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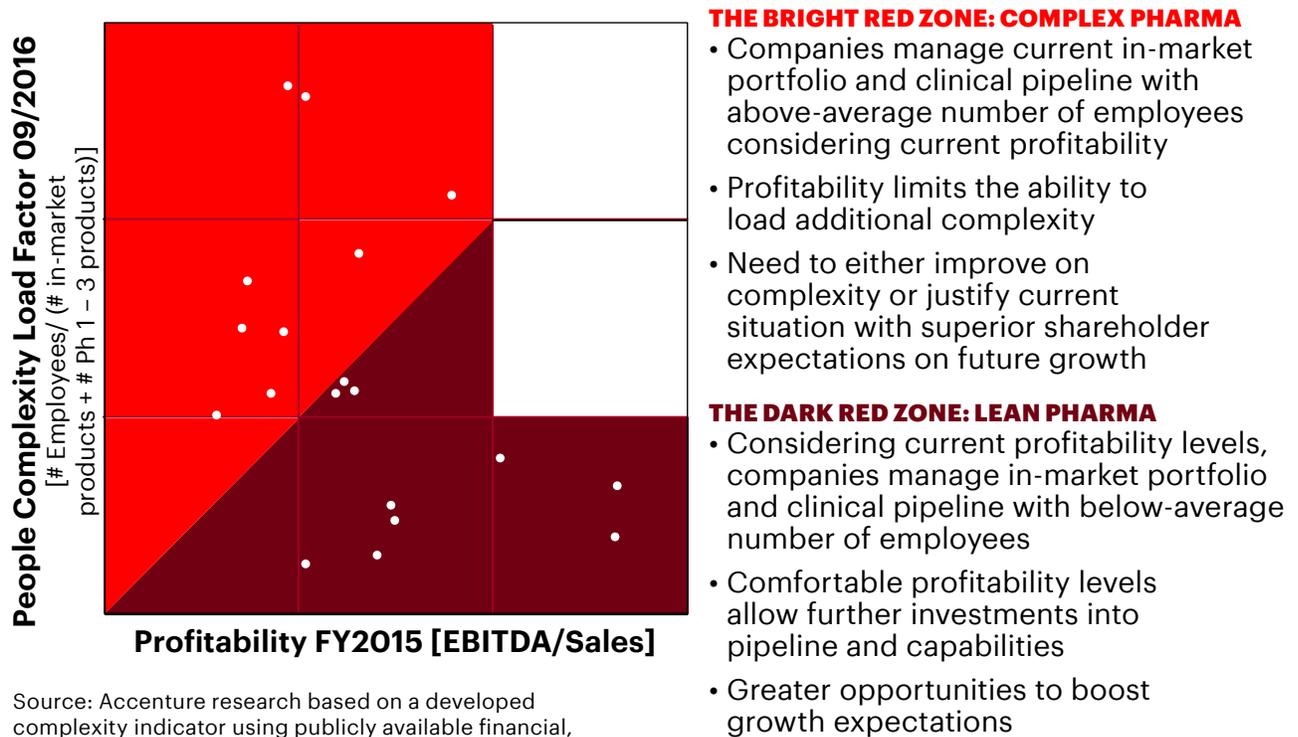for better patient outcomes

CURING
COMPLEXITY

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THE PHARMACEUTICAL INDUSTRY HAS ALWAYS BEEN COMPLEX. Yet over the last decade, complexity has reached epidemic proportions. Nearly half of the largest global pharmaceutical companies have reached complexity levels not in line with current profitability (see Figure 1).[1]

FIGURE 1

COMPLEX PHARMA VERSUS LEAN PHARMA

People Complexity Load Factor 09/2016
[# Employees/ (# in-market products + # Ph 1 – 3 products)]

Profitability FY2015 [EBITDA/Sales]

Source: Accenture research based on a developed complexity indicator using publicly available financial, headcount and pipeline/product data.

THE BRIGHT RED ZONE: COMPLEX PHARMA

- Companies manage current in-market portfolio and clinical pipeline with above-average number of employees considering current profitability

- Profitability limits the ability to load additional complexity

- Need to either improve on complexity or justify current situation with superior shareholder expectations on future growth

THE DARK RED ZONE: LEAN PHARMA

- Considering current profitability levels, companies manage in-market portfolio and clinical pipeline with below-average number of employees

- Comfortable profitability levels allow further investments into pipeline and capabilities

- Greater opportunities to boost growth expectations

Complexity has grown as organizations spend more time trying to master it than minimize it.

FOR EXAMPLE:

- When pursuing mergers and acquisitions, pharmaceutical companies typically focus on integrating to capture revenue and cost synergies. These initiatives are important for meeting shareholder expectations—but many times, they leave the organization more complex afterward.

- Many pharmaceutical companies seized innovation opportunities through scientific collaborations or strategic co-commercialization alliances. But they did so without managing governance or new data standards, tools and technologies.

- Most of these pharmaceutical companies have sought regulatory inspection readiness, compliance and auditor confidence without focusing enough on streamlining policies and training people on those policies.

Over the last several years, we've seen individual functions trying to cut complexity, yet transformation has not reached all parts of the organization.

Consequently, complexity—which is deeply rooted in pharmaceutical operating models—has become a silent killer of operational excellence, innovation, profitability and ultimately, competitive agility.

Simple and agile pharmaceutical companies will have the advantage in today's world where healthcare segments are converging and new technology is reinventing business models. For instance, many leading pharmaceutical players are actively looking into shifting from being drug makers to taking on a broader role in the health ecosystem, where medicines are just one part of holistic treatment solutions. Shifting to the new—such as expanding into the realm of patient services, diagnostics and provider collaborations—should happen in parallel with simplification. Having greater agility in developing, manufacturing and commercializing medicines will pave the way and allow management to focus on new holistic healthcare business models.

CUTTING
COMPLEXITY
TO SEIZE BUSINESS OPPORTUNITIES

Market opportunities lie ahead. New science is in development for areas such as immuno-oncology, anti-interleukin mAbs, PCSK9 inhibitors, stem cell therapy, CAR-T/T-Cell immuno-therapies and gene editing, with new products to be launched.

We saw many product launches in 2014 and 2015 as there were record-high product approval rates of New Molecular Entities by the U.S. Food and Drug Administration (FDA) in those years with more than 40 per annum.[2] While 2016 showed lower numbers of product approvals (22), the future remains promising.

One global pharmaceutical company achieved more than **95 PERCENT** reduction in complexity.[3]

The business was bogged down by an immense volume of procedural documents, conflicting initiatives and functional silos. This led to unclear and ineffective governance and a lack of integration that brought about compliance risks.

Over 12 months, the business aggressively reduced complexity through a radical simplification exercise. The company was able to create a sustainable, cross-functional governance model, make better use of resources and shift the culture from a rules-based to a principles-based environment. A positive side effect of the program was a 3 percent bottom-line cost base improvement.

Pharmaceutical companies can capture such growth opportunities by simplifying operating models. However, many have not yet embarked on that journey.

Part of the problem is that complexity is often a hidden "tax" on the business as it is difficult to identify and remove. Only 19 percent of pharmaceutical executives we interviewed confirm that their company is consistently able to identify and remove business activities and investments across the enterprise that do not add value.[4] Many are hindered by deeply rooted mindsets and the fact that middle management has an interest to preserve complexity. Jobs depend on complexity as it creates work and makes it harder to automate tasks.

THE RIPPLE EFFECTS OF
COMPLEXITY

Complexity is a dangerous prospect as it often lurks beneath the surface, infecting several key dimensions of the business:

POLICY. Over-documented, inconsistent, conflicting policies and unclear direction create a document landscape that is not in line with the process model. In some cases, pharmaceutical companies have almost one policy per employee.[5]

PROCESS. Many pharmaceutical companies have a decentralized process landscape that includes a high number of handovers and wasteful activities. Audit-based improvements are reactive, rather than proactive, and a plethora of quality checkpoints add to the complexity. At one leading pharmaceutical company, more than 30 percent of processes are governance or risk management based.[6]

SYSTEMS. Complex pharmaceutical companies have a high number of stand-alone systems that require inefficient manual effort and increase the number of transactions and data inconsistencies. At one major pharmaceutical company, 25 percent of its systems have less than 50 users.[7]

PEOPLE. Roles are often inconsistent, overlapping and redundant. One leading pharmaceutical company has five roles for each full-time employee.[8] Lack of clear responsibilities and ineffective training put complex pharmaceutical companies at a disadvantage, strengthening silos and weakening opportunities for collaboration.

By looking for ways to radically simplify complexity, pharmaceutical companies can treat the root problem, not just its symptoms.

MAKING SAVINGS
SUSTAINABLE
AND GROWTH
ACHIEVABLE

During crisis years in which revenues showed negative growth, many pharmaceutical organizations focused on one-time cost takeout to protect profitability, but they did not address the root causes. These cost takeout measures, along with new product launches and commercial excellence, have contributed to a return to positive after years of negative growth (see Figure 2). However, cost reduction has not reduced complexity or yielded long-term, meaningful change.

FIGURE 2

EARNINGS GROWTH OUTPERFORMS REVENUE GROWTH WITH ONE-TIME COST TAKEOUT
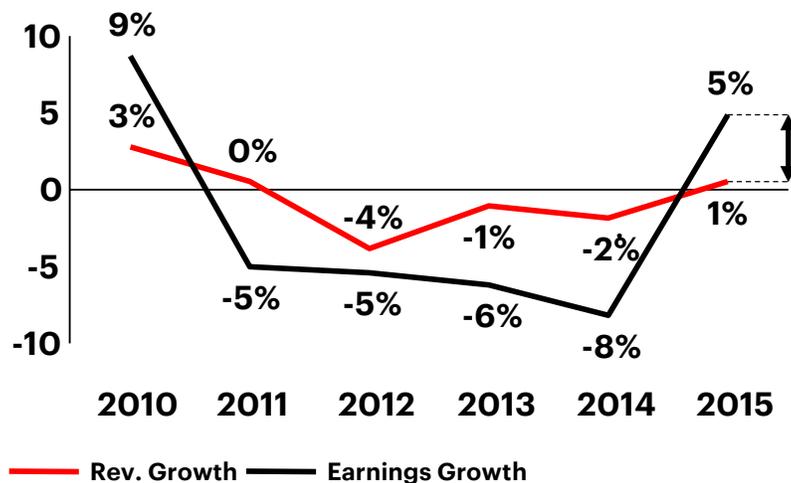
Total Peer Group Revenue and Earnings (Core EBIT) in USD at constant FOREX is analyzed—meaning larger companies' performance does skew trend

Source: Accenture research based on Capital IQ Nov. 2015

By targeting specific complexity, such as cutting the number of policies or processes, radical simplification programs can reduce more than 90 percent of complexity in less than 12 months.[9]

More than three-fourths (76 percent) of pharmaceutical executives agree that complexity reduction is an enabler of sustainable cost reduction.[10] It is sustainable because the business is fundamentally changing how the business operates—which has long-term effects on cost management—rather than simply cutting one area of spending.

Savings are a natural consequence of reducing complexity. If done right, complexity reduction can generate a recurring 3 to 5 percent of EBIT that can be reinvested into new capabilities to drive growth.[11] However, cost reduction is not an enabler of complexity reduction.

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IT'S TIME FOR A RADICAL APPROACH

Pruning the portfolio and streamlining individual processes by applying Lean Six Sigma is helpful, but it's one-dimensional. Lean Six Sigma drives incremental process improvement through reduction in process variation, improved process control, waste reduction and work standardization. Radical simplification drives improvement by challenging the process in the first place.

Furthermore, many organizations have been risk-averse, and therefore followed an incremental, evolutionary approach to complexity reduction. They took time to understand the current situation of complexity and then identified steps to reduce it here and there. While this is good for business continuity, it does not reach the root of the problem.

Radical simplification can recreate a pharmaceutical company as a well-oiled machine that has a fit for purpose cost basis, allowing it to deliver against earnings expectations.

Even more importantly, radical simplification improves quality, compliance and time-to-market across development, launch and commercial excellence to capture the sheer size of growth opportunities without deterioration of profitability. Successful simplification is top-down, uses analytics to quickly identify unnecessary complexity, such as regional variations of procedures and systems with low levels of users, and focuses on momentum and sustainability.

SOME GUIDING PRINCIPLES INCLUDE:

GET RADICAL. To dismantle complexity that has built up over the years, simplification must be radical and follow a zero-based approach. We believe successful programs begin with a blank slate to reimagine the new pharmaceutical company.

TAKE ADVANTAGE OF TECHNOLOGY. Technology has added complexity in the form of abundant data, but it can dramatically help to reduce complexity when organizations use automation, robotics and artificial intelligence to streamline labor-intensive tasks. Consider how disruptive technologies can reduce complexity.

ADOPT AN ENTREPRENEURIAL MINDSET. It is essential for leaders to have more of a startup spirit, looking for innovative ways to improve speed-to-patient, quality, compliance and cost base. The C-suite also can clarify roles and accountability. Innovative training designs will help enable this cultural change.

Pharmaceutical companies can accelerate the path to competitiveness and complexity reduction by embarking on simplification sprints that address complexity at the root—and at speed.

THESE SPRINTS INCLUDE:

IDENTIFY CORPORATE RISK PORTFOLIO WITHIN THE HIGH-LEVEL PROCESS LANDSCAPE. Most businesses typically do not have a clear and concise picture of risk across the company's value chain—from drug discovery to commercialization. Exhaustively identifying the potential threats across patient safety, regulatory, legal and business risk is valuable to top management as it builds the baseline for next steps.

PERFORM IMPACT ANALYSIS AND ASSESS PROBABILITY PER IDENTIFIED RISK to determine the complexity areas to tackle first as quick wins that can be taken out easily. Risks with a low probability and a low impact obviously do not need to be controlled by complex measures, but rather focus on those that are highly likely and would have a significant negative impact on the business.

DETERMINE THE APPROPRIATE CONTROL METHODS NEEDED TO MITIGATE RISKS, following a zero-based approach. Control measures should be as simple as possible. However, controlling for a high impact/ high probability risk may require a more complex methodology.

CLEARLY OUTLINE THE OBJECTIVES AND COMPONENTS for all control measures.

THE PICTURE THAT RESULTS FROM THIS APPROACH MAY BE SURPRISINGLY...simple.

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NOTES

[1] Accenture research based on a developed complexity indicator using publicly available financial, headcount and pipeline/product data.

[2] *Endpoints News*, "The winners, and losers, in the ugly 2016 race for new drug approvals;" posted January 3, 2017.

[3] Accenture Strategy client experience.

[4] Accenture Agility to Compete research, 2015.

[5] Accenture Strategy analysis.

[6] Accenture Strategy client experience.

[7] Accenture Strategy analysis.

[8] Accenture Strategy analysis.

[9] Accenture Strategy analysis.

[10] Accenture Agility to Compete research, 2015.

[11] Accenture Strategy analysis.

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