

Making sense of medicines pricing

Until 2003, one thing was certain for those involved in setting primary care prescribing budgets in the NHS: that the amount spent on medicines would increase year-on-year, typically, by 10-12%, considerably higher than inflation. This all changed when the UK government, in order to curb this growth, decided to cap the price paid for four generic medicines: doxazosin, lisinopril, omeprazole, and simvastatin. Price cuts were imposed in December 2003, with further cuts in September 2004. In January 2005, reductions were made in the overall costs of branded medicines through the Pharmaceutical Price Regulation Scheme (PPRS). Then in April 2005, there was a further pegging of costs for a basket of generic medicines in order to fund the new pharmacy contract. This article seeks to explain these changes and to describe how prices are set for medicines in the NHS.

What is the Pharmaceutical Price Regulation Scheme?

Branded medicines are those still under patent protection and, therefore, usually marketed by a single pharmaceutical company. Costs to the NHS for most branded products in the UK are regulated through the PPRS. First introduced in 1957, this is a voluntary agreement between the government and pharmaceutical companies. It seeks to create a supply of medicines to the NHS at reasonable cost, but enable sufficient incentive to the pharmaceutical industry for sustained research and development. Every five years or so, the terms of the agreement are renegotiated with the Association of the British Pharmaceutical Industry (ABPI). The most recent scheme has resulted in substantial price reductions. All companies that supply branded medicines to the NHS may participate in the scheme; they do not need to be members of the ABPI. However, companies that choose not to participate can have price reductions imposed on them.

How does the scheme work?

Under the new PPRS, which commenced in January 2005, all companies that sold more than £1m worth of branded medicines to the NHS in 2004 have been required to reduce their prices by 7%. The previous scheme, which ran from 1999, had required a price cut of 4.5% (this scheme is reported to have saved the NHS £1.3bn by the end of 2004). Companies can make an across the board reduction of 7%, or make differential reductions between products equivalent to an overall reduction of 7%. An alternative arrangement allows companies to pay 2% of the price cut directly to the Department of Health (DH). The majority of companies choose to make differential price reductions on their products because they can make adjustments anticipating patent expiries, future market share, and competitor activity.

In the PPRS, the common profit target (which is not guaranteed) is a Return on Capital of 21% for each company. Companies can claim a number of allowances to offset against the calculation of their profit. The 2005 scheme has increased the allowance for research and development that companies can offset against profit to a maximum of 28% of NHS sales. There is some variation to provide incentives for innovation and for products with a paediatric indication. A marketing allowance covers the costs of all advertising, selling, and sales promotion of a company's medicines in the UK, and the administrative costs to support these activities. This is capped to impose some control on the extent of marketing permitted. There is an information allowance for the costs involved in the provision of factual information to healthcare professionals, and to government and health technology assessment bodies such as The National Institute for Health and Clinical Excellence and the All Wales Medicines Strategy Group. This allowance also includes the costs associated with producing Summaries of Product Characteristics and the provision of information and support to patients as permitted by law or the ABPI Code of Practice.

If a company exceeds its target profit by more than 40% then it must refund the excess profits, either as a lump sum to the DH, or as price reductions to the NHS. The scheme allows pharmaceutical companies to set the price of new active substances on entry to the market, with some caveats for line extensions and new doses of existing formulations. However, the price of any medicine cannot be increased without the approval of the DH.

Companies can discount sales of branded medicines to hospitals, but the DH expects that the company should take steps to counterbalance any overall extra cost to the NHS. This acknowledges that 'loss leading' via hospitals can stimulate subsequent use and uptake of medicines through primary care prescribing.

The PPRS is the subject of a market study being conducted by the Office of Fair Trading, which is due to be reported on early in 2007.

What about generic medicines?

Generic medicines are copies of pharmaceutical products that are no longer protected by patent. A generic medicine contains the same active ingredient as a branded medicine and is likely to have a similar, but not necessarily identical, formulation. In Wales, the rate of prescribing by generic name is now 80%; actual generic items dispensed account for 77% of prescribing.

Generic products do not come under the PPRS. Historically, manufacturers set the prices for generic products and the price that contractors were reimbursed (for services supplied against an NHS prescription form) was based on an average of prices from a range of manufacturers. This average price was set out in the Category A list of products in the Drug Tariff. However, this reimbursement did not always reflect the amount paid by the

pharmacy or dispensing surgery because, by discounting prices, manufacturers could make their products more competitive and increase profits for the contractors.

In April 2005, new arrangements for calculating the Drug Tariff for many commonly used generics came into force (the Category M product list). The intention of these changes was to link the reimbursement for some generic medicines more closely to the price actually paid. Put simply, this scheme was designed to reflect the average manufacturer's market price after discount rather than the Category A price before discount. The reimbursement price is calculated by the DH, based on information submitted by manufacturers and is set quarterly.

These changes were introduced as a part of the implementation of the new pharmacy contract for 2005-6 which has sought, at least in part, to separate payments to pharmacists from the profit they could generate from purchasing discounted medicines. The Category M prices have been adjusted over the year and have enabled the funding of new contractual frameworks and the development of services in community pharmacy. A knock-on effect has been to reduce the profits made from supply of generic medicines in dispensing practices, which means that dispensing doctors may now be tempted to prescribe more profitable branded products, at greater cost to the NHS. To reduce this risk, changes have been made to the General Medical Services contract with regard to the arrangements for dispensing doctors in England and Wales. Guidance that outlines what might be considered inappropriate or excessive prescribing has also been developed.

Where do "branded generics" fall?

A branded generic is an off-patent medicine that is sold and marketed under a brand name. Following consultation in early 2005, it is proposed that 'standard' branded generic medicines no longer be covered by the PPRS, but be transferred to the new arrangements for the reimbursement of generic medicines. This proposal would not include the original branded product or modified-release medicines that have different bioavailability profiles.

[What is the impact on general practice?](#)

The net effect of the price changes was a reduction in the cost of medicines in primary care for 2005-6 of 2.4%, but this varied across Local Health Boards depending on patterns of prescribing. This does not take into account cash repayments by companies directly to the DH. As these changes were realised after cash allocations and budget setting for this year, considerable funds were subsequently released. However, now that this system is in place and stability is developing, allocations for subsequent years will reflect these changes and medicines budgets will be tight. It remains unclear what price inflation for medicines will do over the next few years.

Information sources, references and further reading

- ◆ Faulding S. Bridging the gap: the national medicines bill – PPRS and impact of new price controls. *Pharmacy Management* 2005; 21(3). www.pharman.co.uk/cms/view.php/3542.html
- ◆ The Pharmaceutical Price Regulation Scheme 2005. Department of Health, November 2004. www.dh.gov.uk/pprs
- ◆ Studies – Pharmaceutical Price Regulation Scheme. Office of Fair Trading 2006. www.offt.gov.uk
- ◆ Changing the arrangements for dispensing doctors in England and Wales. British Medical Association 2006. www.bma.org.uk/ap.nsf/Content/revisionnGMSFeb20062~chap4dispensing

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