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Executive summary



Healthcare systems around the world are in crisis. They are buckling under the pressure of rapidly increasing longevity, rising patient expectations, unhealthy lifestyles, multiple co-morbidities and significant healthcare cost inflation. They are desperate to answer a simple question with a complicated answer: how can we secure better patient outcomes at lower cost?

To realize this ambition, a complete re-evaluation of the healthcare operating model is needed and, in many parts of the world, is already underway. In this report, we argue that pharmaceutical companies ought to be much more engaged than they are currently with this rapidly changing healthcare landscape. Those that are partners to the debate and manage to negotiate through it successfully will find multiple opportunities to improve the bottom-line.

Without a doubt pharmaceutical, medical device and diagnostics and other life sciences companies have the talent and ability to demonstrate their value as a partner to healthcare systems around the world but both elements of the business model and the way it interacts with its stakeholders need to be rethought. There is still time to make these changes but given the scale of the challenge, these should still be driven with unparalleled urgency.

Of course, other industries have been through similar transformations. As an example from the IT industry, IBM reinvented itself in the 1980s and 1990s.¹ First, it shifted its focus from mainframes to PCs. Second, and more importantly, it added professional services to its business. This provided business solutions to large enterprise clients, helping drive higher value, improve margin and grow profits as a consequence. As many industries have recognized, it is the customer (or patient) that ought to sit in the center of the system, and not the provider. As healthcare systems evolve to take account of that fact, it is imperative that pharmaceutical companies do too. IBM's massive transformation resulted in a 10-fold increase in its share price post 1995, well ahead of the three-fold rise in the US market over the same period. That is an outcome that is certainly worth paying attention to.



Chris Stirling
Global Head of Life Sciences



There is considerable opportunity to improve margins for pharmaceutical companies that can capitalize on the changing healthcare landscape.”

Chris Stirling
KPMG's Global Head of
Life Sciences

¹<http://www.forbes.com/sites/davechase/2012/07/28/ibms-reinvention-should-inspire-flat-pharma-businesses/>

Introduction

Healthcare transformation demands a new vision and approach from life sciences companies

The life sciences industry finds itself at a critical crossroads. In one respect, never before have there been so many powerful forces driving increased demand for healthcare. These include aging populations, rising expectations for increased access and better quality healthcare (particularly among the middle classes in emerging markets), and an increase in the prevalence of chronic lifestyle-driven diseases.

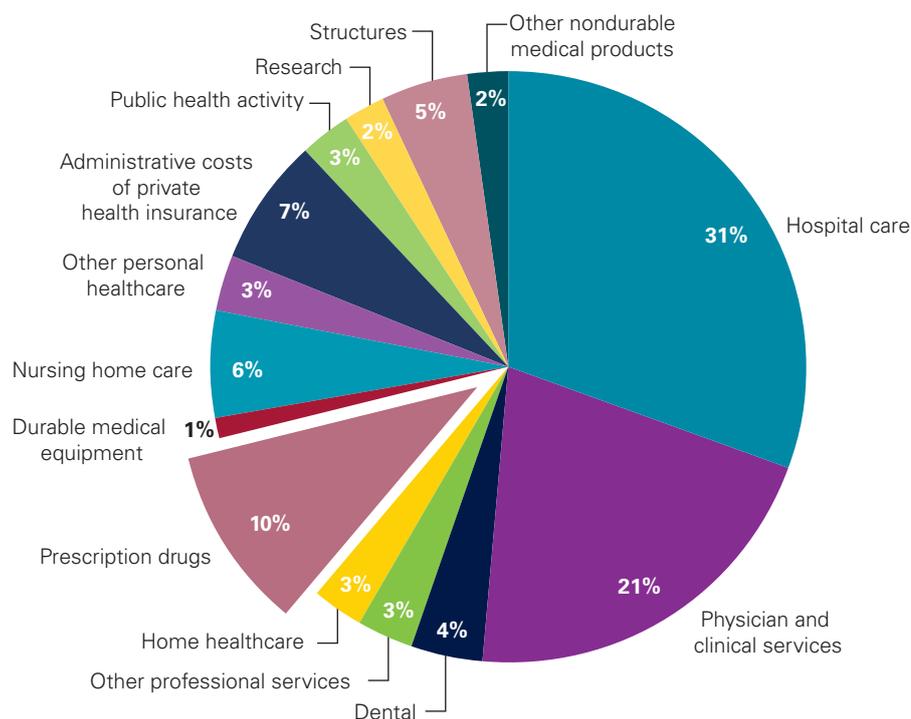
However, life sciences companies are also facing an unprecedented range and intensity of challenges. In Europe especially, the global economic downturn has hurt many pharmaceutical companies who have struggled to be reimbursed for their medicines. Reforms introduced by healthcare systems in desperate need of restructuring have contributed to persistent downward pricing pressures worldwide that have unfortunately coincided with a period during which patent expirations continue to wipe billions of dollars off balance sheets.

The industry still finds itself in the press for all the wrong reasons as historical sales and marketing indiscretions are exposed and multi-million dollar fines levied. There has clearly been a cultural shift across the industry but we are at the start of a long process of rehabilitation.

However, our contention is that the industry has not yet properly addressed one of the most pressing global challenges – the rapidly changing healthcare landscape. This is partly understandable given the need to manage patent expirations and retool research and development (R&D) but it is now time to start to consider this important issue. The new healthcare ecosystems focus on value, and reward better outcomes at the same or lower costs. Accordingly, the interests of the life sciences industry could converge with those of healthcare providers and payers in increasingly integrated delivery and financing models, provided the products and services are of sufficient merit.

How should the industry approach this new healthcare landscape? There are broadly two options. First, business as usual but this is an untenable strategy. The historic adversarial supplier model is only going to get tougher. Payers, more active and influential, are rightly demanding a greater degree of evidence before approving or reimbursing new drugs and the relatively easy wins in primary care in developed markets are no longer available in an era of high quality generics for many chronic diseases. In the emerging markets, there are personal income and budgetary challenges, and specialized markets such as oncology are, in many cases, highly competitive.

However, there is an alternative approach for the industry: be part of the solution, positioned as a partner *in* the system, rather than a supplier *to* it. Medicines constitute just 10 percent of the total healthcare bill in the US (Figure 1) and 9 percent in the UK. If healthcare systems need to achieve better patient outcomes for less money, significant savings could be achieved from the other 90 percent of the budget, in particular, on the amount of money spent treating people in

Figure 1: Breakdown of US healthcare spending (2011)

Source: Pfizer, 2012 (http://www.pfizerplus.com/gi/health_care_spending.aspx)

hospitals. The industry is ideally placed to work with providers and payers to achieve this, not least because better medicines keep people out of hospital, but also because its expertise in market access could be very valuable to new groups of healthcare organizations. Combining the global access infrastructure of the industry with the care experience of providers and risk management experience of payers could create new ways to deliver improved value to the patient. Co-morbidity is a complicating factor that vertical disease models fail to address: the industry could use its extensive disease knowledge to help develop better treatment pathways for the co-morbid patient.

We see three crucial strategies that the industry must consider in the new healthcare environment:

1. Understand the customer and what they want
2. Reshape R&D to provide reimbursable drugs and devices that deliver shareholder value
3. Anticipate shifting power structures in the wider healthcare system

In Part 1 of this report, we first analyze in more detail what is driving the trend towards healthcare 'convergence'. Next, we outline our vision for more successful partnerships between different stakeholders in the healthcare ecosystem. In Part 2, we expand on the three strategies for future industry success given the new healthcare reality.



Part 1

The changing healthcare landscape

What is driving healthcare convergence?

In a system that rewards better outcomes at the same or lower costs, the interests of pharma could converge with those of healthcare providers and payers in increasingly integrated delivery and financing models.

Healthcare convergence is the thesis that all stakeholders in the healthcare ecosystem will increasingly need to work more closely together to achieve one aim: better patient outcomes at lower costs. New ecosystems are built around patients, not providers [see Figure 2]. Companies that can demonstrate the value their products (and increasingly services) bring to the emerging healthcare systems will be able to access broader patient populations in both developed and emerging markets.²

Historically, payment for healthcare products and services has been based on unit or episode. However, payers worldwide are now seeking ways of contracting *value* not *volume*, a trend on which we have recently reported and proposed some solutions to help achieve this critical outcome.³ In a system that rewards better outcomes at the same or lower costs, the interests of pharma could converge with those of healthcare providers and payers in increasingly integrated delivery and financing models, provided the products and services are of a sufficient standard. Given pharma's deep knowledge of testing and measuring the quality of outcomes and related costs, the industry can play a significant role in the evolving, broader healthcare enterprise. But to do this it must demonstrate a clear understanding of the convergence of focus from stakeholders on value and cost.

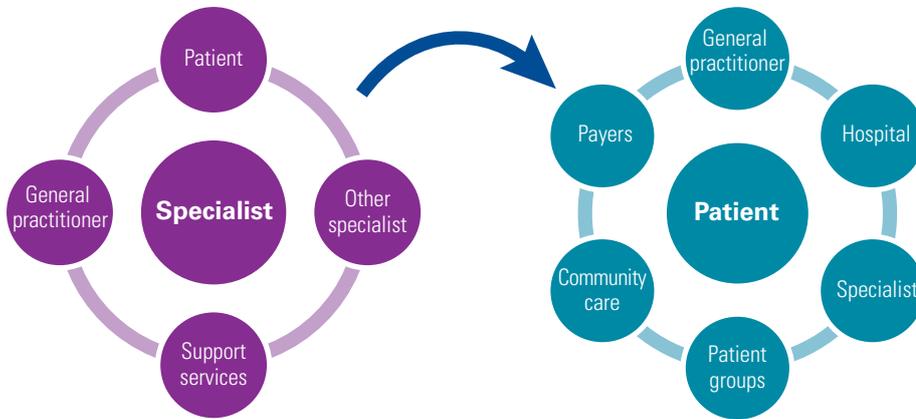
Selected key healthcare policy trends driving healthcare convergence

The key policy trend in healthcare convergence is the move to paying for *outcomes*, not disjointed and uncoordinated *inputs*. We comment on this and three other related policy changes:

- use of health technology assessments and comparative effectiveness
- increasing focus on real world data
- introduction of value-based pricing.

²Future Pharma: Five strategies to accelerate the transformation of the Pharmaceutical industry by 2020. October 2011 KPMG.

³Contracting Value: Shifting Paradigms October 2012 KPMG.

Figure 2: New healthcare ecosystems are centered on the patient

Source: KPMG International, 2012

Paying for outcomes

Recent government healthcare reform acts such as the US 2010 Patient Protection and Affordable Care Act (PPACA) and the UK Health and Social Care Act 2011, focus on improving outcomes for patients, while also cutting healthcare spending. Improved outcomes at the same or lower costs would represent an improvement in value. However, as KPMG's recent report, *Transforming Healthcare: From Volume to Value* highlighted, every existing healthcare payment system partly rewards value: the classic fee for service mechanism stimulates productivity, timeliness and a focus on the patient as the client while the block grant or wholesale budget for a hospital stimulates judicious use of resources, and prevents overuse. Yet these systems are so unrefined and undifferentiated that they can destroy more value than they create.

High quality, low-cost healthcare can only be created by redesigning the care from the patient's perspective [see Figure 2]. Healthcare systems are now looking for the next step forward: paying for outcomes rather than activities, and paying for value rather than reimbursing costs.³ Healthcare systems with the patient, rather than the provider, at the center will need a completely fresh approach from the industry.

Health technology assessments and comparative effectiveness

Health technology assessments (HTAs) are growing rapidly in importance as providers look for ways to determine what treatments should be provided to patients and at what cost. HTAs assess the additional value of a medicine relative to treatment alternatives.

Government payers, whether direct (as in the UK), or indirect through third parties (as in the US and Germany), have turned to comparative effectiveness as a way of determining the value of pharmaceuticals in recent healthcare reforms, although there are subtle and important differences in approach between countries. While the importance of the US to the global market is self-evident (it is forecast to be 31 percent of the global market in 2016⁴), the UK and Germany have global influence

⁴The Global Use of Medicines: Outlook Through 2016 IMS Institute for Healthcare Informatics p.5

Healthcare systems are now looking for the next step forward: paying for outcomes rather than activities, and paying for value rather than reimbursing costs.

that far outweighs their respective shares of the market. UK pharmaceutical prices influence more than 25 percent of the global market through international reference pricing,⁵ while German prices also have some bearing on a number of countries.⁶

In developed markets, the HTAs currently employed by governments in Germany through the Institute for Quality and Efficiency in Healthcare (IQWiG) and in the UK through the National Institute for Health and Clinical Excellence (NICE) have the most short-term impact on pharma. In Asia and the emerging markets the use of HTAs is less mature, but is growing in profile.

Comparative effectiveness in the US

The Patient Protection and Affordable Care Act (PPACA) legislated for the US government to improve the value it receives for dollars spent on Medicare and Medicaid through comparative effectiveness research via the Patient-Centered Outcomes Research Institute (PCORI).

However, PCORI was created to ensure that value is assessed on clinical qualities and not cost-effectiveness measures. It funds and carries out comparative effectiveness research to determine the comparative value of therapeutic alternatives. It is an independent, non-profit organization created to conduct research to provide information about the best available evidence to help patients and their healthcare providers make more informed decisions. Importantly, legislation prevents it from funding and carrying out *cost-effectiveness* comparisons. Furthermore, public providers in the US, such as the Centers for Medicare and Medicaid Services, are prohibited from basing coverage decisions solely on PCORI's research.

Responding to political pressure, US policymakers have attempted to ensure that PCORI's sponsored research will not be used to ration healthcare spending and limit access to new therapies. Under the current legislation, comparative effectiveness research analysis sponsored by PCORI will not include cost-effectiveness studies. This political sensitivity in the US is in contrast with the UK⁷.



⁵The Pharmaceutical Price regulation Scheme, The Office of Fair Trading 2007 p.42

⁶<http://www.thepharmaletter.com/file/111771/german-pharma-criticizes-new-amnog-vetting-procedure.html>

⁷ Miller DW Value-Based Pricing Pharm Med 2012; 26 (4) 217-222

Real world data

The proliferation of data and the emergence of a Big Data landscape are increasing the ability of real world data to generate real world evidence of the effectiveness of healthcare interventions. Public payers in the US, France and Germany are moving to adopt real world data by following the examples of the UK, Australia and Sweden. Evidence of broad applicability is growing. For example, real world data has influenced access in Sweden where evidence generated by registries informs product reassessments and has even improved access. Using data from its rheumatoid arthritis registry, the National Board of Health and Welfare determined that early treatment with TNF-inhibitors was cost effective. As a result, national rheumatoid arthritis guidelines prioritized early treatment with TNF-inhibitors. In the UK, real world data could influence post-launch adjustments of prices under a new value-based pricing system. In the US, CVS Caremark has indicated its intent to use its own claims data to conduct comparative effectiveness research to inform all aspects of its business including guidelines, restrictions, and negotiations with manufacturers.⁸

Value-based pricing

Value-based pricing agreements have been in place for more than a decade in the US where they have been used to increase market share for the first entrant in a new therapeutic category, such as Merck's Zocor⁹ (simvastatin) in 1998 and Novartis' Diovan HCT¹⁰ (valsartan/hydrochlorothiazide) in 2004. In markets where the government plays a role in pharmaceutical pricing there have already been value-based pricing agreements in response to budgetary pressures. Bayer offers performance based contracts for Nexavar, with discount/refund for non-responders, e.g. in Italy, while Johnson & Johnson established a risk-sharing refund scheme for Velcade.

The ability of real world data to generate real world evidence of the effectiveness of healthcare interventions is increasing.

Japan rewards innovation, but HTAs under consideration

Recent changes to the pricing system in Japan are rewarding innovation. Since 1990 drug prices have been set by reference to a comparator product, if available, with a premium based on better efficacy or safety, degree of innovation and orphan drug or pediatric use. In the absence of a comparable product, a cost accounting methodology is applied. In both circumstances reference is made to the average price of the product in foreign markets. Every two years prices are adjusted downwards. The new pricing system provides a sustained premium for innovative medicines that are not subject to biennial cuts, but will eventually suffer a much greater price reduction on first generic entry. This has been described as quasi-value-based pricing, because clinical benefit is taken into account in an arbitrary manner but there is no pharmacoeconomic assessment involved as yet. However, there are signs that the government is now considering moving to a pharmacoeconomic-based health technology assessment model for drug pricing¹¹.

⁸ Real-world evidence: transforming the industry into the 'prove it works' era An extract from Pricing & Market Access. Outlook 2010-2011 Edition.

⁹ Carlson JJ, et al. "Paying for Outcomes: Innovative Coverage and Reimbursement Schemes for Pharmaceuticals." *Journal of Managed Care Pharmacy*. 2009;15(8):683-7.

¹⁰ Møldrup C. "No cure, no pay." *BMJ*. 2005;330:1262-4.

¹¹ Kamae I Overview of recent developments in HTA systems in Asia and the position in Japan Korea-U.S. Healthcare Innovation Seminar 2011, Seoul, Korea 13 June 2011.

The industry will need to be positioned as a partner *in* the system, rather than a supplier *to* it.

Now the UK government is proposing to replace the Pharmaceutical Pricing and Reimbursement Scheme (PPRS), which expires in 2014, with a value-based pricing system. Under the current pricing system, drugs and treatments are assessed using the estimated total health benefits they provide. There is no provision for assigning a greater weight to the drugs that address significant unmet needs or are used to treat severe and life-threatening conditions. Moreover, drug prices are regulated by a mix of price and profit control under this PPRS system. Once set, the drug prices cannot be increased. This system also regulates the profits that companies earn on their sales to the UK National Health Service (NHS), creating pressure to offer competitive drug prices. Although PPRS has these limitations, it has certain flexible pricing options that cannot be ignored. It encompasses attractive features such as freedom of pricing for new active substances and a provision to raise drug prices when more evidence is available. In addition, there is a provision for introducing patient access schemes that offer discounts or rebates to reduce the cost of a drug to the NHS, which have improved patient access to certain costly drugs that otherwise could not have been assessed as cost-effective by NICE.^{12,13,14}

By introducing the concept of value-based pricing, the UK government is aiming to achieve in the following benefits for stakeholders:

- Patients: improve patient outcomes by providing better access to effective medicines.
- Life sciences industry: drive innovation and encourage investments in areas with high unmet medical needs.
- Providers: improve the decision-making process for new drugs by extending the scope of assessment to include a range of factors through which a drug's value and benefits can be assessed.

German healthcare reform introduces value-based pricing

German healthcare reform AMNOG (Arzneimittelmarkt-Neuordnungsgesetz) was enacted in 2010 and introduced a benefit assessment to set the price of a medicine after 6 or 12 months commercialization. Drugs deemed to bring an incremental therapeutic benefit qualify for price negotiations, and may obtain a price premium over the relevant therapeutic comparator. Under AMNOG, the level of added therapeutic benefit granted to newly approved drugs is based on a scoring system ranging from 1 to 6 where 1 defines a major added benefit over a comparator and 6 less benefit than the comparator. Medicines which are either comparable or inferior in terms of patient-related outcomes (a score of 5 or 6) will get a non-negotiable price under Germany's reference-pricing system¹⁵.

¹² A new value-based approach to the pricing of branded medicines, UK department of Health, 18 July 2011

¹³ Operationalising Value Based Pricing of Medicines: A Taxonomy of Approaches, Office of Health Economics, August 2011

¹⁴ Implications of value based pricing in the UK, PMLive, 16 May 2012

¹⁵ <http://healthcare.blogs.ihc.com/2012/02/02/amnog-german-health-reform-pharma-market-access-2012/>



The importance of partnering

As these global healthcare policy changes drive stakeholders to align around the common aim of delivering better patient outcomes at lower costs, we believe the industry will need to redesign its approach to payers and patients accordingly. Currently, the industry acts as one of many suppliers to the healthcare system but this will need to change. It will need to be positioned as a partner *in* the system, rather than a supplier *to* it. Below we outline some opportunities for the industry to use its talent, scale and data to be a partner to emerging healthcare systems.

Aligning economic interests

Several tools could be used to greater effect to improve patient outcomes and lower healthcare costs, including:

- Risk sharing agreements – agreements that link drug reimbursement to outcomes achieved – enable governments to provide access to new drugs for unmet medical need more rapidly than if there are lengthy price negotiations. From the industry perspective they allow earlier market access and potentially better returns in an era when the patentable life of most new drugs is becoming shorter. Risk sharing agreements have become increasingly common in Europe.¹⁶
- Post-launch value assessments using real world data are an alternative assessment tool. These can be based on bespoke patient registries but if a coordinated, multi-country approach to a particular disease and treatment could be agreed on, the time and cost savings to all stakeholders would be significant.^{17, 18}
- Data from patient registries are complementary to that derived from randomized controlled trials (RCTs). Patient registries offer an opportunity to evaluate cost-effectiveness because they permit longer follow-up than RCTs, represent usual standards of treatment monitoring and care, use patients who are less homogenous than in RCTs and include concomitant treatments that are chosen by physicians.

The development of a companion diagnostic together with a new medicine represents an opportunity to develop a partnership with a payer to reduce inappropriate prescribing and drive better value for the payer and patient.

¹⁶ Alexis Sotiropoulos, Pricing Pharmaceuticals by Outcome (London: 2020 Public Services Trust, 2011). http://www.tapestrynetworks.com/initiatives/healthcare/upload/Tapestry_EHILN_ViewPoints_Jul12-pdf.pdf p9

¹⁷ http://www.tapestrynetworks.com/initiatives/healthcare/upload/Tapestry_PVA_WG_-_Post-meeting_briefing_Nov12.pdf

¹⁸ A patient registry is an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. Registries for Evaluating Patient Outcomes: A User's Guide. 2nd edition. Glicklich RE, Dreyer NA, editors. Rockville (MD): Agency for Healthcare Research and Quality (US); 2010 Sep

Finding ways to help improve patient compliance with drug therapy aligns the interests of the industry with those of the patient, healthcare professional and provider: a win for all invested parties.

Sweden's patient registry for heart failure

Sweden has been fast to adopt registries, having established more than 70.¹⁹ For example, the Swedish Heart Failure registry (S-HFR or RiksSvikt)²⁰ was created to give the participating units knowledge about how they diagnosed and treated their patients and to give indications on where further efforts were needed to give patients with heart failure optimal management. S-HFR is an Internet-based registry, where participating units can register their heart failure patients or transfer data from standardized forms or from computerized patient documentations. The US has been a slower adopter although there is a notable cystic fibrosis registry.²¹

Develop companion diagnostics to reduce ineffective prescribing

The development of a companion diagnostic together with a new medicine represents an opportunity to develop a partnership with a payer to reduce inappropriate prescribing and drive better value for the payer and patient. The majority of companion diagnostic deals between pharma companies and diagnostic developers involve cancer therapies. The FDA has approved 15 companion diagnostics as of November 2012, all for cancer therapies.²² However, there are also more companion diagnostic tests that are able to determine the likely efficacy of drugs for common diseases, such as the KIF6 test for statin effectiveness. Whether this particular test is economically viable now that cheap generic statins are widely available is debatable but it does, nevertheless, allow stratification of patients at risk of coronary heart disease²³ and reduce issues of co-morbidity from polypharmacy.

Improving drug compliance

Poor compliance with therapy is a major source of inadequate outcomes and it costs healthcare systems dearly: one estimate put the costs in the US at USD \$290 billion, or 13 percent of total healthcare expenditures in 2009.²⁴ The issue here is the contrast between the efficacy established in RCTs, where patients are closely monitored to ensure adherence, and real world effectiveness, which is usually lower because many patients stop taking prescribed therapies after a period of time.

Progress to improve compliance could come through smartphone apps, designed to help patients stick to medication schedules. These could also incorporate drug interaction information as well as disease awareness and lifestyle advice, depending on the view of individual country regulators.

Finding ways to help improve patient compliance with drug therapy would be one of the most effective ways of improving the value of the medicines themselves and also aligns the interests of the industry with those of the patient, healthcare professional and provider: a win for all invested parties.

¹⁹ http://www.kvalitetsregister.se/om_kvalitetsregister/quality_registries

²⁰ <http://www.ucr.uu.se/rikssvikt-en/>

²¹ The Lancet, Volume 378, Issue 9809, Page 2050, 17 December 2011

²² <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm>

²³ Li et al Am J Cardiol. 2010 Oct 1;106(7):994-8. doi: 10.1016/j.amjcard.2010.05.033. Epub 2010 Aug 11

²⁴ Thinking Outside the Pillbox. NEHI August 2009

IT and Big Data

Information gathering is a critical component of value convergence. Decision makers in government and other providers, as well as consumers, will undoubtedly use IT tools as part of their assessment of the value of medicines and there are clearly routes for the life sciences industry to develop IT and data partnerships.

The industry has massive repositories of marketing data, market research data, sales data and social media data. These could be used to uncover actionable insights about patients, healthcare professionals or the behavior of payers and providers that could be invaluable in supply chain analysis. The industry also has access to clinical trial data. A priori sequence analysis could be developed to predict better clinical outcomes: keyword mining techniques can reveal patterns in clinical records that may provide new treatment pathways and epidemiology trends can be better understood and used to identify underserved patient populations. The industry could use its specialist disease knowledge built over decades in certain therapeutic areas to help providers analyze their data from hospital and general practitioner records. Big Data analytics to understand market opportunities combined with cloud computing, which permits access to large datasets from anywhere, offer the chance for much greater flexibility in customer relationship management. This could further reshape the sales and marketing models that have already moved far from the share-of-voice models of the 1990s.

Mobile health

To date, the life sciences industry has hardly begun to impact patient access to digital information about health. Many mobile-ready websites may be just as useful as apps, particularly in developing countries where the web is accessed directly from mobile devices.²⁵ The use of cloud computing is enabling much more flexible approaches to partnership than the industry has previously experienced.

The industry needs to adapt its model to become part of the relationship between healthcare professional and patients, and helping with adherence and involvement with electronic health records may be one route. The industry is embracing new media, albeit after a slow start: the 2012 KPMG Pharmaceutical Outlook Survey showed that pharmaceutical executives planned to use digital/social/mobile technologies over the next year, to gain customer insights (36 percent), as well as for customer facing applications (31 percent) and for recruiting and brand promotion (29 percent).

The expected publication of FDA rules on mHealth apps in 2013 should provide a much needed framework for greater use of technology in the US. The ban on direct-to-consumer advertising in the EU means companies have to focus on unbranded disease awareness apps. This may be an opportunity to partner with governments to improve health information flow to patients.

²⁵ <http://www.cmimedia.com/wp-content/uploads/2012/03/mHealth+-HTML5pharma-in-2012-Full-Article.pdf>

Faced with business structures established in a different era that largely address older healthcare systems, the challenge of driving innovative business initiatives away from single product offerings is substantial.

The Proteus Digital Health Ingestible Sensor

The approval by European regulators in 2010 and by the FDA in 2012, of the Proteus Digital Health ingestible sensor was potentially a major landmark in improving compliance with therapy. The sensor can be integrated into an inert pill and, once the ingestible sensor reaches the stomach, it is powered by contact with stomach fluid communicating a unique signal that determines identity and timing of ingestion. This information is transferred through the user's body tissue to a patch worn on the skin that detects the signal and marks the precise time an ingestible sensor has been taken. Additional physiologic and behavioral metrics collected by the patch include heart rate, body position and activity. The patch relays information to a mobile phone application. With the patient's consent, the information is accessible to caregivers and clinicians.²⁶ Trials with a variety of medications for chronic diseases are ongoing.

Clinical professional services units

Faced with business structures established in a different era that largely address older healthcare systems, the challenge of driving innovative business initiatives away from single product offerings is substantial. The industry could consider the creation of new business units for clinical professional services to oversee advanced data collection, information sharing, data analysis and stakeholder collaboration tools.

These new services units could:

- collate external solution requirements
- integrate internal pharma products with external partnered diagnostics, provider services, patient biometric input and compliance incentives
- align to payer delivery models and services.

This proprietary solutions-based approach could drive increased brand value, higher margins and better business performance.

²⁶ <http://proteusdigitalhealth.com/proteus-digital-health-announces-fda-clearance-of-ingestible-sensor/>



Part 2 Strategies for success

There are three critical strategies that the life sciences industry must consider in the new healthcare environment.

1. Understand the customer and what they want

Life sciences companies will need to become better at identifying who their new customers are, what they want and how they want it delivered. In the old-world model, the customer was the prescribing physician and, to some extent in the US, the patients on the receiving end of direct-to-consumer advertising. In the new world, customers include the ultimate bill payer in all its various forms, whether it be a third party, government, a budget-holding physician group focused on value for money, or informed patients who are equally focused on value. In different geographies these key customers vary and strategies need to be adapted to maximize returns from new products.

In the new world, customers include the ultimate bill payer in all its various forms.

The changing customer

As healthcare reforms continue their bumpy journey in the US, there are strong indications that the insurance market is already reacting by designing new products targeted at a different set of customers. Whereas once the primary end-payer may have been employers – through employer-sponsored insurance schemes – health insurance is now increasingly being bought directly by patients through individual health plans. The ramifications of this shift, termed ‘strategic diversification’ by the CEO of US-based insurer Aetna, will likely be significant as health insurers begin to think and act more like their colleagues in consumer markets. For example, customer retention becomes more important especially for those relatively healthy consumers who are increasingly likely to shop around.

2. Reshape R&D to provide reimbursable drugs and devices that deliver shareholder value

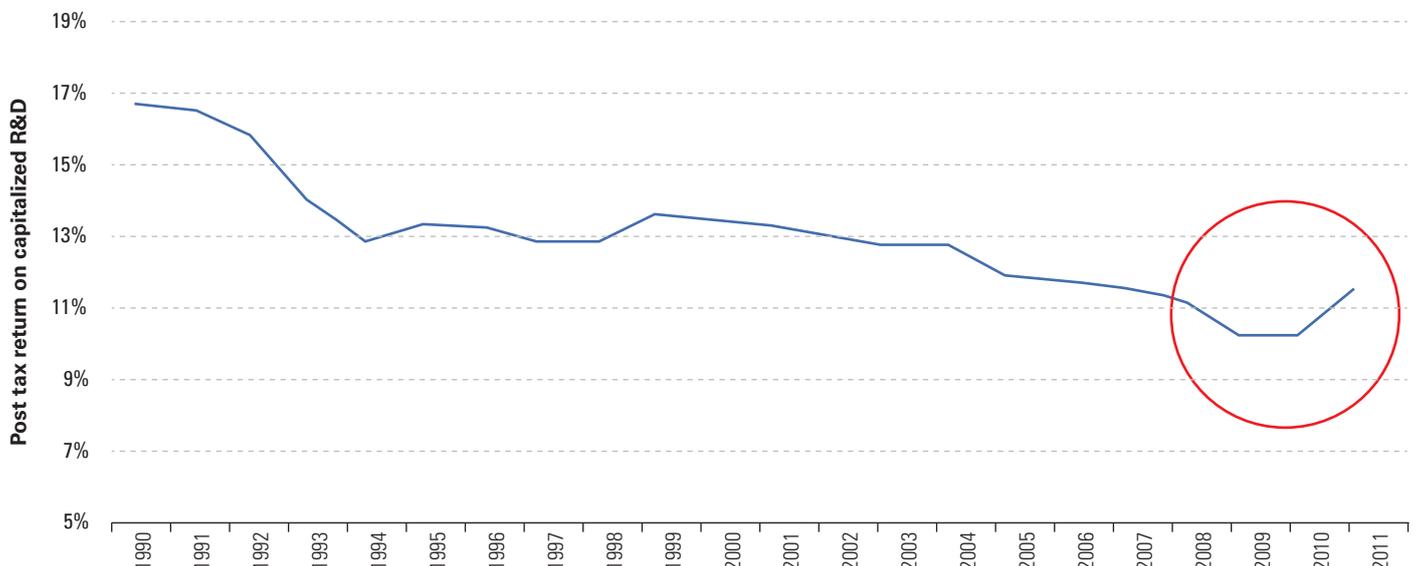
The industry will need to address whether it is investing in the development of the *right* drugs at a cost that will allow satisfactory pricing for the new healthcare environment as well as a return on investment that is acceptable to stakeholders.

Notwithstanding the need to address whether developing drugs alone in the new healthcare space will be enough, the industry will need to address whether it is investing in the development of the *right* drugs at a cost that will allow satisfactory pricing for the new healthcare environment as well as a return on investment (ROI) that is acceptable to stakeholders.

To this end, several companies have already taken some of the following steps to improve the ROI on R&D:

- Increased partnering of research projects with academic institutions and small biotech companies.
- Increasing speed to proof of concept with use of virtual clinical trials such as Eli Lilly's Chorus subsidiary and GlaxoSmithKline's virtual proof of concept discovery performance unit.
- Reducing R&D headcount with a shift to greater externalization, e.g. increased outsourcing of clinical trials.
- Reducing excess R&D capacity, e.g. Roche's closure of its Nutley New Jersey facility; recent closures in the UK by Pfizer and Novartis.
- Introducing pharmacoeconomic evaluations and comparative effectiveness early in the R&D process to enable earlier termination of uneconomic projects.

Figure 3: Illustrative post-tax return on R&D expenditures



Source: PhRMA; KPMG estimates

There are signs that some of the steps now being taken are having an impact. Eighteen months ago, KPMG published an analysis that showed returns on capitalized R&D had been steadily falling over the past 20 years.²⁷ Updating this analysis for 2011 data indicates a sharp increase in returns over the period analyzed (see Figure 3).

However, as the demands of the new healthcare economy deepen and broaden, they are likely to bring further difficulties in maintaining this upward swing in ROI on R&D. Strategies to develop drugs that will satisfy both payers and shareholders will become more complex and challenging to achieve.

As the demands of the new healthcare economy deepen and broaden, they are likely to bring further difficulties in maintaining an upward swing in ROI on R&D.

Oncology: great progress but what about future returns?

A positive outcome from the greater understanding of the biology of disease is the ability to use more highly selected and appropriate patient populations, largely or wholly comprising responders, for clinical trials which will substantially reduce the cost of bringing these new agents to market. This is particularly true for cancer therapies where these developments have improved the identification of the patient population in which these drugs should be used, thereby improving cost-effectiveness.

Comparative effectiveness is not possible with a competitor in development, only against the standard of care for cancer therapies. Failure in market is therefore a significant risk, assuming approval and reimbursement can be achieved. Companies should perhaps look to reduce the risk of negative returns on development compounds by seeking partnerships with other companies working in the field to find the best compound for patients, rather than wasting resources in competition unless there is compelling evidence to support the superiority of a compound in house.



²⁷ This analysis is based on data on R&D spending and revenues from the Pharmaceutical Manufacturers of America. We amortise the R&D spending over 15 years and assume flat 30% operating margins and 25% tax rate over the period. For further details please see Future Pharma: Five strategies to accelerate the transformation of the Pharmaceutical industry by 2020.



3. Anticipate shifting power structures in the wider healthcare system

More time needs to be invested to understand the competing priorities that healthcare systems face. Strong leadership will be needed to manage the impact of regional approaches on the whole business.

There are many parts of the new healthcare systems which are yet to be defined. However, those that can accurately assess where the balance of power will eventually lie will be able to ensure that a company's strategy will be aligned with that of the ultimate decision maker. More time needs to be invested to understand the competing priorities that healthcare systems face. Strong leadership will be needed to manage the impact of regional approaches on the whole business.

The patient

The individual patient has a much greater share of the balance of power than in the past. Three forces are facilitating greater consumer involvement: new technologies and information that provide a better understanding of individual consumer preferences, new products and services that guide choice, and increased cost sharing and decision making by consumers.

The industry does not deliver value to patients by producing products that are poorly differentiated from existing marketed drugs. The choices that formularies make when there is little to differentiate between drugs make little difference to patients, except in the rare cases of specific intolerance. The industry needs to redefine its product offerings, to the extent possible within the requisite local regulatory framework. The provision by the industry of services to a consumer, within which its medicines are embedded, and which can be shown to lead to improved outcomes, is one route to differentiation. One such example is the lifestyle behavior modification program to improve the health of patients with type 2 diabetes recently initiated by Boehringer Ingelheim in collaboration with Healthrageous Inc. This program will involve digital technology intervention combining digital coaching and a wireless glucose meter transmitting data to clinical monitors.²⁸

The payer

If the life sciences industry can position itself as part of the solution to ever-increasing healthcare costs, greater opportunities will result. Using their extensive knowledge and databases of patient and disease profiles, life sciences companies could help new healthcare bodies seeking value to drive disease prevention as well as more appropriate treatment. Investing time and technology in improving compliance with appropriately prescribed therapies would align the economic interests of payers with better outcomes for patients and potentially result in revenue streams of greater longevity.

The healthcare professional

The industry needs to work diligently to demonstrate to healthcare professionals that it is neither the enemy nor just a source of funding – old attitudes that still persist in many healthcare systems. Increased investment in education at all levels, particularly in tertiary educational establishments that are training the next generation of healthcare professionals, is one route to permanently changing such perceptions.

Using their extensive knowledge and databases of patient and disease profiles, life sciences companies could help new healthcare bodies seeking value to drive disease prevention as well as more appropriate treatment.

²⁸ http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2012/10_july_2012_collaborationhealthrageous.html

Conclusion

Global healthcare systems are evolving to deliver better patient outcomes at lower costs. This shift to paying for outcomes rather than units or episodes raises new challenges for the life sciences industry. We believe that by transforming their approach from the traditional supplier role to one of a solution provider through multiple partnerships with key stakeholders, life sciences companies can deliver sustainable long-term value to payers and patients alike and will drive superior returns for shareholders.

Existing corporate structures aligned with the old-world product supplier model will be difficult to change, especially as, in the short term, there is likely to be a divergence of strategy required to deal with the volume growth of demand in the emerging markets as well as the low-growth reality of today's developed economies.

We see an opportunity for the establishment of new business units focused on professional services. These new clinical professional services units would collate external solution requirements, integrate internal pharma products with external partnered diagnostics, provider services, patient biometric input and compliance incentives and payer delivery models and services. This proprietary solutions-based approach could drive increased brand value, higher margins and improved business performance.

Hard questions need to be asked about what products are being developed by R&D and how these products will be positioned to deliver value in new healthcare systems. In today's environment, having an effective product appropriately priced to gain reimbursement may not be enough. Companies need to go one step further: is there also an effective service model to consider in which the new molecule can be used? Bold decisions will need to be made about clinical development programs to ensure that the latest hot compound is compared with the best new marketed competitor, and not simply the standard of care. The earlier the indications that no significant advantages are realized, the more R&D dollars can be reinvested elsewhere.

As always the customer is king, but the kingdoms are changing fast. Corporate cultures should demand that 'know your customer' be a central message for every general manager in every country.

The industry has to change: the new healthcare environment demands a fresh approach.

Hard questions need to be asked about how the industry will transform to deliver value in the healthcare systems of the future.



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Designed by Evalueserve.

Publication name: More than medicine

Publication number: 121552

Publication date: April 2013