Outlook on pharma operations

David Keeling, Martin Lösch, Ulf Schrader

The pressure is building for fundamental change.

Before we look into the future, what do we see if we look back? Overall, pharma operations have not changed much. Yes, companies have gradually cut costs and lead times, and the business is managed more professionally today. But pharmaceuticals are still made and distributed essentially the same way they were 20 years ago. That will have to change.

It's hard to make accurate predictions in a dynamic environment, but we can safely assume that today's challenges will become more severe. The industry and its stakeholders' efforts to resolve pressing issues will likely trigger fundamental changes. Companies that anticipate and adapt to these changes will thrive in the years ahead. Here are the opportunities we believe are most relevant:

Freeing up $25 billion in cash from inventory

On average, pharma underperforms on working capital management. The average pharmaco holds 180 days of finished goods inventory on hand, for example, with top performers at about 100 days. Their peers in the consumer goods industry hold only 60 days' inventory, based on McKinsey benchmarks.

Pharmacos may not want to cut inventory to 60 days, since their margins are higher and the lifesaving role of some drugs calls for higher service levels. But at current inventory values, pharma could free up $25 billion (all figures in US dollars) if it reduced inventories on hand to a realistic target of 80-100 days.

This huge opportunity is within reach, but only for companies that can align across functions and use their capabilities rigorously. Companies will need an increasingly powerful supply chain function, with broader and deeper involvement in planning, production, distribution, and purchasing processes. Data transparency will be necessary to operate an increasingly global supply chain. This will not require expensive new ERP systems, but it will demand a clear IT strategy.

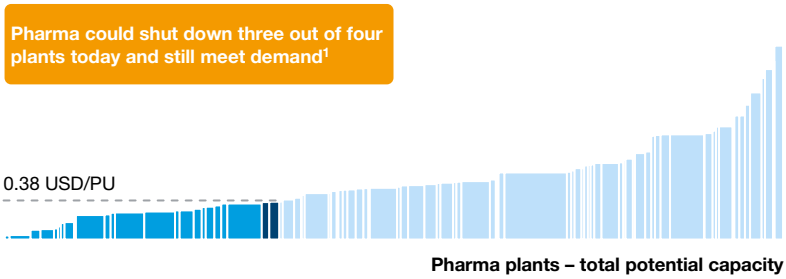
Eliminating overcapacity of 50% or more

Today's 75% overcapacity in solid dose manufacturing[1] (see Exhibit 1) has arisen for a variety of reasons: volume shifts from originators to generic competitors (who often build highly cost-effective assets), "once-daily" and combination medications, shifts in technologies, deliberate over-investments to create safety buffers, and increasing productivity. A McKinsey study of over 30 global pharmacos shows average annual productivity increases of 7% over the past four years, which implies that productivity would double in a decade.

EXHIBIT 1

Pharma industry cost curve

USD per PU



Notes: PU = standard production unit of 30 tablets; based on a sample of 175 plants
1 The sample actual current output could be achieved using the full capacity of just the 24 lowest cost plants (5x3 shift model; 60% OEE)
SOURCE: POBOS

1 This assumes a three-shift utilization of key equipment, average to good performance, and less than 40% downtime on the equipment.

Overcapacity in API production is even worse, thanks to high-potency molecules, improved synthesis routes, better productivity, and a major shift of production to low-cost countries, especially India and China.

Pharmacos must therefore continue and even accelerate network consolidations. These will have to happen gradually to balance the need for a competitive infrastructure with restructuring costs. But as the high-tech industry has painfully demonstrated, those who wait too long will get caught in a trap where the cost of restructuring overburdens their P&L and they start to tumble.

In the past, many pharmacos preferred to sell plants rather than close them. This was not cheaper, but it avoided the social unrest that goes along with closures. We expect it to become more difficult to find buyers, especially for plants without valuable know-how. It is clear that someone will have to carry the cost of downsizing.

Getting third parties under control

With few exceptions, pharmacos have moved away from the belief that they should produce products in-house by default. Today, the dominant model is a balance of in-house and contracted production, with most pharmaceutical production in-house and API outsourced. On average, a global pharmaco works with 100 to 200 contract manufacturing organizations (CMOs)—probably too many.

A more proactive approach to external partnerships is a powerful way to optimize utilization and reduce risk—and it can accelerate innovation. Partners can bring new formulations to the table, along with packaging ideas or devices. As breakthrough research becomes more difficult, these can become key differentiators.

Managing external partnerships requires shifting the focus from manufacturing towards supply. Making this shift involves new capabilities and governance mechanisms. Companies should conduct systematic screenings of high-value partnerships, design contracts to create win-win situations, and create supplier performance management mechanisms. In some cases, supplier development programs will make the best use of a pharmaco's knowledge. Managing a supplier network also requires the involvement of functions beyond Operations, especially Marketing, Quality, and Business Development, to ensure balanced decision-making that considers aspects from "total cost of ownership" and risk exposure to image and competitor strategy.

Making the supply chain more flexible

Capacity needs can change within months or even weeks, while capacity planning often takes a “one-year plus” perspective. This disconnect has to be resolved through a more flexible supply chain, because as today’s vast overcapacity is brought down, the risk of backorders goes up. The right supply chain requires flexibility along five dimensions: assets, suppliers, people, processes and strategy.

Assets need to become more “fluid” to ramp volumes up or down quickly at a reasonable cost. Dynamic capacity management can include in-house production, contact manufacturing, buying, selling and mothballing plants, and creating overflow assets in low-cost regions. Leading pharmacos are contemplating trading capacity among themselves to help balance supply and demand and sharing knowledge and technologies. We estimate that the top 10 pharmacos could generate savings of $1-2 billion using these approaches

Pharmacos often focus too much on negotiating cost savings or ensuring compliance requirements, rather than improving total cost of ownership and value-creation through supplier flexibility. This takes more than rewriting a few contract terms: strategic sourcing planning and supplier integration, development and renewal can help a company gradually create a flexible supply base.

The increasingly global and complex pharma supply chains need highly skilled and internationally experienced talent who can drive supply chain innovation projects around the globe and sustain an edge on competitors. Pharmacos also need to manage demand fluctuations with existing employees by introducing flexible shift systems and shared labor pools.

Leading companies are starting to embed flexibility in their supply chain processes. Lean fulfillment and replenishment, fast-track processing for crucial launches, nimble S&OP processes and forecasting focused on major events help them outpace the competition.

And a coherent supply chain strategy based on segmentation can balance flexibility and cost across all elements and concentrate investments where they produce the biggest returns. Companies that segment their supply chains can reduce the need for flexibility in key products and markets, and standardizing processes reduces variability created in-house. Better information strategies can maximize foresight to allow balancing over time.

Learning the commodity business

In Germany, mutual insurance funds have started to tender drugs for their members, the most prominent example being AOK[2]. Despite legal challenges, they have lowered drug costs by 40-50%. While tendering models differ by country, they are increasingly important and now account for over 15% of the European generics market.

This reflects the increasing commoditization of drugs. Many innovator companies, including Sanofi Aventis, Pfizer, GlaxoSmithKline and Novartis/ Sandoz, have long relied on a hybrid of innovative products and generics, and these companies have made it a strategic priority to maximize the value of their commoditized portfolio. But they will succeed only if they create a new operating model to address the specifics and stand up against competitors like Teva and Dr. Reddy's.

The commodity market requires low production costs and flexibility in the entire organization to grasp emerging opportunities. To select a successful pricing strategy, a company must have a clear understanding of the COGS for a specific product. Coming from a value-based pricing, rather than a cost-plus system, many pharmacos lack the financial systems to know the real cost of products, and may add a disproportionate share of overhead to their commodity products.

While operational performance has improved significantly over the last decade, innovator companies still struggle to create the mindset of a generic company and radically drive down cost. Many "lean" efforts have captured only a fraction of the improvement potential.

Finding the next $20 to 30 billion in savings

On average, the pharma industry is still far from being lean. But there are some examples of operational excellence where further cost reductions are not obvious. How can sites tap into new opportunities to reduce their COGS? Based on McKinsey analyses, quality-by-design and design-to-cost could yield $20 to $30 billion industry-wide.

Few companies today design or tailor technology platforms, or even consider them early on in the development process, to avoid extra equipment, processing steps and rework. Why? First, no single owner in the organization drives platform strategies and simultaneous development. Responsibility for technical development typically lies with R&D, not Operations, and R&D does

2 Allgemeine Ortskrankenkassen

not have the incentives or knowledge to avoid cost during the market phase. We expect organizational changes in the future to address this and to be a major catalyst for savings. Second, platform strategy is by necessity a long-term effort, with payback periods of five years or more.

With a further portfolio fragmentation and a proliferation of technologies, quality-by-design and design-to-cost will become even more important. Portfolios will increasingly cover not only therapeutic drugs but also diagnostics, biomarkers, drug/device combinations, patient packs, and so on.

As companies explore new technologies and process design, they must also rethink technical development. For example, how can they (almost) eliminate changeover times through liquid API? How can they avoid QC testing through process control, rather than the traditional trial and error approach? The opportunities are huge, but so are the investments. Companies will have to think through their strategies carefully.

Lifting the regulatory burden

For obvious reasons, quality will remain the top priority in pharma. But what is the best way to achieve it? Between 25 and 30% of conversion costs today are quality-related, based on McKinsey benchmarks, mostly because more global plants serve major markets. Harmonization efforts have been long underway, but it is hard to predict when they will succeed, especially as emerging markets create their own standards. Many countries are "averaging to the max"—adopting a combination of the strictest developed market standards. It is more difficult to comply with Brazil or Russia today than with the FDA, for example, even though the FDA has increased its scrutiny.

Companies will need to move away from mere "risk avoidance"—an impossible goal in any case—to a more structured risk assessment and prioritization of resources, not to cut costs but to focus more closely on what matters.

Since harmonizing global oversight is at least partly a political process, it is inherently unpredictable. But the industry's willingness to join forces on quality and compliance has already translated into the design of an industry-wide supplier auditing system. This could be a good starting point to engage more with regulators and accelerate harmonization, avoiding a further proliferation of compliance systems.

In the short term, companies can radically simplify their quality and compliance systems, making them cheaper, simpler and therefore safer. Most operational excellence efforts in quality and compliance have delivered unexpectedly high savings.

Catching the train to emerging markets

Emerging markets will be the growth engines of pharma. Seven out of ten people live in emerging markets today, and every year, over 100 million children are born there.

We expect pharma sales in emerging markets to grow from about $80 billion today to $180 billion by 2015 as companies struggle to serve about five billion people there. Life expectancy in these markets is among the lowest in the world and the healthcare infrastructure is poor. Now is the time to lay the groundwork for increasing market share.

While the opportunity is huge, so is the challenge, especially from an operations point of view. In India, for example, prices are 85 to 90% lower than in the US and they continue to fall. Some Indian companies produce tablets at a cost of $2 per thousand, compared to the roughly $60 that multinational corporations spend on average. This has major implications for business models, especially for pharmacos selling into markets with cost-plus pricing structures. Achieving low cost is not just a matter of raising margins—it is a prerequisite to entry.

The challenge of emerging markets goes beyond cost: it also includes innovation, flexibility, and distribution. In India, for instance, combination drugs are driving growth, and Indian companies are quick to launch these new formulations. The innovation model is designed "customer-back" rather than "science-forward." In distribution, models vary widely across countries and pose different challenges. In China, for example, companies face over 1,000 wholesalers in a multi-layer structure; in Mexico, retailers expect pharmacos to provide category management skills; and in other countries, pharmacos such as Sanofi Aventis in Brazil have forward-integrated to ensure distribution and create strategic advantages.

Serving emerging markets at large scale to capture growth requires a different model, not just adjustments. The diversity of these markets requires more flexibility, balanced with global synergies. This is true for the BRIC countries and for Africa, where no pharmaco has developed an effective distribution model. Why do mobile phones sell profitably in Nigeria, but drugs do not?

Nearly all pharmacos use the same strategy to capture growth in emerging markets. The difference will be in the quality of execution, especially in operations. In the years ahead, most pharmacos' output will be destined for emerging markets. Many of these markets will also require that production be local or in a low-cost region. The emerging market supply chain will therefore not be an annex—it will become the *core* of pharma operations.

Winning on talent

There are still huge opportunities in pharma operations. As we have outlined, this will require major changes in operating models, organization, technology, mindset, and geography. Pharmacos will have to consider if they are in a position to manage all these changes themselves or if they will partner with others. This decision depends largely on the talent they can attract, retain, and develop, not only to manage the day-to-day business, but also to lead the change.

But talent and skills matter beyond management. Navigating rising challenges requires that all employees, including operators and first-line managers, are developed and deployed to the maximum of their abilities. Quality space, standard work, JIT, and the other techniques of smart operations all require skilled and motivated staff.

Human Resources and Operations today tend to work side-by-side, not together, and have little understanding of the other's challenges or capabilities. Defining a joint agenda and leveraging training, coaching, career planning and incentives to develop the best people will be essential.

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Operations used to be judged on the delivery of quality product to the market. Today, companies must deliver quality at low cost. While there are still many obvious opportunities to reduce cost further, companies also need to ask "what's next?" We believe that the time has come to rethink pharma operations and create a vision and strategy that go beyond cost reduction and capacity planning for next year's budget.

How can operations accelerate growth—in Africa, for instance? How can innovations in operations trigger new business models? How can a manufacturer organize the integrated and paperless distribution of drugs directly to patients?

Companies that can conceive and adopt a bolder strategy will create a strategic advantage. In the future, nobody in those companies will then dare to claim Operations is not core to business success.

David Keeling (David_Keeling@mckinsey.com) is a director in the Chicago office, **Martin Lösch** (Martin_Loesch@mckinsey.com) is a principal in the Stuttgart office and **Ulf Schrader** (Ulf_Schrader@mckinsey.com) is a principal in the Hamburg office.