Robin Robinson

FINAL PHASE GOAL: Maximize Uptake While Speeding to Launch

Challenges abound in the last phases of drug development, creating a risky environment with narrow success.

In every phase of drug development today, processes are more complex and more costly than ever and the drive to reduce time and expenditure is more critical. In today's ever-changing marketplace, this holds true especially for the last stages of the process: registration, launch, and postlaunch. According to IMS Health, studies of 4,000 product launches over the past 10 years reveal that less than 1% of newly launched brands out-perform in key dimensions of success, such as market share and promotional effectiveness. The fundamentals necessary to complete a successful launch are complex and product-specific, and the window of opportunity is small. According to regulatory affairs and drug development experts Speid & Associates, only 11% of drugs make it through the drug development and registration processes to commercialization.

Therefore, a successful launch will not come easily and will require a balancing act between cutting costs and investing marketing dollars early and wisely. According to Best Practices, overall companies today are investing more in the launch year than in the previous three ramp-up years combined, and this may not be the best course of action. For example, specialty care product launches invest a greater proportion before launch and are more frequent and more efficient in terms of required resources at launch, while 56% of the budget for a primary care product launch is spent during the launch year, with only 44% invested before launch. Primary care launch budgets are typically two to four times more resource intensive, according to the report, New Product Launch Spend: What It Takes to Win in the U.S. Market. According to IMS Health, the success of a chronic care product launch is determined within the first 10 to 12 weeks after launch, making the launch year a bit too late for maximizing the investment.

To complicate matters, there is no one-size-fits-all formula for determining where or how much to spend, according to Stacy Doce Patterson, M.D., executive VP, director of medical affairs, ICC Lowe. "The allocation of the spend is dependent on the specific market and disease area," she says. "Ultimately, the better marketers understand the market and the customers, the better they will be able to make determinations regarding program emphasis and budget. Certain complex or data-driven and KOL-driven areas, such as oncology, will require more credible third-party programs to deliver messages, such as speaker programs. Other areas are more patient-driven and will rely more heavily on direct-to-consumer programs."

Along with the struggle to attain the right level of resources needed for new products to get the jump on earning market share, there are countless other challenges facing the industry in these last three phases of development.

Registration Goes Global

As the industry moves increasingly toward more global drug development strategies, the challenges of global drug registration moves to center stage for regulatory affairs. Going global further complicates the already obscure registration process, adding more layers of regulatory requirements and requires maintaining and managing an even more vast body of knowledge.

Managing and tracking registrations continues to present a significant challenge to pharma companies that operate on a global basis, says Monique Garrett,VP, global strategy, Octagon Research Solutions.

"Regulatory submission content planning is more complex because sponsors have to understand content and format requirements of many different health authorities," Ms. Garrett says. "The process is more complex because these requirements have to be tracked and implemented within the context of a submission to a specific country or region."

This scenario has resulted in a new focus on regulatory information management.

"The term has been around for a while, but as the globe continues to get smaller, the definition has shifted," Ms. Garrett says. "The discipline of regulatory information management now requires sponsors to have global access to local or regional knowledge of regulatory requirements. It requires transparency throughout an organization's worldwide regulatory submission process and it demands deeper insight into how content and metadata can be leveraged and repurposed across the organization. It is a tall order but sponsors are paying attention to it now because they understand the strategic and global value of being good at regulatory information management."

Other challenges that pharmaceutical companies are facing include the need for integrated multi-country strategies and more co-

ANN MOHAMADI ▪ *PwC*

"It is more critical than ever to ensure the sales force is well prepared to identify and respond to deeper customer insights and needs in a more market-oriented, value-based manner than there has been in the past."

ordinated pricing strategies, says Karla Anderson, partner, advisory pharmaceutical and life sciences practice, PwC.

"Integrated multi-country strategies are needed to demonstrate value relative to low-cost alternatives in all countries and while the value propositions are interrelated they do require market specific insight," she says. "With more dependency placed on non-U.S. markets for high growth these market specific intricacies need to be understood and addressed in the launch strategy to ensure maximum adoption happens across the geographic market."

Ms. Anderson adds the reality of global transparency related to product pricing results in a need for a more coordinated pricing strategy than ever before and more scenario-based planning to address the impact of cross-market pricing interdependencies.

Preparing for Launch

Meeting the challenges of a launch — global or otherwise — requires a deep understanding of the total market and all the players, as well as following some industry proven best practices. Since no two product launches are the same, there should be several basic constants of any commercialization plan, to better prepare any market for launch, says David Rear, R.Ph., president, Advanced Clinical Concepts.

He says there are three elements that should be in place at all times: creating the scientific foundation; developing and implementing a macro communications platform; and developing product advocates.

The scientific foundation, generally a function of a publication plan and execution, provides two pivotal, overlapping components of product support that the market demands: evidence-based medicine and a rationale-for-use. Though the clinician may be the first stakeholder considered, virtually all market segments will require, to one degree or another, the net of preclinical and clinical trials, as well as, outcomes research to justify use and adoption, Mr. Rear says. Further, every stakeholder — clinician, pharmacist, managed-care, patient, caregiver, etc. — will be impacted by the established rationale-for-use, the set of reasons why any product should be considered, prescribed, or adopted compared with other options.

A well-planned and executed communications platform provides a consistent context for expressing key clinical communication points and product support.

"Though the manner of expression and wording often differs from one stakeholder to another, all communications should be guided by a common context, supported by evidence, and augmented by clinical experience," he says.

The third element, developing product advocates, remains an important means of preparing the market for any subsequent product launch. A recognized therapeutic expert or clinician who has the benefit of all supportive evidence and an understanding of the rationale-for-use represents an initial reference for all stakeholders.

"These experts can readily explain information pivotal to the treatment decision, including the need for any given product, the mechanism-of-action and clinical trial results, and expressing the optimized application of any product within the clinical setting; thereby better ensuring enhanced patient outcomes," Mr. Rear says.

Another vital best practice is getting everyone on the same page. The team working on the new molecular compound needs to function as a whole to create a unified foundation for the future brand's scientific narrative, says Michael Zilligen, president, Ogilvy CommonHealth Specialty Marketing, part of Ogilvy CommonHealth Worldwide.

"Clear, consistent messaging established as early as possible should include a fundamental scientific lexicon that is ownable by the brand," he says. "The art of creating a scientific lexicon requires the coordinated expertise of bench and applied scientists married to communications and linguistics experts. All stakeholders must be actively engaged creating different perspectives from each discipline that collectively drive a meeting of the minds to arrive at the narrative goal to pull forward into launch.

For Dr. Patterson, best practices must include fully understanding the market, including the needs of healthcare providers, patients, and payers.

"This can be accomplished by traditional means, but current best practices also include more cost-effective mechanisms, such as monitoring social media," Dr. Patterson says. "Also critical are carefully crafting market shaping messages and taking advantage of multiple channels to precisely deploy those messages before launch."

Eric Pauwels, senior VP, chief commercial officer, NPS Pharmaceuticals, agrees that a team must have a deep understanding of the disease and the patients being served, including knowing what the patients' unmet needs are beyond the medication. Maintaining this focus on the patient is key.

"Companies must always make decisions with the patients' best interests in mind," Mr. Pauwels says. "This way, regardless of the outcome, they'll know that they made the right choices for what's best for patients."

Developing a successful launch also requires the right commercial business model and company infrastructure for the product.

"Treatments for rare disorders, such as those

ERIC PAUWELS ▪ *NPS Pharmaceuticals*

"A launch team must have a deep understanding of the disease and the patients being served."

Launch Preferences

Half of the drug manufacturers profiled in a new Cutting Edge Information study target the United States as their primary country to launch new products, followed by Germany (31%) and the United Kingdom (13%). Drug companies have increasingly built global launch sequence strategies into their business plans. Not only do global launch sequences allow companies greater control over the profits, but also they directly impact the success — or failure — of a product's lifespan. A product launched at a low price in a reference country subsequently lowers the drug's price elsewhere and can ultimately result in lost revenue.

Source: Cutting Edge. For more information, visit cuttingedgeinfo.com.

MICHAEL ZILLIGEN ▪ *Ogilvy CommonHealth Specialty Marketing*

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NPS Pharmaceuticals develops, require a different type of commercial model than larger primary-care products," Mr. Pauwels says. "The commercial infrastructure is smaller and highly patient focused, competitors are fewer, and the emphasis is on educating and making physicians, patients, and payers aware of the value of your treatment to ensure that it is accessible to the patients who need it most. It is important to define what's mission critical early in the process, focus on the essential of patient success, and then execute flawlessly."

Once a drug makes it to these last stages, the journey is far from over. Mr. Pauwels encourages companies to make certain the internal organization understands that once the launch milestone is reached, there are always more challenges ahead.

"All of the clinical and commercial questions will not be answered at the time of an orphan drug launch, so the organization needs to prepare itself by building the right degree of support to address patient, physician, and payer concerns on an ongoing basis, including hiring passionate and empathetic team members with a high degree of expertise in the orphan area," Mr. Pauwels says. "This will enable building on success and adjusting the strategy early on after launch."

Sales Force Preparation

Traditional sales reps are taking on more of an account management/relationship manager role with the customers they serve and in that role sales representatives of the future need to be able to leverage multiple channels for communication and relationship development and need to be able to communicate their product messages in the context of their customer healthcare challenges, while adhering to the established constraints of a regulated speech industry, says Ann Mohamadi, managing director, pharmaceuticals and life sciences practice, PwC.

"It is more critical than ever to ensure the sales force is well-prepared to identify and respond to deeper customer insights and needs in a more market-oriented, value-based manner than there has been in the past," she says.

According to Steve Wray, president and CEO, Cadient, building the framework for a digitally enabled sales force can actually help to address a range of challenges, from training to customer interactions.

"A framework of modular, agile tools for promotion and customer service, enabled by easy-to-administer resource-access platforms and integrated measurement systems, can facilitate compliance, customer-centric interactions and optimization of the sales effort," Mr. Wray says. "When the framework is effectively executed, the customer's interaction with digitally enabled sales personnel feels seamless with other product and company experiences."

Supporting Roles in Product Launch

According to Ramana Reddy, practice leader, life sciences, Cognizant Business Consulting, stakeholder management should be used as a strategic and collaborative approach to leverage relationships and insights across the entire development and launch life cycle.

He says stakeholder management integration best practices include: establishing a common lexicon, key deliverables, and accountability across functional areas; early incorporation of clinically relevant insights into labeling, medical information, and brand messaging; identification of key steering committees members, regional experts, and speaker train the trainers; validation of patient-physician communications roadmap, including patient trigger and leverage points; expediting medical congress relationship building and promotional alignment initiatives; creating a robust stakeholder knowledge management database, scheduling, and spend tracking; and legal/regulatory consultant contract services for consistency and compliance.

As organizations seek innovative and cost-effective solutions, many are realizing the potential value of aligning internal resources to leverage their external stakeholder initiatives and learnings throughout the development spectrum as a way to create a competitive advantage.

"As a result, stakeholder management has evolved into a strategic platform, with assigned accountable ownership and cross-functional initiatives that create tangible value along the entire product development cycle," Mr. Reddy says. "The goal is to deliver innovative stakeholder management transformation processes that improve data access, relationship management, insight generation, and leverage efficiencies across functional areas to serve as the foundation for an integrated approach. The resulting benefits include the creation of a collaborative platform to enable improvements in time and resources required to uncover compelling clinical relevancy and foster sustainable behavioral changes within the targeted stakeholders."

A brand can best leverage access to the managed markets arena by engaging payers earlier and more proactively. This is critical to value demonstration and planning for a successful launch, Ms. Mohamadi says.

"The ability to demonstrate relative value vs. low-cost alternatives provides a strong foundation for the eventual adoption of a product by health plans and pharmacy benefit managers," she says. "Enhanced collaboration between manufacturers and payers around programs that stress patient adherence will help immensely in the enduring drive to manage chronic diseases and the associated costs."

Medical affairs also plays a key role in helping to convert data into compelling and actionable messages about product benefits and safety. In turn, this supports market development and awareness.

"Medical affairs is a critical component of a new product launch as this identifies gaps in care and provides evidence-based support to demonstrate a product's value and outcomes across payers and providers," Ms. Anderson of PwC says. "Medical affairs collaboration with the product development teams can drive deeper product understanding and can help shape communications as well as forge relationships with clinicians and key opinion leaders.

Bringing products to market that have demonstrable relative value is absolutely essential for the industry as we move into the future."

Team Integration

Globalization and telecommuting have changed the way enterprises large and small operate. Whether across town or across the ocean, organizations are spread out.

Mr. Zilligen says team integration needs to start earlier than ever before.

"Today's team extends well beyond yesterday's model of the marketing team that took the handoff from the scientist," Mr. Zilligen says. "Today, the team creating the fundamental scientific narrative must be broad-based; the scientists who developed the molecule; the medical, promotional, HEOR, and PR teams; and the agency partners all have a critical hand in the making of a narrative from which the brand can build upon throughout the life cycle."

Mr. Reddy offers these tips for building a dedicated launch team. Dedicated launch teams should include members from project management, research, public relations, finance, marketing, product management, and medical legal departments. Teams can be created with company resources or by using a combination of on-site consultants to staff up and down as needed. It is important to plan plenty of time for up-front preparation. This will assure that all team members are on the same page as they progress through the plan and will ease adjustments as the unexpected occurs.

"Companies need to include the necessary lead time for outside resources and establishing master services agreements, or in-house resource allocation agreements, so the team can start work immediately," Mr. Reddy says. "The use of collaborative technology can unite a dispersed team and facilitate cross-functional integration. Technology also allows for automating activity management and workflow, tracking tasks, and milestone dates, and building a central repository of launch documents."

Optimizing Marketing Channels

During the prelaunch stage, many efforts are focused around identifying targeted customers through online, print, live, and virtual engagements and capturing them in a centralized database. Once the launch transition is ready, this same database is then used to inform the audience of the specific product availability and invite customers to participate in the new branded information, Dr. Patterson says.

According to Will Reese, chief innovation officer, Cadient Group, multichannel optimization is most successful when it is approached at multiple levels within the plan.

"There are some interesting parallels that can be drawn between marketing and healthcare management," he says. "Imagine a multichannel launch as a human body. Most teams focus their optimization on a few organs/programs or, in the worst cases, individual cells/tactics, losing sight of the systems these tactics and programs support. Optimization is most successful when teams take a systemic approach."

A systemic approach entails aligning programs and tactics around a few key macro success criteria. Consistent focus on fine-tuning the details to serve a higher systemic purpose enables the team to identify opportunities to streamline.

"Reducing the patient's steps for education, trial, and support not only saves financial resources; this approach also gives time back to the team so they can deliver a few truly high-quality systems, versus a collection of channels or tactics," Mr. Reese says. PV

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Best Practices for Gaining Physician Access

Experts offer tips to overcome the most significant hurdle in product launch.

Research conducted by Temple University, presented at the International Health Economic Association's congress in June 2011, illustrates the difficulty of achieving physician access and the subsequent ramifications on new product uptake and prescribing. The report also puts forward evidence that patients are potentially put at greater risk when physicians are slow to prescribe beneficial new medications.

The analysis measures the effect of increasing access restrictions to physicians on their speed and extent of prescribing, switching, and adoption patterns while controlling for other factors using econometric methods appropriate for each model design. The study found that variations in access restrictions at the physician level do significantly matter in affecting the decision-making of physicians, both speed and extent of prescribing behavior, when responding to new medical information in a manner that potentially works against protecting patient health. These adverse effects occurred despite the existence of alternative channels of medical information available to physicians. These econometric results provide for the first time clear evidence on a large scale of the unintended adverse effects of pharmaceutical sales representative access restrictions on physician decision-making that potentially works against the interests of protecting patient health.

To combat these hurdles, our experts outline several ways to increase physician access pre- and postlaunch. While technology in the form of apps, e-detailing, and self-detailing has come to the rescue, changing the conversation and where and how it happens can also improve access to today's physician.

Stacy Doce Patterson, M.D., executive VP, director of medical affairs, ICC Lowe refers to the above study, commenting that restricting pharmaceutical sales representative access may limit dissemination of useful knowledge and hinder a physician's ability to make well-informed drug choices, thus working against protecting patient health.

Although physician access is getting more difficult, she says recent research indicates that the majority of physicians still find sales representatives to be an important source of information. Best practices include appropriate physician targeting and providing relevant information. Additionally, physicians are becoming more and more resourceful, taking advantage of new technologies and various self-detailing channels to complement their education of latest news and developments.

"Mobile apps, e-detailing, and virtual consultations are new channels to gain access to physicians," Dr. Patterson says. "These digital programs allow for very detailed targeting and tracking of physician behavior and preferences."

An effective tool for expanding physician access to company representatives is to offer complementary secondary channels that are available 24/7 and on-demand, such as tele-detailing, says Lou Shapiro, senior VP, business development, PhoneScreen.

"Tele-detailing is available at the healthcare providers' convenience to answer product questions, provide information, and process and ship requests for samples," he says. "Additionally, tele-detailing representatives can immediately transfer callers with scientific and clinical questions to healthcare-trained representatives. Adding tele-detailing to a product's sales promotions is an effective, efficient, and cost-effective option for providing valuable information to healthcare providers."

Ramana Reddy, practice leader, life sciences, Cognizant Business Consulting, recommends several methods in conjunction with live visits by field sales reps to efficiently enable and complement the sales force. Nonpersonal promotion such as eInvite, or offline and online collateral material can help boost the rate of physician interaction, as well as call center reps who provide remote, live video detailing. KOLs/MSLs engaging in peer discussions can also take place remotely. And of course, traditional trade shows that provide medically relevant content, as well as self-directed, 24/7 access digital learning platforms, should be used to supplement the sales force efforts.

However, it takes more than technology to effectively reach physicians, says Karla Ander-

LOU SHAPIRO ▪ *PhoneScreen*

"Tele-detailing is a secondary on-demand tool for expanding physician access to company representatives."

son, partner, advisory pharmaceutical and life sciences practice, PwC.

"Enhancing physician access results from a solid understanding of physicians' communication preferences and the ability to seamlessly leverage those channels," Ms. Anderson says. "Best practices include the ability to combine physician interactions and understand the preference patterns as well as the interactions or combination of interactions that impact prescribing behavior."

The landscape, however, will be ever-changing. As physicians establish more significant affiliations with integrated delivery systems, there will be new best practices emerging related to physician access, which will be critical for manufacturers to understand.

"Since physician and integrated delivery system affiliation is happening at different rates across specialties and geographies, it is important for manufacturers to be closely watching this market movement and understanding the new patterns of physician behavior that are emerging," Ms. Anderson says.

Changing the conversation with physicians to emphasize evidence-based data and clinical outcomes is another best practice.

"Changing the conversation may entail leveraging more clinical resources to develop the relationships with physicians as well as leveraging multiple channels of communication that provide insight to thought leadership and clinical discussions so the relationship with the physician expands beyond the traditional face-to-face interaction." Ms. Anderson says. PV

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