The Pharmaceutical Services Negotiating Committee's Final Response

to

The DH Consultation on a Statutory Scheme to Control the Prices of Branded NHS Medicines

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Introduction

PSNC represents pharmacies providing NHS Pharmaceutical Services and our response therefore reflects the implications of the proposals for community pharmacy contractors. It addresses issues not specifically addressed in the consultation but which must be taken into consideration when decisions are made.

Responses to Consultation Questions

Consultation Question 1: The proposed level of price cut and the date from which it would apply

There is an agreement in place between PSNC and the Department of Health to address the consequences for contractors of the reduction in stock value following a reduction in list prices. Under the agreed price change mechanism, for proprietary preparations and Part VIII products where the price is based on a proprietary product, a price change up to and including the 8th of a month is applied for reimbursement purposes to prescriptions dispensed in the following month. For example, a price change on the 1st September would be applied by the PPD to prescriptions dispensed from the 1st October.

If the government decides to proceed with the proposed price cuts, it is essential for agreement to be reached that the price change mechanism will operate as normal in January 2009. Unless this is agreed and communicated, pharmacy contractors will be obliged to minimise stock holdings in the period immediately before the price cut takes effect. This has particular significance in the Christmas and New Year holiday period, when public holidays and urgent patient needs routinely put pressure on the supply system. For this reason January is the worst month in the year for a change to be made with the potential to affect stocks and patient access to medicines. If the government decides to proceed with its proposal, early confirmation that the price change mechanism will operate as normal is essential.

Question 2: Proposal to set prices of out of patent branded medicines at a price that is 1.5 times the reimbursement price of the equivalent generic price

PSNC is extremely disappointed that the consultation paper does not address the issue of off-patent brands (originator and non-originator), being prescribed to undercut the prevailing Category M price. This practice has grown substantially in recent years and the proposals as they stand are likely to further encourage branded prescribing which does not serve the interests of community pharmacy contractors, the NHS or tax payers.

'Standard Branded Generics'

The Department of Health has published two consultation papers in recent years relating to 'standard branded generic medicines', to which PSNC responded, the most recent being in October 2005. Action in the light of these consultations was deferred whilst the Office of Fair Trading undertook a review into PPRS, and now appears to have been abandoned.

In its response dated 25 October 2005, PSNC supported the proposal that 'standard' branded generic medicines should be removed from the PPRS arrangements. The practice of applying brand names, other than by the brand originator or its successor, represents a major distortion of competition in this market. The PPRS scheme is structured to allow

manufacturers to have prices that reflect their work in research and development, and this does not apply in the case of the branded generic manufacturer.

Some branded generic manufacturers sell their brands into the market at prices that, of necessity, include the costs of their marketing efforts with PCTs and prescribers; costs not incurred by "true" generic manufacturers. Branded generic manufacturers have no incentive to compete with other manufacturers of the generic in the discounts offered, therefore they are able to set their list prices lower than those of the equivalent generic drug because they are not contributing, or are contributing only at minimal level, to the delivery of the agreed level of purchase profit that is part of the pharmacy contract funding arrangements.

Another emerging practice is where branded generic manufacturers have undertaken to provide rebates directly to PCTs if their branded generic product is prescribed. This also creates an incentive for PCTs to instruct prescribers to prescribe these products as they see this as a direct short-term saving for the PCT rather than considering the long-term consequences for the NHS. Again, manufacturers would fund these rebates by providing lower discounts to pharmacy contractors.

Off-Patent Originator Products

The practice of promoting prescribing of off-patent originator brands is equally prevalent. Many of the off-patent brands most commonly included in PCT branded prescribing schemes had their prices substantially reduced as part of manufacturer price modulation following the introduction of the 2005 PPRS agreement. In their recent report of PPRS, the OFT[1] also recognised that the PPRS rules on modulation have the potential to distort competition between off-patent brands and generics by creating the incentive for a multi-product company to increase the price of products which are relatively price insensitive and reduce the price, possibly to below marginal cost, of products which are relatively price sensitive.

The Impact of this Practice

For a PCT struggling to keep within budget, branded generic prescribing offers the potential to make short term savings on the reimbursement costs of certain products. But nationally, encouraging the prescribing of off-patent branded medicines will profoundly affect the competition that drives down prices in the generics market and will in the long term drive up costs to the NHS.

These practices act to limit competition and only benefit the manufacturers. In their report on PPRS, the OFT[2] confirmed their view that this practice increases costs to the NHS.

The funding basis for the new NHS Community Pharmacy Contract includes a guaranteed £500m retained purchase margin. This is being monitored by both the Department of Health and PSNC and is managed in part by agreeing and adjusting Drug Tariff prices. Access to purchase margins is monitored nationally so individual PCT policies which impact on access to purchase margins will lead to inequitable distribution of pharmacy funding. Ultimately, for some pharmacies this could lead to under funding and could in the long term damage the pharmacy network.

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[1] [1] The Pharmaceutical Price Regulation Scheme – An OFT Market Study; The OFT; Point 5.32; February 2007
[2] The Pharmaceutical Price Regulation Scheme – An OFT Market Study; The OFT; Point 5.31; February 2007

This practice also has an adverse impact on patient care for example delays in obtaining a particular manufacturer's product that is not stocked by the contractor's wholesaler or having to return a prescription to the prescriber where the product is unavailable. This was recently illustrated by the sudden discontinuation of Efcortelan (Hydrocortisone). The list price of the branded product was lower than the Category M reimbursement price of the generic equivalent. On discontinuation, care was delayed for those patients that had been receiving branded prescriptions whilst generic prescriptions were sourced from prescribers.

DH Proposals

The question in the consultation paper is misleading. It asks whether prices should "be set at a price that is 1.5 times the reimbursement price"; however the relevant paragraph refers to 'limiting' the price to a maximum of 1.5 times the reimbursement price of the equivalent generic medicine as set out in category M of the Drug Tariff. Likewise, in the Department of Health press release[3], announcing the consultation, it states the arrangement to link the price of out-of-patent branded medicines where generic equivalents exist will work in a similar way to proposals in the OFT's recommendations on the PPRS. However, to maintain the impetus for generic prescribing and to retain incentives for generics to enter the market, the OFT[4] made their view clear that the price should be above the Drug Tariff reimbursement price rather than allowing manufacturers the discretion to match the Drug Tariff price or set a lower price.

If manufacturers are able to set their list prices at or below the level of the generic reimbursement price, this is likely to intensify the problem of branded prescribing with the potential for other manufacturers to replicate the marketing practices of branded generic manufacturers in order to protect their market share.

The proposal as it stands would do nothing but encourage branded prescribing, damage the competitive generics market, undermine the basis for funding of community pharmacy and would drive up costs for the NHS in the long-term.

Any new arrangements must remove the incentive for prescribing by brand or manufacturer's name, other than on clinical grounds and include safeguards to ensure competition in the generics market. Options to achieve this include as proposed by the OFT, setting the reimbursement price for any branded generic or off-patent brand with readily available generic equivalent at a price higher than the Drug Tariff Category M reimbursement price with safeguards to ensure the product is available to pharmacies at or below the reimbursement price.

Another possible approach lies in developing a model for generic substitution that is appropriate for the UK market. Generic Substitution is permitted in a number of European Countries; for example it was introduced in Finland in April 2003. The introduction of the scheme was closely monitored and a detailed statistical analysis carried out. The scheme allows Finnish pharmacies to substitute a generic alternative with payment based on the dispensed product. The scheme was introduced along with changes to the reimbursement prices of generic medicines and brought savings worth approximately 5%[5] of the total cost

[3] Big progress in Government and industry drug price deal; Wednesday 18 June 2008 10:24
[4] The Pharmaceutical Price Regulation Scheme – An OFT Market Study; The OFT; Point 5.37; February 2007
[5] Reference: The Social Insurance Institution of Finland Press Release: ; 18th November 2003

of all reimbursed medicines. Research undertaken 2 years after the scheme was introduced indicated that month on month savings were being generated worth approximately 1.5 – 2%[6] of the total cost of all reimbursed medicines in Finland. In 2007, generic substitution generated savings of EUR 35.6 million[7] for consumers and the National Health Insurance Scheme.

Questions 3 & 4: Exemptions from the price cut and freeze and the mechanism be for price increases?

Although PSNC is not commenting directly on the mechanisms, it is essential that any such mechanisms are linked to and can respond promptly to changes in the market.

Question 5: Discounts

PSNC would support use of the list price for application of the price control. Under a statutory scheme it would be prudent to set the discount to be provided by manufacturers, either at the normal level prevailing in the market or within a band that takes into account recovery through the discount scale applied to pharmacies.

Recent changes made by manufacturers to their distribution arrangements, coupled with the level of the discount scale and volatility in the generics market have exposed substantial flaws in the present arrangements for provision of funding for community pharmacy contractors. The extent of instances when pharmacies dispense products purchased at prices above the net reimbursement price is now unsustainable.

In light of this, PSNC believes it is necessary for the Department to work jointly with PSNC to urgently explore options for amending the pharmacy funding arrangements in particular to consider the removal of the discount deduction scale or as a way of adding transparency to the prevailing level of discounts being offered, apply the discount scale (Part V of the Drug Tariff) only to branded medicines. The margins surveys conducted annually by the Department of Health and PSNC provide information that could be used to inform a revision of the scale.

Question 6: Information Requirements

PSNC supports the introduction of information requirements to allow the Department of Health to monitor price controls; this can be supplemented by the information available from the joint margins surveys.

Over the past year, there has been a substantial increase in the problems that contractors are experiencing in obtaining certain branded medicines. A particular problem has been manufacturer's quotas, introduced to better manage the supply of medicines and ensure patient access but instead leading to delays in patient care where stock hasn't been allocated correctly by the manufacturer or managed appropriately by the wholesaler.

Products that have been affected include Cellcept tablets 500mg (Roche), Co-Aprovel tablets 150mg/12.5mg (Sanofi), Cymbalta capsules 30mg and 60mg (Eli Lilly), Keppra tablets 500mg (UCB) and Zyprexa tablets 15mg (Eli Lilly).

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[6] Reference: The Social Insurance Institution of Finland; Generic Substitution Statistics: http://193.209.217.5/in/internet/english.nsf/NET/220703130721MP?openDocument
[7] The Social Insurance Institution of Finland, http://www.kela.fi/

Feedback from manufacturers suggests that at the heart of the current problems are changes in the European import and export market. A weak pound and strong Euro have reduced the benefits from using parallel imported products; increasing the demand for UK medicines. It has also increased the demand in other European countries for the export of UK medicines. We are very concerned that the current problems will be exacerbated by the impact of the proposed PPRS branded medicine price reductions in January 2009.

From a patient perspective, stock shortages and poorly managed quota systems can lead to delays in patient care and can result in increased visits to pharmacies to collect supplies of medicines when the full prescribed order is not initially available. PSNC has raised concerns with the Department of Health in the past about the practices of some manufacturers, for example, we have confirmed a number of reports of a commonly prescribed antipsychotic medicine not being readily accessible to some pharmacies because the manufacturer had inadequate contingency measures in place for when wholesalers had exhausted their quotas. This could have led to harm both to the patient and those around them.

Stock shortages and having to use manufacturer's emergency supply arrangements have an adverse financial impact on pharmacies. As well as increased costs caused by the increased workload burden in sourcing products; there may also be increased costs in procuring medicines for example delivery charges and wholesaler special order charges and in some cases contractors are being forced to pay multiple fuel surcharges to obtain stock from second line wholesalers. Of particular concern has been one key wholesaler's policy of not providing a discount to pharmacies where the wholesaler has exhausted their quota and a product has to be obtained through a manufacturer's contingency supply arrangements, resulting in the affected pharmacies having to dispense individual items at a financial loss, after discount deduction.

From the NHS perspective, shortages are costly. The increased costs to community pharmacy, outlined above, are passed on the NHS through the national community pharmacy funding arrangements. Where alternative products need to be considered by the prescriber, there are costs incurred through increasing workload in GP practice and the unavailability of a key medicine or decreased patient compliance with their medication regimen can also lead to the exacerbation of a patient's medical condition, increasing hospital admissions and associated treatment costs.

In order to protect the timely and efficient supply of medicines to NHS patients, as part of the 2009 PPRS arrangement and the statutory scheme, there should be information requirements placed on branded medicines manufacturers to allow the Department of Health to ensure the appropriate and continued supply of branded medicines to pharmacies so that the needs of patients are met. There is a need for the Department of Health, manufacturers, distributors and community pharmacy representatives to jointly consider, as a matter of urgency, what measures can be put in place to address supply issues including problems caused by manufacturer's quotas.

Question 7: Pricing of New Products
No comment

Question 8: Penalties
No comment