Proposals to simplify the reimbursement arrangements for NHS dispensing contractors: A consultation

CONSULTATION PAPER

PROPOSALS TO SIMPLIFY THE REIMBURSEMENT ARRANGEMENTS FOR NHS DISPENSING CONTRACTORS

Introduction

1. This document seeks views on proposals to simplify the NHS arrangements for the reimbursement of dispensing contractors for the items they supply in accordance with NHS prescriptions.

2. The proposed changes would apply in England.

Background

3. After an NHS dispensing contractor has dispensed an NHS prescription the contractor sends the prescription to the Prescription Pricing Authority (PPA). The PPA then calculates how much money the contractor will be paid. The payment to the contractor is made up of:
   - Remuneration: dispensing and professional fees for the service of dispensing the prescription; and
   - Reimbursement: the Drug Tariff or manufacturer's list price of the prescribed medicine minus where appropriate a discount.

4. The arrangements for the remuneration and reimbursement of dispensing contractors are set out in NHS Regulations or directions with details published in the monthly Drug Tariff.

5. While essentially reimbursement is (as outlined above) relatively simple with contractors being paid the Drug Tariff or manufacturer's list price minus (where appropriate) discount, over time detailed complex 'reimbursement rules' have developed.

6. The Department of Health wishes to simplify the reimbursement arrangements for pricing prescriptions to make the rules more transparent to dispensing contractors and to build in the ability to cope with increasing number of pack sizes while at the same time promote the use of patient packs. It will also enable the PPA to re-engineer its systems making the optimum efficiency from its Capacity Improvement Programme.

Patient Pack Dispensing

7. The Medicines Act 1968 states that dispensers must dispense "in accordance with" a prescription, and this is echoed in the NHS Act 1977. In practice dispensing contractors dispense and are reimbursed for exactly what was prescribed (with a few specific exceptions).

8. Traditionally, UK medicines were supplied in "bulk packs" of, for example, 1,000 tablets. When used for dispensing, the relevant amount tablets were repacked into a small container to meet each prescription. Although bulk

packs are still used, mainly for some generic medicines, it is now much more common for medicines to be supplied in smaller original (or patient) packs.

9. A ‘patient pack’ has never really been defined. However it is generally understood to be a pack made up of a carton with one or more blister strips (sub-packs) and a patient information leaflet.

10. Dispensing contractors often have to split original patient packs if they do not contain the exact quantity prescribed. This may involve removing whole sub-packs or “snipping” packs (e.g. if a strip contains 30 tablets and 28 are prescribed). The practice of snipping packs is particularly unpopular with dispensers as it is considered a waste of their time. Quantities of 28 and 30 are especially important for snipping because, although a “month” is often used as a base unit in both prescribing and patient pack sizes, there is no agreement on whether a “month” is 28 or 30 days.

11. Patient pack dispensing would mean patients receiving their medicines in manufacturers’ original packs containing a patient information leaflet with all the necessary labelling.

12. The Department of Health want to support the use of patient pack dispensing where possible, because of the benefits this will have for patient safety and because it will help us to make better use of pharmacists’ skills (less time will be spent ‘snipping’). We do, however, recognise that there will always remain occasions where patient packs are not appropriate, and where it is vital that the patient receives the exact quantity prescribed.

The Reimbursement Framework

13. The basic current principals of reimbursement are relatively simple.

- In the main reimbursement is based on what is prescribed (rather than what is dispensed). However there are several exceptions in particular with regard to the quantity, when the quantity prescribed might not be the quantity the contractor is paid, for example in the case of broken bulk and special containers (see below for details).

- It is not possible to pay a contractor exactly what they paid for a product. For example, they may have bought the product months ago for a different price to that now listed or they may have bought it with a large discount.

- The intention is that overall contractors should be reimbursed what they have paid plus in the case of pharmacy contractors an additional profit margin which, is used to fund the community pharmacy contractual framework.

- Reimbursement is generally based on averages, recognising that there will be some winning and loosing situations. Contractors are reimbursed the Drug Tariff price or the UK manufacturer list price for medicines and appliances, less (except for products in the Zero Discount lists) a deduction for the discount that it is assumed that they have obtained from the wholesaler or manufacturer.

14. Despite the relatively simple principles, the actual 'rules' applied to pricing prescriptions by the PPA processing staff are complex and made up of a combination of

    - Secretary of State determinations.

    - Requirements of the Prescription Only Medicines Order and the Misuse of Drugs Regulations.

    - Detailed rules developed ad hoc over the years to deal with specific issues that have arisen or to aid quick, accurate processing and avoid the need for the PPA to send prescriptions back to the contractor for clarification.

15. The main principal behind the DH simplification proposals is to continue paying for what is prescribed and reduce the number of exceptions.

16. This will result in a further move towards payments of averages with the potential to increase the number of winning and loosing situations but maintain the intention that overall the contractors should be reimbursed what they have paid (plus in the case of pharmacy the acknowledged retained profit margin).

17. There is no intention under these proposals to reduce community pharmacy contractors' overall retained profit margin on purchase of medicines and appliances. These proposals are to simplify the rules and make them more transparent.

Simplification Proposals:

Quantity

18. Currently the quantity reimbursed is the amount prescribed, with the exception of broken bulk, special containers and calendar packs. The aim is to reduce the number of times the PPA processing staff have to apply the exception rules and so increase the number of times payment is based on the quantity prescribed.

Broken Bulk

19. Current arrangements: If a prescription orders a smaller quantity than the smallest pack available and the contractor is unlikely to get another

prescription for the rest of the pack, the contractor will dispense this quantity, but can endorse the prescription 'Broken Bulk' and be reimbursed for the whole pack. Prescriptions for the same medicine within the next six months will be assumed to be taken from the remainder of the original pack until it has been used up, and will not be reimbursed. The PPA processing staff have to make a judgement that the pack size claimed for is the nearest/ appropriate to the quantity prescribed. The PPA processing equipment has to monitor all claims to see whether another claim for the same product is made within 6 months. Broken Bulk can currently be claimed for medicines, chemical reagents and some appliances.

20. Proposal:
    i. Individual claims will not be allowed on medicines that are readily available (for example products in Part VIII category A and M of the Drug Tariff)
    ii. Individual claims will only to be allowed on other products where the residual stock exceeds a set limit (to be discussed with contractor representative bodies). The 6 month rule to be retained.
    iii. A monthly allowance (to be discussed with contractor representative bodies) will be paid to compensate contractors for the occasions on which packs have been split but not fully dispensed and an individual claim is not allowed.

We would welcome views on the proposals to simplify the broken bulk arrangements.

Calendar Packs

21. Current arrangements: A 'Calendar Pack' is defined in the pharmaceutical terms of service as a blister or strip pack showing the days of the week or month against each of the several units in the pack'. When a product is packed in this way the dispensing contractor can dispense either the nearest pack or sub-pack available, with no need for endorsement and payment is based on the pack or sub-pack nearest to the quantity prescribed. If the pharmacist believes it was the prescriber's intention they can dispense the exact amount prescribed and endorse the prescription accordingly. Payment is then based on the exact amount prescribed. Processing staff have to recognise all calender packs and then, if the prescription is not endorsed, make a judgement on which pack (or sub pack) to pay based on the one nearest to the quantity prescribed.

22. Proposal: Pay for the quantity prescribed but continue to allow the dispenser to dispense either the exact quantity prescribed or the calendar pack (or sub pack) nearest to it. The intention being that there are times when dispensers will round up (and be paid for less than the quantity dispensed) but equally there are times when they will round down (and be paid for more than the quantity dispensed).

We would welcome views on the proposal to allow the dispenser to dispense the calender pack (or sub-pack) nearest to the quantity prescribed and pay them for the quantity prescribed.

Specials

23. Current Arrangements: Where a product needs to be extemporaneously made (i.e. made especially for a particular prescription), it can either be made by the dispenser, and the contractor paid for the ingredients and an extemporaneous dispensing fee, or the product can obtain from a Specials Manufacturer. The dispensing contractor is then charged by the manufacturer and is reimbursed the invoiced amount by the PPA; This often includes an amount for packaging and posting which is claimed as an out of pocket expense (see below).

24. Proposal: List in the Drug Tariff the top 150 (approximately) specials (i.e. products made especially for a particular prescription) and a reimbursement price. This listed price will include the out of pocket expenses so this does not have to claimed separately. The list will be the top 150 prescribed and the list price based on the average historic reimbursement price per 100ml plus an allowance based on historic payments for out of pocket expense. Prices will be reviewed annually and rebased as required.

We would welcome views on the proposal to list a reimbursement price (including out of pocket expenses) in the Drug Tariff for the most common specials.

Out of pocket expenses

25. Where out of pocket expenses, which exceed 10p, have been incurred in obtaining a product to fulfil a prescription the dispensing contractor is allowed to claim them by submitting the full details to the PPA.

26. Proposal:

    i) Individual claims up to a set amount will not be allowed but a monthly allowance (to be agreed with dispensing contractor representative bodies) will be paid to each contractor to compensate for the occasions on which out of pocket expenses have been occurred but not paid.
    ii) Out of pocket expenses exceeding the set limit can be claimed.

We would welcome views on the proposal to only allow out of pocket claims in excess of a set limit and to compensate contractors with a flat payment per month.

Commonly used pack size list

27. This list, which forms Part VII of the Drug Tariff, is used by the PPA processors to determine a pack size for reimbursement. Where there is a choice of pack size to pay from and pack size endorsement has been omitted the processor has to recognise whether the product is one listed in Part VII of the Drug Tariff and if so use the pack size listed as the basis for reimbursement. Where the product is not listed in Part VII the processor has to make an assessment and pay from the pack size nearest to the quantity prescribed.

    Proposal: to abolish this list and where there is a choice of pack size and a contractor does not indicate which was used, payment will be based on the pack with the cheapest unit cost.

We would welcome views on the proposal to abolish the list of commonly used pack sizes and, where the contractor does not indicate which pack was used, base payment on the pack with the cheapest unit cost.

Zero Discount Lists

28. Current Arrangements: Pharmacy contractors are reimbursed the list/Drug Tariff price of the item dispensed less a level of discount. However, where it is known that pharmacy contractors are unable to obtain a discount when purchasing a product, 'Zero discount' (ZD) status is applied and the discount is not deducted from the reimbursement of these purchases.

29. Products that attract 'Zero discount' status are shown in the Drug Tariff under two lists, List A and List B. Where a product can be obtained from at least one supplier with discount it goes onto list B, if the pharmacy contractor does not obtain a discount they need to endorse the prescription 'ZD'. If no supplier provides a discount the product goes onto list A and no endorsement is required.

30. By the very nature of having a ZD category and products on a list, contractors are not encouraged to seek out or negotiate a discount on these products. Particular peculiarities include foods, which may be obtained with a discount prior to being included on the Advisory Committee on Borderline Substances (ACBS) list[1],and then once approved, automatically receive ZD status. Furthermore, as products are added to the lists purely on the grounds of whether discount is or is not available, by not offering discount suppliers are in a position to determine the lists.

[1] In certain conditions some food and toilet products have the characteristics of medicines. The Advisory Committee on Borderline Substances (ACBS) advises as to the circumstances in which such substances may be regarded as medicines. The Advisory Committee's recommendations are recorded in the Drug Tariff, in the ACBS list. At present all items in the ACBS list are automatically on list A of the zero discount list.

31. There are valid reasons why suppliers may not feel able to offer a discount for example because they have incurred additional costs for distributing certain products such as those that have special handling requirements. These include items that require refrigeration, short expiry dates and cytotoxic and hazchem lines. However, these costs are borne by all suppliers equally and in the main need to be considered as part of the overheads of the supplier's provision of service.

32. However, due to the low volume supply of certain products (which results in inconsistent demand) and the NHS having additional supply requirements (e.g. supply critical even if out of hours) it is appropriate that certain products are reimbursed at the full list price with no discount removed.

33. It is proposed that the following changes should be implemented:

a. Abolish the ZD lists. The work on monitoring retained margins as part of the new community pharmacy contractual framework will in the main be able to take account of products where contractors are not able to obtain discount.
b. For products that require suppliers to incur extra costs and where either supply is not distributed evenly across all suppliers or suppliers are subject to additional requirements requested by the NHS, the inability of contractors to obtain a discount will not be easy to take into account in the work on monitoring pharmacy retained margins[2]. In these cases the full list price will be reimbursed.
c. A list will be maintained in the Drug Tariff outlining the products for which the full list price will be reimbursed and the discount clawback not applied. The list will contain
    i. All CDs
    ii. Products requested by the PSNC where all three of the following apply
        1. the manufacturer, Unichem and AAH do not offer pharmacy contractors a discount
        2. less than 500,000 items per year are dispensed for the product
        3. the average net ingredient cost per item is more than £50

            Note: There maybe occasion when this criteria is applied to a group of products rather than an individual product
    iii. The list will be regularly maintained. Where a product is dispensed over 500,000 times in a rolling 12 month period or its average net ingredient cost drops below £50 it will be removed. Products not dispensed in the last 12 months will be removed.

This proposal only applies to pharmacy contractors.

[2] In the majority of cases, the average amount pharmacies pay for products is lower than the reimbursement rate. During the negotiations over the new contractual framework for community pharmacy it was agreed that pharmacies would be able to retain a certain amount of this profit margin and that the money would be used to fund community pharmacy services. The Department of Health and PSNC will be monitoring whether pharmacies are receiving the expected amount of purchase profit.

We would welcome views on the proposals to abolish the zero discount lists and introduce a limited list where the full Drug Tariff or manufacturer's list price will be paid.

Category M

34. Current Position: For products that are listed in Part VIII of the Drug Tariff contractors are reimbursed the Drug Tariff Price. Where there is more than one pack size listed the contractor needs to indicate which pack size was used. In the event that the contractor does not indicate the pack size used, payment is based on the pack size listed in Part VII of the Drug Tariff (drugs with common pack) or if there is no pack listed there, the pack size nearest to the quantity prescribed.

35. While it is not intentional, this could be deemed to limit contractors as to which packs they dispense. It is appropriate that contractors dispense from a pack size that is best for the patient or proportional to the number of prescriptions they regularly receive for the product.

36. Prices for products in Category M of Part VIII are derived by
    a. Taking volume weighted manufacturers' prices to establish a product's relative price compared to others in the Category
    b. Applying a formula to the relative costs to produce a price for each product that if supplied at the same volume in the future will deliver the required level of savings/retained margin.
    c. Prices will need to be adjusted over time as new price data becomes available and volume changes.
    Prices are therefore based on what has actually been purchased for each pack size.

37. Proposal: For Products in Category M of Part VIII a single price will be established for all pack sizes by taking the volume weighted manufacturers' prices for all pack sizes of a particular entity, rather than considering each pack size separately. For Category M entries, contractors would no longer need to indicate the pack size used and there would be no implication that contractors are limited as to the pack sizes they can use for dispensing.

We would welcome views on the proposal to establish one Category M price for a chemical entity rather than differing prices relating to pack size.

Effect of simplification proposals on patient pack dispensing

38. It would not be possible to extend the current calender pack or special container to allow greater use of patient packs. The two main reasons for this are:

- the large PPA processing capacity required to apply calendar pack, special container or similar rules to recognise a patient pack and apply a judgement as to which pack to pay based on the nearest to the quantity prescribed is not tenable. While it may appear simple this judgement has to be made by a processor who has to be aware of the rule, when to apply it (i.e. that something is in a calendar pack, special container or patient pack), and all the available pack sizes in order to know whether an appropriate pack has been supplied. Due to sheer volume this is a large undertaking.

- the number of pack sizes is increasing with many packs now only available for a short period of time. This makes the rules even more difficult to apply and makes any wider application even less feasible.

39. Instead the Department of Health proposes that dispensers have a discretion to round the quantity ordered on a prescription, within certain limits (for example within 10 or 20%), in order to dispense a complete patient pack in the majority of cases.

40. The Department of Health proposes to enable this discretion for NHS prescriptions by indicating the discretion on the prescription form; there may also need to be changes to the regulations (and or directions) governing prescribers and pharmaceutical services. The prescriber will be able to override the discretion, so that the pharmacist will dispense the exact amount prescribed, by ticking a box on the prescription form.

41. A 10 or 20% discretion will allow pharmacists to dispense 28 tablets where 30 have been prescribed and vice-versa. This will remove most of the occasions when pharmacists have to snip packs to dispense the amount prescribed.

42. The pharmacists will be reimbursed for the quantity prescribed. As with the proposal for calender packs, this will increase the number of winning and losing situations however these will balance each other out and the total reimbursement payment will remain the same.

43. This will remove the need for the processor at the PPA to recognise whether a product comes in a patient pack and judge whether an appropriate pack size has been supplied. Furthermore, the dispenser will have the flexibility (so long as staying within the confines of any quantity dispensing discretion) to supply whichever pack is most easily available to them.

44. This proposal does not need to apply to dispensing doctors as they are able to endorse and be paid for the pack size supplied.

We would welcome views on

- **the above proposal for a dispensing discretion with regard to the quantity dispensed to enable a patient pack to be supplied.**
- **the size of any discretion (i.e. 10 %, 20 %, etc.)**

- **the limits that should be placed on the use of the discretion**
- **and the accompanying reimbursement approach.**

Timing

45. Subject to responses to this consultation, there is flexibility for most of these proposals as to when they can be introduced. However:
- Zero discount list. The Department of Health proposes that the changes should be implemented for 1st April 2006.
- Some proposals can only be implemented when the PPA reaches the appropriate stage in its Capacity Improvement Programme.

46. Subject to the responses to this consultation the Department of Health will discuss with the relevant dispensing contractor representative bodies the optimum way to achieve the proposals whether through changes in the Drug Tariff or relevant NHS Regulations or directions.

Conclusion

47. We would welcome views on the proposals:

- to simplify the broken bulk arrangements.

- to allow the dispenser to dispense the calender pack (or sub-pack) nearest to the quantity prescribed and pay them for the quantity prescribed.

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

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

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

- to abolish the zero discount lists and introduce a limited list where the full Drug Tariff or manufacturer's list price will be paid.

- to establish one Category M price for a chemical entity rather than differing prices relating to pack size.

- for a dispensing discretion with regard to the quantity dispensed to enable a patient pack to be supplied, the size of any discretion (i.e. 10 %, 20 %, etc.), the limits that should be placed on the use of the discretion and the accompanying approach to reimbursement.

48. Comments and other responses should be sent by post, fax or e-mail to:

Michael West
Department of Health
Skipton House (4th Floor)
80 London Road
London
SE1 6LH

Fax: 020 79722932
E-mail: michael.west@dh.gsi.gov.uk

Comments and other responses should reach the Department of Health no later than 30th November 2005.

Confidentiality Disclaimer

49. The information you send us may need to be passed to colleagues within the Department of Health, and/or published in a summary of responses to this consultation. We will assume that you are content for us to do this and, if you are replying by e-mail, that your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system, unless you specifically include a request to the contrary in the main text of your submission to us.

Regulatory Impact Assessment

50. As part of modernising Government, the Department of Health is committed to better regulations and the removal of unnecessary ones. A Regulatory Impact Assessment (RIA) helps assess proposals for change and the impact of various options identified. A partial RIA is required as part of the consultation process and this can be found at Annex A. The responses will contribute to the final RIA.

Cabinet Office Code of Practice on Consultations

51. This consultation is carried out in the context of the following criteria contained in the *Cabinet Office Code of Practice on Consultation*:

    1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy
    2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses
    3. Ensure that your consultation is clear, concise and widely accessible
    4. Give feedback regarding the responses received and how the consultation process influenced the policy
    5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator

6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate

52. Respondents are invited to comment on the extent to which the criteria have been adhered to and to suggest ways for further improving the consultation process. Comments or complaints about the consultation process should be directed to:

Steve Wells
Consultations Co-ordinator
Department of Health
Skipton House
80 London Road
London
SE1 6LH

E-mail: steve.wells@dh.gsi.gov.uk

Response Form

PERSONAL DETAILS

Title	Mr / Mrs / Ms / Dr / Professor / Other
First Name(s)	
Surname	
Address	
Post Code	
E-mail Address	

IF YOUR ARE REPLYING ON BEHALF OF A GROUP OR ORGANISATION

Name of Organisation	
Address **(if different from above)**	
Post Code	
E-mail Address	

Please insert 'X' if you want us to keep your response confidential ☐

What are your views on the proposals to simplify the broken bulk arrangements?
Comments

What are your views on the proposal to allow the dispenser to dispense the calender pack (or sub-pack) nearest to the quantity prescribed and pay them for the quantity prescribed?

Comments

What are your views on the proposal to list a reimbursement price (including out of pocket expenses) in the Drug Tariff for the most common specials?

Comments

What are your views on the proposal to only allow out of pocket claims in excess of a set limit and to compensate contractors with a flat payment per month?

Comments

What are your views on the proposal to abolish the list of commonly used pack sizes and, where the contractor does not indicate which pack was used, base payment on the pack with the cheapest unit cost?

Comments

What are your views on the proposal to abolish the zero discount lists and introduce a limited list where the full Drug Tariff or manufacturer's list price will be paid ?

Comments

What are your views on the proposal to establish one Category M price for a chemical entity rather than differing prices relating to pack size?

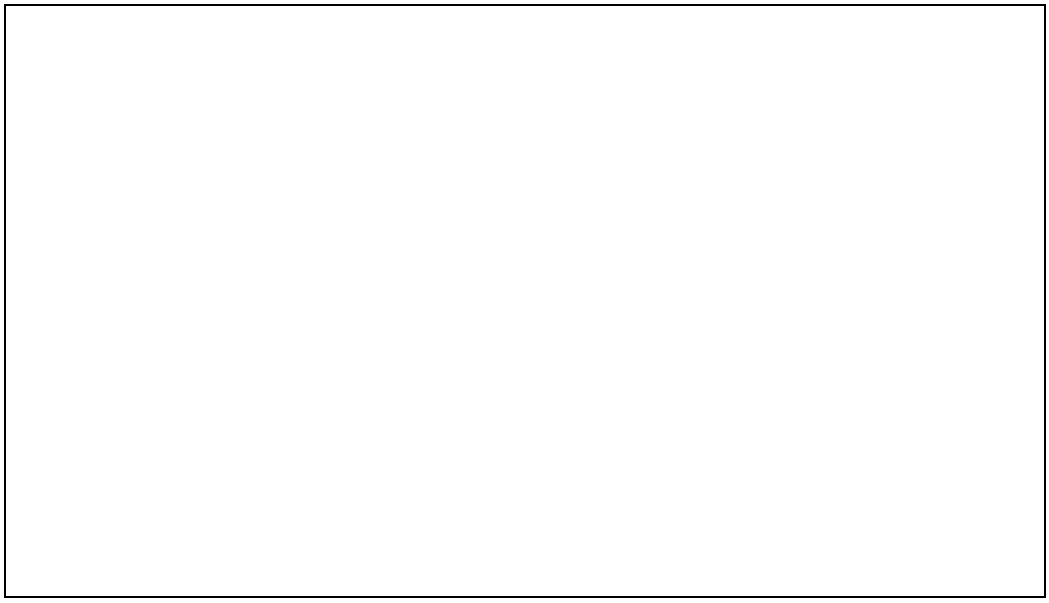
Comments

What are your views on:

- **the proposal for a dispensing discretion with regard to the quantity dispensed to enable a patient pack to be supplied**
- **the size of any discretion (i.e. 10 %, 20 %, etc.)**
- **the limits that should be placed on the use of the discretion**
- **and the accompanying reimbursement approach.**

Comments

Do you have any other general comments you would like to make?
Comments



Please return (to arrive no later than 30th November 2005 by post, fax or e-mail to:

Michael West
Department of Health
Skipton House (4th Floor)
80 London Road
London
SE1 6LH

Fax: 020 79722932
E-mail: michael.west@dh.gsi.gov.uk

Copies of this consultation have been sent to:

Age Concern
All Party Pharmaceutical Group
Association of Nurse Prescribing
Association of British Dispensing Opticians
Association of British Pharmaceutical Industries
Association of Hospice Management
Association of Independent Multiple Pharmacies
Association of Optometrists
British College of Optometrists
British Dental Association
British Dental Trade Association
British Generic Manufacturers Association
British Institute of Regulatory Affairs
British Medical Association
British Medical Journal
Chemist & Druggist
College of Health
College of Pharmacy Practice
Community Pharmacy Magazine
Community Services Pharmacists Group
Company Chemists Association
Consumers Association
Co-operative Pharmacy Technical Panel
Dental Defence Union
Dental Formulary Subcommittee of the Joint Formulary Committee
Dental Protection Ltd
Dispensing Doctors Association
Doctor Magazine
Drug & Therapeutics Bulletin
Drug Information Pharmacists Group
Faculty of Pharmaceutical Medicine
General Dental Council
General Dental Practitioners Association.
General Medical Council
General Optical Council
General Practitioners Committee
Guild of Healthcare Pharmacists
Health Development Agency
Health Professions Council
Health Service Commissioner
Health Which?
Independent Healthcare Association
Joint Consultants Committee
Joint Formulary Committee
Long Term Medical Conditions Alliance
Medical Defence Union
Medical Protection Society Ltd
MIMS Ltd

National Association of GP Co-operatives
National Association of Primary Care
National Consumer Council
National Care Standards Commission
National Patient Safety Agency
National Pharmaceutical Association
NHS Alliance
NHS Confederation
Nursing and Midwifery Council
Ophthalmic Group Committee
OTC Bulletin
Paediatric Chief Pharmacists Group
Patients Association
Pharmaceutical Journal
Pharmaceutical Services Negotiating Committee
Prescription Pricing Authority
Primary Care Pharmacists Association
Proprietary Association of Great Britain
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians & Gynaecologists
Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians (London)
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Speech & Language Therapists
Royal College of Surgeons (England)
Royal College of Surgeons (Faculty of Dental Surgery)
Royal College of Surgeons of England (Faculty of General Dental Practitioners (UK))
Royal Colleges of Physicians : Faculty of Pharmaceutical Medicine
Royal Colleges of Physicians : Faculty of Public Health Medicine
Royal Pharmaceutical Society of Great Britain
Royal Society for the Promotion of Health
Scrip Ltd
Small Business Service
Social Audit Unit
Society of Chiropodists and Podiatrists
Society of Pharmaceutical Medicine
Society of Radiographers
Specialist Advisory Committee on Antimicrobial Resistance
St John Ambulance
UK Clinical Pharmacy Association
Unison

Annex A

Partial Regulatory Impact Assessment
Proposals to Simplify the Reimbursement Arrangements for NHS Dispensing Contractors

Title

1. Proposals for the simplification of the NHS dispensing contractors reimbursement arrangements and a dispensing discretion with regard to the quantity dispensed to enable a patient pack to be supplied.

Purpose and intended effect

2. (i) **Objectives:**
   - To make the NHS dispensing contractors reimbursement arrangements easier to understand and more transparent.
   - To improve patient safety by reducing the number of occasions on which a patient does not receive the appropriate information leaflet with their medicines.
   - To allow pharmacists 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.
   - To allow the Prescription Pricing Authority (PPA) to re-engineer its systems to make the optimum efficiency improvements from its Capacity Improvement Programme (CIP).
   - To allow the PPA's to re-engineer its systems to cope with an increased number of pack sizes.

   (ii) **Background:**

   - After an NHS dispensing contractor has dispensed an NHS prescription the contractor sends the prescription to the Prescription Pricing Authority (PPA). The PPA then calculates how much money the contractor will be paid for dispensing the prescription. The payment to the contractor is made up of:
   o Remuneration: a flat rate dispensing fee for every prescription dispensed; and
   o Reimbursement: a variable amount that depends on the items dispensed.

   - The arrangements for the remuneration and reimbursement of dispensing contractors are set out in NHS Regulations with details published monthly in the Drug Tariff.

   - Although the reimbursement rules for NHS community pharmacy are based on relatively simple principles, the large number of exceptions to these principles means that the arrangements are complex. The PPA processing staff have to be aware of these exceptions and when to apply them. Due to the sheer volume of prescriptions this is a large

undertaking and the increasing number of packs available is making the rules even more complex.

- **Patient Packs:** The Medicines Act 1968 states that pharmacists must dispense "in accordance with" a prescription, and this is echoed in the NHS Act 1977. In practice dispensing contractors dispense and are reimbursed for exactly what was prescribed (with a few specific exceptions).

- Traditionally, UK medicines were supplied in 'bulk packs' of, for example, 1,000 tablets. When used for dispensing, the relevant amount of tablets were repacked into a small container to meet each prescription. Although bulk packs are still used, mainly for some generic medicines, it is now much more common for medicines to be supplied in original (or patient) packs.

- A 'patient pack' has never really been defined. However it is generally understood to be a pack made up of a carton with one or more blister strips (sub-packs) and a patient information leaflet.

- Dispensing contractors often have to split original patient packs if they do not contain the exact quantity prescribed. This may involve removing whole sub-packs or 'snipping' packs (e.g. if a strip contains 30 tablets and 28 are prescribed). The practice of snipping packs is particularly unpopular with dispensers as it is considered a waste of their time. Quantities of 28 and 30 are especially important for snipping because, although a 'month' is often used as a base unit in both prescribing and patient pack sizes, there is no agreement on whether a 'month' is 28 or 30 days.

- The Department of Health want to support the use of patient pack dispensing where possible, because of the benefits this will have for patient safety and because it will help us to make better use of pharmacists' skills (less time will be spent 'snipping'). We do, however, recognise that there will always remain occasions where patient packs are not appropriate, and where it is vital that the patient receives exactly what is prescribed.

3 Rationale for Government Intervention

- The PPA is currently implementing its Capacity Improvement Programme (CIP), making efficiency improvements so that it will be better able to cope with the growing number of prescriptions. However, the maximum efficiency improvements can only be achieved if the reimbursement rules are simplified.

- If the rules were simplified then the PPA could also make other, more general efficiency savings. For instance, it would need to spend less money than at present on training staff to understand and apply the complex rules. (It is difficult to quantify the exact magnitude of the

efficiency savings as this would depend on the extent to which the rules were simplified).

- The number of pack sizes in which medicines are available is increasing. This is making the reimbursement rules more complicated, which in turn places a greater workload on the PPA's processing capacity and makes the rules for contractors less opaque.

- If the reimbursement rules are not changed then the PPA will not be able to deliver the expected efficiency savings from its CIP. This would jeopardise the PPA's work to move from batch to transaction-based processing and to facilitate more timely payments to dispensing contractors.

- Furthermore, the PPA would not be able to deal with the increasing number of pack sizes, and the increasing number of prescriptions, without expanding their processing capacity. This would require more staff and therefore more accommodation. This would mean a corresponding increase in the cost of managing the reimbursement arrangements.

- Patient pack dispensing would mean patients receiving their medicines in manufacturers' original packs containing a patient information leaflet and with all the necessary labelling. At the moment, patients may instead receive medicines drawn from bulk packs or original packs with surplus tablets snipped from the blister strip inside or with tablets snipped from another pack added to the pack.

- The Department of Health are considering giving pharmacists discretion to round the quantity ordered on a prescription, within certain limits (for example within 10 or 20%), in order to dispense a complete patient pack. The pharmacists would be reimbursed for the quantity prescribed. A 10 or 20% discretion would allow pharmacists to dispense 28 tablets where 30 have been prescribed and vice-versa. This would remove most of the occasions when pharmacists have to snip packs to dispense the amount prescribed.

- Under the current reimbursement rules a patient pack dispensing discretion can only be implemented by increasing the number of exemptions to the simple principles on which the rules are based, making the rules even more complex. This would require a large increase in the PPA's processing capacity.

4 Options

Option 1: Do nothing.

Option 2: Continue paying for what is prescribed and reduce the number of exceptions. Flat rate payments would compensate pharmacies for the money they would have received as a result of

these exemptions. DH would revise the relevant sections of the Drug Tariff. This would require changes to the NHS General Medical Services and Pharmaceutical Services Regulations.

Option 3: Carry out the changes outlined in Option 2 and in addition, introduce a dispensing discretion with regard to quantity to enable a patient pack to be supplied. This would also require changes to the NHS General Medical Services and Pharmaceutical Services Regulations.

5 Costs and Benefits

Option 1: Do Nothing

Benefits:

- Dispensing contractors will not have to readjust to new reimbursement arrangements.
- DH and the PPA will not have to rewrite the Drug Tariff or amend regulations.

Costs:

- The arrangements would remain complicated, with a large number of exceptions to the general principles on which they are based. Dispensing Contractors would still have to spend as much time as they do at present trying to spot these exceptions and/or trying to claim allowances.
- The PPA would not be able to gain the efficiency savings expected from its Capacity Improvement Programme. In particular it would continue to spend as much money as at present on training staff to understand and apply the complex arrangements. This would jeopardise any move from batch to transaction-based payment and any move towards more timely payments to contractors.
- The PPA would need to be greatly expanded if were to cope with a greater number of pack sizes. This would lead to a corresponding increase in the cost of managing community pharmacy reimbursement.

Option 2: Continue paying for what is prescribed and reduce the number of exceptions.

Sectors and groups affected: The proposals will affect those community pharmacies and GPs that are NHS dispensing contractors.

Benefits:

- The proposals will make the reimbursement arrangements easier for dispensing contractors to understand.
- The proposal will reduce the occasions on which dispensing contractors have to endorse prescriptions in order to gain additional reimbursement under exceptions and the occasions on which they can claim allowances. This will save dispensers' time.

- Simplification of the arrangements will allow the PPA to make the efficiency savings that are expected as a result of its Capacity Improvement Programme, facilitating any moves from batch to transaction-based payment and towards more timely payments for contracts.
- The PPA would spend less money than at present on training staff to understand and apply the complex arrangements. The amount saved would depend on the extent to which the arrangements were simplified.
- Simplification of the rules will allow the PPA to cope with a greater number of pack sizes at its current capacity.

Costs:
- Dispensing Contractors will have to spend time understanding the new arrangements.
- The proposals will increase the use of an average payment so increase the number of situations in which dispensing contractors 'win' or 'lose' on their reimbursement. At individual level a contractor may 'lose more than 'win' and some may 'win' more than lose'. Overall there should be no change in the profit margin retained by community pharmacy.
- The PPA will need to train staff and amend software in order to re-engineer its systems to deal with changes to the reimbursement rules.
- DH and the PPA will have to spend time and resources revising parts of the Drug Tariff.

Option 3: Continue paying for what is prescribed, reduce the number of exceptions and introduce a dispensing discretion with regard to quantity dispensed to increase the use of patient packs.

Sectors and groups affected: The proposals will affect those community pharmacies and GPs that are NHS dispensing contractors.

Benefits:
- The benefits listed for Option 2 will also apply to Option 3.
- Pharmacists will no longer need to spend time 'snipping' patient packs in order to dispense the exact amount prescribed.
- Patients would be more likely to receive a patient pack complete with the patient information leaflet.

Costs:
- The costs listed for Option 2 will also apply to Option 3.
- Option 3 will increase the number of situations in which pharmacies 'win' or 'lose' on their reimbursement over and above the increase generated by simply implementing Option 2. However, pharmacies do not have to use the dispensing discretion and can continue as before if they wish.

- Calculations by the PPA indicate that given current prescribing and dispensing habits the proposals would be near cost neutral for the NHS. However changes in prescribing or dispensing behaviour resulting from the implementation of the dispensing discretion might result in a change in costs for the NHS.

6 Consultation

There has been informal consultation with the Pharmaceutical Service Negotiating Committee (PSNC) who represent community pharmacy on NHS matters.

7 Small Firms Impact Test

Smaller community pharmacy businesses (identified as independent pharmacies and chains with five or fewer pharmacies) account for 46 % of all pharmacy contractors. By their very nature these proposals will only affect pharmacies in their role as providers of public services.

8 Competition Assessment

The market in dispensing NHS prescriptions is relatively fragmented with only two firms having over 10% of market share and no firm having over 20% of market share.

Neither the proposed changes to the reimbursement rules nor the introduction of a patient pack dispensing discretion would affect some firms substantially more than others. This applies to existing firms as well as new or potential firms. Thus the changes would not affect the market structure.

The sector is not characterised by rapid technologic changes. However, as a result of the new Community Pharmacy Contractual Framework there is going to be an increased use of IT in NHS community pharmacy. Any changes in regulations proposed in this RIA will not inhibit innovation in this area, and so effect competition, as they do not touch on any matters relating to IT.

9 Enforcement, sanctions and monitoring

If the reimbursement rules are changed then the PPA will use them when calculating the payments due to pharmacy contractors for dispensing prescriptions. The PPA's internal quality control mechanisms would monitor to ensure that the new rules are being applied correctly.

10 Race Equality Impact

None identified.

11 **Rural Impact**

None identified.

12 **Environmental Impact**

None identified

13 **Results of Consultation**

The results of the informal consultation have been inconclusive.

14 **Summary and Recommendations**

- The government believes that Option 3 is the most suitable way forward at this stage as it meets the Government's objectives whilst reducing the complexity of the regulatory burden on NHS dispensing contractors.

Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed: Date:

Minister's name and title
Department of Health

Contact Point

Michael West
Department of Health
Skipton House (4th Floor)
80 London Road
London
SE1 6LH

Tel: 020 79722818
E-mail: michael.west@dh.gsi.gov.uk