



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

to

**Department of Health Proposals to Simplify the
Reimbursement Arrangements for NHS
Dispensing Contractors**

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Introduction

The Department of Health has invited the Pharmaceutical Services Negotiating Committee (PSNC) and other organisations to respond to this consultation. In this response, PSNC sets out its views on the questions asked in the consultation and makes proposals for future arrangements that support the new community pharmacy contract. It is not therefore strictly confined to the issues raised in the consultation.

The Drug Tariff is issued by the Secretary of State for Health under powers in Regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005. It sets out the arrangements for funding providers of medicines and appliances in primary care. PSNC believes that the Drug Tariff should seek to secure two key objectives for the NHS:

- 1.** To ensure that patients receive the medicines and appliances that they need that are of the best quality, accompanied by the best information and provided as speedily as is possible;
- 2.** To ensure that the NHS gets the best possible value for money and the best possible service from the providers of medicines and appliances.

As the body representing the principal providers of medicines and appliances, community pharmacies, PSNC expects the Drug Tariff and any amendments to meet the following criteria:

- A.** The NHS obtains the medicines and appliances it needs;
- B.** Medicines and appliances are supplied on terms that offer good value for money to the NHS;
- C.** The terms are fair for contractors and support the funding arrangements agreed as part of the new NHS community pharmacy contract;
- D.** The terms support the best possible services for patients;
- E.** The system is as simple and as transparent as possible to administer.

PSNC strongly supports the aim of the Department of Health to simplify the reimbursement arrangements. The reimbursement rules have built up over the years and are now vast and complex so we welcome moves to increase transparency and make the rules easier to understand.

We need to ensure though that the revisions to the Drug Tariff support patient access to medicines, patient safety and the provision of patient packs where possible. The proposals as they stand, do not support this. There is also evidence that some elements of the proposals are likely to be abused to undermine the basis of the new pharmacy funding arrangements, some are contrary to key government health policy objectives and some will lead to substantial inequity of funding for pharmacy contractors. We explain these concerns in detail later in this paper.



Our greatest concern is the impact of the proposal to only pay pharmacies for the quantity prescribed where products are supplied in calendar packs. This is the proposal that will be the most damaging to patients as no contractor would choose to provide a complete patient pack, with its accompanying patient information leaflet, if only part of the pack will be reimbursed. Other proposals that introduce disincentives to dispense patient packs, such as the proposal to establish a Category M unit price for products based on volume weighted manufacturer's prices for all pack sizes, cannot be acceptable in an environment where patient safety has rightly assumed prominence in government health policy.

The proposals for changing the broken bulk provisions could be detrimental to significant numbers of contractors and affect supplies to patients. This issue could be better resolved by decreasing the number of occasions where contractors are left with residual stock, by allowing pharmacies to supply complete patient packs, unless there are clinical reasons why this is not appropriate.

We also advocate a comprehensive review of the system by which discount is deducted from the majority of dispensed items. In many cases, the level of the deduction is in excess of the discounts actually obtainable. This situation will be exacerbated by the implementation of the proposals to change the Zero Discount arrangements; the result could be to affect adversely the ready availability of medicines for patients.

The consultation states clearly that the overall effect of the proposals will be cost neutral. However, having examined in detail the individual proposals, we believe that a significant number of contractors whose businesses depart from the 'average', will be heavily penalised. PSNC cannot support changes to the current reimbursement arrangements that will have a substantial financial impact on any pharmacies.

PSNC is keen to work with the Department of Health on Drug Tariff simplification, but we believe that there are better ways to achieve the Department of Health's objectives than those set out in the consultation document. We have sought to propose positive ways forward. In preparing this response we have been acutely aware that the Department of Health wants to make changes swiftly, to ensure that electronic pricing systems can be put in place. We are committed to working with the Department of Health to identify solutions that do not compromise the interests of patients, the NHS or community pharmacy contractors.

Summary of PSNC Response and Proposals

A summary of the PSNC Response to each of the proposals can be found below:

Chapter One Effect of Simplification Proposals on Patient Pack Dispensing

The Department of Health must ensure that, so far as possible, all patients should receive their medicines in patient packs and the Department of Health must seek to remove all obstacles to achieving this.

Chapter Two Calendar Packs (Pay based on Prescribed Quantity)

PSNC believes that the only way that the Department of Health will realise the objectives set out in the consultation paper and achieve UK compliance with EC Directive 92/27/EEC is to ensure that pharmacy contractors can comply with the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 by reimbursing pharmacies based on the dispensed quantity for products considered to be calendar packs, and in due course, reimbursing pharmacies for the dispensed quantity where it is acceptable for pharmacies to 'round' to the nearest complete pack. In addition, PSNC believes that the calendar pack rules as they stand should be amended slightly to allow pharmacies to round to the nearest complete pack (rather than sub-pack) on every occasion, since the supply of a sub-pack will often result in failure to supply a patient information leaflet.

We noted that one objective of the consultation was to support the Prescription Pricing Authority (PPA) in coping with an increased number of pack sizes and are aware of concerns around parallel import products packaged in pack sizes that do not correspond with UK cartons. The PPA require a 'payment basis' for paying contractors regardless of whether they are reimbursing the contractor for the prescribed quantity or the dispensed quantity. We firmly believe that a system where payment is based on the dispensed quantity will be no more difficult to administer than a system where payment is based on the prescribed quantity. In any event, the 'convenience' or efficiency gains of the PPA cannot be used as justification for failing to reimburse pharmacy contractors accurately and fully, for products that have been supplied.

Chapter Three Category M

The proposal as it stands would result in a disincentive to dispense patient packs and is completely contradictory to the Department of Health's stated position in support of patient pack dispensing.

PSNC would support a unit price for Category M products where the basis of the price was volume weighted manufacturer's prices for patient packs.



Chapter Four Broken Bulk

PSNC suggests that the best approach is to move cautiously ahead, by permitting patient pack dispensing, with rounding and payment based on the dispensed quantity. This will reduce the need for broken bulk and we would be happy to reconsider with the Department whether there is a need to continue with individual broken bulk claims, once the impact of patient pack dispensing has been assessed.

Contractors must be compensated for the residual stock left when dispensing products in Part IXA of the Drug Tariff and special containers where the sub-pack has been granted special container status. Payments received to compensate contractors for residual stock should be identified clearly on the Contractor Schedule of Payment.

Chapter Five Zero Discount Lists

PSNC sympathises and supports some of the aims of this proposal but we believe that any change in the Zero Discount system must follow a comprehensive review of the discount deduction arrangements to ensure that contractors are not in the position that they must dispense products knowingly at a loss as this could affect adversely the ready availability of medicines for patients.

The criteria for entry into the Zero Discount list should be amended to allow PSNC to request exemption from discount deduction for a product where discount is not available from one of AAH or Unichem and the product has either a Net Ingredient Cost (NIC) of over £50 or is dispensed less than 500,000 times per year in England. Chemical reagents, appliances and products where a pharmacy is unable to secure a discount because the wholesaler incurs additional handling or storage costs in supplying a product should also be eligible for entry to the new list.

There must be an agreed system and timescale for processing requests for products to be added to the new Zero Discount List.

Chapter Six DH Proposal: Specials

PSNC is willing to work with the Department of Health to agree payment levels that will protect the supply to patients of the most commonly prescribed specials.

This work should include consideration of removing Category E from the Drug Tariff and restructuring and re-basing the extemporaneous dispensing fees at a level which includes a fair return to the contractor.



Chapter Seven Out of Pocket Expenses

For the reasons set out in detail later in our response, we do not support this proposal. It would have an inequitable impact on different pharmacies. We believe that there are other ways to achieve the Department's objectives, through changes being made already and as a result of the work PSNC is undertaking with the PPA.

Urgent consideration needs to be given to compensating contractors for expenses incurred in obtaining chemical reagents and appliances listed in Part IXA of the Drug Tariff.

Chapter Eight Common Pack List

PSNC opposes this proposal, but we believe that implementation of our other proposals, as set out in this paper, will do much to address the problems associated with the present arrangements.



Chapter 1: Patient Pack Dispensing

DH Proposal: Effect of Simplification Proposals on Patient Pack Dispensing

The proposal is to allow a dispensing discretion with regard to the quantity dispensed to enable a patient pack to be supplied.

1.1 Patient Pack dispensing offers benefits to patients, NHS pharmacy contractors and the government and PSNC firmly believes that it is vital that patients receive medicines in patient packs, unless there are clinical reasons why they should not.

Patient Pack Dispensing: Benefits for Patients

1.2 Patient pack dispensing allows products to be supplied in their original container, offering assurance to patients and contractors of the quality and integrity of products and reducing the chances of medicines becoming mixed or confused. One of the major problems with supplying sections of a manufacturer's blister strip ('snipping') is that cutting the blister strip to dispense the exact quantity prescribed runs the risk of information on the batch and expiry date of the product being removed so that the product cannot be properly identified. Pharmaceutical products made under the strictest controls can also have their quality jeopardised and their provenance undermined by 'snipping'.

1.3 Patient pack dispensing also ensures that a patient information leaflet (PIL) and the manufacturer's labelling giving relevant patient information is always included within the pack. This reduces the risk of confusion and ensures that patients always have the right information in order to take their medicines correctly, safely and effectively. Concordance with a medication regimen can be further supported by the use of calendar packaging.

1.4 There are clear patient safety benefits from the use of patient packs. The presentation of products in patient packs is far more distinctive than dispensing in bottles of uniform appearance, or in a white card skillet. This minimises the risk of patients confusing their medicines and inadvertently taking the wrong medicine or dose. It is also important to recognise that if the prescribed quantity has been dispensed by 'snipping' from a manufacturer's blister strip, or strips, the patient may be confused if they have several sections of a blister, especially if the original blister was a calendar pack, printed with days of the week.

1.5 Dispensing in patient packs allows patients to benefit from changes to manufacturer's packaging for example the recent EU directive requiring manufacturers to label packaging in braille and changes as a result of the National Patient Safety Agency's work with manufacturers to improve the design of patient packs. Modern packaging technology such as tamper-evident seals minimise the risk of medicines being tampered with as they pass through the supply chain, offering further assurance to patients and pharmacists of the integrity of the product. The use of intact patient packs with manufacturer's tamper evident seals can reduce the opportunities for counterfeits to be supplied.



Patient Pack Dispensing: Benefits for NHS Pharmacy Contractors

1.6 Patient pack dispensing offers NHS pharmacy contractors the potential to improve the efficiency of the dispensing process by minimising the need to split packs and it supports the introduction of robotic dispensing. Other new technology such as bar-code scanning can also be used to increase patient safety. For example, by scanning and recording the batch numbers of dispensed packs, it will be possible to target drug recalls effectively. Scanning can also be used to support technician checking by providing an electronic verification of the product being dispensed and by scanning a product's bar code at the point of dispensing, a check could be carried out on whether the product is out of date or counterfeit. These benefits can only be realised with the use of manufacturer's patient packs.

1.7 Council Directive 92/27/EEC (EU Labelling and Leaflet Directive) was adopted in March 1992 and was implemented in the UK by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994. All suppliers of medicines to the public, including NHS pharmacy contractors, have been obliged by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 to provide approved patient information leaflets with all medicines since 1 January 1999. In 2001, the Department of Health was criticised by the Health Service Ombudsman for failure to ensure arrangements to provide leaflets to patients. No progress has been made to resolve this highly unsatisfactory situation. Initiatives to support the dispensing of medicines in patient packs, wherever there are no clinical reasons why they should not, would support NHS pharmacy contractors in meeting their obligations under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994.

Patient Pack Dispensing: The Legal Position

1.8 During the past 12 years, PSNC has sought to work constructively with the Department of Health and other stakeholders, including other bodies representing pharmacists and owners of pharmacy premises as well as the pharmaceutical industry to find a solution that supports NHS pharmacy contractors in meeting their obligations to provide patient information leaflets. The solution, which the industry and pharmacy bodies are agreed on, is for medicines generally to be supplied in patient packs. This ensures that the patient receives a high quality manufacturer's container, properly labelled and with a patient information leaflet that complies with the Regulations. Unfortunately, the current reimbursement arrangements and the legal framework for the dispensing of medicines do not support this.

1.9 When the deficiencies of the current system were highlighted following complaints to the NHS ombudsman, alternative solutions were proposed by the Department of Health. These included photocopying or downloading leaflets or requesting additional leaflets from manufacturers. None of these suggestions are realistic options. Some patient information leaflets can be downloaded from the Electronic Medicines Compendium but this is not a comprehensive resource and the time-delay involved in contacting the manufacturer and waiting for an additional PIL to be posted to the pharmacy does not support the timely provision of information. PILs are often printed in non-standard sizes so it is often not practical to photocopy them and there are still questions about the legality of this practice under English copyright law. Poorly presented information, for example if the information is split over a number of photocopied pages could lead to confusion, compromise patient

safety and lead patients to question the quality of the pharmaceutical service they are receiving.

1.10 Despite the various attempts to try and implement a structured system of patient pack dispensing in the UK, we are still in the situation where over 30%¹ of medicines in the United Kingdom may currently be dispensed without a patient information leaflet or not in a patient pack. It is essential that this situation is rectified as soon as possible.

1.11 The MHRA is responsible for the enforcement of the 1994 Regulations but as a Department of Health Agency, is in the position of having to turn a blind eye to the deficiencies, at the expense of patient safety. This is not acceptable either for the patient, or for the reputation of the MHRA.

Patient Pack Dispensing: The Impact of the DH Proposals

1.12 Dispensing discretions could offer contractors the legal flexibility to synchronise the quantities of different medicines supplied to a patient. But unless pharmacies are reimbursed for the dispensed quantity, the reality is that pharmacy contractors will only dispense the prescribed quantity to ensure that they are not financially penalised and therefore the benefits of patient pack dispensing will not be realised.

1.13 PSNC is committed to working with the Department of Health where possible to realise patient pack dispensing. If agreement can be reached on reimbursement arrangements which support patient pack dispensing, PSNC is happy to offer support and give detailed consideration to the size of a potential dispensing discretion.

1.14 We believe that this initiative also requires the support and co-operation of a wide range of stakeholders. For example, we believe that the Department of Health should work with the pharmaceutical industry on the standardisation of pack sizes.

1.15 We accept that there will be occasions where there is a need for prescribers to restrict the dispensed quantity for example for psychotropic drugs, analgesics and for patients likely to abuse prescribed medicines. In these situations, contractors should be properly reimbursed for the quantity supplied and compensated for any residual stock. It will be essential for the Department of Health to work with organisations representing prescribers to improve general prescribing behaviour and encourage prescribing in patient pack quantities except in these defined scenarios. Consideration should also be given to how information from the NHS Drugs Medicines & Devices Dictionary (DM&D) is used in prescribing systems to support prescribing in complete packs.

1.16 If the Department moves this proposal forward, particular consideration will need to be given to parallel imports. The supply of parallel imports are opportunistic and although it has been agreed that parallel imports will be included in the NHS Dictionary of Medicines & Devices, it is not guaranteed that a particular PI will be listed in the dictionary at the time of dispensing. Contractors should be able to round to the nearest pack including to pack sizes that may not be listed in the PPA DM&D.

¹ Clear benefits for Patient Safety and Better Use of Pharmacy Resources; Pharmaceutical Journal, Vol 270, page 683 (17 May 2003)



Preventing rounding and thereby restricting the use of non-UK packs would be contrary to Article 28 of the EC Treaty.

PSNC Proposal

1.17 The Department of Health must ensure that, so far as possible, all patients receive their medicines in patient packs and the Department of Health must seek to remove all obstacles to achieving this.



Chapter 2: Calendar Packs

DH Proposal: Calendar Packs

The proposal is to allow the dispenser to dispense the calendar pack (or sub-pack) nearest to the quantity prescribed and pay them for the quantity prescribed

2.1 The case for promoting patient pack dispensing has been set out in chapter one. The proposal as it stands will not achieve the Department of Health's stated objectives to 'improve patient safety by reducing the number of occasions on which a patient does not receive the appropriate information leaflet with their medicines' or 'allow pharmacies to work more efficiently by reducing the number of instances in which they will have to add or remove tablets from a patient pack in order to dispense a prescription' and it will create a system which incentivises non-compliance with the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (EC Directive 92/27/EEC).

2.2 The funding arrangements for the new NHS community pharmacy contract have been designed to incentivise pharmacies to secure the best possible prices for the NHS. Pharmacies are encouraged to purchase at the lowest prices possible and the NHS through transparency of pricing and adjustments to reimbursement prices, benefits from this.

2.3 The proposals are susceptible to being used to undermine the new contract funding arrangements, creating substantial distortion of the arrangements at local level. This proposal will create an incentive for cash strapped PCTs to abuse the reimbursement arrangements to minimise their spend on drugs. For example, Ranitidine 150mg is currently available in a calendar pack of 60 tablets. If this product was always prescribed in quantities of 56 and pharmacies always rounded to the nearest pack of 60, under this proposal, the loss incurred to the pharmacy market through dispensing this product alone would be approximately £1.5m².

2.4 There is substantial evidence available that demonstrates how PCTs are manipulating the existing reimbursement arrangements, for example, through encouraging the use of branded generic prescribing³. Pharmacy contractors in over 20%⁴ of local pharmaceutical committee areas are currently affected by PCT policies to encourage the prescribing of products produced by the branded generic manufacturer, Discovery Pharmaceuticals. PSNC has no confidence that PCTs would not exploit the opportunity offered by the Department of Health's proposal to fix prescribing quantities to make savings in drug spending at the expense of NHS pharmacy contractors.

2.5 PSNC has also identified and reported in separate communications to the Department of Health, the activities of a small number of dispensing doctors,

² Calculation based on data from the 2004 Prescription Cost Analysis

³ Ref: PSNC Response to the DH Proposals for the Reimbursement of 'Standard' Branded Generics Medicines: A Further Consultation

⁴ Ref: PSNC questionnaire on branded generic prescribing, completed by Local Pharmaceutical Committees, November 2005



designed to undermine the profitability of pharmacies which have been allowed to open in controlled localities.

2.6 The averaging referred to throughout the consultation paper would be distorted by changes in prescribing behaviour and as access to the purchase profit agreed as part of the new NHS community pharmacy contract will be monitored nationally, individual PCT policies which impact on access to purchase margins will lead to local variations in funding through the new contract.

2.7 As stated in chapter one, if this proposal is adopted, pharmacy contractors will only dispense the prescribed quantity to ensure that they are not financially penalised and none of the benefits of patient pack dispensing will be realised.

2.8 This proposal will also introduce additional problems into the system, for example, patients may receive different quantities from different pharmacies depending on whether a pharmacy decides to round to the nearest pack or not. This could also lead to an increased workload for GPs who will more frequently be asked by pharmacies to change their prescribing to complete packs and it could damage local relationships at a time when closer working within the primary healthcare team is being encouraged. This would also undermine any proposals to allow contractors to synchronise the prescribing quantities of different products.

PSNC Proposal

2.9 PSNC believes that the only way that the Department of Health will realise the objectives set out in the consultation paper and achieve UK compliance with EC Directive 92/27/EEC is to ensure that pharmacy contractors can comply with the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 by reimbursing pharmacies based on the dispensed quantity for products considered to be calendar packs, and in due course, reimbursing pharmacies for the dispensed quantity where it is acceptable for pharmacies to 'round' to the nearest complete pack. In addition, PSNC believes that the calendar pack rules as they stand should be amended slightly to allow pharmacies to round to the nearest complete pack (rather than sub-pack) on every occasion, since the supply of a sub-pack will often result in failure to supply a patient information leaflet.

2.10 We noted that one objective of the consultation was to support the Prescription Pricing Authority (PPA) in coping with an increased number of pack sizes and are aware of concerns around parallel import products packaged in pack sizes that do not correspond with UK cartons. The PPA require a 'payment basis' for paying pharmacists regardless of whether they are reimbursing the contractor for the prescribed quantity or the dispensed quantity. We firmly believe that a system where payment is based on the dispensed quantity will be no more difficult to administer than a system where payment is based on the prescribed quantity. In any event, the 'convenience' or efficiency gains of the PPA cannot be used as justification for failing to reimburse pharmacy contractors accurately and fully, for products that have been supplied.



Chapter 3: Category M

DH Proposal: Category M

The proposal is to create one Part VIII Category M price for a chemical entity rather than differing relating to pack size

3.1 PSNC would welcome removing the need to endorse the pack size used for all Part VIII Category M products⁵ but is firmly against the proposal that the unit price should be based on volume weighted manufacturer's prices.

3.2 The effect of the proposal as it stands would be to penalise pharmacy contractors who are currently dispensing from patient packs as the price would be calculated proportionally using the price of both patient packs and bulk packs. Over time, more contractors will dispense from bulk packs to ensure that they do not lose out financially, moving the basis of the price further towards the price of the bulk pack.

3.3 This is a disincentive to dispense patient packs and is completely contradictory to the Department of Health's stated position in support of patient pack dispensing, where possible. The benefits outlined in chapter one of our response would not be realised, there would be increased patient safety risks in line with increased dispensing from bulk packs and the cost of running the NHS community pharmacy service would increase with a decrease in the efficiency of the dispensing process.

3.4 The system must incentivise, not act as a disincentive, to patient pack dispensing.

PSNC Proposal

3.5 Reimbursement prices must be set in such a way that pharmacies are not penalised financially for using patient packs. PSNC would support an arrangement where the Category M unit price is based solely on manufacturer's prices for patient pack sizes.

⁵ NB: PSNC's understanding of this proposal was that the unit price would be set for a particular virtual medicinal product (covering all product pack sizes) rather than a price per chemical entity (covering all possible strengths and pack sizes).



Chapter 4: Broken Bulk

DH Proposal: Broken Bulk

The proposal is to simplify the Broken Bulk arrangements by not allowing individual claims for medicines that are readily available and only allowing individual claims on other products where the residual stock exceeds a set limit. A monthly allowance would be paid to compensate contractors for residual stock.

4.1 The purpose of the current broken bulk arrangement is to ensure that contractors are reimbursed for residual stock, ensuring that prescriptions can be dispensed without the contractor being financially penalised.

4.2 Although a product is readily available, it may not be readily dispensed at the individual contractor level and if this proposal is adopted it will inevitably lead to certain contractors incurring financial losses depending on their dispensing volume and the prescribing habits of local prescribers.

4.3 The greatest impact is likely to be felt by those contractors with a large prescriber base or who open extended hours or offer an out of hours service. There is also likely to be a disproportional impact on independent pharmacies dispensing low volumes of prescriptions where it is less likely that residual stock will be used up through filling other prescriptions.

4.4 If contractors are faced with incurring a financial loss on dispensing an item, there is an incentive not to dispense and despite the Terms of Service requirement, this proposal could prejudice prompt supply to patients, damaging patient care and limiting access to medicines.

4.5 PSNC recognises that there is a cost to the NHS of processing individual claims for broken bulk and is committed to working with the Department of Health on ensuring future arrangements are as simple as possible to administer, transparent and compensate contractors appropriately and fairly for residual stock.

4.6 If the Department of Health moves forward with the proposal to pay contractors a monthly allowance, consideration will need to be given to how other changes to the reimbursement arrangements will impact on residual stock. Prescribing in patient pack quantities or authorising contractors to dispense and be reimbursed for dispensing in patient pack quantities, as discussed in Chapters One and Two, will logically decrease the number of times that pharmacy contractors are left with split packs. But, if the Department of Health implements the proposal to only reimburse contractors for the prescribed quantity when dispensing calendar packs, contractors are more likely to split packs when a part-pack is prescribed, ultimately leading to an increase in the volume and cost of residual stock.

4.7 Again, the averaging discussed throughout the consultation document could be distorted by local prescribing policies. Any policy that encourages prescribing in part-packs, where contractors are not reimbursed for dispensing complete packs, either through reimbursement for the complete pack or reimbursement for the part-pack and proper compensation for the residual stock will lead to financial losses for

contractors. Access to the purchase profit agreed as part of the new NHS community pharmacy contract will be monitored nationally so individual PCT policies which impact on access to purchase margins will lead to local variations in funding through the new contract.

4.8 If the proposal is implemented, changes in prescribing habits and other factors which impact on the size and cost of pharmacy residual stock must also be considered both in setting any allowance and increasing the allowance annually. In setting the limit for individual claims, consideration will need to be given to both the cost and dispensing volume of items.

4.9 At present pharmacy contractors are not reimbursed for the residual stock left over when dispensing items in Part IXA of the Drug Tariff. Under the Terms of Service, pharmacies are not contractually obliged⁶ to supply appliances that would not normally be supplied in the course of their business. In reality, this means that if a pharmacy is faced with making a financial loss on dispensing a Part IXA appliance, for example if only a part pack has been prescribed and the contractor will be left with a residual balance, the contractor can choose not to dispense the product; restricting patient care and access to the prescribed product.

4.10 A number of PCTs including Heywood and Middleton Primary Care Trust have issued prescribing advice to nurses to limit the quantity of appliances prescribed, in this case to 14 days supply. This practice has resulted in an increased number of prescriptions being written for part-packs, financially penalising those pharmacies that opt to support patient care by dispensing the product. We are disappointed that the Department of Health did not use the consultation as an opportunity to address this issue. PSNC strongly believes that, to ensure access to these products, NHS pharmacy contractors must be compensated for residual stock when dispensing appliances in Part IXA of the Drug Tariff.

4.11 PSNC also believes that pharmacy contractors should be compensated for the stock remaining when dispensing special containers where the sub-pack has been given special container status. There are only a small number of products which fall into this category, For example Prograf Capsules 5mg are packed in boxes of 50 capsules, packaged as 5 strips (sub-packs) each containing 10 capsules. The sub-pack is classed as a special container. If a contractor receives a prescription for 15 capsules or less, he will be reimbursed for 10 capsules. The manufacturer's list price for this product is £314.84⁷, so at present if the contractor cannot use the residual stock through dispensing other prescriptions for the same product, he would be left with a financial loss of £252. This anomaly could alternatively be resolved by only applying 'special container' status to complete packs.

4.12 One of the stated objectives of the consultation document is to make the reimbursement arrangements more transparent for NHS dispensing contractors. The Department would, in part, achieve this objective by listing the amount paid to each contractor to compensate them for their residual stock on the 'Schedule of Payments'.

⁶ Ref: The National Health Service (Pharmaceutical Services) Regulations 2005. Schedule 1; Part 2; 5.(2)(b)

⁷ Ref: Manufacturer's List Price, November 2005 (Pack of 50 Capsules)



PSNC Proposal

4.13 PSNC suggests that the best approach is to move cautiously ahead, by permitting patient pack dispensing, with rounding and payment based on the dispensed quantity. This will reduce the need for broken bulk and we would be happy to reconsider with the Department whether there is a need to continue with individual broken bulk claims, once the impact of patient pack dispensing has been assessed.

4.14 Contractors must also be compensated for the residual stock left when dispensing products in Part IXA of the Drug Tariff and special containers where the sub-pack has been granted special container status. Payments received to compensate contractors for residual stock should be identified clearly on the Contractor Schedule of Payment.



Chapter 5: Zero Discount Lists

DH Proposal: Zero Discount Lists

The proposal is to abolish the Zero Discount lists and introduce a limited list where the full Drug Tariff or manufacturer's list price will be paid

5.1 The changes made by GlaxoSmithKline (GSK) in April 2005 demonstrated how the PPRS arrangements and use of the Zero Discount system could be manipulated to the detriment of the NHS. This proposal seeks to deter others from following, and PSNC supports this objective.

5.2 At present the Zero Discount Lists offer protection to pharmacies by not clawing back discount on products where discount has not been received from the wholesaler or manufacturer.

5.3 There are a number of reasons why discount is not available when purchasing products. Wholesalers incur additional handling costs when moving products through the supply chain, for example:

- a) Controlled drugs (Schedule 1,2 & 3) require secure handling and strict record keeping throughout the supply chain;
- b) Cytotoxic and cytostatic drugs and hazardous chemicals including highly flammable products have safe handling requirements;
- c) Cold chain products must be stored and transported at a set temperature;
- d) Foodstuffs that have a short expiry date, for example, less than a month and live products, for example maggots, need to travel through the supply chain quickly with minimal stocks held by the manufacturer, wholesaler or pharmacy.
- e) Special order products, for example made to measure hosiery and special formulation products are manufactured to order so wholesalers and suppliers incur additional processing costs
- f) And certain bulky products have additional storage requirements at warehouses.

PSNC believes that where a pharmacy is unable to secure a discount because the wholesaler incurs additional handling or storage costs in supplying a product and is therefore unable to allow a contractor discount, the product should be exempt from discount deduction.

5.4 The other main reason why discount is not available is where a manufacturer has made a commercial decision not to offer discount, an example of this is the change in GlaxoSmithKline's trading terms in April 2005.

5.5 If the Department of Health's proposals are implemented, there is no guarantee that manufacturers such as GSK will change their trading terms to offer discount. Other manufacturers could also amend their terms to withdraw discount from contractors, which will exacerbate the situation. Discount deduction will be applied to these products and contractors will incur very substantial losses. If this proposal is



adopted there must be a change to the clawback mechanism to ensure that contractors are reimbursed appropriately for supplying these products.

5.6 Nationally we estimate that the loss to the pharmacy market of implementing the proposal as it stands to be over £50m⁸ but contractors will be affected in different ways depending on the prescribing habits in their locality. For example, Seretide Evohaler 250/25mcg costs over £50 per unit but has a prescribing volume of over 500,000 items per year in England so under the proposal, as it stands, this product would not be eligible for exemption from discount deduction. The loss to the pharmacy market from dispensing this product alone would be approximately £7.8 million, equating to almost eight hundred pounds per pharmacy. It is understandable that, despite the Terms of Service requirement to dispense medicines with reasonable promptness, in such circumstances, contractors will be reluctant to dispense such prescriptions, potentially damaging patient care and access to medicines.

5.7 There is also an issue that manufacturers and wholesalers can choose to offer different trading terms to their customers, for example one wholesaler may choose to offer discount and another may not. The current system offers contractors some protection in this scenario as products are eligible for entry into Zero Discount List B. To offer protection for contractors in the future and as it makes financial sense for contractors and the NHS, for contractors to only have an account with one full-line wholesaler, PSNC believes that the proposed criteria for entry to the Zero Discount list should be amended to allow PSNC to request exemption from discount deduction for a product where discount is not available from one of Unichem or AAH and the product has either a Net Ingredient Cost (NIC) of over £50 or is dispensed less than 500,000 times per year in England.

5.8 Consideration will have to be given to cases where a product is available in multiple pack sizes. One or more pack sizes may meet the criteria for exemption from discount deduction, for example the packs are priced at less than £50 but another pack of the same product may be priced at above the threshold price. For example, a single Gonal-F Vial 75iu (Serono) is priced at £22.31 but a pack of 5 vials is priced at £111.55. In this situation, we believe that a product should be eligible for exemption from discount deduction if one or more available pack sizes meet the criteria.

5.9 Some manufacturers, for example GSK, have chosen to offer discount only to certain contractors under 'product specific discount' schemes. When monitoring the levels of purchase profit available in the market, to ensure that the funding agreed as part of the new NHS pharmacy contract is available at the level of the efficient independent pharmacy, particular consideration must be given to the fact that discounts may not be available to all contractors.

5.10 At present there are a number of appliances including Coagucheck and Vacuum Pumps for erectile dysfunction where pharmacy contractors cannot obtain discount. The Department of Health has, to date, refused to add these items to the Zero Discount Lists. As stated elsewhere in our response to the consultation, under the

⁸ Calculation based on the difference between our estimate of the current value of drugs excluded from discount deduction and the value to the NHS in 2004 of products that would meet the criteria as it stands (Ref: PCA 2004)

pharmacy contractor's Terms of Service, pharmacies are not contractually obliged⁹ to supply appliances that would not normally be supplied in the course of their business. In the case of coagucheck, the reimbursement price for this product is £123.83¹⁰; discount is not available from the manufacturer or wholesaler so a contractor dispensing this product would make a loss of £13¹¹ per pack dispensed. The reimbursement framework for dispensing appliances must allow for items to be dispensed with a fair return for contractors otherwise contractors will not dispense these products, undermining patient care and limiting access. All medical devices and chemical reagents listed in Part IX of the Drug Tariff should be eligible for entry into the new Zero Discount list.

5.11 At present, PSNC makes requests for products to enter the list but it can take months and in some cases years for a clear response to be given by the Department of Health. This delay has a financial impact on contractors and is not necessary or acceptable. Good practice would suggest that requests should be accepted within one month of the application being made unless the Department disputes the basis for PSNC's proposal.

PSNC Proposal

5.12 PSNC sympathises and supports some of the aims of this proposal but we believe that any change in the Zero Discount System must follow a comprehensive review of the discount deduction arrangements to ensure that contractors are not in the situation where they must dispense products knowingly at a loss as this could affect adversely the ready availability of medicines for patients.

5.13 The criteria for entry into the Zero Discount list should be amended to allow PSNC to request exemption from discount deduction for a product where discount is not available from one of Unichem or AAH and the product has either a Net Ingredient Cost (NIC) of over £50 or is dispensed less than 500,000 times per year in England. Chemical reagents, appliances and products where a pharmacy is unable to secure a discount because the wholesaler incurs additional handling or storage costs in supplying a product should also be eligible for entry to the new list.

5.14 There must be an agreed system and timescale for processing requests for products to be added to the new Zero Discount List.

⁹ Ref: The National Health Service (Pharmaceutical Services) Regulations 2005. Schedule 1; Part 2; 5.(2)(b)

¹⁰ November Drug Tariff price for Coagucheck PT (48 strips)

¹¹ Calculation based on an average discount deduction of 10.5%



Chapter 6: Specials

DH Proposal: Specials

Proposal to list a reimbursement price (including out of pocket expenses) in the Drug tariff for the most common specials.

6.1 PSNC supports this proposal as long as a pricing framework can be agreed that meets the needs of specials manufacturers and includes funding at a level that ensures that products can be delivered to pharmacies in a timely, safe and secure way. This is essential to ensure that the changes do not make it difficult or impossible for patients to obtain supplies.

6.2 The products that the Department plan to list in the Drug Tariff must be available from a number of specials manufacturers at or below the Drug Tariff price to ensure that there is no increased workload on pharmacies in the procurement of products to dispense. There must also be an appropriate mechanism, for example an extension of the 'NCSO' scheme to ensure that pharmacies are properly reimbursed if there are price increases in the market and the product can not be obtained at the Drug Tariff price.

6.3 This change should coincide with changes to the extemporaneous dispensing fees set out in Part IIIA of the Drug Tariff. For those pharmacies that choose to dispense extemporaneously and have invested in appropriate equipment and have staff competent to undertake extemporaneous dispensing, there are benefits for both patients and the NHS for products to be prepared in the community pharmacy setting. Many simple preparations for example, straight-forward dilutions can be prepared more cost-effectively in the community pharmacy setting and patients could have their prescription dispensed on the same day that it was requested rather than waiting for a product to be delivered from a specials manufacturer.

6.4 At present, the extemporaneous dispensing fees set out in Part IIIA of the Drug Tariff do not meet the full costs of extemporaneous dispensing. The fees should be restructured and set at a level which includes a fair return to the contractor. PSNC would welcome the opportunity to discuss this further, and to use the funding models, including 'fair return', that were used to calculate the funding for the national pharmaceutical services.

6.5 As extemporaneous dispensing involves the manufacture of products, PSNC firmly believes that both the cost of ingredients and any extemporaneous dispensing fees should be re-charged to reimbursement monies (i.e. the drugs budget) rather than the New Contract funding arrangements.

6.6 PSNC accepts that some pharmacy contractors, based on a risk assessment have made the decision not to dispense extemporaneously and PSNC believes that no pharmacy should be forced, through the reimbursement arrangements to undertake extemporaneous dispensing. There are currently 20 products listed in Part VIII Category E of the Drug Tariff which must be dispensed extemporaneously and have a fixed reimbursement price. Almost half of these products were dispensed less than

50¹² times in England in 2004 and it is increasingly difficult to obtain the ingredients for some products such as 'Morphine and Cocaine Elixir'. Part VIII Category E should be removed from the Drug Tariff, giving pharmacies the option of extemporaneously dispensing a product or having it manufactured by a specials manufacturer.

6.7 We would also encourage the development of locally commissioned arrangements for specialist community pharmacy extemporaneous dispensing services such as pharmacies compounding homeopathic medicines or aseptically dispensing palliative care syringes in the community.

PSNC Proposal

6.8 PSNC is willing to work with the Department of Health to agree payment levels that will protect the supply to patients of the most commonly prescribed specials.

6.9 This work should include consideration of removing Category E from the Drug Tariff and restructuring and re-basing the extemporaneous dispensing fees at a level which includes a fair return to the contractor.

¹² Ref: Prescription Cost Analysis 2004. The Prescription Cost Analysis provides details of the number of items and the net ingredient cost of all prescriptions dispensed in the community in England. PCA data cover all prescriptions dispensed in the community, i.e. by community pharmacists, appliance contractors, dispensing doctors, and items personally administered by doctors.



Chapter 7: Out of Pocket Expenses

DH Proposal: Out of Pocket Expenses

Proposal to allow only out of pocket expense claims in excess of a set limit and to compensate contractors with a flat payment per month

7.1 Evidence suggests¹³ that there is an uneven distribution of claims by NHS pharmacy contractors for out of pocket expenses, in terms of both volume and value.

7.2 The number of out of pocket expense claims made by a pharmacy is wholly dependent on prescribing habits in a locality and the size of claims can vary greatly depending on what is being claimed and the supplier. For example, postage & packaging rates will vary depending on whether the product can be appropriately sent to the pharmacy using the standard mail service or whether a specialist delivery company must be used to ensure safe and secure handling of the product.

7.3 PSNC does not believe that a monthly allowance would be appropriate for out of pocket expenses. An averaging arrangement would lead to substantial losses being incurred by some contractors and there is a risk that, when faced with a financial loss through dispensing a product and not being reimbursed for the expenses incurred in obtaining it, despite the Terms of Service requirement, contractors will not dispense the product, damaging patient care and access to these products.

7.4 There is also a risk that if a level is set for claiming out of pocket expenses, for example if claims over £7.50 are accepted, some suppliers may manipulate the system by setting their prices at or above the threshold level which would increase the overall costs to the NHS.

7.5 Our understanding is that the driver behind this proposal is efficiency savings at the PPA. PSNC has been working constructively with the PPA on a system for declaring the total contractor claim for 'Out of Pocket Expenses' in a particular month on the FP34C Submission Document. This will be introduced in February 2006 with this information being scanned and processed electronically by the PPA, achieving one of the stated aims of the consultation, 'allowing the PPA to re-engineer its systems to make the optimum efficiency improvements from its Capacity Improvement Programme'. In light of this initiative, we do not believe that there are any additional benefits to be gained by implementing this proposal at this time.

7.6 At present, the first 10p of every out of pocket expense claim is not reimbursed. We believe that there is no valid or justifiable basis for this and for simplicity the restriction should be removed.

7.7 We would also note that anecdotal evidence suggests that out of pocket expenses are currently nationally under claimed, for example pharmacies could claim for the cost of telephone calls made in seeking to obtain a product but because of the workload involved in collecting invoices and identifying a particular call, this is rarely done. There are also occasions where a contractor will pass a prescription for

¹³ Ref: Rules Simplification: Summary of Out of Pocket Expenses/internal PPA document (11th March 2004)

payment before the invoice with details of the expenses incurred is received resulting in no claim being made and it is generally accepted that some locum pharmacists do not pay as much regard to claiming out of pocket expenses as contractors.

7.8 As with the proposals concerning broken bulk and zero discount, urgent consideration needs to be given to reimbursing contractors for out of pocket expenses incurred in obtaining products in Part IXA and IXR of the Drug Tariff. Contractors currently incur costs in obtaining products such as certain laryngectomy protectors and erectile dysfunction vacuum pumps. As pharmacies are not contractually obliged¹⁴ to supply appliances that would not normally be supplied in the course of their business, they can refuse to dispense these items. It is essential that contractors are properly reimbursed for the supply of appliances to ensure patient access and care.

PSNC Proposal

7.9 For the reasons set out here, we do not support this proposal. It would have an inequitable impact on different pharmacies. We believe there are other ways to achieve the Department's objectives, through changes being made already and as a result of the work PSNC is undertaking with the PPA.

7.10 Urgent consideration needs to be given to compensating contractors for expenses incurred in obtaining chemical reagents and appliances listed in Part IXA of the Drug Tariff.

¹⁴ Ref: The National Health Service (Pharmaceutical Services) Regulations 2005. Schedule 1; Part 2; 5.(2)(b)



Chapter 8: Common Pack List

DH Proposal: Common Pack List

Proposal to abolish the list of commonly used pack sizes and, where the contractor does not indicate which pack size was used, base payment on the pack size with the cheapest unit cost

8.1 At present, if a contractor has not endorsed a pack size, the PPA computer system automatically does a 'pack size assessment' to select the most appropriate pack size to base payment on. If a product is in the common pack list and unendorsed, the PPA base payment on the common pack size. If a product is not in the common pack list, and the quantity prescribed is the same as an original pack, payment is based on the original pack. If a product is not in the common pack list, and the quantity prescribed is not the same as an original pack, payment is based on the next larger pack size to the quantity prescribed.

8.2 Under the current proposal, contractors will be forced to endorse prescriptions with the pack size dispensed (other than products that are unit priced if agreement can be reached on an appropriate basis for this – see chapter 3) to ensure that they are properly reimbursed. This has serious implications for both workload and workflow. At present, 'labelling/endorsing' are normally undertaken at a different stage in the dispensing process than 'picking' the product from the shelf, for example the first step is often to produce labels, a dispenser may then go through the process of 'picking' the items from the shelf and note any additional endorsements required before the final check is carried out.

8.3 As we move towards the electronic transmission of prescriptions, endorsements will have to be made electronically so it will not be possible to just note additional endorsements by hand on the prescription. To ensure endorsements are accurate and to prevent accessing the computer more than once during the dispensing process, contractors would need to check what pack size was being used before labelling the item, slowing down the dispensing process and increasing workload.

8.4 We would also note that the PPA Position has been to discourage endorsing¹⁵ so this proposal contradicts current advice.

8.5 We accept that removing the common pack list would simplify the payment system by removing a section of the Drug Tariff that needs constant maintenance but we believe that the pack size assessment (without the common pack list) should be retained and the default should not always be the largest pack. Introducing unit pricing on Category M products will greatly decrease the number of occasions when the pack size assessment is required.

PSNC Proposal

8.6 We oppose this proposal, but we believe that implementation of our other proposals, as set out in this paper, will do much to address the problems associated with the present arrangements.

¹⁵ http://www.ppa.org.uk/pdfs/PressRelease_020703.pdf

