Top 10 Considerations for a Product Launch

Both Established and Emerging companies face substantial business and technology transformation when introducing a new product to the market. For start-up pharmaceuticals, the transition from an R&D organization to a commercial revenue-generating company is a pivotal time that requires careful operational planning. This is to ensure limited resources are maximized not only for that first launch, but also to prepare the path for the company's sustainability and subsequent success of the company's pipeline.

Having led several pharmaceutical launches from a program management perspective, we understand that this is always an exciting yet challenging time for a pharmaceutical company. Leading this type of initiative requires a particular skillset. Launch programs involve commercial, development, clinical and medical, legal and compliance, regulatory, product supply, HR, finance and IT knowledge. A successful PMO will need to have knowledge of all of these disciplines to effectively navigate and lead a very diverse cross-functional team through the most important milestones in the company's journey.

After some retrospection, there are some elements that consistently rise to the top for every one of these launches and are part of the assessment a company would benefit from as it initiates this type of program:

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1 INITIATE LAUNCH READINESS PLANNING AS EARLY AS POSSIBLE

Although the starting point of launch readiness planning is not fixed, there are milestones in the product clinical development cycle that serve as guides to initiate launch planning efforts. Some companies start as early as during phase 3 trials; others initiate efforts at the readout of positive pivotal data, which is a less risky approach, but considerably limits the time to prepare.

2 VALUE PROPOSITION & INNOVATION OF THE PRODUCT

Ensure the company has clearly defined the clinical need for the product in the market, coupled with innovation and/or superiority (quality of life, delivery, outcomes) versus existing therapies. Preparing and offering at the right price point will allow for a better negotiating position and increased approval potential with health authorities, payers and HCPs/HCOs. Clearly define the unmet need, the burden of disease and/or level of dissatisfaction.

3 PREPARE A ROBUST COMMERCIAL STRATEGY & PLAN

A brand team has one shot at effectively launching in an indication. A robust commercial strategy will clearly define the unmet need, the burden of disease and/or level of dissatisfaction, source of business, forecast, market dynamics, competition and prepare for all potential barriers once in the market. A robust commercial strategy will also take into account the next three to five years to continue driving growth and continue evolving with the market and be nimble to react to changes.

4 IMPLEMENT COMMERCIAL & PRODUCT LAUNCH PLANNING PROGRAM

Conduct an assessment of the company's readiness to transition successfully to a commercial organization or launch a new commercial product, and provide a comprehensive plan to accomplish this goal. By engaging the cross-functional leaders, the launch plan will include interdependencies, deliverables and key milestones per function. The integrated plan will also provide project management structure and tools, launch resourcing and talent management plan, gap analysis, risk and mitigations plan and clear team and individual accountability.

5 BUILD YOUR FUNCTIONS WITH THE RIGHT PEOPLE

Launching a pharmaceutical product with limited resources, budget and time is not for the faint of heart. Ensure your functions are staffed with experienced and committed leaders and team members who are flexible problem solvers. These creative team players will be able to manage the rapidly changing environments and priorities. Do not compromise on hiring the right people for each role. While it is difficult to keep work moving while having gaps, finding the right people elevates the function and launch team and lowers turnover in the long run.

6 HAVE COMMERCIAL CMOS IN PLACE FOR PHASE 3

Ideally, the CMOs will be in place and operational when manufacturing the phase 3 clinical product. This provides a better chance for registration batches and corresponding stability studies to be completed in time for submission, ensures your commercial product is an exact reflection of the product used in clinical trials and allows the company to better prepare for pre-approval inspections during review of the submission.

7 ENGAGE THE MSL & MARKET ACCESS TEAMS EARLY

This is particularly important for a company launching its first product or launching a product in a therapeutic area where there has not been any type of innovation for many years. Having these teams early on will help the company identify real life practices and opportunities, as well as help shape a robust publication and HEOR plan and timely correct any false assumptions in the commercial plan. It also allows for start-up companies to begin creating awareness of their presence and clinical programs within the target market, payers and advocacy groups.

8 IDENTIFY THE RIGHT KOLS FOR YOUR PRODUCT

Alignment with KOLs from clinical trials and identifying the true believers in your drug as well as early adopters is critical for Advisory Committees, Speaker Programs and Ad Boards. Ensure KOLs practice in settings beyond academia and clinical research. Sometimes the best KOLs are up and coming doctors who are open to new therapies and new paradigms that benefit patients.

9 FOSTER CONSTANT AND TRANSPARENT COMMUNICATION WITH THE FDA

Consistently communicate with the FDA and ask for feedback and confirmation of the agency's position. By doing so early on, companies are able to change strategies or tactics if needed within reasonable budget and time. Waiting for the NDA filing when there is no time to react to major change requests from the agency is just too late. Also ensure the company is highly responsive, complete, respectful, friendly and clear when responding to FDA questions. Building good relationships with FDA PMs is critical for helping manage through the NDA/BLA process.

10 IMPLEMENT THE PROMOTIONAL REVIEW COMMITTEE AS EARLY AS POSSIBLE

(18 months to 2 years prior to launch) Allow for time to implement the infrastructure, cadence, key claims and SOPs. Foster a common understanding of FDA promotional requirements, changing external promotional landscape and data dissemination considerations in the current environment. Allow for a collaborative review and discussion on core messaging, including perspectives of external advisors if needed. Develop the Core Claims document and build a process and schedule that will allow a timely review of a vast amount of draft material in preparation for an approved label.

Each product launch is unique. Opportunities and successes vary from one product and therapeutic area to another. At a macro level, the above tenants could serve as the main pillars of the launch journey. Keep in mind that you only get one chance to launch the product and this is the mantra by which successful companies and launch teams operate to drive their processes, thinking and decision making.

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