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Market Access Special

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Developing a Market Access Roadmap

Alison Capone and Marsha Pelletier set out the points you should consider when developing and effective and unified 'market access roadmap'.

Historically, many companies have had ill-defined processes for planning market research activities across their product portfolio.

The current issues with planning market access research are two-fold. First, payer research planning is often a rushed initiative after the summer budget planning process. Second, there are overlaps and inconsistencies in the types and timing of payer market research commissioned across a portfolio.

Companies often have similar market access research requests within the same treatment setting across different assets. Ideally, the key learnings would be translated to similar assets. Pharmaceutical companies have been attempting to standardize market research throughout the product lifecycle and across their entire portfolio, and as such there is a growing need to develop a 'market access roadmap'.

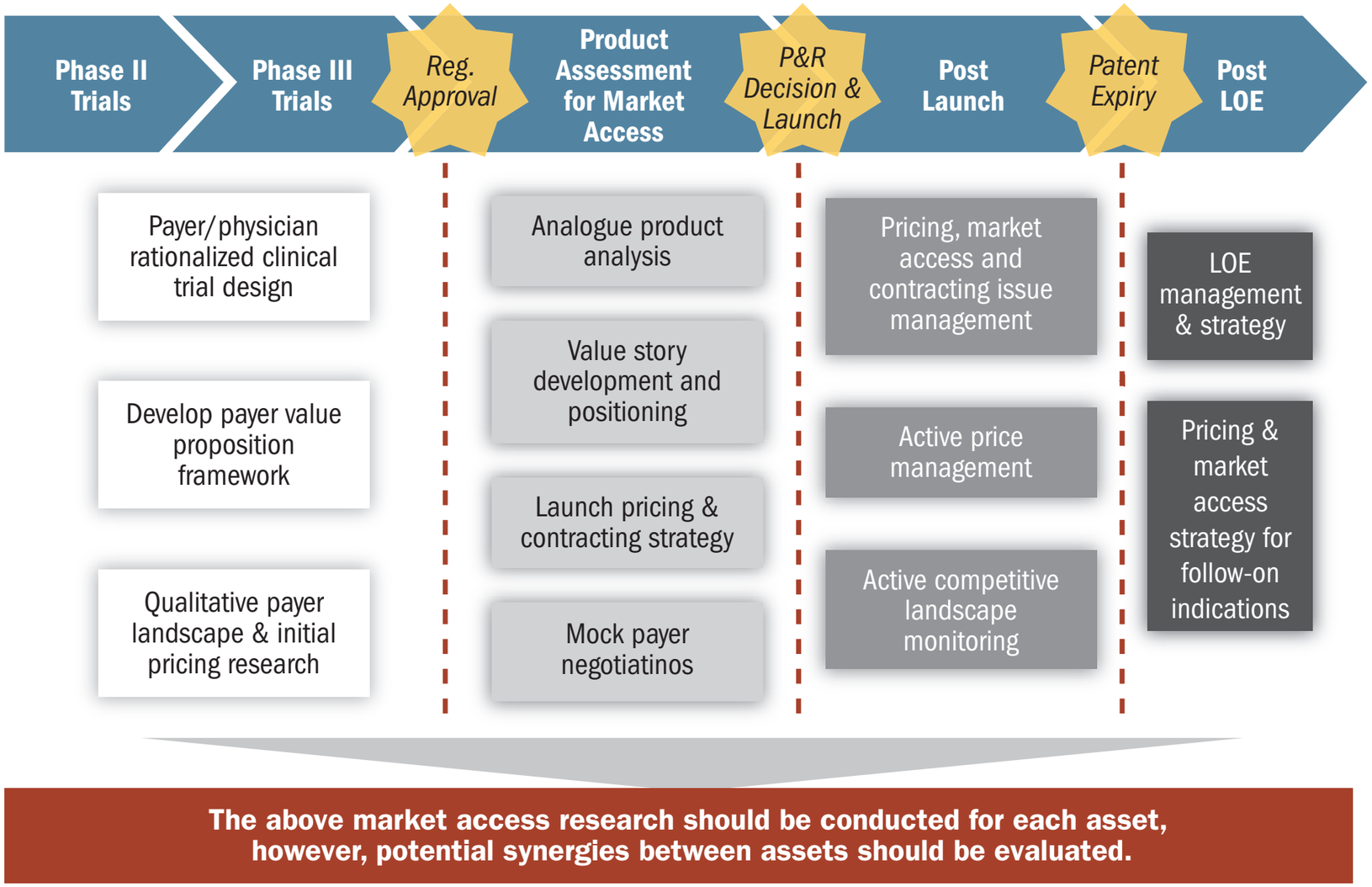
> Many companies have had ill-defined processes for planning market research activities across their product portfolio...

Roadmap for success

Developing a unified roadmap allows for knowledge sharing by highlighting the value of market research planning and defining the necessary payer research initiatives and activities throughout the lifecycle of an asset (see Figure 1). A standardized roadmap necessitates internal alignment across therapeutic areas, brands, and global markets. It can also be used as a training tool for employees who are unfamiliar with market access planning; it allows employees to quickly understand the market access environment and the relevant stakeholders in different countries across various therapeutic areas. With this tool, employees are challenged to take a high-level perspective on a company's product portfolio, to identify assets with similar indications, and/or development milestones and to assess the key research needs within the asset's lifecycle.

Figure 1

Market Access Research Roadmap Across the Product Lifecycle



Source: Simon-Kucher & Partners; Reg. = Regulatory, P&R = Pricing and Reimbursement, LOE = Loss of Exclusivity

standardized structure and centralized storage place for market access information. Since the roadmap outlines objectives and appropriate research sample, it allows companies to efficiently generate requests for proposals ensuring that only the most critical research is executed at each product phase. Additionally, the roadmap can function as a tool for budget planning and ensuring all the important payer research milestones for each product are reached.

Potential bumps in the road

However, implementing the standardization process and developing the roadmap is not an easy undertaking, since it requires buy-in from stakeholders throughout the company; often a significant challenge given the current organizational structure of many pharmaceutical companies. As mentioned, market access research and decisions are typically siloed by disease areas, by the brand team, or as a separate group all together. This structure can result in each team or unit having its own "best practices" for market access and payer research. Therefore, obtaining agreement on one process for payer market research requires buy-in from colleagues with potentially conflicting research methodologies. To facilitate

this buy-in process, companies must articulate the need for this new uniform process.

With the implementation of this roadmap, budgetary conflicts can arise with the current organizational structure. For example, if research synergies between different assets are discovered, there is the potential for conflicts regarding who is the budget holder for the research among the asset teams. Furthermore, research topic priorities could also become a point of contention with such an overlap. Additionally, the internal structure of the company can lead to uncertainty in who is responsible for guiding the roadmap's development, and more importantly, who is responsible for paying for the initial development of the roadmap itself. In order to avoid this conflict, some companies have developed teams within the organization solely responsible for organizing market access activities.

Setting the course

In order to ensure successful implementation of the payer market research roadmap, the developed tool must be specific to the organizational needs and processes. The roadmap should also be integrated with existing tools for other processes, such as physician/patient market research and/or annual budget planning. Most importantly, the roadmap should be simple and straightforward. However, it is critical to keep in mind that the roadmap is only a tool; it is meant to arm employees with a standardized thought process of payer market research, not to be a one-size-fits-all solution.

Throughout the development of the tool, it should be tested by internal stakeholders and potentially even be pressure checked during a planning cycle. The ultimate goal should be to develop a roadmap that is user friendly and intuitive; otherwise, employees will be hesitant to adopt it.

As a final step to ensuring successful implementation of a payer market research roadmap, a detailed roll-out program needs to be developed. The goal of this training is for employees not only to learn how to use the tool, but also to understand the key objectives for developing the roadmap and how it fits into the overall organizational goals. To complement the roadmap, a wider training to build a common baseline knowledge among employees on the critical pricing and market access research methods throughout the product lifecycle can also be of value.

Reaching the destination

Standardizing and centralizing payer research across product lifecycle helps develop an overall vision for pricing and market access research across products and disease areas. This unified roadmap approach ensures a consistent high-level research strategy while capturing product and market specific intricacies. Furthermore, implementing such a roadmap will enable employees to develop a common understanding of various pricing and market access environments and increase their strategic thinking across an asset's lifecycle.

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Embedding Market Access into Your Business Model

Alyse Forcellina and Can Akannac offer guidelines on how to embed an effective market access strategy into your organizational structure.

"Obtaining market access promptly, at an appropriate price, has become critical to company success..."

As private and government payers around the world grow more powerful, obtaining market access promptly, at an appropriate price, has become critical to company success. In the past, if a pharmaceutical product was safe and it worked, market access was usually assured. No longer. Market access today is far more challenging due to a confluence of factors, including the need to contain rising costs, the proliferation of competing drugs in the same therapeutic areas, and reliance on evidence-based medicine (EBM) and health technology assessment (HTA) to drive payer decisions.

Incorporating the "voice" of market access is crucial to effective deployment of the company's most important and costly investments. Underestimating or misjudging payers' likely

Chris Ryan/Getty Images

approaches to managing products can carry a price penalty reaching into the billions of dollars over a product's lifetime.

In response, companies have pushed beyond standard P&R activities to embrace strategies and capabilities across a variety of functional disciplines, which together broadly represent market access.

Some of the notable advances in market access strategy over the past three to five years include sophisticated segmentation of market and payer types, new ways of engaging payers to better understand their needs, and innovative go-to-market models on the local level that bring market access together with sales and public affairs to address specific customer needs.

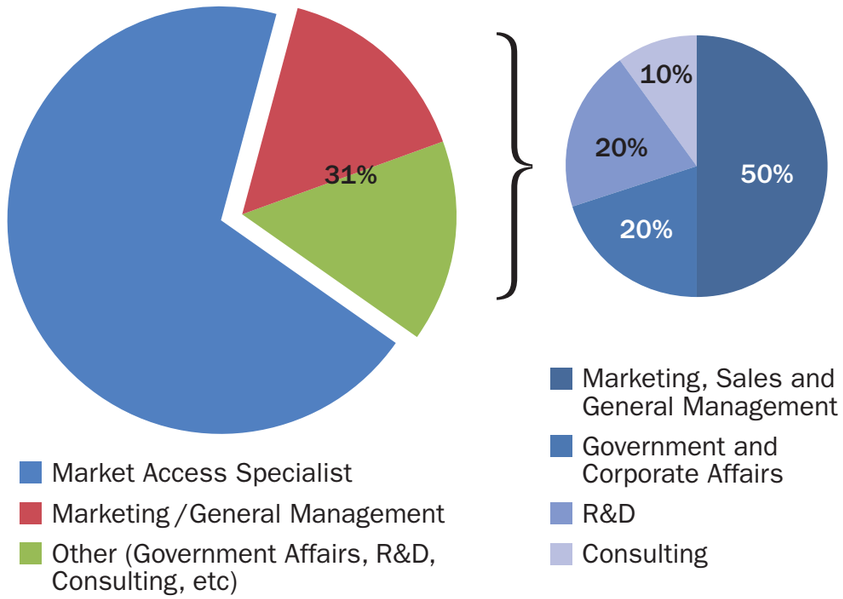
In addition, the industry has established processes and approaches to ensuring market access input into R&D and business development efforts, as well as investing in real world data and analytics to help better define product value to payers.

Discussions we have held with 200-plus global and regional market access executives confirmed that companies can better integrate market access perspectives into their global, regional, and country strategies by addressing organizational structure and processes as well as talent management—including both market access specialists and commercial leaders.

However, several practical challenges that may be preventing companies from doing more on the talent and the organizational fronts have been uncovered.

Figure 1

Background Types of Global Market Access Leaders



Market access: talent and organizational challenges

- Less than 10 percent of the top commercial officers and regional leaders in the 15 largest global pharmaceutical companies have spent any part of their career in a market access discipline.
- Market access leaders are often perceived as the bearers of bad news or the "naysayers." For example, defending a price point that does not match the perceived value of the asset by others in the organization, or becoming known for killing a deal.
- The vast majority of market access leaders are not integrated throughout the organization. Analysis indicates that 69 percent of them have spent on average 12 years of their careers in a market access function, out of a total average of 15 years of industry experience.
- Market access professionals and their teams are often not aligned with each other, as they are spread out geographically, work in different functions, and even report to different leaders, making it difficult to develop a united perspective on strategy or tactics.

Despite these challenges, there are practical steps pharmaceutical companies can take to meet the demand for high-level, broad-gauged knowledge of market access and ensure that a global or regional leadership team has the right talent and capabilities to drive successful market access strategies.

Perhaps the most important is placing the market access function in the top executive team structure. Over the past five years, companies have made the market access role more senior, but these representatives still represent a small piece of the market access pie, limiting exposure to the broader perspective that the business needs.

To address the gap in market access knowledge on the executive team, organizations can do the following:

- Bring a broad range of market access experts in regularly or on an ad hoc basis to address high-profile decisions.
- Create opportunities for senior executives to get hands-on experience with payers.
- Require CEOs and other senior leaders to meet more often with their peers in the insurance, pharmacy, pharmacy benefits management, HTA, and policy arenas.
- Encourage high potentials to rotate through market access roles. Today, over a quarter (31 percent) of global market access leaders have an average of only three years of "market access" experience. While half of these executives

(50%) grew up in the commercial organization (marketing, sales, or general management roles), the other half come from a variety of backgrounds, including R&D, government/corporate affairs, and consulting (see graphic).

- Be clear on the critical success factors for selecting and recruiting market access leaders. Analysis suggests that organizations highly value technical expertise in market access, measured by both depth of experience in the function and educational background and training (see Figure 1). Functional expertise, as measured in years of "market access" expertise within pharma, or training in a scientific discipline, are at the top of the list in seeking future talent. From a leadership perspective, global market access executives will need such critical competencies as strategic thinking, a management for results orientation, and collaboration/influencing skills, much like global marketers and commercial development managers.

- Encourage market access high potentials to move elsewhere in the organization. Giving fast trackers the opportunity early in their career to broaden experiences and skills can both infuse the organization with their knowledge as well as equip them to be better market access leaders of the future. By the time these high potential leaders have risen to a senior level market access role without functional or geographic breadth, it becomes increasingly difficult to develop them further.

From add-on to advantage

To build institutional capability on market access from the very beginning of the drug development process, companies need to ask the following questions:

- Does everyone in the commercial organization define market access the same way, and how broad is that definition?

- To what extent are market access perspectives adequately and consistently represented on the top executive team? Globally? Regionally?

- Are market access executives seen as valuable contributors in the organization today, or are they outside the important circles of influence? If the latter is true, why?

- Does or should your organization value market access experience as a part of developing high potentials? If not, why?

- Are there high potential market access specialists in your organization today who could contribute more to the organization if they were moved outside of their functional area?

- Are the skills/competencies that you are encouraging your market access teams to develop today the same that they will need for the future?

In summary, getting it right requires an enterprise-wide, holistic view of market access. Some leading companies are already moving in that direction — and more are sure to follow to ensure that their products are not only safe and effective, but also accessible and affordable.

About the authors

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Initiating Early Access Programs in Europe: *Five Things to Consider*

Executive Insight's Morteza Yazdani and Francesca Boggio look at the the specific considerations for launching an Early (or Expanded) Access Program in Europe.

Early Access Programs (EAPs) — known as Expanded Access Programs in the US — allow pre-approval access to medicines for certain patients. As well as the patients who benefit from earlier access to potentially life-saving medicines, other stakeholders can also benefit from EAPs.

Physicians are given another option to offer their patients, and gain valuable early experience with a product. Payers have the opportunity to evaluate outcomes in a real-world setting outside of clinical trials, and gain an insight into potential value of the drug. Pharmaceutical companies have good launch preparedness, with the optimal operational processes such as supply chain established, and price guidelines are set for future reference, which may help to facilitate the launch pricing and reimbursement negotiations in the future.

> If the EAP is successful, the physicians involved become early adopters of the product...

If the EAP is successful, the physicians involved become early adopters of, and believers in, the product, relationships are established, and there is a degree of good will formed with physicians and patient groups alike. All of which can help to optimize market penetration when the product is fully launched, ultimately allowing more patients to benefit.

But what are the specific considerations for launching an EAP in a region as diverse as Europe?

1. EAPs in US vs EU: Differences in regulation and implementation

While the name of EAPs varies by country, there are two main types of early access program in Europe; Compassionate Use Programs (CUPs) and Named-Patient Programs (NPPs). Both of these differ in certain ways to typical Expanded Access Programs in the US:

Compassionate Use Programs (CUPs)
A CUP is the most similar to the typical US Expanded Access Program. A

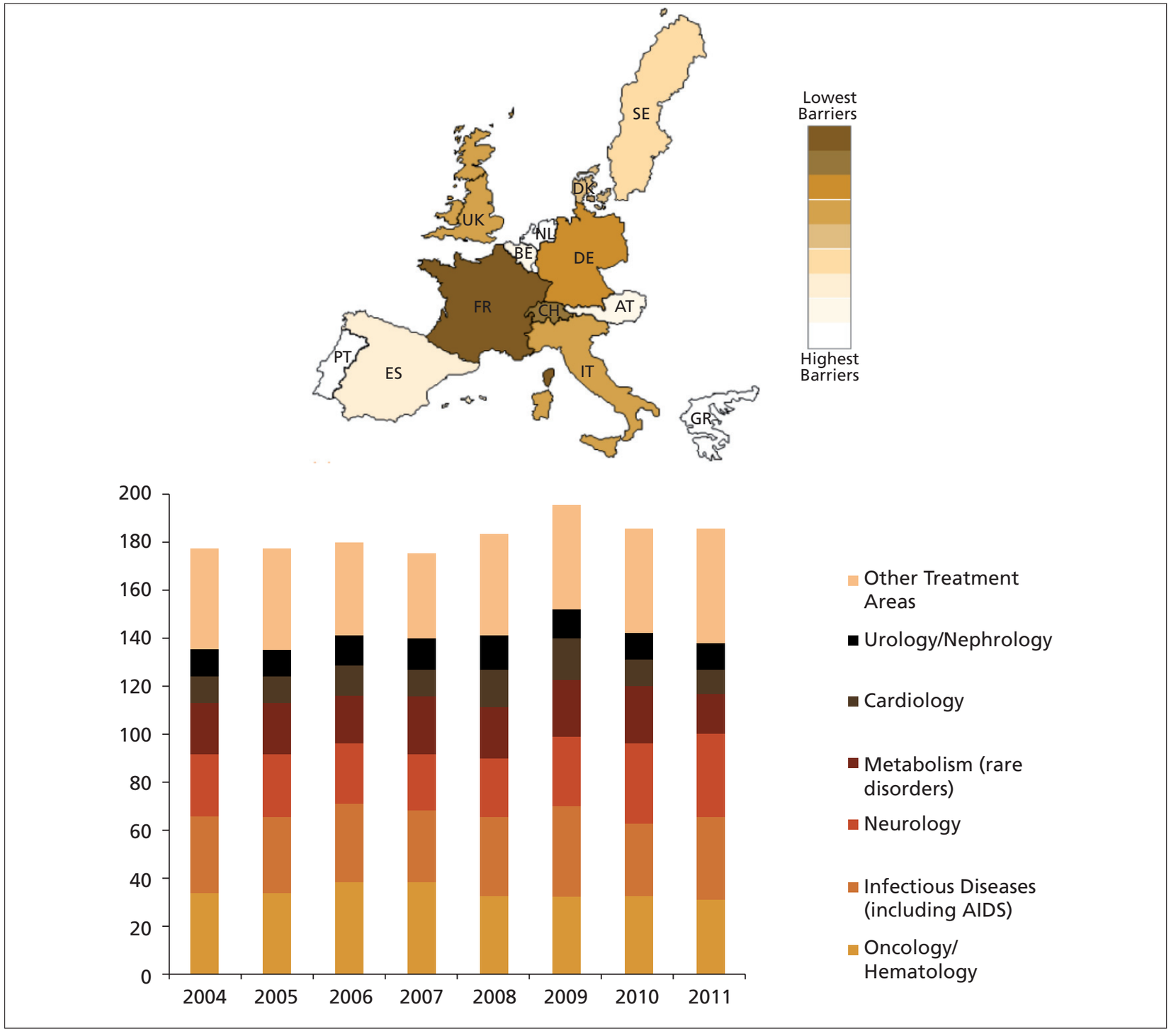
Table 1: Comparison of EAPs in the US to CUP and NPP in the EU

Criteria	EAP (US)	CUP (EU)	NPP (EU)
Legislation in place	• Expanded Access Programs (FDA, 1997)	• Article 83 (1) of Regulation (EC) No 726/2004	• Article 5 of Directive 2001/83/EC
Who initiates the program?	• Manufacturer • Physician	• Manufacturer/Group of physicians (e.g. in Italy)	• Physician
Criteria to define/select target population is set by …	• Manufacturer/FDA	• Manufacturer/CHMP	• Manufacturer/ Physician
Who can benefit from program? Limitation in use?	• Group of patients (treatment INDs & treatment protocols) • Named patients (single patients INDs)	• Group of patients i.e. more than one (permission is granted to a clinic or hospital as opposed to a particular patient)	• Only named patients for whom physician has made a request
Liability	• Manufacturer	• Manufacturer	• Prescribing physicians
Medicinal product *should* be undergoing clinical trials or awaiting market authorization?	✔	✔	✘
Is off-label use permitted?	✘	✘	✔
Are physicians paid for taking part in the program?	✔	✘	✘
Are drugs in program priced?	✘	✘	✔ (possible)

medicinal product is made available for compassionate reasons to a group of patients in a selected clinic or hospital which treats patients with a serious debilitating disease, or where patients whose disease is considered to be life-threatening and who cannot be treated satisfactorily by an authorized medicinal product receive care. In most European countries CUPs are initiated by the pharmaceutical company. Unlike Expanded Access Programs in the US, physicians receive no remuneration for taking part.

Named-Patient Programs (NPPs)
NPPs involve pre-approval access to drugs in response to requests by physicians on behalf of specific, or "named", patients before those medicines are licensed in the patient's home country. Whereas CUPs (and Expanded Access Programs in the US) allow physicians to offer the drug to several patients who fulfill the criteria, NPPs

Figure 1: Number of drugs receiving NPP (ATU nominative) status is France between 2004-2011



are limited to the requested named patient or patients only. Unlike CUPs, NPPs are entirely initiated by physicians, who also bear the liability for it.

Differences in physician remuneration and liability make EAPs in EU more challenging to implement than in the US. On the other hand, the possibility to set a price is an attractive difference in light of future negotiations.

2. EAPs in Europe

There is no 'one size fits all' approach in Europe. Individual national state laws, where they exist, may greatly differ from that of European Union and from one country to another, and some countries have more significant barriers to EAPs than others.

Most countries have NPPs in place, but only a few have programs to allow cohorts of patients rather than individuals, to benefit from early access (as in the CUP model).

There are several factors pharmaceutical companies

should consider when evaluating which countries within Europe to implement an EAP. These include the degree of administrative effort required to initiate the program (eg, timing required to assess the application and patient volume restrictions), and the feasibility of establishing an initial price for the product through the EAP.

Based on such criteria, the below 'heat map' demonstrates the relative degree of difficulty in implementing EAPs (in this case Named Patient Programs) in several European countries - the darker the color, the fewer barriers exist in that country.

France has the fewest barriers – it is the pioneer in Europe for EAPs, and the only country where systematic review and funding of EAPs exists, through the ATU (authorization temporaire d'utilization) system, which is social security-funded and covers both NPPs and CPUs.

Switzerland is also an interesting option, due to the possibility to set a price, the fact that most of the drugs are reimbursed, and that promotion is possible.

Conversely, countries such as Greece and Portugal do not have the infrastructure in place to support EAPs and thus the barriers to implementation are much higher.

Selecting the right countries with highest feasibility for EAP implementation is critical for success and efficient use of resources.

3. EAPs in acute and primary care disorders

There are a number of chronic, debilitating conditions — for example cancer and infectious diseases — which particularly fulfill the criteria for EAPs. But EAPs are not limited to these therapy areas. As an illustration of the therapy areas most commonly associated with EAPs, the graph shows the number of drugs per therapy area which have been granted NPP status in France between 2004 and 2011.

Highlighted in brown are the drugs that received NPP status in the area of cardiology, which include e.g. Argatroban (anti-coagulant), Capoten (hypertension), Simdax (acutely decompensated heart failure) and Syprol (hypertention).

4. Planning timeframes

The timing of EAPs is critical. If the program begins too early, supplies of the drug may not be adequate to meet the needs of both the program and any on-going clinical trials. If the program is started too late, too few patients may be served to justify the effort.

The ideal timing for implementation is usually around 12–18 months prior to launch.

Typically, EAPs involve products that are in Phase III, although planning can begin during Phase II, and should include all relevant stakeholders where possible. The planning element is absolutely essential and should be factored into the timing, allowing for time to prepare documents and contracts, assemble educational materials and establish treatment criteria.

Right timing and advanced planning are important to ensure the EAP runs smoothly and that the patients can benefit as early as possible.

5. Cross-functional teams

Internal buy-in is essential and usually there needs to be cross-functional support for the program to work. This should include involvement from medical affairs, regulatory, marketing and market access (including P&R stakeholders) and supply chain management.

The complexity of conducting EAP feasibility analysis and the implementation itself requires advanced strategic planning to ensure goals are met while avoiding unnecessary hurdles. Strong understanding of the criteria for different types of EAPs, and knowledge of local regulations across different countries, is vital.

If gaps in knowledge exist, for example around some of the specific dynamics in different European countries, some pharmaceutical companies may choose to work with specialized healthcare consultancies who are experts on the design and implementation of such programs in Europe.

Many in the pharma industry believe EAPs will be too risky, too complicated or too costly to consider, but if strategically planned and tightly focused, the benefits outweigh the risks.

Final thoughts

The decision whether to implement an EAP is a strategic one. Pharmaceutical companies should consider all the implications on their product life-cycle before deciding to start the program.

Many in the pharmaceutical industry believe EAPs will be too risky, too complicated or too costly to consider, but if strategically planned and tightly focused, the benefits outweigh the risks.

EAPs have great potential in some European countries to benefit all stakeholders involved, from the patient who receives the medicine early, to the pharmaceutical company who provides it. Although EAPs can represent a significant undertaking, companies who invest in them should see considerable benefit in terms of launch preparedness, relationship building and market penetration.

A proactive strategic plan and a solid understanding of the process and potential barriers involved is essential, as is knowledge around the specific dynamics of each European country. A multi-faceted internal team bolstered by external expertise to fill knowledge gaps may be the optimal approach.

About the authors

Morteza Yazdani is Senior Healthcare Consultant and Francesca Boggio is Market Access VP Lead, both at Executive Insight, a company that assists the pharma industry in the strategy and design of EAPs.

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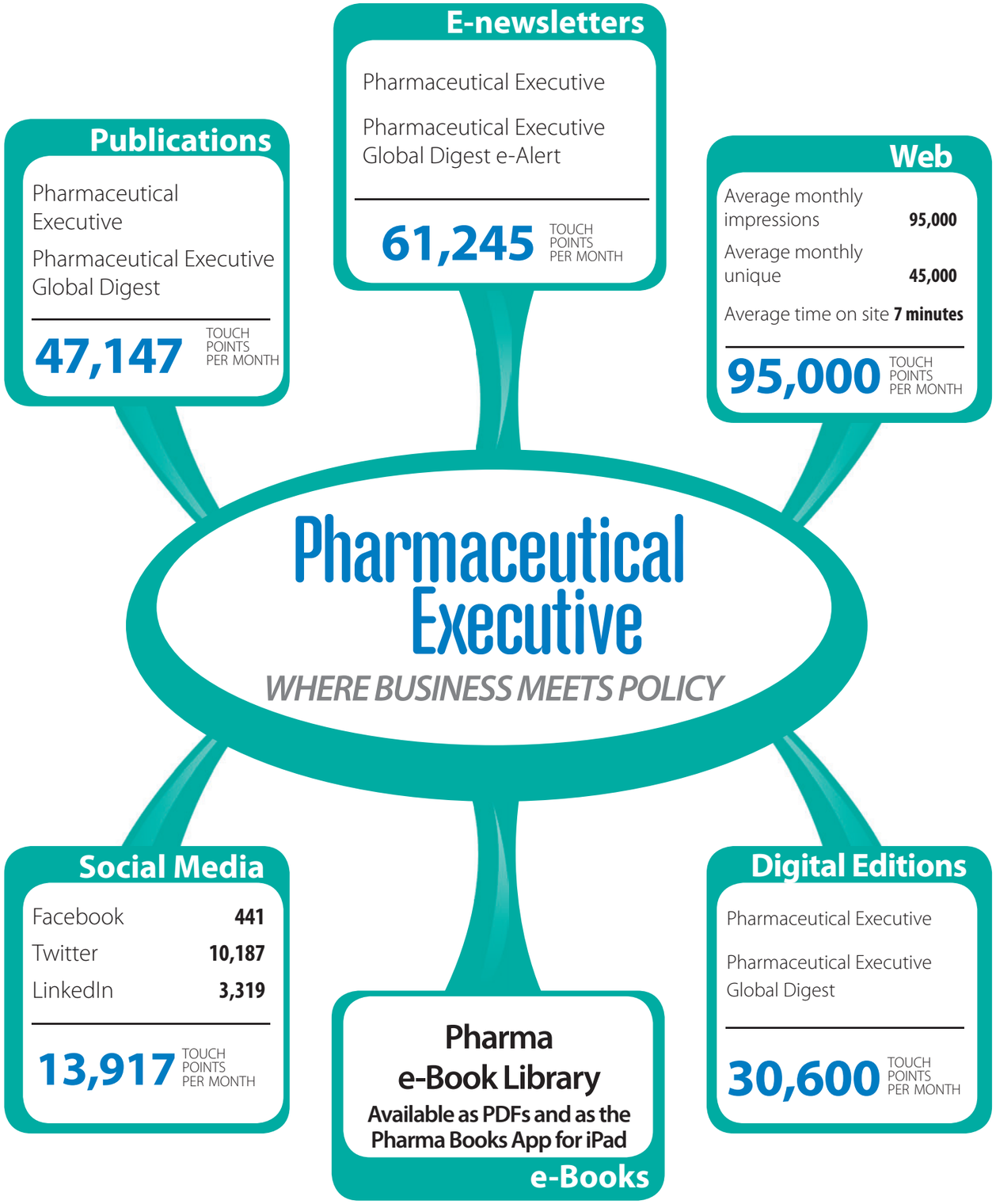

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Making *Social Media* Sell

"Where are patients hanging out? You can't expect them to find you. And what do you do once you have found them?"

Life science companies are widely embracing social media to advertise product, recruit staff and report on corporate philanthropy projects. But is it doing any good? Patrick Homer reports.

The answer is yes, if companies approach it as a way to engage customers in a meaningful way. That is, according to Jeff Molander, author of the book Off the Hook Marketing: How to Make Social Media Sell. Molander has been conducting research into companies' use of social media.

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Molander says that life sciences companies are in the business of improving people's lives. "By nature, these companies are social and problem solvers. Social media provides another platform for solving problems." His suggestions are good whether you are selling over-the-counter pain reliever or building awareness for a new drug to treat a chronic condition.

Where are patients hanging out?

While a life science company's Facebook, Twitter, YouTube or Pinterest page is a stake in the social media ground, you can't expect patients to find you. You need to find them, and find out what they are talking about. Are they on therapeutic area forums run by neutral third parties? Or are they looking at sites that are related to, but not directly about, their condition or concern. For instance, patients with eczema might spend a lot of time checking out blogs and websites with information on dry skin.

And what are the patients doing on those forums? As it is impossible to read through every post, you are likely using some type of sentiment analysis software. Many, though, don't have natural language processing (NLP) capabilities to identify what the real issues are and how they are trending. You might know generally that your company's name is trending up or down, but is it positive sentiment about the efficacy of your product? Is it about availability? Are people talking about in the context of side effects compared to a competitor? NLP provides a very sharp and focused understanding of the issues and what is driving them as compared to just following sentiment.

Once you've found the patients...

... how do you participate in meaningful conversations with them? This is a key point that Molander drives home. Those that are successful in leveraging social media are experts in getting the conversation off the social channels and into the direct response channels. They know how to craft the message to get someone to contact a call center so that a meaningful — and this is critical — a compliant conversation can start to take place with adherence to fair balance.

So where do you start? You need to know what is being talked about, who is out there, where your product's name — or the condition that your product can treat — is being discussed. Static reports simply won't cut it. By the time you get a report back that asthma sufferers have bashed your product on one site, they'll be off at another. And besides, as Molander explains, you want to engage proactively rather than reactively.

Analytics

This is where analytics becomes critical. Take the example of the moldy acetaminophen issue from a few years back. It's likely that the problem (which stemmed from issues at a factory) made it on to more than one Facebook or Twitter account. The ability to analyze social media in real time could have given the company a heads up that could have allowed an earlier intervention on the situation. Understanding that your brand or business is being viewed in a negative or positive light is useful, but understanding which elements of your business are generating that sentiment, which channel this originates in and how this is trending allows you to take action. You need the ability to develop custom taxonomies and concepts that align to the most important business concerns and brings a level of clarity and insight other solutions can't match

The prolific use of social to pursue insight can be likened to a large-scale distributed network of sensors to identify anything from fact finding market research to the potential issues associated with drugs. There is significant commercial and public health benefit in listening to such signals, and integrating them with other sources of information.

About the Author

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Outsourcing, SPOs, and the Three E's

"Pharma wants an acceptable and repeatable level of quality from their outsourced service partners..." Manish Vinayak Soman

PEGD talks to Manish Vinayak Soman, President and CEO of Scientific Process Organization (SPO), Sciformix.

Sciformix Corporation is a Scientific Process Organization (SPO), which offers scientific knowledge-based services to pharmaceutical, biopharmaceutical, consumer, medical device and healthcare companies in areas such as safety & risk management, clinical research & post approval support and regulatory affairs.

Manish Vinayak Soman

Manish Vinayak Soman is the company's President and CEO. With over 21 years of experience heading IT operations, he has held a number of leadership positions, including CEO & Managing Director of Deloitte India; Global Business Leader for IT at Genpact; and Director for BestShore operations in EMEA for HP Enterprise Services.

Here, he talks to PEGD about how the SPO and KPO industries are evolving.

PEGD: Has pharma's attitude to SPOs and KPOs changed over the last few years?

Manish Vinayak Soman: Absolutely. Big Pharma's pipelines and patents are drying up, so there's a lot of focus on managing costs. But, more than that, it's about managing compliance and quality as the authorities are getting more stringent. So pharma wants an acceptable and repeatable level of quality from their outsourced service partners. But what is getting interesting is in the area of small- to medium companies, companies of somewhere between $1–4 billion in revenue. These companies sometimes outsource a lot more of their pre and post marketing activities to KPOs and SPOs compared to Big Pharma. Some of the small companies also outsource end-to-end clinical development operations and safety operations so they can focus on their core strengths.

How does your company help pharma?

There is enormous pressure on our clients to perform the concurrent miracles of significant cost reductions with simultaneous productivity improvements in order to thrive in their business. Drug discovery and development are becoming more complex and more resource intensive, despite increased automation. No corner of the business, regardless of the geography, is immune from these pressures.

As a consequence, the amount of outsourcing/out-tasking/off-shoring that the healthcare industry has undertaken has increased. We focus on the 'three Es' — the economics, efficiency and effectiveness of doing this in an environment where we can replicate it across the industry as a whole rather than one organization at a time. Effectiveness encompasses delivering quality and regulatory compliance, consistently and reliably. Given the volume, magnitude and variety of the functions and tasks involved, and the need to adapt processes to evolving regulations, it is a significant challenge for the sponsor company to comply effectively. Efficiency is defined as the ability to manage "peaks and valleys" in workload with minimal impact on productivity and cost. Cost reduction without compromising quality and compliance is the key principle. The goal is to select outsourcing partners who absorb employee overheads, nonproductive time, etc, in a seamless manner, while maintaining the economic advantage.

What are the current outsourcing service provider challenges?

The toughest challenges I think are around talent and training. When practicing physicians, doctors, nurses, medics, etc, join a KPO or SPO, working as drug safety associates or drug safety physicians requires a different way of thinking and operating. So training them to think like that, to work in that manner, can take five to seven months after they join the organization. Similar challenges around talent and training also exist in other functional areas. The expertise and experience required for most of the SPO activities is not readily available in all geographies. It is equally challenging, for example, to train statisticians to do high quality biostatistics work or life sciences professionals to become good quality scientific writers.

We have been supporting clients through a mix of resources across US, Europe and India. And we have recently established operations in a different geographic location. We have set up an office in Manila, the Philippines in order to get access to an expanded talent pool. There are several doctors and nurses there with US training. We are the first third-party organization to establish pharmacovigilance operations in the Philippines.

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Pharma's User-Friendly Future?

"Putting patients first in this way may require organizations to rethink their business models, which is not always easy..."

Dr Thomas Hein explains why user-friendly dosage forms could help pharma companies navigate over the patent cliff.

Established in the 1980s as a division of Hermes Arzneimittel, an Austrian company founded back in 1907 to promote "healthy living" with herbal teas, HERMES PHARMA is now a leader in developing and manufacturing user-friendly solid oral dosage forms.

Dr Thomas Hein

Dr Thomas Hein, HERMES' Director, Sales & Business Development, has since 2001 been responsible for the division's commercial operations, worldwide portfolio management and marketing. Here, he tells PEGD about how pharma could follow HERMES' lead and "revitalize brands by putting patients first".

What do you see as the post-patent cliff opportunities within the pharma market?

To date, the over-the-counter (OTC) market has remained somewhat insulated from

the patent cliff, growing at around 2–5% annually. Pharma companies that sold their OTC businesses a couple of years ago are now looking to diversify their product portfolios, reduce risk and increase revenues by moving back into the OTC market.

Traditionally, OTC market share has been captured via large (and expensive) marketing campaigns, but with competition increasing in this area, innovative approaches will be required to increase market share in a cost-effective way.

One approach is the development of diverse product portfolios that increase the chances that something will stand out to consumers in a crowded marketplace.

How can companies differentiate their product portfolios?

One such method is to reformulate compounds into new dosage forms designed to add further benefits for patients. A significant area of promise in this space is the formulation of user-friendly dosage forms.

What are user-friendly dosage forms?

In comparison to conventional tablets, user-friendly dosage forms such as instant drinks, effervescent tablets and orally disintegrating granules (ODGs) are not swallowed as a solid — instead, they are dissolved either in a glass of water before administration or upon contact with saliva in the mouth. They are easy to swallow and pleasant to ingest, with modern technologies enabling the bitter taste of active pharmaceutical ingredients (APIs) to be effectively coated or masked using a range of flavors. ODGs and chewable tablets can be taken without water, enabling patients to adhere to medical regimens regardless of where they are or what they are doing. As they are less constricted by physical size, user-friendly dosage forms can also contain larger doses of API, reducing dosing frequency and complexity.

In combination, these features can increase patient acceptance, boosting compliance and enhancing brand loyalty by utilizing medical formulations that patients want to take, rather than have to take.

User-friendly medicine can also be effectively used to expand existing product lines, prolong product lifetime, safeguard market share and revitalize brands. New formulation methods, such as those required to effectively coat user-friendly dosage forms, are also more difficult for generic manufacturers to copy, strengthening IP protection.

What are the barriers restricting the uptake of user-friendly dosage forms?

Bringing them successfully to market requires specific know-how, from formulation, scale-up and testing, to registration, sourcing, tableting, packaging and marketing. In particular, the bitter taste of most APIs is still a challenge, and specific know-how in effective taste masking and coating technologies is required.

Putting patients first in this way may require organizations to rethink their business models, which is not always easy, especially for larger companies. While several forward-thinking companies have made significant progress in this area over the last decade, there is still a lot of opportunity for innovation and market share ready for capture.

Therefore, we expect to see a further increase in the development of user-friendly medicines, both as a way to offer additional value to OTC brands, and to provide novel means of patent protection.

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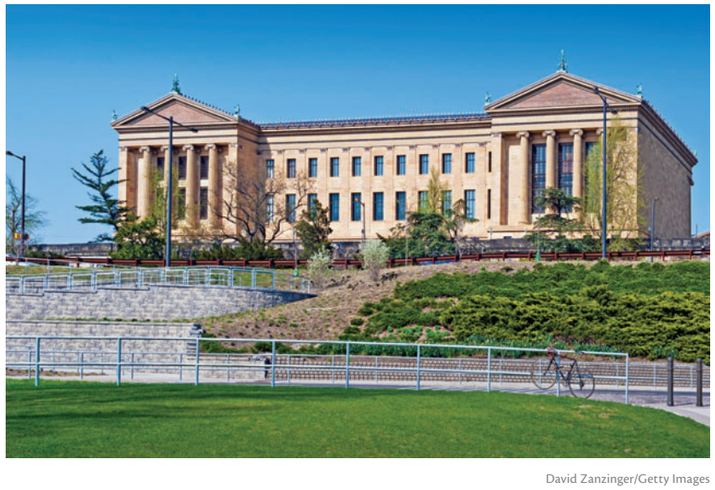

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