

Insights into Pharmaceuticals and Medical Products

Beyond the storm

Launch excellence in the new normal



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Contents

1. Introduction



2. Becoming a launch powerhouse

Understanding the drivers of launch excellence can help companies close the gap between expectations and results.

Hemant Ahlawat, Giulia Chierchia, and Paul van Arkel



Choosing to be great in a handful of make-or-break activities

10. Managing launch uncertainty with scenario planning

Uncertainty abounds before, during, and after a launch, but scenario planning offers a way for companies to manage the risks effectively.

Karam Malhotra, Nisha Subramanian, and Michele Ravisconi

16. Establishing unmet needs

Shaping how your drug's target disease is perceived by medical professionals and the public can make a big difference to the success of your launch.

Jan Adams, Chinmay Bhatt, and Brent Hooper

22. Developing deep customer insights for launch

New market research techniques for understanding customers and other stakeholders are helping pharma companies to position their brand, shape their market, and create competitive advantage.

Hemant Ahlawat and Michele Ravisconi

28. Landing launches in a market-access world

Tightening constraints on market access are creating an increasingly tough launch environment. Success involves differentiating products in a way that pays value.

Fanny Cavalie and Michael Edwards

36. Maximizing launch uptake

Companies have only one shot at getting a launch right. Setting up a launch situation room maximizes their chances of success.

Hemant Ahlawat, Giulia Chierchia, and Martin Uriarte

42. Accelerating launch through superior share of insights

In a data-rich environment, the basis of competition is shifting. By harnessing new sources of information, companies can develop superior real-time insights to help them win at launch.

Jamie Cattell, Fanny Cavalie, and Giulia Chierchia



Creating and embedding distinctive launch capabilities

52. Developing launch capabilities

How do you build launch capabilities quickly and effectively when your team last launched years ago and in a different therapy area? Establishing a launch academy could be the answer.

Lars Hartenstein, Karam Malhotra, and Nisha Subramanian

62. Organizing for launch success

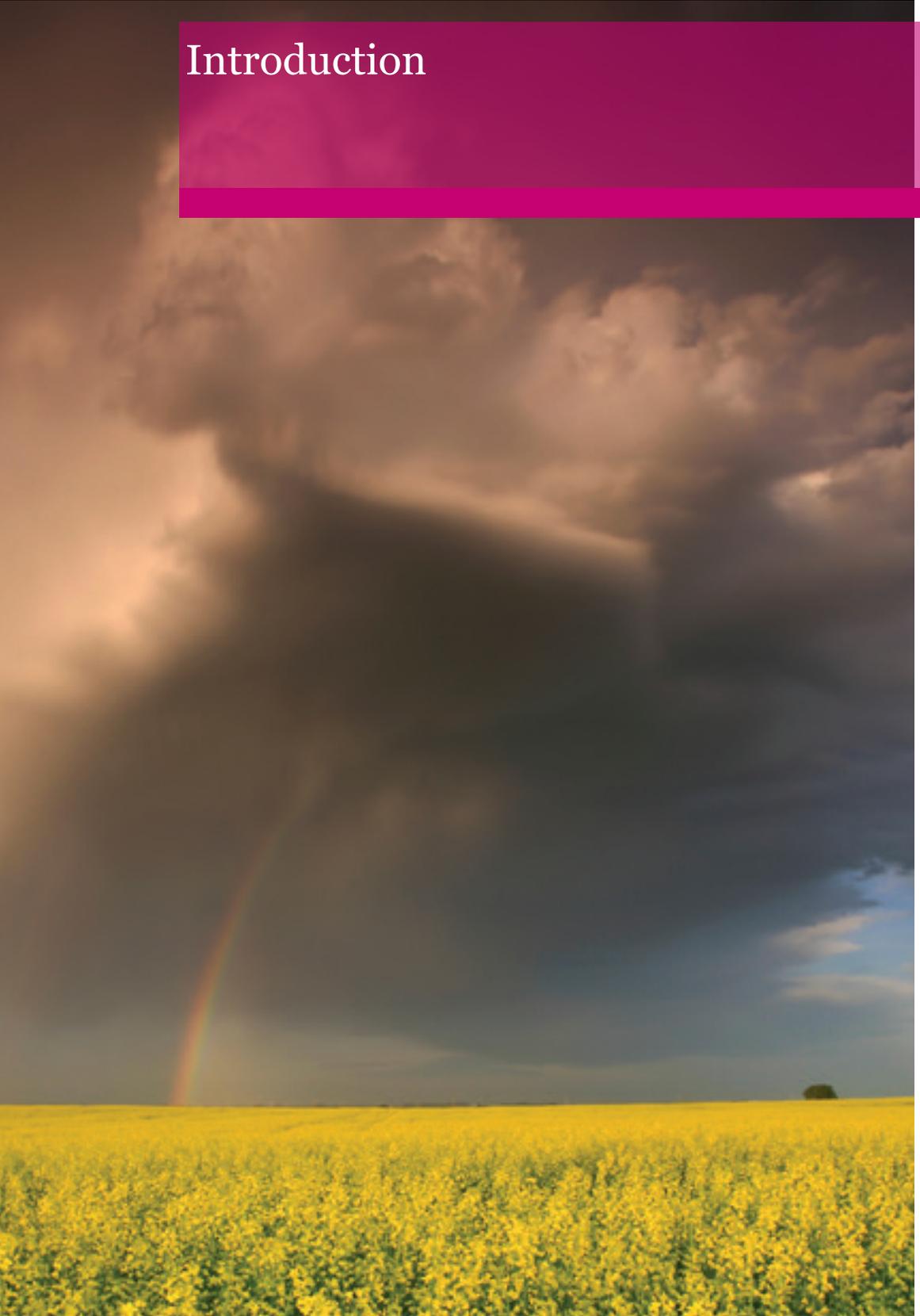
Setting up a launch excellence department is a smart move for most pharma companies – but should it be a program office or a blockbuster launchpad?

Giulia Chierchia, Johannes Doll, and Paul van Arkel



68. About the authors

Introduction



Over the next three years, pharmaceutical companies will launch some 400 products and indications per year, up 146 percent from 2005. By 2015, sales from products launched in the past five years should account for more than US \$80 billion worldwide. In an era of patent cliffs and shrinking pipelines, capturing full value from every product launch is critical. But with only about a third of launches meeting or exceeding analysts' expectations, the challenge is considerable, and unlikely to get any easier.

For one thing, there is no let-up in announcements of austerity plans affecting pharmaceuticals, and many markets are already implementing short- and long-term measures to reduce spending. These austerity plans may not have a major direct effect on product launches, but what is more important is that they change the rules of the game, increasing local and national hurdles to access, raising the bar on value definition and demonstration, and requiring companies to develop a more granular understanding of physician and payor needs.

At the same time, launches are becoming smaller and more competitive. Portfolios are highly fragmented, with sales from the top 10 products in 2014 likely to be half those in 2008, and specialty launches accounting for 75 percent of pipeline drugs, up from 58 percent in 2004. In a world of mounting pressure on margins, growing complexity, and more targeted launches, companies face the question "How can we do more with less at launch?"

Finally, our research suggests that many upcoming product launches will need to be creative in crafting their value proposition and marketing claim. We recently analyzed a sample of 60 upcoming product launches according to two criteria: the product's perceived level of differentiation from existing treatments and the extent to which the target disease is perceived as a significant burden to society. (For instance, diabetes and cardiovascular disease are a priority for healthcare institutions, but not everyone would agree on the urgency of treating ADHD.) Our analysis revealed that just 25 percent of upcoming launches in the sample showed significant differentiation and treated a disease area with a high perceived burden, while more than 53 percent showed moderate or no differentiation and will need to find a positioning edge to make them stand out from the crowd.

Given the complexities, how do you win at launch? The purpose of this compendium is to help pharmaceutical executives answer this question and maximize the value of every product and indication. To that end, we begin by sharing our view on what it takes to deliver excellence at launch, building on lessons learned in other industries as well as pharmaceutical. We then outline our latest thinking on how to address the key decisions that will shape product strategy. Finally, in a setting where only one out of 10 members of a typical launch team has ever launched a product, we close by presenting our thoughts on how to develop the capabilities teams need for a successful launch and embed them in the organization.

We hope you find the ideas in this compendium helpful, and we look forward to continuing a dialogue with you as you prepare for your own launches over the next few years.



Hemant Ahlawat

Principal
Brussels office

Becoming a launch powerhouse



Understanding the drivers of launch excellence can help companies close the gap between expectations and results.

Hemant Ahlawat, Giulia Chierchia, and Paul van Arkel

With patent cliffs rapidly approaching and an increasingly challenging external environment, many pharmaceutical companies depend on new drug launches to fill gaps and drive growth. Yet, the recent track record for launches is sobering at best. Compared to analysts' expectations, real-life results have been extremely erratic.

As Exhibit 1 shows, two-thirds of a sample of 210 launches failed to meet pre-launch consensus sales expectations for their first year on the market. Having done so, they were likely to continue to under-deliver in the next two years. Conversely, launches that managed to exceed year 1 analyst expectations had a strong likelihood of continuing to outperform expectations for the next two years.

The importance of getting launch right first time and the difficulty of recovering from a slow start suggest that there is an overwhelming need for a consistent approach to ensure launch success. Through extensive experience with pharma companies, we have identified four critical areas that drive excellence at launch.

Drivers of consistent launch excellence

If the industry has a recipe for launch success, it could be described as “shape the product, shape the market, shape the company.” Our research confirms that companies do need to do these things, but in themselves, they do not lead to consistent launch excellence.

So what makes the difference? We believe that consistent success with drug launches is a function of four interrelated elements, each of which can be strongly influenced by management (Exhibit 2).

Keeping track of the fundamentals

In many ways, launch is like rocket science. Hundreds of activities all need to happen at predefined moments to a certain standard. As uninspiring as it may sound as a starting point for excellence, companies first need to ensure that nothing falls between the cracks. When the impact of a launch differs considerably from country to country, it's often because of inconsistent execution of the launch plan.

To get the fundamentals right, companies need to focus on:

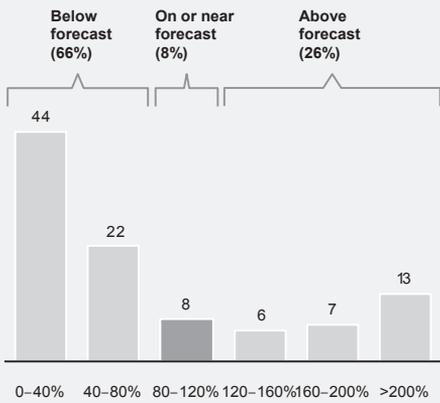
Developing a launch roadmap.

Most companies have some version of this: a detailed work plan

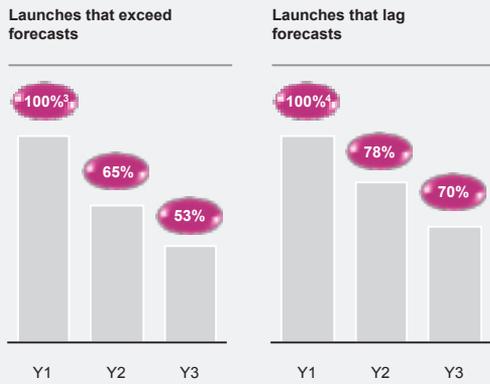
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Exhibit 1: How launches perform against expectations

Ratio of actual sales at year of launch to forecast sales one year prior to launch¹
% of launches



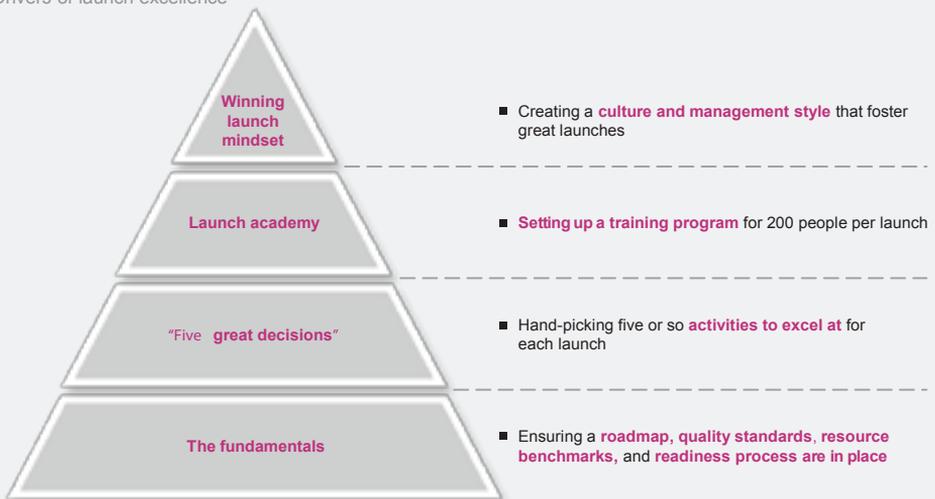
Launches that exceed or lag consensus forecasts in year 1 are likely to continue doing so²
% of launches



1 The sample comprises 210 new molecular entities first launched between 2003 and 2009 for which Evaluate consensus forecasts were available one year prior to launch
 2 We took the launches whose actual sales exceeded (or lagged) forecast in year 1 and calculated the share that continued to exceed (or lag) forecast in year 2, and repeated the calculation for year 3
 3 Represents 30% of launches in the sample (26% of launches with 120% or more of forecast sales from the chart on the left, plus 4% from the "on or near forecast" group)
 4 Represents 70% of launches in the sample (66% of launches with 80% or less of forecast sales from the chart on the left, plus 4% from the "on or near forecast" group)
 Source: Evaluate; McKinsey analysis

Exhibit 2: What it takes to become a launch powerhouse

Drivers of launch excellence



of the 200 to 700 activities and deadlines that lead up to launch.

Monitoring the progress of global, regional, and affiliate activities against the roadmap. Many companies do not have a fully functioning global “heat map” of launch timelines against the plan. Best-practice companies have a monthly global readiness check that is underpinned by objective quality standards (not activity owners ticking their own boxes) and set up as an opportunity to ask for help (rather than a punitive auditing for problems).

Monitoring the progress against objective external key performance indicators (KPIs). Viewed in hindsight, winning launches show signs of success long before the actual launch date. Indicators such as cross-functional collaboration, employee enthusiasm, and buzz in the medical community provide an early window on whether a launch is on track.

Choosing to be great in a handful of make-or-break activities (“five great decisions”)

Every launch has its own set of key success factors. Cialis invested heavily in developing deep customer insights to create a strong positioning against the well-established Viagra in the face of a challenging drug profile, Baraclude needed to follow a targeted and lean launch approach in line with the atypical epidemiology and prevalence in developing countries of hepatitis B, and Gardasil needed to change the perception of human papillomavirus from a sexually transmitted viral disease to a causal factor in cervical cancer. For such key success drivers as these, simply being at a best-practice level is not enough; companies need to go a step further. Out of the many activities they perform to prepare

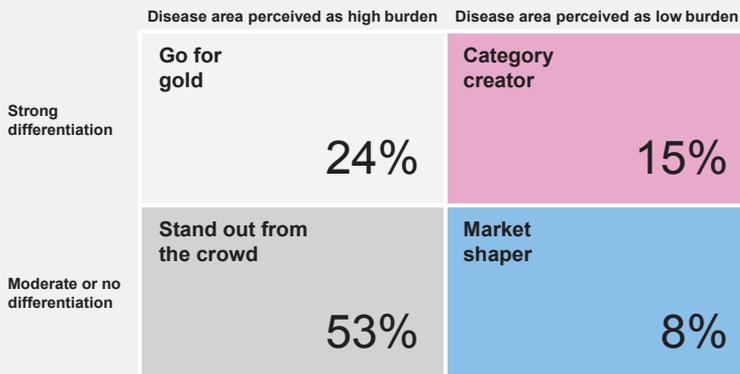
for a launch, they need to pick the three to five that will really make a difference.

In practice, the list of activities that can make or break a product launch will largely depend on the type of launch in question. We recently took a sample of 60 launches in late-stage development and analyzed them along two dimensions: the level of clinical differentiation (“does our drug demonstrate a clearly superior safety or efficacy profile when compared to alternatives on the market?”), and the perceived burden of the disease area in which the drug is to be launched (“does the disease area addressed by our drug have a high or low perceived burden?”). As Exhibit 3 illustrates, the results show that product launches can be broadly categorized in four archetypes, each requiring its own “great decisions”:

Roughly one in four launches can be classified as “go for gold” launches. These involve drugs that are strongly differentiated from competing products and treat diseases with a high perceived burden. Examples include Zytiga, Johnson & Johnson’s recently launched prostate cancer treatment, and Januvia, Merck & Co.’s drug to lower blood sugar levels in people with type 2 diabetes. This kind of launch runs a substantial risk of falling into the trap of “this product is so good it’s bound to sell.” To capture the full potential, pharma companies must ensure they shift substantial resources from inline brands to finance the upcoming launch. They also need to avoid the “good data trap” by seeking out possible barriers to prescription, and should focus on capturing the potential as quickly as possible by creating maximum early exposure to the product, closely monitoring launch uptake, and correcting their course if necessary.

Exhibit 3: Four launch archetypes

Share of launches in sample¹



¹ Based on a sample of 60 late-stage drugs

Source: Evaluate; McKinsey analysis

- At the other extreme, more than half of upcoming launches are of moderately differentiated products in well-established disease areas, and their priority will be to find a way to “stand out from the crowd.” These launches must find or create an edge that will allow the drug to be positioned effectively for particular patient segments and create clear differentiation from existing competitors. This will require innovative approaches to unveil insights into stakeholder needs and behaviors that competitors do not have.
- For roughly 15 percent of launches, the priority will be to establish unmet needs effectively to ensure access for a targeted population to a well-differentiated treatment. We call these launches “category creators.” Gardasil, with its recent launch in the unestablished human papillomavirus (HPV) market, is an example.
- Finally, the remaining 8 percent of launches will face the substantial challenge of launching an

undifferentiated product in an unestablished disease area. Once the decision to market such a product has been taken, the priority for these “market shaper” launches will lie in securing access for the product and effectively establishing unmet needs.

Although we acknowledge that no two launches are the same even for drugs with similar profiles, knowing the archetype a product launch falls into can help companies identify the three to five key strategic choices they need to make to meet or exceed launch expectations. Exhibit 4 provides examples of key success factors for each archetype.

Identifying the great decisions for a specific launch is the first step; the next is to shape and execute them effectively. Pharma companies will need to master new approaches to navigate launch uncertainty, establish unmet needs in the disease area, develop deep customer insights as a basis for a truly differentiated positioning, land the products safely in a market access world, and maximize launch uptake, and use

Exhibit 4: Key success factors by archetype

Perception of disease area

		High burden	Low burden
Perception of disease area	Strong differentiation	<p>Go for gold</p> <ul style="list-style-type: none"> ▪ Starve the rest of the organization ▪ Get out of the blocks fast and maximize exposure to the drug early ▪ Price for value, not competition ▪ Avoid the good-data trap 	<p>Category creator</p> <ul style="list-style-type: none"> ▪ Don't underinvest ▪ Establish unmet need effectively early on ▪ Maximize early exposure to the product ▪ React and course-correct rapidly
	Moderate or no differentiation	<p>Stand out from the crowd</p> <ul style="list-style-type: none"> ▪ If there is no edge, create one ▪ Every dollar matters ▪ Price to compete ▪ Get insights that competitors don't have ▪ React and course-correct rapidly 	<p>Market shaper</p> <ul style="list-style-type: none"> ▪ Secure access ▪ Find an edge ▪ Establish unmet need effectively early on

early experiences in the market to fine-tune ongoing launch activities. The next few chapters in this compendium tackle each of these tasks in turn and provide insights into how to approach them effectively.

Setting up a launch academy to instill distinctive launch capabilities

If keeping track of the fundamentals and deciding to be great in a handful of activities are mainly about shaping the product and the market, setting up a launch academy is about shaping the company. The key activities here are selecting, training, and motivating the extended launch team.

Most global launches succeed or fail by the efforts of 150 to 200 people. These people come from the global cross-functional team (marketing, medical, clinical, regulatory, and so on), and the launch teams in the top ten or so markets (such as the US, Japan, China, the EU5, and Brazil). For a successful launch you would want all of these people to have launch experience – ideally, two recent launches under their belt. In practice,

though, most of them will be on their first or second launch and learning as they go during the critical launch period.

In much the same way that GE has established a corporate learning facility to advance management development, successful pharma companies create a launch academy. The 200 people who are most important to the launch spend time with successful leaders of past launches, reviewing and discussing case studies, best practices, and lessons learned from failures. Between these sessions they build their skills and get individual coaching on the job. Taking this “field and forum” approach enables companies to create a simulation of launch experience in a group of future launch leaders.

Developing a winning launch mindset

Intangible though it may sound, great launches have a different feel from normal launches. There is a real sense that “we’re all in this together.” Senior executives are problem-solving partners. High aspirations are coupled



with a readiness to acknowledge the challenges the product will face.

This “special sauce” is not always present; in fact, most launches have to do without some or all of it. Creating it is not an exact science, but there are a number of leadership behaviors that, if skilfully combined, will help to develop the mindset you are looking for. They fall into eight categories:

- **Direction.** Has the company made key strategic choices on issues such as priority assets and partnering? Has it created a compelling overarching story about the drug being launched?
- **Leadership.** Are senior managers reinforcing the importance of the launch through role modeling? Have they set stretch goals for the organization?
- **Environment and values.** Are the elements of a winning launch culture in place? (For instance, even as Apple launches one of its new products into the market, it is already focusing on capturing insights to improve its next launch.)
- **Accountability.** Do people at all levels feel they own the business and want to help build it? Is there clarity over roles and responsibilities, targets, and metrics?
- **Capabilities.** Does the company have the right leaders in charge of the launch? Do the 25 people who will make or break it have the right training and support?
- **Motivation.** Do launch teams and their leaders have appropriate incentives? Are launch leaders comparable in status to regional heads?
- **Innovation.** Is the company carrying out controlled experiments to road-test new ideas? Do launch leaders tap into wide external networks?
- **External orientation.** Does the company see value creation for customers as its primary objective? Beyond that, is it working to maximize value for all stakeholders?

To instill a winning mindset, companies need to work on developing these behaviors from the earliest stages of their launch.



How best to tackle these four elements – the fundamentals, the “five great decisions,” the launch academy, and the winning launch mindset – will naturally differ from company to company. A small biotech with just one launch to prepare is likely to find it easier to instill a winning launch mindset than a large corporation would, for instance, but it may have more difficulty creating a launch academy. Even so, focusing on all four elements will increase the chances of success.

Clearly, none of them is easy to get right; not even the fundamentals can be taken for granted. But they are all eminently manageable. Given time, focus, and resources, any company can make progress and maximize its chances of meeting or exceeding expectations.

We hope that this article has provided food for thought on what it takes to be consistently excellent, and that it has left you with two questions:

- How well is our company doing in terms of the four core activities in the pyramid in Exhibit 2?
- What do we need to change to be consistently excellent at launching new products?

Managing launch uncertainty with scenario planning



Uncertainty abounds before, during, and after a launch, but scenario planning offers a way for companies to manage the risks effectively.

Karam Malhotra, Nisha Subramanian, and Michele Raviscioni

A pharmaceutical launch is a time of uncertainty and risk for the company involved. McKinsey research indicates that only about 30 percent of compounds that enter the market recover their risk-adjusted R&D cost, and around half of products achieve less than 50 percent of the sales that were forecast a year before launch. Many events, internal and external, can compromise the success of a launch.

In spite of this high failure rate, it is rare for commercial and launch teams in the pharma industry to take steps to frame the uncertainty they face and develop plans to manage it. This may seem surprising for an industry that faces high upfront investments and low success rates. The same is true of the upstream oil and gas industry, for instance, but companies such as Shell have successfully embedded tools for managing uncertainty in their long-term strategy decisions and downstream commercial operations. By contrast, pharmaceutical companies seem to neglect the uncertainties that exist after research and development, and often overlook the contingencies that may affect their commercial operations from launch onward.

In this article, we highlight the many types of uncertainty that can make or break a new drug launch and explore how scenario planning can be used to increase the

chances of success. It can have at least three positive effects on product launches:

- **Operational.** Good scenario planning helps organizations evaluate external and internal uncertainties and define actions that can shape these uncertainties toward the most favorable outcomes. It also helps them be better prepared to react quickly and effectively if things do not go to plan.
- **Financial.** Using true scenarios rather than base case plus or minus leads to more robust forecasts and greater clarity on key assumptions and their likelihood.
- **Strategic.** Scenarios provide a narrative and a language for the organization to use in shaping its future strategies. They also provide a safe haven for contrarian thinking that may provide insights that help minimize risk.

Sources of uncertainty

A drug launch is characterized by three main types of external or environmental uncertainty:

- **Regulatory and access.** Launch preparation starts long before final decisions are taken on a drug's label

or pricing and reimbursement. In some markets, including Germany, the UK, and the US, a product is commercialized almost immediately after its approval by the EMA or FDA, leaving little room for a company to correct its course if payors make unexpected decisions. Changes in their priorities and policies, unpredictable label changes, and budget cuts can all have major consequences for a product's launch strategy, tactics, and eventual success.

- **Clinical.** In principle, a pharma company enters the launch phase as soon as the clinical data from its Phase III registration trial is published. However, data analysis often continues, with subgroup analysis and statistical elaboration of efficacy and safety data. Findings from these analyses, as well as challenging interpretations of results by “antagonist” investigators, can have a considerable impact on a product's launch plan.
- **Market.** Competitors' clinical results, shifts in medical practice, disruptive innovations, and competitors' negative counter-messaging can radically alter a new product's market situation before launch and impair its eventual outcome.

Uncertainties over a company's internal issues can also change the course of a launch plan. Again there are three main types of uncertainty:

- **Portfolio.** A product launch often takes place in a portfolio context. To maximize the value of the franchise, the launch must take into account existing brands and look forward to those later in the pipeline. Swings in commercial success or unexpected clinical results can lead to changes in portfolio strategy that will in turn

affect the launch brand's importance, positioning, and ambition.

- **Organizational.** From M&A to changes in organization structure to the introduction of innovative commercial models, the pharmaceutical industry has undergone numerous shifts in the past decade that have led to changes in brand ownership or commercial approach.
- **Resource.** The resources required for launch are evaluated frequently at global, regional, and local level and can change in response to increasing cost pressure, the needs of other brands, and overall company performance.

The challenges of managing uncertainty

As well as influencing the performance of a product in the market, uncertainties also create a set of challenges that launch teams must be prepared to manage.

Deciding for tomorrow today

Making decisions about a launch is similar to making decisions during product development: both involve placing big bets on the strength of expectations for the future. However, commercial launch teams are used to having much shorter feedback loops for their decisions, and often lack a culture that can cope with uncertainty and forward-looking decisions. Uncertainty can vary along a spectrum from one extreme where the likelihood of an event's occurrence is entirely unpredictable to the opposite extreme where solid assumptions are available to support a firm decision.

We often see launch teams oscillating between these two extremes when



considering their decisions, but on closer inspection it is usually possible to map scenarios in between them, either in the form of a set of discrete scenarios each with an unknown probability of occurrence, or as a combination of plausible scenarios with varying probabilities of occurrence. This middle path often provides a manageable approach for dealing with uncertainty.

Realizing the value of a future option

Uncertainty is not always a bad thing. Surprisingly positive pricing decisions or more promising than expected clinical data, to take just two examples, can significantly boost a planned product launch. However, it's common for launch teams to overlook such possibilities and model only the most likely outcomes. By doing so, they ignore the value that management could derive if it had the flexibility to take advantage of future upside opportunities. Adopting an active approach to managing uncertainty by considering multiple scenarios and possible management responses to them enables launch organizations to prepare themselves to take full advantage of future opportunities and threats.

Reacting quickly to change

Because of their size and structure, pharma companies tend to be slow to register change, react to it, and correct their course. Basing a launch plan on a single likely scenario creates a false perception of certainty and can make even top management less likely to pick up early signals of unexpected events. By contrast, building uncertainty into a launch plan heightens management's sensitivity to events that require a change in course and buys precious time to steer a large and complex organization.

Integrating scenario planning into a launch plan

In our experience, scenario planning can be integrated into a launch plan in four simple steps:

- **Step 1:** Identify the key uncertainties by mapping internal and external variables that may change over time.
- **Step 2:** Prioritize these variables according to their likely impact, the probability they will occur, and the company's ability to influence this occurrence.

- **Step 3:** Combine the variables into an issue tree – a logical method to identify all plausible scenarios – and then prioritize the scenarios using similar criteria to those used in Step 2.
- **Step 4:** Define proactive and reactive steps to be taken to prepare for or respond to each scenario.

While taking these four steps, companies can follow a few guidelines to keep the approach simple and make it more effective:

- Revisit and repeat scenarios as frequently as possible, especially at launch time. In a dynamic market, the probability of changes in external and internal factors is very high.
- To help the organization prepare for only the most important scenarios, try and eliminate scenarios by doing as much prior analysis as possible.
- Define clear trigger events to help manage how a particular scenario is executed or prevent delays in executing it.
- To incorporate competitive moves more effectively into your plans, employ war gaming exercises, which can help you anticipate a competitor's next move and simulate internal competition for funds between products or projects. To do this, give teams a competing brand and ask them to brainstorm its strengths, weaknesses, and overall positioning and product "story." Each team then presents its profile of the competing brand and discusses what effect it might have on your own launch brand. This helps to establish an action/reaction mechanism that will keep you a step ahead of your competitors.

Applying scenarios to improve planning

If a scenario planning exercise is to be effective, it needs to be followed by a rigorous plan with four key components:

- **Strong commitments and big bets.** Don't let your organization become paralyzed in the face of uncertainty; choose your base scenario and commit to it. Align your organization and make investment decisions accordingly, but factor in enough flexibility to deal with unexpected changes.
- **Preemptive no-regret moves.** A launch organization can take two types of preemptive action that always have a positive impact on a launch: *understanding uncertainty* by broadening your understanding to include alternative market research scenarios and deepening your competitor analyses, and *shaping uncertainty* by making a clinical or commercial investment to influence internal and external decisions and increase the likelihood of a favorable outcome.
- **Real options.** Companies can define how they might react to a particular scenario and plan relatively minor investments that can be elevated *if it does come to pass*. Scenario planning can reduce otherwise long lead times for making changes in targeting and salesforce structure, local *clinical trials*, *messages*, and other areas.
- **Contingency plan.** It's wise to create a detailed list of "to dos" for some of the key alternative scenarios. If one of them occurs, the list can be used as a tracker, reducing reaction time and minimizing confusion over next steps.

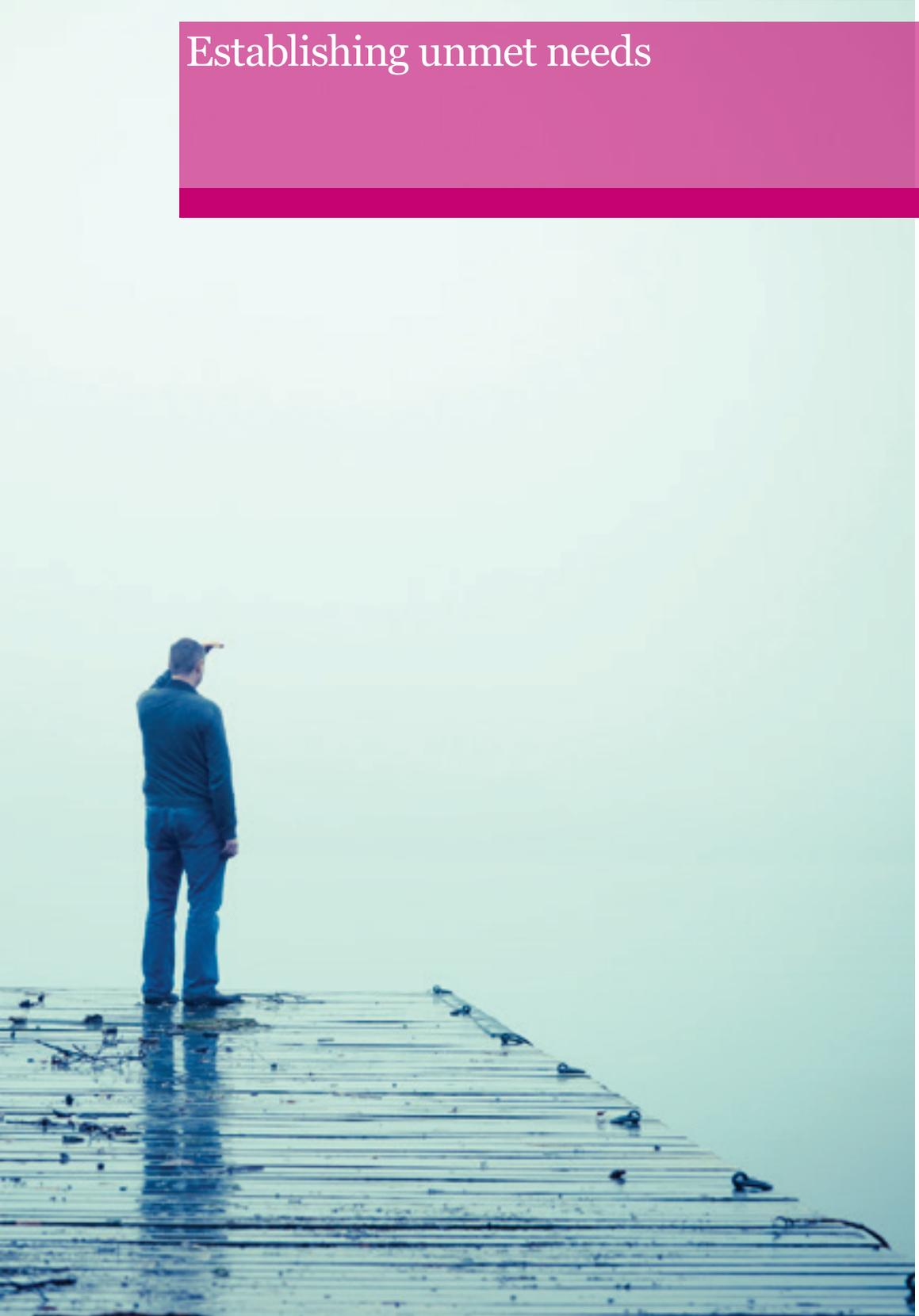


In our experience, most launch teams neglect to describe and manage uncertainty explicitly. Scenario planning is a simple yet powerful device that can be used by any launch team to do just that.

We hope this article has helped you reflect on the importance of managing uncertainty at launch. To end, we suggest you consider three key questions:

- What are the two or three most critical uncertainties that could damage or boost our launch?
- If one of these things happened, what would it take to make the launch a success?
- What are we doing to shape the uncertainty around our launch and prepare for unexpected events?

Establishing unmet needs



Shaping how your drug's target disease is perceived by medical professionals and the public can make a big difference to the success of your launch.

Jan Adams, Chinmay Bhatt, and Brent Hooper

Health outcomes for patients in many major disease areas remain elusive, not always because of a lack of effective therapeutic options. A further complication is the degree and type of attention given to the disease area. Payors are often hesitant to adopt effective new treatment options because of budgetary pressures and their satisfaction with current outcomes. Even after new drugs achieve access, clinicians frequently limit uptake because they do not see the need for these drugs in their clinical practice.

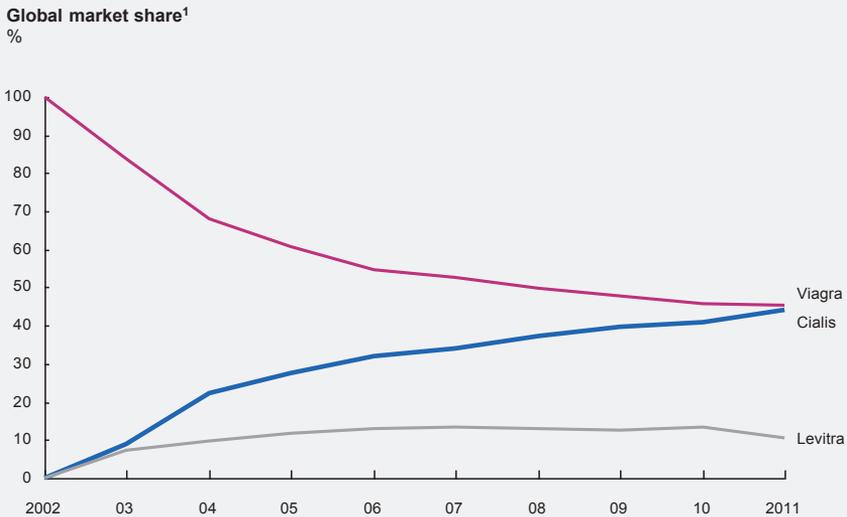
Both of these responses follow from the overall perception of the disease. The extent to which an unmet need is understood and acknowledged defines the resources allocated to it. It also defines how open physicians and other stakeholders are to changing their established behavior. For instance, the emotional response triggered by the term “breast cancer” may differ from that triggered by “lung cancer” because of our underlying beliefs about these diseases. Each has its own image, positioning in relation to other diseases, and set of core messages.

For this reason, launch success is highly dependent on the appropriate perception of the target disease. When fluoxetine entered the market in the 1980s, “major depressive disorder”

was a term reserved for psychiatrists in hospitals. Prozac and its peers helped to reposition depression by clarifying its milder and more prevalent forms. Brochures with titles like “Depression: What you need to know” and media attention on celebrities undergoing treatment were key in repositioning the condition. Today there is much wider public awareness of depression, and diagnosis and treatment rates have increased significantly.

Thus marketers face a dilemma at launch: whether to work to establish the unmet need as well as the drug itself. Many approach this dilemma with the faulty logic that disease awareness will only enlarge the pie for the market leader, and therefore, represents a poor investment for a new entrant. We would argue that on the contrary, the shaping of perceptions of disease can especially benefit launch products because it represents a unique opportunity to transform the dynamics of the underlying market and treatment.

What's more, it is possible to establish an unmet need even in therapeutic areas with high awareness and competitive pressure. For example, at the time of the Cialis launch, erectile dysfunction (ED) was a well-established therapeutic area thanks to the monumental efforts of Viagra. Pfizer had drawn on its long-standing experience in the ED market to emphasize treatment

Exhibit 1: Cialis takes on Viagra

¹ Based on global sales value
SOURCE: Evaluate Pharam

that enabled men to take action and “fix” their condition, an approach primarily targeted at virile middle-aged men. Cialis changed the rules of the game by focusing on couples and their romantic well-being. As Exhibit 1 illustrates, this approach has helped Cialis capture a significant share of the market at Viagra’s expense.

McKinsey’s extensive work with pharmaceutical companies indicates that most launch plans include activities aimed at shaping the market and establishing an unmet need for the new drug. Common initiatives include PR campaigns to raise disease awareness, brochures to leave with healthcare professionals, and efforts to engage with patient organizations. However, these initiatives are often too limited in their scope and focus to achieve their full potential. We believe

companies can achieve greater impact by focusing on five core principles.

The keys to establishing unmet needs

To establish unmet needs effectively among their stakeholders, companies need to act on five principles:

Establishing unmet needs goes beyond raising awareness. Most market-shaping activities are evaluated in terms of how they link to core messages about the brand being launched, so their focus is usually on disease awareness as it relates to these brand messages rather than on shaping unmet needs in a broader sense. To be credible and effective, however, the effort to establish unmet needs must be distinct from the brand. Even well-established needs with high awareness

can be shaped in a way that allows new drugs to be differentiated, as noted above with erectile dysfunction and Cialis. To take another example, when Pfizer launched its Alzheimer treatment Aricept, it focused its support on interactions between healthcare professionals and caregivers that were unrelated to treatment decisions. It invested in nurse-mediated education and counseling programs to improve overall diagnosis and compliance rates, going beyond disease awareness and brand messaging to address disease management in general. Aricept eventually became the world's best-selling Alzheimer treatment, with sales of close to US \$4 billion in 2009.¹

It begins long before launch.

Many brand teams start their market-shaping activities in the months before launch, but shaping an unmet need takes considerably longer. The most effective companies begin work during the clinical development phase so as to transform both the disease perception

and the product profile long before launch. Well before it launched Fosamax, one of the first bisphosphonate drugs to treat osteoporosis and other bone diseases, Merck invested in an intensive campaign to inform physicians (especially gynecologists) and the American public (especially middle-aged women) about osteoporosis and the availability of bone-mineral testing. As part of this effort, it co-sponsored media campaigns with the National Osteoporosis Foundation.

It engages a broad stakeholder set

that goes beyond healthcare professionals and patient organizations and includes public policy makers and media figures. Before launching Fosamax, Merck worked with national and international societies to agree on a common definition of osteoporosis as a bone-density measurement that is a standard 2.5 deviation below the premenopausal mean. This shifted the view on who is the typical patient, expanding the potential



market from 1.3 million new fractures per year in the US to 16 million women at risk.

It requires strong abilities to form partnerships with new organizations beyond the usual physician associations and patient groups. Pharmaceutical companies should evaluate mutually beneficial ties with providers of home care, diagnostics, imaging services, and other related interests. For Fosamax, Merck partnered with diagnostic equipment manufacturers Hologic and Lunar Corporation to finance the roll-out of bone-mineral testing machines in sparsely populated areas.

It leverages best-in-class communication and cooperation tools, including public/private partnerships, word-of-mouth communication, and direct-to-consumer communication through social and other online media. Before Merck launched Gardasil, few women understood the connection between the human papillomavirus (HPV) and cervical cancer. Merck used social and digital media to disseminate information and make sure women understood the risk. Educational campaigns established the link between cervical cancer and HPV and emphasized the need to continue regular screening. A separate social media campaign encouraged women to tell their family and friends.



How a disease is perceived will have a big impact on the success of your next launch. It will determine what resources payors allocate to treatment, how open prescribers are to changing their behavior, and how willing patients are to seek and accept treatment.

Here are some questions you can ask yourself to reflect on your own efforts to shape disease perceptions:

- Does our launch plan include innovative initiatives that will reshape the market? Are we making good use of word of mouth and employing social media and other technologies effectively?
- Are we engaging stakeholders other than prescribers to shape perceptions of our brand's disease area?
- Will our activities transform how the disease is perceived, or are they simply extra vehicles to push our brand messages?
- Are we investing in disease perceptions for our portfolio of future launches? Do our brand teams collaborate closely with our clinical researchers on this area?

Note

¹ Evaluate Pharma.

Jan Adams is a consultant in McKinsey's Munich office, **Chinmay Bhatt** is a principal in the Amsterdam office, and **Brent Hooper** is an associate principal in the Brussels office.



Developing deep customer insights for launch



New market research techniques for understanding customers and other stakeholders are helping pharma companies to position their brand, shape their market, and create competitive advantage.

Hemant Ahlawat and Michele Raviscioni

Pharma companies are coming to appreciate the influence of emotional factors in shaping customers' purchasing decisions. As more and more treatments become available, physicians have less time to weigh up all the options when prescribing, and their decisions will be more likely to be influenced by their personal biases as well as a product's clinical profile and cost. However, the industry has a long way to go to catch up with the consumer packaged goods business, which regards a deep understanding of customers as critical to the process of differentiating a brand from the competition and driving the success of a new launch.

We define a customer insight as the discovery of something fundamental about a customer's needs that can be addressed by marketing strategies and tactics to create customer value and competitive advantage. Such insights may be needed at any moment in a brand's lifecycle to accelerate growth, reverse a negative trend, or prevent stagnation and decline, but they are particularly important at launch, for three reasons:

- The launch team needs to understand what drives customers' choices and be aware of their unmet needs so that it can position a brand in the best possible way.

- The company needs to identify and remove negative perceptions that could create barriers around a disease or drug class, thereby shaping the "landing place" for its launch brand.
- The company needs to gain insights into key stakeholders in pricing and reimbursement and manage an often unpredictable mix of rational, emotional, and political drivers of behavior.

In this article, we offer a perspective on innovative approaches now being adopted in these three areas to gain deeper customer insights for launch.¹

Using today's insights to boost tomorrow's brand performance

In most pharma companies, launch teams start developing customer insights between two years and 18 months before launch in order to allow time for formulating strategy, developing and testing messages and activities, and planning execution. At companies with centralized launch strategy teams, the interval between generating insights and launching a product can be even longer. Launch teams face the challenge of having to draw conclusions about future customer behavior on the basis

of insights from a present that does not yet include the brand being launched.

The methods used in market research can exacerbate this uncertainty. Researchers may try to simulate future scenarios and get participants to role-play their response, ask direct questions about hypothetical preferences and choices, or use techniques such as collage or word association to try and understand how a prospective customer might relate to a new product. The problem is that all these approaches take the prescribing decision out of its context.

In reality, the risk/benefit profile of a product is just one among many forces and influences that shape the prescribing decision. Others include perceptions of the disease, treatment goals, the role of patients, families, hospital physicians, and other healthcare personnel, and budgetary constraints. Moreover, since the brand has yet to be launched and built, those taking part in market research will have no prior knowledge of the product, which will have to be introduced into the consideration set purely through a cold set of rational characteristics.

There is an alternative, however. Market research techniques are emerging that enable companies to go beyond a comparison of product benefits to build a deep understanding of how a prescription decision is reached and the many factors and influences surrounding the decision.

One research technique that we have developed, borrowing principles from a method used in psychotherapy, helps to shed light on the relationship between different elements – physical, rational, abstract, and emotional – in shaping the perception of a brand and influencing a treatment decision. When well executed,

the technique, which we call constellation, reveals the relationships and influences that surround a decision and provides more revealing insights into a customer's decision-making process than any other technique we know (see panel).

We have used the technique successfully for several years in a range of countries and specialties, and find that its focus on the whole decision-making environment rather than a single isolated element makes it a valuable method for extrapolating assumptions about future behavior.

Shaping your brand's landing place

In most launches, the stakeholders in the market will have pre-existing perceptions and opinions of the disease and perhaps the entire therapy area. For instance, cardiovascular is widely perceived as an area of constant improvement where efficacious drugs and surgical procedures have reduced mortality much more rapidly than in oncology. As a result of this perception, the unmet need in the cardiovascular area is often underestimated.²

Some classes of drugs are subject to irrational perceptions by the very practitioners who prescribe them. For instance, in some markets the anti-clotting medications indicated for acute coronary syndrome are considered by some GPs and specialists to be drugs for treating a heart attack. This misconception often leads patients to be given shorter treatments than indicated – perhaps weeks instead of a year.

Perceptual barriers such as this often depress a brand's performance at launch

The constellation technique

This technique originated in psychotherapy as a way to release and resolve tensions within and between people. It was developed by a number of philosophers, psychologists, and therapists, including Edmund Husserl, the father of phenomenology, and pioneers in the field of family therapy. Alfred Adler used the term “family constellations” to refer to the relationships between an individual and his or her parents, siblings, and other family members.

When helping pharma clients to conduct market research, we use a version of the constellation technique with groups of physicians. A trained moderator, ideally a psychologist, helps to run the sessions. Each participant is given a name tag with an element that we want to include in the analysis, either physical, such as a patient or product, or emotional, such as quality of life or fear.

One physician is chosen to lead the exercise and is asked to place participants around the room in positions, distances, and orientations that represent his or her personal assessment of a particular treatment setting, such as the management of coronary failure or diabetes. Once all participants have been placed in the constellation, the moderator asks the physician a series of “why?” questions to elicit the reasons behind the choice of positions. Meanwhile the other participants remain silent.

The other physicians then take turns to ask questions, express differences of opinion, and make changes in the constellation. Their physical engagement in moving people around, coupled with their frustration at remaining silent while others shape reality, generates energy and prompts discussions that yield rich insights.

The fact that companies can choose which elements to include and then modify them to develop alternative scenarios or challenge the group makes this a flexible and powerful technique.

by creating pricing and reimbursement hurdles that lead to sub-optimal product use or discourage adoption altogether. Best-in-class companies look carefully for insights that could reveal unsuspected barriers or opportunities, and adopt a structured approach to shape a favorable landing place for the brand during launch.

Conducting media searches, reviewing position papers from policy makers and medical associations, and consulting patient advocacy groups can all yield helpful insights into perceptions of a disease or therapeutic area, but perhaps the most powerful option is monitoring

consumer-generated media. Many patients choose the internet – in the form of discussion boards, blogs, online groups, and other social media sites – to find information, share experiences, and seek emotional support. A recent study by the Pew Research Center in the United States found that 39 percent of patients use online support groups to discuss their medication and treatment with fellow patients. The anonymity of the internet encourages individuals to share details of symptoms, treatment, experience with doctors, drug efficacy, side effects, and the impact of their condition on their lives. Moreover, physicians themselves are spending



more and more time online in dedicated forums for exchanging expert opinions.

By listening to online conversations, pharmaceutical companies can develop a deeper understanding of how people view specific diseases and treatments and identify opportunities to serve stakeholders better, thereby gaining competitive advantage. Techniques developed by media and internet companies to map internet buzz among stakeholders make it possible to pick out key contributors and recurring themes in online conversations. Pharma companies can use these techniques to listen to what online users are saying about a given brand, therapeutic area, or company, focus on particular consumer segments and compare their reactions, and identify opportunities to provide information directly to key contributors and forums. They can also develop metrics and benchmarks to monitor the impact of their activities, evaluate the effectiveness of their communication and education campaigns prior to and during launch, and track what impact their market-shaping activities are having on the buzz.

Gaining insights into pricing and reimbursement stakeholders

In most markets, pricing and reimbursement conditions are the single most important value drivers at the time of launch. Although many country and regional payors are becoming increasingly sophisticated in their health economic assessments, market access conditions are in practice often influenced by a range of other factors including political agendas, informal social networks within institutions, and emotional drivers such as family members with a particular medical condition. Pharmaceutical companies, on the other hand, tend to focus on pharmacoeconomic models and technical issues, failing to address the political and personal factors that play a part in payors' decision making and thereby limiting the effectiveness of their value proposition.

By generating deep insights into payors' attitudes and their approach to pricing and reimbursement decisions, companies can gain a better understanding of their priorities and concerns, shed light on how the process for updating formularies and protocols really works, weigh up the relative influence of different stakeholders in the final decision, and assess which arguments for articulating a product's value will resonate most with payors.

Different tools exist for gaining insights into payors' priorities and needs:

- ***In-depth interviews*** are permissible in most countries. They should be thoroughly prepared and carefully structured, with easy-to-use analytical and visual support materials that are detailed enough to enable interviewers to explore how payors actually reach their decisions. One effective approach is to show payors a range of different modules that might be used to launch the new brand, and ask them to classify each module as strong or weak. By repeating this exercise with multiple payors, companies can identify which topics and arguments are most compelling and then use them in the value story they develop about their brand.
- ***Focus groups*** are allowed in some markets, although they can be harder to execute than interviews. Companies can use similar research techniques for payors as for physicians or patients. The advantage of focus groups over interviews is the opportunity to hear a range of views and opposing perspectives within the group.
- ***Mock protocol committees***, often involving former members of payor bodies, are the most suitable forum for developing insights into budget impact analyses or the structure of pharmacoeconomic models, but less useful for deriving emotional insights.
- ***Advance notification***, whether formal or informal, is becoming common practice in a number of countries including the UK and Italy. Companies can use interactive modeling tools to help them understand a payor's financial constraints, approach to product evaluation, and decision-making priorities. These tools allow users to vary parameters such as price/volume trade-offs and population restrictions so as to test the payor's likely response to different scenarios.



A robust market understanding is a prerequisite for any successful launch strategy. Today's pharma companies are seeking competitive advantage by developing new approaches to gain deeper insights into their customers and stakeholders. We hope this article gives you food for thought as well as a flavor of some of the innovative techniques companies are now using.

When you think about your own launch plans, we suggest you ask yourself a critical question: are there things that I know (and my competitors don't) about my customers and how they make decisions that I can use to gain competitive advantage? If not, how can I gain more insights that will help me shape my launch?

Notes

1 For a broader perspective on using deep customer insights in pharma marketing, see *The eye of the storm*, McKinsey & Company, 2008.

2 See article on page 16 for more details on establishing unmet needs prior to launch.

Landing launches in a market-access world



Tightening constraints on market access are creating an increasingly tough launch environment. Success involves differentiating products in a way that payors value.

Fanny Cavalie and Michael Edwards

An old physicists' joke says there are 10 types of people in the world: those who understand binary and those who don't. As constraints on market access tighten, launch has gone from a binary process – approval or refusal – to a hugely complex undertaking with ten or more possible outcomes. Gaining regulatory approval has become a cost of doing business, while securing market-access approval for launch requires difficult trade-offs. These might include:

- Can we get sufficient differentiation for a wide population or should we go narrow?
- Should we wait for more compelling evidence or launch now?
- Should we price to ensure rapid access or to maintain a high list price for referencing across Europe?
- In some of our key markets, should we launch at all?

Launch itself is no longer a one-off event. Conditional listings, pricing schemes based on future value, post-launch health technology assessments, and other mechanisms combine to make marketing authorization merely the moment of lift-off. The challenge is to get the product safely back to Earth with the right price and positioning. Only then is the mission truly accomplished.

Proof of the tough nature of the new launch environment isn't hard to find. In just one week in September 2011, Boehringer Ingelheim and Eli Lilly decided not to launch their DPP-4 inhibitor Trajenta (linagliptin) in Germany and Merckle Recordati requested that its statin Livazo (pitavastatin) be reimbursed at a generics price despite its patent protection.

When we speak with pharmaceutical companies, it's clear that many are confident they understand the changes and believe they are well prepared to tackle the challenges of market-access launch and landing. But given the number of restrictions, rejections, and unexpected rule changes, how confident should you be? This article offers some guidelines to help you land your launches safely and ensure your company is set up for success.

Predict the future (or at least plan for uncertainty)

The incentives given to country management teams and many regional teams encourage them to focus hard on the next 12 months. Even those that develop a longer-term vision are unlikely to embed it in their launch assumptions. However, it takes time to understand which way the payor landscape is heading,

and even longer to change direction. Companies' country-level, often brand-focused perspective needs to extend to a long-term view of likely payor needs, evolving market-access mechanisms, and what the system may value.

We recommend companies concentrate on scenario planning at two crucial points in a launch: when they are designing the Phase III program and when they are preparing the market for launch two years ahead. The scenarios should take account of changes in health systems, disease priorities, and patient pathways, and related drivers of both outcomes and funding.

Shape the new world

Regulators, payors, and other authorities are redrawing the rules of the game. If you look ahead to your next major launch, how confident can you be that you know the conditions for success?

Pharmaceutical companies have a critical role to play in the debate about the evolution of market-access rules and regulations. Although payors are introducing these rules and regulations as part of broader reforms to make healthcare funding sustainable, they need to understand the value of maintaining a healthy, innovation-based pharmaceutical industry. One company working alone may not be able to influence the shape of the system, but the pharmaceutical industry can act in consort to engage with public and private payors. Being global by nature, the industry is well placed to help public and private payors understand the pros and cons of different healthcare systems around the world.

In addition, the industry should engage with governments and patient associations to inform the debate on disease priorities and bring to market products that address them.

Across disease priorities and the wider system, companies should agree mid-to long-term policy objectives and use their understanding of payor needs to create a value story that articulates why a particular policy objective is in payors' interest. Active, early, and thoughtful engagement by the industry will be a critical factor in future success.

Start your launch early

The key to winning market access is delivering a product that is differentiated in a way that payors value, yet many product launches continue to be articulated in terms of features rather than perceived benefits. Phase IIb trials need to include the active comparators that payors will view as the standard of care. Phase III must not only show the required level of differentiation, but supply the evidence to ensure that payors will value it.

In an increasingly complex and unpredictable payor world, it is hard for a global team to understand the needs of payors in different markets. They are simply too far removed, and advisory boards and interviews are not representative enough. Instead, this responsibility sits best with individual countries, which are close enough to payors to anticipate how their needs may evolve up to launch.

For pharma companies, this means giving a representative set of markets the capabilities and incentives to act as the eyes of the organization on future

payor needs, and getting global and regional teams to convey these needs to R&D. In turn, to make sound strategic decisions, R&D needs people who have met payors, and understand what they are hearing from the markets.

Get closer to payors – much, much closer

Speak to any pharmaceutical company and it will tell you it understands payor needs. However, much of this insight is usually generic, and anything specific and detailed is often confined to the heads of one or two individuals.

Companies need to become more thorough and systematic in gathering, capturing, analyzing, and acting on payor insights. For any major payor, you should be able to identify:

- The value at stake for you in that organization
- Its key decision-making processes and criteria
- Its major stakeholders and their influencers
- Its current and expected financial position (surplus or deficit)
- Its stated disease priorities and performance against quality and outcomes targets
- Its recent decisions on products and what they reveal about its priorities.

The point is to generate not sufficient insight, but a level of insight that will differentiate you from competitors.¹

This requires a full range of sources.

In many markets there are extraordinary amounts of publicly available information that no one makes full use of. Some of the greatest insights have been generated when companies have analyzed existing outcomes and cost data and taken



them back to payors. For example, one company transformed its relationships with payors in a particular country by holding a series of meetings on the regional challenges in cardiovascular care with six major regions. These meetings enabled the company to reshape its product value story to support growth at a time when competitors were going off patent.

In circumstances where it isn't possible to get close to payors, holding mock committees – whether protocol, formulary, or health technology assessment committees – can provide surprising insights into decision-making processes and help you test and develop your negotiating strategy. You can ask current or former payors, external consultants, or your own teams to play the payor role and explore their potential responses to a product value story.

That said, there is no substitute for having discussions with real payors that are focused not on your products,

but on their needs. In the past three months, how many of your senior managers have discussed health system priorities directly with a payor?

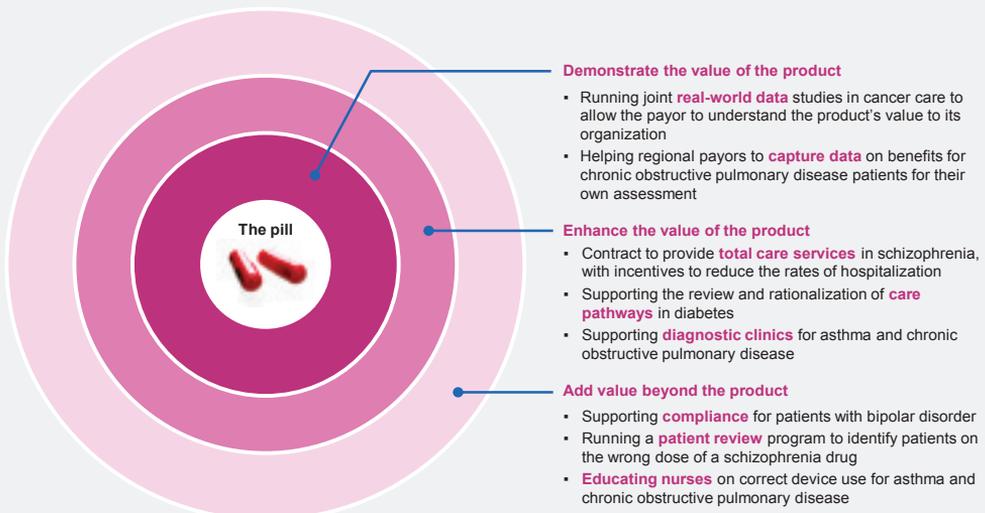
Rethink value

Having generated insights, you need to use them to deliver something payors will value. Initially this may simply involve shaping your product value story to ensure you demonstrate your differentiation. However, the value you aim to deliver can be much more than that. In fact, some changes to healthcare systems are going to require companies to go “beyond the pill” to underwrite launch success, as Exhibit 1 outlines.

Conditional innovative product status or pricing grants you a limited period to show payors that your product deserves its price and position. However, the value it delivers can be jeopardized by poor

Exhibit 1: Three key objectives for partnerships with payors

Hypothetical examples



compliance with treatment, incorrect dosing, use with the wrong patients, and many other factors. You can enhance the product's value by investing in patient adherence and support programs in collaboration with physicians, nurses, and communities. For example, the risk management program for Novartis' Clozaril provides a case administrator to monitor patient appointments and mitigate the risks associated with administering clozapine.

In addition, you may need to generate data to demonstrate the value of your product through real-world data collaborations or the creation of patient registries. In the US, the government has earmarked US \$1 billion to accumulate large data sets on comparative effectiveness, while private payors such as Kaiser Permanente already use real-world outcomes research to increase the usage of generics. Using data in this way should become an intrinsic part of your value proposition. The message is that "our product will improve outcomes, and we will get you the data to justify your investment in it."

You can also consider taking a wider role in delivering value. For example, if your product supports disease prevention, why not offer a broader proposition that combines the pill with lifestyle, education, or screening services? Before launching its osteoporosis treatment Fosamax, Merck partnered with diagnostic equipment manufacturers to roll out bone-mineral testing machines, and before launching Gardasil, its inoculation against human papillomavirus, it invested in intensive education campaigns on the connection between the HPV virus and cervical cancer.

The end point for pharma companies is to take a role in disease management. The industry has seen many false starts: GlaxoWellcome experimented with this

approach in the UK in the mid-1990s, and there have been many other exploratory initiatives. However, the time may be right now that payors understand they need outside support. Janssen-Cilag's management of schizophrenia in Lower Saxony is an example. Working with a third-party care provider, the company has been mandated to manage the treatment of up to 13,000 patients, which will significantly reduce care costs if it reduces hospitalization.

If payors' budgets continue to be under pressure, can they afford to ignore an option like this? It won't work for all markets, but the industry should certainly think afresh and be bolder about the value it could deliver.

Embrace reality

Even before the global downturn, growth in healthcare spending was unsustainable. Payors are introducing measures to ensure the money they spend on drugs delivers value. They may not always use the most effective mechanisms, but the reality is that no health system will pay for new products simply on trust. Designing a fair and transparent way to make these decisions is complex and fraught with tough choices. To launch products successfully, companies should first acknowledge payors' unenviable position in deciding where to spend on health, which patient to treat, and which disease to prioritize.

Under these circumstances, your only option is to go after fair share at a fair price: the part of the market for which you can justify differential value, at a price that is fair to all. Without evidence to support differentiation, it is unrealistic to chase a mass-market launch at a

price premium. Instead, accept that you must start in the part of the market where you can demonstrate incremental value. For some it will be hard to abandon the ambition of treating all patients, but if you don't restrict yourself, payors will do it for you, threatening the wider success of your launch.

- Will our activities transform how the disease is perceived, or are they simply extra vehicles to push our brand messages?
- Are we investing in disease perceptions for our portfolio of future launches? Do our brand teams collaborate closely with our clinical researchers on this area?



How a disease is perceived will have a big impact on the success of your next launch. It will determine what resources payors allocate to treatment, how open prescribers are to changing their behavior, and how willing patients are to seek and accept treatment.

Here are some questions you can ask yourself to reflect on your own efforts to shape disease perceptions:

- Does our launch plan include innovative initiatives that will reshape the market? Are we making good use of word of mouth and employing social media and other technologies effectively?
- Are we engaging stakeholders other than prescribers to shape perceptions of our brand's disease area?

Note

¹ See article on page 22 for more on this topic.



Maximizing launch uptake



Companies have only one shot at getting a launch right. Setting up a launch situation room maximizes their chances of success.

Hemant Ahlawat, Giulia Chierchia, and Martin Uriarte

More often than not the success of a launch determines the success of the product. When we analyzed a random sample of 20 drugs launched in the US market between 2005 and 2008, we found that only 15 percent of them achieved a significant improvement in market share in their therapeutic area after the first six months of launch. The message is clear: there are no second chances; launch teams simply have to get things 100 percent right first time.

Much of a product's launch trajectory is determined before launch. However, simply executing your launch strategy, however well planned it may be, will not automatically maximize uptake. To achieve the best possible impact in the first months of launch, you need to be able to manage uncertainties once you are in the market by rapidly spotting external and internal signs of change and correcting your course accordingly.

This presents a challenge for pharmaceutical companies, since their limited access to market feedback and relatively inflexible commercial models don't make it easy for them to monitor performance and correct their course within the first six months of launch. For example, to understand that the product messaging is not resonating well with physicians, adapt it, and roll out the new

communication through the sales force will usually take at least a full sales cycle of six months. Similarly, designing a clinical study could take 18 to 24 months. With lead times like these, how can companies ensure they are agile enough to maximize launch uptake?

Our experience from past drug launches and from other industries such as fast-moving consumer goods and media suggests that pharmaceutical companies should set up launch "situation rooms" for specific markets to enable country teams to achieve the best possible performance in the first six months after launch.

The launch situation room

A launch situation room is a team of cross-functional decision makers with an office and a mandate to adapt the launch plan as and when needed to accelerate uptake. It should focus on three critical areas: preparing the organization to be agile in the market, monitoring market feedback and ensuring rapid decision making, and enabling course correction.

Preparing the organization to be agile

In the early stages of launch, when the launch team is working at peak intensity, questions critical to the brand's success

can often be left unanswered. Some typical examples are illustrated in Exhibit 1. The first task of the launch situation room is to provide frequent – usually fortnightly¹ – insights into these questions and develop a deep understanding of the links between what the company is doing and the effects on its future performance. To achieve these aims, a company will need to make shifts in what it monitors, and how:

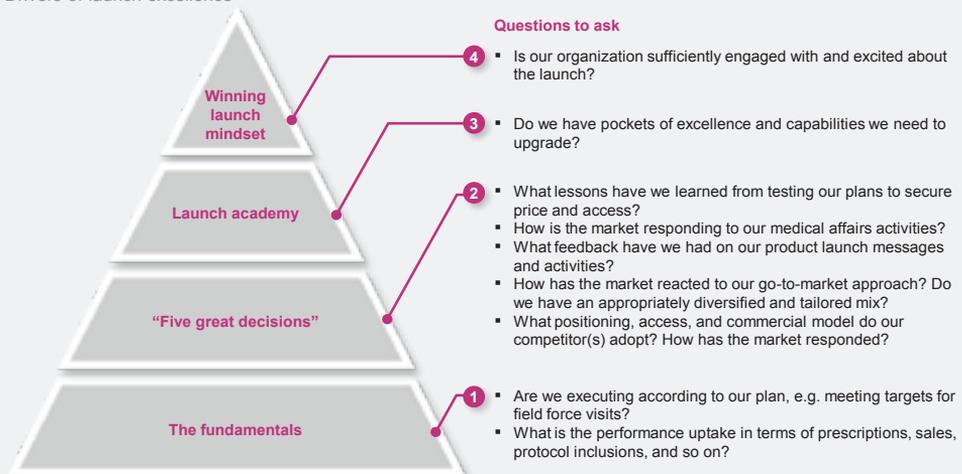
- **From monitoring lag indicators to tracking lead indicators.** Tracking weekly sales and monthly prescriptions data is not enough; these lag success indicators need to be complemented with lead indicators across functions. These should include key performance indicators such as percentage of targeted physicians reached in each segment and percentage of hospital protocols on which the product is listed. Companies should also track raw market reactions to understand early perceptions of the new product and how it is changing the competitive dynamics. Having rapid insights into stakeholders' reactions will help companies to

shape their long-term performance, especially since real-life clinical practice at launch can differ substantially from that during a controlled trial. For instance, moderate side-effects that appear to be manageable in a trial setting can become cumbersome to manage at scale and, when less experienced physicians initiate treatment. Being able to understand day-to-day hurdles in clinical practice and the effects they have on product perceptions will allow companies to focus on the messages and activities that truly resonate with physicians.

- **From developing a general overview to understanding micro-segments.** Brand teams often feel a disconnect between the deep customer understanding they developed before launch and the complexity and unpredictability of real-life experience after launch. However sophisticated a launch strategy may be, it will never be granular enough to address the needs of all physicians, payors, and patients. Gathering insights at the

Exhibit 1: Monitoring performance in the first six months of launch

Drivers of launch excellence



level of micro-segments (such as early adopters versus followers) will allow companies to identify local hurdles (such as the limiting of prescriptions to a niche sub-population despite broader label or national guidance), patient behaviors (such as poor adherence in deprived communities), stakeholder profiles (such as early adopters), and physician prescribing patterns.

- **From traditional to launch-specific sources of insight.** For most companies, launch monitoring rarely provides tailored and dynamic market feedback. It typically relies on prescription data and traditional market intelligence techniques that assess customer reactions to a launch without taking into account the local ecosystem. Few teams exploit the internet's potential to listen to what customers say, or develop solid quantitative insights into payor and physician reactions, or invest in structured approaches to exploit the wealth of rep feedback. To succeed at launch, pharmaceutical companies need to develop post-launch feedback mechanisms to address these limitations through fortnightly, weekly, or even daily feedback. One such mechanism might be a small team shadowing the field force to evaluate the quality of execution, identify local best practices, and understand whether the messaging is successful in addressing a critical customer need or barrier.²
- **Run fortnightly checks on the performance and health of the launch,** focusing on understanding any differences between the target outcomes set before launch and the actual performance in the market during and after launch. These checks should trigger rapid flag raising where needed and should also identify actions that should be continued or strengthened locally or shared more widely as best practices.
- **Ensure it is equipped with a clear mandate from top management** so that all parts of the organization can work effectively together to maximize launch uptake.
- **Coordinate fortnightly cross-functional workshops** with the core launch team and other key decision makers in the organization, including the country managing director and vice presidents of marketing, sales, medical, compliance, and market access. These workshops should build on the insights and facts that have been gathered to construct scenarios, agree on any immediate actions that are needed, and discuss what measures competitors are likely to take.

Monitoring feedback and ensuring rapid decision making

The second key role for the launch situation room is to ensure that input from the market and the organization is properly captured and discussed, and that decisions on how to respond are taken in a timely fashion. To do this, it should:

Enabling rapid course correction

The third and final step for the launch situation room is to coordinate course-correction measures and ensure timely implementation. These measures should include both short- and long-term course correction:

- **Dynamic short-term adjustments** will need to be made to manage market uncertainties and local differences. Typical examples include adjusting (but not recreating) the emphasis of product messaging; strengthening the



commercial effort for a specific segment; focusing on key “blockers” in each area, such as a payor, champion, or key opinion leader; sharing local best practices across all areas (for instance, through peer-to-peer payor discussions); and tailoring field force training to local gaps or hurdles.

- **Long-term course-correction measures** are likely to be needed across all key commercial levers: capabilities, governance, market access, medical, targeting, messaging, and mindset. Examples might include pushing management for early decisions on value demonstration trials; refocusing brand positioning on patient sub-segments; offering a pricing scheme to improve affordability; and implementing account management in hospitals through new roles, appropriately aligned incentives, robust cross-functional processes, clear governance, and granular account planning.

Prerequisites for your commercial model

In order to ensure they have a flexible commercial model and effective course correction, companies will need:

- **A detailed physician segmentation** with a deep understanding of needs and behaviors by segment. Segments should be easy to identify and measure so that companies can track the impact of their actions on individual segments and refocus their commercial efforts on specific segments if necessary.
- **A strong digital marketing strategy.** Given that the internet is the preferred source of professional information for almost 40 percent of European physicians, a strong digital marketing strategy is essential to any drug launch. In the context of a launch situation room, it has tactical as well as strategic value. By using e-detailing and web-based communication via the company’s website or third-party platforms, launch teams have the flexibility

to adjust the emphasis of product messaging as often as every week.

- **Regular account reviews and contact with the field force** through a monthly forum for district sales managers followed by discussions between the managers and their rep teams to generate insights and share knowledge.
- A mechanism for sharing **product-specific best practices for launches** and identifying long-term course corrections required across markets.
- **A mindset that the launch will be a success.** This is critical when mobilizing the entire organization to respond quickly to emerging indications from the market.



As we said at the beginning, there are no second opportunities with a launch. Once a product is in the market, its fate is usually sealed within the first six months. Setting up a global or regional launch excellence team and country-level situation rooms will help you maximize your chances of getting global launches right by ensuring you develop a good understanding of what works where and enabling best practices to be shared.

We hope this article has given you some preliminary ideas about what it takes to win in the first six months of launch, and that it has left you thinking about a few key questions:

- Are our local organizations well equipped to manage the market uncertainties in the first six months?
- Do we have the necessary feedback mechanisms in place to capture qualitative and quantitative market signals promptly?
- Is our commercial model flexible enough to allow us to correct our course rapidly as needed?

Notes

1 A fortnightly rhythm enables the company to generate and respond to insights in a timely way without putting too great a strain on resources.

2 See article on page 42 for more details on how companies can develop early market insights to improve the success of a launch.

Accelerating launch through superior share of insights



In a data-rich environment, the basis of competition is shifting. By harnessing new sources of information, companies can develop superior real-time insights to help them win at launch.

Jamie Cattell, Fanny Cavalie, and Giulia Chierchia

The day after Hollywood releases a new movie, studio executives know who watched it, where, and what they thought about it. It's much the same at Procter & Gamble: in an environment where the first three days of a launch are critical in determining a product's success, brand teams monitor launches and adjust their strategy in close to real time.

The pharmaceutical industry is heading in much the same direction. It's already possible to launch a drug and know, in close to real time, which doctor has prescribed it, where, and to whom, and what both doctor and patient thought about it. The data explosion in healthcare is shifting the basis of competition away from "share of voice" toward "share of insights."

The new competitive landscape

Launch is a critical moment in a product's lifecycle. For 85 percent of pharmaceutical launches, the drug's trajectory is set in the first six months. In the past, limited access to real-life insights and an inflexible commercial model made it impossible for pharma companies to monitor performance dynamically and make corrections to their course. To be fair, until recently, companies didn't need to make

swift adjustments to their well-prepared plans in order to make a launch a success.

But the world has changed. For one thing, launching products has become more complex because the healthcare environment has become much more dynamic and diverse. Continuous shocks across the competitive environment and ever-higher hurdles to local access call for granular real-time insights and rapid reactions. Complex treatment pathways that differ by area and even by provider mean that companies need a detailed understanding of local adoption patterns and a fine-grained monitoring of local variations.

What's more, the wealth of data now available is enhancing the industry's ability to respond to greater market complexity. Data sets from claims, clinical settings, and social media are exploding. Although the ability to access this data varies by country, most markets are moving toward increased transparency. Consider the UK, for instance, which has published script data at the level of GP practices since December 2011.

With the advent of greater data transparency, pharma companies need to harness new sources of information, develop superior real-

time insights, and act on them rapidly to achieve winning launches.

Learning from other industries

By itself, generating insights would be little more than an expensive indulgence; to achieve business impact, companies must be able to flag any areas where they might need to deviate from their launch plan and rapidly take action to correct their course. Leaders that excel at rapidly translating insights into actions reduce their response times with thorough pre-launch scenario planning, prioritizing risks, creating insights into what could go wrong, and detailing corrective plans.¹ They also create an effective and efficient cross-functional decision-making process that allows them to adjust commercial tactics quickly in response to competitors' actions, customers' reactions, and distribution hurdles.

The pharmaceutical industry can learn lessons from other industries that have already adapted to the world of real-time granular insights. In the fast-moving consumer goods (FMCG), high-tech, telecommunications, and auto industries, companies have industrialized their process for generating insights, creating "war rooms" or "control towers" where marketers can monitor recently launched products and visualize how well they are performing at a granular level.² For example, FMCG companies can see how their product sales are taking off in different retail chains and why they are performing better in some than others.

What could the pharmaceutical industry learn from this? We see two areas where it could use the wealth

of data to create distinctive real-time insights that will enhance launches:

- By developing granular customer insights to create individualized launch plans at the level of locality, prescriber, and even patient
- By stepping up the rhythm of insight monitoring so that companies can flag any deviation from the launch plan before it is too late and make adjustments on the fly.

Creating individualized launch plans

Pharma companies often find it challenging to create differentiated, granular, and actionable customer insights, and this hinders their ability to fine-tune launch tactics to specific customer segments. Like the blind men feeling the elephant in the fable, teams from marketing, sales, and market access tend to generate separate views of the customer that are difficult to reconcile into a single actionable perspective. Marketing teams develop sophisticated attitudinal segmentations based on deep knowledge of customers; the sales force segments customers by their value and draws on qualitative insights from its interactions with them in the field; and market access produces a range of insights that may not be fully crystallized or easy to act upon.

It is now possible – and necessary for a successful launch – to do much more to master the complexity of local pathways and differentiate your company from fierce and fragmented competitors. Launch teams need to gain insights into prescriber behavior, payor needs, competitive dynamics, and patient profiles and harness them to tailor their launch plan to each customer's characteristics.



Adopting such an approach will require companies to shift their approach to launch from a single monolithic country effort to multiple individual launches with their own timing, target customers, channel mix, and resources. There are three areas where this approach is particularly applicable:

- **Identifying and targeting innovative physicians** who will step beyond current treatment paradigms. The idea of targeting innovators is nothing new; in fact, it is an integral part of most launch preparations. What is new, however, is the exponential increase in companies' ability to identify and understand innovative physicians as a target group. In the past, companies had to run market research with a limited number of GPs to define segments and then rely on their sales force to categorize prescribers. For instance, before launching Januvia, its type 2 diabetes treatment, Merck had its reps categorize the GPs they visited as "innovator," "conservative," or "traditionalist." With the wealth of information now available, companies can calculate an "innovativeness score"

for the entire universe of GPs based on their actual behavior: the mix of drugs they are prescribing, and the speed at which they adopt new treatments. It is also possible to elucidate other factors that influence the decisions prescribers make – such as the size of the practice, the physician's age, the extent and role of nurse prescribing, co-location with a dispensary, and economic constraints – and then create an individualized engagement model using a mix of channels appropriate to these factors.

- **Segmenting payors** beyond the traditional archotyping approaches. With healthcare budgets under enormous pressure, launch teams need to understand what individual payors can afford. This may mean categorizing thousands of them, such as primary care trusts and hospitals in the UK and GP practices and sickness funds in Germany. Just as GPs can be categorized by their innovativeness, individual payors can be allocated an "affordability score" based on publicly available financial statements, disease incidence rates, levels of generics

prescription, and other factors. Such a score helps launch teams optimize the product value proposition for each payor. For example, in the case of a local payor with limited short-term funds and a significant potential budget burden, launch teams could consider delaying launch or offering a discount for the first three to six months. For payors with structural deficits, launch teams could explore collaborations to redesign pathways to identify where money can be freed up. Depending on how attractive and prepared local accounts are, local operating companies should also decide where and when to switch on the sales force, and redeploy resources where they matter most.

- ***Understanding which patients receive the new drug.*** Brand teams have traditionally developed patient profiles and used them in salesforce messaging to help clinicians recognize appropriate patients. However, it is now possible to take this approach to a new level by capturing data on patients who are actually receiving a drug to identify where they come from (their previous treatment), what they look like (demographics), what their medical history is (lab results, scores, and events), and how they behave (adherence and switching history). This enables companies to understand real patient profiles as well as outcomes and ascertain whether physicians – and even patients – perceive their experience as successful. During launch, sales representatives can identify which patients are being treated and work down from the most suitable patient group to identify the next cohorts that could be transferred to the new treatment, and discuss them with physicians.

Adapting the go-to-market approach

In the first months of launch, launch teams often experience as much frustration as excitement. That's because they lack timely and accurate information on what's really going on, making it difficult to respond quickly when action is needed. After spending months perfecting the launch plan, they typically delegate execution to the sales force and then have little scope to intervene and make adjustments as the market evolves. The first real opportunity to adjust the launch trajectory is often during the next planning cycle, by which time six crucial months may have elapsed.

However, a number of recent developments have made it possible for launch teams to fine-tune the trajectory of a drug with greater precision and timeliness. In particular, the availability of up-to-date information, the use of multichannel, and the increasing flexibility in companies' resource-allocation processes and deployment of their sales force have opened up opportunities to identify and act on market insights at an unprecedented rate.

In the United States, pharma companies are already exploiting patient-level data such as that provided by iKnowMed, which captures information from community-based oncology practices across the country in real time and provides instant data on individual prescriptions and related claims. One pharma company uses this information to detect potential bottlenecks in treatment or administration: it can immediately detect when a claim is denied because a doctor has recorded the wrong price in the system, and contact the practice to resolve the issue. The company found that its sales channel, with a four-week call cycle, was not sufficiently responsive to take advantage of this new opportunity, so it had to use phone and

digital channels to develop its ability to respond to customer needs in real time.

Europe's commercial databases tend to be less sophisticated than those in the US, but even so, data based on patient-level medical records can be accessed at least once a fortnight (more frequent access usually comes at a prohibitive cost), and online panels, social media, and the field force can provide continuous updates. This kind of rapid feedback needs to be interpreted with caution, since variations may be driven by a small number of data points or by temporary factors. However, it is critical in enabling companies to flag unexpected deviations from the launch plan, make immediate investigations, and, if necessary, take rapid action.

For instance, if the first prescriptions of a new drug are limited to a subset of the target population that is easier to acquire, brand growth will flatten out after a few months, when it is too late to change the "niche" perception of the drug. In addition, if the first prescriptions go to off-label patients, safety issues may compromise the brand image in the first months of launch. It is therefore critical to understand why the first adopters do not prescribe to the right patients and intervene promptly to mitigate the risk.

Monitoring perceptions of the drug in close to real time by tracking social media or mining medical records can flag unexpected reactions that may be linked to factors such as competitors' actions, uncommon side-effects, or uneven salesforce execution. Unless they are corrected quickly, such misperceptions could hinder the drug's trajectory.

To succeed with a launch, companies need to act on their insights by modifying their tactics (and sometimes their strategy) in a timely way. In practical terms, this means that a launch team can adjust most of its launch plan on the fly by adapting messages (for instance, communicating the risk for off-label patients if the first prescriptions are inappropriate), developing new tactics, and redeploying resources across areas or channels in response to initial feedback and impact (for example, shifting extra resources to accounts with unexpected competitor actions).

How to make it happen

We hope that by now you are convinced that stepping up launch insights leads to greater business impact. Even so, you may be skeptical that this approach can work in pharmaceuticals. Admittedly, this is a more complex, opaque, fragmented, and highly regulated industry than, say, consumer goods or high tech. All the same, we are convinced that it can harness the flood of new data to individualize and adapt launches in an effective and practical way.

To seize the opportunity, companies need to take three steps:

- Secure access to the most valuable data by collaborating with payors, providers, academics, and third parties
- Develop unique insights by combining advanced analytics with creativity and investing in visualization technologies
- Create a launch "situation room" that enables launch plans to be rapidly adjusted.

Securing access to the most valuable data

Although pharmaceutical companies inhabit a world of rich data, they seldom make full use of it. Salesforce feedback is often poorly captured, social media data is considered too risky to use, and payor and provider data is hard to access and analyze. This is not to say that pharma companies should try to digest as much information as possible; the volume of data is a poor proxy for its value. Rather, the first step is to make an inventory of information sources and prioritize those that lead to the most powerful insights.

The second step is to secure access to the desired data, which may come from a variety of sources. For example, private and public payors such as AOK and BIPs in Germany and Assurance Maladie in France sit on valuable claims data. Hospitals also have large episode data sets such as those managed by HES in the UK and FHF in France. Both payors and hospitals perform basic analysis and have started to experiment with outcomes research, but they do not make full use

of their data because of limited analytical skills and, until recently, a lack of need.

Now that reducing healthcare costs has become imperative, these bodies are much more interested in developing a granular understanding of patient pathways and cost drivers. Pharma companies could contribute analytical skills and additional investment to make the most of their data in a win/win collaboration. A joint data-mining initiative could make it possible to monitor whether the right patients are getting the right drugs, as well as uncovering patient adherence patterns and related outcomes.

Developing unique insights

There is an ocean of data accessible to you and your competitors, but much of it is underused and sitting in silos that hinder the development of holistic customer insights. With the right analytical expertise and creativity, you can develop insights that others lack by identifying the micro-segments that drive your brand, monitoring their dynamics, combining data from different sources – such as claims,



hospital episodes, social media, and your field force – and simulating likely customer responses (for instance, by modeling the trajectories of prescribing budgets to predict when GPs' behavior may change).

Analytics is nothing without the ability to visualize complex data in an intuitive and actionable way. To harness the full power of this data, it is critical to use the latest visualization tools and adapt them to the right channels for the people using them – for instance, by putting them in reps' pockets on their smartphones.

Imagine an interactive map of the UK that shows you the level of innovation, preparedness, and penetration of individual GP practices through the shape and color of the dots on the map. Imagine you could point at St Thomas' Hospital and immediately see its protocol status, level of clinical support, and number of new prescriptions.

Visualization technologies can be used to generate insights; allow comparisons across accounts, localities, patient types, and prescriber segments; provide real-time updates; and flag vital information such as early deviations from the launch plan. Digital channels can be used to deploy these technologies to the front line on a smartphone or a tablet. Some tools and insights can even be shared with customers so that you can hold conversations about the local health ecosystem that are based on the best available insights.

Creating a launch “situation room”

Borrowing an idea from other industries with long expertise at launching new products, pharma companies should establish a launch “situation room” with the following elements:

- A dedicated team of cross-functional decision makers
- An office equipped with technologies for visualizing launch insights
- A mandate from top management to rapidly adapt launch plans to accelerate uptake.³

In the launch situation room, the brand lead should hold weekly or fortnightly working sessions with the cross-functional team and the company's key decision makers – including the country managing director and vice presidents of marketing, sales, medical, compliance, and market access – to discuss feedback and agree on immediate actions.

Rapid course corrections are feasible only if companies set up an agile commercial model using remote channels and technologies such as tablet detailing and web conferencing, a flexible resource allocation system, and a versatile sales force that can work effectively in different territories and swiftly move from one account to another.

Finally, a warning note: one pitfall to avoid is using the new sources of data as a tool to control performance. The greatest value of the data lies in informing local decision making, not pursuing above-market performance management.



In an increasingly dynamic and diverse healthcare environment, launching new drugs is more complex than ever. However, pharma companies now have access to a wealth of data that can help them not only respond to this complexity but

turn it into a source of advantage. By combining new data with analytics and creativity, they can open up opportunities to compete on the basis of share of insight.

To help you seize these opportunities, we suggest you ask yourself the following questions:

- What internal and external data do we under-exploit at the moment? What are the most valuable decisions that it could inform? What additional data would be of most value to us, and how could we access it?
- How easy is it to aggregate, analyze, and visualize insights from data? How actionable are these insights? What could we do to increase their impact?
- How frequent is our “refresh rate” for insights? How much ability do we have to monitor launch insights, and how quickly can we decide on course corrections?
- How flexible are our launch plans and how adaptable is our commercial model?
- What are we doing to shape the uncertainty around our launch and prepare for unexpected events?

Notes

1 See chapter 2 for more on scenario planning.

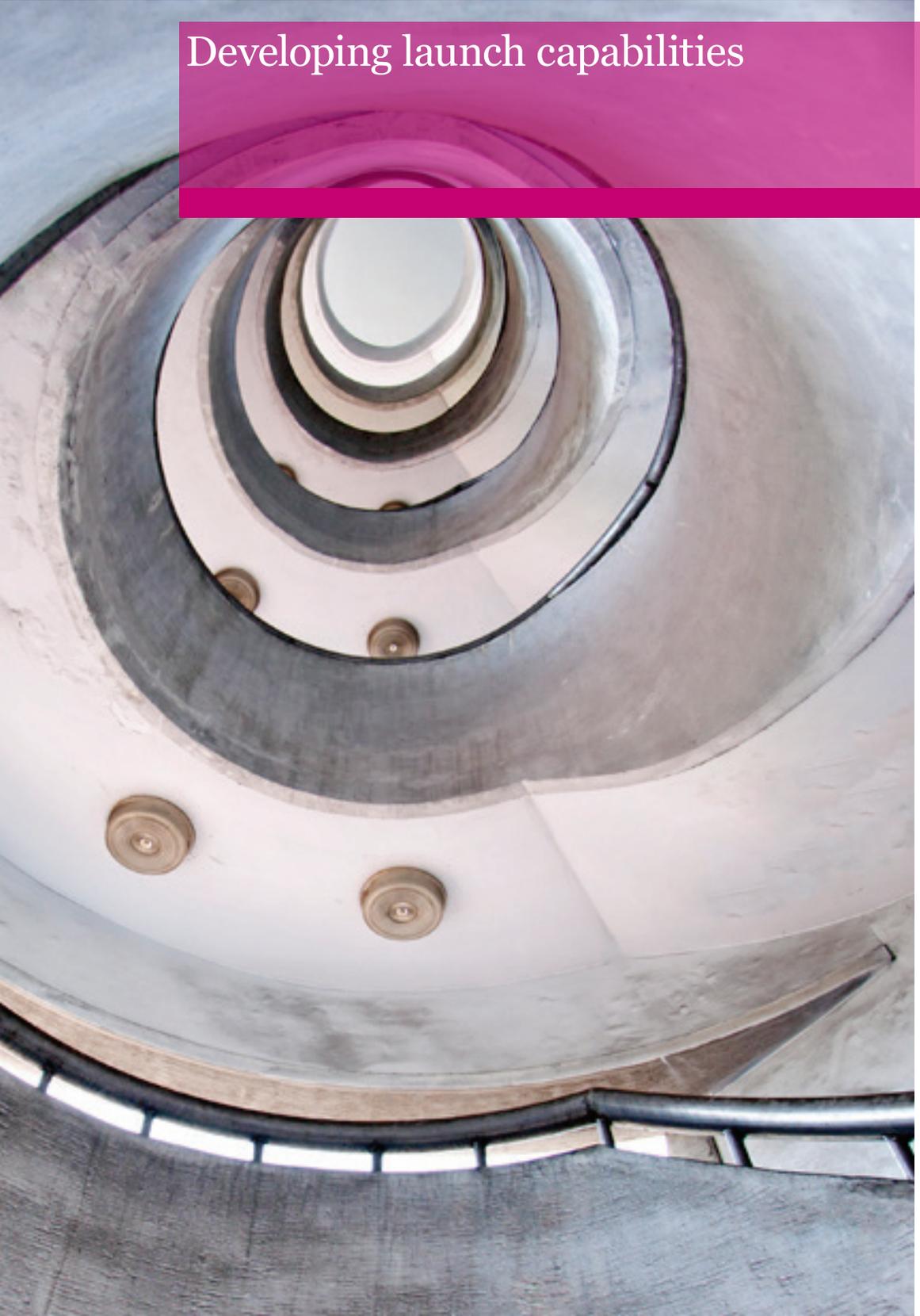
2 In the article on page 36, we apply the concept to pharma and the creation of a launch “situation room.”

3 For more on this topic, see the article on “Maximizing launch uptake” (page 36).

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Developing launch capabilities



How do you build launch capabilities quickly and effectively when your team last launched years ago and in a different therapy area? Establishing a launch academy could be the answer.

Lars Hartenstein, Karam Malhotra, and Nisha Subramanian

Over the past ten years, the top fifty pharmaceutical companies launched around 350 new molecular entities, an average of 0.7 per company per year.¹ If we include launches of new indications and formulations, the average rises to 1.6 launches per company per year. Yet, when we meet newly formed launch teams and ask who has previous launch experience, few people put up their hands. We would put the average at less than 10 percent across global, regional, and local team members.

So why are launch teams so inexperienced? There are several reasons. First, launch team members often move up the organization after a successful launch. Second, launches tend to come in waves, and so a company's last important launch may have been some time ago. Third, launch teams are more cross-functional than they used to be, and involve members from functions that may not have been involved in planning a launch before. Whatever the reasons, the industry is left with a fundamental challenge: how can pharma companies prepare their people for launch?

Whether a global launch succeeds or fails ultimately depends on the work of the 150 to 200 people involved in planning and executing it at headquarters and in key markets. Faced with a lack of readily

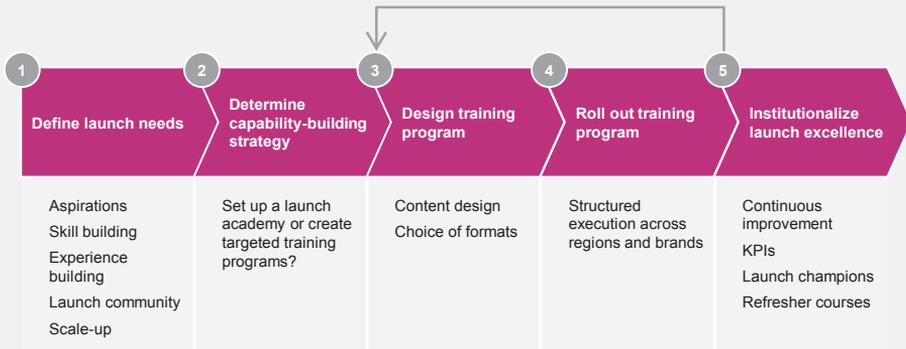
available talent within the organization and the need to fill a large number of roles, many companies hire externally. Although this may be a suitable approach for a few roles, it is not a practical solution for the whole team given the industry-wide shortage of launch talent, which is even more severe in emerging markets. Companies thus need to develop a systematic approach to building the capabilities of launch teams and helping them to develop a winning mindset.

How to build launch capabilities in your organization

A systematic approach to building launch capabilities generally consists of five main steps (Exhibit 1):

- Identifying the organization's launch needs, including target skills, target mindset, and need for continuous improvement
- Determining an appropriate strategy for building capabilities, whether it is setting up a launch academy or focusing on targeted training programs
- Designing the capability-building program, including content and delivery formats

Exhibit 1: Five steps to building launch capabilities



- Rolling out the program across the organization
- Institutionalizing launch excellence.

Step 1: Identifying your organization's needs

To determine an appropriate capability-building strategy and design a best-in-class training program, an organization needs to consider five sets of needs:

- **Define launch needs.** Before teams can grasp the full extent of what they are being asked to deliver and set the quality bar at the right level, they need to develop a thorough understanding of the organization's current launch capabilities and desired end state. Armed with this, they can then plan how to close capability gaps and secure impact.
- **Building skills: "Do I know how to build a best-in-class launch plan?"** Teams need to understand the elements involved in building and executing a launch plan, including key

concepts, tools, and best practices from other industries.

- **Building experience: "Do I feel as though I have launched before?"**

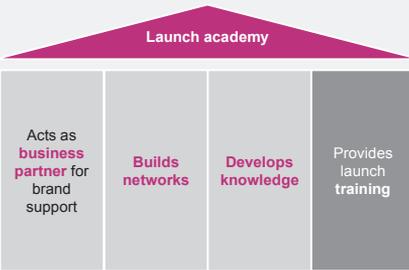
As well as equipping teams with practical tools, it is critical to build the right experience and mindset among team members who are launching for the first time. To help overcome their lack of familiarity, companies can provide them with "live" experiences by explicitly linking hands-on work on fictional case studies to the challenges of a real impending launch.

- **Creating a launch community: "How can I learn from my peers?"**

To promote long-term capability building, companies need to develop a community of experts and practitioners who share a common language and understanding of critical success factors in a launch. This will enable leaders and teams to coach and challenge one another and facilitate the sharing of best practices across the organization.

Exhibit 2: Launch academy or tailored training program?

1 Launch academy



2 Tailored training program



- Needs addressed**
- **Broad need** to build launch capabilities **throughout the organization** in line with CEO agenda
- Approach**
- Holistic **organizational transformation**
- Flexibility**
- **High**: approach can be tailored to country or brand needs and will evolve over time

- **Clearly defined** gaps in launch capabilities among individuals and teams
- **Targeted training**
- **Medium**: off-the-shelf modules can be selected as needed

- **Institutionalizing launch excellence: “Do we deploy and maintain our capabilities in the best possible way?”** In addition to creating the training program, companies need to develop the right metrics to measure its impact and ensure that the desired capabilities are deployed in all relevant parts of the organization. They also need to define processes to retain skills between launches and ensure continuous improvement.

Step 2: Determine capability-building strategy

Having carefully assessed their needs, companies can then go on to choose a strategy to build their launch capabilities. There are two basic options: setting up a launch academy or designing a targeted training program (Exhibit 2). These are not mutually exclusive; in fact, setting up a launch academy is a comprehensive

approach that generally includes a set of targeted training programs.

A launch academy will be the right choice for a company that sees launch as a strategic priority and has needs across all five of the categories in Step 1. The objectives of a launch academy are determined by the CEO’s strategic agenda. The academy acts as a service provider for launch teams across the organization, offering support for their current and planned projects. It is an institutional system that helps to develop a pipeline and network of launch experts and share best practices across teams. It continually works on closing capability gaps and shaping mindsets at different levels of the organization.

Contrary to popular belief, developing a launch academy does not require a major organizational effort, but can be carried out by a small group of global launch leaders,

supported by launch teams at regional or country level. The main challenge is to create a sustainable engine that can build and share capabilities through generations of launch efforts without creating additional dedicated roles.

On the other hand, if an organization's capability needs are specific to individuals or teams, targeted training programs may be a better option. An example might be launch training for market access teams in a region that has recently undergone regulatory changes or where capability gaps exist.

Step 3: Design training program

A launch training program can take the form of a stand-alone capability-building strategy or become a pillar of a launch academy. A well-designed program can build alignment on the aspirations for launch and provide new skills and capabilities. Supported by the right metrics and processes, it can also act as a nucleus for scaling up capabilities across the wider organization. Correctly timed, it serves as a primer for the actual launch planning process.

In our view, the key principles in designing a launch training program are to:

- **Develop a modular approach.** Training must be adaptable to the needs of different countries, launch phases, and brands. With a modular approach, different groups can select the training topics that best meet their needs, whether they are deep customer insights, payor excellence, scenario planning, portfolio strategy, or launch execution. The chosen modules can then be combined in a two- to three-day program to deliver tailored experiences and learning. For instance, a small launch team with limited resources in a

developing market may need to focus on lean launch, whereas a team in a Western European developed market with a complex stakeholder environment may need to learn about shaping the market for launch and payor excellence. In much the same way, programs can be tailored to the launch phase a team is about to enter. A team eighteen months ahead of launch may derive the most benefit from modules on deep customer insights and scenario planning, for example, whereas a team just six months from launch may benefit more from training on high-impact go-to-market activities and key performance indicators.

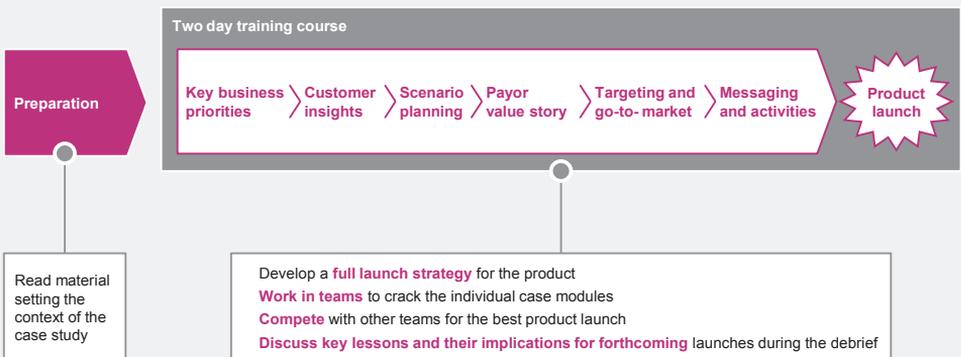
- **Create a hands-on experience.** “Fail and learn” is a more effective way to build capabilities than “learn and do.” Participatory hands-on exercises can be used to simulate experience and reduce the fear of failure. By allowing participants to become aware of their lack of capabilities in a given area and understand why they are essential before starting to acquire them, this approach creates longer-lasting learning. Training should be built on a realistic fictional case, ideally modeled on a future launch, which teams work through for the entire training session with limited guidance. In the debrief, participants’ attempts to address the challenges presented by the case should be linked back to the real business challenges they face with their brand launch, thereby creating a “live” and highly relevant experience.
- **Include examples from other industries.** Although it has managed a number of very successful launches, pharma still has longer cycles to market and lower marketing capabilities than industries such as consumer

A two-day training course to build launch capabilities

Our experience indicates that a two-day in-person training course is an excellent foundation for a program to build launch capabilities, especially if an organization needs to develop skills across a broad range of topics. In cases where capability needs are more narrowly defined, such as developing a payor value story, other formats, such as web-conferencing sessions, may be more appropriate.

Exhibit A illustrates a training course that we used with a client to provide 32 participants with experience of a realistic launch from beginning to end. The whole course was based on a case that was fictitious, but closely related to participants' everyday business: for instance, the drug had familiar properties and belonged to a relevant therapeutic area. Four launch teams of eight were formed and were asked to launch the product over the course of two days. The training was modular in design and tailored to the audience: for example, a module on advanced segmentation was offered only to participants from countries where it was relevant.

Exhibit A: Using a case study to build launch experience



Each module took about two hours to complete and consisted of:

- An *introduction* to the topic starting with an example from another industry that is more advanced in that business area. For scenario planning, for example, participants watched a four-minute video on how Shell uses scenarios as a foundation for its business strategy.
- A *breakout* exercise where the group addressed the same topic in the context of the case study. In the scenario planning module, the team had to identify key swing factors for launch and prioritize the top two scenarios, taking into account the uncertainties over the market access environment, competition, resource allocation, and other external and internal factors 18 months before launch.
- A *debrief* in the plenary session covering approach and results, followed by a discussion led by regional and brand business leaders who linked the debrief to uncertainties over their own forthcoming launches.
- Finally, the moderator synthesized *key lessons* from the course and *provided templates and tools* to enable participants to carry out the activities back in their own businesses.

electronics or fast-moving consumer goods. Using examples from these industries in training programs can raise the bar on aspiration and energize an audience. Consider the launch of the Nintendo Wii games console, regarded as the epitome of launch excellence. Nintendo developed deep customer insights and transformed the perception of gaming from a pastime for young men to a family activity. It then expanded the market through word of mouth and innovative channels such as blogs to reach segments as unlikely as rehabilitation units and retirement homes.

- **Provide ready-to use templates and tools.** Developing how-to guides covering the core themes of a training module is a practical way to facilitate learning and ensure it is put into practice. Examples include profiling tools that can be used to segment key opinion leaders at launch and database tools for mapping and segmenting hospitals.
- **Stimulate innovation as well as covering the basics.** A distinctive training program will not only address the fundamentals of a successful launch strategy, but also cover new and less obvious content areas such as the use of alternative channels and innovative payor collaborations. One practical approach is to hold short sessions of 15 to 20 minutes on basic elements such as medical education, stakeholder mapping, and local clinical activities, supported by simple case examples and online tools.

As well as developing the content of the training, companies need to decide how the various elements of the program will be delivered. Would a

web-based approach be appropriate for teaching a clearly defined skill, or does the organization need a series of short training sessions? Is a classroom format suitable, or would coaching in the field work better? Before beginning to roll out their training programs, companies should test concepts and formats with members of the target audience to ensure smooth delivery and create momentum for the wider capability-building initiative.

Step 4: Roll out training program

Even the best capability-building program can be compromised by poor roll-out and execution. Yet this step is often under-resourced, delegated to people who lack the very capabilities in question or relegated to a single functional team.

A few simple principles can help make roll-out more effective:

- **Work across functions.** Launch is a cross-functional affair, so training should target the cross-functional team that will actually run the launch, with participants from marketing, medical affairs, market access, and finance.
- **Keep the roll-out schedule short.** Launch planning activities need to stick to a tight timetable and avoid diverting limited resources from business priorities, so a launch training program should be rolled out briskly. If there is a time lag between training for different regions or levels (such as leadership and frontline staff), the sharing of best practices locally and across regions will be less effective.
- **Prepare early for the second and third waves of roll-out.** A successful training program will generate demand in the organization, so it is crucial to prepare for a full 12-month roll-



out period from the outset. As local organizations often want to extend capability building to lower levels, companies should broaden the base of facilitators and run “train the trainer” sessions early on. This also provides a basis for building a network of launch experts throughout the organization.

Step 5: Institutionalize launch excellence

Establishing launch excellence calls for a dynamic approach to capability building. The content and delivery of training programs must be continuously monitored and enhanced. Organizations also need to create the right setting for building launch capabilities. Our experience in a wide range of situations suggests they should:

- **Ensure reach.** The key measure of business impact is the share of the target population who receive training. The number of employees trained should be included in the performance

targets of local and regional executives. In addition, the training should be part of official development plans; for instance, human resources should position it as a prerequisite for advancing to the next level.

- **Monitor quality and continue to innovate.** Participant feedback is the most immediate indicator of training quality and provides input for refining the material and approach. Questions that elicit qualitative comments rather than quantitative assessment are particularly helpful. A training program will usually need a complete redesign after about three to five years, or as the organization’s capabilities and experience build over time.
- **Involve line management in delivery.** Training is a leadership task. When business leaders at different levels of the organization are closely involved, they help to keep the focus on specific

business issues as well as acting as role models for others.

- **Enable the continuous sharing of best practices.** E-platforms can be a powerful tool for sharing knowledge among launch practitioners. Companies also need to provide a forum for exchange where practitioners can learn from one another and drive innovation, whether in the form of web conferences or face-to-face receptions to foster informal discussions.



Because pharma launches happen at irregular intervals, sometimes years apart, companies are unlikely to keep enough launch talent on tap in the organization, making capability building a prerequisite for success. Irrespective of the approach chosen, the program needs to be kicked off at least 18 to 24 months before the first pivotal launch. Senior leaders should hold an early discussion on launch capabilities and follow it with concrete steps. Setting up a launch academy offers a powerful way to build the capabilities of launch teams and institutionalize launch excellence in the organization.

Notes

¹ An analysis of Evaluate Pharma produced a total of 343 new molecular entities across all therapeutic areas and most countries.

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Organizing for launch success



Setting up a launch excellence department is a smart move for most pharma companies – but should it be a program office or a blockbuster launchpad?

Giulia Chierchia, Johannes Doll, and Paul van Arkel

No pharmaceutical company needs reminding that launch is a highly complex endeavor. A huge variety of tasks need to be completed in the short period leading up to launch. Multiple stakeholders are involved at both corporate and local level, and a seemingly endless number of interfaces must be managed between headquarters and countries and between different functions.

Many pharma companies have set up central “launch excellence” departments to improve their chances of success and ensure consistency across countries. However, these units vary widely in their role, set-up, staffing, and impact. This article aims to answer two questions: what design choices should pharmaceutical companies consider in setting up a launch excellence department? And what does it take to build one that will justify the investment and make blockbuster launches happen?

Design choices

When pharma companies are discussing how to prepare for a launch, several tasks will naturally come up:

- Creating and implementing a road map for the launch

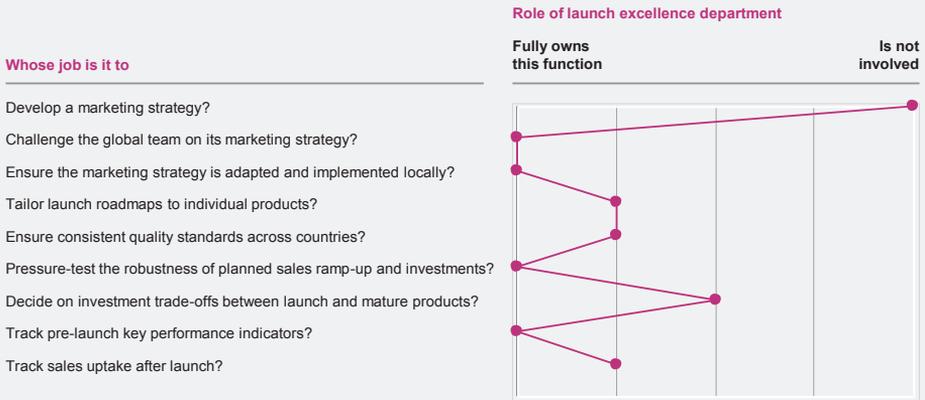
- Challenging proposed strategies to ensure a world-class launch
- Coordinating activities across corporate functions such as marketing, medical affairs, and market access
- Tracking launch readiness and following up any gaps identified with corporate and local teams
- Pressure-testing and aligning commercial forecasts and undertaking appropriate investment planning
- Ensuring that best practices are shared between countries.

While a launch excellence department can play an effective role in all these tasks, different companies tend to assign different owners to different tasks, and as a result their launch excellence departments exhibit different degrees of involvement (Exhibit 1). Since setting up a new department creates new interfaces in the organization and can add complexity if done in the wrong way, companies should put special emphasis on defining the new unit’s role and making sure the rest of the organization is adapted accordingly.

Launch excellence departments vary, and we have never seen two the same. They tend to fall somewhere

Exhibit 1: Defining roles, responsibilities and interfaces

Anonymous example



on a spectrum between two extremes: the launch program office and the blockbuster launchpad.

Launch program office

The focus of a launch program office lies on the execution element in launch preparation, or the “fundamentals” in the pyramid in Exhibit 2, article 1 (page 4). The single most important responsibility of a launch program office is ensuring that launch readiness tasks are completed in a timely and consistent manner. This involves creating tailored launch roadmaps at corporate and local level, defining quality standards for crucial tasks, and setting up an effective tracking process.

The role of a launch program office is typically embedded in existing structures such as marketing excellence. For that reason, it runs the risk of being perceived as no more than a box-ticking exercise in some cases.

Blockbuster launchpad

Companies willing to invest heavily in building blockbusters adopt a fundamentally different philosophy and approach, focusing on all the drivers of launch excellence in the pyramid in chapter 1. They give their launch excellence unit a clear top-management mandate to enable all parts of the organization to achieve the best possible launch. This may include giving local launch teams responsibility for implementation and the authority to grant additional resources or remove roadblocks by bringing them onto the top management agenda.

The blockbuster launchpad plays an active part in challenging launch strategies and pushing thinking to the next level. Another of its key roles is to build a launch academy and design a tailored “field and forum” training program for those colleagues who will make or break the success of the launch. It should also create excitement about the upcoming launch to promote a blockbuster spirit that will focus people’s energy on achieving the best possible

Exhibit 2: Skills required for launch excellence

Model	Launch program office	Blockbuster launch pad
Main task	<ul style="list-style-type: none"> Ensure consistent and timely completion of launch readiness tasks 	<ul style="list-style-type: none"> Enable the organization to maximize the value of the launch product
Key skills required	<p><i>'The tracker'</i></p> <ul style="list-style-type: none"> Expertise in project and process management and control, and experience with project planning tools Strong analytical skills and sound business sense Ability to organize and direct diverse activities, often under time pressure Strong communication skills to ensure that project plans, status, risks, issues, and results are clear to all parties involved 	<p><i>'The challenger'</i></p> <ul style="list-style-type: none"> Proven leadership and management experience, preferably in a country organization Ability to motivate and inspire teams across functions and countries Sound understanding of early- and/or late-stage drug development, launch, and commercialization (including clinical development, regulatory affairs, strategic and medical marketing, market access, manufacturing and supply chain, and intellectual property) Ability to balance risks and benefits

launch. It will typically report directly to a board member and be generously staffed.

Different solutions – program office, blockbuster launchpad, or something in between – suit different situations, and the right choice for a given company will depend largely on how centralized it is. However, we have seen well-executed blockbuster launchpad approaches make a real difference and send a strong signal that launches are a top priority for the organization.

Making it happen

Having decided to build or enhance a launch excellence department, an organization then faces a series of questions about its size, leadership, training, and toolkits.

How big should our launch excellence department be?

Naturally, the size of a launch excellence department will be determined by the number of upcoming launches, the number of countries involved, and the extent of the department's involvement before and after launch. The other important factor in determining size is the nature of the unit's role. In a typical launch program office, each employee could easily oversee between three and five products for key countries, whereas a blockbuster launchpad is likely to have a full-time employee for each major launch.

A blockbuster launchpad will also require dedicated analytical support to help it perform functions such as pressure-testing commercial forecasts, challenging local investment plans, making comparisons between countries, conducting external benchmarking analyses, and training staff for the launch academy.

What kind of leadership do we need?

Whereas a launch program office requires mostly project management skills, a blockbuster launchpad approach requires a broader range of attributes (Exhibit 2). In our experience, success depends on the following qualities:

- **Hands-on experience and track record.** Although it may seem obvious that the effort should be headed by a leader with previous launch experience in a relevant country, in practice that is not always the case.
- **Seniority.** A candidate with previous experience as the head of sales, a business unit, or marketing in a major country, or a job of equal weight, will have more credibility and influence in driving implementation across countries and corporate functions. The leader will need to be equipped with a clear top-management mandate and solid measures for consequence management.
- **Independence.** The head of launch excellence will need to maintain an objective view and be prepared to take on controversial debates with senior executives in the organization. This is unlikely to be a suitable post for someone with a classic corporate profile seeking the next step up the career ladder; it's hard to hold a challenging launch discussion with a country head when that individual could be your next boss.
- **Content knowledge.** A deep understanding of the product and the dynamics of the market will be needed to enable the leader to go beyond box ticking and act as an equal thought partner.

How do we train people?

Executives in the launch excellence department will need a combination of targeted training and on-the-job coaching. In our experience, the most effective approach is a “field and forum” program in which classroom training sessions covering the product, tools and processes, soft skills, and so on alternate with real-life experience back at the office with support from a senior coach.¹

What tools do we need?

The launch excellence department should be equipped with a standard toolkit that enables it to manage the basics and free up capacity to focus on what drives launch success. The toolkit should include:

- **Launch readiness roadmaps.** Each individual product should have its own tailored roadmap covering all launch activities that need to be completed in the three years prior to launch at both corporate and local level.
- **Key performance indicators.** A manageable set of KPIs is indispensable for tracking launch progress. A small set covering input and output KPIs as well as pre-launch and post-launch KPIs should prove effective.
- **Quality standards and case studies.** Critical activities should be backed up by case studies and quality standards to help the organization develop a shared understanding of what “great” looks like.
- **Resource benchmarks.** These should cover the size of the launch team and spending levels in different functions at corporate and local level as well as the size of local field forces.

- **Launch tracking tool.** Having an intelligent solution for tracking launch progress around the globe in real time instead of having to rely on sending around Excel spreadsheets will make performance management considerably more efficient.



As companies approach their next wave of launches, they have a number of key questions to consider:

- Do we need a launch excellence department? Where should it aspire to be on the continuum from launch program office to blockbuster launchpad?
- If we have a launch excellence department, does it have the mandate, scale, staffing, capabilities, training, and tools to enable it to live up to expectations?
- Have we provided the essentials – roadmaps, KPIs, resource benchmarks, quality standards, and web-based tracking tool – to enable the department to be successful? How do we fill gaps?

Notes

¹ We look at training in more detail in article 8 on page 52.

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