

ost of today's new therapy launches are global, but the strategy behind those launches has changed significantly, due to the advent of more specialty drugs targeting smaller populations, and the impact of the shift in decision making from physician to payer. The industry can no longer rely on physician promotion only for a successful global launch.

As the life-sciences industry continues to expand into new markets globally, companies are challenged with balancing the need for coordinated global strategies and local flexibility. Because each geography has its own linguistic, cultural, and market profile necessitating an individualized approach, having the business flexibility and agility to respond quickly to change is crucial.

According to IMS Health, in the last decade, the pharmaceutical industry has seen extremely rapid changes in the environment for new launches. Understanding how the environment has changed and what this means for today's launches is a vital launch preparation activity.

"However, some companies are still stuck on inflexible, aging legacy systems to support

FAST FACT

TWO-THIRDS OF A SAMPLE GROUP OF DRUG LAUNCHES FAILED TO MEET PRELAUNCH SALES EXPECTATIONS FOR THEIR FIRST YEAR ON

Source: McKinsey

THE MARKET.

areas most crucial to a successful launch, including customer relationship and content management," says Paul Shawah, VP of product marketing, Veeva. "Content and customer information is disconnected, trapped in separate systems, making it difficult for commercial teams to tailor messaging to customers' preferences and interests."

The fragmented landscape of medical and promotional content also increases cost and complexity while limiting visibility. Although brand success is rooted in science and data, communicating evidence to many varied stakeholders grows increasingly complex in a global market.

A shifting market landscape requires new strategies for global launches.

"Information silos, for instance, make it difficult for teams worldwide to access the latest claims, content, and messaging," Mr. Shawah says. "This means that each region often creates entirely new assets rather than adapting core materials, thus increasing cost, complexity, and the risk of propagating inconsistent claims."

Striking the balance between developing a clear, consistent story while enabling regions to adapt materials based on local needs remains a challenge.

With the level of variability in different markets, ranging from language to treatment and cultural paradigms, marketers must ensure messaging is locally relevant while still aligning with global themes and data.

"Another key component to delivering globally harmonized campaigns is leveraging a single source of truth for commercial content across the digital supply chain," Mr. Shawah says. "This helps ensure that all geographies are using the latest, approved claims and minimizes the risk of outdated information. Starting with a base of core assets that can be modified for local conditions helps ensure consistency, while freeing marketers from the time and cost of creating new content for each

Organizations now have the technology to be able to sync core claims that are driven by the scientific platform related to a brand. Regional marketers can then leverage the core claims associated with the brand and deliver those to their geographies that make sense based on market, regulatory, and cultural requirements, as well as local patient demographics.

According to Mark Degatano, consultant

How Technology Is Influencing Global Launches

Digital tools allow for better targeting of customers



ERIN BYRNE
Chief Engagement
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Technology brings both opportunities and challenges. Information created for one country is available to all oth-

ers, which means messaging must be as consistent as possible across boundaries.

I did a series of interviews for a client a year ago for a brand that had been launched in the United States and was preparing to launch in other countries. I asked a physician from a European country: "What will you do when the patient asks you for more information on this product and the pharmaceutical company is not allowed to communicate directly to the patient?" The physician said: "I'll just send them to the U.S. website."

So, it's no longer enough to create a set of messages and standard launch materials and be done. Marketers need to think about their products more like consumer brands and think about the overall experience of the product and the brand.

Another opportunity lies in that the Internet can viewed almost as a real-time focus group, so customizing messaging for different markets can be done in real time by reviewing how patients access content, how patients are talking about their disease, how they're talking about their treatment, and what is most important to them.

Using technology to facilitate messaging research in this way can result in having feedback in a week versus several weeks from the methodology used 10 years or 15 years ago.

MARK DEGATANO

Consultant, Verix

The ever-growing importance of the patient in treatment decisions is further reinforced with the



explosion of information tools, website, devices, social media, and increased patient accountability.

The result is that the commercialization models have to be better designed for quickly

adapting to new changes as they emerge. Big data has to turn into big action. Fast action has to become faster action because the competition continues to intensify and there is no end in sight.

Fortunately, new analytic and reporting solutions are emerging to help commercialization teams transform big data into action. These technologies can optimize data assets and provide sales and marketing personnel with easy-to-use tools that enable them to analyze their particular situation, such as identifying which physicians are most important right now, and act on the insights.

Furthermore, new solutions are emerging that provide transparency to account and sales teams regarding the performance of market access campaigns. This common platform approach provides the collaboration needed to drive more effective pull through, because everyone is on the same page instead of pointing fingers.

While sales calls are still a functional marketing channel, there's a clear shift to receive information on new pharmaceutical products through online communications, whether emails, online database, or other digital media.

In fact, pharma companies are now sending almost 50% more digital messages than the number of personal face-to-face calls. With the younger generation of doctors using the Internet as a data source and for communication purposes, this marketing strategy should have worked wonders for the pharma industry.

But doctors are so bombarded with marketing

messages from the industry that they gradually ignore them, fulfilling pharma marketers' worst nightmares.

The best way to win physicians' hearts is by tailoring a unique marketing and sales contact for them. With meticulous metrics and accurate analytics of physician contact preferences, pharma companies can approach each physician with the best-suited tactics.



PAUL SHAWAH VP, Product Marketing, Veeva

More and more, life-sciences organizations are evolving the customer journey. Technological advances in the

digital space, including the growing use of data science, are allowing the pharmaceutical industry to start the transition away from mass promotion to a more diverse and intelligent way of customer engagement. But this requires distilling all of the data into genuine customer insights that sales and marketing teams can act on quickly.

Across the healthcare landscape, physicians, patients, and other stakeholders expect the same experience with pharmaceutical companies that they have as consumers in every other aspect of their lives. They expect to receive the right information, on demand, through the channel of their choice — and this channel is increasingly digital. Another factor driving the prevalence of digital in the launch space is the growth of specialized drugs. The rare disease space requires continued focus on digital tactics, because building and nurturing a relatively small community of patients and often spread around the world is so key to these audiences. Digital can help create and nurture that community efficiently.

and an advisory board member at Verix, the differences in healthcare systems, patient populations, and underlying treatment paradigms can be significant challenges across countries; however, in some ways, the world has become smaller with the sharing of information, the availability of healthcare-related technologies

and websites, and the widespread and rapid diffusion of medical and scientific discoveries.

"Global commercialization today requires a greater skill in developing the product positioning and key-selling messages that meet the needs of local markets while also supporting the product worldwide," he says. "Marketers must deeply understand the features of their products, ensure that they have fully captured the needs and perceptions of relevant audiences across countries, and then craft the benefit statements that best align product features to their customers."

Using technology and digital channels to

drive physician behavior worldwide, marketers are leveraging databases that capture the influence networks among and across physicians. Marketers can identify physician influencers at local levels, in contrast to the KOLs who are international or national influencers, and activate their sales and marketing efforts to deliver messages via these physician connections at the territory or district level.

Getting input from stakeholders in the various localities early in the game is extremely helpful for streamlining the launch process, says Erin Byrne, chief engagement officer, GHG.

Managing a global brand with regulatory differences from market to market can be very challenging.

ERIN BYRNE GHG

"When doing a global launch, one of the things we find to be helpful is getting involvement and alignment from colleagues in other regions early on because we can then pull those opinions into the global brand platform. This can potentially minimize customization and reworking down the line."

Creating this type of coordinated launch requires collaboration between all custom-er-facing teams, including medical affairs, sales and marketing, and market access, which will result in more orchestrated customer experiences, Mr. Shawah says. "Traditional methods of sourcing stakeholder data — in which each team acquires demographic lists of active KOLs in each territory — will no longer

suffice," he says. "Today, achieving competitive advantage will hinge upon having a single, global source of stakeholder information and unique, qualitative insights."

For instance, understanding stakeholders' clinical interests, sentiments, and attitudes toward particular therapies can make the difference between delivering a valuable customer interaction and missing the mark with generalized outreach.

"The challenge becomes if there

are messages that are different market to market, it's important to make sure that there's a very logical reason for this strategy," Ms. Byrne adds. "The Internet levels the playing field, so to speak. At the same time it's important to not create confusion or conflicts in the messaging."

The Shift From Physician to Payer Power

One of the biggest changes today in both global and local markets is the shift away from physicians as primary decision makers. The increasing power of payers over prescribing decisions is dramatically influencing global launch strategy, reports IMS Health.

The research company has been studying launch trends that go back 16 years, and over that time has documented the trend of the decreasing impact of audited prescriber-focused promotion.

IMS reports have showed that physicians have increasingly less control over what gets prescribed, as payers impose restrictions and patients become more involved in paying for their healthcare.

According to IMS, in its very first Launch Excellence study six years ago, all eight countries — U.S., U.K., Spain, Japan, Italy, Germany, France, and Canada — studied showed a measurable relationship between cumulative share of voice in promotion to prescribers and

Key Challenges to Global Launches

More than ever, companies must seek to eliminate avoidable inconsistency in the execution of their launches, because every launch, and every country within a global launch plan, will count.

This is a consequence of:

- The trend to a larger number of smaller launches in shorter spaces of time, in other words, a higher intensity launch environment, and
- An indefinitely restrictive launch environment in the European countries that constitute five out of eight key mature launch markets, meaning that, while these countries still continue to be very important to launch, companies have to seek ways to make other markets, such as pharmerging markets, matter more.



The Launch Environment Is Changing Rapidly Yesterday **Today** Tomorrow? ▶ 4-6 major brands ► Genetic profiling and biomarkers ▶ 1-2 launches a year segment brands further ► Mature market focus ▶ RWE extends launch across the lifecycle Primary care focus ▶ Increasing pressure for pharmerging to deliver ► Mix of highly segmented specialist & primary care markets Prescribers the key stakeholder ► Patients become significant stakeholders ▶ RWE, feeding into HEOR measures and increasingly dominant ► Traditional distribution channels lifetime pricing accelerates competition **Easy to manage competition:** complexity other branded on patent agents ► Slow impact of biosimilars Source: IMS Health Launch Excellence Study

therapeutic market share achieved in a given country at a specific point post launch.

Now, there are at least three countries where that correlation doesn't exist, and for the countries where the relationship continues to exist, it is much weaker than it previously was. The United Kingdom is the most extreme example, with a complete breakdown between the cumulative share of promotional spend a launch achieves in its early quarters in its therapeutic market and the market share it achieves in its therapeutic market. According to IMS, the driver behind this is simple: prescriber-focused promotion can only be a clear driver of market share if prescribers are primary decision makers on whether launch products get used.

High-profile launches, well-supported by major pharmaceutical companies, such as Exubera and Caduet from Pfizer, and Rasilez/Tekturna from Novartis, failed to achieve their originally predicted potential as a result of this shift, IMS reports.

"Global launch plans have undergone a shift with the evolution of healthcare," Mr. Shawah says. "Years ago, companies would disseminate a uniform set of key messages, primarily directed at prescribing physicians. There were no insights into customer behavior derived from their individual use of personal and nonpersonal channels. Similarly, information sharing between commercial and medical teams was virtually nonexistent."

However, certain prescribers still remain influential and in certain therapy areas they

retain more influence. In fact, the strong shift of launch activity into the specialist — and often extremely specialist, even orphan — sector can be a countervailing factor. In addition, new stakeholders have appeared in the form of patients, who have rising interest in, and influence on, new treatment uptake, and payers themselves have changed, with power fragmenting to local players in some countries, or re-consolidating at a national level in some countries with extreme financial stress, IMS reports.

There are many challenges shaping global launch success today, including cultural differences, Ms. Byrne says.

"Certainly, the payer environment in different countries is a challenge, the approval process in different countries is a challenge, but sometimes there are even situations where personal preferences in different countries may dictate product success or failure," she says. "For example, in the contraception category, some products may not do as well in one country as in others even though they offer greater efficacy because there may be a personal preference by women who may not want to use a certain type of product."

The Shift from Blockbuster to Specialty Therapies

As more and more primary care therapies are offered in generic form, the number of launches in these therapy areas has reduced. Global value growth for protected products

has moved decisively toward specialist products, reports IMS.

"As small molecule products jump off the patent cliff, companies are rapidly shifting their focus toward specialty and biologic products," Mr. Degatano says. "Specialty product launches have been the most successful launches in recent years."

These launches have mostly been conducted by smaller to mid-sized companies, because they can act more quickly, be more innovative in their commercial model, and be more focused on targeted populations, such as orphan drugs and biomarker defined populations.

"And, it's no surprise, highly specialized therapies don't need massive scale clinical developments nor the huge marketing and sales efforts put into primary care products," Mr. Degatano says.

This trend will continue to accelerate in the coming years as more small molecule therapies lose patent protection, which will lead to new industry products becoming almost entirely specialist and biologic, and the focus of launch activity becomes increasingly specialist-focused on areas such as oncology, autoimmune diseases, multiple sclerosis, and others, IMS reports.

"The growth of specialized treatments requires a huge mind shift within the life sciences and a major evolution of its approach to commercialization," Mr. Shawah says. "More complex diseases increase pressure on life-sciences companies to provide medical and



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healthcare stakeholders with the specialized scientific information they need, ultimately leading to better patient outcomes."

Additionally, companies are faced with the challenge of creating more valuable interactions with multiple external expert resources, through a variety of channels, at each stage of a drug's life.

In this new world, it's critical to navigate the stakeholder environment effectively.

"Companies need to understand complex networks of influence, including relationships between individual stakeholders, and those individuals' connections to institutions such as integrated delivery networks and accountable care organizations," he says. "This detailed view will enable life-sciences companies to allocate resources to their best effect."

Patient advocacy groups, for example, are quickly becoming a core component of launch success, exerting significant influence on how a product is accepted in the marketplace. While it may be impossible to reach out to every key member of these groups, companies with deep, finely attuned insights into a specialized space will be able to identify the local experts and community leaders who drive acceptance and decision making.

"The real opportunity in specialty diseases centers around technology, which allows the creation of personal experiences for relevant patients," Ms. Byrne says.

Reaching Physicians in Global Launches

Using digital analytics is key to building relationships.

Remember the days when the only available information on new pharma products came from the sales reps themselves? A one-on-one visit to the clinic and a personal physician-rep acquaintance? Well, those days are now gone, but a combination of digital technology and smart analytics can create a renewed, dedicated, and more personal relationship between sales reps and physicians. With digital marketing tactics bombarding today's physicians, pharma companies with a selective-tactics approach to physicians will be the ones to win attention, over all the other marketing noise. The best way to win physicians' hearts is by tailoring a unique marketing and sales contact. With meticulous metrics and accurate analytics of physician contact preferences, companies can approach each physician with the best-suited tactics. For example:

Listen

To really address physicians' needs for their patients, you need to listen and learn what information they'd like to get. Digital revolution? Great, use it. Tailor your content for each HCP based on measured engagement in each channel.

Be relevant

Sales reps, today, need to understand they're selling more than just a pill and talk more about the economic and clinical value of their medicine. They need to know how their drug fits into the physician's needs rather than just thinking of the physician as a "target for their promotional message."

Be timely (like, now is good)

It's been shown that many doctors are more prone to meet with sales reps during the first weeks after a drug

launch, as they consider trying it with their patients. It's also critical that the rep meets with the physician several times within the first six months of a drug launch, when they have fresh insights to offer from their initial treatment experience with their patients.

Be prepared

Now more than ever, your pre- and post-call planning need to be meticulous. Because, whenever you

finally do get access to physicians, remember, your reps have little time to make their point. Equip them with the most recent, relevant KPI's and HCP profile info to know exactly who they're talking to, and what they're talking about.

Source: Mark Degatano, consultant and Verix advisory board member

Social media allows the patient to find information on the company and the therapy, which provides a chance to create unbranded experiences that serve as disease education.

"The goal is for the patient to request the medication from his or her physician and for the physician to prescribe it," Ms. Byrne says. "These are certainly very meaningful opportunities."

It's easy to scale launches to rare disease populations because it's easy to find the patients.

"Patients are connecting with the company, other patients, and even the KOLs," Ms. Byrne says. "We have witnessed in the rare diseases space that in some cases, the KOLs even know the patients by name."

In the specialty market, commercialization efforts can be more focused on relatively

smaller target physician audiences. The messaging has to be more disease-focused and backed with key publications.

"For example, Vertex launched Incivek with fewer than 100 sales representatives," Mr. Degatano says. "This was the first commercial launch by Vertex and it was a huge success."

Another advantage of niche markets is that these diseases are underserved by current therapies and therefore the market — physicians and patients — is open and receptive to new products. Furthermore, patients tend to be deeply engaged in these life-threatening diseases and seek information and act, such as talk to their physician, quickly, Mr. Degatano adds.

Editor's Note: For more information on the rare disease market, please see the related article in this issue.

