

Trends, Challenges, and Best Practices of Global Product Launches

Companies both large and small are expanding their global launch approach.

With all the variances and complexities involved in launching a product globally, especially around regulatory and approval requirements within various regions across countries, one could argue that there is nothing really global about a global launch. Instead, it is more a region-by-region launch that occurs worldwide. However, that isn't slowing the industry from executing them. On the contrary, large pharma companies have been globally focused for several years, and today more midtier and specialty companies are also expanding their launch horizons. The challenges remain the same for large or small companies: collaborative planning, organizational alignment, and managing the complex regulatory environment, to name a few.

Emerging Markets, Emerging Opportunities

According to Andrew Hunter, senior manager, Kalypso, the United States has traditionally been the largest market and typically the first market chosen for launching new products. However, more companies are now launching their products in other markets.

"This is a function of the growing importance of markets outside of the United States, especially emerging markets," Mr. Hunter says.

ClearPoint is also witnessing this trend through the activity of its clients.

"More clients are thinking globally now



than five years ago, when it was primarily the global top 10 companies that were recognizing the need to coordinate their global markets," says Kerry Greenwood, director, product launch, ClearPoint. "In the past 12 to 18 months, the midtier growth segment and the midtier and specialty companies with a global footprint have begun to focus on global launches."

The complicated process may actually be easier for these types of companies, Ms. Greenwood notes, as their smaller size makes it easier to align infrastructures and support functions.

"It took the larger companies many years to figure out how to effectively plan a global launch, and most still haven't figured it out

perfectly," she adds. "But we have seen a real interest from many clients in addressing the challenges and seeking partners to help guide them through the process."

Mr. Hunter says early commercial involvement by individuals with real decision-making authority for clinical development programs is improving across the industry and this is critical to the financial success of a product.

"Commercial teams must have input into the development strategy and target product profile for launch," he says. "There is a reluctance by many R&D organizations to share decision-making but companies that fully embrace this concept are having more successful launches."

The global nature of a product launch introduces even more pieces to an already complicated process, and an efficient process is crucial to cost-savings and efficiency.

"If a product is being launched in one country, sometimes the company can get away with being a little less organized, but when orchestrating a global launch with many different countries hitting in the same time frame, the team needs to be much more disciplined in its approach," says Matt Singer, associate principal and global lead of product launch practice, ZS Associates.

More companies pursue global market launches because cost-cutting pressures, reimbursement and regulatory challenges, and competitive environments have put the squeeze on their domestic markets and they need to search elsewhere for revenue gain.

"There is no question that given the dynamics in the market today that continuing to make progress around global product launch

Major Stumbling Blocks in a Global Launch

Industry launch leaders surveyed by Best Practices identify the biggest hurdles of launching globally.

» INTERNAL RESOURCE MISSTEPS AND

RISKS: Leaders identified sales communication and declining resources as the greatest pitfalls to market entry.

» SAFETY, SIDE EFFECTS, AND TARGET

PATIENT POPULATIONS: Failure to address safety signals, lifecycle planning, and competitive positioning errors are currently at high-risk for launch mistakes. If there are safety concerns from clinical trials, a creative, competitive positioning strategy needs to be developed before coming to market. Competitive positioning errors will be at higher risk for mistakes in the next three years, according to half of the research participants in our study.

» **MISREADING PATIENT PRIORITIES:** A majority of launch leaders identified misreading patient priorities and patient support failure as current market entry pitfalls, although they placed those pitfalls only at low risk or medium risk.

As pharma companies look to cut launch costs, areas that need to be protected are physician education and medical marketing. In some therapeutic areas, such as oncology and diabetes, a successful launch can hinge on getting physicians comfortable with a new drug.

Source: Best Practices.
For more information, visit best-in-class.com.

is not optional; it is critical,” Ms. Greenwood says.

Pharmaceutical companies rely upon successful management of new product launches to drive sales and earnings growth. With pipeline deficits, patent expirations, price pressures, and increasing development costs in the industry, companies must achieve faster and higher sales uptake with their new products to stay ahead of competitors. This is why, according to Cameron Tew, executive director,

“Given the dynamics in the market today, continuing to make progress around global product launches is not optional — it’s critical.”

KERRY GREENWOOD / ClearPoint



marketing, publishing and research/research and advisory services head, Best Practices, the direction of the global launches of the future will be driven by medical teams.

“Companies are starting to invest heavily in educating the medical community, getting them comfortable using a drug, supporting their research initiatives, and getting MSLs into the field to answer questions,” he says. “This movement is not going away. In the future, I think more medical marketing-driven strategies are the key in the differential success with product launches, especially in targeted therapeutic areas such as oncology and diabetes.”

Meeting the Challenges

Team building, organizational alignment, and the need for contingency plans are just a few of the challenges facing a global launch team today. A team will typically start with a global brand leader and a few people from the clinical organization who have been working on the clinical trials and collecting data. Then the other organizational functions get pulled in and the fully assembled team keep communications open to prevent any detail from slipping through the cracks.

“This is a challenge within big pharma,” Mr. Singer says. “The biggest challenge with global launches is how to structure launch teams effectively to make sure there is the appropriate level and type of resourcing and the

“To be successful during a global launch plan, pharma companies must be more flexible and comfortable with uncertainty.”

MATT SINGER / ZS Associates



right accountability and alignment among the many different people who are involved.”

Experts say there is no standard approach for the many functions and silos to follow throughout the process, including the development of scientific programs. According to Ann Walz, founder and CEO, Medisys, most scientific platforms are developed in isolation, by one or two people from the same functional group, who are involved with a pharmaceutical product at an early stage in its development. Once created, these platforms are not effectively shared across function teams within an organization and are rarely pressure tested with external constituents. The final scientific platform is a narrative document or binder that is cumbersome to use and most often gets filed or left on a shelf, she adds.

“Other iterations may include hundreds of Powerpoint slides that unsuccessfully attempt to narrate complicated science,” Ms. Walz says. “These ad hoc approaches do not provide a globally accepted, easy-to-use, or secure electronic scientific platform that can be accessed by all product constituents representing all functional areas of responsibility.”

Another challenge is being prepared with a contingency plan. Flexibility can go a long way in helping companies meet the challenge of the constant changes that occur during the launch, but this goes directly against the industry’s culture.

“To be successful during a global launch plan, pharma needs to be much more flexible and comfortable with uncertainty,” Mr. Singer says. “Pharma companies like certainties, but there are none in a global launch, so companies need to start thinking about contingencies.”

Organizations mobilize well until the assumptions made while defining the plan change, and with the unpredictability of the market, changes occur often along the global launch process. Companies need to react quickly to these changes and to do that, they must anticipate them and develop a plan for how to cope with them. The launch team needs to spend time asking what could possibly go wrong or happen differently, and prepare a plan that accommodates for events before they happen, instead of coming up with a solution at the 11th hour.

“This is a very different paradigm from what most companies are doing,” Mr. Singer says. “Smaller companies are more nimble and able to adjust easily, whereas big pharma companies still struggle with this.”

Organizational alignment is important to the success of a global plan, because everyone

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ANN WALZ / Medisys

needs to be on the same page at all times, and that isn’t easy across oceans, borders, and time zones. Not only do the regions have to agree collectively on the global strategy, but there must also be buy in from all the key countries within the regions as well, Ms. Greenwood says.

“This is a concept that is easy to articulate and extremely hard to execute,” she says. “But it all starts with alignment, and if that initial alignment does not exist, it makes it very difficult to execute an effective global launch plan.”

Ms. Walz agrees that organizational alignment is key to the success of a global product launch.

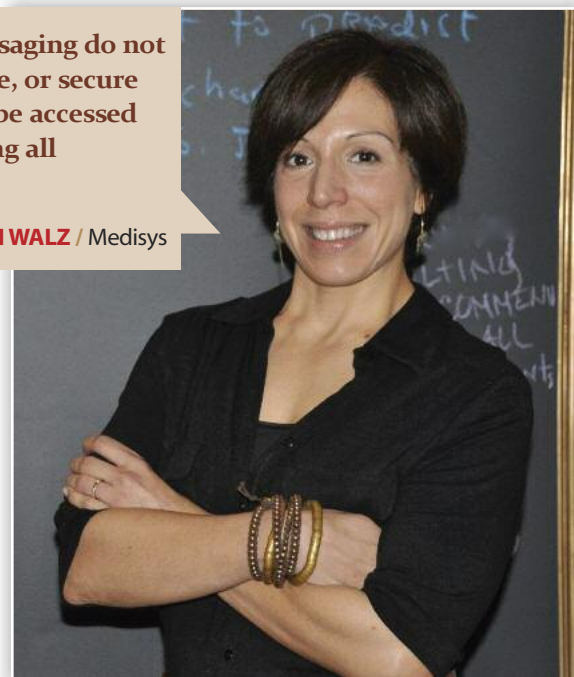
“Once a clear, consistent narrative is developed, an organization will have a platform that is clear and consistent across the globe,” she says. “Organizational alignment around this is a simple, basic concept, but too often, we’ve found that organizations develop scientific messaging in a disconnected, siloed fashion, where one task force within a company may be developing the unmet medical need narrative while another works on the MOA story, and yet another is demonstrating the clinical value, all without the benefit of cross-communication.”

This approach results in the creation of fragmented messaging, pasted together without a cohesive framework and with no thought to the complete story.

“No matter how large or small a company is, without a consistent voice, different representations of the same product’s scientific attributes come to light within the different regions where the drug is being marketed,” Ms. Walz says. “Peri-launch is an organization’s first chance at defining its compound, and so it’s to the company’s benefit to relate it with one coherent voice across multiple internal and external constituents.”

Getting that agreement or alignment can be an even bigger challenge when team members around the globe are not properly invested in a successful outcome, Mr. Singer says. The last thing a team leader wants to discover close to launch is that some people aren’t on board with the global strategy.

“To prevent this from happening, team members from all the different regions and



functions need to be engaged from the beginning, which is a big challenge since most of these people also have other daily responsibilities that keep them very busy,” Mr. Singer says. “But you can get team members engaged by getting their feedback and buy-in early on, and involving them in some of the decision-making.”

However, Ms. Walz cautions against too much regionalization of product launches. “Completely regionalizing a product launch increases the risk of ending up with an inconsistent and incoherent perspective of the product,” she says. “The primary attributes of a product must be described in consistent language, regardless of where the launch is taking place. The regionalization of product launches is my biggest concern in the industry. I personally believe it is one of the biggest missteps of the industry today. It seems counter-intuitive in the electronic age.”

After those attributes are firmly established, supportive work can be done to tailor messaging to the specific needs of countries or regions where market or clinical dynamics vary.

This points back to the need for alignment within the organization as well, Ms. Greenwood says.

“The supporting functions to the commercial organization — medical, legal, regulatory, technology, creative services — all need to be well-aligned, not just within the local region, but across the organization’s own constituency globally for the launch to work well,” she says. “Organizational alignment is the No. 1 critical success factor and in many instances it is also the most significant challenge.”

According to Mr. Tew, differentiation and the ability to communicate well are key factors in launch success. Educating the marketplace and sharing with payers, physicians, patients, and advocacy groups on what differentiates the product from the competition can be seen as a challenge or a great opportunity. Companies should focus on efficacy and safety to separate their products from the rest of the crowd, he suggests.

Studies at Best Practices also reveal another pitfall: under spending on global launches.

"Companies reason that their new drug is so great that physicians are just going to go ahead and prescribe it," Mr. Tew says. "To be successful, companies have to put in the time, the planning, the effort, and the investment to make a global product launch a success."

The word global could be considered a misnomer in terms of what really happens during a product launch. The focus is not so much on global but on segments or regions of countries. Going global means there are more layers of customization or localization needed.

"There isn't just a Spain strategy or even a U.S. strategy; plans need to be much more localized than that," Mr. Singer says. "In Spain, for instance, there are 17 different communities, so the product requires 17 strategies, not just one."

In the United States, the trend toward consolidation of physician practices has changed the localization of launch strategies.

"Five to 10 years ago, the focus was mainly on the physician with some attention on the payer, but now the doctor, nurse, patient, payer, and economic decision makers are all in the game, and that requires a more holistic approach involving meeting the different needs of different consumers," he says.

According to Ms. Greenwood, one of the factors of a global launch that is most often underestimated is the complexity of the review process for any promotional or educational material.

"It is a consistent theme," she says. "Even the biggest companies continue to underestimate that complexity."

Often there are sweeping assumptions made early on by a commercial team without any collaboration or internal communication with the other functions involved around how all the moving parts of the project are going to get done, and then there is extreme pressure on those functions in the critical days or weeks leading up to the launch in any market.

"Some of this is simply the reality of the nature of our business, but some is based on

the underestimation of the complexity and the amount of time and planning needed to make sure that everything gets done efficiently," she says.

Global Brand Team Experience Key to Success

Most companies will have to look outside of their own resources to include highly qualified execution partners with global experience and the footprint to execute, because no company has the infrastructure to execute on plans this large.

"Companies end up relying on lots of external partners, which are often a group of small niche regional players," Ms. Greenwood says. "Execution becomes extremely complex, and thus partners need to have a global perspective, experience, and footprint, all of which are critical components of success as well."

Each launch team should have at least one member who has global experience, and that doesn't mean just someone working outside the headquarter's country. Global experience should imply that the person has worked in different countries and regions and has an understanding and a feel for the complexities across the local markets.

"Many companies recognize the value of global experience and have taken proactive steps to provide experiences outside of a region, but it is still common for there to be no one with global experience on the team," Ms. Greenwood says. "If the global team is made up of 55 people in different geographical re-

gions and no one has global experience, that team will have a very hard time finding alignment and driving execution."

Another solution is to create an internal consulting team that includes people dedicated to the launch, which would include the brand lead, people on the clinical team, and then experts from different functions in the organization who may not be working on the product but understand the issues that relate to market access or medical affairs at a high level, Mr. Singer suggests.

A key component of a successful launch revolves around companies using market-shaping practices, a mix of education tactics and key timing factors for the distribution of education materials prior to launch.

Such market education practices allow launch executives to focus and adapt their new drugs as they enter a crowded and diverse marketplace.

Launch leaders must raise the bar for differentiation to set their new products apart from first-to-market drugs that focus on the same disease mechanisms.

According to Mr. Hunter, the commercial success of a new product depends on a well-coordinated and meticulously planned product launch.

"This requires two to three years of preparation and planning with strong cross-functional involvement so there is ownership of the plan, goals are understood, and accountabilities are clear," he says. "It also requires an empowered governance structure for rapid decision making because nothing ever goes according to plan." **PV**

EXPERTS ►



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