White Paper

REALISING THE COMMERCIAL PROMISE OF EUROPE FOR EMERGING BIOPHARMA

The compelling case for launching in Europe and how to succeed

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INTRODUCTION

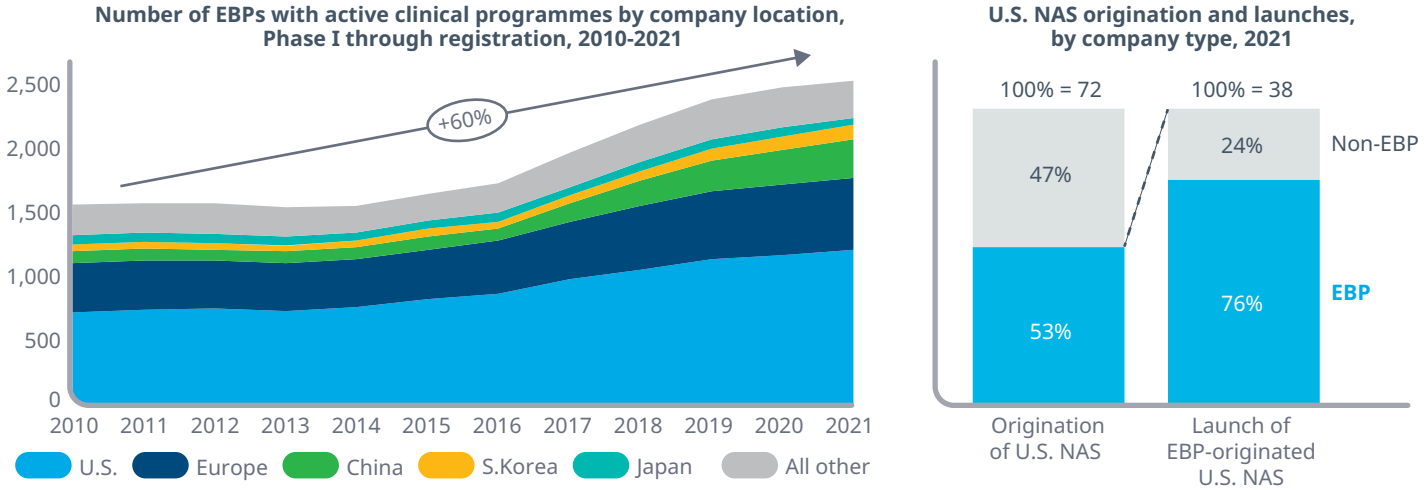
Emerging biopharma companies (EBPs) have steadily expanded their role as key drivers of biomedical innovation over the past 15 years. For the purpose of this publication, we define EBPs as companies having less than $200 million annual R&D spend or under $500 million annual global revenue.[1] By 2020, this EBP segment accounted for over 80% of candidates in the early-stage pipeline, from discovery through Phase I, and 64% of late-stage development, from Phase II through registration.[2]

Over the past decade, the universe of clinical-stage EBPs has grown by 60% to over 2,500 globally. At the same time, these companies have increasingly held on to their products to file and commercialise their assets themselves, thereby maximising the value they capture. For example, in 2021, 53% of new active substances (NAS) in the U.S. originated from EBPs. Subsequently, 76% of those NAS were launched by their originator EBPs, up from 27% a decade earlier.[3]

For most emerging biopharma companies, the U.S. market is the natural first priority for their own commercialisation efforts, given its sheer size and the favourable environment for rewarding innovation. However, to maximise the value of their products, EBPs should expand their horizons beyond the U.S. Europe, as the second largest pharmaceutical market after the U.S., is the obvious next choice. Indeed, we are seeing a growing number of EBPs embrace the European opportunity. In the last decade, 42% of all global NAS commercialised by their EBP originators were launched by those same EBPs in Europe.

In this white paper, we will explore opportunities and challenges for EBPs commercialising in Europe and discuss the key choices these companies have to make to succeed in launching their products into the European market.

Figure 1: The growing clinical-stage EBP universe; many EBPs now launch their own products



Source: IQVIA Pipeline Intelligence, Dec 2021; Global trends in R&D through 2021; IQVIA Institute report 2022.
Note: EBPs assigned to geography based on their HQ location. NAS: New Active Substance.

THE PROMISE OF EUROPE

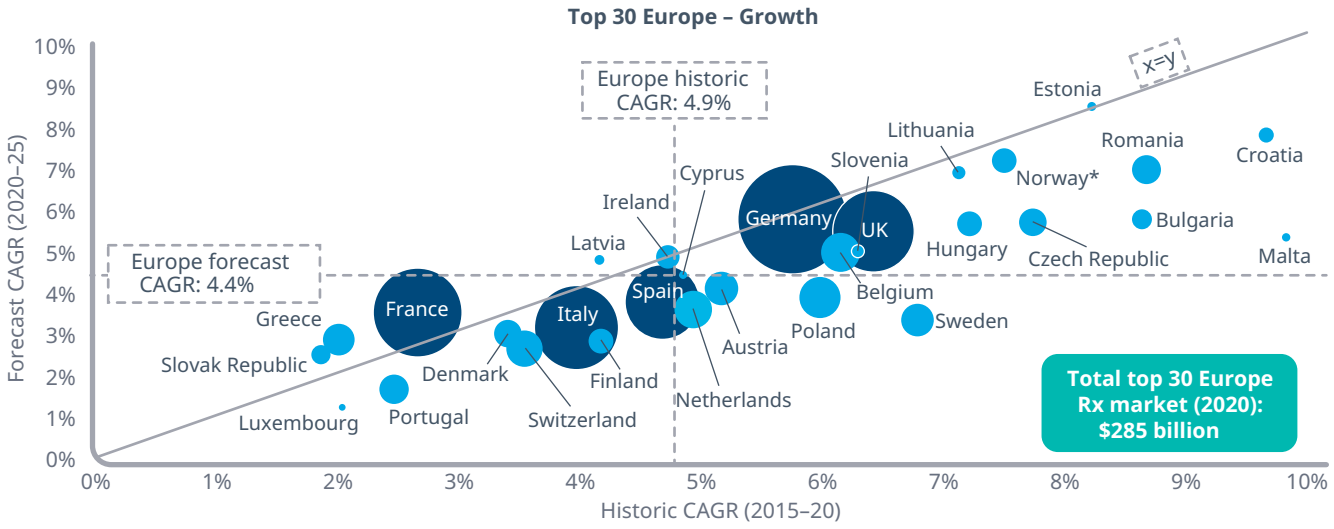
Europe offers a sizeable and attractive commercial opportunity for innovative medicines. The 27 member states of the European Union together with several non-member states, including the UK, Switzerland and Norway, are home to 525 million people.[4] Europe's five largest countries, France, Germany, Italy, Spain and the UK, alone have a combined population of 330 million, which is comparable to the U.S. population of 334 million.[5] Many Western European countries spend around 10% or more of their GDP on predominantly publicly funded healthcare with broad population coverage, while per capita healthcare spend in those countries is well above the OECD pre-pandemic average of $4,087 (2019 values).[6]

As a region, Europe represents a pharmaceutical market of $285 billion (at ex-manufacturer prices, as measured by IQVIA MIDAS), the second largest after the U.S., and it is forecast to grow at 4.4% CAGR through 2025.

The European Medicines Agency (EMA) is the dominant regulator for Europe and the regulatory gateway to the region. It conducts a single evaluation of new products for the centralised marketing authorisation of medicines for sale in the 27 member states of the European Union, representing a population of 447 million and a pharmaceutical market worth $240 billion under a single regulatory regime. Other European regulators in non-member states, e.g. Swissmedic, the Norwegian Medicines Agency and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) are likely to mirror EMA decisions, although the recent exit of the UK from the EU may lead to some regulatory divergence in the future.

Crucially, Europe is a key contributor to the commercial success of innovative launches. As our extensive Launch Excellence research has shown, 85% of cumulative 2-year launch sales are generated in just seven countries: the U.S., EU4 (France, Germany, Italy, Spain), the UK and Japan.[7]

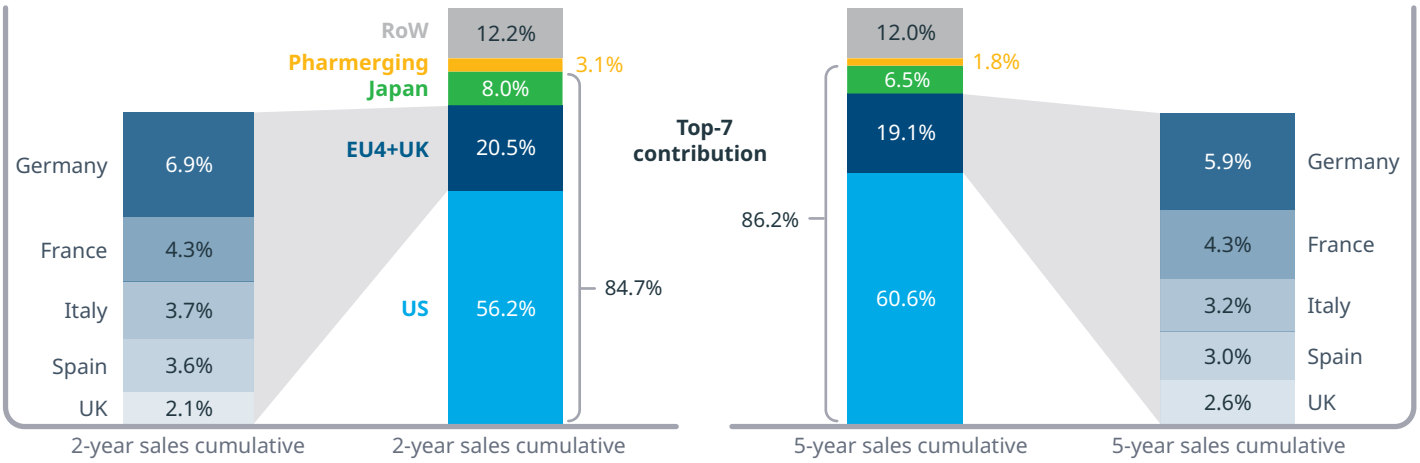
Figure 2: Europe is a sizeable and attractive market



Notes: Excludes COVID vaccines. * Norway 2015-2020 growth estimated. Growth calculated using constant exchange rates, at ex-manufacturer prices; rebates and discounts are not considered. Contains Audited + Unaudited data; Europe CAGR includes EU27 + UK + Switzerland + Norway; Size of bubbles refers to 2020 Market Size in U.S.$.
Source: IQVIA European Thought Leadership; IQVIA Market Prognosis September 2021.

Figure 3: The EU4 and UK are significant contributors to global innovative launch sales

Country share of 2-year and 5-year cumulative global sales of new launches
(New Active Substances, NAS, 2011–2020)



Source: IQVIA European Thought Leadership, MIDAS QTR, NAS 2011–2020 included, Rx only, innovative branded products only; excludes viral hepatitis products.

Combined, the EU4 and the UK account for 21% and 19% of cumulative 2-year and 5-year global sales, respectively, of innovative new products launched between 2011 and 2020.

Europe is also making great strides to strengthen its innovation friendliness and improve patient access to innovative medicines. This is driven by a number of initiatives at both country and European Union level. For example,

- In the UK, the new Innovative Licensing and Access Pathway (ILAP) will enable companies to engage with key stakeholders, e.g. the UK regulator MHRA, NICE and the Scottish Medicines Consortium, at an earlier stage in the development process to accelerate time to market and facilitate patient access to novel medicines.[8] In addition, NHS England has set up the Innovative Medicines Fund to provide an additional £340 million of funding for non-oncology drugs. Together with the existing £340 million Cancer Drugs Fund, it ensures a total of £680 million of ringfenced funding is available for fast-tracked, innovative medicines.[9]

- Italy will use its 2022-2024 budget to improve access to treatment, including a 30% boost to the funds for innovative medicines over the next three years and a higher ceiling for hospital drug expenditure. A new Consolidated Law on Rare Diseases will improve and accelerate access to orphan drugs across Italy.[10]

- France has declared its aim to be 'the leading European nation in innovation and sovereignty in health' by 2030, supported by a €7 billion programme over the next five years. The Social Security Finance Bill (PLFSS) pledges extra funding for drugs and devices in the order of €1 billion in 2022 alone and also includes policies to accelerate access to high-priced innovative therapies.[11]

Europe is making great strides to strengthen its innovation friendliness and improve patient access to innovative medicines.

The European healthcare environment is very different from the U.S. Understanding the specific challenges for commercialising in Europe, especially as an emerging biopharma company, is a crucial first step towards achieving success.

- Meanwhile, EU4Health 2021-2027 – a vision for a healthier European Union, provides an ambitious funding programme for health initiatives underpinned by a dedicated €5.3 billion budget. It is aimed at improving health in the EU, strengthening health systems post-pandemic, accelerating their digital transformation and making medicines available and affordable.[12]

At this point it is worth dispelling common misconceptions about the relative attractiveness of other regions compared to Europe. While Europe is complex, the U.S. is not a single market either, and it has its own complexity stemming from a fragmented payer landscape (e.g. Medicare, numerous commercial payers) and healthcare-related legislation at state level. The need for DTC advertising can make commercialisation in the U.S. prohibitively expensive in certain therapy areas, e.g. immunology, something that does not apply in Europe. Other distinctive aspects of the U.S. market, for example rebates, discounts or co-pay cards erode the seeming profitability that high list prices may imply.

Japan and China represent the only other markets for generating substantial launch sales, but both are smaller contributors to global launch success than the U.S. or Europe, as our analysis shows. They also present their own challenges for EBPs launching innovative products, such as pricing pressure, the scale of commercial infrastructure needed as well as cultural barriers.

Therefore, Europe not only holds great promise for innovators, commercialising in Europe becomes critical to unlock the full potential of innovative products. As emerging biopharma companies look to retain the maximum value of their assets by launching these themselves, they too must consider making a European play.

However, launching a product is a daunting prospect for any company and even more so for EBPs, most of which lack any prior launch experience. Furthermore, the European healthcare environment is very different from the U.S., in terms of stakeholder dynamics and the approach to assessing, and rewarding, innovation.

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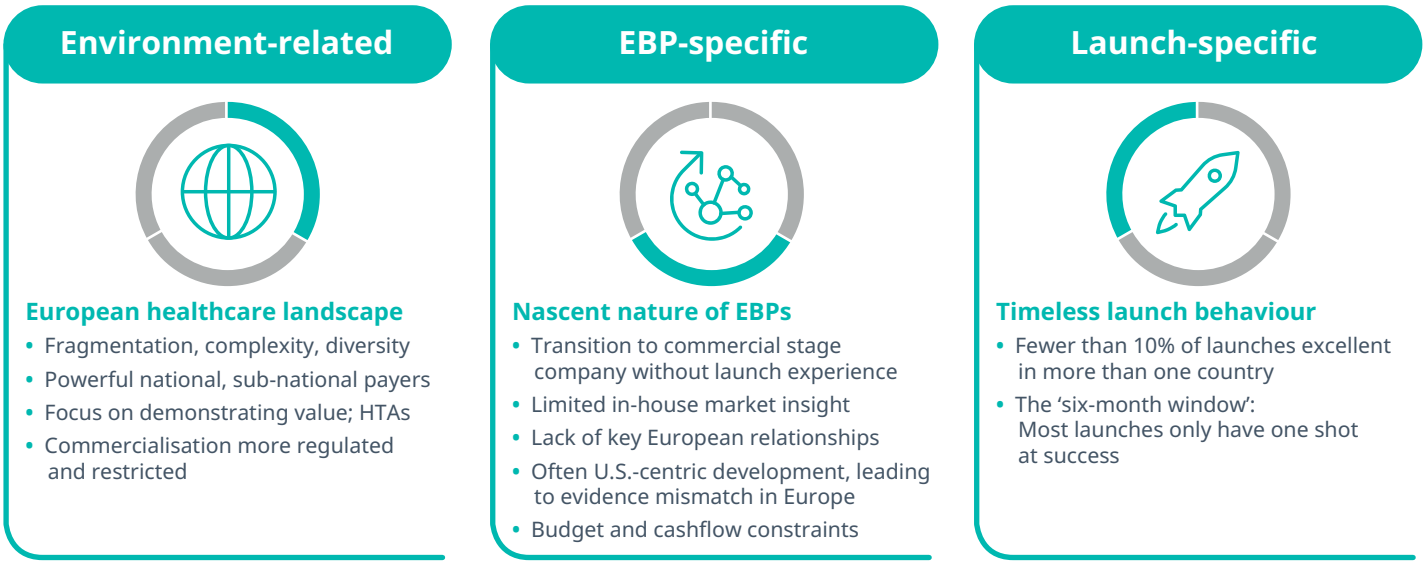
Figure 4: Challenges facing EBPs that seek to commercialise in Europe



Source: IQVIA EMEA Thought Leadership

CHALLENGES FACING EBPS COMMERCIALISING IN EUROPE

Emerging biopharma companies seeking to launch their products in Europe face three types of challenges: (i) environment-related; (ii) specific to the nascent nature of EBPs; and (iii) the timeless truth of launch behaviour.

I. ENVIRONMENT-RELATED CHALLENGES

The European healthcare environment is unique and differs considerably from the U.S. in several, important aspects which necessitates a Europe-specific strategy:

- **Fragmentation, complexity and diversity:** Europe is not a single country; nor is it one homogenous market for pharmaceutical products. The 27 individual EU member states and several non-member states, e.g. the UK, Switzerland and Norway, represent a wide spectrum of population and market sizes, each with their own distinct healthcare system, specific stakeholders and decision makers, local laws, languages and indeed culture. Cultural differences have many manifestations, including physician preferences for the way they want to interact with biopharmaceutical companies. For example, for the period January-September 2021, Italy saw 28 million HCP contacts of which 84% were in-person rep calls, compared to under 17 million HCP contacts in the UK of which 54% were made via digital channels.[13]

- **Payer power:** Regulatory approval by the EMA does not equal uniform, Europe-wide market access. In publicly funded health systems, national payers are powerful and are often at the forefront of implementing cost containment measures, such as access restrictions, reference pricing or pay-for-performance contracts. As a consequence, the availability of approved medicines to patients varies dramatically between European countries. In 2020, for example, 88% of medicines approved by the EMA between 2016 and 2019 were available in Germany (i.e. the product gaining access to the country's public reimbursement list), compared to 63% in France, 49% in Belgium and 28% in Poland.[14] A more decentralised approach in some countries with sub-national payers, for example at

regional level in Italy or Spain, creates an additional layer of complexity in securing market access. Many countries face a significant lag between regulatory approval, reimbursement and market access of new medicines, with international reference pricing (IPR) requirements often adversely impacting timelines. For example, in 2020, the median time to availability from EMA marketing authorisation of medicines approved between 2016 and 2019 was 50 days in Germany, 357 days in Italy and 378 days in Spain.[14,15] Furthermore, a cost containment focus by national payers means European drug prices are typically lower compared to the U.S.

- **Focus on value:** Health Technology Assessments (HTA) play an important part in Europe to inform market access decisions. Unlike the Institute for Clinical and Economic Review (ICER) in the U.S., European HTA agencies are public bodies with a formal remit and role in the healthcare system. However, different HTA bodies use different criteria for assessing 'value'. For example, Germany's IQWiG/G-BA and France's HAS tend to focus on added clinical benefit against a comparator, while England's NICE focuses on cost-effectiveness using cost per QALY (Quality-Adjusted-Life-Year).

Meanwhile, overall budget impact is typically in focus in Italy and Spain. Consequently, not only are HTA bodies' evidence requirements very different from what regulators typically need to approve a new product, these requirements also differ between countries and their respective HTA agencies. Increasingly, many European HTA agencies consider RWE in their assessments, e.g. as external comparators to provide clinical context to support submissions based on single arm trials.[16]

A new European regulation on health technology assessment provides a permanent framework for joint clinical assessments, joint scientific consultations, the identification of emerging health technologies and voluntary cooperation across the EU.[17] While this may streamline parts of the HTA process, healthcare financing, reimbursement and market access decisions ultimately remain a matter for individual member states.

- **More restrictive:** Commercialisation in Europe is more regulated than in the U.S.. For example, DTC advertising is not permitted, many countries restrict the extent of physical access of sales reps to physicians, while the EU's General Data Protection Regulation (GDPR) governs the collection and processing of personal information from individuals who live in the European Union, which applies to healthcare professionals and patients, with implications for how to compliantly conduct promotional activities.

Such an environment presents unique challenges for anyone wishing to commercialise in Europe. Success will depend on careful market prioritisation and launch country sequencing, with international reference pricing implications firmly in mind. It also follows that a one-size-fits-all commercialisation approach will not work and that instead country-specific commercial models are needed that reflect local market dynamics and stakeholder requirements.

II. CHALLENGES SPECIFIC TO THE NASCENT NATURE OF EBPS

EBPs face additional challenges which are related to the nascent nature of these companies:

- Many EBPs have never launched a product before and find themselves at an inflection point of transitioning from a development-stage company to a commercial-stage enterprise. As such, they have to fundamentally change their organisational mindset, from focus on science and clinical development to driving business results. This means building new requisite capabilities, which often involves bringing in external talent, especially with commercial experience, while executing launch preparations, all without the comfort of legacy launch processes, infrastructure or experience to fall back on. Rapid scaling up of headcount presents a particular challenge, and risk to stability, which can see an EBP's organisation double or triple in size over a short period of time, without key supporting processes and functions yet being fully established.

- As small, emerging companies, navigating the complexity of Europe is a daunting task for EBPs, with their typically limited in-house resources for generating deep market and stakeholder insight that is essential for informing a robust European market entry strategy.

- Emerging biopharma companies usually lack existing relationships with key European healthcare stakeholders, especially payers. Where relationships do exist, these are typically limited to a small number of investigators involved in their clinical trials. This situation is compounded by often U.S.-centric development programmes, driven by the importance of the U.S. market, resulting in the dominance of U.S. trial sites and U.S.-based investigators. This U.S. bias may also manifest itself in the choice of trial endpoints that do not reflect the evidence requirements of ex-U.S. stakeholders, such as European payers or HTA bodies. For example, they would expect comparators based on the relevant European standard of care, some may even want to see local data.

- Unlike larger pharma companies with established revenue streams, many EBPs have to operate within tight budgets and cashflow constraints. As such, they face the intractable dilemma of how to achieve, as small, new entrants of limited means, the critical scale in more complex European launch infrastructure. Furthermore, EBPs are more exposed to the financial impact of uncertainty, for example absorbing upfront launch infrastructure fixed cost in a constrained budget if regulatory or market access decisions face delays.

- It is not uncommon for commercialisation to be low on the list of priorities that EBPs tackle during most of their early existence, with budgets often very limited prior to Phase III readout. Consequently, EBPs tend to be late in starting key commercialisation activities and often find themselves having to catch up and deliver against compressed timelines.

These challenges set up EBP-specific success factors for commercialising in Europe, such as the need for flexible cost structures, the ability to ramp up resource fast to plug capability gaps, and the fundamental question of the infrastructure ownership model: Which capabilities does an EBP need to build in-house vs. accessing them via an external partner?

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III. THE TIMELESS TRUTH OF LAUNCH BEHAVIOUR

Launching a new product is an inherently complex endeavour. It also represents the single-most important event in a product's lifecycle and is the culmination of years of investment in clinical and commercial development. The stakes for getting it right could not be higher.

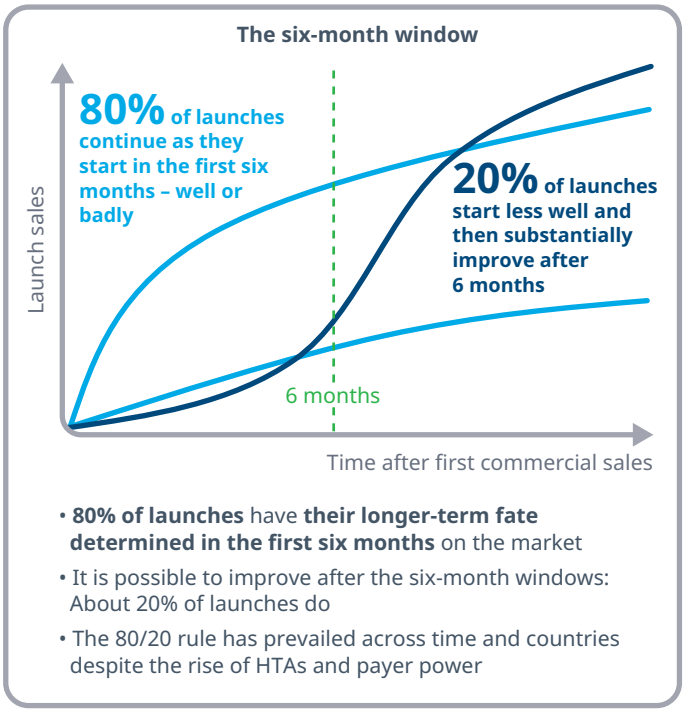
This sets the context for emerging biopharma companies seeking to launch in Europe in which they will need to overcome the other challenges we discussed. It is governed by the well-established, timeless patterns of launch performance.

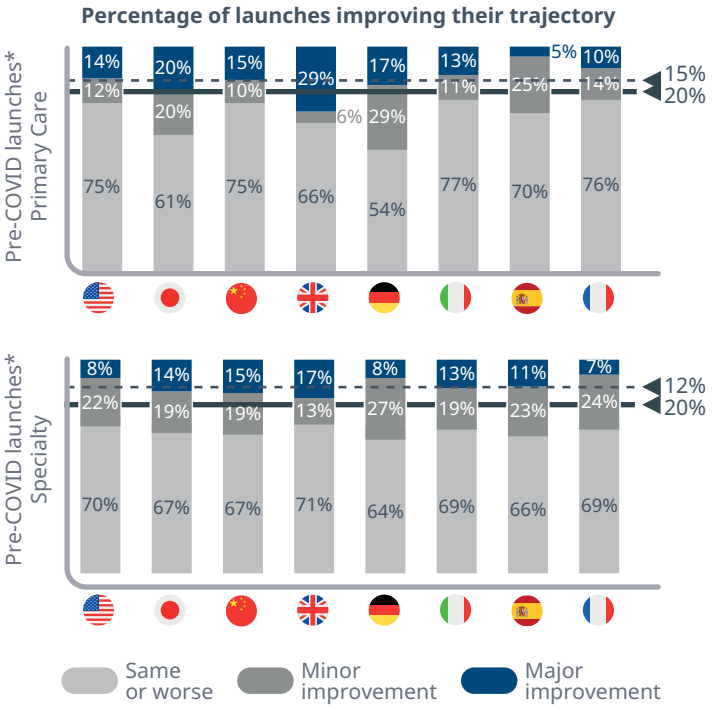
As IQVIA research has shown, the bar for launch excellence is high, with fewer than 10% of launches achieving this much coveted title in more than one country.[18] To add to the challenge, 80% of all launches have their long-term fate determined during the first six months on the market, after which their sales trajectory is set. This 'six-month window of opportunity', first identified in the IQVIA Launch Excellence I publication in 2007, has stood the test of time[7], with profound consequences for the industry: the vast majority of launches are only afforded one shot at success.

The implications are clear: Robust launch preparation is paramount, and it must start early.

However, launch readiness has very distinctive ramifications for EBPs. Unlike big pharma, emerging biopharma companies must do this while being resource and budget constrained, with a need for flexible cost structures and without the benefit of a legacy 'launch playbook', a deep market insight foundation or prior launch experience to draw on. Even so, the market place is unforgiving and does not distinguish between types of companies; they all compete for the attention of HCPs, for funding from payers and, ultimately, for patients being treated with their products.

Figure 5: The 'six-month window': Most launches have only one shot at success



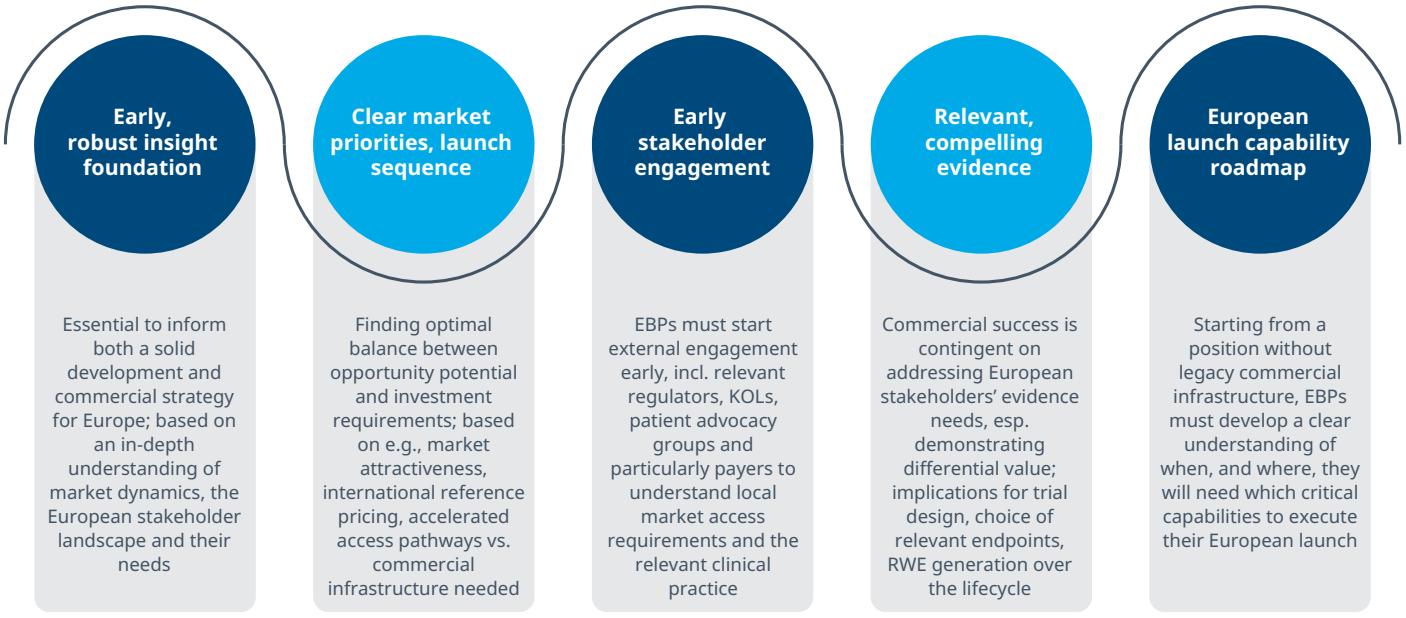


Source: IQVIA EMEA Thought Leadership, Launch Excellence VII, 2021; MIDAS December 2020; Rx-only.
Notes: * Includes NAS launches only; Pre-COVID launches: Feb-14 to Sep-18 followed for 18 months post-launch; major improvement means launch jumps 2 or more in sales decile ranking.

HOW TO SUCCESSFULLY LAUNCH IN EUROPE AS AN EBP

To achieve launch success in Europe, emerging biopharma companies must address five critical success factors that are distinctive to EBPs. They reflect the unique challenges these companies face compared to established, big pharma players, as we elaborated on earlier:

Figure 6: Five critical success factors for EBPs launching in Europe



Source: IQVIA EMEA Thought Leadership.

1. **An early and robust insight foundation:** This is essential to inform both a solid development and commercial strategy for Europe, based on an in-depth understanding of market dynamics, the European stakeholder landscape and their needs. This also includes a realistic understanding of the opportunity potential, both epidemiological and commercial, and robust forecasts for product uptake.

2. **Clarity about priority markets and the launch sequence:** Ultimately, EBPs need to find an optimal balance between opportunity potential and investment requirements, based on considerations such as market attractiveness, international reference pricing, accelerated pathways to market, e.g. local early access programmes, vs. the commercial infrastructure needed to serve those markets.

3. **Early stakeholder engagement:** Given their typical lack of relationships with key European stakeholders, EBPs must start external engagement early. This includes relevant regulators, but once priority markets have been identified, engagement of KOLs, patient advocacy groups and particularly payers becomes very important, to understand local market access requirements and the relevant clinical practice into which a new product will be launched.

4. **Relevant, compelling evidence for European stakeholders:** Commercial success in Europe is contingent on addressing stakeholders' evidence needs, especially the ability to demonstrate differential value. Therefore, the careful design of pivotal trials and the choice of relevant endpoints for European stakeholders, particularly payers, is key for launch success. This extends to generating relevant RWE to address stakeholder needs along the product lifecycle, from pre-launch through maturity. Given the typical lead times for generating evidence, launching in Europe must be considered early on as part of an EBPs commercial ambitions, including what it takes to do so successfully.

5. **A European launch capability roadmap:** In their transition to a commercial-stage company, starting from a position without legacy commercial infrastructure, EBPs must develop a clear understanding of when, and where, they will need which critical capabilities to execute their European launch.

Emerging biopharma companies need to make a number of strategic infrastructure choices on how to deliver their launch. A robust launch capability roadmap is a prerequisite for informing those choices.

EBP LAUNCH INFRASTRUCTURE: KEY CHOICES ON CONFIGURATION AND SCALE

Four drivers determine the requirements for a fit-for-purpose commercial model:

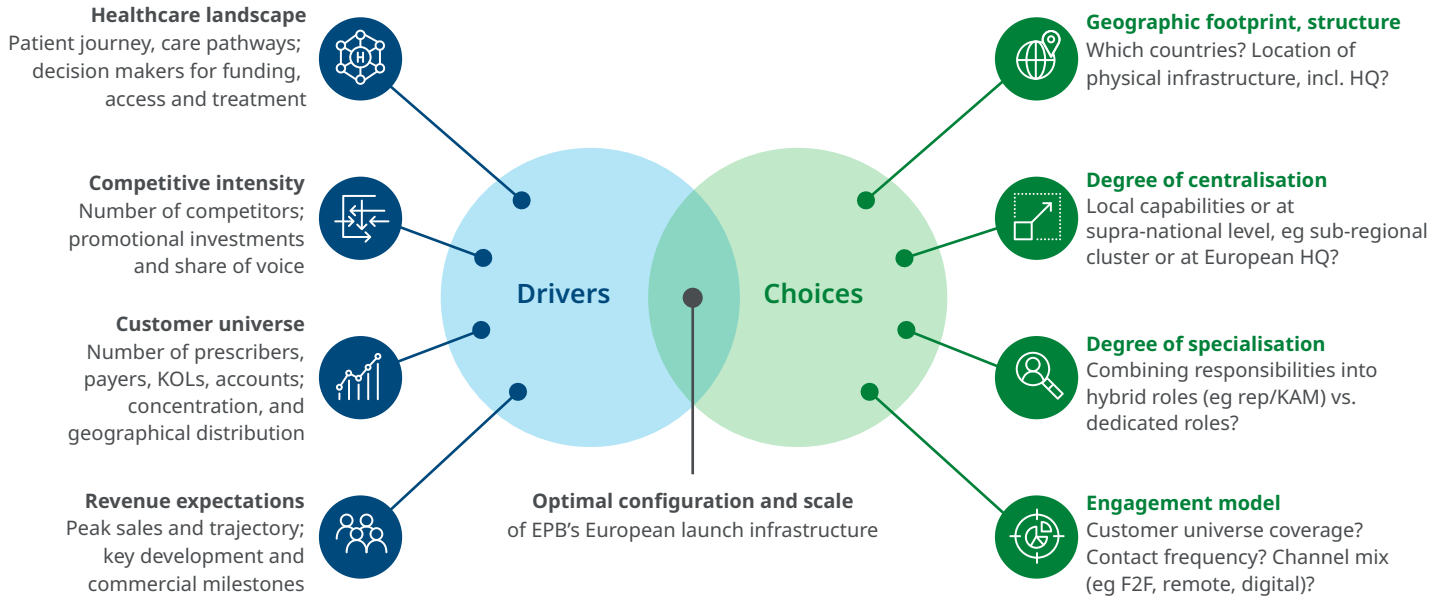
i. The local healthcare landscape, e.g. patient journeys and care pathways, decision makers and influencers for funding, access and treatment;

ii. the competitive intensity, i.e. what does it take to stand out in the market;

iii. the shape of the customer universe, e.g. number and concentration of HCPs or accounts;

iv. revenue expectations for the launch.

Figure 7: Drivers of European commercial infrastructure and key choices



Source: IQVIA EMEA Thought Leadership.

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Establishing a successful commercial organisation in Europe requires careful trade-offs between achieving a competitive presence with adequate customer coverage and engagement, and the ability of the future P&L to carry the European commercial infrastructure.

To strike this careful balance, EBPs need to make a number of strategic choices that define the optimal configuration and scale of their launch infrastructure:

- **The geographic footprint and structure**, including which countries to cover, the location of any physical infrastructure, for example the European HQ and local offices, and how to organise countries, for example into sub-regions or clusters.
- **The degree of centralisation**, i.e. which capabilities to establish locally within countries vs. at supra-national level, such as in a sub-regional cluster or at European HQ.
- **The degree of specialisation of roles**, for example combining responsibilities of a traditional rep with a KAM into a hybrid commercial role vs. having a dedicated role for each customer type, HCP and institutional accounts, respectively.
- **The engagement model**, including the extent of coverage of the customer universe, based on concentration of patients and value; contact frequency and the channel mix for engagement to create awareness and advocacy, e.g. use of in-person details vs. remote or digital contacts. Digital engagement, as a key component of a multi-channel approach, deserves particular consideration as it enables on-demand delivery of highly tailored content and experiences combined with broad customer reach at lower cost.[19] EBPs, as natural digital natives, have a unique opportunity to leapfrog incumbents with legacy commercial infrastructure.

Together, these trade-offs determine headcount requirements and investment levels for an EBP's European launch infrastructure.

In our extensive work with emerging biopharma companies, we have observed the following, common infrastructure choices made in preparation for a European launch.

Many ex-Europe EBPs choose Switzerland for setting up their European HQ, driven by a business-friendly environment and a deep talent pool, who honed their skills and gained relevant launch experience at big pharma, or indeed another, commercial-stage EBP. Hiring a European GM is the critical first step in establishing a presence, typically about 3 years before launch for EBPs entering Europe, while European EBPs tend to fill that role about 2 years pre-launch. Often initial support is provided by external consultants or contractors, while the European leadership team is recruited, including the VP Commercial, VP Medical, VP Market Access, VP Clinical Operations and VP Regulatory. This European senior leadership team is empowered to make key business decisions, on strategy, budgets and resources. Eventually, once the EBP organisation has reached scale, the European HQ also serves as a hub for centralised support functions for the region, e.g. procurement, HR, legal, finance, and business insight.

Attention then shifts to establishing legal entities in key European launch markets, with Germany being a high priority for most EBPs. Physical infrastructure, such as local offices, is set up in priority markets, however, we see more flexibility now as a result of emerging hybrid working practices, especially post-COVID. Affiliate GMs and their local leadership teams may operate as virtual teams, with emphasis on bringing on board the best talent, regardless of where they are based.

Successful EBPs invest at risk in early market preparation, to create awareness and build advocacy with key European stakeholders, including regulators, payers, KOLs and patient advocacy groups. Timely deployment of MSLs in the field is particularly critical, starting as early as 18-24 months pre-launch, because EBPs are often unknown to many stakeholders.

As their European organisations grow, successful EBPs adapt their ways of working to reflect the increasing complexity. Alignment around strategic priorities and tactical plans between functions, the European HQ and local teams becomes formalised via clear processes and incentives.

EBP LAUNCH INFRASTRUCTURE: OWNERSHIP MODEL

For most emerging biopharma companies, it does not make sense to build the required launch infrastructure entirely in-house, for both financial and practical reasons. Building too many capabilities in-house saddles EBPs with a large, upfront fixed cost base and exposes them to greater financial risk, e.g. in case of regulatory or market access delays. Furthermore, fierce competition for talent acts as a barrier to establishing in-house capabilities, often resulting in considerable lead times, which impact speed and agility in ramping up execution capacity by closing capability gaps.

Therefore, a clear strategy for mitigating such risks is critical, which should consider externalisation of key activities. Working with a third-party clinical and/or commercial solutions provider is a viable option for EBPs for partnering on both selective capabilities and end-to-end. It offers local market knowledge and presence, well-established relationships with key healthcare stakeholders and a broad range of critical capabilities, such as clinical, regulatory, medical, market access and commercial, including contract medical, sales and patient-supporting in-field teams, all available for immediate deployment. It can also provide access to cutting edge technology and analytics infrastructure, for example to power commercial operations.[20]

Unlike the option of out-licensing or working with a distribution partner, in this partnering arrangement EBPs retain full control of their assets and commercial strategy, while benefiting from speed, scale and a flexible cost structure to mitigate financial risk.

CASE STUDY 1: LONG-TERM EVIDENCE PARTNERSHIP TO MAXIMISE WINDOW OF OPPORTUNITY

SITUATION

A European EBP with a multi-indicational asset in development had the potential to be first-to-market in several of its indications. Time was of the essence to maximise its window of opportunity, ahead of fast following competition. This required accelerated generation of relevant evidence to address the needs of key European stakeholders, including regulators, payers, HCPs, and to support value differentiation of its asset across multiple indications.

Despite being well funded, the EBP faced the practical and operational challenge of rapidly scaling up its evidence generation capabilities to deliver such complex, multi-indication programme across both clinical trials and RWE, while ensuring it is fully aligned with key stakeholder needs.

SOLUTION

The EBP entered an extensive, multi-year partnership with IQVIA to define and deliver an accelerated evidence programme as a foundation for seizing the first-to-market opportunity. Drawing on deep market and stakeholder insight, IQVIA shaped the respective differentiated target product profiles (TPPs) for different indications and developed the supporting integrated evidence strategies, comprising both clinical and RWE programmes.

Leveraging the scale of IQVIA's clinical and real-word operations combined with state-of-the-art technology, rapid start-up of the evidence programmes followed which are on track to deliver timely, compelling evidence to support regulatory approval, market access and successful commercialisation.

To maximise impact, this was complemented by comprehensive commercialisation planning to advance launch readiness, including stakeholder mapping, e.g. KOLs, payers; strategies for customer engagement, and support for effective evidence dissemination and patient advocacy.

IMPACT

Through partnering, the EBP created the evidence foundation and commercialisation plans for success as first-to-market entrant in Europe in a number of indications. By tapping into IQVIA scale, technology and domain expertise, the EBP was able to rapidly close critical capability gaps and dramatically accelerate timelines for evidence generation and launch readiness.

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CASE STUDY 2: PARTNERSHIP TO SUPPORT EUROPEAN COMMERCIALISATION JOURNEY

SITUATION

A U.S.-headquartered EBP with a novel primary care asset was establishing its commercial organisation in preparation for its first European launch. Given the size of the potential primary care customer universe, commercial precision was critical for effective, impactful customer engagement. Furthermore, a digital launch component was important to enable cost-effective, broad engagement and delivery of highly tailored content for a unique customer experience.

The EBP wanted to focus its own efforts on building its European organisation and engaging key stakeholders in its pre-launch market preparation, while accessing deep market and stakeholder insight, customer data and enabling technology infrastructure via a partner to rapidly scale country launch readiness.

SOLUTION

The EBP partnered with IQVIA to provide critical commercial capabilities and enabling infrastructure, with a particular focus on setting up a digital launch, including:

- **Expertise and analytics:** Country-specific market access strategies, targeting and segmentation, territory design, sales force compensation
- **Technology:** Fully integrated commercial ecosystem powered by AI/ML and orchestrated analytics designed for remote detailing, multichannel marketing, call centres, virtual congresses and meetings
- **Data:** Deployment of Big Data for country-specific analysis of market trends, prescriber characteristics and channel dynamics

IMPACT

The IQVIA partnership provided the EBP with a fully-integrated customer engagement ecosystem, to be deployed across 14 countries as a turnkey solution that is ready from day 1. It dramatically accelerated and scaled the EBP's launch readiness across key European countries to deliver against its ambitious launch timelines.

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CONCLUSION

As emerging biopharma companies increasingly seek to retain maximum value of their innovative assets by commercialising these themselves, launching in Europe as the second largest pharmaceutical market after the U.S., home to over half a billion people and with well-funded healthcare systems, must feature in their plans.

While the European healthcare environment is different from the U.S. and presents its unique challenges, these can be overcome by addressing critical success factors that are distinctive to EBPs.

By making the right strategic choices about their European launch infrastructure, where partnering with a third-party clinical and commercial solutions provider must form a key consideration, EBPs are poised to realise the commercial promise of Europe.

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