

Axiom

Bi-annual newsletter from Pope Woodhead

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Focus on

RISK sharing

Recent high-profile negative NICE appraisals for new products and tougher bargaining by HMOs, Medicare and EU payers is leading pharma companies to look at risk or cost-sharing commercial strategies as a means to secure market access. Turn to page 9 for this edition's 'Expert opinion' on this new wave of commercial innovation.

Also in this issue:

- The who, what, when, how of local EU payer engagement
- Using registries to gain competitive advantage
- Industry perspective on clinical trial disclosure



popewoodhead
and associates limited



Pope Woodhead and Associates

The Old Grammar School
1 Ramsey Road
St Ives
Cambridgeshire PE27 5BZ
UK

Tel: +44 (0)1480 300 300
Fax: +44 (0)1480 497 970

Email: mail@popewoodhead.com
Website: www.popewoodhead.com





Foreword by Andrew Hobbs, Managing Director

In the new era of heightened safety and cost-consciousness, regulators and payers increasingly seek reassurance of favourable benefit/risk balance under real-world conditions. For a variety of reasons, pivotal trials are often unable to address key questions about how a drug will perform post-launch. Given this uncertainty we are seeing a range of risk sharing and risk management approaches being adopted.

In this edition of Axiom, we discuss a range of real-world patient and payer centred programmes that contribute to meeting this need by collecting patient level data and acting on this information to reduce risk and/or increase benefit. We also show where these approaches can be combined to the benefit of all stakeholders.

In the opening article we discuss a practical approach to enhancing local payer interactions. We then look at how to make best use of registries for both regulatory and reimbursement purposes. Our feature on risk sharing and innovative commercial solutions illustrates the benefits of linking a risk sharing scheme with a risk management programme.

Elsewhere we report on a survey of industry stakeholders examining the changing environment of clinical trial disclosure, and an award-winning research project that identifies how to derive synergy between risk management and compliance.

In summary, we see significant opportunities for the industry to innovate by combining aspects of risk sharing, risk management and compliance.

I hope you enjoy this, our third edition of AXIOM and, as always I welcome your feedback.

A handwritten signature in blue ink, appearing to read 'A. Hobbs'.

Andrew Hobbs
 Managing Director
 Contact: andrew.hobbs@popewoodhead.com

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Who?

Local

EU payer

engagement

Chris Easley, Senior Consultant, Market Insights and Strategy
Contact: chris.easley@popewoodhead.com

Dr François Lucas, Head of Market Insights and Strategy
Contact: francois.lucas@popewoodhead.com

In many EU markets, decentralisation has given local payer organisations ever greater control over allocation of healthcare expenditure via drug usage guidelines, tracking of prescribing behaviour and increasingly influential physician prescribing incentives (or disincentives).

We have already seen pharma starting to address in-country local and regional payer value communications; specifically, what to communicate, to whom, when and how. However, Pope Woodhead's discussions with local EU payers have revealed that few companies have identified and implemented an approach that fully delivers value to this important audience and the complex, and diverse range of stakeholders it comprises.

In this article Chris Easley and François Lucas provide a framework for:

- Segmenting local payers by need
- Delivering value communications
- Going beyond product-centric value communications to local payer-targeted value communications.

Who to engage with

Local payers are a complex network of clinicians, administrators, pharmacists and policy makers or managers within regional or local healthcare administrations. They are an increasingly important link in the value communications chain that comprises national level payers and Health Technology Assessment (HTA) bodies at one end, and physicians and patients at the other.

As pharma companies continue their quest to optimise payer strategies across EU markets, they



Figure 1: Local payer groups with different communications needs

must overcome the issue of local and regional variations between payer networks. This necessitates finding a way to segment local payers into groups with common objectives and information needs. Figure 1 shows three examples of local payer groups with communications needs ranging from economic to clinical.

What to communicate

Most of pharma's local payer communications centre on published product information, but resources that provide insight (information not readily available in the public domain) are deemed by local payers to add significantly more value.

Value communications with personal relevance to individual payers are the 'holy grail'. A good example is insight that directly assists payers to achieve their objectives, e.g. optimising drug expenditure within defined, local patient populations.

Local payers ultimately want to know how to use their limited resources more efficiently to improve healthcare outcomes. They need initiatives that support appropriate use of the new therapy to deliver better clinical outcomes, and services that make healthcare utilisation more efficient – not just product-focused value communications! This approach creates value and generates real openness among payers to engage with pharma.

When to communicate

The timing of interactions with local payers is crucial. Local payers believe pharma often addresses them too late. The pre-launch and immediate post-launch periods are two of the major opportunities to work with payers and influence local market access decisions and guidelines. Pharma is typically more effective at local payer communications during lifecycle events (e.g. publication of significant new data) and formulary reviews, which provide additional opportunities for engagement. Figure 2 illustrates the main windows of opportunity for local payer engagement.

How to communicate: Payers as partners

Pharma should look for opportunities to expand the local payer relationship to a partnership that supports appropriate, 'smart' use of products. Such innovative approaches are challenging to develop and deliver. The resource required may not be justified for all products. However they can provide a powerful means to secure local payer endorsement and sustained competitive advantage.

An understanding of the opportunities available to engage with, and influence, local payers in each market is an essential input to the communications strategy. The current lack of appropriate interaction (via well trained and experienced personnel) is a frustration that local payers frequently voice.

Many pharma companies feel the strain when it comes to finding ways to access and positively impact local payer market access decisions and prescribing guidance. Industry can position to gain, by:

- Increasing their understanding of local payer segments and the communications that meet their needs
- Delivering value communications timed to coincide with payers' need for insight and decision points
- Ensuring that specialist, skilled company personnel manage the partnership with payers
- Creating value through services that support appropriate, efficient use of the therapy.

An understanding of the opportunities available to engage with, and influence, local payers in each market is an essential input to the communications strategy.

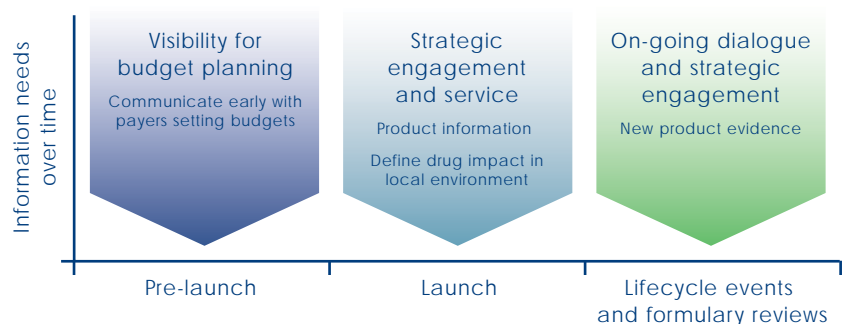


Figure 2: Windows of opportunity for local payer engagement

In conclusion, local payers are a critical audience. Developed with their input, this strategy for payer engagement is a validated, practical approach for developing, targeting and delivering communications that optimise the opportunity for new brands. We will explore this subject further in future editions of *AXIOM*.

Real-world for knowledge competitive advantage

*Dr Simon Ingate, Senior Consultant,
Regulatory and Risk Management
Contact: simon.ingate@popewoodhead.com*

Real-world information – knowing, not guessing

The launch of a new drug carries many dimensions of uncertainty and never more so than in this so-called “new era of drug safety”. The industry today faces a risk-averse environment where real-world data plays an increasingly important role post-launch. Clinical trial data (Phases I to III) demonstrates efficacy and safety in specific populations and under strictly controlled conditions; however, these results may have limited resemblance to real-world usage. Regulatory risk management requirements oblige companies to consider the safety implications of real-world use. Additionally, payers are interested in ensuring that products are used in line with relevant treatment and reimbursement guidelines. However, in reality, it is difficult to predict who will get the drug post-launch and if they will benefit from it as expected. Therefore companies increasingly find they have to commit to expensive post-marketing studies to demonstrate the product’s safety or value and are held to account on these commitments, particularly through conditional approval.

If we accept the premise that this is unavoidable, are companies optimising their commitments and using them to provide competitive advantage?

Promoting better decisions

When we consider the various stakeholders, it is clear that they all may have an interest in utilising real-world data on drugs to enable more informed decision-making.

Post-marketing safety and efficacy data is of primary interest to healthcare professionals, patients, and pharmacovigilance and regulatory functions. For these stakeholders, real-world data can be used to identify those patients who will benefit from treatment and those at risk or in need of closer monitoring. Payers, hospital administrators and health authorities may have a specific interest in health economic outcomes data which can aid them in determining how best to use the treatment cost-effectively. For clinical development and commercial stakeholders, post-marketing data might be used to identify new market segments or alternative indications for their product. It is also helpful in assessing the effectiveness of risk management activities.

Utilising registries to deliver competitive advantage

Randomised clinical trials (RCTs) and observational or drug utilisation studies can all provide information to inform decision making, yet all suffer from inadequacies (i.e. costs, data availability, sample size etc.). Registries (see Box 1), represent a powerful alternative for collecting real-world observational, epidemiological, health management, and economic data, and can be used where RCTs are inappropriate or impractical (e.g. pregnancy exposure or rare disease). Registries provide an integrated approach to satisfying diverse information needs, which can result in better-informed decision-making for stakeholders.

Strengths of registries include:

1. Less strict inclusion/exclusion criteria (so broader populations are monitored)

2. Physicians decide how to treat and monitor their patients, providing comparative information on actual practices
3. Larger sample sizes enable better estimation of event rates
4. Follow-up is longer term
5. Opportunity for international/multinational implementation
6. Hard outcomes and endpoints are easier to obtain
7. They can satisfy multiple stakeholders' data requirements
8. They can be implemented more cheaply than randomised trials.

Weaknesses of registries include:

1. More challenging data analysis due to variations in patient visit intervals, treatments, populations and settings or changes in practice over time
2. Bias, confounding and loss to follow-up can make data interpretation difficult
3. Data protection laws can hamper implementation.

Box 1

Types of registry

- Product registry – Observe patients given a specific drug
- Healthcare registry – Observe patients undergoing a common procedure
- Disease registry – Observe patients with a common diagnosis (can be used to study the natural history of diseases).

The key to delivering competitive advantage is the early development of registry plans that are in line with robust licensing, labelling and pricing negotiation strategies. The focus must be on maximising post-launch opportunities and generating competitive advantage for the product.

Critical steps in setting up and running registries

To ensure that a registry delivers value, three process elements are essential:

Design – Before the registry is commissioned and built, it is important to define who wants the data, what questions it will answer, what data needs to be collected, how and by whom.

Implementation – Unsurprisingly, communication is key to encouraging the recruitment and active participation of patients, physicians and healthcare centres. Clinicians, for example, will be particularly interested in the opportunity to analyse data and publish findings. During the active life of the registry, all stakeholders need to be kept informed of progress, recruitment and preliminary results. Successful registries include internal and external members on their governance committees who determine policy on registry administration, content, recruitment planning, investigator and analyst training, external communications, safety monitoring, ethics, data quality, access and publications.

Delivering results – The transformation of registry data into meaningful high quality results that answer the defined research questions is critical. Ultimately, it is specific results that will inform stakeholders' decisions.

Conclusions

Today's product launch environment requires pharmaceutical companies to collect real-world data demonstrating the efficacy, safety and economics of their products. Registries are becoming popular alternatives to more traditional post-marketing data collection techniques and should integrate with launch and post-launch plans, focusing on stakeholders' needs to ensure they deliver valuable competitive advantage.

Award-winning research combines patient compliance and risk management

For the past few years Pope Woodhead has enjoyed an ongoing collaboration with the Institute of Biotechnology at the University of Cambridge business school. Each year future bio entrepreneurs have the opportunity to work with PW on research-based projects that will contribute to their Masters in Bioscience Enterprise. One such example of this is the work carried out by Mathieu Michalet under the supervision of Dr Swapu Banerjee and Dr François Lucas, whose dissertation won the RSA Dissertation Award in 2008.

The research project examined the potential for combining compliance and risk management, using an anti-depressant drug as a case study. Practical solutions proposed included regular SMS

or email reminders, interactions with nurses, and capture of patient-level, treatment-related information on a common database.

This type of multi-faceted approach should be acceptable to both patients and healthcare professionals because it meets regulatory requirements, reinforces the benefit/risk balance of the drug and is driven by patient choice. The proposed approach is efficient because it shares common resources across risk management and compliance programmes.

This type of compliance enhancing programme linked to the prescription of a drug could create added commercial value by differentiating a product from competitors while tackling the important issue of non-compliance.

This award-winning research will be discussed in more detail in the next edition of *AXIOM*.

Has clinical trial disclosure helped the average patient?

Dr Lia McLean, Principal Consultant
Contact: lia.mcLean@popewoodhead.com

Whilst great advancements have occurred in the area of clinical trial disclosure, much remains to be done to improve transparency, access and awareness, particularly for patients. This was the overall conclusion of a survey of industry stakeholders carried out by Pope Woodhead and Associates. In this article, Dr Lia McLean (Principal Consultant) tells us more about the background to the survey and its findings.

"People can verify for themselves that the industry is doing its best to be transparent; it is not just words."

In recent years, the medical research community and the pharmaceutical industry have taken steps to improve transparency in the area of clinical trial disclosure, prompted by legislation and demands from key journals. As a consequence, the general public now has access to a mass of information, which may have multiple benefits in terms of increased access to suitable clinical trials, increased understanding of the clinical trial development process, greater transparency of information, and the potential of increased trust in the pharmaceutical industry and its products.

In complying with disclosure requirements, pharmaceutical companies have chosen various approaches in providing clinical trial information. We conducted a survey amongst a sample of pharmaceutical companies of varying size to determine their views on the current situation, the challenges that they face, and the future of the clinical trial disclosure initiative.*

The specific goals of our survey were to understand, from the perspective of those inside the pharmaceutical industry:

- Whether the creation of clinical trial registries achieved the International Committee of Medical Journal Editors (ICMJE) objectives of increasing transparency and accountability of clinical trial activities and reducing the potential for publication bias
- Whether current clinical trial registries meet users' needs
- How pharmaceutical companies view the future of registries and clinical trial disclosure in general.

The initiative has improved industry image and increased transparency

Most respondents believed that the clinical trial disclosure initiative has helped to improve the image of the pharma industry. And most also agreed that the creation of clinical trial registries has achieved the ICMJE objectives of increased transparency, accountability and bias reduction – although they regarded bias reduction to be more difficult to assess and/or achieve.

Patient awareness is still an issue

Awareness of registries was thought to vary for different groups, ranging from very high for key opinion leaders and researchers to low for the general patient population, with general practitioners and certain unique patient groups lying somewhere in between. Patient awareness was perceived to be slightly higher for company-sponsored than for independent, non-branded sites (i.e. ClinicalTrials.gov), and was thought to be higher in the US. Low patient awareness is not surprising given that most respondents reported that their companies had spent very little effort and resource on communicating about registries to the general public.

The majority of companies hosting their own registries considered the users when setting up their sites, consulting with various user groups and aiming for patient-friendly language. Companies posting on ClinicalTrials.gov chose

this site for its independent nature and considered it to be user-friendly for professionals and experienced users, but less so for the average patient.

There are many issues and challenges facing the disclosure initiative

The most frequently cited issues and challenges in the area of transparency and trial disclosure were:

- **Results disclosure** – particularly the potential requirement of lay summaries and misinterpretation of results through meta-analyses
- **Proliferation of registries** – whilst a good thing in terms of the amount of available information, multiple entries can lead to problems for patients and extra work for companies
- **Compliance with legislation** – the interest of the patient may be being lost in increasing legislative demands
- **Lack of resources** – frequently compounded by unrealistic compliance timelines and lack of clarity or consistency in the legislation
- **Lack of clarity regarding the role of external organisations** – no clearly defined co-ordinating roles.

Results disclosure is one of several major challenges

Results disclosure is the area where there is the greatest amount of change at present, with many new legislative demands and procedures. Participants cited the lack of clarity of the legislative demands and the additional time and resource requirements associated with compliance as their major challenges. They also mentioned their concerns about lay summaries and the potential for misinterpretation of results.

The existence of too many registries can lead to confusion

The proliferation of registries, whilst a good thing in many respects as a sign of increasing availability of trial information, was also cited as a problem for users. There is potential for confusion with multiple entries of the same trial in different formats, and the need for multiple searches. The recent initiatives by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the

World Health Organisation in setting up global clinical trial portals are a welcome development and show the importance of independent organisations taking a lead.

Patient needs are critical

The results of our snap-shot survey show that whilst the industry believes that advancements in clinical trial disclosure have occurred, much still needs to be done in this area. The issues and challenges mentioned are echoed in other publications.¹⁻³ The recently updated IFPMA joint position paper on clinical trial registries and databases shows that the industry is taking this issue seriously and is committed to transparency and openness.⁴ Compliance with disclosure directives and legislation takes effort and resources, but our survey showed it can have other unintended but beneficial consequences for pharma companies. For instance, resource devoted to this area can lead to increased awareness of the importance of clinical research transparency and to improved internal procedures. Above all, however, patients' needs should not be forgotten in the increasing demands and complexity of the legislation, and all stakeholders (including the legislators), should consider this critical. Ultimately, an informed and empowered patient population that trusts in the medicines that the pharmaceutical industry develops will benefit all of society.

"It is important that patients should be aware [of the availability and use of registries], but on the whole they are not."

"I am not sure that it [increased legislative demands] is helping the patient to have better access to trials."

At a glance

Key learnings from this survey:

- Transparency is thought to have improved substantially, but more so for the scientific community than for the patient
- Awareness and use among patients is perceived as relatively low
- The proliferation of registries is seen as causing problems for both patients and companies
- Increasing demands of legislation may be causing us to lose sight of the patient
- There was felt to be a need for strong international coordination
- The trial disclosure initiative has had many other, unintended but often positive consequences.

* Ten representatives (working in the area of clinical trial disclosure) from various pharmaceutical companies were interviewed between November 2007 and February 2008. The survey results have been presented at two conferences (CBI 3rd Annual Premier Forum on Clinical Trial Registries and Results Databases, 28-29 April 2008, Vienna VA, USA; and DIA Current Advancements in Clinical Trial Disclosure: The Changing Tide, 15-16 October 2008, Chicago IL, USA) and have been submitted to the Drug Information Journal.

1. Foote MA. Clinical Trial Registries: A practical guide for sponsors and researchers of medicinal products. Basel - Boston - Berlin, Birkhauser Verlag 2006.
 2. Zarin DA, Ide NC, Ise T, Harlan WR, West JC, Lindberg DAB. Issues in the registration of clinical trials. JAMA, May 2007;297(19):2112-2120.
 3. Geishi D, Clarke M, Berlin J, et al. Reporting the findings of clinical trials: a discussion paper. Bulletin of the World Health Organisation, June 2008;86(6):492-493.
 4. IFPMA, JPMA, EFPMA, PhRMA: Joint Position on the disclosure of clinical trial information via clinical trial registries and databases. January 2005. Available at: http://clinicaltrials.ifpma.org/fileadmin/files/pdfs/EN/Revised_Joint_Industry_Position_Nov_2008.pdf (accessed 4th February 2009).

Focus on commercial innovation and **RISK sharing**

*Dr François Lucas, Head of Market Insights and Strategy
Contact: francois.lucas@popewoodhead.com*

*Chris Easley, Senior Consultant, Market Insights and Strategy
Contact: chris.easley@popewoodhead.com*

Innovative, commercial, so-called ‘risk sharing’ schemes aim to improve cost effectiveness, lower budget impact and, in some cases, reduce the risk to healthcare systems of paying for a drug that ultimately proves ineffective.

Such schemes emerged in response to payers denying reimbursement of novel and expensive drugs with an uncertain clinical and risk evidence basis at launch. Various types of scheme exist, these can broadly be classified as performance-based or finance-based (Table 1). This article addresses how such schemes work and some of the critical issues around implementation; focusing mainly on individual patient strategies.

allowed access to multiple sclerosis drugs through conditional reimbursement (Table 2). The agreement stated that the drug’s price would be revised downwards or upwards, based on the results of an observational study.

For performance-based schemes, the therapy is free or refunded if the individual patient’s response is below an agreed threshold (Figure 1a).

This mechanism was used to secure NICE approval for Velcade (Janssen-Cilag) in multiple myeloma (Table 2).

Performance guarantee schemes reduce the risk taken by the payer because cost-effectiveness of the drug becomes more certain. The benefit of the scheme to the pharma company is that it allows reimbursement without the need for a drastic price reduction.

Proposing this type of scheme suggests to payers that the manufacturer is both confident in the future performance of its drug, and incentivised to promote it responsibly, to ensure that it is only prescribed for patients likely to respond. This credibility factor should help the manufacturer to negotiate a favourable price that compensates to some degree for the loss of revenues from non-responder patients. However, patient eligibility criteria and definition of ‘response’ to the drug need to be carefully

	Performance-based ('risk sharing') schemes	Finance-based schemes
Population level	Conditional reimbursement – reimbursed price and/or reimbursement conditions are modified based on post-marketing evidence (from an observational study or randomised clinical trial)	Price-volume agreement – the number of patients that will benefit most from therapy is agreed in advance, and usage beyond this patient volume is penalised financially
Individual patient level	Performance guarantee – the drug is funded only for patients who respond, based on pre-agreed surrogate or clinical endpoint	Cost/treatment duration 'capping' – the therapy is free (or discounted) beyond a specified number of doses or cumulative cost per patient Free treatment initiation – the drug is free up to a specified number of doses

Table 1. Broad types of commercial agreements used to facilitate market access

How performance-based schemes work

With performance-based schemes, the cost of the drug to payers depends on the level of response to therapy as determined post-launch. The first well-publicised scheme of this kind

thought through to maximise the proportion of patients in the scheme that will demonstrate a satisfactory response.

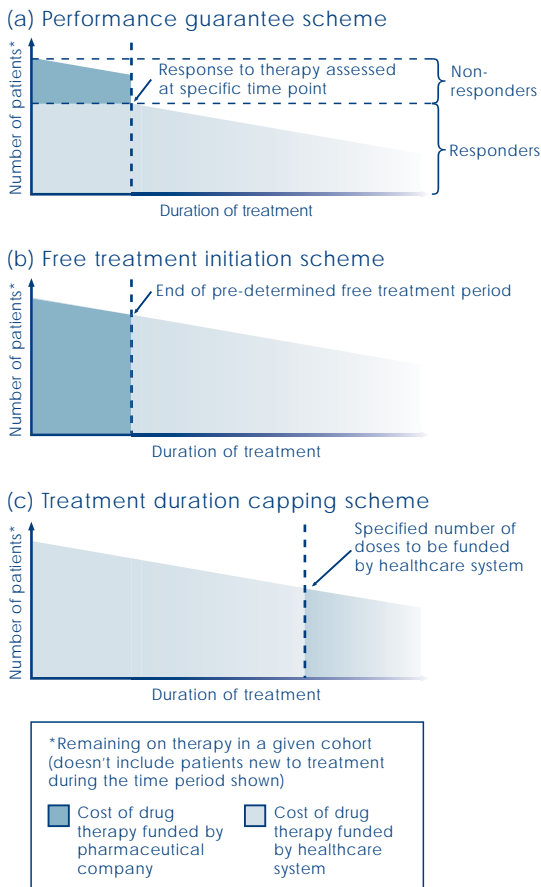


Figure 1. Examples of commercial schemes based on individual patient data

How finance-based schemes work

Finance-based schemes at an individual level are a form of flexible discounting (Tables 1 and 2).

One scenario is to offer the initial phase of the treatment for free, then charge the drug at full price (Figure 1b); this is the case for Sutent in the UK. This scheme may to some extent encourage prescribers to initiate a new therapy as part of a trial period ('try before you buy'), since they can discontinue treatment early if the patient does not respond. However, payers and physicians may fear creating demand that is difficult to curb once treatment has been started. This type of scheme works best for drugs that have an early onset of action or that most patients will receive as a long-term treatment.

Another scenario is based on charging full price for a drug until the cumulative dose or treatment duration (recommended in clinical guidelines) is reached, this is known as a cost or treatment

duration 'capping' scheme (Figure 1c).

The manufacturer funds treatment for the individual patient once a specified number of doses (e.g. Lucentis and Revlimid, Table 2), or cost (e.g. Avastin, Table 2) has been exceeded, thus removing the risk to payers of having to fund lengthy treatments. Theoretically this scheme encourages prescribers to treat patients for longer, for example to the time point where the maximum response rate to the drug is achieved (hence it can help the manufacturer to demonstrate good response rates in a real-life setting). How much the average price is reduced depends on the treatment pattern – the greater the proportion of patients put on short treatment courses, the lower the effective 'discount'.

Cost or dose/duration 'capping' addresses affordability by offering some guarantee about maximal budget impact, and has an indirect effect on cost-effectiveness. This type of scheme has been used in various forms in several countries including the UK (Table 2) and USA. In France, a similar capping approach exists, but at a population level.

Scheme implementation is a critical step

Performance guarantee schemes are often difficult and costly (both to set up and run) because they require agreed criteria and tracking of somewhat complex patient-level data. Finance-based schemes are easier to implement because the administration is simpler and the data needed to track usage is more easily obtainable.

Payers expect the drug manufacturer to bear the implementation costs. Efficiency can be improved by linking the scheme with other patient-centric initiatives. For example, data collected through the patient registry of a risk management programme may be sufficient to support the commercial scheme or it may be that the required additional data collection entails only marginal costs.

Effortless real-life implementation is crucial in getting buy-in from payers, pharmacists and physicians wary of the prospect of any additional administrative burden. The pharmaceutical company should ensure that local payers and care providers understand the value of the scheme for their organisation. In our research we have noted scepticism from some payers who felt that a number of past schemes had not really delivered the benefits that were promised.

Effortless real-life implementation is crucial in getting buy-in from payers, pharmacists and physicians wary of the prospect of any additional administrative burden.

Drug (manufacturer)	Therapeutic area	How it works	Comments
Performance-based schemes			
Betaferon (Schering), Avonex (Biogen), Rebif (Merck Serono), Copaxone (Teva/Aventis)	Multiple sclerosis	Annual revision of pricing based on effectiveness from ongoing 10 year, registry-based observational study	Approved by NICE and introduced in 2002 in the UK
Velcade (Janssen-Cilag)	Multiple myeloma	Cash-back or credit for patients with less than a complete or partial response after 4 cycles	Approved by NICE and introduced in 2008 in the UK
Finance-based schemes			
Sutent (Pfizer)	Metastatic renal cell carcinoma	First cycle free	Approved by NICE in 2009
Avastin (Roche)	Metastatic renal cell carcinoma	Free once the patient has reached a cumulative dose of 10,000 mg	NICE considered the scheme in their appraisal consultation document in 2008, but still found the drug not cost-effective
Lucentis (Novartis)	Wet age-related macular degeneration	Full price for first 14 injections per eye then free	Approved by NICE and introduced in 2008 in England and Wales
Revlimid (Celgene)	Multiple myeloma	Full price for first 26 cycles then free	Approved by NICE in 2009

Table 2. Examples of innovative pricing strategies proposed to NICE in the UK

So will innovative commercial agreements flourish?

The schemes we have reviewed suit innovative, expensive, high-margin drugs that treat conditions with high unmet needs and face market access denial due to an uncertain evidence base. Since these schemes may help to achieve a high tariff price, they should also be useful in limiting the impact of price comparisons with other countries or other indications for the same molecule.

Whether innovative commercial strategies will flourish or remain limited to exceptional cases is a subject of debate. Recent negative appraisals by NICE (UK) and tougher bargaining by Medicare (USA) may encourage companies to propose these schemes. Alternatively, the recent proposal in the UK to allow greater access to expensive therapies offering marginal therapeutic benefit in life-threatening or end-of-life conditions may reduce pharma's need to fall back on discounting or performance-based reimbursement schemes.

More fundamentally, performance-based agreements can be viewed as testing grounds for value-based pricing of health technologies. The new pharmaceutical price regulation scheme (PPRS) in the UK paves the way by advising that the price of drugs be revised upwards or downwards depending on post-marketing evidence. In the meantime, we would like to think that payers view well-designed performance- or finance-based deals as opportunities to support innovation, not just as another way to cut down the average price of innovative medicines.

NICE recently announced their intention to approve a patient access scheme for Celgene's Revlimid in multiple myeloma (final decision in April 2009) – a move considered to be a win-win for all stakeholders. Pope Woodhead are pleased to have worked alongside Celgene to achieve this.

Forthcoming events

On March 4th PW will be hosting its 2nd annual Market Access Summit. Topics include innovative strategies for market access, HTA and drug affordability, improving value propositions and NICE's Scientific Advice Programme.

PW's 3rd annual Risk Management Colloquium will be held in June. The overall theme will be 'Meeting the challenges of EU and FDA requirements'.

For further information on PW events, please contact Marianne Cassidy: marianne.cassidy@popewoodhead.com

Bulletin board

New faces at PW

Aruna Jeans, Kate Downey, Diane Lace, Debbie Swann and Karen Witherick have joined PW since the last edition of *AXIOM*.



Aruna joined the Development team in August as a writer/analyst. Her previous experience has been in Regulatory Affairs at Sanofi Pasteur MSD.



Debbie joined the Process Design and Implementation team in December. Her previous experience includes medical writing and project management in healthcare communications.



Kate joined in September as a consultant in the Commercial team. Her communications and project management expertise is gained from twelve years within pharma.



Karen joined the Risk Management and Regulatory team in January. Her experience includes nine years in pharmacovigilance, in both the pharma and biotech industries.



Diane began her career at PW in 1989, and has recently returned as a writer/analyst in the Market Insights and Strategy team.