Valuable collection

What are the prospects for grouping complementary services around a product?

In the article, 'If the Shoe Fits' (*PME* January/February 2010), four emerging pharmaceutical market strategies were identified, based on uniqueness of positioning and type of competition (www. pmlive.com/ shoefits). This next article in the series concentrates on the bottom right quadrant of the grid depicted in that opening feature: situations where a product without unique positioning has a competitive advantage on outcomes through value-added services.

New healthcare combination solutions, such as diagnostic-drug, diagnostic-device or novel delivery mechanisms, are at the forefront of a newly emerging pharmaceutical (and medical device) strategy that wraps complementary products and services around drugs (and devices) to deliver superior outcomes. Such holistic approaches include the total diabetes management service offered by Sanofi, for example. However, both pharmaceutical companies and payers struggle with the key question of who pays for these combinations. In most countries, healthcare budgets are fragmented and reimbursement of products, such as drugs or devices, is separate from healthcare services, such as ambulatory doctor treatment or homecare.

The uptake of telemedicine solutions in cardiovascular risk management has been slowed significantly by the difficulty of obtaining reimbursement for an integrated healthcare solution cutting across a variety of spending categories. For example in France, the T2A reimbursement system has only recently been changed to recognise telemedicine activities. Previously, payment by social security was quite simply not possible. Many countries are in similar situations and so these cost-effective healthcare solutions combining technical-medical and information/communication technologies remain limited to small-scale pilots that often end when the project funding stops.This is not simply about evaluating another product for the same indications in which the company is established. It is about assessing the relative commercial attractiveness of additional new diseases or indications in order to provide strategic direction to business development and licensing teams on future disease areas with high commercial opportunity. This provides a 'search and selection' focus for business development activities and a framework against which individual products can then be considered.

This article outlines the prerequisites for favourable reimbursement, the most promising therapeutic areas for combination solution opportunities, and the strategic implications for the healthcare sector.

CHALLENGE

Traditionally, healthcare products and services are disaggregated and evaluated individually: every pill and activity has a price. For each component, the price is agreed with the relevant (reimbursement) authority and the total for the overall healthcare bundle is just the sum of all individual parts.

Unfortunately, the approach has limitations, particularly for chronic diseases evolving over a long period, such as diabetes mellitus type 2. According to the KoDim study based on German payer information, only 10 per cent of the total direct costs from diabetes (both type 1 and 2) are related to treatment with oral anti-diabetics (OAD) and insulin. Over 78 per cent of the total diabetes-induced costs relate to complication costs due to cardiovascular disease, dialysis and others. Hence, the study authors advocate more prevention and earliest identification of high-risk patients so that they can receive intensive care.

The diabetes numbers show the limitations of pricing each healthcare service individually. The optimisation of each

component fails to manage the overall picture (across all components and/or time). Hence, in some countries payers have started to accept the pricing for an overall healthcare solution through capitation (fee per patient). Providers typically have to deliver specifically negotiated outcomes with the payers, which are then imposed as a condition for payment. However, payers are resistant to bundled offerings as they are always suspicious of price inflation compared to the individual items, making the overall solution more costly. Indeed, in the US it is almost forbidden to use this word when speaking to Managed Care Organisations.

Successful providers must therefore operate under the threshold of current costs while establishing quality and superior outcomes as additional criteria. More advanced programmes extend the capitation model to cover all costs related to the disease, including complications. South Africa implemented such an approach in 1996 with its Diabetes Management Programme. Under this scheme, diabetes teams within a Preferred Provider Network are responsible for all costs related to diabetes. As well as health professionals trained in diabetes management and a 24-hour telephone hotline, these include support by healthcare professionals such as dieticians, podiatrists and ophthalmologists, medications and hospital treatment. In addition to improving glycaemic control among both type 1 and type 2 diabetics, hospitalisations among people with diabetes covered by the programme have reduced by 90 per cent. Many Eastern European countries, such as Romania with oncology therapies, are increasingly concentrating patient flows to specialist centres compensated on a capitation basis.

CHRONIC DISEASES

In Europe, authorities and payers continue to exercise significant pressure on drug prices. Pharmaceutical companies are now forced to show outcome improvements for their offerings if they want to avoid commodity pricing, particularly as first-in-class generics hit the market. They have responded with a variety of tactical approaches driven by the need for positive reimbursement decisions for their new product launches:

- Compliance management, eg. patient segmentation according to drug compliance coupled with segment-specific programmes (bisphosphonates supplier in the US)
- Risk management, eg. drug suppliers pay for complications costs should the drug fail (Novartis Aclasta pilot studies in Germany and Italy for payment of hospitalisation and nursing costs)
- Pay-for-performance, eg. pharma company charges only when the drug is effective (Janssen-Cilag's Velcade Response Scheme in England).

Medical societies, such as the European Society for Hypertension, differentiate their recommendations according to the severity of hypertension (normal, high normal, grade 1-3), advocating difficult-to-achieve lifestyle changes and elimination or limitation of other risk factors, such as smoking and obesity before, or in addition to, drug treatment. The guidelines make chronic disease treatment complex due to combination strategies and condition-specific recommendations reflecting cost considerations, which can change significantly with patent expirations.

However, neither route has delivered convincing results. Despite the drug arsenal doctors have to treat chronic diseases such as hypertension, hypercholesterolemia and asthma, the unmet medical need is still significant when outcomes achieved are examined. According to the US Department of Health and Human Services, over 50 per cent of diagnosed hypertensive patients do not achieve blood pressure control (around 40 million patients).

Perhaps better treatment, and not necessarily new products, is what is needed. Could combined product and service offerings be the answer? Pharmaceutical companies with a combination of patent-protected and mature products could realise this opportunity through various novel business models, focused on patients and payers:

The problem, however, is patent expiry. According to EvaluePharma, over $120bn of drug sales are at risk from patent expirations in 2011-2012. Most major drug classes will soon contain generics, particularly in chronic diseases. The cardiovascular and respiratory ATC classes will be hit particularly hard by the expiration of blockbuster patents during the next one-to-three years:

- C09 – Angiotensin II antagonists (Novartis' Diovan)

- C10 – Serum lipid lowering agents (Pfizer's Lipitor)
- R03 – Anti-asthmatics (GlaxoSmithKline's Advair)

Generic entry reduces the likelihood of turning a profitable but perishable drug franchise into a long-term solutions business. When the drug sells for pennies, who will pay pounds for the complementary services needed to make it work better? The window of opportunity is closing for solution offerings wrapped around drugs for many chronic diseases.

WHICH DISEASES AND CONDITIONS?

In fact, few companies have been able to build successful businesses with healthcare bundles or solutions, particularly in the ambulatory sector. Those that succeed have rarely started from a pharmaceutical product offering. However, product companies can be successful in offering product and service healthcare solutions for fixed fee reimbursement, with the following prerequisites:

- Product companies should only embark on transforming their business model if they truly believe in synergies with the existing business. They must create more value from the integration of products and services into a healthcare solution than from the components alone.
- Product companies need to develop superior treatment/management standards and demonstrate improved outcomes. Their deep disease understanding, strong access to (medical) opinion leaders and ability to develop standards/protocols for continuous outcome measurement are powerful assets that must be mobilised here.

This will enable large international companies to compete on achieved outcomes and overall quality. For example, in most countries today, dialysis services are reimbursed according to a fixed fee, enabling the emergence of international dialysis chains, such as Fresenius Medical Care, the best known example of a strategic move from products to a combined products-services business model.

However, significant investments should only be made in diseases where novel products are not going to alter the medical practice significantly, thereby making expensive healthcare infrastructure obsolete. Companies can reduce their risks by building entry barriers, for example through strong quality standards and branding, as done successfully by IVI in the area of human reproduction with a total of 20 clinics in Spain, Europe and the Americas.

EXPERIMENT AND PILOT

Since healthcare systems are different in each country, companies need to experiment with and pilot their business models locally. This requires a strong entrepreneurial culture in the company. Conversely, despite having a proven and established business model in other countries, entering a new country poses a significant challenge in adapting to the local environment. Euromedic International, another healthcare success story, employs over 5,000 medical professionals, operating diagnostic, clinical laboratory, cancer treatment (radiotherapy) and renal care centres across 15 European countries. Its rapid expansion into ambulatory healthcare

Executive summary

- New healthcare combination solutions are at the forefront of a newly emerging pharmaceutical (and medical device) strategy that wraps complementary products and services around drugs (and devices) to deliver superior outcomes
- The traditional disaggregated pricing approach for healthcare products and services has limitations, particularly for chronic diseases. Payers have started to accept the pricing for an overall healthcare solution through capitation (fee per patient)
- Generic entry reduces the likelihood of turning a profitable but perishable drug franchise into a long-term solutions business. The window of opportunity is closing for solution offerings wrapped around drugs for many chronic diseases
- Significant investments should only be made in diseases where novel products are not going to alter the medical practice significantly thereby making expensive healthcare infrastructure obsolete
- Laggards without a strategic response to the fundamental market changes driven by the demand for outcomes will see their revenues and profits evaporate. Many disease areas will rapidly commoditise unless companies can extract a premium from loyal customers

NOVEL BUSINESS MODELS

Primary stakeholder	Patients	Payers
Offering	Support lifestyle changes and elimination/limitation of other risk factors through a disease management programme	Manage the blood pressure for a certain population through necessary drugs and services according to guidelines
Revenue mechanism	Out-of-pocket fee from patients plus costs for drugs	Capitation fee for achieved outcomes (including bonus/malus)

started in 1998 with several diagnostic centres in Hungary focusing on expansions through public-private partnerships in Eastern Europe, initially in Poland, Bosnia & Herzegovina and Romania. The focus has always been on healthcare solutions that are "privately funded, publicly trusted and government backed". In each market the solutions are slightly different, but the concept remains the same.

"Countries open to the new reimbursement approach will be fertile ground for ... pilots"

The examples and future trends suggest that combined healthcare solutions will come to dominate treatment within certain diseases. Countries open to the new reimbursement approach will be fertile ground for entrepreneurial pilots, leading to radical transformations. The new business opportunity is open to all, not just pharmaceutical companies: this is why companies such as T-Mobile and Orange are at many healthcare conferences. The most obvious players are specialised healthcare providers, such as Euromedic, e-health companies, including IT companies and telecom operators, as well as medical wholesalers, media companies and healthcare insurers.

Medical product companies have already been successful in establishing a strong position in some conditions. Through a series of transformational acquisitions since 1996, Fresenius Medical Care has become a leading healthcare products and solutions company for end-stage renal disease. In 2010, it generated an EBIT of $1.9bn on $12bn of sales, representing a margin of 16 per cent, and treated almost 215,000 of the global 1.89 million dialysis patients, corresponding to a patient share of more than 11 per cent.

Historically, pharmaceutical companies have not involved themselves with services/solutions because the margins are lower than those for drugs. When drug margins were high, they could offer services for free to drive market share and still make money. As a consequence, payers, providers and practitioners now expect such services to be free. Pharmaceutical companies that want to be successful in these emerging markets need to transform their operations from drugs to solutions. While some baulk at accepting a somewhat lower profit margin compared to the past, Fresenius Medical Care's 16 per cent margin would please many pharmaceutical company shareholders!

In conclusion, laggards without a strategic response to the fundamental market changes driven by the demand for outcomes will see their revenues and profits evaporate. Increasing price pressure and patent expirations will rapidly commoditise many disease areas, unless companies can extract a premium from loyal customers. However, combined solution providers will be able to protect and even grow their revenues and profits using a robust business model that is separate from the fate of individual drugs.

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