

# Axiom | Digest

A collection of the best articles from Pope Woodhead's bi-annual newsletter

2009

## 5 phases to a **profitable** mature product **portfolio**

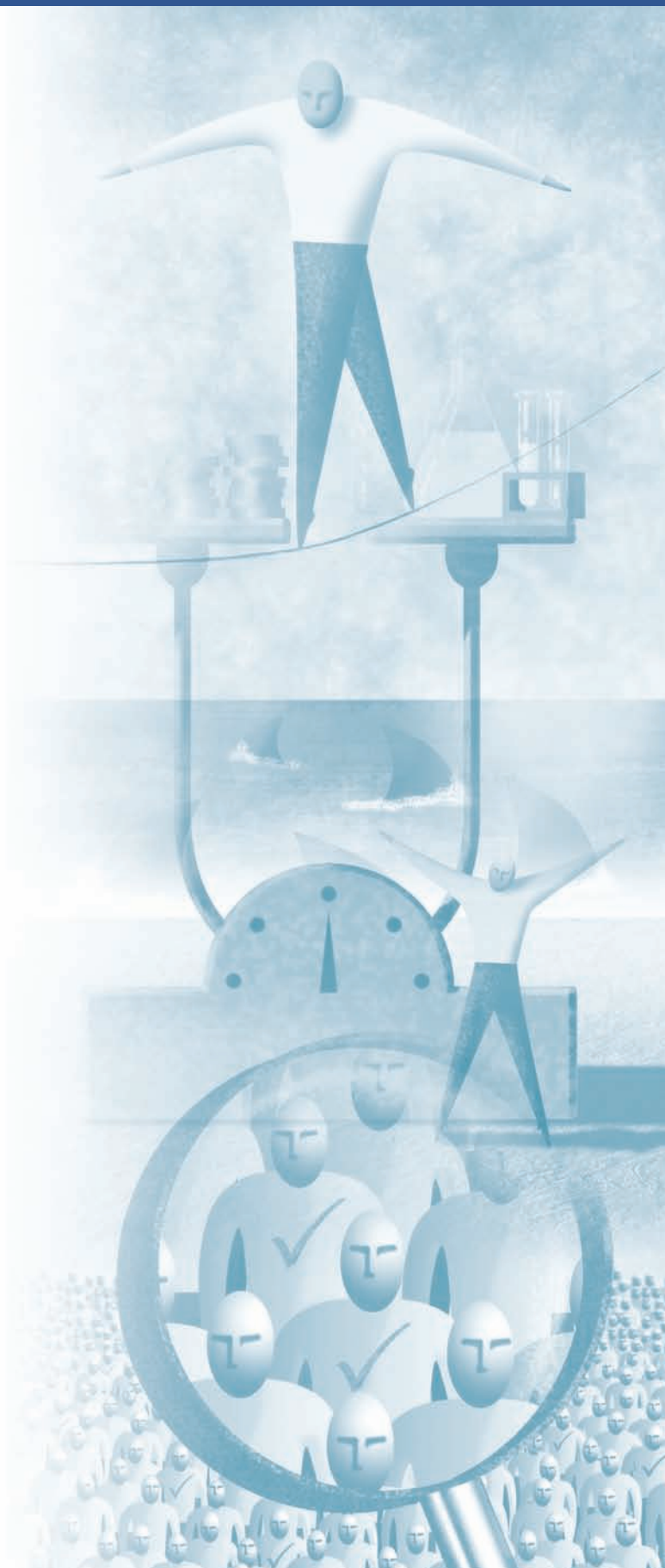
## Opinion on **RISK** Management


## 5 steps to an integrated **value** proposition

## Focus on **RISK** sharing



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## Foreword by Andrew Hobbs, Managing Director

Pope Woodhead has provided consulting and communications services to the pharmaceutical, biotech and medtech sectors since it was established in 1981. Over this time the drug market and industry practices have changed dramatically, and we now face an era of heightened cost and safety consciousness. Regulators, payers, prescribers and patients want reassurance that a favourable risk/benefit balance exists in the "real world".

This dynamic environment has led us to develop our services in both commercial and development consulting, where we have had the opportunity to work with clients in many challenging and innovative areas such as:

- Value strategy and market access
- Product and portfolio management
- Risk management and drug safety
- Regulatory affairs and clinical development.

This experience is underpinned by our long standing heritage in working with companies to improve the efficiency and effectiveness of their internal processes and communications.

In 2007 we introduced our house journal Axiom which aims to provide an informative and useful introduction to some of the key issues facing the industry, and illustrate our thinking and experience on these topics. We have selected some of the best articles from previous editions of Axiom to produce this digest. We hope that you enjoy reading it and welcome any feedback you may have.

**Andrew Hobbs**  
**Managing Director**

Contact: [andrew.hobbs@popewoodhead.com](mailto:andrew.hobbs@popewoodhead.com)

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# 5 phases to a profitable mature product portfolio

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

The composition of the mature product portfolio is frequently an unknown quantity for senior management in mid-size and large pharma companies. Yet 50–80% of revenues in most major pharma companies (and a higher percentage of the profit) comes from these products and active management of these assets is therefore essential.

## Searching for value

Active performance monitoring and product management have traditionally been focused on new products, whilst the resources and overheads committed to mature products and the margin being achieved is rarely completely visible. This situation can be exacerbated following company mergers and acquisitions. But as new product launches dry up and revenue growth slows, companies are increasingly focusing on improved management of the mature portfolio in the search for incremental value. Three additional imperatives are driving this trend.

- Firstly, cost-sensitivity of payers is making the long-term profitability of mature products increasingly fragile. Price cuts, formulary reviews and product de-reimbursement all threaten the viability of older product classes with weaker or outdated comparator trials and health economics/outcomes research evidence.
- Payers' demands for cost-effectiveness and incentives for generic prescribing are coupled with aggressive expansion from eastern European and Asian generic players, who are making acquisitions and competing higher up the value chain. The roll-out of generics (increasingly, value-added versions) after patent expiry is also becoming more rapid across all geographies.

## At a glance

- Mature products represent 50–80% of most companies' revenues, but are rarely actively managed
- Improved management of mature products is required to meet challenges presented by cost-sensitive payers, aggressive generic competitors and fewer new products
- Leading pharma companies have been able to optimise their mature product portfolios. These activities can be grouped into five phases: focus, reshape, enhance, expand and value

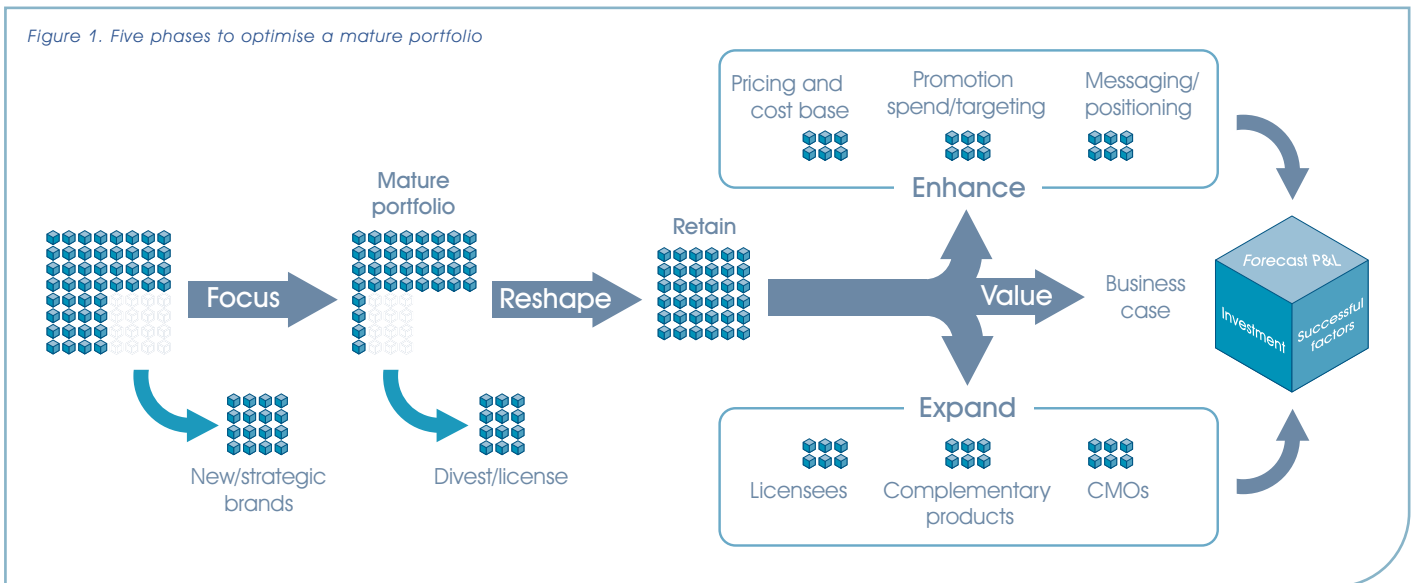
- Finally, the well-documented decline in R&D productivity and shorter double-digit product growth phases are forcing pharma companies to explore other avenues for sustained growth.

## Optimising profitability

The good news is that leading pharma companies have successfully implemented frameworks for optimising management of the mature portfolio; these typically comprise five phases of activity (see Figure 1).

- Phase 1: Focus – define and segment the mature portfolio based on appropriate performance metrics. Identify and collate relevant data from all markets about the company's products.
- Phase 2: Reshape – identify products no longer fitting the company's goals or those that are financially unviable. Strip these out of the mature portfolio into a separate category and assess divesture or out-licensing options.

Figure 1. Five phases to optimise a mature portfolio



- Phase 3: Enhance – identify mature brands that appear to have successfully sustained sales over time. Review current pricing, positioning and cost base; conduct a top-line assessment of potential options to create additional value through life cycle management.
- Phase 4: Expand – look at opportunities to grow the market for mature brands, e.g. use Contract Marketing Organisations (CMOs) or licensing agreements to gain better penetration or access in new markets. Assess the viability of in-licensing to complement existing mature product franchises.
- Phase 5: Value – evaluate top-line profit and loss of potential options to support the business case for selected strategies.

*“...mature products can be a sizeable part of sales and profits but are not always actively managed”*

Successful implementation of this process results in more than a one-time win for companies. Improvements in the management processes can be embedded in the organisation (and to some degree automated) to deliver optimal 'rolling' performance of any future products entering maturity.

## Market Access Panels (MAPs)

Targeted expert advice to identify and overcome market access challenges

Being able to foresee and navigate market access hurdles is a key determinant of success for new products. However, often in today's complex and demanding HTA and payer environment, the rules of this high stakes game are unclear or evolving rapidly.

PW's MAPs help companies to turn the odds in their favour. Comprising payer advisors and health economists, MAPs provide an insiders' view of the risks, critical success factors and the product value proposition and tradables that will optimise the outcome of P&R negotiations at the time of launch.

Our MAPs offer several advantages:

- a tailor-made approach designed around the development phase and unique product challenges
- a panel of independent experts involved at development milestones, without the expense of being formally retained
- independent expert opinion consolidated, validated and translated into practical strategy and actions by PW's internal team of market access experts.

When it comes to optimising market access, companies need to harness every advantage they can - we'd be delighted to discuss how our MAPs can support your success.

If you would like to know more about our Market Access Panels, please contact [francois.lucas@popewoodhead.com](mailto:francois.lucas@popewoodhead.com)

# Opinion on **RISK** Management

Interview with Dr. Swapu Banerjee, Head of Development Consulting  
swapu.banerjee@popewoodhead.com

Updated EU legislation means that pharmaceutical companies must generate risk management plans (RMPs) as part of the submission process. The pharmaceutical industry has to respond to this increased emphasis on risk management from regulators, and taking the right approach is now more important than ever, both pre-filing and post-launch. In this interview, Swapu Banerjee (Head of Development Consulting at PW) describes how risk management can be tackled proactively, benefiting both companies and patients.

**Axiom:** What are the implications of the updated EU pharmaceutical code, which includes modifications to RMPs?

**SB:** This legislation allows the EMEA to specify conditions on an RMP as part of a marketing authorisation<sup>1</sup>. It puts the EU slightly ahead of the USA, because the FDA requirements are only guidelines. We are now in a risk-averse climate, but I'm hopeful that risk will be seen by industry as a strategic opportunity, not just a regulatory requirement. Proactive risk management could be a differentiator between companies and competing brands.

**Axiom:** Risk management is now a big issue in the pharmaceutical industry. Are there comparisons with other industries?

**SB:** Yes, and we can learn from sectors outside pharma such as the oil and petroleum industry. Here, effective risk management is crucial to meet regulatory requirements, and it can affect the share price.

A public report into the explosion at BP, Texas City, USA was very critical of the company's safety culture and accused senior management of not taking risk and safety seriously enough\*. And that's something that all corporate leaders need to be conscious of. So, the pharmaceutical industry's risk/benefit profile and the associated public perception of the safety of medicines is crucial, but not unique.

## At a glance

- New EU legislation means that submissions for marketing must include risk management plans (RMPs)
- Risk management can be a strategic opportunity
- There are lessons to learn from other industries, such as the oil and petroleum sector
- RMPs are relevant from phase II through to post-launch
- They require good cross-functional teamwork
- PW uses FMEA (failure modes and effects analysis) to pinpoint risks in the treatment pathway
- Well-developed tools are the cornerstone of a successful risk management plan

*"...the pharmaceutical industry's risk/benefit profile and the associated public perception of the safety of medicines is crucial, but not unique."*

1. The European Parliament and the Council of the European Union, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, April 30, 2004.

\* The BP Texas City (USA) refinery explosion in 2005 killed 15 workers and injured 180. A subsequent investigation and US Chemical Safety Board Report alleged that BP directors "did not exercise effective safety oversight".



**Axiom:** Which attributes should every risk management programme have?

**SB:** Good multi-disciplinary team working and communication is very important. Commercial aspects of drug development may not always be seen by the safety department, but equally the commercial side of the business isn't always aware of the safety constraints and regulations. A consultancy such as PW can assess the overall picture using experience gained from working across different functions. We can advise on and facilitate cross-functional risk management processes, both to the client's benefit and, ultimately, for the safety of patients. This means that good risk management can become a distinct competitive advantage.

Describing an effective way of evaluating risk management tools is also an important part of any RMP. We use FMEA (failure modes and effects analysis) to pinpoint where risk tools are needed in the treatment pathway. This provides logical reasoning for selecting specific tools in the RMP. We are also developing innovative ways of evaluating the success of RMPs that have already been rolled out.

**Axiom:** The industry is entering a new era of risk management, but how prepared are pharma companies to deal with this, and what is your advice to those who work in this area?

**SB:** Risk in mid-size companies tends to be dealt with by the safety department. Risk management processes have only been running for a couple of years, which often restricts experience to a single-company view, leading to a safety rather than strategic focus. It is useful to meet with specialists from different areas and learn how other companies manage risk. Internally, ask for input from different groups and make sure that stakeholders are aligned. Safety is paramount, but receiving input from clinical development and the medical, regulatory and marketing functions, together with senior management's perspective, is necessary too. External communication to patients, where necessary, and prescribers is also very important. The tools selected for this task must be of excellent quality because they are the cornerstone of a successful RMP.

**Axiom:** How do you think risk management might develop in the current risk-averse environment?

**SB:** A more proactive approach should be considered, which is also a requirement of EU legislation and FDA guidance.

*"Companies are approaching us at phase II and then planning their phase III plans from a risk/benefit angle, not just from a safety, efficacy and quality standpoint."*

An RMP is necessary for new biologics and molecules with a novel mode of action where they might impact on public health. It should not just be developed in a hurry at the time of filing. At PW we can generate and offer advice about developmental RMPs. Companies are approaching us at phase II to add a risk/benefit angle to the safety, efficacy and quality parameters in their phase III plans.

Class effects of drugs become more prominent post-launch, and a company may divest, in-license or out-license a drug based on risk issues that affect its whole class. So, assessing the risk/benefit profile is crucial throughout the whole product life cycle. Risk communications can also become more innovative, which is an area of great potential growth.

## Further information

### FMEA approach to risk

- Proactive technique with the aim of preventing adverse events before they occur
- Analyses risks of component parts in a system, in terms of likelihood and impact
- Risks that would concern regulatory authorities are identified
- Measures to mitigate these risks are designed and implemented

# 5 steps to an integrated value proposition

*Dr François Lucas, Head, Market Insights and Strategy*

*francois.lucas@popewoodhead.com*

Generating the right clinical and health economic data to achieve market access is a challenge for global teams. Political and emotional factors, such as the public health agenda, can affect payers' value judgments and further complicate the task. In addition, the multiplicity of stakeholders involved in market access across and within countries makes the analysis even more complex. But there are ways to overcome these difficulties, as François Lucas explains.

Here at PW, we don't see market access as just another set of hurdles to jump. We prefer to think of payers and their influencers as another set of customers; the needs and perceptions of whom we should strive to understand in depth. The value proposition for the product should be constructed with all key customer groups (prescribers, patients and payers) in mind at once. There are five important steps.

## Step 1: Map stakeholders and spot trends

National pricing and reimbursement (P&R) negotiations and evidenced-based guidelines (e.g. from The National Institute for Health and Clinical Excellence [NICE]) impose the first set of challenges for market access. Regional or even more local bodies (e.g. primary care organisations in the UK, autonomous regions in Spain, or hospital formulary committees in all countries) can impose additional controls on market access. Obviously, affiliates are best placed to map payers in their own countries, and will contribute accordingly to the product's strategy. However, the global team needs to grasp the general dynamics that operate within and across markets, the important commonalities and differences between them and the trends in the global P&R environment.

To help with these challenges, PW has developed a proprietary key opinion leader management tool and is building a P&R knowledge bank. The former enables us to map key influences

between stakeholders, and eventually engage these groups to support market access. The latter captures the important facts and trends of the P&R environment, supplemented with forward-looking commentaries.

## Step 2: Find out what is most important to payers

The starting point for creating a value proposition is a deep understanding of what the customer, e.g. a payer, would value most in a potential new offering. Deciding which rational features of a new drug are relevant and important is already a challenge. But, importantly, emotional and political factors can play a great role in payers' decisions (e.g. certain patient groups may be seen as more 'deserving' than others), and such factors are not necessarily clarified in the public domain. In addition, there is great value in understanding early on in development payer's specific evidence requirements at the pre- and post-launch stages. Insight into payers' perceptions will also be precious in preparing for negotiations; this can help the company propose the right trade-offs to reduce uncertainty to the payer and increase the perception of value.

PW has substantial experience in digging through complex environments (such as the payer world) and extracting the relevant insights quickly. Our Live Voice interviewing approach allows us to very effectively explore multiple stakeholder groups (payers, physicians and patients across markets).

## Step 3: Look at appropriate comparators

Payers and, increasingly, regulators demand that value be demonstrated relative to active comparators. This is challenging because in most cases only small increments in, say, efficacy are shown and potential downsides, such as the small chance of a serious adverse event, could cancel out the incremental benefit. Figure 1 illustrates how incremental benefits and risks (relative to appropriate comparators) are the basic blocks for evaluation with the financials added on by the latter stakeholder group.

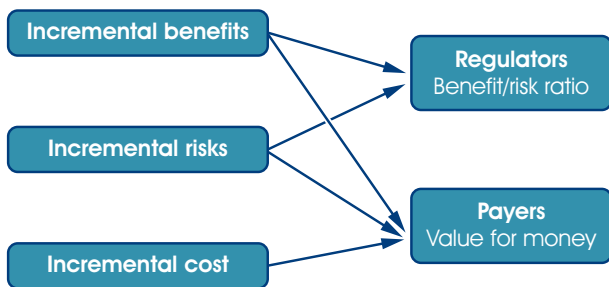


Figure 1. Role of benefits and risks in regulators' and payer's drug assessments

## Step 4: Analyse the value levers

The value proposition for a new product must revolve around criteria (benefits and risks) that are important to the stakeholders and are demonstrated relative to one or more comparators (see Figure 2). This is a great challenge for various reasons. One is that the relative importance of the criteria (y axis) and even the evaluation of how the drug scores on each criteria (x axis) is influenced by political and emotional factors, in addition to objective clinical considerations. Another difficulty is figuring out a way to evaluate the overall value of the product based on multiple criteria.

We have devised a semi-quantitative approach to resolve this challenge, drawing upon a combination of qualitative insight research, desk research, clinical review and consensual expert opinion. Figure 2 shows a simple, hypothetical example where we plotted the current (e.g. phase II) situation (dark grey) and what the potential situation could be near launch (light grey). The plot provides a view of the balance of clinical benefits and risks (so can be used for a formal risk/benefit evaluation). But in this particular example, the focus is on understanding what will really drive the value of this product – here the value proposition would revolve mainly around the relapse rate benefit.

This analysis should be done with prescribers, patients and even regulators in addition to payers (Figure 3), to get a full picture – keeping in mind that the value propositions to these groups must be consistent.

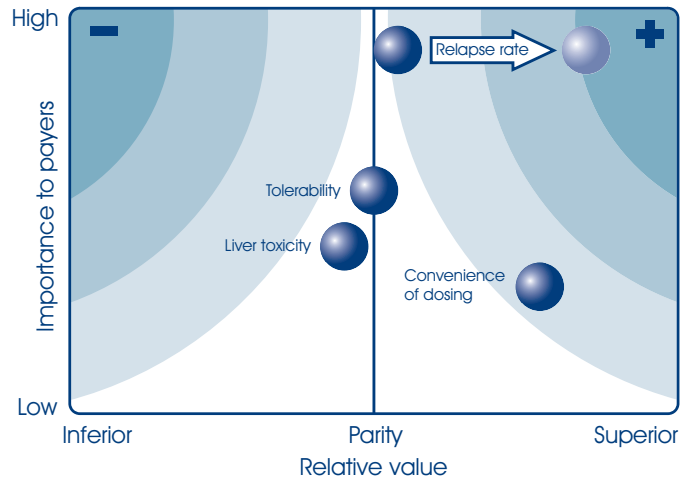


Figure 2. Value lever analysis. The + and - regions represent areas where the perceived relative value (or utility) of the drug is respectively greatest (positive) and lowest (negative)

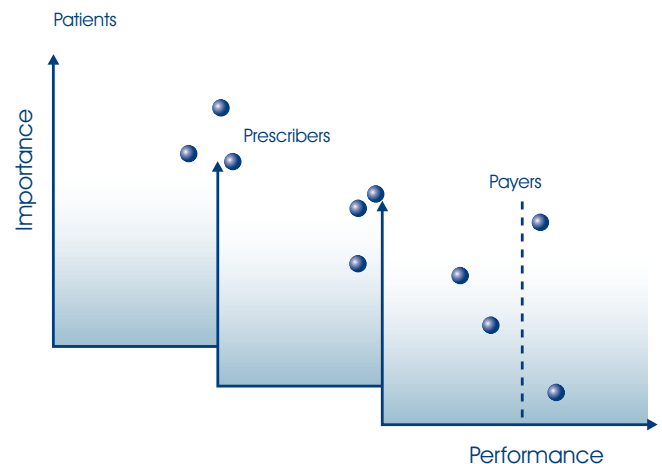


Figure 3. Value levers for the range of stakeholders

## Step 5: Assess the net expected commercial value

The analysis just described enables the development and marketing teams to focus on a value proposition. If the value proposition is realised, a rough amount of commercial value can be estimated. However, the likelihood of success (which can be estimated from the previous analysis) is used to discount this value. But risks or downsides also need to be factored in. These are the risks that will emerge from an analysis of, for example, the technical difficulties, competitive situation, complications of clinical trials and investments needed. In essence, the result is a qualitative (or semi-quantitative) assessment of the components of the net expected value of the product. The utility of this approach is that it supports decision-making (e.g. go/no go decisions) by providing a full view of the risks and benefits from a commercial perspective.

# Focus on commercial innovation and **RISK** sharing

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

*Chris Easley, Senior Consultant, Market Insights and Strategy  
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.

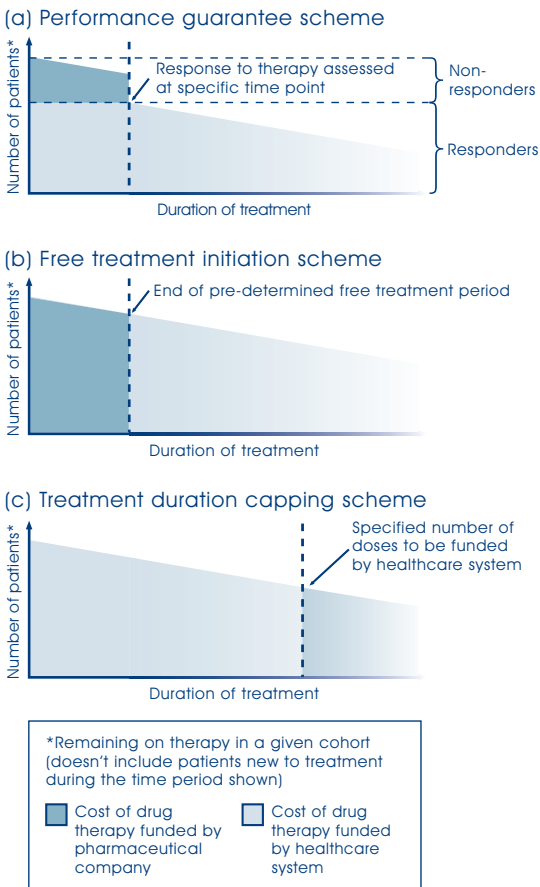


Figure 1. Examples of commercial schemes based on individual patient data

## 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, a move considered to be a win-win for all stakeholders.

Pope Woodhead are pleased to have worked alongside Celgene to achieve this.

## PW contacts



**Andrew Hobbs**  
Managing Director  
(Head of Commercial Consulting)  
andrew.hobbs@popewoodhead.com



**Swapu Banerjee**  
Board Member  
(Head of Development Consulting)  
swapu.banerjee@popewoodhead.com



**Marianne Cassidy**  
Business Development  
marianne.cassidy@popewoodhead.com

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

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We are always searching for bright, hard-working, motivated people willing to join our organisation. If you like what you have read about some of the services we offer, please visit the careers section of the PW website ([www.popewoodhead.com](http://www.popewoodhead.com)) to find out if your skills and experience would complement our team, or contact [deborah.ellmer@popewoodhead.com](mailto:deborah.ellmer@popewoodhead.com)

## Risk Sharing Master Class

Pope Woodhead will be organising a Risk Sharing Master Class this autumn. To register your interest please complete the form on our website at [www.popewoodhead.com/events\\_register.htm](http://www.popewoodhead.com/events_register.htm) or contact [marianne.cassidy@popewoodhead.com](mailto:marianne.cassidy@popewoodhead.com) with your contact details.