

# Pay-for-performance arrangements

IFRS Revenue Recognition Guidance





## Foreword

In recent years and particularly within Europe, we have witnessed the development of various Pay-For-Performance pricing schemes as payers' budgets have come under increasing pressure. Under these schemes, the price paid for a given medicine is generally linked to the efficacy of a drug and the economic benefits that flow from it. Such arrangements can be complex to administer and present a number of commercial and accounting challenges for management.

This paper discusses the factors that should be considered to determine when it is appropriate to recognise revenue under a Pay-For-Performance arrangement. This paper provides a framework for consideration and each situation should be assessed based on the specific facts and circumstances. Over time we expect these types of arrangements to be more common, and planning for the practical application together with an understanding of the financial reporting consequences will be important as the implications could be significant. I hope you find this paper informative and useful in understanding the revenue recognition issues that these complex arrangements can present.

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## The principle of 'Pay-for-performance'

Pay-for-performance is a pricing concept under which the price paid for a given medicine is intended to reflect the economic benefits of a drug at an individual patient level.

The idea that those that fund healthcare, whether it be insurances companies (as in the USA) or Governments and the public purse (as in much of Europe), should only pay for drugs that have a demonstrable benefit over other treatments is not new and in recent years both Governments and regulators have showed increasing reluctance to pay for "me-too" or "copy-cat" drugs.

There have been two recent events that suggest Pay-For-Performance is likely to become an even more significant factor in determining how much the UK NHS and other payers are prepared to pay for medicines:

- The UK Office of Fair Trading, following its recent review of the UK PPRS scheme, recommended that the current "profit cap and price cut" scheme be replaced with a value-based pricing system in which the prices of products are set by comparing their clinical value with that of other treatments for the same condition.
- The UK National Institute for Health and Clinical Excellence put in place an innovative scheme with Janssen Cilag and its treatment for Multiple Myeloma, Velcade. Under the scheme termed "The Velcade Response Scheme" the NHS will only pay for the treatment in those patients in which it shown to be effective.

There are many different ways in which a Pay-For-Performance pricing model could operate and it is likely that different healthcare payers and funders will agree different pricing models depending on the dynamics within different individual markets. In broad terms we can envisage two different ways in which a Pay-For-Performance pricing model could operate, as set out below:

### 1. Peer pricing or benchmarking performance model

Under this type of model prices would be agreed up-front based on an agreed performance model. For example prices could be set based on comparison with currently available medicines or other treatments. This would mean reviewing clinical data upfront to establish the effectiveness of a particular medicine against its

peers or against alternative (non-drug) clinical therapies or treatments.

If prices are agreed up-front and then a product is shipped subject to standard terms and conditions then we would not envisage this type of arrangement leading to particularly complex or challenging revenue recognition issues.

### 2. Outcomes-based performance model

Under this type of performance model a healthcare payor may agree to only pay for a medicine based on a successful or agreed clinical outcome, for example the Velcade Response Scheme.

Clearly, agreeing what a successful clinical outcome is likely to be a difficult and time consuming commercial exercise between payers and companies. There could be any number of different possible outcomes and the pricing may be structured accordingly. For example:

- A cancer drug could be priced based on the number of years/months that the patient lives following the commencement of treatment.
- An anti-viral drug might be priced based on a percentage reduction in viral load in the blood stream over a given period.

From a practical perspective this type of model could be administered in a number of different ways:

- The product could be sold at an agreed price and then a refund given where it didn't achieve the required clinical outcome.
- For specialist medicines the product could be held on consignment in hospitals and only paid for once it was shown to have achieved the required clinical outcome.
- The product could be sold at a 'floor' price and a premium received once outcomes data proved efficacy and other agreed target responses.

Not only do these type of models present cashflow and other commercial issues, they also pose a significant challenge to revenue recognition.

## Accounting for an outcomes-based performance model

The key issue in accounting for an outcomes-based performance model is that the outcome at the inception of the arrangement (or a patient taking the drug) is unknown. There may also be a significant time delay between the point that the drug is shipped (or ingested by a patient) and establishing the clinical outcome and therefore determining how much, if anything, will be paid for it.

In determining whether revenue can be recognised in respect of a particular transaction the relevant accounting standard is IAS 18 paragraph 14 and in particular paragraphs (c) and (d) shaded below:

Revenue from the sale of goods shall be recognised when all the following conditions have been satisfied:

- (a) *the entity has transferred to the buyer the significant risks and rewards of ownership of the goods;*
- (b) *the entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;*
- (c) *the amount of revenue can be measured reliably;***
- (d) *it is probable that the economic benefits associated with the transaction will flow to the entity; and***
- (e) *the costs incurred or to be incurred in respect of the transaction can be measured reliably.*

Demonstrating that the criteria in the shaded paragraphs have been met is likely to hinge on the same factors and outcomes. In particular (notwithstanding credit issues) it is only likely to be probable that economic benefits will flow to the entity when the other criteria above have been met.

## Risks and rewards, continuing involvement and costs incurred

These criteria will generally be met when the product is delivered to the patient. The seller has no access to the risks and rewards of the medicine and has no further involvement. The cost of the medicine should be known to the seller.

## Reliable measurement

We believe the reliable measurement requirement may preclude immediate revenue recognition at the start of an outcomes based performance arrangement, unless a floor pricing mechanism is in place. In such circumstance the floor price (assuming it is not refundable) could be recognised, but a premium only recognised once agreed with the payer. Under many types of outcomes-based performance model without the benefit of a historical track record it could be difficult to demonstrate that revenue can be measured reliably (or certainly for any portion of revenue that is subject to a clinical outcome) because:

- There may be an unquantifiable level of expected refunds or;
- The actual amount that will be paid may not be agreed until the end of a specified term or until outcomes are known.

Although the drug will have been subject to a clinical trial the performance outcomes under a commercial arrangement may be different to the endpoints in the clinical trial. Also the patient population used in a clinical trial may be quite different to that for which the drug is prescribed. Clinical trial data may provide sufficient evidence to demonstrate that revenue is capable of reliable measurement but there will need to be a very careful assessment as to whether the population in the trial provides a meaningful basis to estimate efficacy in the market place i.e. there needs to be a very clear parallel between the clinical trial population and the 'real' market.

In addition there may well be some real practical difficulties in measuring outcomes for example:

- Several years may elapse before the outcome is known.

- There may be a structured tier of graded outcomes and associated payments.
- Collecting patient data may be difficult and costly.
- Performance amongst patient groups will vary

Depending on the nature of the arrangement, with time it may be possible to build up a sufficient record of outcomes such that a level of refunds / premiums can be estimated. To be able to rely on historical data one should be able to demonstrate that there was a stable and predictable level of refunds and that they can be subject to reliable estimation. Provided the other criteria for revenue recognition are met it may be appropriate to recognise revenue subject to an allowance for refunds. Such an assessment may be required for individual indications and may be very dependent on the terms of an individual arrangement.

The second aspect of reliable measurement is that it will be imperative at the outset of the arrangement that there is an agreed and clear basis for measuring performance. If this is not in place then not only will this present difficult commercial issues but there will be no benchmark against which to measure performance and no basis to measure revenue.

### Other practical matters

As revenue recognition is likely to be a key consideration for most pharmaceutical companies it will be important to ensure that the finance department has adequate input into the terms of any arrangement. Even if the revenue recognition issues noted above cannot be avoided they can be minimised and they need to be clearly understood at the outset of the arrangement by all the relevant parties.

### Summary

Pay-For-Performance is likely to become more common in the future. Outcomes based performance models are likely to present a challenge from a revenue recognition perspective and may be complex to administer from both a commercial and accounting perspective.

The basis for revenue recognition under a Pay-For-Performance arrangement will depend on the specific terms of the contract. It will be vital to consider when

the risks and rewards under an arrangement are transferred and whether the revenue can be measured reliably.

While there will be contract specific considerations we believe that in general revenue should not be recognised on an outcomes based performance model unless all the following criteria are met:

- There is a clear and contracted basis for measuring performance/outcomes.
- There is robust evidence to support any estimate of outcomes, efficacy and potential return/refunds. This may only be available through a historical track record of outcome data and in many cases clinical trial data will not be sufficient to support revenue recognition.
- There is a clear and demonstrable transfer of risks and rewards.

Unless a floor price mechanism is in place it may be that revenue will need to be deferred until the specified outcome has actually been achieved or reliably estimated and there is no potential for a refund.

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