The New UK Pharmaceutical Price Regulation Scheme: Just What the Office of Fair Trading Ordered?

The UK's new price regulation scheme contains some welcome innovations, but it remains to be seen how they will work in practice, says *Elisabethann Wright.*

The United Kingdom's Pharmaceutical Price Regulation Scheme, which covers all branded licensed medicinal products sold through the National Health Service, has been renegotiated and the revised scheme came into operation on 1 February 2009[1-3]. It contains several new features, including flexible pricing and patient access schemes, and while these are to be welcomed, in practice they may be difficult to operate.

Products covered by the PPRS include vaccines, *in vivo* diagnostics, blood products, dialysis products, branded medicinal products supplied through tendering, off-patent branded medicinal products and biologics.

The newly negotiated scheme has had an eventful history. Its revision was partly a result of a study into the functioning of the PPRS launched by the Office of Fair Trading in 2005[4]. In its report published in February 2007, the OFT recommended that the PPRS be reformed with the aim of delivering better value for money from NHS expenditure on drugs and focusing business investment on those medicinal products with the greatest benefits for patients[5].

The study identified a number of products where the OFT considered prices to be significantly out of line with patient benefits. It highlighted the fact that some medicinal products currently prescribed in large volumes were up to ten times more expensive than substitute treatments that delivered very similar benefits to patients.

The OFT recommended that the existing profit-cap and price-cut scheme be replaced with a patient-focused, value-based pricing scheme, in which the prices the NHS paid for medicines reflected the therapeutic benefits they brought to patients. It concluded that this would enable the NHS to obtain greater value for money from its existing spending on medicinal products.

In May 2008, the OFT published a further report in the form of a market study into medicines distribution[6]. In that study, the OFT expressed concerned about the impact that direct-to-pharmacy schemes had on the discounts companies provided on the list prices of pharmaceutical products. In the view of the OFT, diminished discounts would have an impact on the functioning of the PPRS in its then current form.

Despite its concerns over the direction that pricing in general and the PPRS in particular seemed to be heading, the OFT considered that the PPRS should be retained. It concluded that the best and most appropriate way of dealing with concerns arising from the DTP schemes, and reductions in the number of wholesalers, was to enhance the PPRS so that it could accommodate different distribution methods. In the context of the renegotiation of the PPRS, the OFT recommended that the UK government should change the scheme to ensure that discounts currently obtained by pharmacies were safeguarded. While a practical approach, this conclusion was arguably somewhat at odds with the OFT's previous, somewhat critical, approach to the scheme.

The new PPRS is still essentially the profit-cap and price-cut scheme that was the subject of the original OFT study. In keeping with its predecessor, it permits companies to maintain their freedom to determine the price of new products and to modulate prices. However, the system also introduces a 3.9% price cut on medicinal products sold to the NHS. The price reduction applies to the NHS list prices of all products on the market as of 31 December 2008 and for all companies with NHS home sales of branded pharmaceuticals above £5 million in their financial year ending in 2007.

For companies with sales of £25 million or less in 2007, the first £5 million sales will be exempt from the price cut. However, a further price cut of 1.9% will be introduced in January 2010, with further price adjustments foreseen in January of each year.

The new PPRS includes provisions intended to support innovation so patients have faster access to new medicines that are both clinically and cost-effective. It also introduces new and more flexible pricing arrangements that will enable pharmaceutical companies to supply medicinal products to the NHS at lower initial prices, with the option of raising prices if value is proven at a later date. Also envisaged is a more systematic use of patient access schemes by pharmaceutical companies to allow access to medicines that have not initially been assessed as cost- or clinically effective by the National Institute for Health and Clinical Excellence. Furthermore, subject to discussion with affected parties, the Department of Health will introduce generic substitution from January 2010.

There are undoubtedly innovative elements to the new PPRS. However, the scheme will not function in isolation. While some of the innovations are surely welcome, it remains to be seen whether they will function in practice, given the environment in which they will operate.

The horizon scanning process

The DoH intends to establish a single, unified horizon scanning process to identify new technologies in development by industry. This process will be developed in co-operation with NICE and various groups throughout the UK. It is expected that industry will play a full part in the design and development of a database to capture such new technologies. However, the actual benefit of the process, in particular the extent to which it leads to the practical application of new technologies, may depend on the manner in which it can interact with both the existing NICE process and some of the new policies foreseen in the revised PPRS.

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Flexible pricing

The new PPRS allows flexible pricing, whereby a company can increase or decrease its original list price in light of new evidence or a new indication. While this is welcome and attractive, it may prove difficult to operate in practice.

The PPRS foresees two circumstances under which flexible pricing may be relevant. These are:

- when significant new evidence is generated that changes the value of an existing indication; and
- where a significant new indication is proposed.

This suggests in principle that a certain flexibility in pricing will be granted to pharmaceutical companies, but it may not be the case in practice. The value of indications for medicinal products is notoriously difficult to demonstrate in any circumstances. Moreover, there is no definition of what will constitute the "significant new evidence" necessary to justify such a claim and a related price increase.

A number of issues will affect the ability of pharmaceutical companies to rely on the flexible pricing policy. These include the point in the life of a medicinal product at which a change in value is claimed or a significant new therapeutic indication is granted, or the current lack of guidance on the conditions needed to demonstrate such a change and entitlement to a related change in price. Moreover, flexible pricing will only apply when medicines are subject to NICE appraisal. A review by NICE will be required to determine whether the revised price provides value to the NHS.

For medicinal products not selected for NICE appraisal, flexible pricing will not be an option. A review of the potential to increase prices via modulation will, however, be a possibility.

The Patient Access Schemes

The Patient Access Schemes, another attractive element of the new PPRS from both the patient's perspective and that of industry, may also be difficult to apply in practice. These schemes are intended to facilitate earlier patient access to medicinal products that are not, in the first instance, found to be cost- and clinically effective by NICE. They will be proposed by a pharmaceutical company and agreed between the DoH (with input from NICE) and the company. The aim is to improve the cost-effectiveness of drugs so as to enable patients to gain access to them.

The arrangements for applying the Patient Access Schemes must respect the role of NICE in providing the NHS with an independent assessment and appraisal of the evidence relating to an intervention. They will also carry a variety of obligations and responsibilities that pharmaceutical companies must fulfil. Furthermore, it is not clear how far NICE will be prepared to cede its decision-making role, even if this is likely to be solely in the short term.

Generic substitution

The policy on generic substitution that is referred to in the new PPRS has not yet been elaborated in detail. The generic substitution requirement is increasingly common in other European Union member states. However, as with a number of aspects of the PPRS, obstacles may arise in reconciling generic substitution with other matters falling outside the application of the PPRS.

The current Royal Pharmaceutical Society Code of Ethics says that, except in an emergency, pharmacists should not substitute a specifically named product with another product without the approval of the patient/carer and the prescriber. Any generic substitution policy would need to take account of this code. This would be necessary irrespective of the fact that general practitioners in the UK commonly write prescriptions by international nonproprietary name. The tendency of practitioners to prescribe by INN is unlikely to appease at least some in the profession if their existing prerogative to prescribe by brand name is restricted by a nonbinding scheme concluded outside the scope of their practice.

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