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OPPORTUNITIES | MEDICAL AFFAIRS

Is A Key Function Of Product Launch Excellence Being Overlooked?

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Understandably, most pharmaceutical company leadership teams are doing their very best to do as much as possible with limited resources. As part of the streamlined pinch, smaller companies in certain geographies tend to either leave the medical affairs function off the organizational chart in the early stages of establishment or create a lean medical affairs structure. In larger organizations, while medical affairs may be a fully functioning unit, the team tends to be relied on as an ad hoc service provider, brought in as internal advisers. In both cases, pharma organizations may miss major opportunities to set their new products up for launch excellence by preparing the market and differentiating products from competing ones post-launch.

Today, many of the best drug therapies generally address a clear unmet need, were developed in less-crowded markets, fit into existing reimbursement and payment models, and are clearly differentiated from established standards of care. Particularly as the healthcare industry continues to shift to be more value-based and patient-centric, excelling at each of these factors requires a deep scientific understanding of the clinical landscape and trusted connections to the patient, provider, and payer communities. To this end, medical affairs can make a critical difference in launch excellence.

MAKING CONNECTIONS FOR SUCCESSFUL LAUNCHES

As one of the key functions within a pharmaceutical organization that can affect any stakeholder at any time, medical affairs can be a driving force in helping KOLs access clinical evidence and other investigational product information they are interested in pre-launch. This allows them to confidently select an appropriate drug treatment to meet patient needs post-launch.

Furthermore, while KOLs generally are early adopters who are eager to be the first to know of innovations that promise to significantly improve the safety and efficacy of care standards, they also tend to be skeptics. For KOLs to become interested in and convinced of the promise of a new investigational or marketed product, they require scientific evidence. Whereas commercial teams legally must keep their conversations with healthcare providers in line with approved product labeling and only discuss registered drug therapies, medical affairs — per definition of its functional role and responsibilities — can hold scientific discussions with physicians, including conversations relating to clinical trial results of investigational products. That means that medical affairs is uniquely positioned to share meaningful, insightful, and significant clinical data with KOLs.

In addition, in conversation with KOLs, and in an unsolicited manner, medical affairs staff can cover the range of perspectives, including the competitive, payer, and healthcare system landscapes. They can interpret and contextualize scientific evidence, so decision makers can understand the safe-

ty and efficacy of given products. They also can support the generation of real-world evidence following the registration of a product to assist the healthcare community in developing treatment guidelines and provide insights into product use in a real-life and real-time patient treatment setting.

Furthermore, medical affairs can help identify and engage key patient advocacy groups, medical associations, and payer groups (together with the market access team) to help build awareness of a company and product. During these interactions, they also can help to optimize patient access and use of medical treatments by demonstrating the pharmaceutical value of medical products to healthcare professionals, payers, and other stakeholders.

At the same time, through all of these exchanges and the provision of responses to medical inquiries from healthcare professionals and the general public, medical affairs will be gathering insights to inform their organization's multifaceted launch strategy and laying the groundwork for adoption and product positioning.

GETTING A HEAD START ON STAKEHOLDER ENGAGEMENT

As key liaisons to the external stakeholder community, medical affairs team members should be integral parts of the launch-planning process. While theoretically, organizations can map and begin conducting outreach to KOLs in short order, building trust takes time and multiple touchpoints, especially for lesser-known companies that do not have the benefit of legacy and reputation. Ideally, organizations should begin outreach 18 months or more prior to product launch and plan to conduct a range of engagement efforts, including participating in one-on-one meetings, scientific conferences, advisory boards, and roundtables. They should also plan to disseminate compelling scientific data and disease-state content to drive disease awareness (especially for rare diseases).

With all this in mind, realistically, pharmaceutical companies should be considering the design of their stakeholder outreach strategies far earlier in the product life cycle, ideally during the Phase 3 pivotal clinical trial stage when preliminary results become available relating to drug safety and efficacy. At that stage, usually enough is known for medical affairs to initiate conversations on the drug profile with KOLs and, as appropriate, other stakeholders. Another benefit of holding these discussions earlier is that medical affairs can glean crucial insights from KOLs that can help inform and shape the launch strategy from product development through commercialization and ongoing promotions.

GENERATING EVIDENCE-BASED, COMPELLING CONTENT

Because of their scientific understanding of the clinical landscape and their access to KOLs and other external stakeholders, medical affairs has a holistic view of the needs of target audiences and influencers. As such, research and evidence generation represent additional important areas in which the expertise of medical affairs can inform and strengthen the product launch strategy.

For example, medical affairs can help design compliant, tailored training modules and assist in the development of content for scientific platforms. All these materials need to be evidence-based, compliant, scientifically sound, and compelling. With their clinical understanding and access to external stakeholders, medical affairs is again uniquely positioned and qualified to weigh in throughout the entire product life cycle and notably during the pre-launch phase of any investigational product.

In addition, by bringing the medical affairs team into early content strategy and deliverables planning processes, marketing can effectively and strategically streamline the content generation and materials review processes. The medical affairs team can help the marketing team home in on compelling product claims and key statements that are compliant and resonate with KOLs and other target audiences for the development of thought leadership and marketing materials for dissemination post-launch. Medical affairs also can provide guidance on what clinical information can be shared from a compliance, product label, and medical governance viewpoint.

FOSTERING CROSS-FUNCTIONAL ALIGNMENT

These are just a few of the important ways medical affairs can help advance a product strategy for launch excellence. As externally oriented scientific experts, medical affairs can help inform many other facets of product planning and overall decision-making, encompassing R&D and clinical development, sales and marketing, and market access. (For reference, the Medical Affairs Professional Society offers the comprehensive *Medical Affairs Launch Excellence: Best Practices for Medical Affairs* guide.)

By involving medical affairs early in the pre-launch planning process, cross-functional teams can work together to develop a forward-looking strategy for all necessary launch phases and ongoing commercialization efforts related to clinical strategy, product positioning/differentiation, and stakeholder engagement. Because of its focus area and responsibility, the medical affairs function is uniquely positioned to help set the strategic commercialization plan early in a product's life cycle, assess current and future market and competitive landscapes, and establish strong product narratives. Leveraging medical affairs as a key business partner can help propel the entire cross-functional team toward success. L

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