SPECIAL TEAMS

Specialty companies seeking a promotion partner typically look for one that can amplify the brand's reach among high-prescribing PCPs. As Kowa Pharmaceuticals America's **Roger Graben** and **Mark Sullivan** explain, that's hardly the only capability to look for in a partner

Although there are many factors which lead a specialty pharma company to seek a co-promotion partner, typically the primary reason is to expand the share of voice in the marketplace for their product or products. In addition, the company typically seeks to partner in a manner that enables their product to be promoted beyond specialist physicians alone. It is often imperative to reach a significant number of high-prescribing primary care physicians in order to maximize the true potential of the brand. Although this increased share of voice (SOV) is the initial driver, it is critical for the specialty pharma company to identify what other key capabilities are sought in a partner. Below we outline a process similar to the one Kowa Pharmaceuticals America, a specialty pharma company focused on cardiovascular therapeutics, has used in selecting and establishing recent partnership activities.

Seeking synergies

The goal is to look for a partner whose capabilities add to the overall strength of the combined partnership. Although the specialty company may be a fully integrated pharmaceutical company, certain areas of the company are almost always more or less developed than others.

With the ever-growing influence of managed care, it may be beneficial to partner with a company which has a large established presence in managed care. While distribution capabilities may exist or may be easily outsourced, a partner with a large dollar volume of distributed products may obtain significantly better terms with wholesalers. A company's specific wholesaler terms are usually confidential, it is, however, general knowledge that sales volume dramatically influences terms, as is typically true in most areas of business.

Each company seeking a partner should identify their areas of strength and weakness prior to initiating the search for a partner. This will enable a more objective evaluation of what each potential partner might bring to a deal. Ultimate success in partnering is obtained only when the partnership is more than the simple addition of individual capabilities. When synergies are captured, the partnership has the potential to contribute to the total business, not simply increase SOV.

The seeking of a co-promotion partner to increase SOV centers largely on post-launch sales activities. However, there are significant pre-launch advantages as well. For example, an upfront payment from a partner may be important in contributing to pre-launch expenses which may be significant for an emerging or newly established specialty pharma company. Any capabilities added may significantly contribute to launch preparedness.

Pre-launch success is critical to initial uptake which we know may dramatically influence long-term brand success, or lack thereof. One key long-term advantage is that a co-promotion partnership may allow an emerging specialty company to grow their brand(s), while using the revenue generated to more fully develop internal capabilities and infrastructure.

Biz-dev speed dating

There are many avenues for seeking a co-promotion partner. Much like marketing activities, typically an arsenal of activities are employed and no single avenue leads to success. One avenue is one-on-one

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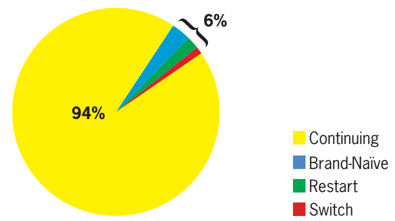
Measuring specialty brand growth

Measuring specialty products with multiple indications and understanding their underlying performance drivers are daunting challenges for brand managers. Until recently, brand managers for specialty products also lacked sufficient integrated information regarding the performance of their products—and their competitors'—within the specialty mail-order channel.

An opportunity for growth



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Source: IMS Health

How can one manage the growth of specialty products without knowing how much business is coming from each indication or distribution channel? Knowing such answers has far-reaching implications—in identifying new growth opportunities, positioning against the competition, developing effective messaging, allocating sales and promotional resources, and understanding the performance of brand and sales teams. Thanks to the recent availability of longitudinal, de-identified, patient-level data from specialty pharmacy providers (SPPs), specialty brand managers can better understand the dynamics of their market.

Following is an example of how one top-10 pharmaceutical company was able to identify whether its maturing product was losing share or whether newer entrants with multiple indications were growing in areas in which the company did not compete. Prescription volume was reported for the products of interest for the following eligible patients:

Brand-Naïve New to therapy for the product of interest and not on therapy for any of the products in the defined market during the 12-month look-back period

Switch Filled a prescription in the look-back period for a different biologic product

Restart The product of interest was dispensed in the look-back period, but far enough in the past to exceed the typical refill period (in this case, a 45-day allowable gap)

Continuing The current biologic product was the same as the prior product and was refilled within the 45-day allowable gap

Tapping the dynamic market Initial results were helpful in determining the degree to which the competition within its indications was impacting its business. For the product's primary diagnosis, results revealed that 94% of the market continued on therapy (see Fig. 1). Total continuing patient volume increased for all leading specialty products in the most recent 12 months. However, during the same timeframe, the client's product lost share within the dynamic portion of the market—the 6% of patients who were starting or changing therapy. Meanwhile, competing products increased share and new specialty products had entered the market.

Also, over the prior year, physicians within a specialty of interest increased their use of biologics for a specific diagnosis. They did not, however, treat the disease with any of the leading products, including the client's, suggesting that there existed an opportunity for growth.

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partnering meetings. Pre-meeting software allows attendees to search for in-licensing, out-licensing and co-promotion opportunities, and request and arrange brief 15- to 30-minute meetings with a number of companies over the course of two or three days. Some describe this as business development speed dating, and it allows one to interact with numerous potential partners in one location in a limited timeframe. Examples of these meetings include—but are not limited to—BioNetwork East, BioNetwork West, BIO Windhover, Bio, BioPartnering North America and others.

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Another method is to prepare a non-confidential summary of the opportunity and proactively send to other companies. It is typical to begin with targeted partners with perceived interests and advantages then widen the audience as needed. This is most effective with known contacts, but certainly others are targeted as well. Membership directories such as the Licensing Executives Society membership directory may be very helpful in identifying contacts. Professional networking sites such as LinkedIn are becoming popular methods of sharing business development opportunities as well.

Not to be overlooked is general networking, public relations and serendipity. Maintaining a company presence by attending and participating in various business development meetings and events is critical to general awareness of a company and potential partnerships.

Press releases regarding completion of significant steps such as successful completion of clinical trials, filings and approvals are significant means of heightening awareness of a specialty pharma company, its pipeline and products. Although many partnerships appear to begin serendipitously, usually a company has been proactive in the above activities and this results in what appears to be serendipity.

In-depth discussions

Once potential partners are identified, confidentiality agreements are put in place and more in-depth discussions and exchange of information may begin. Although business development teams and legal are involved very early in the process, it is critical to expand the team as soon as it appears discussions will significantly advance. Input from brand management and other key implementation and operational leadership is critical to the ultimate success of the partnership.

A co-promotion agreement developed by business development and legal alone and "handed-off" late in the process has little chance of success. Due diligence teams require participation from all areas of each company. For example, a co-promotion agreement around a product with regulatory or supply chain issues would be a liability, not an accomplishment.

It is obvious that issues such as number of sales reps, physicians to be targeted, sales metrics and so forth be identified at least at a high level relatively early in the process. As discussed above, the ideal case is to partner with an organization that brings capabilities to the partnership that the specialty pharma company may not have fully developed.

Defining the deal

The most critical component of the agreement is to thoroughly define how the deal will be implemented and governed once the partnership is in place. The organizational make-up of key functional teams and executive oversight teams should be clearly defined in the agreement. Dispute resolution and ultimate decision making authority in various scenarios should be clearly defined. The key governing bodies are identified below;

■ **Executive Committee:** The senior most leadership team associated with the brand. Responsible for reviewing the overall strategic direction for the partnership, this group approves the annual business plan for the brand, the forecast and the operating expense budget. This committee also oversees and rules on items that have been escalated from the other committees below it. A solid partnership works out their issues within their own committee and rarely has items that need to be escalated to this level.

■ **Operating Committee:** Comprised of sales, marketing, finance and operational leaders who handle the day-to-day promotion of the brand. They meet monthly or quarterly to track the brands progress. This team is responsible for developing the annual brand plan and sets the strategic direction for the brand.

■ **Manufacturing Committee:** Comprised of operations, marketing, sales forecasting and manufacturing & packaging personnel. This team meets monthly to track product shipments and adjust product manufacturing up or down based on current or anticipated brand sales trends.

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■ **Research & Development Committee:** This team is comprised of medical affairs, regulatory, research & development and marketing personnel. This group is accountable for any Phase IV commitments, Phase III work toward new indications, line extensions, formulation development and overall lifecycle management. Marketing sits on this committee to ensure future work on the brand is in line with the long-term strategy for the brand.

■ **Promotional Review Committee:** This team is comprised of medical affairs, regulatory, legal and compliance and is responsible for reviewing promotional materials ensuring consistency with DDMAC guidelines.

Once the agreement is in place, brand leadership leads the implementation and operational aspects of the deal. In addition, Alliance Management should play a key role in monitoring and reporting adherence to the agreement itself and assist in facilitating governance committee meetings and activities. Alliance Management may also assist in connecting people across the organizations. ■

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