

# Pharmaceutical Brands versus Generics

How to leverage a digital supply chain network to manage products across their lifecycle and tackle the growing competition from generics





# HOW PHARMA BRANDS CAN USE SUPPLY CHAIN AS A COMPETITIVE ADVANTAGE AGAINST GENERICS

Pharma brands are currently navigating a challenging time in terms of managing their product portfolio and countering the threats from generic brands as late cycle molecules near the patent cliff and rampant product substitution starts taking place.

The product portfolios in large Brand Pharma companies also vary, and that creates a compounding stress impact on their supply chains, and the challenge of creating and sustaining a scalable supply chain operating model.

Although Pharma supply chains are typically global in nature (40 percent of Pharma products are traded locally/in-region as opposed to 50 percent in other sectors) there are critical ingredients, raw materials that are sourced locally that make some parts of the supply chain vulnerable to regional risks.

Pharma companies have also outsourced their production to a great extent to Contract Development and Manufacturing Organizations (CDMO) than other sectors (more than 60% of Pharma manufacturing is currently outsourced). This exacerbates the need for greater visibility and collaboration with CDMOs and upstream (Tier 2+) suppliers in order to respond to changing supply and demand shocks, and to make continuous adjustments.

Typically, Brand Pharma companies classify their product portfolio into three groups:

A. Early Life Cycle Products – Research and development stage: from the drug discovery up to its launch to the market. Focus on this stage is more on commercial innovation and less on operational excellence.

B. Mid Life Cycle products – The middle stage: the period between its launch and the loss of market exclusivity. This is a phase of growth and supply issues could cause serious impact on market reach and penetration.

C. Late Life Cycle Products – The late stage: the period after the loss of market exclusivity, when generics can enter the market. Operational excellence assumes critical importance as there is increasing margin pressure and push to reduce operating costs.

# HOW DO SUPPLY CHAIN STRATEGIES SHIFT **ACROSS THE LIFECYCLE OF A PRODUCT?**

Early Lifecycle – The key focus areas for products at this stage is speed to market. There are usually complex supply chain processes which lack scale, and there are multiple partners in the Sourcing, Manufacturing, and Distribution mix. Visibility and transparency across partners become key. Quality and batch release procedures play a big role in determining supply chain risk and resilience.

Mid to Late cycle - When the formulation stabilizes, Brands look at multi-supplier sources and manufacturing/distribution attains scale and operational efficiency. Lead times become an important attribute to measure and optimize and demand and supply shocks have a substantial impact on product profitability and market share.

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The pharmaceutical supply chain represents a network problem that requires real-time information and a single version of the truth for all parties. A network problem can't be solved with enterprise-centric thinking. We need a true network, with a supply chain control tower purpose-built for networks.

The supply chain of the future is no longer a chain. Redefined in its name and how it functions, the modernized value chain network enables optimization across every decision point, from research and development through manufacturing and distribution to consumers.

To maximize agility, optimization and resilience, we need to orchestrate processes across the entire supply network, not merely within an enterprise or node. This means orchestrating across customers to suppliers, from internal plants and contract manufacturers to distributors and logistics providers around the globe.

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# NINE WAYS PHARMA BRANDS CAN USE A MULTI-PARTY, MULTI-TIER NETWORK TO COMBAT COMPETITION

Let's examine how Pharma companies can leverage a digital supply chain network to manage products across their lifecycle and tackle the growing competition from generics.

#### 1. Leveraging Vendors from Multiple Sources

Moving to multi-source sourcing models provides leverage to reduce raw material costs. Historically screening and cGMP requirements have made switching vendors difficult in life sciences. Now, with multi-tier supply networks with prescreened supplier profiles, switching suppliers is faster and easier than ever.

#### 2. Improving Material Availability and OTIF Across the Value Chain

Pharma companies have grappled with fulfillment issues across their supply chains in spite of significant investments in forecasting engines. As pharma production moves from batch to continuous manufacturing models, material visibility across the value chain is critical to ensure stock availability. This is especially important given how the pandemic exposed the vulnerability of supply chains to sudden demand shifts and supply constraints that leave firms too little time to react and course-correct. A multi-tier, hub-to-hub control tower solution gives companies the opportunity to balance fulfillment and carry out effective Multi Echelon Inventory Optimization (MEIO), to optimize the trade-off across push-pull boundaries.

# **3.** Quality and Batch Release Process with Digitization and Predictive Intelligence for Greater Supply Chain Responsiveness

Quality yield could be a true wild-card in the supply planning and distribution flow, throwing standard scheduling rules off kilter. This is especially true with early lifecycle products that have changing assay rules, formulation and lower predictability of batch failures. A Quality System of Intelligence operating on a multi-party network that digitizes the batch release process and provides predictive insights, alerts, and scenario planning that provide significant value for Planning, Scheduling and Fulfillment teams.





#### 4. Smart Logistics

Cold chain monitoring and lot and batch-level traceability is crucial as Brand Pharma moves more towards biologics and cell therapy-based products. Product traceability across nodes and early warning of quality degradation as part of lot genealogy is critical in the wake of newer FDA regulations such as the Drug Supply Chain Security Act (DSCSA). An endto-end, multi-party network with a robust chain of custody is critical to ensure regulatory and patient compliance and to reduce brand financial and reputational risk.

#### **5.** Real-Time Visibility and Transparency Across Tier 1 CDMOs and Upstream Tier N Suppliers

As more and more Brand Pharma companies outsource their manufacturing, CDMOs have emerged as a strategic business partner for brands. A big Pharma company can have as many as 100-130 CDMOs to manage. They can no longer treat them as black boxes. Siloed legacy tech and non-standard data exchange models and formats have compounded the problems. With the emergence of multi-party networks with standardized API interfaces, companies can now attain real-time visibility across all trading partners. It's critical for Brands to gain visibility across several tiers of manufacturing to fully understand what suppliers are doing at every step of the way. This in turn, enables Brands to quickly adjust early in production cycles.

#### 6. Increased Supply Chain Responsiveness with Demand Sensing for Personalized Medications

The advent and growth of personalized meds has created a new concept known as "patient-centric supply chains." This is particularly relevant for chronic and complex ailments such as Alzheimer's, hypertension, COPD, and hemophilia. Patient Centric Supply Chains (PCSC) strive to optimize cost and service while shaping and improving the patient experience. With patients as hubs, supported by robust demand sensing models, and creating a connected network that allows each party to respond to changing demand trends, is a key strategic lever for Brand Pharma, particularly in areas involving complex therapy.

#### 7. Moving from Batch Planning to Orchestrated Multi-Tier Execution

Pharma Manufacturing processes have been traditionally batch or campaign-oriented. With the rise of Flexible MES, we can now significantly reduce changeover lead times. As a result, brands are moving towards concurrent planning engines which are turning traditional planning systems on their heads. In addition, platforms that provide unified planning and execution in a single system, are able to capture and consider real-time constraints. This integrated planning and execution is a major reason why organizations are moving towards multi-party control towers.

#### 8. Dynamic Supply Chain Risk Monitoring

In a recent survey by LogiPharma, 70 percent of supply chain heads in Pharma companies rated supply chain risk and volatility as one of their top three concerns. The pandemic has taught us new definitions and vistas of supply chain risk and disruption, and emphasized the importance of continuously and dynamically measuring risk across each node of the supply chain. Static risk engines that evaluate supply chain risk sporadically can't deal with ongoing global

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disruptions where supplier risks change almost on a daily or weekly basis. The key to solving this, is capturing risk related data and inputs across the several tiers of the supply chain, and putting data-engineered and curated AI models to work to deliver actionable risk monitoring protocols.

#### 9. Accelerating New Product Launches

As the Pharma industry undergoes a series of mergers and acquisitions, changing product mix and portfolios have become table-stakes. In addition, changing disease and epidemiological conditions, along with the emergence of new types of infections, have made new drug launches so common that they akin to cloud software companies regular product updates. This has put enormous strain on the drug supply chain as they grapple to balance operational excellence with commercial innovation.

New product launches bring a host of new supply challenges, including: manufacturing complexities, more CDMOs in the mix, a variety of packaging techniques, changing quality guidelines, and changing bill of material (BOM) and formulations, as well as the need to time product launches effectively to match demand and supply.

To deal with all these moving parts Brands need a multi-tier control tower that provides visibility, transparency, and drives collaboration across all nodes of the value chain.

# WHAT MAKES ONE NETWORK'S SMART CONTROL TOWER AND DIGITAL SUPPLY CHAIN NETWORK™ DIFFERENT?

All One Network solutions are multi-party, designed to connect and coordinate across trading partners, systems and networks. They are adaptable and extensible, to meet your needs now and in the future.

Because all solutions run on a single network, they work together intelligently and in real-time, so planning is always synched to execution, and supply is always synched to demand and coordinated with logistics.

Typical planning solutions run in batch process, using stale data, guesstimates for lead times, and take hours to prepare and run. So, by the time you have a forecast, no one has any faith in it.

The Digital Supply Chain Network's unique integrated business planning engines use actual demand and supply conditions to recalculate plans for every item at every location in real-time as needed. The optimized execution engines use these highly accurate plans to automatically execute the vast majority of transactions with real-time decision-making technology (NEO), enabling human intelligence to focus only on the exceptions that NEO cannot handle.





NEO Predictive Analytics and Smart Prescriptions are key elements of the NEO Platform. NEO intelligent agents continually monitor your supply chain to find and fix potential problems before they impact your customers and your business.

For example, NEO continuously analyzes real-time demand at the shelf, adjusts the forecast accordingly, and helps synchronize supply to demand. NEO also provides Smart Prescriptions which guide users step-by-step to optimally resolve complex issues.

# ABOUT ONE NETWORK ENTERPRISES

One Network is the leader in supply chain control towers and provider of the Digital Supply Chain Network<sup>™</sup>. It is the only solution that gives supply chain managers and executives end-to-end visibility and control with one data model and one truth, from raw material to last mile delivery. Powered by NEO, One Network's machine learning and intelligent agent technology, it enables seamless planning and execution, across inbound supply, outbound order fulfillment, and logistics, matching demand with available supply in real-time. Lead your industry by providing the highest service levels and product quality at the lowest possible cost.

For more information visit: <u>www.onenetwork.com</u>.

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