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Why Launching in Europe Is Unlike Launching Anywhere Else

Mike Ryan, *Executive Vice President, EMEA*

Franjo Hanzl, *Vice President Commercial Development Europe*

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INTRODUCTION:

FACTS AND MISCONCEPTIONS ABOUT LAUNCHING IN THE EU

Launching a new therapy in the European Union (EU) and United Kingdom (U.K.) has traditionally involved complex navigation of service providers, price sequencing and the rich diversity of patient and healthcare provider populations. As a result, bringing a pharmaceutical or biotech product to Europe has been, and continues to be, intimidating for most manufacturers.

Today, there are more than half a billion people in the EU and U.K. Passing over this part of the globe puts patients and manufacturers at risk for negative outcomes. Many manufacturers still believe that the traditional launch model – signing a handful of disjointed partnerships – is the only way to launch a new product in the EU and U.K.; but this is no longer the only solution.

It's true that, traditionally, manufacturers could choose to sign one deal with a large pharma company or develop multiple partnerships with service providers to commercialize their product in Europe, forgoing the most challenging option: launching on their own. With this out-licensing model, manufacturers sign with partners, known as "distributors," in every European region and country.

The truth is, there is stiff competition in the European market, with about 97 new medicines launching in 2020 and 36 new substances being granted marketing authorizations (MAs) each year. Once a manufacturer is past the R&D phase of product development, it becomes more difficult to work with just one large pharma partner to launch across Europe, which is a slim chance to begin with. Most countries will not enter reimbursement, access or pricing discussions if a manufacturer has not begun the application process for marketing authorization or has one already. In fact, only 1% of post-approval deals become European commercialization partnerships, as 99% of deals are signed in Europe before regulatory approval is granted. The longer a manufacturer goes in the product's life cycle without a commercialization partner, the more difficult it becomes to distribute in Europe. Manufacturers that don't have the opportunity to partner with large pharma companies end up in four to six partnerships for commercializing and distributing the product in Europe, and these partnerships may not reach every country and EU region.

Facts and Figures: Launching in Europe

Only about **30 of 4,058** product licensing or alliance deals between 2016-2021, globally, across all product development stages were signed for Europe as a whole (EU and U.K) after the product was already approved. **This is less than 1% of total global product pharma partnerships.**

Today's manufacturers have another option. Rather than racing to sign a commercialization deal during R&D, settling for complicated partnerships in post-approval, or facing the logistical and financial burdens of launching alone, there's a partnership option that meets the needs of manufacturers and their patients with one point of contact for global commercialization.

SECTION I

FILLING IN THE GAPS: A SINGLE COMMERCIALIZATION PARTNER TO MEET GLOBAL NEEDS AND CAPABILITIES

"Directly launching a drug in Europe is the most difficult path for U.S.-based biopharma companies, many of which decide to out-license rights for that territory." – Biopharma Commercial Strategies

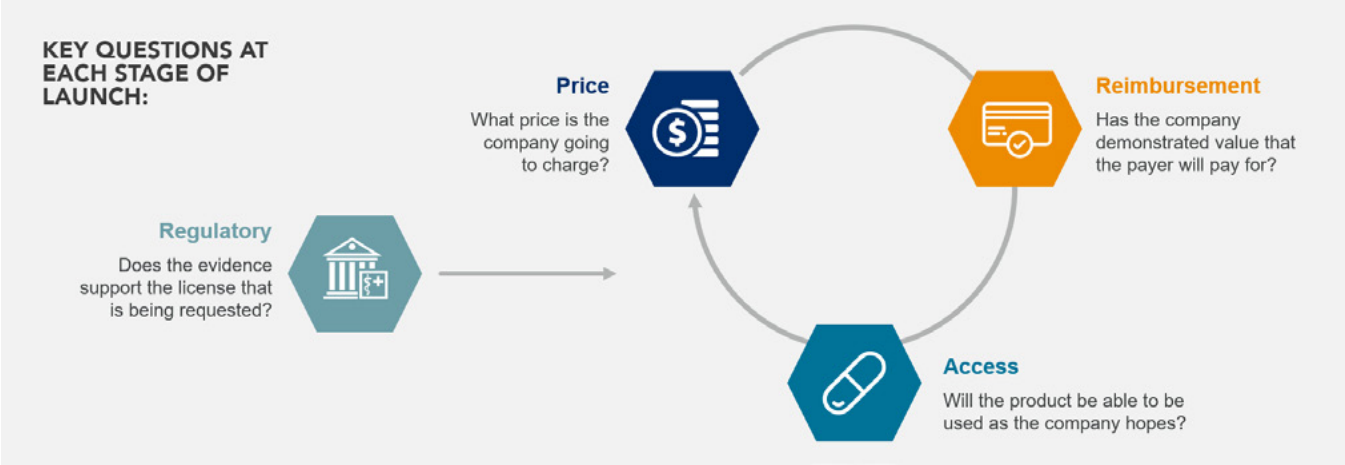
With traditional commercialization models, manufacturers are often not fortunate enough to sign in Europe; or if they do, it's a piecemeal partnership structure that is set up to serve very specific patients and locations. In this situation, neither the patients nor the product is set up to reach their full potential. By choosing to partner their launch, manufacturers can avoid large investment risks, prioritize research and development (R&D) investments, and find the simplest route to commercializing in the EU and U.K. A fully equipped, single commercialization partner can help answer essential launch questions while meeting Europe's diversity demands.

There are 24 official languages in Europe, with at least 200 languages spoken by residents of different cultures and nationalities. To launch successfully in this region of the world, manufacturers need a team and infrastructure that can serve the deep diversity among HCPs and patients. Because there are considerable expenses and risks in building a team and services that are this extensive on your own, manufacturers need to rely on partners for European commercialization of their product.

Launching in the EU and U.K. costs between **60 and 120 million euros** per year, yet **66%** of drugs don't meet launch expectations. An unpredictable landscape, coupled with inevitable industry pressures, is forcing manufacturers to seek a more complete commercialization approach with more value.

Until now, manufacturers partnered with separate service providers in each European country (or regions) where they wanted to launch their drug, and most of the time this partnership matrix still couldn't serve all patients in the EU. For instance, salespeople in Sweden can't sell the drug in Germany. Additionally, due to different regulatory and cultural nuances in each country, manufacturers need financial and human resources capabilities in every country as well, requiring a local presence with global capabilities.

Rather than attempting to coordinate often up to 10 independent local distributors, manufacturers can now launch in Europe with a single sourcing point. EVERSANA acts as the "single point of contact,"



EVERSANA's Global Presence

ensuring all necessary service lines are working together and meeting the same standards with your product and all patients in mind. As one of the only partners with all the key pieces for holistic commercialization across Europe, manufacturers sign a single contract to access all necessary services, including:

In addition to logistical ease, a single commercialization partner can prevent manufacturers from overspending by 23% in additional investments and losing product value.

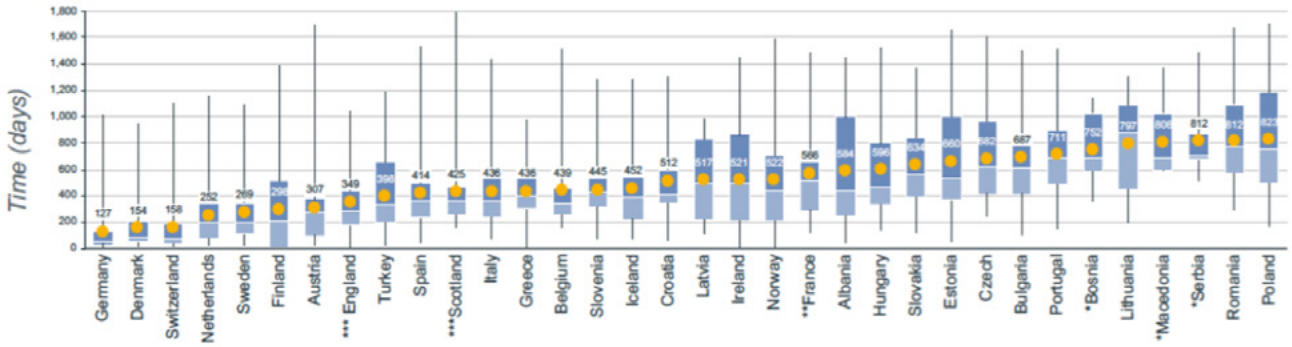
SECTION II

STREAMLINING COMMERCIALIZATION TO MAXIMIZE PRODUCT VALUE

Launching in the EU and U.K. costs between 60 and 120 million euros per year, and the payoff for manufacturers is not guaranteed (Him, Schuler). When manufacturers are forced to manage multiple demanding partnerships across the continent, challenging hurdles must be overcome to have a working European supply chain. This system becomes even more complex as companies try to navigate and strategize the most profitable launch sequences for their product.

There are 27 countries in the EU, and manufacturers cannot ensure that individual vendors are protecting their investments and product promotion. Each vendor focuses on earning as much revenue for itself as possible, potentially dissipating the manufacturers' brand value. The best price a

Average time to availability in days (2015-2018)



Source: EFPIA & IQVIA

manufacturer can expect is the first price offered, which will go downhill, especially as the product's value is shared among vendors.

The EU and U.K. have a reference pricing system in which prices are usually regulated separately in each country and can vary across Europe significantly. As a result, launching in Europe is unlike launching anywhere else. Manufacturers, especially first-time launchers, could face lengthy launch delays (up to two years) and complicated pricing and launch sequencing. For example, in Germany it takes 150 days on average after receiving marketing authorization for a manufacturer to receive reimbursement and placement in the German national health system. In France, the wait expands significantly, to 450 days.

Contrary to traditional launch methods, working with local distributors across Europe is not the most efficient way to meet financial goals. As manufacturers look for launch models and sequences to maximize the amount of time during which their product will get the best price, a single-source partner is the answer to better protecting investments through launch sequencing optimization.

A Global Pricing Solution: NAVLIN by EVERSANA™

EVERSANA leverages a single, integrated global platform, NAVLIN by EVERSANA™, to help partners navigate the toughest market challenges with global solutions. With a focus on speed and accuracy, this global pricing solution allows manufacturers who are launching in even the toughest markets to answer challenging price and access questions.

Powered by this proprietary, best-in-class price and access platform, EVERSANA also offers partners a European Commercial Readiness Assessment to evaluate the holistic launch opportunity for their product in Europe. With this program, manufacturers work alongside a team of experts who provide the necessary information to maximize revenue potential. With this single approach backed by actionable data and strategies for the entire EU market, manufacturers can add value to their launch plan, reduce risk and, ultimately. retain more value and control by avoiding local distributors.

NAVLIN by EVERSANA™ synergizes data, software and insights, covering over 100 markets, to help manufacturers plan, evaluate and execute pricing strategies that drive global access. This platform includes:

- Powerful, timely and accurate competitor data
- Enterprise pricing, governance & management software
- Deepest insights on your most pressing market access needs

In one Biopharma Commercial Strategies study, most launch companies saw positive and meaningful share-price increases, with an average share-price increase of 48% (median 46%) over the two-year period. However, the range was considerable, from -117% to 205%, highlighting the risk and reward trade-off of the decision.

With a greater understanding of the European region and the individual countries' nuances, manufacturers can make more informed choices, secure better deal terms with partners and explore their global commercialization options. Unlike other markets, regulatory approval, price, reimbursement and access are all intimately linked in Europe, and understanding how to proficiently navigate these launch complexities is key in protecting product value and future investments. When manufacturers lose investments, the global healthcare market loses, too. Lost investments equate to less money to invest in future drug research and development, hurting patients in the long run.

SECTION III

SUPPORTING PATIENTS GLOBALLY WITH LOCAL SERVICES

As home to many of the largest drug developers in the world, Europe is at the forefront of pharma development but struggles to be at the forefront of treating patients. An industry study from Simon-Kucher & Partners shows that treatments in the EU and the U.K. target 2.6 patients of every 10,000, with an average cost of around 150,000 euros per year, leaving significant healthcare gaps in this region of the world.

One reason for gaps in patient treatment is the complexity of launching in Europe. Rather than tackling the challenges and spending the resources associated with multiple vendors in a lowest-price market, manufacturers may simply choose not to distribute their product in Europe, ultimately hindering treatment availability for patients. If manufacturers choose to launch products only in specific global regions, there will be an overall reduction in global welfare, resulting in the following:

- Regional healthcare disparities
- Varied treatment plans within disease areas
- Non-global therapy distribution
- Potential product shortages or discontinuation
- Reduced investments in product quality or research and development

With the onset of the COVID-19 pandemic, Europe joined the rest of the world, hurriedly getting vaccines to the public, and did so as one mass market, proving a successful rollout. For instance, Malta is one of the smallest and most vaccinated countries in the world thanks to access to the vaccine through the EU's market. By coming together in this extraordinary circumstance, European countries proved how a single-market distribution could work while ensuring access and serving diverse patient needs.

Even while acknowledging that different countries have different product needs, it is possible to mimic the COVID-19 vaccine rollout as a model for other critical drugs launching in Europe. EVERSANA approaches patient support services in the same single-contact, holistic approach while delivering a local presence in every country and region. We work to ensure patients are receiving a best-in-class experience by helping manufacturers support and engage patients throughout their treatment journeys.

One way we're meeting patient needs is with digital health solutions, such as our S3 Connected Health partnership. This award-winning partner in

digital health solutions complements EVERSANA's end-to-end commercialization services (including patient support and adherence models), enabling manufacturers to:

- Impact brand planning and optimize performance with digital health solutions, providing personalized support based on real-world insights.
- Improve outcomes through next-generation patient services and meet the demands of value-based care using digital health solutions and human-based support.

In a world where over **400M patients** have rare diseases, cutting-edge therapies need to get to patients everywhere faster.

EVERSANA is also partnering with European manufacturers, such as MINDPAX and Shorla Pharma, to navigate their global product launches and support patients across therapeutic areas. We recognize that Europe is united under a banner of diversity, and patients deserve to have their individual needs met in every country and region. At the end of the day, being able to provide the citizens of Europe with the highest standard of healthcare is the priority and the number one reason to optimize and streamline global commercialization.

CONCLUSION

Ultimately, as the EU focuses on the future of pharma, manufacturers should consider this region and its possibilities for launch opportunities. Despite launch complexities, the EU, U.K. and emerging markets across eastern Europe present a major opportunity for U.S. biotechnology companies and other global manufacturers. If overlooked, products that do not launch in Europe often fail to achieve full value potential. While, traditionally, launching in Europe may not have been worth the risk, EVERSANA's global solutions, including the EVERSANA™ COMPLETE Commercialization model, are helping today's manufacturers meet global launch challenges head-on.

We believe manufacturers of every size should be able to launch their life-changing products to patients without developing an infrastructure from scratch or losing value to multiple distributors and large pharma companies. Thanks to EVERSANA COMPLETE, the best of both worlds is possible. To ensure that your product is globally competitive, EVERSANA COMPLETE is a ready-to-deploy, high-performance commercialization and distribution option that can be customized for individual product and patient needs.

Pharmaceutical manufacturers have a responsibility to share products across the globe. In failing to do so, manufacturers put themselves and their products at a huge disadvantage while contributing to global healthcare gaps. Patients need access to novel therapies now, and a single commercialization partnership can ensure Europe's patients receive the quality of healthcare and treatment access that everyone deserves.

EVERSANA and our partners have access to a full suite of global experts who offer strategic solutions for market insights, commercialization, growth maximization, pricing and market access, data analytics and more. Our goal is to work with you to assess and adapt product development and commercialization strategies to retain the value of your product globally – reaching all patients no matter where they live.

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REFERENCES

1. Breazzano, S.P., Easton, R.J., & Gilbert, A.J. (2013). Launch or License: Taking Your First Drug to Europe. Bionest. https://bionest.com/wp-content/uploads/2015/10/In_Vivo_Article_Bionest_web_final_IV1312.pdf

2. Him, L., Schuler, C. (n.d.). Seven Secret Ingredients for Successfully Launching and Commercializing a Biopharma's First Drug in Europe. https://www.simon-kucher.com/sites/default/files/Whitepapers/Sept_2019_CHSC_Whitepaper_Digital_Edition_GESO_112019.pdf