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PHARMACEUTICAL DISTRIBUTION —

Right-Sizing the Channel Strategy for Maximum Impact

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Bringing innovative, life-enhancing therapies to market is at the heart of the pharmaceutical industry's mission. But today more than ever, it is imperative to explore novel, strategic points of access to connect the therapy with patients and providers. For maximum impact, the goal of any product distribution strategy is to innovate in ways that can compress the supply chain and reduce the number of steps and handoffs along the way.

The pharmaceutical industry has been experiencing unprecedented complexity in many forms — from the steady rise in specialty therapies that require time- and temperature-sensitive delivery modes to the ongoing supply chain shocks and pinch points, shifting sites of care, the complex reimbursement landscape and the changing rules of patient-provider engagement. This backdrop calls for a bold reimagining of the traditional channel distribution model in favor of a more agile, innovative one that integrates a select array of services to best fit the needs of the brand and the concerns of prescribers and patients.

Fortunately, there are more and more options available — options that were not available decades ago. When done right, such efforts can help to reduce risk and ensure reliable and timely drug delivery and demonstrable value for all stakeholders.

For drug developers — particularly in certain therapeutic categories and for smaller or startup companies — an enormous competitive advantage can be created when the distribution channel that connects the manufacturer to prescribers and patients can be made as short and as taut as possible. The two prevailing models today — the full-scale wholesale distribution model and the specialty distributor model for niche therapies — are already fully established, but they are not ideal for every situation.

Instead, implementing alternative models can create new opportunities and advantages. One of the biggest challenges for new manufacturers is that the costs associated with using the existing channel models can be very high — creating a disproportionately high financial impact on the brand in an effort to gain access to select customers.

In recent years, there has been increasing appetite among manufacturers — and growing capabilities among specialized channel-distribution service providers — to shorten the value chain. The goal is to create a nimble, data-driven infrastructure that can connect the therapy to the customer base more effectively, helping to speed therapy onboarding for patients while improving visibility.

> "Failure to right-size the distribution model imposes avoidable financial penalties on the brand, wasting expenditures that could be focused on supporting the prescriber or patient while undermining the ability to reliably deliver therapies on time every time."

Challenging the Status Quo in Channel Selection

For pharmaceutical companies, the primary focus is on what they do best — discovering and developing therapies, working out the underlying chemistry and devising the optimal manufacturing and scaleup strategies. Their marketing and market access experts are always thinking about the right commercialization strategies, ease of access and optimal distribution channels. However, those endeavors do not always move in lockstep, and this can have a significant impact on the gross-to-net performance of the brand.

When drug manufacturers reflexively commit to a distribution model that is too cumbersome, they forfeit the flexibility that is needed to increase efficiency, maximize return on investment and minimize risk on a product-by-product basis. Alternatively, implementing a lean, customized distribution channel that is developed in close partnership with an experienced, end-to-end service provider enables improved visibility into all stages of product movement while helping to deliver therapies wherever the patient needs them — to pharmacies, hospitals, clinics and residences — with accurate, on-time delivery.

A defined channel distribution strategy is a connective tissue that links all stakeholders. It is counterproductive for the manufacturer to invest in its strategic field deployment team only to have a sales representative successfully convert a prescriber but then the patient experiences delivery delays.

DSCSA Is Changing the Delivery Paradigm

The pharmaceutical industry is moving swiftly toward March 27, 2023 — the date when full enforcement of the Drug Supply Chain Security Act (DSCSA) goes into effect. Yet many feel the industry as a whole is not ready yet. Complex track-and-trace requirements (down to the package level) that once were not required will soon be mandatory, with the overarching goal of putting safeguards in place to ensure that specialty pharmaceuticals for chronic and rare diseases are safely managed throughout the entire supply chain in ways that ensure product authenticity and integrity and are reliably available to patients when needed. Similarly, DSCSA will establish national licensure standards for wholesale distributors and third-party logistics providers and requires these entities to report licensure and other information to the FDA annually.[1] To ensure DSCSA compliance, pharmaceutical companies must select experienced, capable partners that are able to meet the FDA's requirements, helping to minimize risk for the drug manufacturer and ensure unimpeded access to life-saving therapies for patients.

Re-evaluating Operations Amidst Today's Supply Chain Challenges

While the pendulum seems to swing with drug companies moving between just-in-time manufacturing and inventory-management practices and a more conservative approach to maintaining adequate product supply, the patient at the end of the value chain is the focus and beneficiary of enhanced

Fundamental Access Strategy Considerations:

- Are you working with an agile and independent channel partner that has proven expertise, experience and infrastructure?
- What visibility is essential to support all stages of product movement, inventory and transportation?
- Can your supply chain partner provide state-of-the-art data analysis to ensure actionable insights and data-driven responses as issues arise?
- Does your partner have the connectivity and infrastructure to synergize high-value information across distribution, the patient hub and field deployment teams?

demand planning that acknowledges the inherent volatility throughout the pharmaceutical supply chain and the various options available to dampen the impact. The goal is to take all steps necessary through strategic planning and partnerships to ensure that patients don't experience any delays that can impede their ability to get on and stay on therapy.

The ability to work with an established, independent service provider gives commercial teams the opportunity to tailor the most efficient and appropriate channel strategy. For example, in certain therapeutic spaces (such as ophthalmology and dermatology), the team may be able to better target specialists (their key constituents) using a nimble, independent distribution channel, rather than flowing their product through the broader wholesale distribution channel. When commercial teams and their third-party service partners can address prescriber and patient concerns more quickly, they are able to improve brand reputation and value over time.

An agile distribution model can improve financial stability from the start, through the use of secure order and invoicing operations and processes. Manufacturers should choose a service provider that optimizes the order-to-cash operations through a scalable customer service team and working to minimize revenue leakage that can occur when managing account receivables. For instance, by using a comprehensive, full-service e-Commerce platform, patient-focused transactions can be automated and handled efficiently without the need to involve intermediaries such as wholesalers, specialty distributors and other middle players in the supply chain.

Today, an evolving array of tailored channel distribution solutions are available to meet the needs of today's complex therapies. Over time it has become increasingly clear that the traditional approaches — using the wholesale distribution model or specialty therapy distribution model — create undue burdens and missed opportunities for some brands. The existing infrastructure may not be focused or efficient enough, and these models often impose unnecessary costs when a more nimble distribution model would be more effective. The ability to partner with an experienced, independent service provider — one that invests in the necessary infrastructure, facilities, technologies and staff — can help manufacturers to deliver the goods in a more efficient and cost-effective way while reducing risk for the pharma brand team. Failure to right-size the distribution model imposes avoidable financial penalties on the brand, wasting expenditures that could be focused on supporting the prescriber or patient while undermining the ability to reliably deliver therapies on time every time.

REFERENCE:

1. https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

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