Preparation of the Market for a New Drug With an Effective ‘Medical Affairs Launch’

The Medical Affairs function can play a vital role in today’s product launch process

By Gary Tyson and Kayler Doyle, Campbell Alliance

MEDICAL AFFAIRS IS GROWING INTO AN INCREASINGLY critical function in today’s biopharmaceutical industry. Access challenges are limiting contact between sales representatives and physicians at a time when therapeutic areas are becoming increasingly crowded. Prescribers want to remain informed, and pharmaceutical companies are looking for ways to raise awareness of the attributes of new products to distinguish them from competitive alternatives. Further, reimbursement policies from global payers are exerting greater influence on prescribing behaviors, leading companies to shift some of their focus from physicians to managed care organizations.

With the ability to educate key opinion leaders (KOLs), a well-executed medical affairs launch strategy can help inform important stakeholders regarding the promise of an upcoming drug.

Although the roles of Medical Affairs have not been altered, the new industry climate has raised the visibility of the functional area, and their activities have become increasingly critical for communication with important stakeholders.

There are risks to how deeply Medical Affairs is involved in launch activities. FDA guidance on permissible activity is unspecific. The primary precaution to take is to have a corporate compliance function, with documented guidelines for internal company practices, and to review Medical Affairs activities against these guidelines.

The importance of Medical Affairs at launch

The role of the Medical Affairs (MA) function is to educate stakeholders through the delivery of accurate, complete, and unbiased information that supports a product. MA activities must comply with federal, industry, and company regulatory policy and are not designed to “promote” a product or substitute for Sales and Marketing practices. All materials distributed through the activities of MA should be reviewed for compliance with existing regulatory policies.

With the ability to carry out peer-to-peer discussions, medical science liaisons (MSLs) have frequently been granted greater access than the sales force to physicians and KOLs. (MSLs often operate within an MA department.) Whereas sales representatives must limit discussion to the product label of a marketed product, discussions with MSLs center around scientific exchange related to broader topics. KOLs look to MSLs to provide information that could benefit their research interests, including information on pipeline drugs and the development plans for those drugs. This communication of meaningful information is the foundation of ongoing relationships between KOLs and MSLs.

How to carry out a Medical Affairs launch

Launching a pharmaceutical product requires an immense amount of operational planning, and effective execution of a medical affairs launch is no different. As the medical affairs launch is meant to prepare the market prior to entry, many critical activities must take place well in advance of actual launch. To facilitate planning, the medical affairs launch needs to be coordinated as a set of activities divided by time frames prior to and following market launch. Time frames are divided into Early Market, Pre-Launch, Launch, and Post-Launch phases, each with a set of objectives and activities (See Table).

Early market

The Early Market stage of the medical affairs launch includes activities that initiate the market planning and preparation in the time frame greater than 24 months prior to actual launch. At this early stage, the primary objective of Medical Affairs is to propagate thought leader interest in the product.

To begin to generate thought leader interest in the drug, the Medical Affairs team must first develop a KOL strategy associated with the product. The strategy will include a detailed list of KOLs to engage, based upon their interest in research and education for the given indication. MA departments must make a judgment as to which KOLs to target, and they often consider input from commercial and clinical development in those decisions. For example, there could be only a handful of KOLs for a rare disease, or a completely new indication being
targeted by the developmental drug. On the other hand, a new drug entering a market where there are already approved treatments could involve a large number of KOLs, since physician preferences have already become established. KOL identification is a targeting exercise.

During early interactions, MSL teams should begin to inform KOLs regarding the science behind the new product, ongoing trials and timelines, and the results of emerging data as they are made public. Of course, it is important to reiterate that interactions must comply with FDA regulations that prohibit the promotion of an investigational drug as being effective or safe, and balanced information including both positive and negative results should be disclosed.

Further external education activities should also take place during the Early Market stage. Scientific exchange resources, such as mechanism of disease (MOD) and mechanism of action (MOA) presentations, slides summarizing key data from medical meetings and congresses, and summaries of changes to practice guidelines, should be created to facilitate sharing of information. In addition, speaker programs can be initiated to raise awareness of the disease state, current therapeutics, and current gaps in patient care. During this phase, the function within MA responsible for medical communications should create their publication and congress plans.

MA should also lend support to registrational trials. Through its ties with KOLs, MA can contribute to site identification and patient enrollment when needed. Further, they can provide general support for clinical trials to monitor progress. Where needed, a designated Clinical Trial Liaison (CTL) may be assigned to help supervise trial management and keep progress moving forward with minimal delays.

In terms of internal education, MA is tasked with helping the new brand team become familiar with the science of the drug and the disease area itself. MA also needs to keep the competitive intelligence section of Marketing informed by collecting and reporting relevant information from congresses and KOLs on therapeutic trends in clinical practices related to the disease, current standard of care, and competitive compounds in development and on the market. (This is an example where information flows from MA to Sales/Marketing.)

Pre-launch

Pre-Launch includes the time between 24 and 12 months prior to market. At this stage, MA must ensure that key thought leaders who drive treatment guidelines and protocols understand the drug.

Within the Pre-Launch phase, KOLs who are part of the defined strategy need to be assessed to determine their base knowledge and experience with the pipeline drug. This baseline measurement will be critical to monitor increased awareness with continued outreach and facilitate an assessment of how extensive the scientific exchange will need to be in order to accomplish desired levels of drug knowledge. Further, the interests of the KOLs can be assessed during discussions to gauge appropriate scientific exchange and any potential opportunities for future investigator-initiated studies (IIS). Again, to steer clear of any regulatory compliance concerns, it is important that trial concepts be derived from the investigator and not initiated by the MSL.

How outside research, through IISs or otherwise, is funded has been a hot-button issue for regulatory review. Pharma companies stay on the safe side of these guidelines by not initiating the subjects of studies. On the other hand, however, a drugmaker is not compelled to fund every study that is proposed. It can be helpful by publishing, for public review, topics that it is interested in pursuing, and that those topics have been vetted by the corporate compliance department and the IIS review committee.

External educational activities during this stage include presentations of appropriate data at key congresses, advisory boards, and clinical investigator meetings. These meetings are imperative to share relevant data with thought leaders and continue to foster relationships. The MA function responsible for medical communications should begin publishing and presenting the pivotal trial data as reflected in the timeline of the overall launch strategy.

During Pre-Launch, Medical Information (a division of MA) should establish an operational plan for the call center function, which will manage adverse-event reporting, handle queries from prescribers and others. Medical Information should also monitor trial data and scientific literature to prepare for specific questions about the product itself as well as general questions about the competitive space.

The Pre-Launch time frame is appropriate for generation of an IIS strategy. The process for submission and review of study proposals needs to be developed and approved. For registrational trials, MA should continue to contribute to patient enrollment and support the trials as needed and appropriate.

Internal education during this period should focus on the sales force and the managed markets function. Clearly, these groups need to know information about the indication and the unmet needs in the market. These stakeholders should be well-informed with regard to the disease state, the drug in development, trial data, and ongoing studies. Market updates related to competitive intelligence should continue to be collected and provided to relevant stakeholders.

Launch

The Launch period includes the time from 12 months prior to the market launch. During the Launch phase, the objective of Medical Affairs is to make sure that prescribers have a clear understanding of the use for the drug.

When in the Launch phase, KOL outreach needs to focus more on the product itself than the general disease state. As such,
<table>
<thead>
<tr>
<th>Medical Affairs Activity</th>
<th>Early Market (over 24 months before launch)</th>
<th>Pre-Launch (24 to 12 months before launch)</th>
<th>Launch (from 12 months before until launch)</th>
<th>Post-Launch (up to 12 months after launch)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External Education Activities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KOL Planning and Engagement</td>
<td>• Create KOL strategy, profile, and detailed KOL list&lt;br&gt;• Create specific KOL strategy related to health economics / outcomes research&lt;br&gt;• Collaborate about science (e.g., MOD, MOA), trials, and timelines&lt;br&gt;• Share emerging data as appropriate</td>
<td>• Establish appropriate level of scientific exchange to determine KOL knowledge base, opinions, and interests</td>
<td>• Expand scientific exchange to include compound-specific attributes and physician perceptions&lt;br&gt;• Support speaker training activities as appropriate</td>
<td>• Solicit feedback from KOLs related to the acceptance of product among various physician specialities&lt;br&gt;• Learn, report, and document issues faced by physicians&lt;br&gt;• Continue expansion of scientific exchange to include clinical practice guidelines and additional areas of study</td>
</tr>
<tr>
<td>External Education and Scientific Exchange</td>
<td>• Create scientific exchange tools and resources&lt;br&gt;• Oversee speaker programs on disease state, current therapeutics, and patient care gaps</td>
<td>• Present appropriate data at key congresses, advisory boards, clinical investigator meetings, and other appropriate groups</td>
<td>• Present appropriate data at key congresses, advisory boards, clinical investigator meetings, and other appropriate groups</td>
<td>• Present appropriate data at key congresses, advisory boards, clinical investigator meetings, and other appropriate groups</td>
</tr>
<tr>
<td>Medical Communications / Publication Planning</td>
<td>• Create a publication / congress strategy and plan&lt;br&gt;• Disseminate disease state awareness information as appropriate or needed&lt;br&gt;• Communicate early trial data and any distinguishing attributes</td>
<td>• Publish and present pivotal trial data consistent with overall strategy</td>
<td>• Publish and present pivotal trial data consistent with overall strategy</td>
<td>• Publish and present pivotal trial data consistent with overall strategy</td>
</tr>
<tr>
<td>Medical Information / Call Center</td>
<td>• N/A</td>
<td>• Establish operational plan for medical information / call center function&lt;br&gt;• Monitor literature and trial data to prepare for questions about the product and the competitive space</td>
<td>• Respond to patient and physician inquiries&lt;br&gt;• Generate information to disseminate to patient and physicians</td>
<td>• Respond to patient and physician inquiries&lt;br&gt;• Monitor adverse events</td>
</tr>
<tr>
<td><strong>Trial Activities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registralional Trials</td>
<td>• Contribute to site identification and patient enrollment as appropriate&lt;br&gt;• Provide general support for clinical trials</td>
<td>• Contribute to patient enrollment as appropriate&lt;br&gt;• Provide general support for clinical trials</td>
<td>• Solicit KOL feedback on strengths and potential weaknesses of data supporting registration</td>
<td>• N/A</td>
</tr>
<tr>
<td>IIS</td>
<td>• N/A</td>
<td>• Create IIS strategy and process</td>
<td>• Review ISS proposals if consistent with ISS strategy</td>
<td>• Review ISS proposals&lt;br&gt;• Oversee approved IIS progress</td>
</tr>
<tr>
<td>Phase 4 Studies</td>
<td>• N/A</td>
<td>• N/A</td>
<td>• Contribute to Phase 4 strategy and planning&lt;br&gt;• Lead or contribute to health economics / outcomes research programs</td>
<td>• Initiate and oversee Phase 4 studies</td>
</tr>
<tr>
<td><strong>Internal Education Activities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal Education</td>
<td>• Help newly formed brand team get up to speed on science and disease area</td>
<td>• Educate sales force and managed markets function on disease state, drug, clinical data, and trials</td>
<td>• Educate sales force and managed markets function on disease state, drug, clinical data, and trials</td>
<td>• N/A</td>
</tr>
<tr>
<td>Market / Competitive Intelligence</td>
<td>• Collect and report relevant information gathered from congresses and KOLs about clinical practice and therapeutic trends, standard of care, and specific compounds and products</td>
<td>• Collect and report relevant information gathered from congresses and KOLs about clinical practice and therapeutic trends, standard of care, and specific compounds and products</td>
<td>• Collect and report relevant information gathered from congresses and KOLs about perceptions of the product to be launched</td>
<td>• Collect information about how the launched product is being received</td>
</tr>
<tr>
<td><strong>Medical Affairs Objectives</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Objective for Product</td>
<td>• Help generate thought leader interest in product</td>
<td>• Ensure all key thought leaders who drive treatment guidelines and protocols understand the drug&lt;br&gt;• Make sure that there is clear understanding of the use for the drug</td>
<td>• Ensure prescriber questions are answered and that they know exactly how to use drug</td>
<td>• Ensure prescriber questions are answered and that they know exactly how to use drug</td>
</tr>
</tbody>
</table>
Preparing the Market for a New Drug With an Effective ‘Medical Affairs Launch’

scientific exchange should increasingly include information regarding compound-specific attributes and physician perceptions of the drug profile. Data from these interactions can help determine strategy for further outreach to prepare for market launch. External educational via congresses and advisory boards should also expand the scientific exchange to include further information regarding the product. Publication of trial data that differentiate the product from its competitors is critical and needs to occur at this stage.

With regard to trials, KOL feedback regarding the strengths and potential weaknesses of the data package supporting registration should be collected (another example of how MA data-gathering efforts can flow over to sales/marketing). Review of IIS applications should proceed, and those that fit into the overall IIS strategy should be accepted. During this period, the generation of a Phase IV strategy should also commence to map out studies that can further differentiate the product post-marketing.

The task of informing internal stakeholders during Launch includes further education of functions and teams as needed. While in the Launch phase, Competitive Intelligence should remain up-to-date on perceptions of the product gathered through congresses and interactions with KOLs. This will allow brand teams to respond accordingly with further outreach and marketing campaigns during this critical time.

Post-launch

The Post-Launch phase of the medical affairs launch is the time frame up to 12 months following market launch. During this period, MA must ensure prescriber questions are answered and that they know exactly how to use the product.

During Post-Launch, MA should seek feedback from KOLs related to the market launch of the product. Specifically, information must be collected regarding acceptance of the product among prescribers and issues being faced with the drug. Scientific exchange needs to expand to include discussions surrounding clinical practice guidelines and potential additional indications or areas of study. Further, the product call center should respond to all patient and physician inquiries and monitor adverse events reports.

Post-Launch is the appropriate period for commencement of non-registrational trials. During this stage, IIS and Phase IV studies can be initiated. MA should continue further review of IIS proposals and facilitate overseeing the ongoing studies.

For competitive intelligence, MA should maintain the collection of information relating to how the launched product is being received by physicians and patients. These valuable data will help to update marketing efforts as deemed necessary.

Conclusion

With increasingly crowded therapeutic areas in the pharmaceutical industry and a more restricted promotional environment, MA must increase its role in product launch. Clearly, preparing the marketplace for new product launch can drive increased awareness at launch and increase the probability of success. Taking a structured approach to enhance medical affairs activities surrounding launch can increase the knowledge of thought leaders for the indication, who subsequently educate other physicians.

Although this framework demonstrates best practices, it is not without challenges. Many MA groups are already stretched in their abilities to adequately cover the activities related to inline products and are not staffed to allow taking on further responsibilities until they are an absolute imperative. Further, the enhanced roles of MA are still relatively new, and many groups have not developed programs to optimize effectiveness prior to launch. In fact, some internal company policies restrict the ability of the field MA teams to discuss pipeline products with thought leaders.

To maximize product awareness and uptake as soon as it hits the market, there needs to be a shift towards MA taking a more proactive role in launch preparation. Since thought leader influence over prescribers occurs progressively, the medical affairs launch must begin early in the planning process, and many key activities must take place well before the actual launch.

There seems to be clear case, today, for expanding the roles and responsibilities of Medical Affairs. How much is enough? There is no exact rule to follow; deciding how much is “enough” is more art than science. Generally, drugs for conditions addressed by primary care physicians will require more MA effort. And medical specialties that are heavily driven by the latest science—such as oncology—will require more MA effort.

Preparing for launch is massive exercise in operational planning. Proper market conditioning through medical affairs activities can have a real impact on increasing product awareness at launch, but has largely been neglected in terms of practice. With an increased focus on medical affairs activities prior to launch, the brand team will find physicians more knowledgeable about the drug and its distinguishing characteristics, thereby facilitating early success. PC

ABOUT THE AUTHORS

Gary Tyson is Senior Vice President, Clinical Development and Medical Affairs Practice Area, for Campbell Alliance (8045 Arco Corporate Drive, Suite 500, Raleigh, NC 27617; tel: 919 844-7100; www.campbellalliance.com. Kuyler Boyle is Principal Consultant, Thought Leadership, at the firm.