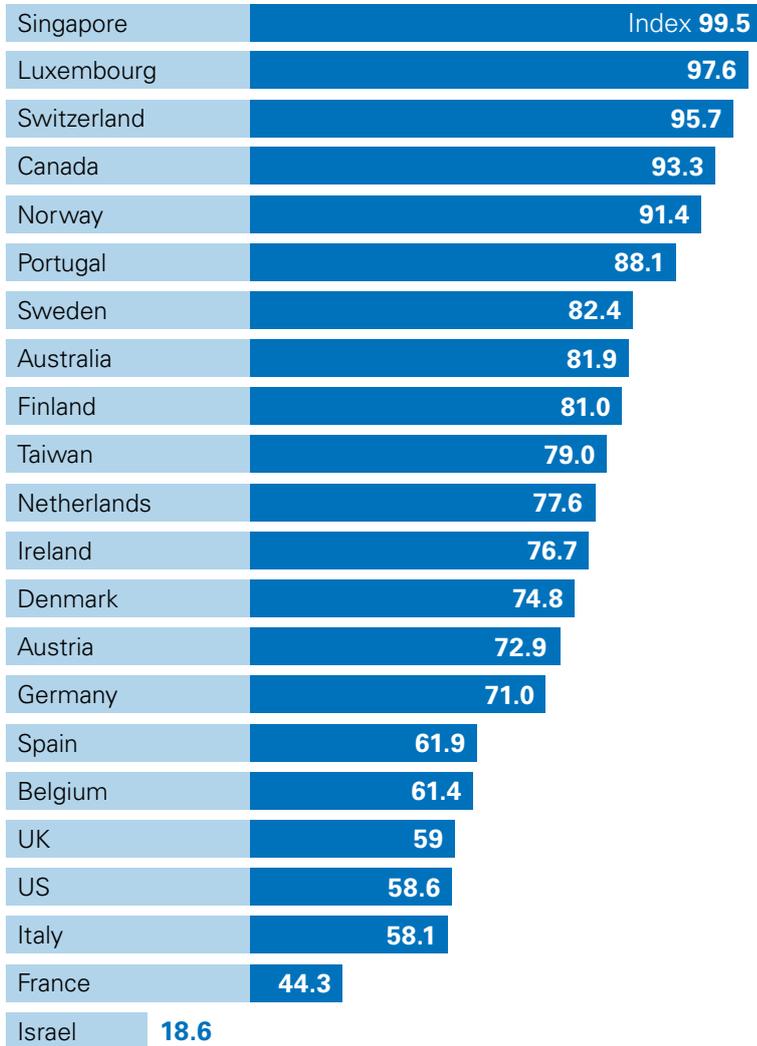
there are differences in form and scope. The UK, for instance, has never been part of the Schengen Area in which people can travel on a single visa. Following Brexit, the UK will cease to be part of the EU as well and will have to strike separate trade deals with the EU and other countries. Being a member of the EU is not the only way to enjoy free movement of people. Switzerland, for example, benefits from the EU single market via a free trade agreement, and also has a free trade agreement in place with China.

International treaty network

Country	Schengen Area	Access to EU single market	Free trade agreement with the US	Free trade agreement with China	Parent Subsidiary Directive	EU member state	Eurozone member state
Austria	Yes	Yes	In discussion	No	Yes	Yes	Yes
Belgium	Yes	Yes	In discussion	No	Yes	Yes	Yes
Denmark	Yes	Yes	In discussion	No	Yes	Yes	No
Finland	Yes	Yes	In discussion	No	Yes	Yes	Yes
France	Yes	Yes	In discussion	No	Yes	Yes	Yes
Germany	Yes	Yes	In discussion	No	Yes	Yes	Yes
Ireland	No	Yes	In discussion	No	Yes	Yes	Yes
Italy	Yes	Yes	In discussion	No	Yes	Yes	Yes
Luxembourg	Yes	Yes	In discussion	No	Yes	Yes	Yes
Netherlands	Yes	Yes	In discussion	No	Yes	Yes	Yes
Norway	Yes	Yes	In discussion	No	Yes	No	No
Portugal	Yes	Yes	In discussion	No	Yes	Yes	Yes
Spain	Yes	Yes	In discussion	No	Yes	Yes	Yes
Sweden	Yes	Yes	In discussion	No	Yes	Yes	No
Switzerland	Yes	Yes	No	Yes	Yes	No	No
UK	No	Yes, until March 2019	In discussion	No	Yes	until March 2019	No
Australia	No	No	Yes	Yes	No	No	No
US	No	No	Yes	No	No	No	No
Canada	No	No	Yes	No	No	No	No
Singapore	No	No	In discussion	Yes	No	No	No
Taiwan	No	No	In discussion	Yes	No	No	No
Israel	No	No	Yes	No	No	No	No

Source: KPMG study, 2018

Political stability

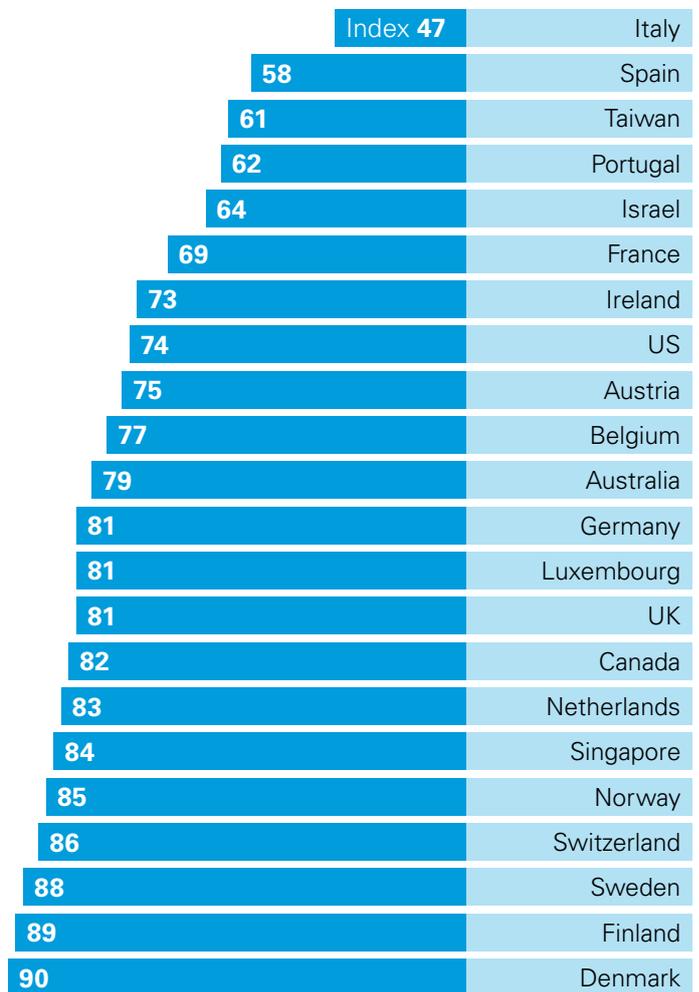


Source: Worldbank, 2017, (Scores 0 to 100)

Political stability, absence of violence

Measured as the ability of governments to build and maintain a business and legal environment, which offers clear and attractive conditions for business, political stability is a key feature of locations that are attractive for foreign direct investment. The World Bank's Worldwide Governance Indicators (WGI) project reports aggregate and individual governance indicators for various dimensions of governance relevant to doing business. Unsurprisingly, all European countries rank very favorably compared to many other countries worldwide. There is nevertheless a significant spread in certain sub-sectors such as political stability and absence of violence/terrorism, which accounts for the variation in scores between countries.

Corruption Perception Index



Source: Transparency International, 2017

Corruption Perception Index

The Corruption Perception Index is a significant indicator of how companies can operate in certain jurisdictions. A high level of corruption is particularly problematic for Life Sciences companies as they have to act in a highly regulated environment including many touchpoints with governments and regulators.

FM Global Resilience Index

Whether as a location for business operations or key suppliers, a country’s business resilience matters to companies. The FM Global Resilience Index is the first data-driven tool and repository that ranks the resilience of 130 countries and territories according to their enterprise resilience to disruptive events. Key decision-makers can use the insights to evaluate the countries of relevance to their organization. More comprehensive information drives better-informed decisions around a company’s own business and supply chain resilience.

Switzerland tops the table for overall resilience, followed by a cluster of high-scorers: Luxembourg, Sweden, Austria and Germany. Spain, Portugal and Italy are the worst European performers in terms of resilience.

Global Resilience Index

Contries	Index	Ranking
Austria	94.6	4
Belgium	85.2	14
Denmark	91.1	7
Finland	91.1	8
France	88.1	11
Germany	94.4	5
Ireland	82.8	20
Italy	68.2	33
Luxembourg	95.9	2
Netherlands	87.5	12
Norway	93.3	6
Portugal	73.7	28
Spain	79	24
Sweden	94.7	3
Switzerland	100	1
UK	84.4	16
Australia	85.1	15
Israel	63.3	34
Canada	84.1	17
Singapore	74.4	27
Taiwan	61.1	36
US East	89.2	10
US Central	90.6	9
USWest	83.7	18

Source: FM Global, 2017



Growth Promise Indicators

Country	Ranking
Netherlands	1
Switzerland	2
Luxembourg	3
Norway	5
Finland	6
Denmark	8
Sweden	9
UK	13
Germany	14
Ireland	15
Belgium	16
Austria	19
France	24
Portugal	30
Spain	32
Italy	44
Singapore	7
Canada	12
Australia	17
US	23
Israel	26

Source: KPMG Growth Promise Indicators Report, 2018

Growth Promise Indicators

KPMG’s Growth Promise Indicators (GPI) report helps governments and steers investors to the best long-term bets based on the factors that influence a nation’s potential, from business rights and best practice culture to transport systems and mobile coverage.

The GPI report analyzes data from a wide-range of sources to build a global picture around three broad themes: Openness, technology and institutional strength and transparency. The GPI report – which ranks the Netherlands, Switzerland and Luxembourg as one, two, three – helps investors to make more informed decisions about long-term location decisions. For governments, it shines a light on who is leading the pack and provide insight into how they are doing it.

The report drills into three broad themes:

- **Openness:** Is the world a less open place to trade today? And does remaining “open” pay dividends?
- **Technology:** Which countries are accelerating their development through smarter investments in technology?
- **Institutional strength and transparency:** Which lower-income countries are stealing a march on their wealthier peers?



Change readiness

The 2017 Change Readiness Index (CRI) indicates the capability of a country – its government, private and public enterprises, people and wider civil society – to anticipate, prepare for, manage, and respond to a wide range of change drivers, proactively cultivating the resulting opportunities and mitigating potential negative impacts. Examples of change

include shocks (such as financial and social instability and natural disasters) and political and economic opportunities and risks (such as technology, competition, and changes in government). Switzerland took the number one spot for the first time in the 2017 ranking, with Sweden and Denmark also representing Europe in the top five.

Change readiness

Country	Ranking	Enterprise capability	Government capability	People & civil society capability
Switzerland	1	2	4	1
Sweden	2	5	3	3
Denmark	5	4	8	2
Netherlands	7	8	10	4
Finland	8	12	5	7
Germany	9	11	9	6
UK	10	7	14	8
Norway	11	18	6	5
Ireland	15	22	13	9
Austria	16	15	16	16
Belgium	18	23	18	12
France	20	13	25	18
Portugal	23	27	28	19
Spain	27	35	35	22
Italy	40	44	60	28
Australia	14	16	15	11
Canada	17	19	17	14
Israel	22	17	29	23
Singapore	4	3	1	15
Taiwan	35	57	27	35
US	12	9	23	13

Source: KPMG Change Readiness Index, 2017



Continental European countries clearly outperform the UK and Ireland in regards to quality of infrastructure: Top ranked countries include France, Finland, Denmark, Switzerland and the Netherlands.

3.4 Infrastructure, workforce and productivity

Companies in the midst of business transformation benefit significantly from simple workforce scalability and flexibility of labor laws. Salary costs, workforce productivity, hours per year and paid vacation need to be weighed up to get a true picture of cost and rewards.

Quality of infrastructure

Infrastructure quality is of great importance in Life Sciences, where disruptions in manufacturing or logistics can have a significant impact not

only on profits but also patients. Continental European countries clearly outperform the UK or Ireland in this respect.

Quality of infrastructure

Country	Quality of overall infrastructure	Quality of roads	Quality of railroad infrastructure	Quality of air transport infrastructure
Austria	9	9	13	38
Belgium	33	46	18	20
Denmark	11	13	22	8
Finland	7	21	8	5
France	8	7	5	18
Germany	12	15	9	16
Ireland	52	41	43	32
Italy	58	45	34	60
Luxembourg	16	20	15	23
Netherlands	5	5	6	4
Norway	24	58	36	10
Portugal	13	8	31	29
Spain	18	16	11	14
Sweden	15	18	21	15
Switzerland	1	3	1	7
UK	27	27	19	28
Australia	33	40	36	37
US	12	13	13	9
Taiwan	20	11	10	33
Canada	21	22	18	16
Israel	31	28	40	30
Singapore	2	2	4	1

Note: Ranking from 1 to 144

Source: World Economic Forum: The Global Competitiveness Report 2017-2018

Flexibility of labor laws and regulations

The Heritage Foundation defines economic freedom as the fundamental freedom of every human to control his or her own labor and property. An economically free society is one in which individuals work, produce, consume, and invest in any way they please. The Heritage Foundation assesses factors such as immigration policies to provide a ranking of various countries' economic freedoms. There

is a general divide in the way Anglo-American countries on the one hand and continental Europe on the other approach to aspects such as notice period, collectively bargained labor agreements or sick leave provisions.

Denmark and Switzerland are a notable exception in continental Europe, which fails to feature in the top third otherwise.

Flexibility of labor laws and regulations

Country	Labor freedom ranking [note 1]	Flexibility of labor regulations [note 2]
Austria	66.7	38
Belgium	59.5	53
Denmark	82.8	1
Finland	50.5	49
France	45.0	61
Germany	53.3	34
Ireland	76.4	15
Italy	50.3	48
Luxembourg	46.2	20
Netherlands	61.5	32
Norway	54.6	16
Portugal	44.1	47
Spain	59.0	50
Sweden	53.7	24
Switzerland	73.9	2
UK	74.4	10
US	91.4	9
Canada	71.3	13
Israel	65.1	28
Australia	79.7	41
Taiwan	84.9	44
Singapore	92.6	3

Note:

[1] Index of Economic Freedom by The Heritage Foundation 2018 (scores from 1 to 100), <http://www.heritage.org/index/ranking>

[2] IMD World Competitiveness Yearbook 2017 (Labor regulations)

Global Talent Competitiveness Index

Empirical evidence shows that the performance of diverse teams is stronger than that of individuals, provided team members collaborate effectively. 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.

Global Talent Competitiveness Index

Country	Score	Ranking
Austria	63.70	18
Belgium	65.23	16
Denmark	68.59	8
Finland	68.56	9
France	55.93	24
Germany	64.94	17
Ireland	67.57	12
Italy	51.51	40
Luxembourg	68.66	7
Netherlands	67.80	11
Norway	68.01	10
Portugal	55.40	31
Spain	53.90	35
Sweden	69.14	5
Switzerland	74.55	1
UK	69.40	3
<hr/>		
Canada	67.16	13
Israel	58.53	25
US	69.34	4
Australia	69.06	6
Singapore	74.09	2

Note: Score from 1 to 100; Ranking from 1 to 93

Source: Insead, GTCI Report 2017



Switzerland

1st



Singapore

2nd



US

3rd

Switzerland, Singapore and the US lead the Global Talent Competitiveness Index

Attractiveness to highly skilled foreign workers

The weight of individual factors affecting working and living conditions depends on industry and employee function. The existence of sector clusters, in Life Sciences for example, offers prospects and security to skilled laboratory workers. Tax, legal or finance professionals are more likely to seek out the most competitive compensation packages, while foreign executives value quality of life

for their families, including access to excellent international schools and a thriving expatriate community.

Switzerland offers the most attractive overall conditions for highly skilled foreign workers and multinational companies, followed closely by Singapore and then the US. Within Europe, Luxembourg, the Netherlands and Ireland score in the top ten, while Portugal, Finland and Italy are significantly less attractive.

Attractiveness to highly skilled workforce

Country	Index	Ranking	Percentage of workforce international
Austria	5.78	26	14.28%
Belgium	5.76	28	11.33%
Denmark	5.80	25	6.09%
Finland	4.35	43	4.34%
France	4.98	33	5.85%
Germany	6.53	16	9.27%
Ireland	7.53	10	15.46%
Italy	3.56	53	11.04%
Luxembourg	7.80	6	67.86%
Netherlands	7.63	7	
Norway	6.07	19	11.72%
Portugal	4.80	35	2.51%
Spain	5.94	22	11.97%
Sweden	5.78	27	
Switzerland	8.84	1	23.53%
UK	7.40	12	8.64%
Israel	5.33	31	3.99%
US	8.16	4	16.51%
Canada	7.49	11	1.80%
Australia	7.57	8	23.83%
Taiwan	4.33	44	5.00%
Singapore	8.22	3	37.22%

Source: IMD World Competitiveness Yearbook 2017 (Foreign high-skilled people, Foreign Labor Force)

Workforce productivity, hours worked per year and vacation

Salary costs vary from country to country, with Switzerland clearly ranking first. At the same time, Switzerland is highly productive, second only to Germany. Workforce productivity is measured as an approximation of how efficiently work is organized and capital invested and can be a factor in higher salaries, as is the case in Switzerland. Currency fluctuations, e.g. between the EUR, GBP and CHF, can exaggerate differences between salaries.

European countries lead the productivity league, with Germany and Switzerland taking first and second place and the Netherlands, Austria and Ireland close behind. Other European countries score less favorably, however, including the UK in 38th place just ahead of Italy at number 40.

Annual vacation shows much wider variability. With 32 days per year on average, workers in Italy and Luxembourg enjoy around twice as much vacation as those in Israel and nearly three times as much as those in Taiwan.

Workforce productivity, hours worked per year and vacation

Country	Annual vacation (score) [1]	Average no. of working hours per year	Productivity of workforce (score) [2]	Ranking
Austria (Vienna)	27	1,786	7.78	5
Belgium (Brussels)	18	1,730	7.5	10
Denmark (Copenhagen)	25	1,674	7.27	12
Finland (Helsinki)	29	1,713	6.65	18
France (Paris)	29	1,600	6.34	22
Germany (Frankfurt)	28	1,743	8.35	1
Ireland (Dublin)	31	1,707	7.74	6
Italy (Rome)	32	1,826	5.38	40
Luxembourg (Luxembourg)	32	1,788	6.24	26
Netherlands (Amsterdam)	27	1,755	7.99	3
Norway (Oslo)	25	1,749	7.7	7
Portugal (Lisbon)	23	1,696	5.76	33
Spain (Madrid)	26	1,747	6.32	23
Sweden (Stockholm)	25	1,795	7.56	8
Switzerland (Zurich)	24	1,890	8.28	2
UK (London)	25	1,787	5.42	38
Canada (Toronto)	19	1,985	6.28	25
Australia (Sydney)	24	1,829	4.99	48
US (New York City)	27	1,847	7.48	11
Taiwan (Taipei)	13	2,141	6.7	15
Israel (Tel Aviv)	17	1,966	6.09	28

Note [1]: Paid working days (excluding legal holidays)

Source: UBS Prices & Earning 2015, IMD World Competitiveness Yearbook 2017

Note [2]: Figures are normalized scores (from 1 to 10), [2] Range from 1 to 60

Source: IMD World Competitiveness Yearbook 2017 (Workforce productivity)

3.5 Families and quality of life

Often thought of as a soft factor, standard of living is a vital consideration in the site selection process, especially when senior executives are joined by their families. The ability of countries to welcome international organizations' key functions hinges on factors as wide ranging as quality of life and cost of renting.

Quality of life

Country	Quality of living [note 1]	Environmental performance [note 2]
Austria (Vienna)	1	8
Belgium (Brussels)	22	15
Denmark (Copenhagen)	9	3
Finland (Helsinki)	31	10
France (Paris)	27	2
Germany (Munich)	4	13
Germany (Berlin)	14	13
Ireland (Dublin)	34	9
Italy (Rome)	52	16
Luxembourg (Luxembourg)	19	7
Netherlands (Amsterdam)	11	18
Norway (Oslo)	31	14
Portugal (Lisbon)	41	26
Spain (Madrid)	51	12
Sweden (Stockholm)	19	5
Switzerland (Zurich)	2	1
Switzerland (Geneva)	8	1
UK (London)	40	6
Israel (Tel Aviv)	105	19
Canada (Vancouver)	5	25
Taiwan (Taipei)	85	23
Australia (Sydney)	10	21
Singapore (Singapore)	25	49
US (San Francisco)	27	27

Note 1: Range from 1 to 205

Source: Mercer Quality of Living Index 2017

Note 2: Score from 1 to 100; Ranking from 1 to 180

Source: Environmental Performance Index Report 2018

Quality of life

Quality of life is vital to attract the best of the international talent pool to a given location. 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.

The Mercer Quality of Living Index focuses on the standard of living in various cities in combination with the typical compensation packages that companies offer their employees when sending them to those countries. Austria (Vienna) has held the top position for almost a decade, just ahead of Switzerland (Zurich). Germany (Munich) and Canada (Vancouver) are hot on their heels, however.

To give a more comprehensive view of quality of life, the table also displays the 2018 Environmental Performance Index (EPI) scores. This index gauges the environmental policy progress of 180 countries based on 24 performance indicators across ten issue categories covering environmental health and ecosystem vitality. European countries perform well in general, with Switzerland the global leader, followed by France and Denmark. Singapore, for once, is the worst performer of the countries covered in this report.



+12,00.50

+11,00.00

Work-life balance

Striking the right balance between work, leisure and other commitments is a universal challenge and one that affects families in particular. A healthy approach supports the wellbeing of all members in a household. 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.

Residential rent prices

Country	Average monthly cost for a 120 sqm apartment
Paris (France)	3,192
Dublin (Dublin 1, Ireland)*	2,572
Stockholm (Sweden)	1,887
Amsterdam (Netherlands)	2,569
Vienna (city center, Austria)	2,312
Copenhagen (Denmark)	2,071
Brussels (Belgium)	1,471
Rome (historical center, Italy)	1,999
Lisbon (Portugal)	1,744
Madrid (city center, Spain)	2,060
Helsinki (Finland)	2,718
Frankfurt (Germany)	1,825
Luxembourg (Luxembourg)*	2,568
Oslo (Norway)	2,160
Zurich (Switzerland)**	3,140
London (UK)	5,308
Toronto (Canada)	2,761
Sydney (Bellevue Hill, Australia)***	2,994
New York City (Manhattan, US)***	7,011
Taipei (Taiwan)	922
Tel Aviv (Israel)	3,688
Singapore	2,886

Source: Global Property Guide

*) Average 4 bedroom apartment

**) Average new and old apartment (100-110m²)

***) Average 3 bedroom apartment

Work-life balance

Country	Ranking
Australia	38
Belgium	13
Denmark	5
Germany	16
Finland	12
France	25
Ireland	17
Israel	32
Italy	11
Canada	9
Luxembourg	10
Netherlands	2
Norway	8
Austria	21
Portugal	26
Sweden	3
Switzerland	22
Spain	15
UK	29
US	28

Source: OECD better life index, 2017

Cost of renting

With the right compensation package, a temporary or permanent move abroad should be affordable for employees. Rent is one of the most significant recurring expense items for most households, making it an important location factor for companies to consider. Accommodation is most expensive in London by some margin, with workers in Paris and Zurich also paying high prices, especially in the central business districts. It should be noted that high rents reflect other attractive aspects for businesses and individuals.

3.6 Tax environment

Tax implications have always been a significant factor in site selection for Life Sciences companies. The Action Plan on Base Erosion and Profit Shifting (BEPS) aims to counter the extensive use of special tax regimes offered by various jurisdictions and addresses the arbitrage between different tax rates and different interpretations of tax principles that arise as a result of tax sovereignty.

Efficient and forward-looking tax planning takes BEPS into consideration. Companies need to weigh up the many aspects that influence a site’s suitability, from ordinary income tax rates and tax rulings to double

taxation treaty networks and transfer pricing regulations. Many governments also offer attractive incentives granted by governments to companies performing certain activities such as R&D within their borders.

International corporate and individual tax rates 2018



Source: KPMG’s Swiss Tax Report 2018

“Input” incentives for the development of IP

Country	R&D tax incentives	Other incentives
Austria	An invention premium of 12% of the expenses for R&D may be claimed. The premium applies in respect of certain R&D activities carried out within a company, as well as such activities that have been contracted out. For the latter, the amount of expenses is limited to EUR 1 million per year (EUR 100,000 before 2012).	n/a
Belgium	<p>Costs for research can be deducted immediately as business cost, while for development costs (including salary costs) one has the option to record an intangible fixed asset that can be depreciated over a period of at least three years).</p> <p>An additional deduction from taxable income or a tax credit is available on top of the normal depreciation cost for R&D related assets. For R&D investments made in the 2017 assessment year, the rate of the deduction is a one-off 13.5% of the investment value or 20.5% of the annual depreciation on the assets. The alternative R&D tax credit (calculated as the investment deduction multiplied with the nominal corporate income tax rate) is cash refundable if not utilized after four years.</p>	<p>For qualifying patent income, a reduced corporate income tax rate of maximum 6.8% applies (20% of income taxable at the nominal corporate income tax rate of 33.99%).</p> <p>A deduction for innovation income is available, which broadens the scope of qualifying intellectual property rights (IPR) beyond patents and reduces the corporate taxation level on the net qualifying income to 5% (15% of the income at 33.99%).</p>
Denmark	Tax incentives for R&D are available, including instant tax deduction of R&D costs or amortization over five years and unlimited loss carry-forward. In addition, growth credit is available, whereby losses on certain R&D activities can be converted to payment (based on a tax value of 22%) from the tax authorities. Payment is capped at DKK 5.5 million per year, i.e. 22% (the corporate tax rate for 2017 of DKK 25 million).	Acquisition of patents and knowhow is fully tax deductible in the first year. Acquisition of other intangibles is amortized over seven years.
Finland	R&D-related costs may be deducted annually, or capitalized. Patents and other transferable rights (including goodwill if acquired for consideration) may be written off applying the straight-line method over a period of ten years or the right's economic life, if less.	Tax depreciation on production capital expenditure is maximum 50% in 2013-2016 on machinery and maximum 14% on buildings.
France	R&D tax credit of 30% is available for the portion of R&D expenses below EUR 100 million, reduced to 5% for the portion exceeding that amount. Amortization is allowed on certain specific intangible assets such as patents, software and shares in certain companies. Start-up costs may either be deducted as operating expenses or amortized over a five-year period.	Financial support is available in various forms. In addition, small and mid-sized innovative start-ups (“JEI”) may benefit under certain conditions from a one-year corporate tax exemption and a 50% rebate for the following year. A new temporary measure enacted on 6 August 2015 provides that companies can benefit under certain conditions from an exceptional deduction on assets depreciation (deduction from the taxable result of 40% of the asset's fair value excluding financial expenses) for industrial assets purchased or manufactured between 15 April 2015 and 14 April 2017.
Germany	Germany does not offer R&D tax incentives. State grants in cash for eligible R&D projects are applicable instead.	Financial support is available in various forms, e.g. regional subsidies as well as subsidies at European, federal and state level.
Ireland	Tax credit of 25% on capital and revenue expenditure on qualifying R&D expenditure. It is possible to claim excess R&D credits as a cash refund. Tax depreciation is granted for patent rights and some capital expenditure for scientific research. Capital expenditure on qualifying scientific research may be fully written off in the year incurred.	Certain start-ups are exempt from tax in each of their first three years.

Country	R&D tax incentives	Other incentives
Italy	<p>Until 2020 any company investing in R&D activities can be eligible for R&D tax credit of up to EUR 5 million per year.</p>	<p>An innovative start-up company is exempted from the payment of stamp duties and fees related to its registration, and the annual Chamber of Commerce fee. Furthermore, an innovative start-up company may issue non-voting shares to the public, even if constituted as a limited company, and institute stock-option and work-for-equity schemes.</p> <p>Companies investing in an innovative start-up company may deduct from their taxable income 30% of the amount invested. The maximum deduction is set at EUR 540,000 each year. To benefit from the tax incentive, the investor must maintain the equity participation in the innovative start-up company for at least 3 consecutive tax years, and the investment in each innovative start-up company may not exceed EUR 2.5 million per year.</p>
Luxembourg	<p>Luxembourg provides various incentives. Besides the general tax incentives, companies doing R&D activities can benefit from innovation loans with a lower fixed interest rate. R&D projects receive financial support up to a certain percentage depending on their size.</p> <p>The most common incentives are tax credits. The first tax credit is 13% of the increase in investments in tangible depreciable assets made during the tax year. Independently, companies can also benefit from an 8% tax credit on qualifying new assets on the first EUR 150,000.</p>	n/a
Netherlands	<p>A wage tax reduction of 32% is granted to employers with respect to salaries, up to a ceiling of EUR 350,000, paid to employees who carry out certain research and development (R&D) activities. For start-ups developing technological products, this reduction is increased to 40%. For wage costs above this ceiling, the reduction is limited to 16%.</p>	<p>Financial support is available in various forms including accelerated depreciation, investment deduction, energy saving deduction and environmental deduction.</p>
Norway	<p>RSMEs can apply for an R&D credit for 18% or 20% of relevant expenditure up to NOK 25 million. This expenditure limit is raised to NOK 50 million if the services are purchased from a university or other research organization. To qualify, the research must be approved by the Research Council of Norway.</p> <p>Groups may apply for support with several projects, provided that they are organized in different companies, each of which meets the criteria.</p> <p>Tax credit of 18% is granted to companies that do not meet the qualification criteria for 20%.</p> <p>The credit is granted in addition to the regular deduction (either directly or through depreciation) of the underlying R&D expenditures and excess tax credits are repaid to qualifying companies.</p>	<p>In addition, partially state-owned organizations and governmental agencies, such as Innovation Norway (Innovasjon Norge), also provides for financial support by granting cash and loans with favorable terms for R&D qualifying projects.</p>

Country	R&D tax incentives	Other incentives
Portugal	<p>Tax credits are granted on qualifying R&D expenses, in the period 1 January 2013 to 31 December 2020 (extended from 31 December 2015 originally). The total amount creditable consists of:</p> <p>A basic credit equal to 32.5% of the qualifying expenses for the relevant year plus an additional credit of 50% of the amount by which the qualifying expenses for the relevant year exceed the average R&D expenses incurred over the two previous years. This amount is capped at EUR 1.5 million.</p> <p>Unused credit may be carried forward for up to eight years (or six prior to 2014).</p> <p>Companies cannot use this R&D investment tax credit in conjunction with any other similar tax incentive.</p> <p>There are also some specific rules for SMEs.</p>	n/a
Spain	<p>There is the possibility to apply for a tax credit on expenses and certain investments made on R&D which distinguish between R&D projects and Technological Innovation projects. The general applicable fixed percentage rate for R&D tax credit is 25%, but if annual expenses exceed the average expense of the preceding two years, 42% will be applicable to the excess. An additional 17% credit is available for personnel expenses relating to qualified researchers and 8% for capital expenditure (excluding real estate) exclusively related to R&D. In addition, a tax credit of 12% of the expenses incurred on technological innovation in the tax period can be deducted from the tax liability.</p>	<p>Certain types of assets, e.g. assets used in R&D activities, may be freely depreciated.</p> <p>There is a reduced tax rate (15%) for new enterprises in the first and second year which there are taxable profits and the year thereafter.</p>
Sweden	<p>Limited R&D incentives are available for certain companies. Maximum potential savings of SEK 230,000 per month (SEK 2,760,000 per year). There is also an expatriate tax regime under which a 25% reduction of taxable income paid to a foreign employee is granted, provided that certain requirements are fulfilled. The relief applies to foreign key personnel, as well as foreign experts and scientists with knowledge and skills that are scarce in Sweden. Hence, this relief could apply to any category of employees and is not strictly limited to employees working in R&D.</p>	n/a
Switzerland	<p>Accruals for future R&D projects carried out by third parties are permitted for up to 10% of taxable profit to a maximum of CHF 1 million.</p> <p>Switzerland's pending Tax Proposal 17 provides for a voluntary deduction on R&D costs at the cantonal level. The basis is the additional deduction of a maximum of 50% for the directly attributable personnel expenses for R&D plus an additional 35% surcharge for other R&D expenses or 80% of the expenses for R&D performed by third parties.</p>	<p>Although there are currently no specific tax incentive regimes with regard to the promotion of R&D activities in place, Switzerland generally provides a wide range of tax incentives and grants to innovative companies. The cantons, together with the federal government, may grant tax incentives under restrictive conditions</p> <p>Full or partial tax holidays of up to ten years at cantonal and – in certain regions – federal tax level can be granted for substantial investment projects.</p>

Country	R&D tax incentives	Other incentives
UK	<p>For R&D, an immediate write-off of the qualifying expenditure is allowed.</p> <p>Tax incentives for R&D expenditure are available from 100% to 230% for small and mid-sized enterprises. SMEs are defined for these purposes as having <500 employees and either turnover not exceeding EUR 100 million per annum or gross balance sheet assets not exceeding EUR 86 million. There is an “above-the-line” tax credit for large companies (also known as an “R&D expenditure credit”) equivalent to 11%.</p>	n/a
Israel	<p>There are various investment incentives. Certain R&D expenses, net of grants received and accelerated depreciation for certain industries, are deductible. R&D annual depreciation rates vary between 33% and 100%. Tax benefits are directed towards corporations deemed “preferred companies” and divided into two priority zones (A & B) with lower tax rates. More beneficial reductions apply to large manufacturing companies.</p>	Preferred companies can also accelerate depreciation for assets and buildings during the first five years of operation.
US	<p>R&D expenses can be deducted in the year incurred or amortized over a 60-month period. Increased expenditures for R&D are eligible for a 20% tax credit to the extent they exceed a base amount determined by reference to a fixed-base percentage of the taxpayer’s average annual gross receipts for the preceding three taxable years. A 20% R&D credit may also be claimed for qualified basic research payments.</p>	Incentives are provided which permit expense deductions and bonus depreciation, in lieu of capitalization, for qualified property purchased for use in a trade or business. Furthermore, accelerated depreciation is permitted under the MACRS system for tangible property used in trade or business.
Australia	<p>Concessional treatment takes the form of a refundable or non-refundable tax credit in respect of the qualified expenditure. It applies to approved R&D expenditures as well as certain environmental costs.</p>	Pooled development funds, venture capital entities (entities providing equity for small and medium-sized Australian enterprises) enjoy additional taxation preferences. Tax concessions are available for investments in Early Stage Innovation Companies and Early Stage Venture Capital Limited Partnerships.
Taiwan	<p>Tax credits for R&D are available for up to 15% of qualifying R&D expenses incurred, with the maximum amount of tax credit capped at 30% of the tax payable for the year in which the expenses were incurred. Unutilized R&D credits are forfeited, and may not be carried back or forward.</p> <p>Foreign subsidiaries established in Taiwan by foreign companies with the approval of the government are treated as domestic companies of Taiwan and may enjoy tax incentives which do not apply to branches of foreign companies in Taiwan.</p> <p>R&D tax credits are granted for up to 35% of qualifying R&D and HR training expenses incurred in the biotech and new drug industries, with the maximum amount of tax credit capped at 50% of the tax payable in each fiscal year. Unutilized R&D credits may be carried forward for up to five years.</p> <p>Income from shares of qualified biotech or new drug companies issued in exchange for technology in kind contributed by the top professional management and technical investors is not taxed until the shares are further transferred.</p>	n/a
Singapore	<p>Special tax deduction is available for R&D expenses, intellectual property expenses, expenses incurred for the promotion of export and market development, overseas investment development and financial R&D expenses.</p>	Various tax incentives are available in Singapore which may grant full or partial tax exemption, reduced tax rates, investment allowances or special deductions. The tax incentives apply to a range of industries.

Country	R&D tax incentives	Other incentives
Canada	Special tax credits may be claimed in respect of qualifying expenditures. For example, a 15% investment tax credit may be claimed in respect of qualifying scientific research activities. Any such tax credit claim will generally reduce the depreciable cost of the asset in question.	There is a preferential tax rate on manufacturing and processing activity and on the first CAD 500,000 of active business income earned by Canadian-controlled private corporations. Furthermore, various provinces have provincial tax credit program to encourage specific activities.

Source: KPMG Global Corporate Tax Handbook 2017

Patent box regimes

A patent box is a special tax regime for intellectual property revenues. It is also known as an intellectual property box regime, innovation box or IP box. A patent box enables

companies to apply a lower rate of corporation tax to profits earned by intangibles and patents. See below for an overview of patent boxes in different countries.

Country	R&D tax incentives
Austria	No patent box regime.
Belgium	85% patent income deduction of net income received applying to income from patents. The effective tax rate is therefore lowered to approx. 5.1%.
Denmark	No patent box regime.
Finland	No patent box regime.
France	Net income of sales and licensing fees relating patents or patentable inventions can benefit from a 15% income tax rate in comparison to the standard tax rate of 33%.
Germany	No patent box regime.
Ireland	Profits qualifying for Knowledge Development Box (KDB) are effectively taxed at 6.25%. This tax relief applies to income from qualifying patents, computer program and, for smaller companies, certain other certified intellectual property.
Israel	<p>Since 2017, Israel has an innovation box regime. IP-based income and gains from sale of IP are taxed at a reduced tax rate of 6%. This tax rate applies to qualifying Israeli companies that are part of a group with global consolidated revenue of more than ILS 10 billion.</p> <p>Qualifying companies with a global consolidated revenue below ILS 10 billion are subject to a 12% tax rate. Also the withholding tax rates of qualifying companies is reduced to 4%.</p>
Italy	According to the patent box regime, up to 50% of income derived from qualifying intangible assets (i.e. software protected by copyright, patents, legally protectable designs and models, legally protectable processes, secret formulas, and industrial, commercial or scientific knowledge including knowhow) can be deducted from corporate income tax (IRES) and local tax (IRAP). For calendar year taxpayers, the percentage excluded from the tax base is 50% in 2017. This results in an effective tax rate of approx. 15.7%.
Luxembourg	A new IP box regime starts in 2018, providing for an 80% exemption on income derived from the commercialization of certain intellectual property rights (i.e. patents and functionally equivalent IP rights that are legally protected by utility models, extensions of patent protection for certain drugs and phytopharmaceutical products, plant breeders' rights, and orphan drug designations, copyrighted software) and a 100% exemption from net wealth tax.
Netherlands	The "innovation box" is available for income from self-produced qualifying intangible assets, taxed at an effective rate of 5%.
Norway	No patent box regime.

Country	R&D tax incentives
Portugal	No patent box regime.
Spain	The Spanish patent box regime exempts qualifying income (i.e. patents, designs and models, plans, secret formulas or processes, rights on information concerning industrial, commercial or scientific experiments) at a rate of 60%. This results in a 12% effective tax rate in comparison to a standard rate of 30%.
Sweden	No patent box regime.
Portugal	No patent box regime.
Spain	The Spanish patent box regime exempts qualifying income (i.e. patents, designs and models, plans, secret formulas or processes, rights on information concerning industrial, commercial or scientific experiments) at a rate of 60%. This results in a 12% effective tax rate in comparison to a standard rate of 30%.
Sweden	No patent box regime.
Switzerland	<p>As of 1 January 2011, the Canton of Nidwalden introduced the "license box" system. IP companies located in Nidwalden benefit from a cantonal tax rate on net license income reduced by 80%. The effective corporate income tax rate (including federal tax) amounts to 8.8%. The reduced tax rate applies to net license income from both "old" IP (held prior to 1 January 2011) and "new" IP as well as self-developed IP and IP acquired from third parties or group companies. Capital gains on IP assets also qualify as license income.</p> <p>At federal level, the pending Tax Proposal 17 provides for the introduction of a patent box regime at cantonal level covering income from patents and similar rights, considering R&D of the taxpayer (nexus approach) and a reduction limitation of 90%.</p>
UK	On 1 April 2013, the government introduced the patent box regime which applies an effective 10% tax rate on profits generated from patented innovation (which is significantly lower than the main corporation tax rate of 20%). In conjunction with the wider global review of tax practices as a result of the OECD BEPS project, the UK has revised its patent box regime. In particular, as of 1 July 2016 benefits are only available in proportion to the amount of R&D activity undertaken by the claimant in developing the IP or the product incorporating it. Additional administrative requirements need to be satisfied in order to benefit, but the effective tax rate of 10% is unaffected. There are "grandfathering" arrangements for businesses that opted into the "old" regime for periods beginning before 1 July 2016.
Australia	No patent box regime.
Singapore	The Intellectual Property Development Incentive (IDI) became effective as of 1 July 2017. It is similar to the European patent box regimes and will provide concessionary income tax rates on income from qualifying IP rights (i.e. patents and copyrighted software). Broadly, this means that royalties and license fees for qualifying IP rights and part of the income from the sale of products incorporating qualifying IP rights can potentially benefit from lower corporate income tax rates.
Taiwan	No patent box regime.
Canada	No patent box regime at a federal level. Patent box regimes in the provinces of Quebec, British Columbia and Saskatchewan.
US	No patent box regime.





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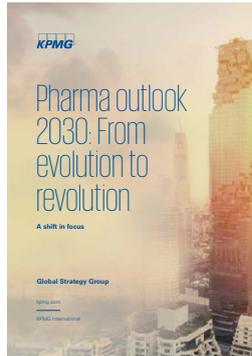
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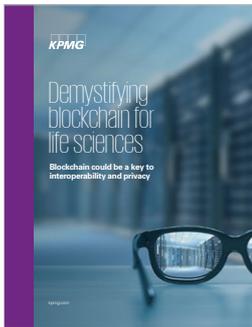
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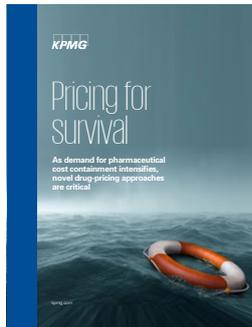
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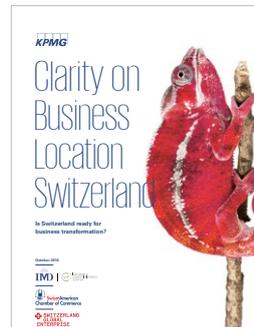
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