strategy&

A critical makeover for pharmaceutical companies

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Overcoming industry obstacles with a cross-functional strategy

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Executive summary

This is a difficult time for global pharmaceutical companies — so difficult, in fact, that many are reconsidering their business models. The litany of concerns that pharmaceutical companies face includes payors tightening up on cost management, strained government healthcare budgets, the need to understand and adopt new technologies, and challenges to their traditional pricing mechanisms by empowered stakeholders, from patients to payors. Moreover, the regulatory maze in many parts of the world is tough to navigate, with unique rules and varied outcomes depending on national policies, issues, and bureaucratic processes.

Compounding the external obstacles, however, is the internal culture of most pharma companies. This is an industry that has long operated through disparate components — silos that separated R&D, commercial, production, and supply chain. And, in turn, these walled-off parts of the organization have been disconnected from the external-facing parts, which are responsible for managing relationships with regulators, policymakers, the medical community, and the rest of the industry. These silos can obstruct patient access and breed inefficiency and waste. They affect drug approval time and pricing, influence support for specific drugs by the medical community, and seriously hinder financial performance.

It is time for pharmaceutical companies to restructure their operating models in a way that brings all of these interdependent functions together. To accomplish this goal, they should build the organization around what we call critical teams. These teams should be directly responsible for gathering information, developing insights, and drawing up strategic plans about the facets of the pharmaceutical business that are often overlooked in the formal organizational structure: namely, regulatory affairs, pricing and market access, government affairs, and medical affairs. These four categories are the subteams of a pharma company's critical team.

Rather than having knowledge about these aspects of the business model buried in other pharmaceutical functions — an inefficient and ultimately unsatisfactory approach — the critical team would be independent but cross-functional, working closely with R&D and pharmacovigilance; sales, marketing, and key account management; and supply chain. A primary task of the critical team would be to make sure that each function is aware of what the others are doing and benefits from the knowledge of the team.

As a concept, critical teams are not new; most pharmaceutical companies already rely on experts in external healthcare industry activities for ad hoc strategic advice and direction. But that does not go far enough; it fails to apply the critical team as a bridge across key functions. Thus, the ability of the team to effectively advance the needs of the entire organization is significantly diminished.

This report offers a detailed framework for implementing a successful critical team strategy. It provides an analysis of the pharmaceutical landscape through the lens of critical team activity, allowing management to reflect on how connected and effective the company's current critical team is and how the organization can improve its capabilities by fully leveraging its team.

Disruptive times

The global pharmaceutical industry has long been known for unpredictability. Returns on investment from research efforts are volatile, and payor pressure and the vagaries of regulatory decisions often add to the uncertainties of the sector. Still, it would be difficult to find a period in the past when pharmaceutical companies faced a more challenging and disruptive time than they are experiencing now — a time, that is, when drug companies have no choice but to reevaluate their business model to survive.

Consider the range of global trends affecting pharmaceutical businesses:

- **Aging population.** In Western Europe, about one in five people are age 65 or older. By 2030, that proportion will climb to one in four. As populations age, payors are forced to reconsider how to pay for the treatments needed by an older cohort of individuals and how to achieve the best patient outcomes.

- **Squeeze on healthcare budgets.** Public and private payors are relying more on patient outcomes to make decisions that are aimed at managing scarce budgets and focusing on cost-effectiveness and comparative clinical effectiveness.

- **Rise of health technologies.** Advances in mobile communications and the digitization of health diagnostics, treatment, equipment, and services are changing how care is delivered and how pharmaceutical companies conduct R&D. As new technologies emerge, new regulatory policies follow, adding complexity to the approval and reimbursement processes.

- **Empowered consumerism.** Consumers are playing a more critical role than ever before in their own care, demanding enhanced access to information relevant to their conditions and treatment programs. The change is influencing payors, regulators, and policymakers. Pharmaceutical companies are affected in a wide range of areas: pricing, the types of drugs they develop, return on research investment, and the role they must play in patient compliance.

A disjointed system

Pharmaceutical companies around the world confront substantial regulatory constraints. Increasingly complex and strict regulatory policies in Europe and the U.S. demand multiple submissions of drug approval applications to satisfy the rules in every region, and extensive documentation to meet clinical trial and pharmacovigilance standards.

At the same time, regulators are taking steps to accelerate innovation and efficiently license medicines, diagnostics, and digital applications that demonstrate positive outcomes. By communicating with regulators proactively, pharma companies now have the opportunity to grant patients early access to new medications, particularly those that target unmet diagnostic and treatment needs. At the same time, regulators — as well as providers and payors — appreciate fast-cycle analytics on patient progress to support value-based healthcare solutions.

By communicating with regulators proactively, pharma companies have the opportunity to grant patients early access to new medications.

Amid this context, patients are playing a bigger role in the healthcare dynamic than ever before. They increasingly want to be partners in determining their healthcare strategies and lifestyle choices, joining with providers in making informed decisions. Valid decisions are dependent on clear and timely demonstrations of drug outcomes and efficacy by pharmaceutical companies. (For a survey of the external pressures that pharmaceutical companies face, see *Exhibit 1, page 9.*)

To illustrate the regulatory maze that pharmaceutical companies must navigate, Strategy&, PwC's strategy consulting business, analyzed payor decisions related to 19 drugs approved by the European Medicines Agency and the U.S. Food and Drug Administration in 2013 and 2014. We found a significant discrepancy in reimbursement decisions for similar drugs among four large E.U. payors:

- France's Haute Autorité de Santé: Reviewed 19 drugs and approved all for reimbursement. Approval criterion was comparative clinical effectiveness.

- Sweden's Tandvårds- och läkemedelsförmånsverket (TLV): Reviewed 16 drugs and approved 13 for reimbursement. Approval criteria focused on cost-effectiveness.

- Germany's Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG): Reviewed 18 drugs and approved 12 for reimbursement. Approval criterion was comparative clinical effectiveness.

- U.K.'s National Institute for Health and Care Excellence (NICE): Reviewed nine drugs and approved six for reimbursement. Approval criteria focused on cost-effectiveness.

Separately, we found that, as with Sweden's TLV, the U.S. Centers for Medicare & Medicaid Services reviewed 16 of these drugs and approved 13.

Decision making appears to be even less predictable in specific therapeutic areas (*see Exhibit 2, page 10*). For example, the three metabolic drugs under consideration in the two years we analyzed received approval from all payors and regulators except IQWiG, which rejected all of them because the agency was unhappy with the choice of comparator drugs used in the clinical studies.

Moreover, even the terminology used in the approval process can be confounding, forcing pharmaceutical companies to work their way around mutable definitions. For oncological and neurological drugs, Strategy&'s review found that half of the time, clinical outcome — that is, mortality rate — was the primary factor. But for the other half, surrogate endpoints, such as changes in a diabetes patient's glucose level, were favored metrics. With the metabolic drugs, surrogate endpoints were the sole criterion for reimbursement, and with respiratory drugs, this approach was preferred in 75 percent of the cases.

Pharmaceutical companies are at a disadvantage — especially in comparison with other healthcare stakeholders (for example, national health programs or payor organizations), which are increasingly working together to accomplish critical goals, such as lower prescription costs. Some of this is a problem of the pharma industry's own making. Over the years, insularity has begun to infect many pharmaceutical companies. Silos have emerged that separate, for example, R&D from the commercial, production, and supply chain parts of the business. And all of these parts are disconnected from the critical outward-facing aspects of the industry: regulatory affairs, pricing and market access, government affairs, and medical affairs — the very parts of the business that must cope with the greatest degree of disruption in the current

Exhibit 1
What external forces want

Regulator

"I want to accelerate innovation and license products and diagnostics that demonstrate real outcomes."

Patient

"I should be informed of decisions relating to my health and be able to manage my condition to fit my lifestyle."

Payor

"I must contain healthcare costs without compromising patient outcomes."

Policymaker

"My policies need to encourage uptake of innovation and meet my stakeholders' needs."

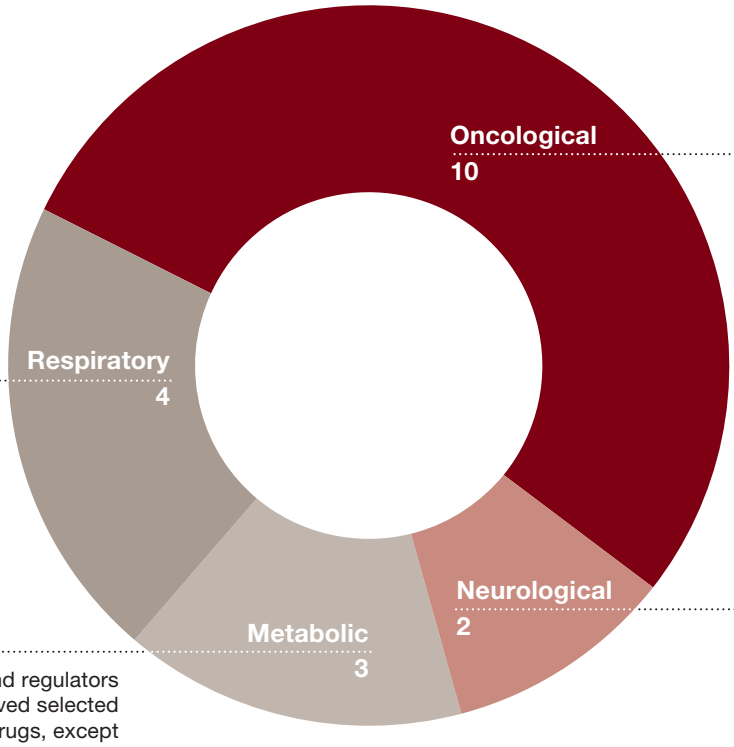
Provider

"I need to adhere to evidence-based medicine to optimize my performance and deliver excellent patient outcomes."

Source: Strategy& analysis

Exhibit 2

E.U. payor approval rates for drugs, 2013–14



40% of reviewed oncological drugs were approved by all five payors and regulators

The most common reason for payors not approving was high drug costs

75% of reviewed respiratory drugs were approved by all regulators and payors; the fourth was an orphan drug product

All payors and regulators approved selected metabolic drugs, except IQWiG, which rejected all three (due to choice of comparators)

One drug received 100% approval; the other was not approved by IQWiG (choice of comparator) or NICE (high cost)

Source: www.ema.europa.eu; www.fda.gov; www.iqwig.de; www.g-ba.de; www.tlv.se; www.nice.org.uk; www.has-sante.fr; www.cms.gov; www.q1medicare.com; www.blueshieldca.com/bsca/bsc/public/member/mp/home/

environment. The result is myopia: pharmaceutical companies that fail to see clearly how the disjointed approval system is affecting patients, payors, and providers.

The dangers of silos may not always have been obvious, but today, with more stringent regulatory requirements, greater oversight of healthcare spending, and more demanding patient and doctor constituencies, there is much less room for inefficiency and waste. A product's costs and returns will be disappointing if a company makes decisions without considering the impact on all stakeholders. Say, for example, a company launches a new compound without a clear window into how much payors will earmark for the product, or what regulators will accept as the minimum data set for accelerated approval, or even the education and support that will be needed to prepare the medical community to embrace the drug. These examples are not isolated; repeated over and over with different variables in an incohesive pharmaceutical organization, they have a cascading effect that weakens the company's performance.

The critical team strategy

To fix this broken system, pharmaceutical companies must address the shortcomings in their operating models. At its optimum, the front line of the pharmaceutical operating model would be composed of what Strategy& calls a critical team. The critical team is composed of four subteams that gather knowledge about and monitor issues pertaining to regulatory affairs, pricing and market access, government affairs, and medical affairs. These subteams act as cross-organizational threads to link together pivotal pharmaceutical functions that focus on evidence generation and management (R&D and pharmacovigilance), customer management (sales, marketing, and key account management), and connected delivery (supply chain).

Most pharmaceutical companies have the capabilities needed for effective critical teams, and many have certain facets of critical teams in operation. But few companies have taken these teams as far as they can go, to act as a bridge between all of the company's key functions. Critical teams represent a new framework for the industry, and there are various ways a company might structure them. For companies that operate under highly decentralized business models, our vision is that the subteams would all report to a local critical functions (CF) leader, who in turn reports directly to the global or regional CF leader. Depending on how aggressive companies want to be with their transformation, we advocate the creation of a board-level position for the top CF leader, given the important role we expect the teams to play in the future and the critical nature of the customer and business insight they will bring to the organization.

Critical teams are particularly pivotal in today's pharmaceutical organizations because they're the company's internal communicators and its liaison to external stakeholders. They provide market insight and analysis that informs customer- and patient-centric activities across the pharmaceutical value chain. They can be used to leverage all possible avenues of evidence available to a company, ultimately to assist project teams in determining regulatory and market strategies for molecules from research through life-cycle management. In today's pharmaceutical industry environment, it is no longer sufficient to have,

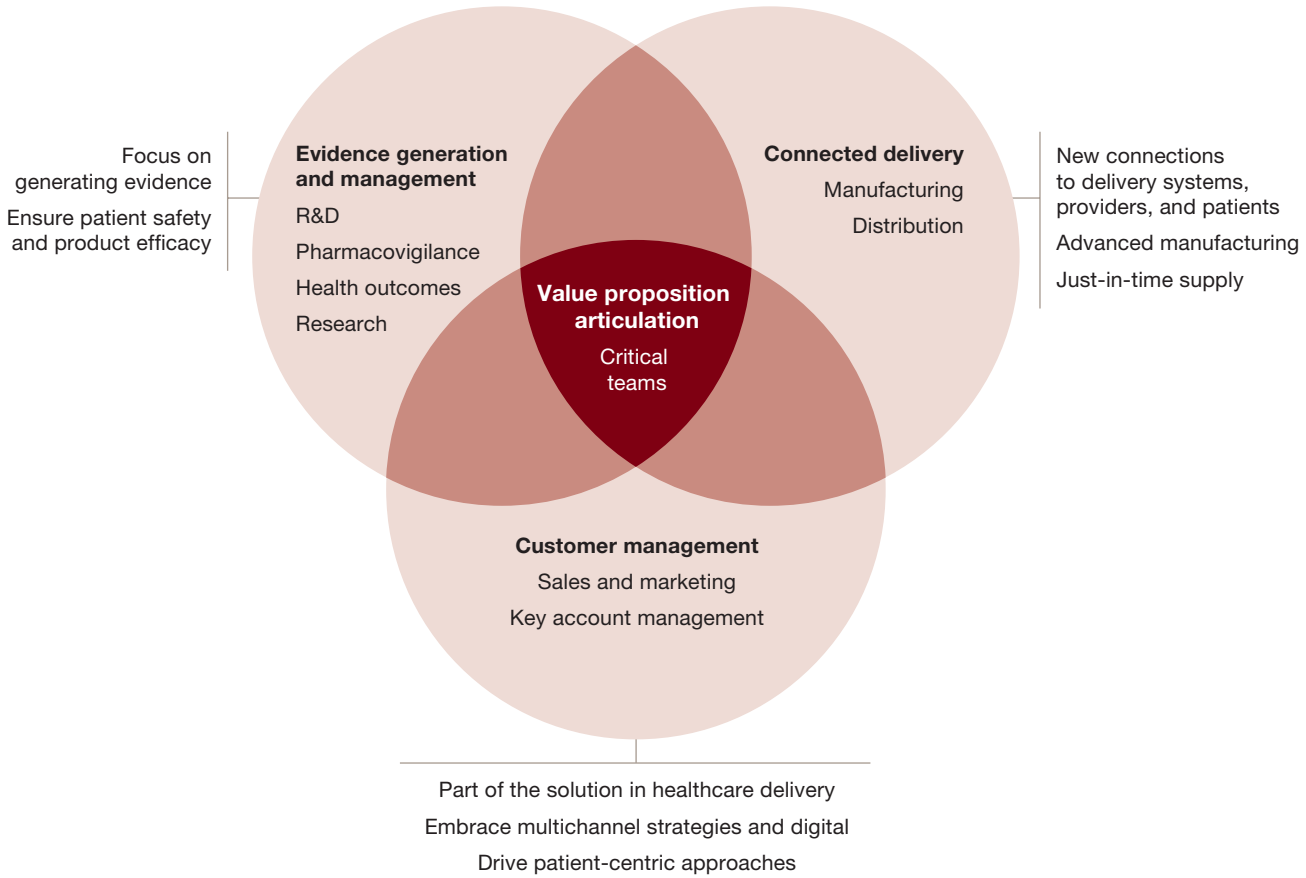
The critical team is composed of four subteams that monitor issues of regulatory affairs, pricing and market access, government affairs, and medical affairs.

for example, sales reps promoting products alone or regulatory experts shaping R&D activities without input from other parts of the organization. Indeed, given the changes in the landscape, the company should look to the critical teams to determine the most important strategic path forward.

Because critical teams are cross-functional, they will accomplish their goals only if there is consistent and ample overlap, cross-collaboration, and communication among the four operating model categories within the organization (*see Exhibit 3, next page*). If these parts of the business are separated and unable to communicate among themselves effectively, it won't matter how robust the company's critical team is, because its impact will be lost in a vacuum.

Exhibit 3

New pharma company operating model



Critical teams

(subteams: regulatory affairs, pricing and market access, government affairs, medical affairs)

Foster cross-functional collaboration

Proactively share customer feedback

Prepare and shape the external environment

Source: Strategy& analysis

Operating levers

An organization must develop a series of operating model levers for the critical teams in order to profitably deploy them. These levers should also be the building blocks for a pharmaceutical company's new operating model:

- **Strategy** must be explicitly spelled out and coherent across the critical teams, and aligned closely with business objectives that are regularly validated against shifting requirements and regulations in the industry. Stakeholders should know about the strategy too, and buy into it.

- **Organizational structure** should be built around clear roles and responsibilities, globally and locally, that leverage functional expertise across the organization. Noncore activities can be outsourced to improve efficiency, and the organizational structure can be linked to business needs while providing room for mobility and innovation among the ranks. Mobility across the critical teams should be encouraged to inspire the development of creative ideas that can improve and expand on the benefits that each of the critical teams' subteams can bring to critical team capabilities.

- **Process, systems, and tools** emphasize tracking the progress of critical teams in achieving specific strategy goals focused on demonstrating value, quality, and compliance in a cross-functional environment. Relevant IT systems are vital to support and enhance (a) knowledge sharing across local and global teams; (b) customer-centric services to meet needs of key stakeholders and to demonstrate patient and economic outcomes; (c) transparent interactions with stakeholders; and (d) efficiency gains. Measuring the contribution of critical teams to the business can be difficult because the work these units do cannot be directly linked to sales. Nevertheless, key metrics need to be defined to measure progress against objectives. As digitization becomes increasingly important in the pharmaceutical industry, critical teams must be early adopters of technology.

Organizations must develop operating model levers — from strategy to culture and skills — for critical teams to profitably deploy them.

- **Skills and culture** address awareness of external stakeholder needs and combine it with business acumen and strategic insight to deliver value to customers, suppliers, patients, and providers. Well-developed on-boarding and training programs are necessary to improve the performance of proactive, motivated individuals — in short, problem solvers, not blamers — who are inspired to work in critical teams. A critical team must be driven by the desire to adopt innovation and facilitate it across the organization to enable patient-centric products and services.

The roles that the individual operating levers play in each of the subteams vary depending on the organization's needs. But in all cases the purpose of implementing these levers is to enable critical teams to improve organizational insight and responses to payor, regulatory, and competitive challenges. In other words, the levers position and enable the critical team to perform its necessary role as the fulcrum of the company's transformed operating model. Strategy& has created a maturity model that explains how each of the operating levers can best support the development and cultivation of each of the subteams.

Insight from the regulatory affairs teams should shape R&D and marketing plans.

Subteam: Regulatory affairs

- **Strategy:** Regulatory insight helps shape drug development and marketing plans across R&D and product life-cycle management using all available innovative regulatory pathways. The goal is to actively harmonize regulatory and payor requirements for earlier access.

- **Organizational structure:** Financial and staff resources dedicated to regulatory issues and communications are allocated efficiently, including outsourcing arrangements when needed, which allows the pharmaceutical company to anticipate and manage the cost of these activities while getting the most out of them. Bringing market access and regulatory subteams together under the critical team umbrella can result in more efficient and effective product development programs and life-cycle management.

- **Process, systems, and tools:** All available regulatory pathways and early access schemes to accelerate approval are proactively assessed and, if appropriate, adopted. Upcoming regulatory changes are anticipated, allowing the organization to adjust its operations plan to align with new rules and policies, a much more efficient strategy than reactively adjusting processes and procedures following inspections. The regulatory affairs team aggressively tries to reduce

time to filing and uses new technology to facilitate faster global dossier compilation of key regulatory documentation needed across multiple territories.

- **Skills and culture:** The confidence to maintain an ongoing dialogue with regulators is fostered, even to the point of challenging status quo and conventional wisdom. Rather than treating regulators as obstacles, regulatory affairs teams should consider alternative beneficial approaches to regulator requests and policies, working across the company to enable faster access and broader involvement in healthcare delivery and transformation.

Subteam: Pricing and market access

- **Strategy:** Market research and discussions with payors are leveraged to produce payor insight that informs R&D and commercial strategies, as well as a coordinated pricing and reimbursement approach meant to replace the typical reflexive individual reactions to local payor restrictions.

- **Organizational structure:** Silos are eliminated in favor of proactive interaction across organizational teams to enable integration of the input from a critical team.

- **Process, systems, and tools:** Diseases and patient pathways are assessed and analyzed using all available external and internal data to generate evidence for patient-centric drug development programs. Analytical techniques are used to assess revenue leakage and define processes to better manage pricing transparency in the context of increased tenders and pricing pressure.

- **Skills and culture:** The ability to develop trusted partnerships with payor groups leads to creative contracting and pricing agreements focused on outcomes rather than defensive pushbacks and adversarial negotiations.

Pricing and market access teams need to create partnerships with payors to deliver outcomes.

Subteam: Government affairs

- **Strategy:** Government policy changes are assessed and prioritized in real time to determine how they affect business objectives, avoiding the "fire drill" of panicky reaction to policy decisions that are divorced from company goals and programs. Also, forward-looking policies are developed pertaining to transparency in real-world data studies and pricing.

- **Organizational structure:** Capabilities are needed at both corporate and local levels. Policy positions are proactively drawn up at the corporate level and distributed to be tailored to local requirements and help shape the local policy environment. Every part of the organization must be involved in policy shaping so that the message being communicated is consistent.

- **Process, systems, and tools:** Since government affairs teams are cross-functional, strategy execution vis-à-vis government policy decisions is spread across the organization, allowing the company to proactively take advantage of opportunities and better manage risk. Technology is a good facilitator, allowing strong stakeholder management and effectiveness tracking. For example, a tool akin to a customer relationship management program could be used to capture interactions with external organizations so that the pharmaceutical company's in-field resources have access to the information at a moment's notice. Alternatively, dashboards could be tailored to pull information from multiple company-wide sources to measure the success of critical teams in meeting business-aligned objectives.

- **Skills and culture:** An ongoing dialogue in a trusted advisor relationship with relevant policymakers is maintained, obviating the typical transactional policymaker engagement that predominates in the industry now and often leads to mistrust. With an ongoing relationship, the pharma industry can be proactive, providing valuable input into policy development, rather than simply reacting to new policies.

Government affairs capabilities are needed at both the corporate and local levels.

Subteam: Medical affairs

- **Strategy:** Pre- and post-approval, cross-functional teams compile real-world data analyses to demonstrate a new drug's strength as a patient-centric solution offering positive patient outcomes. Medical affairs in-field resources take over the medical education role that sales reps formerly had with primary care prescribers. But they focus on scientific exchange rather than sales, challenging the standards of care and identifying gaps in disease management and opportunities for pharmaceutical companies to partner in the healthcare system.

- **Organizational structure:** In-field medical professionals from medical affairs teams support sales reps and key account managers while remaining distinct from them. In addition, medical affairs' insight from the field — particularly about gaps in care and opportunities to serve new populations, formulations, and digital solutions — are fed back into R&D to help determine future development strategies.

- **Process, systems, and tools:** Innovative medical education campaigns are developed and linked to assessments to show improved patient outcomes. These efforts, delivered to the healthcare professional community, are designed to raise awareness of gaps in care that current and future products can close. Digital and multichannel strategies are used to inform but also to collect feedback that can be the foundation of product development and patient outreach programs. Processes are in place to enable full transparency of interaction between the medical affairs team and healthcare professionals, and systems are used to track the effectiveness of different channels and campaigns. Collected information is proactively shared throughout the organization to increase touch points and outreach to the medical community, while reactive responses will become a thing of the past.

- **Skills and culture:** Strategic channels to key opinion leaders and clinicians are opened, providing data, ideas, and insight for brand planning. These dialogues and analytical insights are crucial in translating healthcare professional needs into opportunities for pharmaceutical companies. Scientific strength is balanced with commercial acumen, strong relationship building, and alliance management skills, fostering public–private collaboration.

Medical affairs teams identify opportunities for pharma to partner in the healthcare system.

These descriptions portray the ideal state for pharmaceutical companies, when operating levers and critical teams are perfectly aligned; silos are eliminated; cross-functional, open communication is the norm rather than the aspiration; and strategic goals mesh with tactical product development and go-to-market campaigns. In actuality, though, given that most pharmaceutical companies have some critical team activities but usually in silos, change will be gradual. More commonly, companies will go through a series of organizational maturity stages as they implement each aspect of critical team capabilities: reactive, tactical, strategic, and leading (*see Exhibits 4–7*).

Most pharmaceutical companies are currently in the tactical stage. Depending on where a company's critical teams are on the maturity curve at subteam level or collectively across the subteams, a decision can be made about whether to simply improve capabilities in the current organizational model or more radically turn the operating model upside down — in other words, begin again in light of the disruptive operating environment. Experimenting with a company's operating model is more easily done locally, where there is less complexity and fewer moving parts, but we have observed that some pharmaceutical companies are taking aggressive steps to transform themselves at the corporate level. Typically, the demands for greater connectivity across critical teams are

motivating more sweeping changes. To accomplish transformation, companies will need to answer a number of key questions about how their critical teams will operate: Should there be one critical team leader across subteams? Where should critical teams sit within the organizational structure? How will the critical viewpoint be represented at the board level?

Exhibit 4
Regulatory affairs (RA)

Reactive	Tactical	Strategic	Leading
Strategy			
RA enables R&D strategy but has limited involvement in product life-cycle management	RA enables both R&D and product life-cycle management strategy	Regulator and payor needs are balanced, while consideration is given to innovative regulatory pathways There is proactive engagement to shape regulator policy	RA provides regulatory insight to enable innovation across R&D and product life-cycle management, including faster, parallel filing and accelerated access globally
Organizational structure			
RA teams are split by activity performed Local RA doesn't report to global RA No outsourcing	Local RA reports to global RA, but RA sits within R&D Limited outsourcing (e.g., publishing)	Local RA, medical affairs, and sometimes pricing and market access and government affairs report to the same head Global RA reports outside R&D Outsourcing of all noncore activities	Local RA reports to local CF leader, who in turn reports to global or regional CF leader Outsourcing leverages cross-functional efficiencies (e.g., with clinical)
Process, systems, and tools			
There are siloed regulatory processes only, with complex written procedures focused on R&D needs Global oversight of local activities is limited	End-to-end regulatory processes are used Simplification efforts are under way for procedures and short-term business priorities, including resource allocation	RA proactively anticipates regulatory policy changes, using an embedded optimizing filing and tracking approach Global division oversees local activities via global tracking systems There is a robust process for resource allocation	RA leverages all available regulatory pathways and early access schemes to accelerate approval RA takes a risk-based approach to change management Team is ready to implement identification of medical products (IDMP)
Skills and culture			
Reactive and unconfident regulator interactions lead to a perception that RA is nonstrategic	Ad hoc interactions with regulators raise queries about regulatory concerns Regulators seen as blocking business	Ongoing dialogue with regulators helps RA understand requirements and have confidence to connect input from other critical functions	RA maintains continuous dialogue with regulators as a trusted advisor where appropriate, bridging payor and healthcare provider needs

Source: Strategy& analysis

Exhibit 5

Pricing and market access (P&MA)

	Reactive	Tactical	Strategic	Leading
Strategy	Responses to payor demands on drug pricing are defensive	P&MA uses payor demands to inform future pricing decisions	Team uses market research to generate payor insight that informs commercial strategies	P&MA uses market research and payor discussions to generate insight that informs R&D and commercial strategies
Organizational structure	P&MA is absorbed within commercial and siloed	Local P&MA teams are separate from commercial and report to global P&MA teams	Strategic P&MA is in same team as government affairs, while sales-focused P&MA is in commercial	P&MA reports to CF team leader at global level Local CF teams report to global or regional CF team
Process, systems, and tools	There are no clear systems or tools for value proposition creation or real-world data generation, and no use of analytics	Process and tools focus on short-term issues with limited knowledge sharing and no use of analytics	Systems and tools are designed to provide value propositions and convincing evidence to payor community throughout the product life cycle	Process focuses on diseases and outcomes to generate patient-centric solutions
Skills and culture	Team lacks interaction with payors and the ability to respond adequately to pushbacks during pricing negotiations	Interaction with payors is on ad hoc basis; relationship-building skills are limited; tendering is not seen as strategic	Trusted relationships with payors help in negotiating the best drug pricing CF team supports interaction among P&MA and all of the other critical functions	Trusted partnership with payor groups fosters strategic pricing and utilization negotiations and creative contracting

Source: Strategy& analysis

Exhibit 6

Government affairs (GA)

	Reactive	Tactical	Strategic	Leading
Strategy	There is no clear GA strategy linked to business objectives	Ad hoc GA strategy addresses short-term issues without a company-wide remit	GA strategy focuses on long-term issues, prioritizing key trends and building trusted advisor status	Real-time assessment and prioritization of policy changes informs a GA strategy aligned to business objectives GA acts as policy shaper for business-critical issues
Organizational structure	There are no local or global GA teams; CEO has no engagement in shaping policy	There is a limited global-level team with no local GA teams; CEO has limited engagement in shaping policy	Local GA teams report to global, and CEO is fully engaged in shaping policy	Local GA team is part of local CF team, which reports to a global CF leader CEO is an industry leader in business-critical topics
Process, systems, and tools	There is no process, tools, or communication strategy for critical topics	Policy positions are available on short-term issues, but are only sporadically communicated internally	Execution of GA strategy via cross-functional GA teams is based on policy positions for short- and long-term issues	Proactive GA strategy development and execution take advantage of opportunities and limit risk, including use of technology and analytics to track GA campaigns
Skills and culture	GA skills are limited, and there is no plan to build capabilities, since GA is not considered strategic	Company is building global GA capabilities and cross-functional interactions to facilitate relationship building with policymakers	GA maintains continuous dialogue with policymakers and influencers, with the company enjoying advisor status for key issues with policymakers	Company earns trusted advisor status with policymakers and influencers and forms external coalitions and partnerships as needed GA seen as the connecting glue for CF teams

Source: Strategy& analysis

Exhibit 7
Medical affairs (MA)

Reactive	Tactical	Strategic	Leading
Strategy			
There is narrow remit for post-launch input into commercial strategy only, and no cross-functional disease area strategy	MA develops disease area strategies while providing input to real-world data strategy and contributing to development of patient-centric solutions with limited attention to outcomes	MA generates customer insights from market research and medical information to develop cross-functional disease area strategies incorporating real-world data to drive patient-centric approaches with the ability to track outcomes	There is a cross-functional effort to develop real-world data strategy pre- and post-approval, and to develop patient-centric solutions with demonstrable patient outcomes, aligned to a digital strategy; company acts as a trusted advisor and partner to healthcare providers
Organizational structure			
There are no in-field local MA resources MA reports to commercial locally There are separate medical information teams	Limited in-field MA resources report to the same leader as regulatory affairs MA reports globally to commercial, but there are stronger links with clinical	There are more in-field MA resources than sales reps for specialty Local MA reports directly to global MA Involvement of MA teams across product life cycle is growing	In-field and headquarters resources are optimally leveraged across MA MA reports to local CF leader, who in turn reports to global or regional CF leader
Process, systems, and tools			
MA provides advice to clinical development team on request MA reactively provides medical education in response to product queries Healthcare provider payments are manually tracked	MA provides advice to clinical development team and produces medical education material for key products Team standardizes medical information responses for key products System for healthcare provider aggregate spend data analytics is implemented	Approach to input into clinical is proactive Medical information responses are consolidated globally, running outcomes-based medical education campaigns and generating insights from key opinion leaders	MA informs clinical development through customer insights and develops innovative medical education campaigns, focusing on improved patient outcomes MA enables superior transparency for interactions with healthcare professionals Enterprise-wide data analytics are leveraged
Skills and culture			
Siloed culture focuses team on purely MA activities, with limited business acumen and relationship-building skills	MA implements tactical relationship management while building capabilities in real-world data know-how and strategy development	Team learns digital approaches and analytics while leveraging strong alliance and relationship management skills	MA implements digitally enabled engagement and relationship building with key opinion leaders, based on strong scientific knowledge balanced by strong business acumen

Source: Strategy& analysis

Two companies, two successes

To illustrate the potential impact that building more integrated critical team capabilities can have on a pharmaceutical company, consider the case of a global pharma company that assessed the cost of government activities — including regulations, insurance and payor policy decisions, and agency rule making — on its business at US$1 billion a year. In doing this analysis, the company realized that its operating model lacked strong and cross-functional critical teams, particularly pertaining to understanding and anticipating policymaker sentiment and decision making. As a result, the company was in reactive mode, unable to respond effectively to government actions in a timely manner.

With a lack of visibility into regulatory deliberations, pricing, and market access, each sector of the operating model acted independently, ensuring an inefficient outcome. For example, in the absence of relevant intelligence to guide strategic launches, the company would begin to think about preparing the market for a drug just a year before the product's introduction, far too late for a successful pharmaceutical launch. But without a connected critical team, there was no other option for developing an external strategy aligned to the business strategy.

Unhappy about the money it was losing due to its own shortcomings, the pharmaceutical company created a framework for building a critical team capability that most mattered to the success of the business. Specifically, it created subteams to support ongoing communication and interaction with marketplace influencers, regulators, pricing decision makers, and the healthcare community. Members of these teams were not just policy wonks but also business strategists. This gave them credibility within the company to help craft strategic options as well as the ability to be on equal footing with outside sources whose activities affected the company.

On the wings of this organizational transformation, the company has succeeded in areas where it was previously failing. The primary change is that the company is now a close-knit partner with regulators and government agencies, helping to craft healthcare policy. Simultaneously, it has opened vital external channels for collecting intelligence and insight that can inform internal strategic options about product development and launches.

In another instance, a pharmaceutical company found itself facing policy changes on the payor side in Europe and Asia, supported by government decision making, that negatively affected revenues from some of its leading brands by as much as 20 percent. Worse, pricing actions involving these drugs took the company by surprise because it had invested little effort and few resources in understanding and anticipating what payor and physician communities, as well as governments, were considering to address spiraling healthcare costs.

However, after a campaign to build critical team capabilities, things changed radically for the company. By adding substantial skill sets in medical affairs, government affairs, and market access, in particular, the company was able to integrate a much more well-rounded view of the external payor, healthcare professional, regulatory, and policy landscape into its internal market discussions. Unlike before, the company could proactively address fundamental questions: How can we protect our cornerstone brands by having more

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coordination between our commercial side and the critical teams? How do we communicate our points of view to the medical and payor communities, and how do we address their concerns consistently? How do we provide the right level of data to influence payor decisions without compromising the conditions the product is approved for? How do we educate providers about the value of our pharmaceuticals and work with them to drive efficiencies in healthcare delivery?

Previously, various silos were responsible for answering these questions and others. That, inevitably, led to duplication of effort and inconsistent messaging in the marketplace. But now the stronger and more coordinated capabilities of the critical teams are essentially serving as an early warning tool, a way to sound the alarm within the organization that an issue about a planned or existing drug would affect the company's projected performance and that tactics and strategies would need to be altered to address the potential problem. The successful difference at this pharmaceutical company can best be described as a shift in emphasis and in internal planning cohesion. In the past, the commercial team would go to market without enough information to navigate conditions as they changed; now, the commercial team is benefiting from the collated foresight that external-facing critical teams are amassing, using this new knowledge to drive a more logical and lucrative marketplace strategy for their leading brands.

Conclusion

Combined with a diligent effort to cross-pollinate the pharmaceutical organization with strongly supported interdepartmental communications and collaboration channels, critical teams can serve as a catalyst and oversight engine for better-informed business decisions, from R&D through commercial and supply chain activities. And perfecting the capabilities of these critical teams will lead to development of fundamental operating levers involving strategy, organizational structure, process, and skills, further improving company performance, productivity, and innovation. Having an integrated critical team can make the difference between seizing the opportunity to get ahead of the curve or becoming the victim of inevitable disruption.

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