



# Your first European launch: a prescription for growth



# Injecting your first drug into Europe

For non-European biopharmaceutical companies, launching a drug in the EU can be extremely challenging. But, with the right drug and a clear strategy, it can also be extremely rewarding.

## So, you're ready to grow... Welcome!

Congratulations! After years of research and development you have successfully launched your first drug in your home market. Now, you are looking to expand beyond your borders and inject your flagship drug into Europe.

For a host of reasons, it can be overwhelming to establish a brand and gain a foothold in Europe. Still, with the right chemistry – the right drug, a robust strategy, and smooth implementation – breaking into the European markets can be extremely rewarding.

## Get ahead

For starters, determining the best market-entry strategy can be challenging for small and mid-sized biotechnology companies. That's where KPMG comes in. We work with you to tailor a go-to-market strategy specific to your goals and your company objectives.

96%

**Did you know?** EMA approves 96 percent of novel applications in the first cycle, versus the FDA's 62?

## Benefit from...



**A winning strategy tailored to you.** Get your life-enhancing and potentially life-saving drugs out into the European markets first. We help you avoid delays in the launch phase significantly, thus keeping your competitors at bay.



**Efficiencies that maximize and manage your recovered investments.** Entering new markets is like starting up a new business. It comes with costs. We work with you to balance your strategy, so you can hit that sweet spot between long-term, enduring profit, and a nice short-term boost.



**Clearer focus on the right priorities.** There is no one-size-fits-all approach. A risk for one company can be a boon for another. We work with you to leverage your best assets, build infrastructure and relationships that make sense while minimizing risks, liabilities and costs.



**A holistic view.** You gain a broader understanding of the challenges unique to entering the European market. We will work with you to roadmap your European-entry strategy and implementation, so you're never lost and always reaching the next milestone – efficiently and in a timely manner.



**An experienced and knowledgeable team you can trust.** KPMG has the industry know-how, the regulatory savvy, and the business acumen to be your navigating partner on your expansion journey. To boot, we have teams and expertise in all your top markets. Visit pages 4 and 5 to see our tried-and-tested two-phase approach.

# License or launch? Key indications

How much control over your product, branding, the sales pitch and marketing strategy do you want to maintain upon market entry and beyond? Licensing and launching – and sometimes even a hybrid of the two – are common strategies. Developing the best strategy for your company’s expansion goals, always keeping your key stakeholders in mind, is our commitment to you.

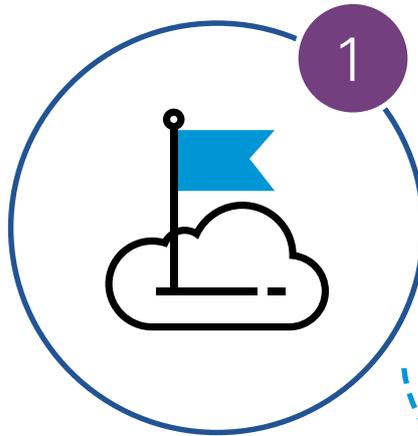
Key license or launch decision-making criteria	License	Launch	Hybrid
<b>Disease indication</b> If your product targets a disease area served by specialists or if it addresses an orphan indication			
<b>The nature of your product</b> If your product covers an unmet need and is eligible for an early access program			
<b>Pipeline and long-term business strategy</b> If you want to establish global presence and facilitate upcoming product launches			
<b>Financial rewards</b> If the mid-term price performance is a key factor influencing your investors’ confidence			
<b>Price and reimbursement</b> If you want to have full control of commercial negotiations with authorities, distributors and clients			
<b>Brand visibility</b> If you want to achieve brand exposure through direct selling to customers			
<b>Initial investment and costs</b> If your short-term ambition is to obtain funding for new product development			
<b>Control over product flow and customer interaction</b> If you want to understand the EU market but maintain control over your supply chain and the sales process through to patient experience			

**Given Europe’s second position after the US in terms of branded pharmaceutical spend, launching in Europe is a logical step in any quest to become a global pharmaceutical company.**

# Phase 1: Strategize a Smooth Entry

After investing more than a decade in drug development and clinical trials, biotech executives often look towards Europe to expand their market presence. Your go-to-market strategy needs to serve your company's and your stakeholders' goals, and include a clear roadmap that considers the various legal and regulatory frameworks across the region.

To succeed you need clarity and a team of trusted advisors with functional and industry expertise.



## Roadmap to entry

In the highly regulated European market, KPMG supports you in deciding whether to license or launch your first drug in Europe. You will benefit from an expansion roadmap across workstreams to achieve your growth ambition.

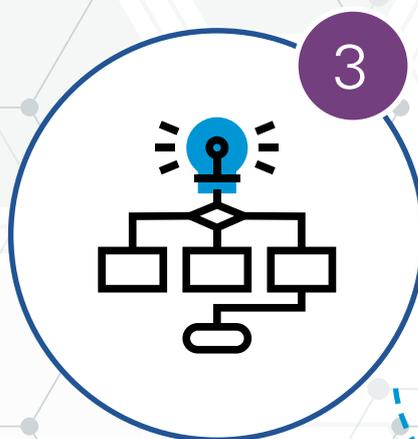
## Commercial excellence

Our commercial excellence methodology and KPMG assets worldwide facilitate achieving competitive price and reimbursement across the selected European markets.



## Tax-efficient business model

At the core of your future expansion strategy lies a business model compliant with key European tax laws, such as the upcoming EU GMP Annex 21 regarding the import of medicinal products.



## Clearing the road for you

Authorizations and licenses are fundamental business enablers. So, we place a great deal of focus on defining the specific licenses you need to operate, establishing your legal presence, and outlining right filing strategy for you.



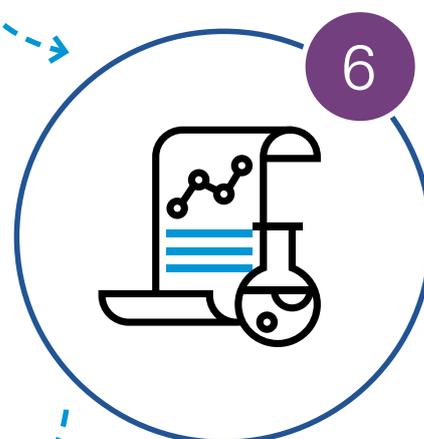
# Phase 2: Operationalize to Commercialize

Planning is essential. Once you have made the decision and the plan to market your drugs in Europe, careful planning is essential to drive implementation and get the desired results in a complex and competitive market. Launch delays and launches with a low trajectory can quickly lead to a slump in sales. What differentiates the launch plan from a licensing plan is a launch plan puts you in the driver's seat of your go-to-market strategy.



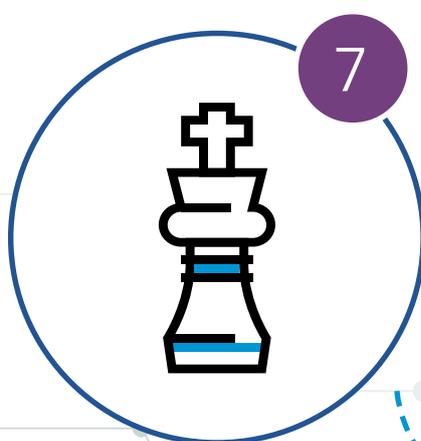
## Dynamic investment plan

A responsible investment approach lined up with the key milestones of your expansion journey allows for adjustments along the way. Our dynamic investment plan is tailored for you and includes investment strategies, such as inflection point investments.



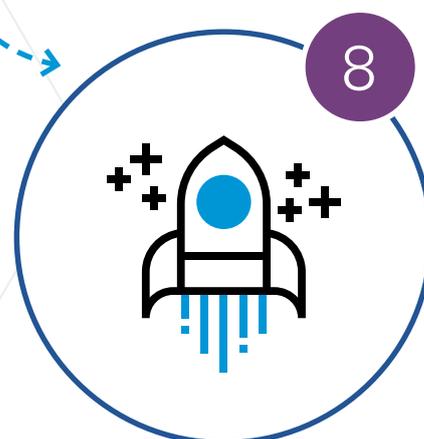
## Infrastructure build for agility

Country builds include the supply chain and distribution setup that suits your requirements. We help biopharmaceutical companies develop an infrastructure build that enables launch agility.



## Strategic sequencing

Sequencing country launches is key for maximizing the price of your drug in Europe. KPMG suggests a wave-based country launch approach, guided by external reference pricing and endorsed by inflection investment points.



## Post-launch care

Your expansion journey begins with your product launch, but it continues with ongoing competitor analysis and assessing an extension of your drug to new markets or to new indications.

It takes 10-15 years  
and 870 million USD  
to launch a drug.

Those that succeed  
benefit from a clear  
roadmap.



# Client success story

## Client Challenge

An American biotechnology firm decided to launch its first drug in Europe. Without an already existing presence in any of the EU countries, the client asked KPMG to assist in defining the market entry strategy along with a fit-for-purpose business model that was tax-efficient and compliant with the European regulatory and legal framework.

## KPMG Approach

Our approach aimed at ensuring market, product and supply chain readiness while also addressing key interdependencies across the functional areas involved in it.

- **A market-entry analysis** recommended a direct launch approach as the preferred approach for this client and product.
- **A country-by-country analysis** helped identify the regulatory and licensing requirements to ensure the timely delivery to patients in new markets.
- **A detailed pricing and reimbursement analysis** helped secure the highest price possible for launch in each of the countries in scope.

Additionally, KPMG's multidisciplinary team provided functional expertise in such areas as finance, tax, project and change management as well as information systems, ensuring successful and timely product launches across several European countries.

## Client Benefit

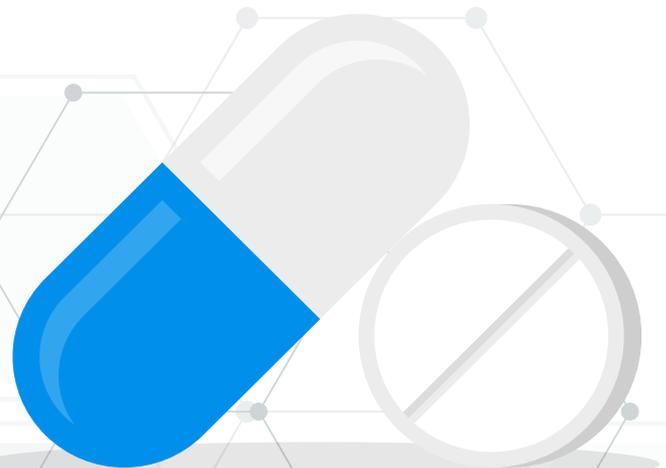
- The client successfully introduced into Europe its first drug, effectively expanding the client's industry footprint.
- Increased value for the client's patients and shareholders.
- Simplified complexities ensured a smooth geographical expansion.

# Biotech experience, fit for your needs

Biopharmaceutical companies have a unique set of needs for which we can develop, tailor and package for you the full range of market-leading methodologies, tools and services. Areas where we can assist include:

- **Market entry strategy:** assessing and developing a business model, as well as gathering and sharing industry/company intelligence on value-generating factors, including market analysis, new entrants, and upcoming products and services.
- **Commercial excellence:** supporting you on pricing and reimbursement, market access and product launch activities.
- **Business model design:** defining for you a tax-efficient business model, fully compliant with the European legal and regulatory framework.
- **Client-side advisory:** connecting you with multidisciplinary experts in areas such as Tax, Legal, Finance, Regulatory, Supply Chain & Distribution and IT/ERP to support you along every phase of your expansion.

At KPMG, we understand that implementing a strong and sustainable business strategy requires robust and trusted support along your expansion journey, from early development to launch and post-launch.



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## Contacts

### **KPMG AG**

Badenerstrasse 172  
PO Box  
CH-8036 Zurich

**[kpmg.ch/lifesciences](http://kpmg.ch/lifesciences)**

### **Martin Rohrbach**

Partner, Head of Life Sciences  
KPMG AG – Basel, Switzerland

+41 58 249 71 28  
[martinrohrbach@kpmg.com](mailto:martinrohrbach@kpmg.com)

### **André Guedel**

Director, Head International Headquarters KPMG  
AG – Zurich, Switzerland

+41 58 249 28 24  
[aguedel@kpmg.com](mailto:aguedel@kpmg.com)

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