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Rare and Orphan Disease Special

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Specialty Drugs: A Tempting Target...

...But what to do? Pharm Exec Editor-in-Chief William Looney looks at how US payers are responding to access and financing challenges for specialty medicines.

William Looney

A key issue for biopharma marketers today is balancing cost and value factors around specialty biologic drugs, particularly those for cancer and other high profile, life-altering diseases. The financial and reputational stakes for players in this hotly contested commercial space are high, compounded by a startling lack of awareness of the incentives that drive specific actions by payers, providers, health professionals, drug manufacturers — and, ultimately, the patient.

Bridging this perception gap was the theme of Pharm Exec sister organization CBI's annual conference on Access and Reimbursement, held in Philadelphia, USA, last month. Speaker after speaker noted that pharmacy spend is now the fastest growing cost segment for insurers, and specialty drugs are the principal factor.

A sea change is expected in management of oncology specialty drug spending...

A highlight of the meeting was release of a survey by a new community-based practitioner network, The Health Payer Council (view the results here), examining how US payers are responding to access and financing challenges for specialty medicines. The Council conducted interviews with 52 US-based medical and pharmacy directors — whose decisions affect 60 million commercial policy lives — earlier this month. The objective was to identify what payers are doing at present to manage pharmaceutical costs and to assess cost control measures that are likely to be applied over the next three years, particularly in the oncology space.

Three key findings

1. Current strategies emphasize the application of standard pharmacy benefit techniques to infused medicines and biologics, reflecting their higher visibility in terms of reimbursement exposure. Some 44 per cent of the survey group have programs underway or in the pilot stages. Significantly, 39 per cent are working on strategies to wean physician practices away from their dependence on

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revenues from these drugs — a difficult task in light of the fact that most oncology practices would be insolvent without the income from administered drug treatments. Especially relevant here is the offering of performance bonuses to physicians when plan-approved clinical treatment pathways are observed; 36 per cent have this in place or under pilot. In lowest order of use are drug capitation/bundling and differential ASP reimbursement, at 31.2 per cent and 21 per cent, respectively.

2. Overall, there was no ringing endorsement of the success of these approaches: the majority of plans consider their efforts to be only "somewhat successful." Pharmacy benefit management techniques [86 per cent] were rated the highest in terms of success, followed by differential ASP reimbursement [67 per cent]. In contrast, efforts to wean physicians off of drug revenues received a high 17 per cent score for being "somewhat unsuccessful." And no one was particularly enthusiastic about performance bonuses — a full 100 per cent of the survey population ranked this tactic as "somewhat successful" rather than "very successful."

"Payers are still fixated on a philosophy that relies on the incentive of the carrot or the stick."

3. A sea change is expected in management of oncology specialty drug spending over the next three years. More than two thirds — 69 per cent — believe aggressive cost controls targeting this therapeutic segment will be in place before mid-decade; half think this will happen over the next year. An interpretation of the poll results suggest in turn that capitation/bundling and pay for performance will be the toolkit of choice for cost cutters, since these two have captured the most interest among payers; they are seen as the most effective methods not currently in wide use.

Roger Green, an industry veteran and consultant who conceived and administers the Health Payer Council, tells Pharm Exec the survey evidences a "disconnect" between what payers are doing now to manage high drug costs in specialty and strategies that are not being applied — despite the perception that these are the ones most likely to be successful. "Payers by and large are still fixated on a philosophy that relies on the incentive of the carrot or the stick. This is not the optimal way to accomplish what is necessary to facilitate change, which is getting the various silo'd parts of the system to cooperate, share and work in partnership. More emphasis must be placed on changing basic behaviors." At root, Green says, is a lack of awareness. "It's simple. No one in the system understands how anyone else makes money."

The Council, which now has 107 members drawn from the medical director and pharmacy payer community, has a mandate to do just that. It won't make policy but is to serve as a forum to exchange information and build dialogue, with Big Pharma a principal focus. You might call it a Venn diagram of the payer community, writ real.

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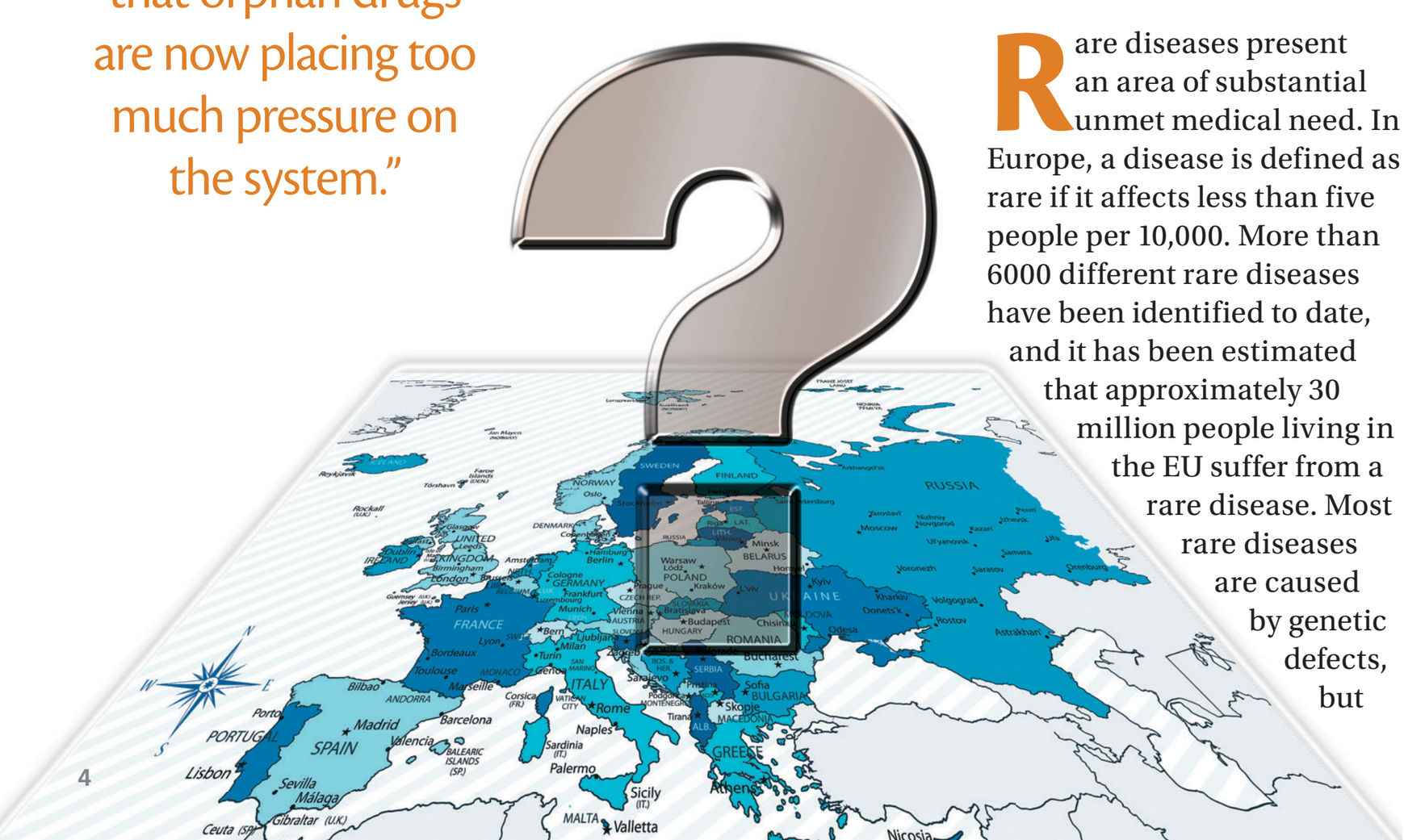
Europe's Orphan Drug Dilemma

Orphan drugs for rare diseases are a major area of investment for pharma, but are they becoming too expensive for Europe? Nathan Jessop reports.

"There is a concern that orphan drugs are now placing too much pressure on the system."



Rare diseases present an area of substantial unmet medical need. In Europe, a disease is defined as rare if it affects less than five people per 10,000. More than 6000 different rare diseases have been identified to date, and it has been estimated that approximately 30 million people living in the EU suffer from a rare disease. Most rare diseases are caused by genetic defects, but environmental exposure during pregnancy or later on in life, often in combination with genetic susceptibility, could also be a cause.

As most pharma companies showed little interest in developing drugs for rare diseases because they were unlikely to generate sufficient return on investment, treatments for these disorders became known as orphan drugs. To stimulate research in this area, a number of governments developed specific orphan-drug legislation, which provided incentives to companies who invested in this area.

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In 1983, the US adopted the Orphan Drug Act, with Japan and Australia implementing a similar legislation in 1993 and 1997, respectively. Europe followed relatively late in 1999 when it adopted Regulation (EC) N° 141/2000 on orphan drugs, but the legislation has been widely considered to be successful. Since its introduction, the European legislation has resulted in the review and approval of 69 treatments for some 55 different conditions.

Despite improvements in the situation for patients with rare diseases and their families, efforts are continually being made by stakeholders to raise awareness of the condition, widen access to treatment and ensure appropriate medical representation. Due to the political make-up of the EU, competencies for healthcare are split across countries; hence, the authorization of a particular orphan drug does not necessarily mean that it is available to all patients in the region. A key annual event

Critics argue that industry is taking advantage of the incentivized system to maximize profits.

to raise awareness is Rare Disease Day, which is held on the last day of February. A main co-ordinator of this event is the European Organization for Rare Diseases (EURORDIS), which represents 585 rare disease patient organisations in 54 countries covering over 4000 diseases.

The high price of success

A controversial issue regarding orphan drugs is their pricing. Although they receive incentives to develop orphan drugs, particularly market exclusivity for 10 years in the EU, companies argue that they must still charge high prices to guarantee sufficient return.

European healthcare systems are already struggling to cover the costs of treatment

for citizens and there is a concern that orphan drugs are now placing too much pressure on the system.

Although the need for orphan drugs is recognized, critics argue that industry is taking advantage of the incentivized system to maximize profits and that healthcare systems cannot cope with such pricing in the long term. In the past, small specialized companies focused on orphan drugs, but in recent years, a growing number of large pharmaceutical companies have moved into this field.

Thomson Reuters Life Sciences estimated that the current global market for orphan drugs is worth US$50 billion and growing at 6% per year.

Companies continue to state that it costs around US$1 billion to develop a new drug and that they need substantial revenue to cover the costs of developing drugs that fail during R&D. However, many observers believe that a number of the orphan drugs on the market have exceeded the costs of their development by a wide margin.

A report by the BBC in January 2013, based on the views of Dr Carl Heneghan, director of the University of Oxford's centre for evidence-based medicine, suggested that approximately one in 10 orphan drugs has generated more than £620 million (US$ 967 million) of revenues.

Furthermore, the pricing of these drugs in relation to the patient population appears to be very high. For example, nine of the most expensive orphan drugs on the market, which cost more than £125,000 ($195,000) a year, treat diseases afflicting fewer than 10,000 patients. Soliris (eculizumab), used to treat patients with paroxysmal nocturnal haemoglobinuria and atypical haemolytic uraemic syndrome, was approved in 2007 and is frequently cited as one of the world's most expensive drugs, at £250,000 a year. Nevertheless, the manufacturer, Alexion,

> There is a likelihood that countries will be asked to fund additional orphan drugs in the future.

believes that the price is fair. It states that one third of patients died within five years before Soliris was available.

One of the harder arguments for companies to justify in today's cost-conscious healthcare environment is when an existing therapy has been modified and adapted to become an orphan drug.

In the BBC report, Dr Heneghan cited the example of oral ibuprofen, which costs approximately £0.08 per gram. The drug also exists on the market as an intravenous form (Pedea) for the treatment of the orphan disease patent ductus arteriosus, where it costs £6575 per gram. To account for this price variation, Orphan Europe, the manufacturer, explained that the drug was specially developed for a rare-disease population and should not be compared in such a straightforward manner with ordinary oral ibuprofen.

The case of Firdapse

In 2009, Firdapse, which contains the active substance amifampridine, was approved in the EU as an orphan drug for Lambert-Eaton myasthenic syndrome. However, a 2012 paper in the Orphanet Journal of Rare Diseases suggests that the branded product represents a slight modification of an unlicensed and low-priced compound that has been available for several decades. The unlicensed drug is 3,4 diaminopyridine (base form) whereas Firdapse is the phosphate-salt formulation of 3,4 diaminopyridine. It was suggested that the pricing of the Firdapse was 50- to 70-fold higher compared to the unlicensed formulation.

This issue prompted a number of physicians to write an open letter in the British Medical Journal (BMJ) to

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UK Prime Minister David Cameron complaining about the way in which companies were unfairly using orphan-drug legislation to their advantage.

A series of exchanges between BioMarin, the manufacturer, and the signatories to the BMJ letter took place, culminating in the lead author writing an FP10 prescription for the cheaper unlicensed drug, 3,4-diaminopyridine.

Although BioMarin then voluntarily cut its prices for Firdapse by 10%, the UK commissioners network did not recommend funding of the drug. The UK commissioners network took the view that although legally Firdapse and 3,4 diaminopyridine were two separate clinical entities, the two forms of the drug could be considered to be bioequivalent.

It was calculated that on average, the base form of the drug costs £1200 per patient per annum, whereas Firdapse costs, on average, £44,000 per patient per annum. This development apparently led to some prescriptions of the unlicensed 3,4 diaminopyridine (base form), which could be legally challenged by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) or Biomarin. However, as the lead author of the BMJ letter pointed out, such a legal challenge might prove embarrassing for these organizations.

So what's next?

Despite the controversy concerning certain high-cost orphan drugs, at present, these treatments only account for a small percentage of the overall European drug budgets.

In 2007, orphan drugs accounted for 1.7% of the French drug budget, 2.1% in Germany, 1.0% in the UK, 1.5% in Italy and 2.0% in Spain

But healthcare systems need to be designed to cope with future demand, and given that most rare diseases are not well treated, there is a likelihood that countries will be asked to fund additional orphan drugs in the future.

A delicate balance will need to be struck so as not to reverse the advances made in orphan-drug development and treatment access.

One study suggested that there will be between eight and 12 new orphan drugs approved in Europe each year. With patients wanting access to these treatments but companies seeking to maximize revenues, European governments are now placed in a difficult situation of over pricing.

Although there has been speculation that governments will take a tough line with the industry, it remains to be seen what form such action will take and whether they will remove some of the specific market incentives that were designed to stimulate orphan drug R&D in the first place.

A delicate balance will need to be struck so as not to reverse the advances made in orphan-drug development and treatment access.

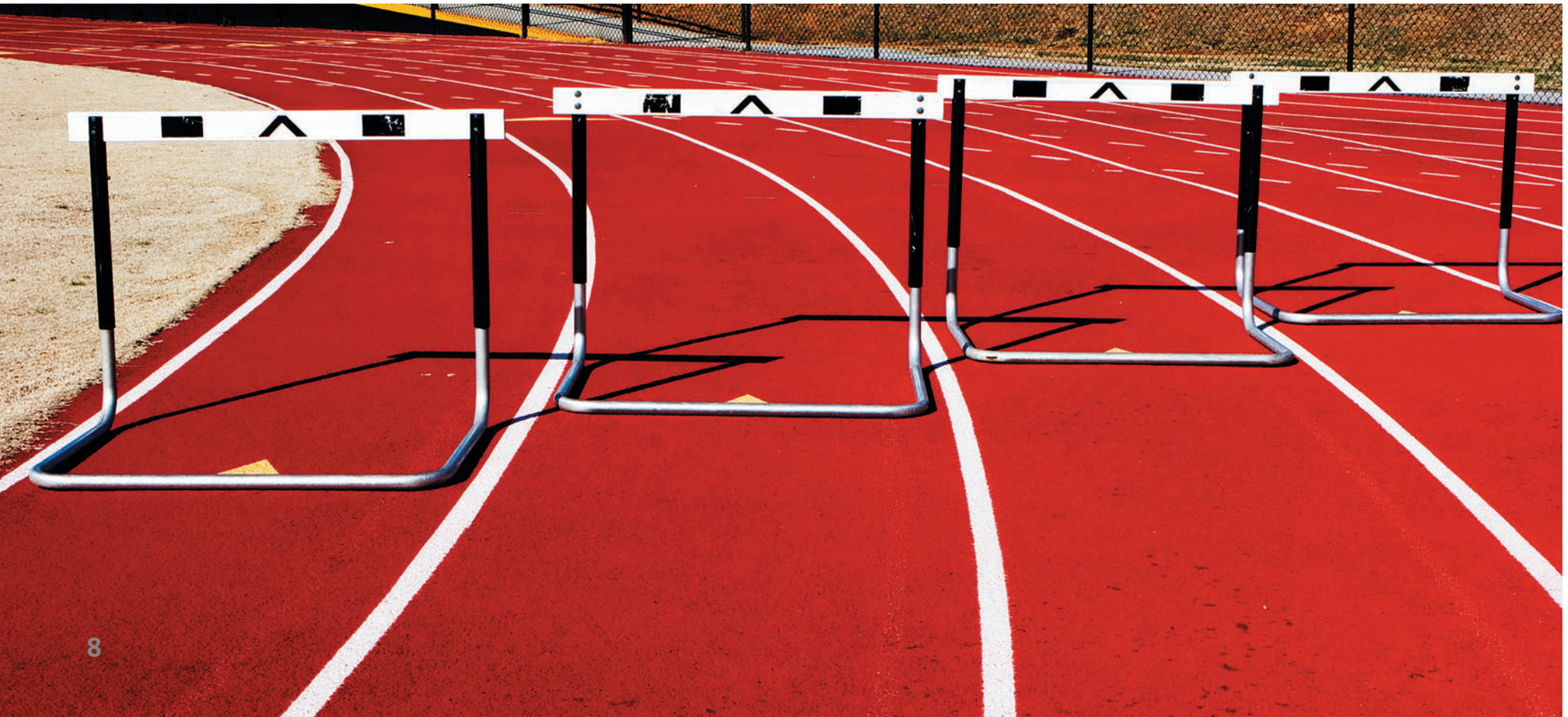
Orphan and Rare Diseases: Strategies for Success

Nathan J. Dowden outlines the current obstacles to negotiate and the opportunities to be had in rare disease development and commercialization.

"Orphan indications and 'rare' diseases are not necessarily the same thing..."

Why is Big Pharma only just discovering orphan drugs? Over the past three years we seen a growing interest in the rare disease and orphan drug model, with a range of companies noting that this is a capability they feel they need to build and asking if and how they can participate effectively.

Although orphan indications routinely make up nearly a third of approvals in any given year, larger companies have until very recently been reluctant to jump headlong into this business. Perhaps it is because only 5% of drug spend comes from rare diseases? Perhaps it is because larger companies have had difficulty getting comfortable with the orphan disease pricing model? Whatever historical rationale for avoiding this space, the



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extraordinary value creation associated with companies like Genzyme (acquired for over $20 billion), Alexion (five-year return of almost 400% and market cap of over $21 billion) and even smaller groups such as Biomarin (five-year return of over 100%) is hard to ignore. It is also, as one CEO related to me, a matter of professional pride to be able to address the most difficult clinical challenges with effective medical technologies.

A rare disease strategy is really just a business model strategy.

Orphan or rare?

As it turns out, Big Pharma has been participating in the orphan disease space for a long time. The catch is that orphan indications (fewer than 200,000 relevant patients as per the FDA standard) and "rare" diseases (no set definition but commonly held to be fewer than 15,000 patients) are not necessarily the same thing.

As an example, Humira, the anti-TNF monoclonal antibody from Abbvie, generated approximately $9.2 billion in turnover last year, yet this is a drug that could be placed in the "orphan" category, since there are indications associated with its use that qualify. In fact, by 2012 six of the top ten and seven of the top fifteen drugs, as measured by global sales, carried at least one orphan indication. Many of these are household names: Botox, Cialis, Fosamax. At the other end of the spectrum is that universe of drugs that will probably never drive substantial shareholder value or captivate big biopharmaceutical business development attention. These are small revenue-generating products targeting niche populations, which are used to treat a wide range of rare conditions. These are the "ultra-orphans".

Toward a rare disease strategy

"Innovation is not invention. It is a term of economics, rather than of technology", said Peter F. Drucker. A rare disease strategy is really just a business model strategy. It is a model that favors the lean and flexible organizations that have built some unique insight into the needs of, a tight relationship with, and an uncommon expertise in the service of a very small group of very sick patients and the people who care for them.

The practical organization and application of resources here is a little bit different from the educational, support and promotional efforts that larger companies are used to. It is a model that is need driven and (almost) epidemiology agnostic. Participation represents a willingness to engage in real innovation — the application of existing and novel technologies in creative ways that improve value for the customer.

Rare diseases and orphan indications can be found in areas of research ranging from neurology to dermatology and everywhere in between. "Rare disease" after all is not a therapeutic category, and companies that look to pursue a rare disease strategy without some additional focus risk seriously stretching their research and development investments to the point of ineffectiveness. From an R&D perspective, a rare disease strategy is simply a disease strategy. If strategy is as much about deciding what you are not going to allocate capital and time to, then a rare disease strategy is no strategy at all.

Six questions to ask

Thus the process by which you pick an R&D target needs to be thoughtful. Six questions need to be answered in order to provide the organization with effective long-range guidance:

1. How will the development of the global economy, payer systems and healthcare

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infrastructure impact product discovery and development, and patient and physician choice?

2. Which diseases and indications are most attractive for the business and how do the indications compare, both clinically and commercially?

3. What target product profiles are necessary to compete in indications of interest given evolving standards of care?

4. What products (both internal and external) are most attractive in priority indications?

5. What organizational structure and capabilities are required in order to succeed in the future and how does that differ by region?

6. What are the appropriate financial expectations the company should have from a top and bottom line perspective?

These questions inform critical elements of the planning process including technology investment, lead target product profile development, lifecycle planning, risk analysis, etc.

Access and reimbursement is relatively straightforward in the rare disease marketplace.

Common investor traps

But let's assume for the moment that you are a biopharmaceutical executive considering investing in this area. We would caution that despite all of the above, the myth that if you follow the science and the rest will take care of itself is as fantastical in rare disease as it is anywhere else.

The common trap investors make is the following:

1. Small patient numbers = high pricing
2. Small patient numbers = small R&D and commercial investment
3. High pricing = high turnover
4. High turnover less small R&D and commercial = high profit.

One might expect that, in an efficient market where products were priced "fairly" based on the morbidity and mortality benefits conferred and the total number of treatable patients you would see a reasonable (inverse) correlation between annual price per patient and the size of the population. Outliers would be explained by outstanding clinical data. Sadly, this isn't what we find.

After looking at a wide range of the largest thirty orphan disease products addressing populations with fewer than 15,000 potential patients, sales are all over the map. Controlling for label, data, population size, competitive intensity and even time on the market, one sees no readily discernable pattern.

Further, and most interesting, when looking at recent representative examples of "pure play" rare disease companies with substantial sales, it turns out that they are no more profitable than larger global biotech and biopharmaceutical organizations, registering net income numbers somewhere in the range of 20%–30%. Respectable, enviable, but not outstanding.

Thus, when looking at the unusually high valuations associated with these rare disease specialists one really has to believe in the growth story. In light of that, one must look to the future and ask: "What could possibly go wrong?"

One advantage that rare disease companies have always relied upon in the marketplace is relatively straightforward access and reimbursement. Unmet need, limited competition, pediatric emphasis and the

limited impact on any given pharmacy or medical budget allowed many of these drugs to effectively fly under the radar. They were considered too small to be worth managing.

Execution challenges

The world is changing though. Budgets are tightening appreciably, while payers are becoming more effective at collecting patient data and measuring real world outcomes.

At the same time payers (both private and public) are attempting to push accountability to institutions and physicians and the physicians are in turn beginning to lower their expectations. Coverage is increasingly limited to on the label populations of tightly defined patient groups, while patient out of pocket burdens continue weigh heavily on the decision to engage in and persist with treatment. In summary, rare disease focused companies are not immune to the general pressure on pricing and access. They are simply some of the last to feel the pinch.

Execution is therefore a challenge. There are very few ways to do things right and a lot of ways to do things wrong. Tolstoy was quite correct when he observed that "all happy families are alike; each unhappy family is unhappy in its own way." Over the past two decades we have observed (and made) a number on the way to and through company formation, development and product launch. These are neither small biotech or Big Pharma specific (see Table 1).

Given the above, companies must spend time on commercialization planning very early in lifecycle development. While this is standard operating procedure for larger biopharmaceutical companies, much of this activity is neglected by smaller groups which focus their capital on "mission critical" activities or expect that one day a commercialization partner will provide them

Table 1

"All Happy Families Are Alike; Each Unhappy Family Is Unhappy In Its Own Way."

Our Experience With Challenges Across The Value Chain & P&L

Reaching Market	Achieving Uptake	Building a Business
• Poorly defined target populations and labels	• Neglecting the need for clinically meaningful longer term data prior to launch	• Miscalculating cost per patient benefit from payer perspective
• No clarity regarding regulatory standards or requirements	• Ignoring evolving standards of care	• Ignoring the institutional impact in a DRG like system
• Mistaking regulatory requirements for physician adoption and reimbursement requirements	• Ignoring provision of care limitations / displacement of other procedures	• Patient out of pocket impact and sensitivity
• Ignoring your own data / ignoring competitive data	• Neglecting physician and patient advocacy champions	• Ignoring the lessons learned by primary and specialty care
• Reliance on meaningless surrogate markers	• Referral to specialist dynamics	• Ignoring macroeconomic trends
• Unrealistic trial accrual / time to market assumptions	• Assuming product availability will grow the market	• Focus on revenue while forgetting cash flow

with this insight. These include create a product and patient flow map, identifying the role and the relative influence of each stakeholder in the buying process, determining the access to care challenges based on setting and patient segment, and develop a picture of overall system infrastructure requirements (product acquisition, product delivery, procedure and follow up).

Organizational challenges

For the larger biopharmaceutical company, the more challenging question to address is organizational. A review of development and commercialization capabilities, governance and incentive alignment, communication structures and funding support is warranted. Perhaps most importantly there are a host of very good reasons to invest in this area ranging from revenue and profitability growth, to business model diversification, through to social mission. For many emerging companies, product development is personal and the ties between management, employees, advocacy groups, patients and physicians are extremely intimate. A company's reputation, built conversation by conversation, trial by trial, can be a powerful generator of support and loyalty. It can also be quickly destroyed. Building the positioning and communication structures to ensure honest dialog both internally and to the clinical community can make the difference between success and failure, particularly over the long term.

Six tenets of success

For companies large and small taking the first tentative steps down the road of orphan drug development there are ultimately six tenets of success:

1. Communicate clear vision/goal from inception and put the patient first.

2. Recruit a senior champion from commercial and R&D. Someone credible from the research community.

3. Focus on products and market requirements rather than platforms.

4. In large companies, strive for limited core business involvement/ownership; but anticipate reflex response to independence.

5. Expect a 24–36 month business creation process before you make substantial progress clinically, and organize your capital and human resource plan accordingly.

6. Plan from the outset for longer term integration or complete spin out (exit from incubation).

Missing on any of the above will result in strategic confusion, tactical disarray, lost time and wasted capital.

Conclusion

For companies (particular larger companies) still wondering whether or not to participate in rare disease development and commercialization, I will end this article by posing a final rhetorical question. Remember the comment "rare disease is not a therapeutic category"? Well, personalized medicine is not a therapeutic category either. But it does result in very small target populations, of people with very specific needs. So if you are investing in personalized medicine … you are probably investing in rare disease.

About the author

Nathan J. Dowden is Managing Director of The Frankel Group LLC.

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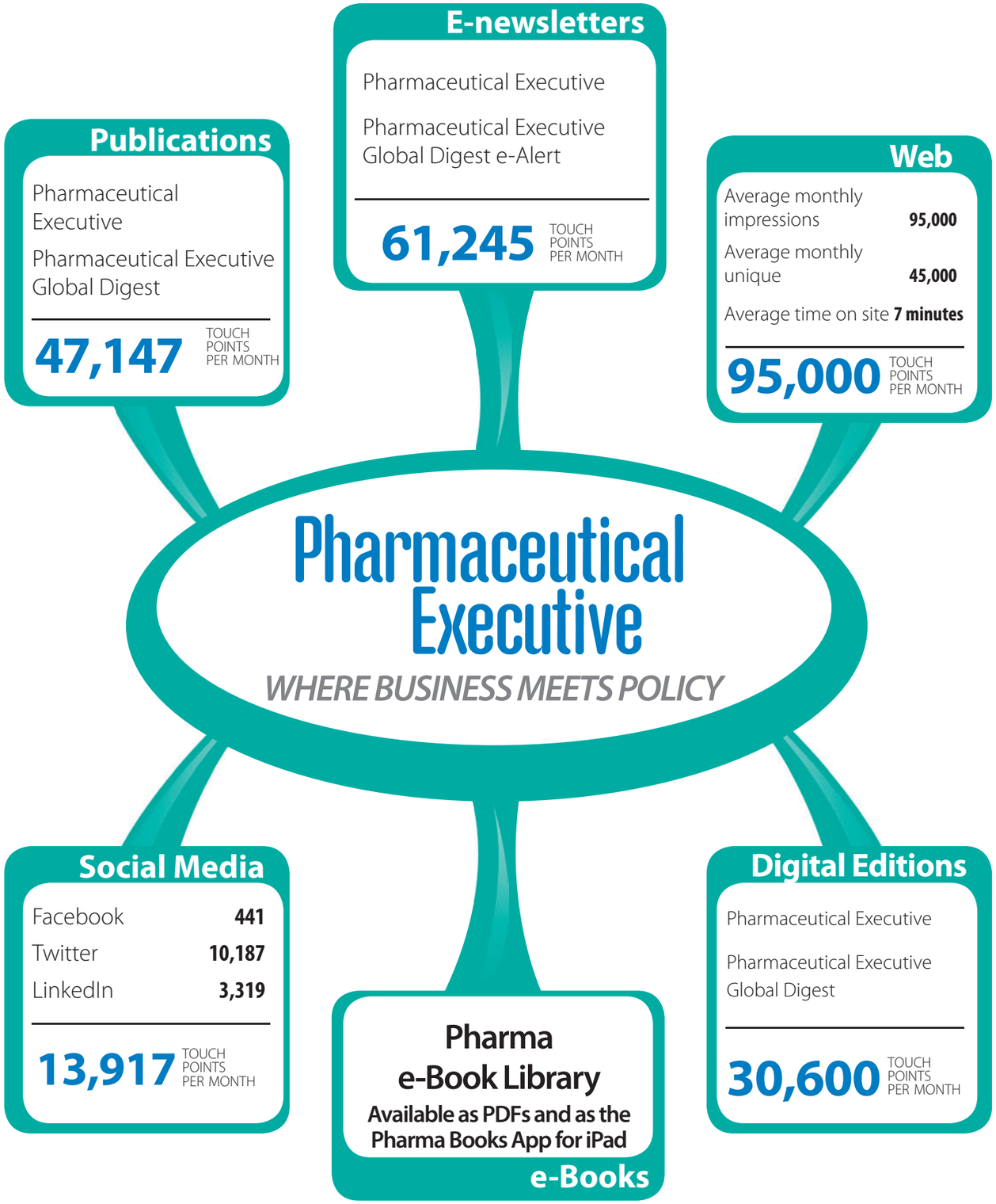

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Using Mobile and IT Solutions to 'Glocalize' in Emerging Markets

"Affordable, scalable, and integrated global IT and mobility solutions should play a vital role in addressing specific local challenges"

Himanshu Parmar outlines how cloud-based mobile and IT solutions can help tackle operational challenges in the emerging markets.

Pharmaceutical companies are making changes to their organizational structures for expansion/entry into the emerging markets. Many have established regional headquarters/offices or local subsidiaries, and many are regionalizing or localizing certain value chain functions, either through their direct presence or local partnerships.

Sanofi, for example, has manufacturing facilities in Brazil, which accounts for over 95 per cent of total company sales in Latin America, and a local manufacturing/R&D

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presence in China. Bristol-Myers Squibb is active through its research partnership with Biocon in India and via local research facility/partnerships in China. Some companies also maintain local sales forces, such as Sanofi in China and GSK in India.

Global reach, local efficiency

Pharma companies have also been launching patented drugs in emerging markets and have adopted a combination of various models, such as localized pricing, acquisitions, JVs, and local distribution/marketing partnerships, to increase their market penetration.

A good example of this is GSK India, which has adopted a very country-specific strategy. The local management follows the global ethical and commercial framework, but has full autonomy to run the day-to-day operations. It uses a global tier-pricing strategy for patented products, and has been aligning its product portfolio to local requirements through in-licensing and branded generics.

The company has also successfully launched the "Reach" initiative, targeting doctors and patients in rural markets. This has focused on achieving operational efficiency in India through extensive use of IT solutions, such sales force automation, purchase order visibility, human resource management and e-procurement systems.

There are also global/regional programs that use local customization — eg, pricing and market access programs — that share the global vision and mission, but focus on regional aspects. These programs use a global set of activities and deliverables, with the team working collaboratively from Europe and India, supported with various training modules and IT tools. For example, Eli Lilly has diabetes R&D center in China that leverages global alliance (with Covance) and local resources to meet local and global needs.

How mobile and IT solutions can help

Although the emerging markets present similar challenges, a unique and highly localized approach to each country based on the level of maturity and complexity of that region is needed. Affordable, customizable, scalable, and integrated global IT and mobility solutions should play a vital role in addressing the specific local challenges, while enabling adoption of global governance guidelines.

One of the key areas IT and mobility solutions can have a hugely positive impact is on the supply chain. Global companies are still looking for cost-effective ways to address supply chain visibility issues in the majority of emerging markets. Typically, these supply chains have poor or no visibility into secondary sales, which means there is no timely warning of imminent stock-outs.

Infrastructure and technology adoption in these markets is still at a very early stage. Technology use is not only limited to pharmaceutical companies but there is a lack of technological capabilities at channel partner level as well.

A cloud-based supply chain solution can help to meet these challenges by enabling organizations and networks to best serve both the local needs and the broader global supply chain strategy. Cloud-based mobile solutions can enable the cost-effective order capture from pharmacies and facilitate sales force automation, and provide seamless POS data acquisition based on trading partner's maturity.

Creative localized strategies enabled with cloud-based/mobile solutions can also help in cost-effective integration with channel partners, while enabling higher visibility and auto-replenishment to reduce risk of stock-outs.

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Case studies

Novartis introduced a simple but creative mobile strategy for malaria drugs known as "SMS for Life" that leverages the growing mobile coverage in Africa. The initiative uses a combination of mobile phones, SMS messages, and electronic mapping technology to trace weekly stock levels at local health facilities. The company provides incentives (such as free talk time on Vodafone) to retailers and hospitals to encourage data sharing from them. Novartis rolled out the program across Tanzania (over 5000 facilities) and also expanded the coverage to add tuberculosis and leprosy medicines.

Another area where IT can help expansion in emerging markets is through the adoption of digital marketing strategies. Sanofi for example is leveraging various digital initiatives for their products in India. Its successful campaign, "For Our Mothers against Flu", used Facebook to create an online target community for flu vaccine. The Facebook page acted as educating media on flu and flu vaccines by using regularly organised polls, quizzes and discussion forums. The campaign was complemented by traditional tactics such as celebrity endorsements and online advertisements.

Conclusion

Cloud-based and mobile solutions are an effective answer to operating challenges in emerging markets, where affordability and coverage volume are the key considerations to generate business value. This trend is likely to strengthen in the next few years.

About the author

Himanshu Parmar is a Senior Consultant, Life Sciences, with the Management Consulting Practice at Infosys.

Smartwatches: Time for Health?

The smartwatch has a long way to go before it becomes a disruptive technology. Key to its adoption may be health apps, writes Peter Houston

Still getting used to the idea of a smartphone? Better be quick, the smartwatch is on its way ... or maybe not if iOS is your tech platform of choice. But despite usual whirl of rumours that accompany any major product announcement from Apple, the much imagined iWatch will not sit alongside the iPod, iPhone and iPad range any time soon.

Apple has demurred for the time being, but there has been a real flurry of activity in the smartwatch market recently.

Earlier this month, Samsung grabbed the headlines with its Galaxy Gear 'fashion icon', a smartwatch with a colour screen that shows alerts, run apps and can be used to make voice calls. But its hardly revolutionary when you realise it's a "partner device" that has to be used with a Samsung phone or tablet.

Sony has been a little bit more egalitarian in its approach — its Smartwatch2 will connect to any android device, but it is still essentially a second screen for your existing smartphone. And at more than $200, a fairly expensive one at that.

So expectations for the Smartwatch market are relatively low, at least until someone develops the killer app and the conversation around must-have applications is all health related.

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Yes, the sheer marketing clout of companies like Sony and Samsung coupled with phone-watchconnectivity could see smartwatches giving fitness devices like the Nike Fuel Band and the Fitbit Flex, a real run for their money. But that's not really a major advance on what phone-based fitness apps already do.

Intriguing then that early in the day that Apple didn't announce the iWatch, serial entrepreneur and co-founder of The Next Web technology blog, Boris Veldhuijzen van Zanten, wrote that he would be buying buy six iWatches when they are finally introduced — one for himself, and one each for his two kids, their mother and his parents.

Ahead of Apple's press conference, Boris asked several people if they would be interested in buying the iWatch. The stock response was 'No', with people unable to see why they would need one. But Boris based his hypothetical spending spree on the idea that Apple wouldn't introduce the iWatch unless it is revolutionary and for it to be revolutionary he thinks it will be wearable health and medical tracking device.

Remote patient monitoring still faces some big obstacles...

Notions that Apple is developing a device like this centre on the rumour that the company has poached several scientists away from companies like AccuVein, C8 MediSensors, and Senseonics. These are people that know about sensors that measure body level information and pick up data that will give users, or their doctor, a snapshot of their health.

Boris imagines the device monitoring blood pressure, movement, temperature and a host of other parameters. "If Apple would be able to achieve something like this we would definitely see another revolution. It would be game changer for the medical profession."

This maybe all seems a little bit Star Trek, until you see that the market for remote patient monitoring is forecast to double to more than $20 billion by 2016 according to a 2012 study by Kalorama Information. VC spending on remote monitoring has been put at over $100 million by Rock Health, a seed fund for digital health, with investors banking on legal and budgetary requirements forcing increased care for patients outside the hospital setting.

None of this means health-centric Smartwatch technology — even Apple's — is a shoo in. Remote patient monitoring faces some big obstacles, from older patient's reluctance to pick up unfamiliar technology, to a lack of standardization on data and the ubiquitous difficulty in managing regulatory approval.

But if Apple is looking for another market to disrupt, smartwatches with a heavy healthcare focus would seem a better bet than just shifting people's iPods from their pockets to their wrists.

This maybe all seems a little bit Star Trek, until you see that the market for remote patient monitoring is forecast to double to more than $20 billion by 2016

About the author

Peter Houston is an independent media consultant and founder of Flipping Pages.

APPOINTMENTS

Robert Landry, a former Senior VP at Pfizer, has joined Regeneron as Senior VP, Finance. He will succeed the Regeneron's current CFO, Murray Goldberg, when Mr Goldberg transitions to a new role within the company in October.

Forest Laboratories has named Brenton Saunders, former head of Bausch + Lomb, as its new CEO and President. Mr Saunders succeeds Howard Solomon, who has CEO of Forest since 1977.

Idis (Princeton, NJ, USA and Weybridge, UK) has appointed Jeff Thomis as Chairman, with responsibility for overseeing its managed access programs for medicines. Thomis spent 11 years at clinical research organization Quintiles, where he was appointed President, Global Clinical Development Services, in 2006.

Cardioxyl Pharmaceuticals (Chapel Hill, NC, USA) has appointed Dr SHi Yin Foo as Chief Medical Officer. Dr Foo joins from Novartis, where she was responsible for multiple programs in the cardiorenal space.

Takeda has appointed François-Xavier Roger as its new Chief Financial Officer. Mr Roger is returning to pharma after a spell as CFO at Millicom International Cellular, a digital and mobile telecoms company.

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