

# Light-footed operations: The virtues of agility in volatile times

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*Pharmaceutical operations are exposed, as never before, to disruptive events and volatile demand shifts. Agility thus is becoming a prerequisite for success, yet many pharmacos remain in firefighting mode. The leaders, by contrast, are developing a structural approach to agility, which helps them to improve their cost-competitiveness and to drive profitable growth through faster ramp-up of launches and fewer stockouts. Here's how to realize a step-change in supply chain agility.*

In a world that's getting "hot, flat, and crowded," to use Thomas Friedman's succinct phrase,<sup>1</sup> pharmaceutical supply chains are increasingly at risk. Because supply chains have become more global and interconnected, natural disasters such as the recent Japanese earthquake and tsunami, or political upheavals in the Middle East, can wreak havoc on the business.

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<sup>1</sup> Thomas Friedman, *The World Is Flat: A Brief History of the Twenty-First Century*, Farrar, Straus and Giroux, 2005.

When the 2010 volcanic eruption in Iceland stopped European air traffic, many pharmacos struggled to find alternative transport, leaving some lifesaving drugs out of supply for two weeks. The Japanese tsunami damaged numerous pharmaceutical plants, some of which may never reopen.

Other changes in the environment have combined to raise the pace and complexity of competition, which puts a premium on the ability to rapidly and efficiently adapt operations. Among the most important factors are these:

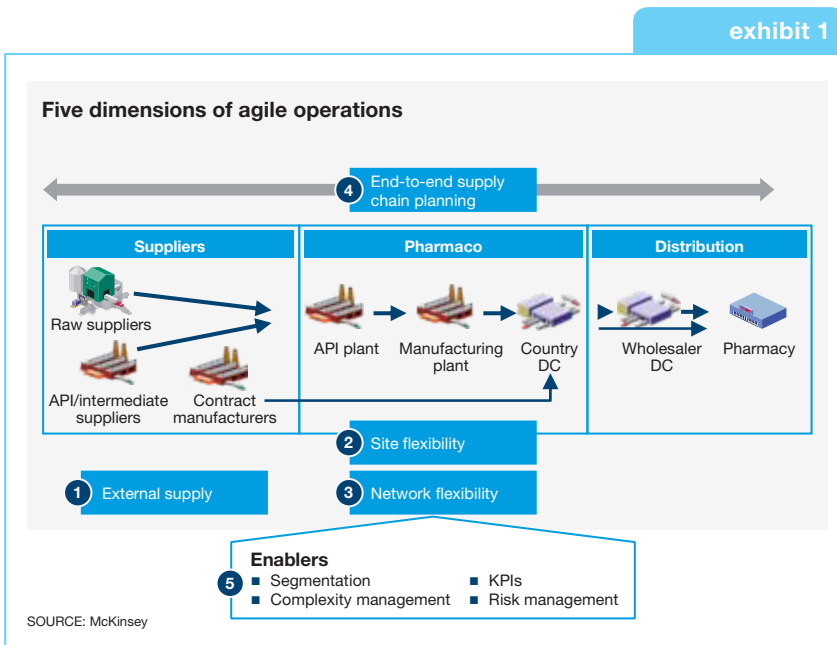
- **Demand volatility.** The traditional model of stable demand is being supplanted by more erratic patterns driven by tenders, rebate contracts, and unexpected pandemics and epidemics.
- **Generic challenge.** Between 2010 and 2015, drugs representing roughly 40 percent of pharma revenue are coming off patent, leading to higher levels of volatility and uncertainty.
- **Demand fragmentation.** As pharmacos focus on lifecycle extensions, new drug delivery systems, dosage forms, and packaging/marketing innovations are all increasing the number of SKUs, lowering the average SKU size and making product portfolios more complex.
- **Regulatory scrutiny.** Regulators are turning up the pressure on pharmacos to improve quality compliance and performance, as observed by the increased number of warning letters, fines, and import bans.
- **Higher working capital targets.** To free up more liquidity, companies need to tap the next level of inventory reductions. This will require a business model that features shorter lead times through a more agile supply system.

## Toward a system of agility

Some pharmacos have made reactive adjustments to improve their agility. For example, they might charter special airfreight capacity to respond to a natural disaster, or rush production orders after a batch failure to avoid a stockout on a critical product. Such fast issue resolution extinguishes the crisis fire, but it doesn't anticipate or prevent the next fire.

Pharmacos must be able to set up a system of *structural* agility that goes clearly beyond issue resolution and firefighting. Our research shows that building structural capability generally involves five operating dimensions (Exhibit 1):

- **External supply.** Creating and maintaining an agile supply base to quickly scale up or down the supply of materials and services.
- **Site flexibility.** Quickly adapting local capacities with minimal cost.



- **Network flexibility.** Supporting structural flexibility, and being able to rebalance it quickly and easily.
- **End-to-end supply chain planning.** Creating information transparency and use planning to keep supply synchronized with demand at any point in time.
- **Sustaining agility.** Ensuring and maintaining the right conditions for agility, in areas such as segmentation and performance measurement.

### External supply: Sources of agility

Many pharmacos are not capturing the full potential of an agile supply base. One reason is that they don't manage suppliers' flexibility with the same rigor and professionalism as they do pricing and compliance.

Consider the automotive industry by comparison. For a seat manufacturer delivering to a major automotive OEM, the annual frame contract defines an average output (say, 7,000 units per week) as a non-binding plan, calculated based on available supplier capacities at 90 percent utilization (five days, three shifts, running at 100 percent). Call-off orders against that contract follow clear contractual rules for upside/downside flexibility:

- Orders placed become binding three days before delivery date, with sequencing of orders possible until one day before delivery to align with the OEM production schedule.
- With four weeks' pre-advance, average output per week can be exceeded by 15 percent.
- With three months' pre-advance, average output per week can be exceeded by 30 percent, and with more than six months' pre-advance by 40 percent.
- Higher volumes require additional capacity and investment, which needs agreement by both parties.

Besides defect rate, unit cost, and adherence to sequence, upside/downside flexibility is a key dimension in the supplier scorecard. In exchange, the supplier has access to critical planning information, especially full visibility of the OEM production schedule and volume plan.

Pharmacos can substantially upgrade their own capabilities in supplier management by covering points such as: leveraging annual agreements to include call-off order and flexibility rules, exchanging demand and production plan information with key suppliers, running a supplier sales and operations planning (S&OP) process to proactively address capacity issues, and collaborating on projects to eliminate bottlenecks.

### Site flexibility: The living, breathing plant

When it comes to individual sites, volume flexibility—being able to increase or decrease production based on demand—is only part of the answer. Mix flexibility also figures in, even if volumes are stable, because changes in product mix can pose a major challenge. A third lever, smoothing fluctuations up front through capacity sharing, can be even more effective.

**Volume flexibility.** First of all, this involves labor. During the recent financial crisis, companies such as Volkswagen, T-Mobile, and Bosch used methods like adjustments to standard work time in order to deal with the drop in demand. Besides labor flexibility, companies need to develop the ability to make small, fast increases in capacity. The limiting issues here involve internal quality and external regulatory validation of new equipment. Pre-qualification of equipment could be a solution, although it comes at a cost.

**Mix flexibility.** This requires multi-skilled employees and flexible production equipment. Automotive players lead in this regard. BMW, for instance, can produce multiple models on the same production line in its Leipzig plant and can even easily integrate new technologies, such as new engines, as

needed.<sup>2</sup> But how can these capabilities be transferred to pharma? The key is to incorporate production considerations in the product design phase, so as to achieve maximum pack harmonization—the same blister pack or bottle formats that can be handled with less changeover time on one machine. Our experience shows that a radical harmonization of dosage forms, pack types, and pack dimensions can lead to substantial improvements in overall equipment effectiveness and unit cost.

**Capacity sharing.** Managing demand peaks and troughs can be addressed through active collaboration with other players. Bayer organized its human resource pool as an external company,<sup>3</sup> supplying labor both to Bayer and other companies and thus smoothing Bayer’s own fluctuations in labor demand. Looking outside the production context, many consumer companies have pursued such collaborations. Rivals Mars and Nestlé, for example, joined forces to manage the logistics related to the Christmas peak in confectionary sales, while Kimberly Clark and Unilever operate a joint warehouse to level out demand fluctuations.

## Network flexibility: Greater than the sum of its parts

When confronted with sudden demand shifts or disruptive events, a pharma should be able to quickly shift volumes in the network. Chiquita, for instance, shifted production to other regions when a hurricane struck its plantations in Honduras, which resulted in a 4 percent revenue increase during this crisis.<sup>4</sup>

For pharmacos, regulatory requirements once again pose a challenge, specifically the need for local authorities to approve each production site separately for each drug. Pre-certification thus is essential, ideally done in a structured manner, such as having two sites certified per product in order to ensure backup availability for strategic or high-risk products. Auto makers have been doing this for many years with a “round robin” scheme in which Product group A can be produced in plants 1 and 2, Product group B in plants 2 and 3, and Product group C in plants 3 and 1.

Shoe manufacturer Crocs exemplifies a truly agile network. Crocs balances in-house with outsourced manufacturing and production close to markets as well as in low-cost regions through its U.S. and overseas facilities. It has flexible relationships with suppliers, including minimal contractual obligations with primary third-party manufacturers in China. Crocs also has evaluated and qualified more than 15 alternative manufacturers in the event that current

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<sup>2</sup> BMW Plant Leipzig website.

<sup>3</sup> Jobactive website.

<sup>4</sup> A.J. Schmitte, “Using Stochastic Supply Inventory Models to Strategically Mitigate Supply Chain Disruption Risk,” *Logistics Spectrum*, 2008; and “Managing supply-chain risk for reward,” report of the Economist Intelligence Unit, 2009.

suppliers reduce or cease production. As a result, the company can rapidly adjust production as needed, shifting to meet demand surges in new regions, or for different models or colors. Crocs' mixed strategy reduces its own assets while simultaneously reducing complete reliance on just a few suppliers.<sup>5</sup>

While plastic shoes are significantly less complicated to produce and have lower quality requirements than pharmaceutical products, there is still a lesson to be learned. Indeed, some pharmacos are actively shaping their outsourcing strategy, choosing which production steps to outsource—and gaining flexibility for those steps. And others are pre-qualifying subcontractors to preempt a possible shutdown of current manufacturing partners.

## End-to-end supply chain planning: Running in sync with demand

The computer industry lives by the creed that “the best forecast is a customer order.” Laptop manufacturers supply large European retailers in an assemble-to-order process out of Asian factories with just five to seven days' order lead time.

Attaining such a short lead time will be hard for pharmacos that take four to six months for multi-step drug substance production. Knowing that they cannot accelerate the process to manufacture to customer order, pharmacos should compensate by planning farther ahead. Why, then, are many pharmacos whipsawed by poor planning practices, especially when it comes to linking upstream steps like materials and active pharmaceutical ingredients with patient demand? We see pharmacos clearly lagging behind consumer goods companies, despite the fact that forecasting and planning are so important in the context of long lead times.

One pharmaco decided to focus on end-to-end planning in order to reduce excess inventories and write-offs, as well as to stabilize the production system and better capture upside sales opportunities. The company made several changes:

- It defined three clear planning “loops” to ensure that each part of the value chain synchronized with patient demand—materials supply, drug substance production, and finished product replenishment.
- It defined one owner for each planning loop, managing supply according to a vendor-managed inventory/pull logic. Chemical production planners, for example, had full visibility of drug substance stocks worldwide, and were

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<sup>5</sup> Crocs' company financial statements, Hoover's.

responsible for adjusting chemical production to meet demand scenarios and stock targets.

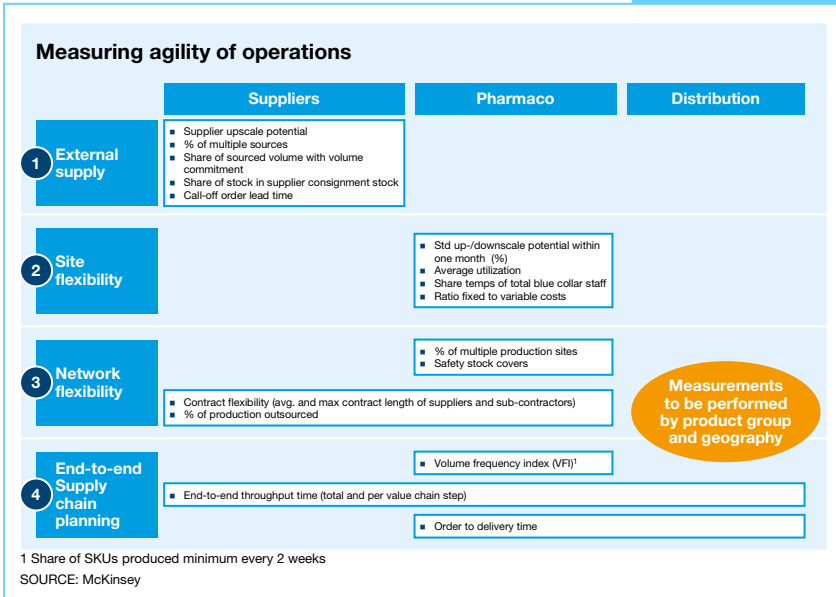
- It systematically challenged demand figures, by flagging key changes or inconsistencies, and through scenario planning for strategic products.
- It set the right planning frequency (such as a monthly review of the chemical production program) and alerts that trigger action through the whole supply chain (immediate handover of a high-probability tender forecast).
- It uses an S&OP governance that picks up the need for decisions or escalation across the three loops, and anticipates management decisions on key potential issues and bottlenecks.

For this pharmaco, implementing end-to-end planning led to a 5 percent revenue increase through scenario planning and forward-looking issue resolution, plus a 30 percent reduction of supply variability through enforcement of frozen time windows and elimination of root causes of variability. End-to-end planning is the most effective way to reduce response times to external events and to compensate for long process times.

## Sustaining agility: Setting the right conditions for agile operations

Agile companies use a set of methods that help them create and sustain a system of structural agility. Here are the most important methods:

- **Product segmentation.** To focus agility where it matters most, such as products in launch phase and critical hospital supplies.
- **Complexity management.** To reduce the number of costly and time-consuming process variants, SKUs, suppliers, and technologies, mainly by using a platform approach.
- **Risk management.** To steer efforts to those areas where agility can mitigate risks for strategic products.
- **Key performance indicators (KPIs).** To understand performance, drive awareness and focus, and set aspirations (Exhibit 2).



## Questions for senior leaders

Achieving a step-change in agility requires some bold changes in how people work, stretch targets, and cross-functional collaboration among Production, external suppliers, and Supply Chain. That's why C-suite involvement is critical.

To start, senior leaders will need to understand the size of their exposure to volatility and risk, as well as the current level of agility of different product lines and geographies, so that they can focus their investments. Leaders should ask several questions:

- How affected are we by day-to-day volatility in our different product lines and geographies?** Look at week-by-week demand fluctuation by product group and geography, supply fluctuation (number of supply bottlenecks per year), and predictability of these fluctuations (forecast accuracy).
- How vulnerable are we to disruptions?** This could be measured by a backward look at the number and severity of disruptions in the past few years, or with a forward-looking approach of assessing diversification. (Do all our suppliers come from one region or are they spread globally?)



- **Given our risk of day-to-day volatility and disruptions, how agile are we in response?** Key dimensions to examine are the ratio of variable to fixed costs, the volume-frequency index (share of SKUs produced at minimum every two weeks), standard upscale/downscale potential in one month, average line utilization, and end-to-end throughput time.

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Greater agility clearly offers substantial benefits for pharmaceutical companies. Significant cost reductions can be achieved through optimized product and plant allocation, as well as reduced idle time. In addition, inventory and thus working capital can be reduced through faster replenishment processes, a clear segmentation strategy, and reduced throughput times in manufacturing and packaging. Further benefits come in the area of growth. An agile company can increase revenues with better market penetration, faster delivery into new markets, faster ramp-up of launches, and fewer stockouts. By developing agile operations in the right places, pharmaceutical firms will be better equipped for a volatile world.

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