

PHARMACEUTICAL GOMMERCE

Business Strategies for
Pharma/Bio Success

Fine-Tuning Specialty Distribution

Specialty manufacturers have a range of options to consider in how to go to market

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SPECIALTY PHARMACEUTICALS ARE THE FASTEST growing segment of drugs in healthcare in the United States. With projected US growth of 178% from 2003-2010, the dollar value of available specialty drugs will surpass that of generic prescription medications.[1] Sales of specialty drugs are estimated to exceed \$75 billion in 2009 with cancer drugs representing over 30% of these sales.[2]

Most specialty drugs target complex diseases such as cancer, rheumatoid arthritis and hepatitis C, representing a relatively small population of patients when compared to prescriptions dispensed by retail pharmacies. These drugs are composed of complex molecules and biologics. Vaccines and cosmetic dermatological drugs are also included in the category of specialty pharmaceuticals. Conditions treated with specialty drugs generally require infusion or injection of prescribed treatments; however, oral oncology drugs are emerging within the fast-growing specialty pharmaceutical market.

About 35% of specialty drug therapies are administered in a physician's office or clinic as part of a longer term therapy regimen. Another 22% are administered in a hospital. Approximately 19% of specialty drugs are mailed from a specialty pharmacy directly to the patient who self-administers or has a caregiver administer therapy at home or in a nursing care facility. The remaining 22% of specialty pharmaceuticals are purchased by retail and independent pharmacies and nursing homes.[3]

Specialty drugs, biologics and plasma have unique characteristics posing challenges to each stakeholder involved in the product life cycle: manufacturer, distributor and healthcare provider. They are complex and therefore, expensive to manufacture. In distribution, they require specialized temperature and handling controls. At a hospital or clinic, they are often injected or infused, producing another level of complexity.

Temperature controls

Because of their unique composition and limited shelf life, specialty drugs frequently require special handling to ensure product viability when received by the hospital, physician,

Disease State	Monthly Cost-Specialty Drug Treatment
Cancer	Oral drug therapy: \$3,500-\$5,000
	Multi-drug therapy: > \$15,000
Rheumatoid Arthritis	\$1,500-\$3,000
Multiple Sclerosis	\$1,700-\$4,000

Fig. 1 Cost of treatment by disease state. Source: Medco

caregiver or patient. Cold chain management and temperature controls are critical to the product being received by the end user in manufacturer-recommended conditions.

McKesson uses a customized Warehouse Management System (WMS) that tracks items on a first-expired, first-out (FEFO) basis. This system prompts product rotation according to lot numbers and corresponding expiration dates and conducts cycle counts by lot number to ensure accurate receiving and shipping. Electronic scanning is used at each touch point in the distribution process to track the lot and date of each shipment received. A unique ID used during each inventory step collects additional tracking data and increases accountability. As cold chain and inventory management are critical for manufacturers in choosing and retaining a distribution partner, McKesson encourages customers to audit these processes on a regular basis.

In addition to temperature controls inside the distribution center, product-specific packaging and shipping is often required, and recipients must be properly educated as to how to manage the package upon receipt. For example, vaccines shipped from McKesson to physicians across the United States and its territories in support of the Centers for Disease Control & Prevention's (CDC) Vaccines for Children Program are clearly marked "Refrigerate upon receipt" and include specific temperature controls and instructions inside the package.

High costs

Annual costs of therapy for a complex disease requiring specialty pharmaceuticals can be more than \$100,000 with the highest costs being multi-drug therapies to treat cancer. The combination of high costs and low volume for specialty drugs in comparison to non-specialty prescribed medications

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highlights the need to ensure that the distribution channel partners have the necessary process expertise and experience to minimize waste or spoilage. High drug costs also heighten the need for manufacturers and physicians to understand the reimbursement landscape and work effectively with payors to ensure needed therapies are supported and out-of-pocket costs to patients are managed. For biotech manufacturers, developing effective reimbursement and/or patient assistance strategies can become as important as identifying the appropriate distribution channel. For physicians, understanding payor reimbursement requirements and ensuring practice management systems adhere to those coding and therapy guideline directives is imperative to profitability and ultimately, optimal patient care.

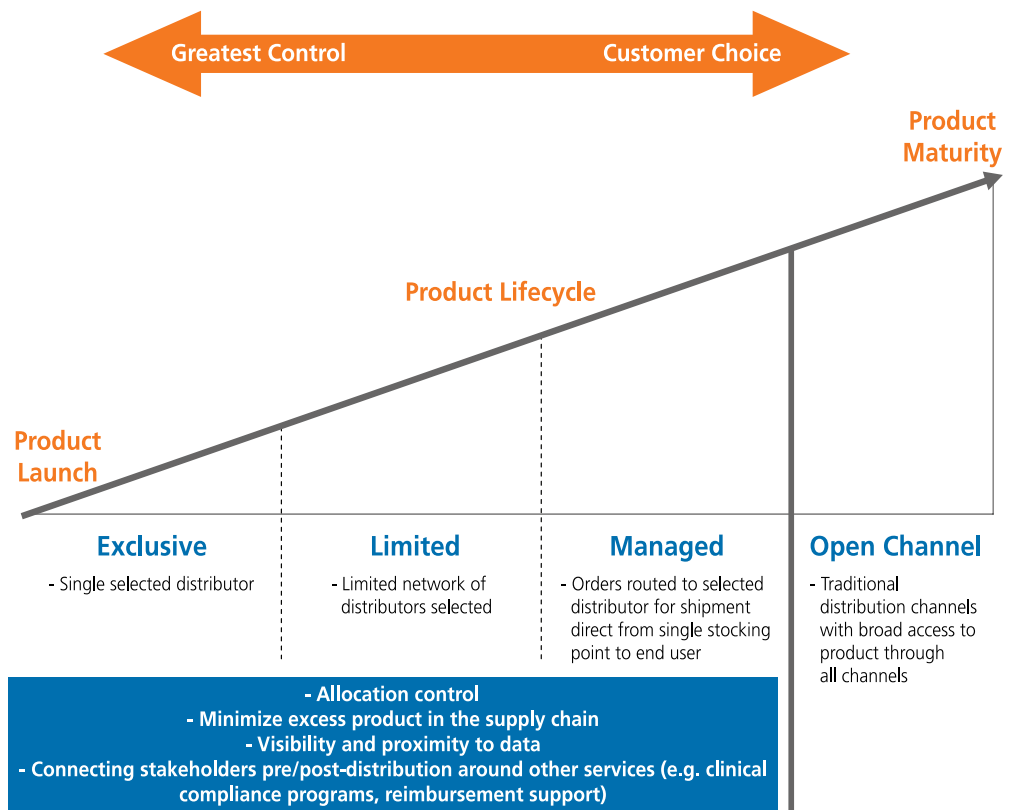


Fig. 2. Distribution strategy options range from exclusive agreements to open channel distribution. Source: McKesson Specialty Care Solutions

Controlled distribution

As discussed, specialty drugs have unique compositions that require temperature-controlled environments. Even with optimal temperature management, however, specialty pharmaceuticals have a shorter shelf life than other over-the-counter or prescribed medications. As well, the cost to manufacture a specialty drug and the relatively low demand when compared to other prescribed medications results in limited production and availability.

In some cases, such as with plasma, available quantities are limited and require allocation management. Inventory management processes within the distribution channel become vital in managing allocations and ensuring the biologics and plasma are directed to the most appropriate customers in the needed timeframes.

In addition, external factors intensify the unique needs related to specialty distribution. Increasingly, the Food and Drug Administration (FDA) is requiring Risk Evaluation and Mitigation Strategies (REMS) to be in place in order for a manufacturer to receive FDA approval for a new and/or existing specialty drug. REMS is “a strategy to manage a known or potential serious risk associated with a drug or biological product.”[4] According to the FDA website, “A REMS will be required if the FDA finds [it] necessary to ensure that the benefits of the drug or biological product outweigh the risks of the product, and the FDA notifies the

sponsor. A REMS can include a Medication Guide, Patient Package Insert, a communication plan, elements to assure safe use and an implementation system and must include a timetable for assessment of the REMS. Some drug and biological products that previously were approved/ licensed with risk minimization action plans (RiskMAPs) will now be deemed to have REMS.”

Another factor weighing into the manufacturer’s choice of distribution solution is desired control, access and proximity to the information that may be available. Increasingly at launch, manufacturers want near real-time information regarding purchasing behavior, enrollment in mandatory REMS or insight into a complex payor landscape. The power of channel strategy comes to life when these important decisions are contemplated and designed into the market launch strategy.

The above demands call for high distribution controls to ensure that available quantities of specialty pharmaceuticals and biologics are distributed optimally; timely data are accessible to the manufacturer; and safety programs are utilized to meet FDA-mandated requirements that accompany the specialty drug’s approval. The “pick, pack and ship” wholesale distribution process commonly used to support brand and generic drug distribution will not support these unique needs of specialty pharmaceuticals, biologics and plasma.

Specialty distribution strategy & options

Specialty pharmaceutical and biologics manufacturers must develop a distribution strategy that meets their market penetration goals and manages the necessary controls to drive optimal usage and ensure required safety. Because each specialty pharmaceutical or biologic may come with unique needs and circumstances that may change throughout the product life cycle, all distribution channel decisions are made on a product-specific basis by the manufacturer.

In many cases, the selected vendors use a traditional open channel distribution model where the distributor takes full ownership of the specialty drugs when it receives the product in the distribution center and bears all credit and collection risks and responsibilities with the customer. This model drives significant economies of scale with operating efficiencies in supply management, contract pricing administration and credit and collection processes. Manufacturers, therefore, dramatically decrease their own logistics and material-handling costs and credit risks.

In some cases, the business model may require third party logistics (3PL) services, and the distributor does not take ownership of the product but does provide warehousing, contract administration and pick/pack and/or shipping services. A current example of a 3PL distribution model is the CDC's Vaccines for Children Program exclusively distributed through McKesson. Being federally-mandated, this program is a very unique business model. Vaccines distributed by McKesson in support of this program are federally-funded to the grantees; therefore, no cost of goods is transacted, large stockpiles are managed in case of epidemics and substantial variation in seasonal demand exists particularly during flu season.

Exclusive Distribution:

Choosing one vendor to distribute a specialty pharmaceutical provides the maximum control over which customers will have access to the product. In cases where product availability is limited or allocated due to manufacturing or supply constraints, exclusive distribution can be employed to direct product to specific hospitals or physician clinics. In addition, using a single distributor optimizes the ability of the manufacturer to drive physician and/or patient education, improve patient therapy adherence and track safety programs to meet FDA requirements.

Exclusive distribution is most often used when a new product is launching, and the manufacturer seeks timely and targeted market access and needs to ensure that risks are managed relentlessly throughout product launch and growth. In cases where exclusive distribution is the chosen strategy, manufacturers should engage their distribution partner early in the pre-FDA approval planning and

expect their specialty distributor to be a subject matter expert in REMS consultation, program development and management as well as needed reimbursement and patient access programs.

Limited Distribution:

Offering similar benefits but with less control than exclusive distribution, limited distribution enables a manufacturer to enlist a small network of distributors to supply the marketplace with their specialty pharmaceutical. With limited distribution, the manufacturer is not reliant solely on a single distribution partner.

If limited distribution is chosen and the manufacturer requires a reimbursement and/or patient assistance program, utilizing a distributor with the expertise to develop and support these programs may offer the manufacturer efficiencies in process and economies of scale. Having a single partner provide an integrated solution supporting patient access and/or reimbursement programs, distribution and/or REMS enables a seamless flow of information for the manufacturer and drug recipients who may be physicians, patients or caregivers.

Managed Distribution:

Managed distribution is often employed by emerging manufacturers or those who do not want to invest in the infrastructure needed to meet growth objectives and/or intensifying FDA-required safety and risk mitigation programs. Infrastructure includes logistics, controls and supply management that, without product scale, are costly investments for a manufacturer to make for a high cost, low volume pharmaceutical product.

A large specialty solutions organization like McKesson has the infrastructure in place that enables manufacturers to cost-effectively meet needed control requirements without making the capital investment. McKesson's specialty business is supported by three distribution centers with a total of 125,000 square feet all designed specifically for high volume, low unit-of-measure orders. Each facility has 15-19 hours of continuous shipping and receiving daily with a total of over 56,000 units shipped per day. In addition, the state-of-the-art LaVergne, TN specialty distribution center has ample room for expansion to support this fast-growing segment of healthcare.

Employing a managed distribution strategy, orders are routed to the selected distributor for shipment directly to the end user from a single stocking point. The managed distribution service provider has a dedicated telephone number and client service representatives for that manufacturer program making the end user experience seamless and transparent.

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Non-exclusive Distribution:

Non-exclusive distribution is commonly called an “open channel” environment and is most often utilized for more mature specialty drug products and/or those that have the least need for controls. Manufacturers optimizing an open channel environment will generally utilize multiple distributors to drive distribution to hospitals, physicians and patients or caregivers.

A non-exclusive channel strategy will likely include a specialty distributor such as McKesson with a large, established base of hospital, clinic and physician office customers who are using a “buy and bill” approach to specialty therapy as well as a specialty pharmacy that mails specialty drugs directly to the patient or the patient’s caregiver which may include a nursing home or home care nurse. In all cases, a reasonable set of competencies are needed to ensure drugs are received in manufacturer-recommended condition and patient adherence and education are supported.

Market penetration beyond distribution

Manufacturers should look to their distribution partners to support their objectives for appropriate utilization and provide subject matter expertise as external factors such as REMS intensify. Larger, established distributors such as the 176-year-old McKesson have a built-in base of hospital and physician customers to whom they can provide access for new specialty products.

Beyond the chosen distribution strategy, manufacturers can also work with Group Purchasing Organizations (GPOs) to ensure appropriate utilization of a specialty pharmaceutical. GPOs, such as Onmark, a McKesson Specialty Care Solutions company, have physician and/or hospital members for whom they aggregate purchasing volume to negotiate competitive pricing with manufacturers. Manufacturers benefit from the potential volume growth of a GPO marketing their product to its members, and the GPO members benefit from the discounted pricing.

GPOs also offer additional benefits to manufacturers. For example, in addition to providing manufacturers ready access to its 4800+ physician members, through McKesson’s proprietary Lynx® technology (used by providers in practice management), Onmark provides manufacturers an innovative suite of information services, including demographic, diagnosis, drug administration and reimbursement data on more than 100,000 unique patients each month. Lynx technology includes HIPAA-compliant, web-based practice management solutions used by physician offices to improve

charge capture, inventory and cost management tracking and treatment and reporting. The data captured through the Lynx technology platform are aggregated and give manufacturers valuable insight to help them work with physicians to ensure appropriate utilization of the specialty drug therapy.

Choosing a distribution strategy and a partner for a specialty drug or biologic is essential to success. While distribution is critical to getting the product to market safely and swiftly, the chosen organization should be considered a strategic partner helping the manufacturer navigate the increasingly stringent external factors including FDA approval, REMS management, patient access and reimbursement of specialty drug therapies. As well, that partner must possess a 360-degree view of the landscape to support the manufacturer in driving awareness, penetration and ongoing appropriate usage of the specialty drug therapy to optimize patient outcomes. Finally, identifying a distribution partner that can effectively serve multiple distribution models will enable the manufacturer to drive success and continuity of service levels to end users throughout the product life cycle from a more controlled distribution at product launch to supporting and implementing a marketing strategy for the product as it matures. **PC**

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