Small molecule products are no longer the growth engine of the pharmaceutical industry. Rather, growth in today’s market is driven by specialty products, due in part to the unique opportunities in oncology, rheumatoid arthritis, multiple sclerosis, and rare diseases. Pharmacy benefit manager (PBM) Express Scripts projects that US spending on specialty prescription drugs will increase 67% by the end of 2015. In its drug trend forecast, Express Scripts also predicts that prescription drug spending on 8 of the top 10 specialty therapy classes will continue to increase over the next three years due to the strong pipeline of new biologics as well as physicians delaying treatment of patients until the new drugs hit the market.

Specialty drugs, many of which are delivered via injection or infusion, are high-touch products often requiring special handling and distribution, including cold chain storage or refrigeration. The FDA may also mandate specific patient education and administration requirements for these products in the form of a risk evaluation and mitigation strategy (REMS). While specialty products are high touch, expensive, and have special handling requirements, they ultimately need to be managed just like any other asset with respect to the product life cycle. This is particularly true when it comes to developing a distribution strategy.

In a specialty market, the distribution strategy is as important to healthcare professionals and patients as is the product’s overall clinical and economic value proposition. And as the brand evolves, the distribution strategy needs to evolve to support the brand needs at any given point in the life cycle.

In fact, a suboptimal distribution strategy at launch could compromise the life-cycle trajectory for the brand. This article provides a framework for developing a specialty distribution strategy in order to maximize the long-term potential of a specialty brand by reflecting on the needs of all key stakeholders: physicians, patients, and critical intermediaries, including specialty pharmacies and distributors.

Consider Key Elements

A number of key considerations will help determine the type of specialty network that will be required:

- Disease state
- Patient type
- Product profile
- Route of administration
- Handling requirements
- Healthcare professional demands
- The competition
- The portfolio

The framework for the specialty distribution strategy starts with an understanding of the disease state and the patient type.
The target patient population, patient site of care, and route of drug administration are all important elements that assist with informing the demands of a product distribution strategy.

The next step is to determine the demands of the product from a handling or management standpoint. Is there a requirement for cold chain storage or is there a REMS program assigned to the product? Is patient education required?

The third level is the demand on the healthcare professional. What does the product mean in terms of how the physician office goes about its daily business? Does ordering or administering the product disrupt customary practice patient flow? For example, does use of the product require a lengthy patient observation period following administration?

The competitive landscape must also be considered. If the product is not the first to market, what are the distribution strategies of the currently marketed products? What do the distribution strategies look like, and which intermediaries are involved in the product fulfillment process?

Finally, manufacturers must give consideration to their broader portfolio (e.g., other in-line specialty products and late-stage development programs). The manufacturer must also be mindful of line extensions, including different routes of administration and other indications that would influence how it develops the distribution strategy and evolves the distribution strategy over time. What other labels is the company pursuing? What is the current distribution landscape in those other diseases?

An additional consideration to be taken into account throughout the life cycle of the brand is the potential impact of healthcare reform. Reform provisions will be coming into effect in 2014 and beyond, affecting things like reimbursement and CMS quality measures. Such changes could have implications for a specialty distribution strategy over the life of the product.

**Determine the Size**

Determining the size of the specialty network at launch is contingent on the objectives of the distribution strategy. For example, if the goal is simply to have a distribution platform/strategy in place to get patients on the drug as quickly as possible once a prescription is written, then a wide open network that allows all specialty pharmacies to be able to purchase the product through wholesalers might be preferred. However, if the objective of the distribution strategy is to have more control over where the product is being used and visibility into distribution partner progress, then the manufacturer may opt for a preferred network. In a preferred network, the manufacturer facilitates fulfillment of its drug through a select group of preferred trade partners.

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**Types of Distribution Partners**

<table>
<thead>
<tr>
<th>Parent Company</th>
<th>Specialty Pharmacy Provider</th>
<th>Partners Within Parent Company</th>
<th>Third-Party Logistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSG</td>
<td>US Bioservices</td>
<td>Lash Group TheraCom</td>
<td>Integrated Commercialization Solutions (ICS)</td>
</tr>
<tr>
<td>Cardinal</td>
<td>OncoSource Rx</td>
<td>Access Services</td>
<td>Specialty Pharma Services (SPS) Integrated Logistics Services</td>
</tr>
<tr>
<td>Express Scripts</td>
<td>CuraScript</td>
<td>HealthBridge</td>
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</tr>
<tr>
<td>Medco*</td>
<td>Accredo</td>
<td>Proherant</td>
<td>Accredo 3PL</td>
</tr>
<tr>
<td>McKesson</td>
<td>Oncology Rx Care Advantage</td>
<td>Patient Relationship Solutions</td>
<td>Supply Chain Solutions (SCS) Pharmacy Systems</td>
</tr>
<tr>
<td>US Oncology†</td>
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<tr>
<td>Omnicare</td>
<td>Advanced Care Scripts</td>
<td>Rx Crossroads</td>
<td>Rs Crossroads</td>
</tr>
<tr>
<td>Walgreens</td>
<td>Walgreens SP</td>
<td>Has Hub Capabilities</td>
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<tr>
<td>BioScrip‡</td>
<td>BioScrip</td>
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Notes:
*Medco purchased by Express Scripts in April 2012.
†US Oncology purchased by McKesson in December 2010.
‡BioScrip purchased by Walgreens in May 2012.
A third option would be a limited or controlled distribution strategy, in which only a small handful of partners have access to the product in order to provide the manufacturer with complete visibility into product movement and allow for a very intimate understanding of what is happening with the drug and with the patients.

This option may be selected in circumstances in which a rigorous REMS is called for, requiring the manufacturer to have a level of control in managing the product.

**Determine the Key Players**

When it comes to determining the key players that should be involved in the distribution strategy, consider the following factors:

- Business model (e.g., payer-owned, PBM-owned, retail-owned, wholesaler-owned, independent)
- Therapeutic expertise, including clinical program support
- Market coverage

Figure 1 provides examples of various types of distribution partners, and Figure 2 shows the affiliations of some of the well-known specialty pharmacy providers.

The appropriate mix of distribution partners (e.g., third-party logistics providers, specialty distributors, specialty pharmacies) is a function of the product and its specific fulfillment requirements. However, trade partners generally fall into three main buckets: the must-haves, the nice-to-haves, and selected regional partners.

The must-haves are the foundational building blocks necessary to reach critical mass. Generally, the must-haves are represented by some of the larger specialty organizations. It is important for manufacturers to carefully consider these organizations in their network because of their reach and scale. Strategically, they are also valuable due to specific relationships with other market stakeholders such as payers, retailers, or wholesalers.

Nice-to-have specialty partners can add value and help to round out a distribution strategy network. Then there are various regional players that are useful to have in a network depending on the therapeutic area in which the product competes. The regional players provide spot-market value, and, strategically, they help hit certain market areas.

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**Affiliations of Specialty Pharmacy Providers**

<table>
<thead>
<tr>
<th>Specialty Pharmacy Providers With Managed Care Organization/Pharmacy Benefit Management Affiliation</th>
<th>Pure-Play Specialty Pharmacy Providers</th>
<th>Specialty Pharmacy Providers With Parent Company</th>
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</thead>
<tbody>
<tr>
<td>Affiliation</td>
<td>SPP</td>
<td>Affiliation</td>
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<tr>
<td>Aetna</td>
<td>Aetna Specialty Pharmacy</td>
<td>Acaria Health</td>
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<td>Argus Health Systems</td>
<td>Amber</td>
<td>Avella (Apothecary Shops)</td>
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<td>Anthem</td>
<td>Precision Rx</td>
<td>Ascend Medical / Medfusion Rx</td>
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<tr>
<td>Cigna</td>
<td>Cigna Specialty Pharmacy</td>
<td>Axium</td>
</tr>
<tr>
<td>Kaiser Permanente</td>
<td>Kaiser Specialty Pharmacy</td>
<td>Biologics</td>
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<td>RightSource Rx</td>
<td>BioPlus</td>
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<td>Procare Rx</td>
<td>ProCare PharmacyCare</td>
<td>CareMed</td>
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<tr>
<td>WellCare</td>
<td>Exactus WellCare</td>
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Assess the Strategy Over Time

The specialty product manufacturer needs to manage the network as the product matures. The distribution strategy that is right at launch may not be the same strategy required 18 months out, three to five years out, and beyond. As the product matures, the distribution strategy needs to factor in various external environmental considerations, such as evolving competition in the therapeutic category. Manufacturers will need to think differently about the distribution strategy when new products enter the market.

The manufacturer will need to periodically re-assess and recalibrate the strategy. At launch and during the first 12 to 18 months on the market, the drugmaker should be looking for product trajectory and uptake. Getting the appropriate patients on the medicine—and keeping them on—is key to the success of any product, particularly a specialty drug.

Presuming a wide open network at launch, after 12 to 18 months, it generally makes sense to examine how the network is performing by reviewing specific metrics (e.g., drug approval rates, time to fill, duration of therapy). It is also important to look at how specific specialty partners within that network performed, identifying the top performers as well as those organizations that have not done as well getting patients on product or on performance metrics like time-to-fill and patient adherence.

From that analysis, companies can begin to make decisions around unmet specialty network needs and the degree to which specific launch goals have been attained. It may also be necessary to reconfigure how the company engages with these partners to improve performance.

Three to five years out and beyond, when the company is dealing with a more mature product, life-cycle considerations and the competition become a major focus. New entrants will likely emerge, and the manufacturer will need to make strategic decisions around the level of investment to maximize the top-line revenue of the brand.

Shape the Patient Experience

With a high-cost agent that requires some level of management, the ability to engage and inform the patient is vital. The patient experience hinges on engaging the patient as soon as the doctor prescribes the product. The specialty pharmacy partners play a key role in ensuring the patient has a positive experience with the medication.

For example, depending on the programs the manufacturer has put in place, once the patients are prescribed the drug and go home, they may receive a phone call from a hub or specialty pharmacy’s call center. The call will likely come from a nurse or nurse practitioner who will check in with the patients about the product and share information about when they can expect to receive it. The nurse likely will check back with the patients after the drug has been delivered.

Patients can also opt into voluntary programs that share patient information via web presentations or direct mail. A major aim of these programs is to provide a positive experience to patients and in the process capture and activate them. Anything a manufacturer can do through its distribution network to engage and retain patients is vital to the long-term success of the brand.

Conclusion

The industry has historically focused on shaping a clear brand equity position to physicians and patients. And more recently, companies have come to appreciate the importance and need of developing an appropriate pricing and market access (i.e., payer coverage) strategy. For specialty products, an equally important aspect of product performance at launch and throughout the product life cycle is the distribution strategy.

The distribution strategy is no different from any of the other key considerations in launching a brand. It needs to be the right strategy for that product, which includes making sure it meets the patient’s needs, the physician’s needs, and even the physician office staff needs, particularly if it is a buy-and-bill product that physicians are purchasing. If done improperly, it can cost a specialty product a significant amount of business on the front end of the launch. Further, the distribution strategy needs to evolve over time to factor in product life-cycle management, the competitive landscape, and healthcare reform and other policies that can come into play and necessitate a change in strategy.

A great product with a poor distribution strategy not only hurts at launch, it also negatively affects the overall life-cycle trajectory. When it comes to the specialty distribution strategy, the old notion “you live with what you launch” very much applies.

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