

# ● absorb the impact

Innovative schemes give reassurance to payers in exchange for market access

**D**rug manufacturers bear the risk of failing to commercialise a drug adequately after heavily investing in its development, and the payer bears the risk of accepting to fund a drug that is not worth it or drains the healthcare budget. Innovative commercial risk-sharing schemes emerged in response to payers increasingly denying reimbursement of novel and expensive drugs that had an uncertain clinical evidence basis at launch. These agreements reallocate the risks by reducing uncertainty about cost effectiveness and/or budget impact in exchange for allowing market access to the new drug.


Various types of scheme exist, which can broadly be classified as performance-based or finance-based (see Table 1). Although publicised recently in the UK, examples have

been highlighted by researchers, in one form or another, in the US, Canada, Germany, Italy, Denmark, France and Australia.

## PERFORMANCE-BASED

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

In more recent cases, 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 National 

➔ Institute for Health and Clinical Excellence (NICE) approval for Velcade (Janssen-Cilag) in multiple myeloma (Table 2). Merck Serono and Novartis have proposed similar schemes to local UK payers for Erbitux (in metastatic renal cell carcinoma) and Xolair (in IgE-mediated asthma) after negative NICE reviews.

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 drug manufacturer is that it allows reimbursement without the need for a drastic price reduction.

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

## FINANCE-BASED

Finance-based schemes at an individual level are a form of flexible discounting. One scenario is to offer the initial phase of the treatment for free, then charge the drug at full price (see Figure 1b); as for Sutent in the UK. This scheme may encourage prescribers to initiate a new therapy for a trial period, or 'try before you buy', since they can discontinue treatment early if the patient does not respond. However, payers and doctors may fear creating demand that is difficult to curb once treatment has 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 a 'capping' scheme, based on charging full price for a drug for a given treatment duration or until a cumulative dose is reached by the individual patient (see Figure 1c). Recent UK examples include Lucentis and Revlimid (Table 2). A similar approach can be found in the US, where Genentech offers free Avastin to patients who earn less than \$100,000 and have used \$55,000 worth of the drug in a year. In France, a capping approach exists in the form of price-volume agreements - but these are made at a population rather than individual patient level. Cost or dose/duration capping addresses affordability by offering some guarantee to payers about maximal budget impact; it also has the effect of somewhat increasing cost effectiveness. Theoretically, these schemes encourage prescribers to treat patients for longer, for example to the time point where the maximum response rate to the drug is achieved. This can help the manufacturer to demonstrate good response rates in a real-life setting. The reduction on the average price depends on the treatment pattern - the greater the proportion of patients put on short treatment courses, the lower the effective 'discount'.

## IMPLEMENTATION

Performance-based schemes are often difficult and costly to set up and run because they require agreed criteria and tracking of rather complex patient-level data. Finance-based schemes are easier to implement because the administration is simpler and the data needed to track usage are 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 collecting the required additional data entails only marginal costs.

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

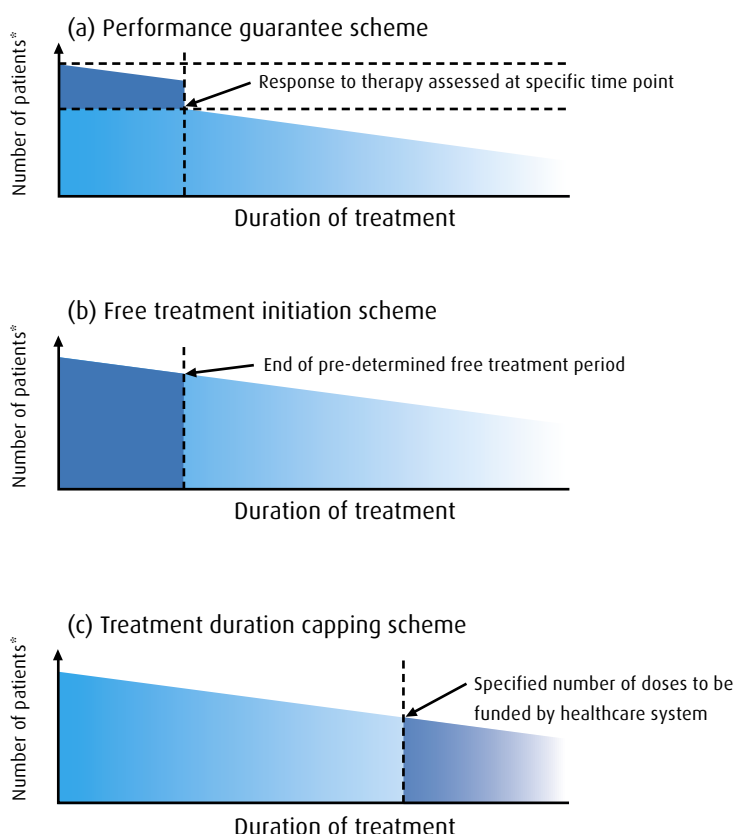
## INNOVATIVE AGREEMENTS

The schemes we have reviewed suit innovative, expensive, high-margin drugs that treat conditions with high unmet needs and face market access denial because of 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

**Table 1. Agreements to facilitate market access**

Performance-based schemes	Finance-based schemes
<p><b>Population level</b> Conditional reimbursement - reimbursed price and/or reimbursement conditions are modified based on post-marketing evidence (from an observational study or randomised clinical trial)</p>	<p><b>Population level</b> 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</p>
<p><b>Individual patient level</b> Performance guarantee - the drug is funded only for patients who respond, based on pre-agreed surrogate or clinical endpoints</p>	<p><b>Individual patient level</b> 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</p>

**FIGURE 1. SCHEMES BASED ON INDIVIDUAL PATIENT DATA**



\*Remaining on therapy in a given cohort (doesn't include patients new to treatment during the time period shown)

■ Cost of drug therapy funded by pharmaceutical company    ■ Cost of drug therapy funded by healthcare system

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 (US) may encourage companies to propose these schemes. Interestingly, 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 could have a mixed impact. On the one hand, the relaxed criteria from NICE seem to have helped the Sutent scheme to hit the cost effectiveness requirement and thus be accepted by NICE. On the other hand, a lower barrier may in future reduce pharma's need to fall back on discounting or performance-based reimbursement schemes.

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, rather than just another way to cut down the average price of innovative medicines.

**The Authors**

**François Lucas** is principal consultant and **Chris Easley** is senior consultant at Pope Woodhead and Associates [www.popewoodhead.com](http://www.popewoodhead.com).

**Table 2. Innovative pricing strategies proposed to NICE in UK**

Drug (manufacturer)	Therapeutic area	How it works	Comments
<b>Performance-based schemes</b>			
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
<b>Finance-based schemes</b>			
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 10,000mg	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