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Launch success in specialty medicine

Successfully launching specialty medicines requires marketers to adopt a new set of skills and priorities.

By Med Ad News staff with Tig Conger, partner, and Kevin Butler, managing partner, Heritage Partners International

A growing proportion of pharmaceutical industry revenue is coming from products used by specialist physicians. Launching these specialty pharmaceuticals requires a very different approach to ensure their commercial success. In years past, a unique product addressing a broad-based patient population could be built into a blockbuster by developing a solid scientific story, gaining the support of key opinion leaders, and then deploying significant investment to promote the product. Today's specialty pharmaceutical business must address multiple constituents and work within tight financial parameters to be successful.

To understand the fundamentals of successfully launching a specialty brand and managing a specialty pharmaceutical business in general, Tig Conger and Kevin Butler, with the retained executive search firm Heritage Partners International, recently spoke with several leaders of specialty pharmaceutical businesses. These leaders have all experienced the dual success of leading the launch activ-

Primary care versus specialty care

Market characteristics

| | Primary care | Specialty care |
|---------------------------|-----------------------------------|---|
| Relevant constituents | Physicians | Physicians, treatment clinics, payers, patient support groups, pharmacies |
| Prescribers | Primary care physicians | Specialist physicians |
| Number of prescribers | 100,000's + | A few 1000's |
| Administration of therapy | Self administered by patient | Often administered via I.V. or I.M. by physician or staff |
| Patient population | 1,000,000's + | 1000's to 100,000's |
| Cost of therapy | \$100's to \$1000+ per year | \$10,000's to \$100,000's per year |
| Geography | Focus on top eight global markets | Focus on top 20+ global markets due to limited patient population |

Drivers of launch success

| | | |
|-------------------------|---|--|
| Unique clinical profile | Incremental benefits to an existing class of molecules | A truly breakthrough therapeutic |
| Non-personal promotion | Optimal share of voice | Physician and patient identification followed by highly focused communication |
| Sales force | Optimal targeting, reach, and frequency with key messages | Consultative relationship with physician and ability to resolve "payer" and "distribution" questions |
| Payer access | Gain access by rebates and driving market share | Critical to success; gain/maintain access by ensuring use only in approved indication |

Leadership characteristics

| | | |
|-----------|---|---|
| Knowledge | An understanding of traditional marketing and sales | A deep understanding of the dynamics among the physician, the patient, and the healthcare system |
| Vision | Has a clear vision for the brand/business based on solid understanding of the underlying science and market dynamics and ability to communicate the vision in a way that engages the organization | Has a clear vision for the brand/business based on solid understanding of the underlying science and market dynamics and ability to communicate the vision in a way that engages the organization |
| Culture | Often internally focused and financially driven | Often externally focused with a high degree of "customer touch" |

About Heritage Partners International

Tig Conger is partner and Kevin Butler is managing partner of Heritage Partners International, a senior-level executive search firm that focuses on delivering superior work to a select group of clients globally in the life-sciences industry. Please contact them at 203-789-0000 or visit the Website at HeritageLeaders.com.

ities of a big pharma primary-care product and launching a brand in the specialty segment.

The leaders Mr. Conger and Mr. Butler spoke with are leading three different types of specialty pharmaceutical businesses: specialty products for ultra-orphan indications, specialty products with multiple indications and used exclusively by specialists, and specialty products promoted to specialists and also promoted to primary-care physicians.

Their discussions with each of these leaders focused on gaining a better understanding of the skills and experiences required to successfully lead and launch a specialty pharmaceutical business and comparing these to their experiences in launching primary-care products for big pharma.

“The executives we recruit for our specialty pharma clients have a particularly broad background with early experience in primary-care products at big pharma and more recent experience with specialty or biologic products,” Mr. Conger says. “These executives understand the interrelationship among payers, physicians, and patients and enjoy being closely involved with their customers.”

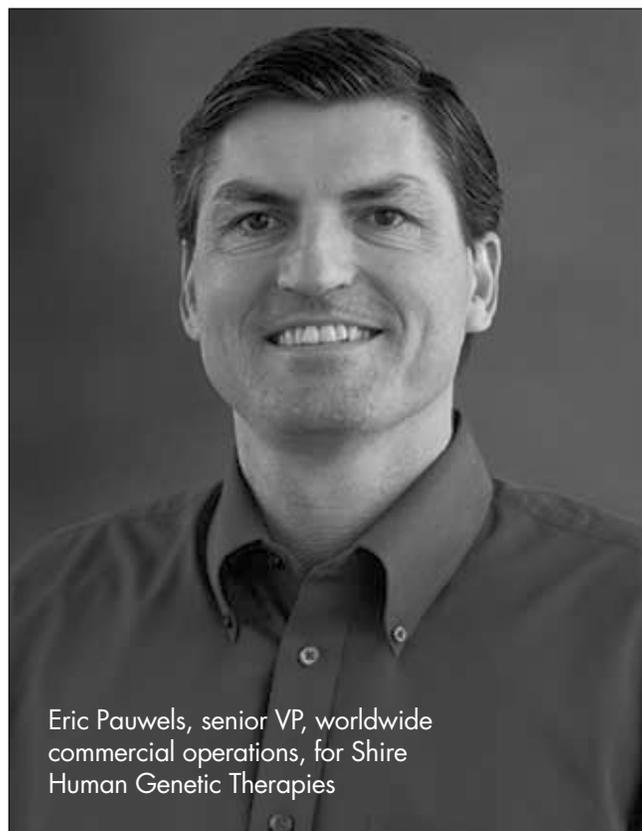
The skills required to lead a spe-

cialty pharma business have some similarities to the traditional primary-care business. A clear vision for the business based on solid understanding of the underlying science and market dynamics and ability to communicate the vision in a way that engages the organization is key to both types of businesses. The individuals Mr. Conger and Mr. Butler spoke with believe that a deep understanding of the dynamics among the physician, the patient, and the healthcare system are most important for running a specialty pharma business. In addition, the leader of a specialty pharma business must actively develop a culture that encourages a high degree of “customer touch.”

“To successfully launch a specialty product still requires yesterday’s experiences and insight – but with a twist,” Mr. Butler says. “The new breed of successful specialty marketers take what worked in the past and artfully develop launch plans that address today’s market needs. Some of those changes are subtle but hugely impactful.”

Patient connection

Shire’s Human Genetic Therapies group has pioneered a business model designed to best serve those patients with ultra-orphan diseases. The business model is built around finding and servicing centers of excellence that identify and treat patients with these very rare diseases, according to Eric Pauwels, senior VP, world-



Eric Pauwels, senior VP, worldwide commercial operations, for Shire Human Genetic Therapies

wide commercial operations for Shire HGT (shire.com).

“There often is no particular medical specialist that treats these conditions,” Mr. Pauwels says. “The centers of excellence may be composed of a treatment center that is supported by a physician who has chosen to develop a specialty in this disease, a patient advocacy group, a specialty pharmacy that deals in treatments for the condition, and nurses or administrators who understand the treatment regimens and the payers. We organize our business based on a ‘high customer touch-point.’”

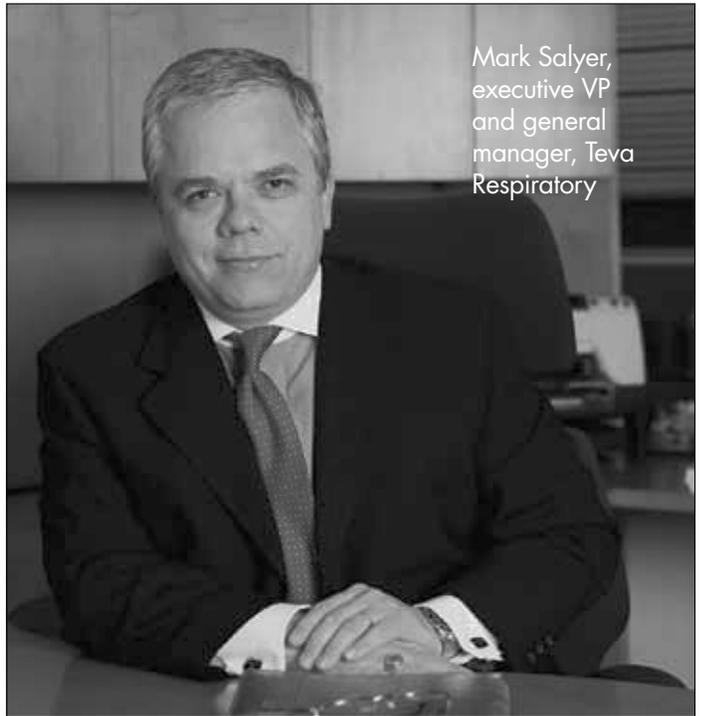
Shire HGT assigns a case manager to each patient, and that case manager is responsible for addressing all therapeutic issues for the patient and the patient’s family as well as the physician.

“For the family, we address issues such as payer information, co-pays, and life-time caps,” Mr. Pauwels says. “For the physician, we take on the paper work burden so the physician is not bothered with this and can fo-

Hans Bishop,
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specialty
medicine business
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Pharmaceuticals



Mark Salyer,
executive VP
and general
manager, Teva
Respiratory



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cus on treatment. The case manager's role is highly tailored to the needs of the individual patient."

Execution becomes strategy

A key characteristic that distinguishes the specialty products business versus the primary care products business is the base of relevant constituents. In the primary-care model, the prescribing physician has long been the most important player in determining the success of a product. Success in this market is often a function of a solid scientific story, supported by opinion leaders and heavy promotion to primary-care physicians, according to Mark Salyer, executive VP and general manager, **Teva Respiratory** (tevausa.com).

The range of relevant constituents in a specialty pharma business is much broader. In addition to physicians, the relevant audience includes treatment clinics, payers, patient support groups, and pharmacies – any group that can help the patient gain appropriate access to the drug.

Developing a launch strategy for a specialty pharmaceutical product

requires marketers to step back and take an objective, critical look at the disease state being treated, the available therapies, and the clinical need that will be addressed.

"While the successful launch of a specialty pharmaceutical still requires solid science and the support of opinion leaders, the launch planning is much more detailed than that done for the primary-care blockbuster model," Mr. Salyer says. "Because specialty pharmaceuticals often address a more limited patient population, the financial investment in these products is carefully scrutinized. There is typically a very close collaboration between the launch leader and the finance group."

A successful launch plan has to be developed using key market analytics and meet the financial metrics set by the organization. A tight, well-thought-out launch plan should address each of the key constituents, define the roles and programs to be executed by each of the functional groups, and make financial sense.

"When the strategy is clear, execu-

tion becomes the strategy," Mr. Salyer says.

Go global

The patient population for specialty products is often small – ranging from a few thousand patients to a few hundred thousand in the United States. As a result, geographic expansion is necessary to widen the pool of targets.

Mr. Pauwels manages a global portfolio of products with ultra-orphan indications addressing the needs of patient populations from 2,000 to 30,000 worldwide. This requires him to think globally.

Even in larger specialty markets such as Teva's respiratory business managed by Mr. Salyer, as many as a million patients may be treated by specialist physicians such as allergists and pulmonologists. This is a fraction of the patients being treated by the hundreds of thousands of primary care physicians.

Broad geographic availability for specialty pharmaceutical products is vital, according to Hans Bishop, president, specialty medicine business unit, **Bayer Pharmaceuticals** (bayer.com).

“Global launches of primary-care products were disproportionately dependent on the United States and a handful of other big markets,” Mr. Bishop says. “With these products, we’ll launch in a hundred countries, and all of these countries are crucial to the overall success.”

Because global markets are so important to the success of specialty drugs, Mr. Bishop recommends executives hoping to excel in the specialty arena should gain international experience as early as possible in their careers.

“International experience used to mean that if you went to a developing market, you were being sent to the Wild West,” Mr. Bishop says. “Today you should take that job because they’re staffed with very capable, well-educated people who are hugely important to your company. Get the experience as early as possible. Whereas 10 plus years ago there were only eight important country markets, today there are very few unimportant markets.”

Other drivers of success

Market access used to be contingent purely on regulatory approval. Today, however, marketers must have reimbursement approval as well to achieve

the necessary market access. The global nature of the business adds to the complexity of the reimbursement issue.

“If one out of five countries in Europe severely restricts your price, it can impact the entire continent,” Mr. Bishop says. “The higher priced countries will just buy it from the lower priced country. While parallel trade has been with us for many years in Europe, the main impact focused on high volume products. It’s not the case anymore.”

Another key driver of success is the specialty pharmaceutical company’s ability to facilitate the relationship among the healthcare provider, the patient, and the payer.

“The payers have far greater control than in the past,” Mr. Salyer says. “A successful launch is often affected by the ease of access that a patient has to the product. You have to take the burden off the physician in enabling the patient to have access to the product.”

The objective here is to ensure that the patient has access to the drug – that the payer is providing coverage to patients who are within the approved indication.

The final key for success is the sales force, which takes on a broader responsibility that includes consultative

services to the physician as well as the ability to resolve payer and distribution questions.

“Our sales professionals are all very science oriented and operate as solution providers to the healthcare providers,” Mr. Pauwels says.

According to Mr. Bishop, the best reps know what value means to patients, providers, payers, and politicians. They also work closely with the office staff to manage through clinical and administrative issues. In contrast, the primary care sales representative is heavily focused on delivering very specific messages to the prescribing physician.

A new business paradigm

In many ways the specialty pharma business is a natural evolution from the traditional pharmaceutical business. By all accounts it more completely recognizes the forces of medical care, payers, and patients that affect the industry. In many instances the business is a pioneer in developing not only the therapeutic for these patients but also the healthcare structure to treat them. For those executives interested in continuing their career advancement, this is a sector that will continue to offer significant opportunities.