Five Essential Factors for a Successful Biopharma Product Launch

Rapid changes in the biopharma industry are making it increasingly difficult to launch new products successfully. Especially challenging are novel treatment modalities such as gene and cell therapy; increased use of biomarkers; rare diseases with patients who are hard to identify, diagnose and access; and expanded requirements to demonstrate economic value.

In addition, biopharmas must navigate declining access to physicians, digitalization, more informed and demanding patients, intense competition, and the need to launch globally across the U.S., Europe and Asia to maximize revenues. Shareholders' expectations are also increasing, driven in part by the high prices paid to acquire the limited number of attractive assets available.

Faced with such challenges, biopharma companies must optimize their launch planning and execution process to ensure successful launches of strong products.
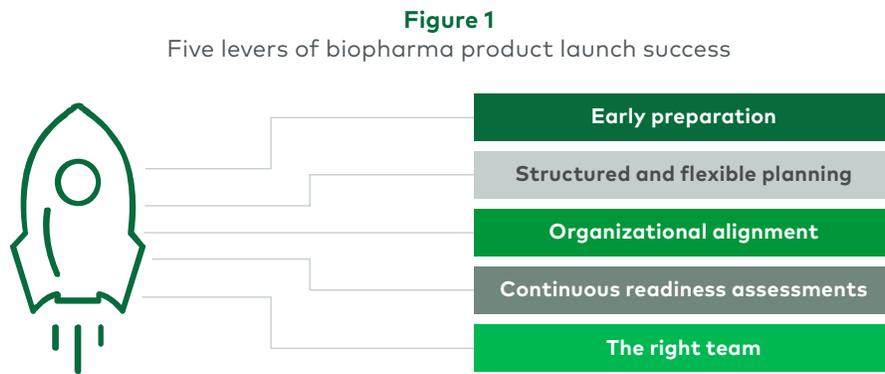
Based on our experience supporting a range of product launches, L.E.K. Consulting has identified five key levers for biopharma launch success (see Figure 1).

In this *Executive Insights*, we review these five levers and explain how they inform the creation of a high-performing product launch framework.

Five levers for successful launch

1. Early preparation

A successful launch requires evidence generation for reimbursement, the identification and development of a new set of advocates, and/or the identification of a suitable patient group.

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Figure 1
Five levels of biopharma product launch success

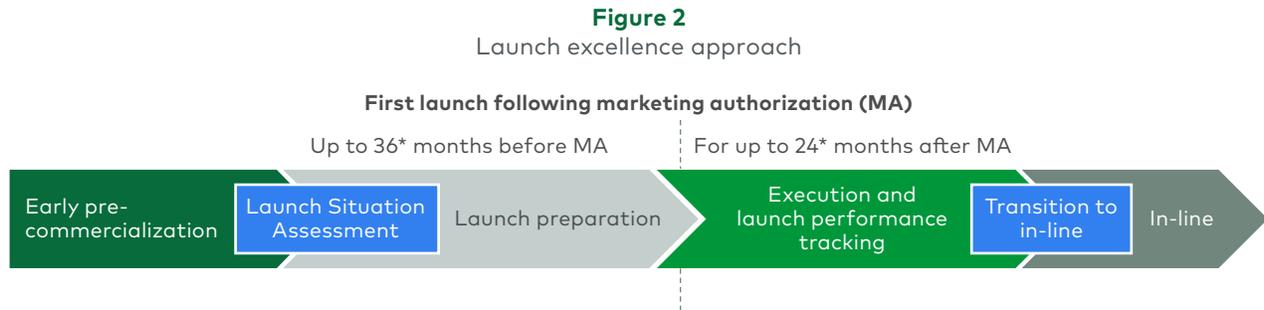| Early preparation |
| Structured and flexible planning |
| Organizational alignment |
| Continuous readiness assessments |
| The right team |

Source: L.E.K. research and analysis

The planning process should start approximately three years before launch, though this may not always be possible if an asset is acquired or in-licensed, or if there are budget constraints. However, starting late will most likely lead to missing or lower-quality deliverables, regardless of how many resources are invested, thereby resulting in either a delayed launch or poor launch performance.

When launch planning, the first step is to conduct a thorough Launch Situation Assessment (LSA) to determine the unique aspects of the launch, asking questions such as:

- How large is the patient population?

- Are patients easy to identify and diagnose?

- What is the current level of disease and treatment awareness among key stakeholders? Is the standard of care consistent across the key markets?

- Are there product-specific requirements for patient access and/or product distribution (e.g., biomarker needed, specialized centers required for treatment administration)?

- How large is the call point universe?

- How differentiated is the product?

- How much variability is there in competitive dynamics across key markets?

During this initial assessment, the core launch team, led by the brand or launch lead, identifies priorities, assembles the global launch team, defines timelines and establishes the launch readiness assessment process. This ensures proper focus on the critical success factors and helps the launch team to define timelines and milestones.

In addition to the early start, biopharmas should implement a well-defined launch excellence approach that guides the process along a clear path from situation assessment to planning and readiness, through to execution and launch performance tracking, until the brand transitions to "in-line" (see Figure 2, which illustrates both preparation time frames and key planning phases).
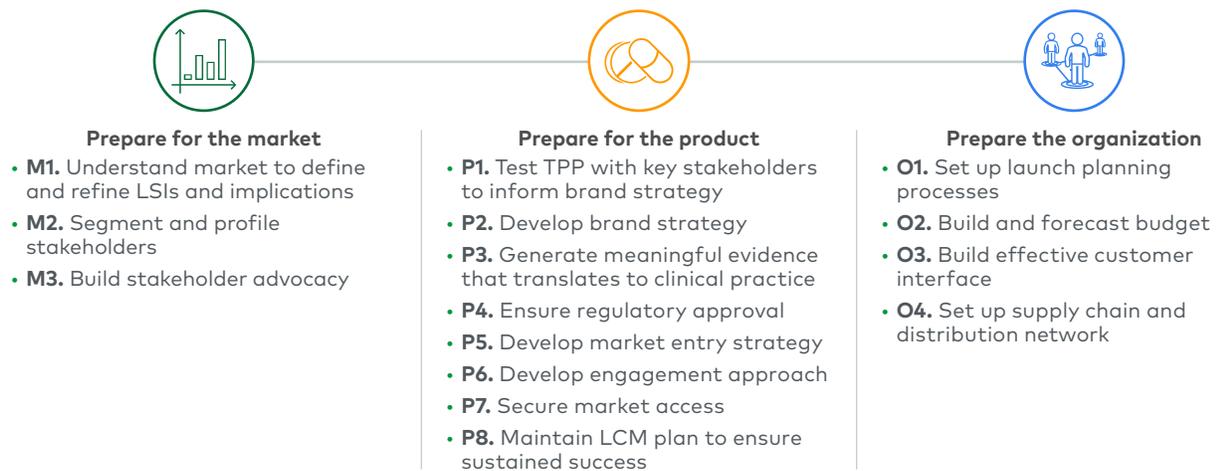
Figure 2
Launch excellence approach

First launch following marketing authorization (MA)

Up to 36* months before MA | For up to 24* months after MA

| Early pre-commercialization | Launch Situation Assessment | Launch preparation | Execution and launch performance tracking | Transition to in-line | In-line |

*Timing will be customized to the unique circumstances of each launch
Source: L.E.K. analysis and research

2. Structured and flexible planning

Launch planning tools are often not adopted because they are too complicated and inflexible. To be useful, the planning process must help the launch team identify and focus on only those deliverables that support specific success factors.

L.E.K.'s launch excellence framework has three main dimensions (market, product and organization), which cover 15 strategic launch themes with a total of 60 deliverables (see Figure 3).

Figure 3
Launch excellence framework 60 deliverables sit under the 15 Strategic launch themes, aligned to the three dimensions within the launch excellence framework

Prepare for the market
- **M1.** Understand market to define and refine LSIs and implications
- **M2.** Segment and profile stakeholders
- **M3.** Build stakeholder advocacy

Prepare for the product
- **P1.** Test TPP with key stakeholders to inform brand strategy
- **P2.** Develop brand strategy
- **P3.** Generate meaningful evidence that translates to clinical practice
- **P4.** Ensure regulatory approval
- **P5.** Develop market entry strategy
- **P6.** Develop engagement approach
- **P7.** Secure market access
- **P8.** Maintain LCM plan to ensure sustained success

Prepare the organization
- **O1.** Set up launch planning processes
- **O2.** Build and forecast budget
- **O3.** Build effective customer interface
- **O4.** Set up supply chain and distribution network

Note: LSIs=Launch strategic imperatives; LCM=Lifecycle management; TPP=Target product profile; LRR=Launch readiness review
*Timing will be customized to the unique circumstances of each launch.
Source: L.E.K. analysis and research

During the initial situation assessment, the core launch team uses market and product information (e.g., product forecasts, competitive dynamics, key product dimensions, R&D/business development timelines) to determine the success factors that will drive the product in the focus market, as well as the overall launch timeline. Based on the success factors identified, the launch team can select critical deliverables and map them to the defined timeline, adding owners and expected levels of completion that will later help establish the launch readiness assessment process.

3. Organizational alignment

A successful launch team needs to be cross-functional, with a clear division of responsibilities between global and local representatives.

Typically led by the product vice president or brand head, the global launch team must have representation from key functions and affiliates; many fail to include enough functional expertise or the input of key personnel. Alongside undertaking the LSA, the global team is also responsible for ensuring deliverables are met and intervening when needed to address locally arising issues.

Affiliate launch teams are responsible for planning and executing the launch locally. They are often led by general managers, business unit heads or marketing leaders and should comprise cross-functional members. Global and affiliate launch teams would need to agree upon the hand-offs and the decision rights, for example, how much autonomy would the affiliates have to set pricing, target different subspecialties or alter the key promotional messages. Asian markets (including China) are increasingly part of the "Wave 1" global launches, forcing launch leaders to address these critical questions earlier than before.

At a minimum, the functions across both teams must include R&D/medical affairs, marketing, market insights, market access, health economics and outcomes research, and regulatory. Depending on the situation, other functions may be required, such as manufacturing/supply chain, finance, HR, compliance and public affairs.
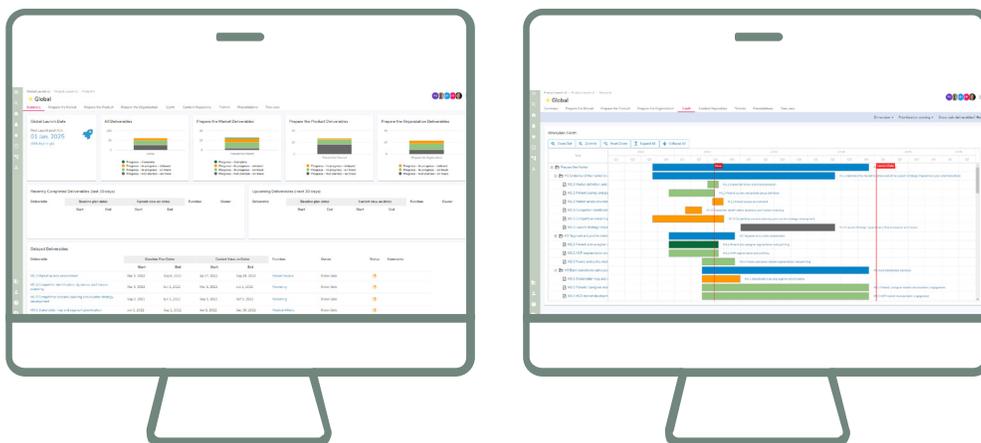
Finally, genuine two-way dialogue between the global and local teams is an integral part of the launch process. Affiliates must be empowered to ask for support and global representatives must have realistic expectations about what individual affiliates can deliver, especially if there is limited time to prepare.

Organizational alignment is inherently complex. From structural barriers such as functional and geographical silos to logistical issues such as variable communication/support technology, alignment is difficult to implement — and therefore a key barrier to launch.

To facilitate this process, we recommend launch teams adopt a planning and tracking tool. The L.E.K. launch excellence framework and web-based launch excellence management tool or "tool" are tailored to meet your product's particular launch situation so users can prioritize and invest in activities that truly impact launch success. The framework and tool are designed to seamlessly fit into your team's ways of working, since they are customizable to each organization's workflow. They offer both cross-functional and cross-regional transparency so teams can collaborate in real time, wherever they are located.

Each launch stakeholder has access to a set of interactive, self-updating dashboards, facilitating reporting and tracking of all launch activities (see Figure 4). This simple, intuitive

Figure 4
L.E.K. launch excellence management tool

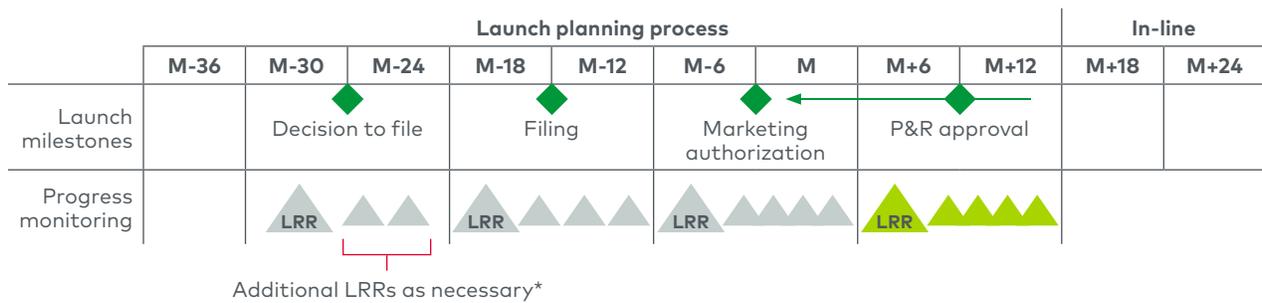Source: L.E.K. analysis and research

and automatized process provides the launch team as well as the overall organization with a powerful, transparent and automated tool to track launch roadmap progress.

This cross-functional global and affiliate team approach needs to continue throughout the readiness phase and after the launch is completed, though the participation of some functions may be reduced over time.

4. Continuous readiness assessments

To help participating countries prepare for launch and facilitate collaboration with global representatives, the team should conduct regular in-depth readiness reviews around key milestones such as the decision to file, filing and marketing authorization. Additional reviews should be scheduled as necessary (see Figure 5).

Figure 5
Illustrative time frame for launch readiness reviews

	Launch planning process									In-line	
	M-36	M-30	M-24	M-18	M-12	M-6	M	M+6	M+12	M+18	M+24
Launch milestones		Decision to file		Filing		Marketing authorization		P&R approval			
Progress monitoring		LRR		LRR		LRR		LRR			

Additional LRRs as necessary*

Note: LPR=Launch performance review; LRR=Launch readiness review; P&R=Pricing and reimbursement
*Additional LRRs/LPRs may be scheduled to address specific issues
Source: L.E.K. analysis and research

The initial launch situation assessment defines the priorities and timeline of readiness reviews and sets expectations regarding the progress of critical deliverables at any given point in the launch process. Importantly, the readiness reviews should not be "tick the box" audits, but rather high-value sessions that ensure overall alignment regarding progress and next steps. As such, they are integral to launch success.

Launch tools, such L.E.K.'s launch management tool illustrated in Figure 4, can help monitor readiness and provide input for qualitative discussion at reviews, and these tools should also be used to ensure delays are addressed through actions defined by the launch teams.

5. The right team

Regardless of the product, the process, and the launch planning frameworks and/or tools, having the right team in place to properly plan and execute the launch is critical to its success. Without the appropriate experience, passion and collaborative mindset at both the global and local levels, the launch is unlikely to succeed.

For biopharmas with limited previous experience, this can be particularly challenging, and it is even more important for these companies to start launch preparation early to allow time to hire and/or train new team members. The complexity of a product launch means that the team must include some members with prior launch experience. This will help to identify problems faster, build cross-functional and organizational consensus, sustain motivation and morale, and reinforce the importance of the launch to executive leadership.

Preparing for launch success

Any biopharma company preparing to launch should consider seven key questions to determine whether they are on track with planning and execution:

1. Do we understand the key market and product dynamics for our launch?
2. Have we identified the critical launch success factors/imperatives?
3. Are we focusing our efforts on these factors/imperatives?
4. Do we have a strong cross-functional global team with representation across affiliates, focusing on key affiliates (e.g., five to seven markets with greatest commercial opportunity)?
5. Have we identified and do we track launch readiness indicators specific to our launch?
6. Do we have a plan to monitor launch execution and performance?
7. Will the organization be prepared to launch our product successfully?

The biopharma industry is evolving quickly and launching products is more challenging than ever. By considering the key levers outlined in this paper, biopharma companies will find themselves able to execute their launches in a more targeted and effective way, and increase their chances of success.

For more information, please contact lifesciences@lek.com.

About the Authors

Peter Rosenorn

Peter Rosenorn is a Managing Director in L.E.K. Consulting's Boston office. He joined L.E.K. in 2010 and specializes in the life science and pharma sector, with a focus on growth strategy and organization and performance. Peter advises clients on a range of critical business issues including organizational scale-up and development, launch planning and commercialization, transaction support, forecasting and valuation, and post-merger integration.

Christian Seiffert

Christian Seiffert is a partner in L.E.K. Consulting's European Biopharmaceuticals and Life Sciences practice. He has more than 17 years of consulting experience, providing strategic advice to leading pharmaceutical, biotechnology and medical technology organizations. Christian has advised clients on a wide range of assignments including commercial excellence, product launch, brand management, pricing and market access, and corporate strategy.

Sej Brar

Sej Brar is a partner in L.E.K. Consulting's London office and is a member of the Life Sciences and Pharma practice. Sej has more than 12 years of consulting experience, and his work has spanned many client types, including large-cap global companies, midcap/specialty players and financial sponsors, such as hedge funds and private equity funds.

Sean Dyson

Sean Dyson is a Partner in L.E.K. Consulting's London office and a member of the European Healthcare practice. He focuses on the life sciences sector and advises a diverse set of pharmaceutical, biotech, private equity and venture capital clients. Sean has extensive experience in strategic planning, with a focus on corporate and franchise-level strategy, portfolio planning and optimization, go-to-market strategy, and launch planning.

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