

Stakeholder Value: Overcoming Complexity in European Market Access

Janice Haigh, Consulting Practice Leader, Market Access Europe

Louise Parmenter, Senior Director of Global Strategic Operations, Quintiles Outcome

Chris Pepler, Head of Commercial Solutions, Europe

Introduction

In the New Health, healthcare suppliers are no longer selling technology, they are selling health outcomes and value. Payers responsible for commissioning care on behalf of their citizens are primarily seeking better health, and are focused on carefully managing their budgets to bring greatest improvements for patients with a range of conditions.

Yet there is no consensus between countries or even sub-national health authorities on what defines a product as innovative, and how to measure or value health gain. Innovation means different things to different people, but what is clear is a new molecule or even a new class of treatment falls short of the definition held by key stakeholders.

For patients and payers, innovation relates to value and impact, not patents. The onus now falls on healthcare suppliers to show the value of a product to all stakeholders, instead of simply relying on it being new. If companies want stakeholders to view a product as innovative, they must develop evidence to show its value.

A value-driven approach to product development is more likely to find favor with the new gatekeepers in European market access. Healthcare providers face the challenge of generating better outcomes in ageing populations while keeping spending in check. These pressures make them increasingly skeptical of new medicines, demanding evidence of safety, effectiveness and value in their specific patient population(s).

Knowledge of payer priorities and the specific health outcome improvements they want are now vital to companies. It is not just about the measuring outcomes achieved: companies need to better identify drivers of value when planning their development strategy. Starting early helps.

Early planning gives companies time to understand stakeholder evidence requirements and design strategies to meet them. Companies can then weigh up if the potential commercial payoff justifies the time and money needed to generate evidence. Instead of just go/no-go, healthcare suppliers must assess the pros and cons of multiple 'go' strategies.

This is the reality of the *New Health*.

What payers want

All stakeholders have a shared aim – healthier humans – but their unique pressures, perspectives and priorities affect how they go about this task. Healthcare suppliers that understand the needs of fellow stakeholders – and engage with them early in development – are best positioned to succeed.

The needs of patients, regulators and, increasingly, payers must be taken into account. In the past, companies tried to push a product past the regulatory hurdle as quickly as possible. Yet this is no guarantee of commercial success. Regulators simply set minimum standards. To make a product commercially viable, companies must consider what their customers want.

Payers are one of many customers that healthcare suppliers must now satisfy. A 2010 [paper published in Nature Reviews Drug Discovery](#)¹ nicely summarized the rise of the payer: “Over the past decade, the role of payers has become more prominent, and time-to-market no longer means time-to-licensing but time-to-reimbursement.”

¹ Eichler H, Bloechl-Daum B, Abadie E, Barnett D, König F & Pearson S. *Outlook: Relative efficacy of drugs: an emerging issue between regulatory agencies and third-party payers*. Nature Reviews Drug Discovery 9, 277-291 (April 2010) | doi:10.1038/nrd3079

In many cases, however, there is a gap between what companies are offering and what payers want. Smoking cessation illustrates the discrepancy. For healthcare suppliers the answer is a new intervention but payers are often unable to see the link between a product and better health outcomes.

Companies which design trials to show a drop in smoking after six months may be asked by payers: “But how many people have still quit five years later?” An even bigger question for payers is likely to be: does investment in cessation drugs cut the healthcare costs of long-term smoking? Payers will increasingly want to pay for outcomes, not products.

Healthcare suppliers face a growing pool of budget-holders, including those at a sub-national level. Devolution of budgets in European healthcare has created local payers, such as UK PCTs (Primary Care Trusts), which add layers of complexity. Negotiations can continue right down to the level of pharmacists, and steps taken by the UK show more fragmentation is possible.

This is a recent development. In the past, healthcare suppliers negotiated with national bodies and – after winning their approval – were free to promote to physicians. Newer products were assumed to be better. Those days are gone. Negotiation with local and regional bodies is now the norm and evaluation of a product continues throughout its life cycle. New data can see payers reverse or alter earlier decisions.

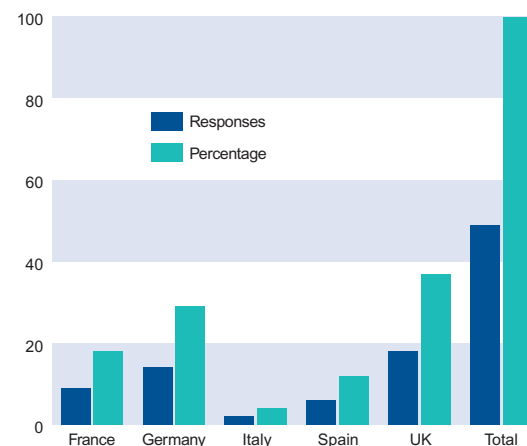
Change at the heart of Europe

In Europe today, companies are facing an intensification of the ongoing assessment of their product’s outcomes and value, with companies facing ongoing, continuous assessment of their products’ outcomes and value. Payers are increasingly commissioning their own research rather than simply accepting the manufacturer’s approach to the evidence.

The UK is leading the move towards this model of healthcare provision and the industry is wary of where it will lead. More than one-third of attendees at a Quintiles’ webinar in September 2012 said the UK will be the most difficult of the top five European markets to access in the future.

All graph data compiled from webinar hosted by Quintiles Outcome.

Which country do you think will be most difficult to access in the future?



Along with Germany, the UK is making the most dramatic reversal of former policies. Both were strongholds of liberal pricing and reimbursement where approval meant the chance to sell to all physicians. That has changed. Germany now has policies tying a drug’s price to evidence of additional benefit (most often in terms of effectiveness), and is regarded as one of the hardest markets to access.

In the UK payers are pushing for long-term, real-world health outcomes and are open to new ways to achieve this goal. Whereas in the past companies largely competed against each other, increasingly a drug must show value over all possible approaches to achieving better health outcomes. Using the smoking cessation example, a new drug in the space must show it offers better long-term value than health management strategies intended to curb use.

The shift is being driven by increased budgetary flexibility. In the UK commissioning groups and PCTs can choose to invest in areas they think will bring the biggest health gain, instead of being restricted to reimbursing drugs and paying hospitals. The upshot is UK budget holders can trade-off investments in new products with spending on outreach campaigns and other health management steps.

Armed with this flexibility and a brief to do more with less, payers are likely to say ‘so what?’ to clinical data showing modest improvements compared with existing standards of care. In a constrained economic environment where effective and affordable treatments are already available for many major diseases, clinical data must be accompanied by an appropriate economic evaluation of additional cost effectiveness against the current standard.

Redefining innovation in development

All stakeholders agree that providing compelling evidence of safety and efficacy against a placebo is no longer good enough. New products must be innovative. This takes more than just a patent, however. Truly innovative products cause significant, demonstrable improvements in the lives of patients and the running of healthcare systems. These are impactful products with real value.

Yet patients, payers and other stakeholders all value different things. More than half of the nearly 400 executives in a [Quintiles-sponsored Economist Intelligence Unit poll](#)² said different perceptions of value are the biggest obstacle to showing the worth of a product. It is a big challenge, but adopting a multi-stakeholder mindset early in development makes the shift more manageable. The first step is figuring out what each stakeholder values and how the new product could meet their needs. Payers, for example, value products that clearly lead to better health outcomes than the standard of care. Cost is an important but often secondary factor. It is value that matters. Companies that begin thinking about value early will have the edge.

From the start of development companies must consider how the healthcare landscape will look when a product reaches the market. How will health systems interpret unmet need and value? What will people pay for in the future? Which health problem are we solving? Why will the drug be a better solution than anything else?

Answers to these questions can guide development strategies, helping to shape design of RCTs (Randomized Controlled Trials) and post-launch evidence generation. While many payers are increasingly looking for long-term outcome data, RCTs will continue to play a central role and can be optimized and augmented to show the value and innovation of a product.

Early planning is needed to make sure RCTs gather the right data, instead of getting to Health Technology Assessment (HTA) submissions and realizing evidence to support claims is lacking. Having a long-sighted view of evidence generation allows work to be run in parallel, thus maximizing the time a drug is on the market before its patent expires.

² Kiestra, *The Value Challenge – Reinventing biopharma: strategies for an evolving marketplace*, Economist Intelligence Unit, 2012

Many companies recognize this, with close to half of webinar attendees polled by Quintiles starting evidence planning in Phase II. This gives companies time to validate PRO (patient reported outcome) instruments or “piggyback” economic outcome evaluations on to an RCT. Augmenting RCTs can help generate evidence for a broader set of stakeholders, instead of just satisfying regulators.

Companies should also consider active comparators in their pre-approval RCTs. However, the incorporation of active comparators pre-approval remains rare, with regulators demanding placebo controls and methodological design challenges. Adoption of “adaptive licensing” approaches, based upon iterative phases of data accrual and regulatory appraisal may be the solution.

Real world, real value

RCTs will only get a company so far, however. Some European payers, led by Sweden and Denmark, are pushing for more real-world data. A September 2012 Quintiles poll found two-fifths of webinar attendees have already included real-world data in HTA submissions.

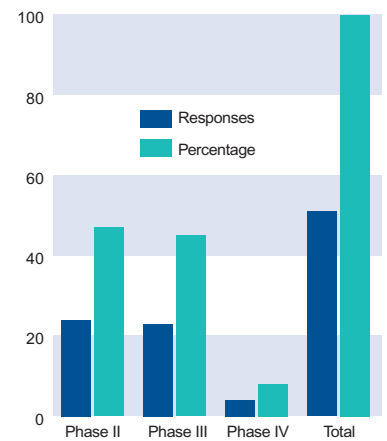
Motivations for the shift away from relying solely on RCTs were neatly summed up in a 2004 paper published in *The Milbank Quarterly*³. In the paper US academics said that while clinical trials are the best way to assess whether an intervention works, they are arguably the worst way to tell who will benefit.

Having seen the discrepancy between stellar RCT data and disappointing real-world health outcomes, payers are likely to become even more skeptical. In an analysis, conducted as part of Quintiles’ *HTA Watch* service, of responses to antidiabetics a lack of long-term data was found to be one of the most common reasons for rejecting submissions.

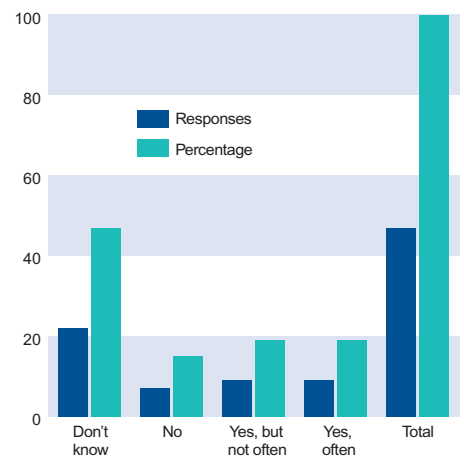
Companies will have to expand their pre- and post-launch evidence generation toolkits to overcome these roadblocks to reimbursement. The idea of generating long-term data pre-launch seems contradictory, yet there is a lot that can be done before reaching the market.

Registries, for example, have huge pre-launch potential, particularly if a company is entering a new geography or therapeutic area. Information on how a disease is managed, the process for treating patients, and the role of competitor products is available. Armed with this insight, companies can show payers the unmet need and how a new product can help. Also, disease registries set up pre-launch give a platform for data capture on the product when it reaches the market.

When does your company formulate a Market Access Plan?



Has your company ever used real world data in a HTA submission?



³ Kravitz RL, Duan N, Braslow J. *Evidence-based medicine, heterogeneity of treatment effects, and the trouble with averages*, *Milbank Q.* 2004;82(4):661-87.

Technology is opening up other new opportunities too. Access to online patient communities could transform observational research and how data on long-term health outcomes are gathered. Patient-centric studies, which fall between limited retrospective research and costly prospective trials, become possible. Quintiles Digital Patient Unit (DPU) helps patients and sponsors tap into the power of online communities through its three million member community on www.MediGuard.org or www.ClinicalResearch.com.

People coming to these sites are motivated to manage their own health, and this makes them ideal participants for patient-centric research. Once an individual is signed up for a study, data are gathered using PROs (Patient Reported Outcomes), EMRs (Electronic Medical Records) and laboratory testing.

Communicating value

Collecting the right data is just the first step. Effective analysis and communication of the data – and how they meet the needs of each stakeholder – is equally important. To prosper, companies must understand and communicate exactly where the value lies in a new product.

Creating a global value dossier is the best preparation for discussion with national and sub-national payer bodies. This is the document that equips companies to answer the ‘so what?’ question. The preparation process helps companies understand what aspect of the product delivers value. Equally importantly it makes companies consider how the various stakeholders assess value. In doing so the value dossier shows how the product meets the needs of payers.

Gathering this information in a single document provides a reference point for when it comes to preparing local dossiers. With multiple markets to target and compressed timelines, having all the information to hand is vital. Any delays at this stage put back the date at which a drug can begin generating revenues.

How significant those revenues are is also partly dependent on the dossier. Convincing payers of the value of a product with an effective dossier and pricing discussions become easier. The perceived value determines the price. It is these knock-on benefits that make it worth investing lots of time in delivering, articulating and demonstrating value. With this framework in place companies can spend less time working to get the financial reward a good product deserves.

A common goal

On the surface, biopharma and healthcare providers appear to have the same goal – better health outcomes. Trust is an issue, however. Quintiles’ [New Health 2012 report](#)⁴ illustrates the problem. Close to two-thirds of the 100 biopharma executives polled said the potential for competitors to benefit from information generated in risk-sharing agreements is a problem.

Payers and healthcare suppliers recognize the difficulty in finding common ground. Close to two-thirds of both stakeholder groups said agreeing on a definition of success is an obstacle. Players on both sides of the divide can be quicker to see differences than shared purposes. In some areas this is changing and it must continue to do so.

Pharmaceutical companies and payers may not be traditional allies but it is in every one’s interest to overcome friction and collaborate. As companies consider their exposure in Europe amid the current financial crisis, effective working relationships between all stakeholders in the health care system will be essential in achieving better health for patients at a reasonable speed.

⁴ *The New Health Report – Rethinking the Risk Equation in Biopharmaceutical Medicine*, Quintiles, 2012

The result is an increased number of risk-sharing agreements between drug companies and payers. Three-fifths of biopharma executives polled in the New Health Report 2012 expect to see more risk- and cost-sharing arrangements with payers over the next five years. This is a positive development. By treating payers as important customers, rather than barriers to be overcome, companies can identify better ways of bringing products to patients.

With healthcare suppliers and payers facing new, intense pressures, the conditions are right for new ways of working. Consider the UK, where throughout the 2000s the government upped healthcare investment. Now, with Labour out of power and the Conservative-Liberal Democrat coalition targeting spending cuts, the UK National Health Service (NHS) faces a new set of challenges.

It is the NHS, charged with the task of making growth in the provision of healthcare outstrip funding increases, that has pushed collaboration to the forefront. 'Joint working' has entered the healthcare lexicon. As NHS veteran Peter Rowe said, "fighting pharma [is] not a sensible strategy."⁵

The model has seen [GlaxoSmithKline work with healthcare providers in Walthamstow](#)⁶ to create a COPD (chronic obstructive pulmonary disease) care service. The collaboration quadrupled the number of patients receiving an annual COPD review and cut the cost of non-elective admissions by one-fifth. GSK benefited from a 10% increase in the number of moderate to severe COPD patients receiving ICS/LABA (inhaled corticosteroid/long-acting beta agonist) combinations .

Since the GSK-Walthamstow pilot project UK authorities have entered into many more joint working relationships. In the first seven months of 2012 Roche publicly entered into six projects to improve cancer outcomes and other areas of healthcare. Other companies are also working extensively with partners in the NHS.

Armed with experience from these projects UK authorities have begun trying to formalize the collaborative process. The ABPI (Association of the British Pharmaceutical Industry) has drafted [a guide for starting collaborative relationships](#)⁷. In a seven-step plan the ABPI walks readers through what must be considered when forming such alliances and provides tips for making them a success.

Other countries have the opportunity to learn from experiments in the UK but to date have been slow to remodel healthcare provision. Germany has agreed to some initiatives, such as the Pfizer pain detect scheme that helps physicians determine if a patient is suffering from physical or neurological pain, but much more can be done.

A tailored approach

In each country the healthcare industry will face specific challenges in gaining acceptance for collaboration. Italian payers, for example, are unlikely to want to take on responsibilities. A lack of standardization across Europe – and even within countries – means companies must tailor their approach each time they look to initiate collaboration in another region.

Overcoming these hurdles requires a market access team with people in each of the major markets to gain understanding and build relationships. Few teams know a healthcare system well enough to propose improvements to those who run the operation. Even fewer have strong ties to the forward-thinking people within healthcare systems who are open to new ideas and have the power to drive change internally.

⁵ Rowe P. And Williams G. *Opportunity Knocks, Inside Market Access*, PME, June 2012.

⁶ *A Fresh Approach that Benefits Patients, the NHS and Industry*, GSK

⁷ *Joint Working – A Quick Start Reference Guide for NHS and Pharmaceutical Industry Partners*, ABPI, 2012

Companies must consider whether building market access teams capable of showing the value of products and pushing new ideas is a desirable core activity. Market access units must bring together medical departments, marketing, regulatory, sales, clinical development and other teams. The move to greater integration is a huge cultural change and a massive challenge.

In the past the clinical team worked to satisfy the primary stakeholder, regulators. Now, with patients, payers and other stakeholders playing a more prominent role, internal operations at healthcare suppliers must adapt to mirror the shift. Cross-functional teams that represent the breadth of stakeholder opinion are needed.

Individuals need to become more cross-functional too. Now, the ideal clinical development employee will have a grasp of health economics, validation of PRO instruments, and other skills outside of their traditional remit. Having this knowledge improves communication with other members of the team.

Market access units also need a new type of team member. These members must combine local knowledge and high-level negotiating skills with personal credibility. It is these people who will ally and collaborate with payers to know their needs better than anyone.

Without a solid understanding of the needs of payers and close relationships with all stakeholders, the team will struggle. Creating an effective team is a big, long-term commitment, but one essential to knowing what products and value messages payers will find compelling.

Outsourcing could help. Third-party vendors with clients across the industry handle far larger portfolios than any one company. Operating at this larger scale necessitates the creation of a far-reaching market access team that has close relationships with stakeholders across Europe.

Third parties also have less of a trust problem. Free from the pressure to sell more products, CROs (contract research organizations), consultancies and other impartial experts could form the bridge between industry and payers. Armed with deep therapeutic, methodological and market expertise, plus strong relationships with key players on both sides of the divide, these organizations are well positioned to facilitate more positive interactions.

While many leading healthcare suppliers view market access as a core activity, this could change as they assess the scale of the challenge. Five years ago sales was viewed as a core activity. Now having a huge in-house sales team is an anachronism. The environment is ripe for the attitude towards market access to change just as quickly.

Driving change

If healthcare suppliers want to see such initiatives spread throughout Europe they will have to push for change. All payers are interested in extracting maximum value from healthcare investments but are unlikely to move quickly towards collaborating without encouragement. If companies can show payers how to save money through remodeling of services they stand a better chance of getting their new product to patients than if they just ask for reimbursement.

All stakeholders can learn from pioneering collaborative projects. In the UK data collection aspects of early patient access schemes – where rebates are used to cut the cost of a drug – faced resistance from healthcare providers. With more focus on long-term health outcomes the question of how data collection is handled is unlikely to go away, however. More trust is needed if all stakeholders are to pull in the same direction.

There is willingness from some leaders in the payer and biopharma community. NHS veteran Rowe has said the organization “must be prepared to work in partnership to help capture outcomes data.”⁸ Such statements should encourage companies, but the industry needs to recognize that a one-size-fits-all approach to data capture and collaboration is insufficient. By listening to local healthcare providers companies can create outcomes research initiatives that fit with the workflow in each region.

Once payers and healthcare suppliers begin collaborating the relationships could lead to far-reaching changes. Taking data as an example, healthcare generates a lot of information but to date many payers, particularly in Europe, have failed to capitalize on the potential. Failing to collect and effectively use data means healthcare providers are missing out on efficiencies.

“Think of big data as an epic wave gathering now, starting to crest. If you want to catch it, you need people who can surf,” Thomas Davenport and DJ Patil wrote in [Harvard Business Review](#)⁹.

Many healthcare providers are ill-equipped to benefit from the vast amounts of data they are generating. Outsourcing companies can help. Data capture and other technical tasks are ingrained in healthcare product development. Using these skills to support healthcare providers and help them come to terms with the new landscape can benefit companies. It is in everyone’s interest to have an efficient, evidence-based healthcare system that has resources to invest in innovative products.

Conclusion

Healthcare suppliers face a fragmented and evolving situation in Europe. The stakeholder landscape is changing. Companies that do best in European market access will be those that recognize the growing importance of the payer and adopt new ways of working.

With change comes opportunity. Companies have the opportunity to reshape the provision of healthcare in Europe and their role in the system. Healthcare suppliers must be willing to undergo internal changes to better meet the needs of payers.

Market access thinking must extend way beyond traditional commercialization approaches to inform what questions drug development strategies ask. We live in an evidence-driven value world that necessitates clinical-commercial convergence. It is only through such changes that the industry can align its products with the unmet needs of payers.

So far, many companies have just dipped a toe in the market access waters. It is time to jump in.

⁸ Rowe P. And Williams G. *Opportunity Knocks, Inside Market Access*, PME, June 2012.

⁹ Davenport T. And Patil D. *Data Scientist, The Sexiest Job of the 21st Century*, Harvard Business review, Oct. 2012



Janice Haigh is Practice Leader for Market Access, Europe within the Consulting division at Quintiles. In this role she is responsible for leading a team of consultants who undertake payer and pricing research, health economics analysis and value development for clients.

Before joining Quintiles, Janice was the Head of Pricing and Market Access for Astellas Pharma Europe where she was responsible for developing and implementing pricing and market access strategy for new and in-market products, working closely with brand teams and affiliates.

Janice has almost 25 years' experience in healthcare across Europe and is a Fellow of the Chartered Institute of Marketing. She holds an MSc in Management Science from Imperial College and a BSc in Mathematics from Royal Holloway College, University of London.



Dr Louise Parmenter is accountable for strategy and planning for Quintiles' Real-world & Late Phase Research. In this role Louise is responsible for understanding the evolving healthcare market to ensure that Quintiles remains at the forefront of innovation and best practices to optimize real-world & late phase development.

Louise has spent 20 years in the pharmaceutical industry and has experience comprising significant strategic, operational, project management, commercial and business responsibilities.

Louise has a PhD in Neurophysiology, and a BSc in Physiology with Biochemistry from Southampton University, UK. She is currently studying for an MSc in Epidemiology run by the London School of Hygiene and Tropical Medicine through the University of London International Programmes.



Chris Pepler is Head of Europe for Global Commercial Solutions. In this role, he oversees operations across 19 markets and with service offerings including commercial partnerships and fee-based outsourcing, spanning sales, patient-centric, brand management, and market access solutions.

Chris has been with Quintiles (formerly Innovex) for 15 years and most recently held the position of UK Head of Commercial Solutions and Global Head of Commercial Business Development and Operations. He has extensive experience of the global biopharma marketplace, having spent 15 years various senior sales and marketing positions at both Schering Plough and Fisons.

Chris has a BSc in Biology from Exeter University.

