

The New PPRS

The new PPRS scheme, effective from January 2014, represents a major change of process for the pharma industry, as the DoH's cost-recovery programme for pharmaceuticals has moved from a simple periodic price reduction approach to one employing caps to limit overall growth of the UK drugs bill, with manufacturers paying monthly levies at set national percentages of their UK sales. The scheme is interesting on many levels, including the new provisions that have been included and also the discussed initiatives which have not been incorporated and those which have carried over from previous PPRS arrangements.

No Value Based Pricing

One main feature of the new arrangements is the absence of Value Based Pricing (VBP), which the current government had intended to effectively supersede the PPRS with from January 2014. VBP, which was to take health technology assessment (HTA) into account in price determination, was so fraught with technical problems that it was never likely to replace the PPRS by 2014 as the DoH had originally declared (and has since tried to distance itself from). However, it is to be applauded that the significant amount of work done on VBP has not been wasted, as it is now (as the rebranded concept of "Value Based Assessment," VBA) scheduled to be applied to effect more enlightened HTA by NICE. VBA and how it may effect NICE decision-making is currently out for public review, with comments to be received by June 20, see link below.

<http://www.nice.org.uk/getinvolved/currentniceconsultations/MethodsOfTechnologyAppraisalConsultation2014.jsp>

Rebates replace Price Reduction

The main difference between this 2014 PPRS and previous agreements is that the NHS cost-saving mechanism has been fundamentally changed, so instead of a cross-portfolio list price reduction every 5 years, we now have a system of a cross-industry cap on sales growth with quarterly cash rebates paid to the NHS by each scheme member, initially representing 3.74% of companies' net sales on qualifying products.

Although the calculations are very complicated, for the manufactures they will just have a single % figure they will need to calculate the size of the rebate each quarter. What will be more complicated is interpreting the exclusions criteria to figure out which drugs are excluded/included for the purposes of the rebate, as there are a number of detailed provisions.

There are several issues related to this new methodology. Small firms appear to have been hit hardest as under the former PPRS, if a company's sales were <£5m at the start of the agreement, it would have been exempted from the price reduction for the whole 5 year period. Furthermore, if a company's sales were say £5.5m, then the reductions would have only been applied to the sales over £5m, in this case just £0.5m. However, under the new PPRS if the company sales exceed £5m in any year of the scheme, then not only will the rebate be triggered, but that rebate will be based on 100% of the sales value, not just the increment above £5m.

Also, drugs excluded from the new rebate arrangements include newly-launching drugs (launched after December 31 2014) according to clause 3.7, although their sales value will be included in the DoH's calculations for UK sales and growth (which dictates the size of the rebate that PPRS members must pay each quarter). This means that pharma companies with established portfolios will effectively be subsidizing companies with more innovative products, by picking up the tab for their contribution to the overall UK pharma market. This does seem somewhat unfair.

Principal Features Carried Over

It is to the DoH's and the ABPI's credit that the new PPRS (as with previous versions) eschews international reference pricing (IRP), a discredited and irresponsible mechanism used in many other European countries as part of their drug price-setting process. Put simply, it is inappropriate that higher GDP countries lower their prices to those seen in lower GDP countries, as this applied over the long term will inhibit those wealthier markets from making a fair contribution to international research and development, which would be to everyone's benefit. Simplistic IRP fails to take into account the value of a technology in that particular market, more detailed methods of HTA, such as are seen in France and the UK, are better able to assess value in the context of price.

It should also be noted that the DoH has continued to buck the trend seen in many other countries where the processes for drug pricing and value assessment (reimbursability) are effectively one in the same, carried out by the same governmental body. It is clear that long term British (or at least English/Welsh) policy is to maintain NICE as a secondary stage to PPRS in terms of establishing (net) drug price levels in the UK. This 2-stage, devolved approach is not without its own problems, and to a certain extent VBP was one way that some of the inherent issues could have been addressed, but it is clear that it is here to stay.

Patient Access Schemes and Discount Arrangements

In the past PAS programmes, agreements at product level to effectively restrict the costs to the NHS for acquiring certain medicines, have been the exception and not the rule, as only some drugs went through a formal NICE appraisal and only some of these went on to have a PAS, mostly when NICE determined that without a PAS, and at the list prices stated under the PPRS, the drug would not be considered cost effective and so would not be covered by the NHS.

The very detailed attention provided in the new PPRS agreement to Patient Access Schemes (PAS provisions cover 8% of the main document) imply a clear expectation by the DoH that in order to comply with NICE's cost per QALY threshold of £20,000, manufacturers are in many cases going to be obliged to provide a level of price-lowering discount because the 'natural' price level, considered acceptable in mainland Europe, will be adjudged too high for NICE for the UK. Thus, the increasing use of PAS is seen as predominantly a response to NICE appraisals consistently failing to recognise a drug's value as assessed by other European countries. Perhaps the solution is a fairer and more realistic appraisal by NICE (with a relaxation of the QALY threshold which seems increasingly out of line with how other countries are assessing the value of a drug) and thus doing away with the need to run complex, and both difficult and costly to administer PAS programmes.

[The recent comments by NICE's chairman David Haslam speak to NICE's discomfort in compelling itself to make difficult decision. He wants pharma companies to be more transparent about the price levels which they propose, thus enabling NICE (presumably) to approve reimbursement for high-cost medicines as long as it understands why they are high cost. How such considerations would manifest in NICE's standard review procedures has not yet been clarified.]

A major factor relating to PAS is the confidentiality of the discount level. Given that a main rationale for such schemes is to maintain a higher list price than transaction price (so that the manufacturer agrees a price that NICE is prepared to grant reimbursement for whilst at the same time not damaging prices abroad through IRP to the 'low' net UK prices), then this will only work if the referencing countries use NHS list prices (as printed in the BNF, MIMS and Chemist and Druggist for instance) and not the post-PAS transaction prices. However, it does not seem clear from clauses 5.45-5.46 in the new PPRS just how confidential the PAS scheme details will now be. If other European countries which reference the UK can easily access the PAS scheme details and modify down the UK price in their reference baskets accordingly, then the 'game' is effectively up and one the main reasons for the PAS is removed, compelling manufacturers to think harder about the financial benefits of launching new drugs in the UK and compelling NICE to reconsider the level of price it is prepared to grant reimbursement for in order to ensure that new drugs are launched in the UK.

Orphan and Rare Disease Drug Pricing

It is notable that there is still no clear provision for an exceptional process for dealing with the prices of potentially expensive drugs for orphan and rare diseases. It seems that responsibility in this area will be placed with either the new Rare Diseases Advisory Group (RDAG) committee (responsible to NHS England) and/or NICE, but the former has not yet established its terms of reference and NICE's recent (3 March) pronouncement on eculizumab (Soliris) in atypical Haemolytic Uraemic Syndrome suggests that it is formulating policy on a case by case basis, which is far from satisfactory.

Andrew Dillon, NICE's Chief Executive, recently stated that "drugs for very rare conditions that affect just a few people in the country are inevitably more expensive than for more common diseases with companies having to recover their costs at much lower volumes", but there are no formalised benchmarks for what level of R&D cost is considered acceptable to support an NHS price of £x and hence it remains unclear what the companies would need to demonstrate in order to support their prices. Clearly, expensive medicines with a budget impact of >£100k / year require some degree of formal review and assessment, but the age-old problem with R&D for drugs for orphan diseases with so few patients (<5 per 10,000 population), is the degree of flexibility that should be granted on price as the regular HTA tools cannot work given that prices may simply have to be disproportionately high to incentivise and reward the manufacturer for its R&D and risk. It is important to note that there are only about 68 drugs like eculizumab which have such orphan drug status and are approved by the European Medicines Agency.

With the PPRS not addressing this issue, it may be that the best way forward is to have RDAG provide guidance on this, but its terms of reference will only be finalised once the full committee and chair are appointed (April/May 2014) and so it remains to be determined how orphan and rare disease drug pricing will formally be evaluated for the NHS in England in the short-medium term.

UK vs The Regions

With VBP, an issue which would have needed to be dealt with was Scottish drug pricing, as with VBP either the SMC's role would have needed to change significantly or, rather implausibly, Scotland require separate drug pricing to the rest of the UK. Under (English*) VBP this would have been addressed, but with VBP now abandoned, the UK-wide PPRS and devolved HTA arrangements will continue and will only be reviewed again within the next 5 years if the Scots vote for independence in September 2014. (*it was never 100% clear whether VBP would apply to the whole of the UK or just England, Wales and Northern Ireland).

Exclusions

It is helpful for the pharma industry that branded generics and biosimilars remain within the scope of the PPRS, where freedom of pricing remains for these and all NCEs. In some other countries these drugs do not have freedom of pricing but their prices are set at a fixed percentage of the branded original version. By including biosimilars in the PPRS, the DoH is recognising that these drugs are fundamentally different to generic drugs and that market competition will effectively influence price levels.

Recognising and Rewarding Innovation

Whilst it is stated in the PPRS agreement that one of its tenets is the support of R&D innovation through the IHW (Innovation, Health and Wealth) initiative, referred to in clause 4.11 of the new PPRS, the rigorous application by NICE of a cost per QALY threshold of £20,000 has been seen to run counter to this ambition. With VBA, which may incorporate an innovation consideration as VBP had originally been planned to include, NICE is more likely to be able to adhere to the principals of IHW, but with its standard appraisal approach, many observers have suggested that R&D innovation is not adequately dealt with.

Opportunity for UK Price Increases

Flexible Pricing, a provision of the PPRS which provides the opportunity for a manufacturer to increase prices, has been greeted with collective cynicism, partly based on the fact that no increases have been granted so far (despite the same provision being available in the past). The industry is very sceptical that price increases would be granted if good data becomes available at some time after launch and due to the irresponsible practice of international reference pricing in other countries, a 'low' UK launch price is unlikely to be sanctioned under the circumstances that a price increase could be anticipated based for example on expected outputs from ongoing clinical studies.

Also related to price increases, clause 5.23 in the new PPRS suggests that if a drug is granted a new indication, there is provision that it could have a higher price than its established price. The regulation states that under such circumstances, the manufacturer would need to offer a discount for any subsequent sales of the drug for the original indication so its purchase price remains the same. Needless to say, and especially with single branding, from a pharmacy and administrative perspective this would raise enormous processing issues.

In past PPRS agreements price modulation was quite important, with companies tactically increasing/decreasing prices but maintaining the same overall DoH cost recovery contribution through the price reduction. It is considered that such movements, still allowed for under the new PPRS, will be much less common going forward as such movements will not affect the levy amounts and companies have in many cases already made the portfolio price adjustments for those products which were out of line.

Reporting Procedures

The threshold at which a company needs to supply an Annual Financial Return (AFR) has been reduced from £50m to £35m, and the DoH will only be asking 20% of such companies to complete a full AFR, so the administrative burden of producing these very detailed reports will be considerably lessened.

Statutory vs Voluntary Scheme

As before, there are still the two options for companies selling medicines in the UK, membership of either the voluntary scheme (with the provisions as described in the article) or the statutory scheme. Under the statutory scheme, instead of the rebate process, the DoH will manage cost containment through a 15% reduction of list price on companies with sales >£5m. It is a single reduction to cover the 5 year period. Previously, the scheme was mainly used by smaller companies with a mostly hospital drug portfolio where there would be a certain amount of discounting negotiation downstream from the list price. The DoH is now looking at changing the statutory scheme to a reduction in the net sales price, so if this were to happen, it is likely that more companies would move into the voluntary scheme.

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