Lessons Learned from Rare Disease First Commercial Launches

There's nothing more exciting, and more nerve-wracking, than a new product launch — even more so when it's a company's first commercial launch. We've had the privilege of working on more than 10 first commercial launches, most of them in rare disease. As an agency partner we've worked with biotechs as they've evolved from R&D to commercialization, marshaling the expertise and experience of an entirely new team. Here are some lessons learned along the way.

Establish the Decision-Making Teams

Most companies have a shared vision of how to approach launch. Key to executing on that vision is ensuring the decision-making process is clear. Establishing roles and responsibilities at the outset is crucial, including identifying the cross-functional team that will own the launch planning. As a newly formed team comes together to work on a first commercial launch, there is much excitement, enthusiasm, and relevant experience that fuels the team. But there is a big difference between engaging team members to solicit input and the final decision-making process. The lack of clear decision-making can slow things down and put timelines and budgets at risk. Also, established decision-makers can be charged with sharing critical decisions across the team to ensure strategic and tactical alignment.

Plan for Curve Balls

The ability to plan effectively for multiple scenarios is another critical success factor. As essential as scenario planning is, it's often minimized. In a survey of global pharmaceutical executives, Blue Latitude Health found that "scenario planning for uncertainty" ranked at the bottom of executives' view of organizational launch readiness.

Scenario planning involves thinking through the what if's regarding approval, competitive moves, and planning for the inevitable curve balls. What if a competitive product receives expedited approval? What if your approved label is drastically different than expected? It's important to consider the implications for patients, prescribers, payers, and for the company's ROI. In working with clients to map out different possibilities, we've consistently found that detailed scenario planning has helped ensure effective launch plan execution within the planned launch window.

Annemarie Armstrong
Executive VP, Director of Client Services
Dudnyk

We've helped companies successfully execute a "plan B" when the anticipated label didn't materialize. Thorough scenario planning made the difference.

Build a Marketing and Sales Infrastructure

As companies move from R&D to commercialization there are several operational needs required to support the marketing and sales functions. Decisions about technology platforms to support regulatory submissions, customer engagement, data management, and analytics need to be made well in advance of launch. These operational tools are critical to ensuring that your marketing and sales materials are ready to go at launch.

An associated area of launch readiness is establishing your regulatory philosophy and process. There should be alignment across the organization about risk tolerance and the approach to medical, legal, and regulatory review. A clear regulatory philosophy is needed to determine whether you will pre-clear launch marketing materials with the FDA's Office of Prescription Drug Promotion (OPDP) for example. The advantages of pre-clearing include getting OPDP feedback or suggestions on how to revise select claims and gaining insight into how "consistent with labeling" guidance is being applied by the FDA. The disadvantage of pre-clearing is largely related to speed to market. After submitting draft launch materials, the sponsor company should not disseminate the same or similar claims while an OPDP review is pending. This typically means a delay of three months to a full commercial launch.

Align on the Day-of-Approval Plan

Successful launch teams develop a compelling value proposition, an insight-driven brand strategy, prioritized customer segments, and a highly targeted engagement plan identifying the tactics required at approval and for the first 90 to 120 days after approval. But what happens at approval? This requires a very specific plan.

A day-of-approval plan identifies the actions and responsibilities within the first 48 hours after approval. It's a highly detailed plan that identifies what needs to happen when and by whom within one hour of approval, within four hours, eight hours, etc. The first 48 hours after approval are intense, and the entire cross-functional team as well as your agency partners and external vendors need to be ready. Be realistic about what you can get through your MLR team. It's not unusual to need three full days of MLR to get through everything requiring approval. Keep in mind that one change to one core marketing piece can have an impact on 10 to 15 other pieces. It's critical that there is a clear process for tracking and reviewing changes and ensuring consistency across all the newly developed materials. We've found it helpful to have an agency team member on-site during the important 48-hour launch window to help support this work.

Fostering a Launch-Ready Organization

The creation of a launch readiness team and a launch roadmap are logical starting points for companies approaching their first commercial launch. Harnessing the enthusiasm and collective experience of a newly formed team — internal and external — requires leadership, planning, and clear decision-making. The road to a first commercial launch is exciting, and yes, stressful at times. But when helping to bring a lifesaving or life-changing new therapy to patients, it's worth the trip.

Dudnyk *is a full service healthcare advertising agency that provides rare insights and creativity, with a rare approach, with rare talent, all within the rare disease space.*

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WHY UNIFY

In specialty and rare disease communities, HCPs do not always see the totality of a patient's disease burden or the benefits that new therapies may provide. Likewise, patients often struggle to express their needs or be their own advocates for treatment.

It is our belief that only by uniting these audiences—through empathy, understanding, and shared responsibility—can we help specialty brands reach their true potential.

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