



**The Pharmaceutical Services Negotiating Committee's
Preliminary Response**

to

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

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Introduction

This is a preliminary response to the Department of Health Consultation on a Statutory Scheme to Control the Prices of Branded NHS Medicines; PSNC will send a further detailed response to questions 1 and 2 in September.

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

The proposal to introduce statutory measures to have effect from 1st September 2008, freezing prices at February 2008 list prices appears to PSNC to be a sensible and necessary measure to provide price stability in the event that a voluntary scheme is not concluded by that date, or to apply to companies that do not sign up to the scheme.

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.

The price of a small number of branded medicines has increased since February 2008; therefore to ensure contractors do not suffer financial loss as a consequence of the price freeze in September 2008, the price change mechanism should be applied as normal.

If the government decides to proceed with the proposed price cuts, it is also 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 in the light of the Office of Fair Trading's 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 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 OFT¹ 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

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

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 of the manufacturers. In their report on PPRS, the OFT² 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.

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 return a form to a prescriber where the product is unavailable. For example, a number of PCTs have been recommending branded prescribing of Efcortelan (Hydrocortisone) as the list price was lower than the Drug Tariff Category M reimbursement price. This product was recently discontinued with little notice resulting in care being delayed for many patients until a generic prescription for the product was provided.

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 release³, 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 OFT⁴ 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.

PSNC View

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.

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

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

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. We will respond further in our final response to this consultation.

In light of the misleading question in the consultation paper and statement in the related press release, we would be grateful for further clarification of the Department's proposals linked to off-patent brands in advance of the final consultation deadline.

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

PSNC believes it is sensible to incorporate provisions that would permit exemptions to be made where necessary to protect access to medicines, but does not have the expertise to propose a detailed framework for those exemptions. There seems to PSNC to be no reason why medicines should be excluded from the scheme because they are not POM, have a low price or are placed on the market by a small company. This applies equally to measures that would apply to 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.

In recent years there have been increasing reports of supply shortages and quotas being imposed by manufacturers on the volume of a medicine that a pharmacy can obtain. These supply issues have an adverse impact on patients, pharmacy contractors and the NHS.

From a patient perspective, stock shortages and quota supply 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.

From the NHS perspective, shortages can also be very costly. As well as the increased costs of sourcing alternatives, the unavailability of a key medicine or decreasing a patient's compliance with their medication regimen can lead to the exacerbation of a patient's medical condition, increasing hospital admissions and treatment costs.

Stock shortages can also 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 which are not always reimbursable, for example delivery charges or wholesaler special order charges. Some key wholesalers operate a 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.

It is predicted that these problems are likely to increase through changes in the European medicines import/export market following the proposed price reductions in January 2009. In order to protect and ensure the timely and efficient supply of medicines to NHS patients, PSNC believes that the Department of Health should undertake a review in conjunction with

manufacturers, distributors and community pharmacy to identify what measures can be put in place to address these supply issues.

Question 5: Discounts

PSNC would support use of the list price for application of the price control.

There is nothing in the paper to suggest that the Department of Health is considering a review of the maximum allowable distribution margin. In the last eighteen months many major manufacturers of branded medicine have announced changes in their distribution arrangements and terms of supply. PSNC would support a requirement that manufacturers be obliged to offer a minimum discount, but sees practical difficulties in giving effect to or monitoring this. 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.

The introduction of Category M in the Drug Tariff in April 2005 established a mechanism for regulating reimbursement prices of generic medicines. The discount scale is applied to generic medicines as well as to appliances, borderline substances and to branded medicines (other than those listed as products for which discount is not deducted). PSNC believes that it would add transparency to the prevailing level of discounts being offered if the discount scale (Part V of the Drug Tariff) was applied 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.

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 the light of these proposals PSNC believes it to be necessary to explore urgently options for amending the pharmacy funding arrangements.

Question 6: Information Requirements

Information should be provided by manufacturers; this can be supplemented by the information available from the joint margins surveys.

Question 7: Pricing of New Products

No comment

Question 8: Penalties

No comment