

PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Pharmaceutical Subsidy Eligibility and Delivery Review

Discussion Paper

October 2009



Introduction

PHARMAC is reviewing the ways people receive subsidised pharmaceuticals in New Zealand.

The review intends to answer the question: Once PHARMAC has made a decision to list a product in the Pharmaceutical Schedule, how should patients access that product?

The two key components of this review are:

- 1. to determine whether a wider range of health professionals should be able to generate a subsidy for pharmaceuticals;** and
- 2. to review the various delivery mechanisms used for providing certain pharmaceuticals to eligible patients.**

For the purposes of discussion, we have raised a number of specific issues within this paper, and have included a number of specific questions at the end of the document, although we welcome any other comments in relation to the scope of this review as well. This review does not include the funding decision process, and relates only to how pharmaceuticals, once subsidised are made available to eligible patients.

This review includes issues that overlap with the community pharmacy agreement consultation that is in progress. Many of these issues have arisen out of that process, and the parties involved support PHARMAC undertaking this review. Any changes that may come out of this review may be able to be incorporated into post-2010 pharmacy agreements. Several of these issues were also raised during the Actioning Medicines New Zealand pharmacist workforce workshop earlier this year.

This paper aims to stimulate discussion on these issues, and does not represent any current view of PHARMAC, or proposal under active development.

Once we have had the opportunity to consider and evaluate all of the responses that we receive, and to discuss various options with key stakeholders, we will be in a position to develop particular proposals and seek specific feedback on these with all interested parties.

Any substantive changes arising out of this review would likely take some time to implement, due to a variety of technical and contractual changes that could be required involving the Ministry of Health, District Health Boards and relevant professional bodies.

While we will be in touch directly with several organisations to discuss these issues, but welcome all feedback on issues raised in this paper. If you wish to provide feedback in writing, please send it to:

Sean Dougherty

PHARMAC

PO Box 10 254, Wellington 6143

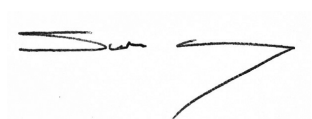
Email: sean.dougherty@pharmac.govt.nz

Fax: 04 460 4995

We request that all feedback to this discussion paper be submitted in writing by **Thursday, 24 December 2009**.

Thank you for taking the time to review this paper and the issues that we have raised. If you would like to discuss these issues further or if you have a question about this review, please contact Sean Dougherty directly on 04 916 7534, or at the email address above.

Yours sincerely



Steffan Crausaz

Acting Chief Executive

Generation of subsidies

Background

The Pharmaceutical Schedule is the list of medicines and medical devices that District Health Boards fund for use in the community. The Schedule includes a wide range of pharmaceuticals with varying regulatory restrictions over their sale. These include controlled drugs, prescription medicines, restricted medicines, pharmacy only medicines, general sale medicines, medical devices and nutritional products.

However, in order to be subsidised these products almost always require a prescription. There may be benefit in amending this restriction to allow for a wider range of health professionals to provide access to subsidised pharmaceuticals.

Discussion

At present in New Zealand, in order for a patient to receive a subsidised pharmaceutical in the community (for simplicity, anything listed in the Pharmaceutical Schedule is considered to be a pharmaceutical, even if it is a medical device or a food), its use must be initiated by a health professional with prescribing rights.

Prescribing rights are currently limited to doctors, midwives, dentists, nurse prescribers and optometrists. The scope of practice for each prescribing group, and therefore the list of products for which they can generate a subsidy, varies.

While a pharmacist or nurse (and other groups) may recommend and even sell or provide certain products, they are unable to generate a Government subsidy for a community pharmaceutical. It may be considered appropriate and beneficial for more health professionals to be able to generate a Government subsidy in their own right for certain products, for example nicotine replacement therapy, gynaecological anti-infectives, respiratory devices, condoms and emergency contraception.

Should such provision be made, it could be for a very narrow or very wide range of products. There may also be requirements in excess of standard practicing rules, either contractual or professional, to be able to perform such a role.

Any changes would need to take account of the clinical appropriateness of wider access, issues around decentralised primary care and financial implications, not just to PHARMAC and DHBs, but to pharmacies, PHOs, patients and other groups.

We note that such a situation is currently in place in a limited capacity through the Ministry of Health's Quitcard programme, for nicotine as part of smoking cessation programmes.

Alternative approaches have been taken in other countries. For example, in the United Kingdom the National Health Service (NHS) has instituted a Minor Ailment Service where community pharmacists can independently claim a subsidy for a narrow list of non-prescription products for certain indications (e.g. constipation, hayfever, headlice, thrush).

Delivery of subsidised pharmaceuticals

Background

Community pharmaceuticals are delivered to patients through a variety of mechanisms, either through community pharmacy, directly by prescribers through the use of supply orders, or directly from suppliers through PHARMAC's direct distribution system.

The mechanisms and restrictions that are in place have been largely unchanged for some time, but the constantly changing landscape of community pharmaceuticals indicates that the way in which these products are distributed and dispensed may need to be updated to ensure that the system is functioning optimally.

The current distribution mechanisms and restrictions are outlined below.

Pharmacy dispensing

A majority of prescriptions are able to be dispensed through any community pharmacy, and have a common reimbursement structure. However, many products have a restriction on which pharmacies may dispense them. These are given effect by relevant claiming agreements with DHBs.

The hospital pharmacy [HP1] restriction identifies those products that require the Complex Medicines Variation to the Pharmacy Services Agreement for a pharmacy to be able to claim a subsidy. HP1 products, such as antiretrovirals and cytotoxics, have a 50% higher dispensing fee, in consideration of the "reasonable additional requirements"¹ associated with their dispensing.

Most DHBs have community pharmacies with the capacity to claim for HP1 medicines; for those that do not, dispensing of these products is done through the DHB hospital pharmacy. Slightly less than a quarter of all pharmacies nationally are able to claim for HP1 medicines.

The hospital pharmacy [HP3] restriction covers a large number of products that were formerly dispensed through DHB hospital pharmacies, but are now dispensed through community pharmacy. As the capacity to claim for HP3 pharmaceuticals requires that the pharmacy is a party to the Pharmacy Services Agreement (or an equivalent agreement), all community pharmacies can dispense HP3 pharmaceuticals, and so this restriction has very little practical implication.

The exception to this is special foods, which are listed in Section D of the Pharmaceutical Schedule. All special foods have the HP3 restriction, and require a specific amendment to the claiming agreement to be able to claim a subsidy. Not all pharmacies are able to claim a subsidy for special foods. In some areas, centralised distribution of special foods is used, meaning that they are not dispensed by community pharmacy.

Dispensing products that have hospital pharmacy [HP4] restriction requires the Monitored Medicines Variation agreement. Pharmacies are paid a double dispensing fee because "the provision of these pharmaceuticals is likely to involve the review of service user diagnostic tests or telephone conversations with the prescriber each time the pharmaceutical is dispensed²." At present the only HP4 pharmaceutical is clozapine.

There are other adjustments to the payment structures, including extemporaneous compounding and methadone services, but these are not within PHARMAC's domain, and are not covered by this review.

¹3.2(c)(ix) of Schedule H1 of the Pharmacy Services Agreement

²3.2(c)(viii) of Schedule H1 of the Pharmacy Services Agreement

Supply orders

There are also mechanisms by which doctors may provide a pharmaceutical directly to a patient: Practitioner's supply order, bulk supply order and wholesale supply order. The Schedule listing for a particular product may specify that it is available, only available, or not available, through one of these mechanisms.

Under a practitioner's supply order (PSO), doctors can obtain a quantity of certain pharmaceuticals for direct provision to patients. The list of products that can be requested on a PSO, and the maximum quantities per order, is contained in Section E of the Pharmaceutical Schedule. Rural practitioners are able to order a much wider list of products.

Some of the most commonly used products through a PSO are (representing around half of total PSO usage):

Amoxicillin	Condoms	Paracetamol
Amoxicillin clavulanate	Flucloxacillin sodium	Salbutamol
Azithromycin	Medroxyprogesterone acetate	Sodium chloride

The current intention of the PSO mechanism, as detailed in the Pharmaceutical Schedule, is to "ensure medical supplies are available for emergency use, teaching and demonstration purposes, and for provision to certain patient groups where individual prescription is not practicable."

Some products in the Pharmaceutical Schedule require injection/implantation by a doctor or nurse but are not in the PSO list. Many of these do not fall within the intended use of the PSO mechanism – however we are also aware that some products on the PSO list do not meet the intention of this mechanism.

We intend to review the list of products that are available directly to clinicians through PSOs and other supply orders, although this would be after we review the purpose of each of the mechanisms that we currently have.

The bulk supply order (BSO) allows private hospitals and similar institutions to order publicly funded pharmaceuticals to enable them to have sufficient stocks of products to enable the treatment of patients under their care.

The most commonly dispensed products through a BSO are (representing around half of total BSO usage):

Cyclizine lactate	Morphine hydrochloride	Pethidine hydrochloride
Dexamethasone sodium phosphate	Morphine sulphate	Sodium chloride
Diclofenac sodium	Oxycodone hydrochloride	Water
Meteoclopramide hydrochloride	Paracetamol	

Products ordered on wholesale supply order (WSO) are provided directly by a clinician to their patients. WSO products are not distributed through pharmacies, rather they are shipped directly by the New Zealand distributor to clinicians, and do not attract a patient co-payment.

The list of WSO products is small and has been unchanged for some time:

Spacer devices and masks	Pregnancy tests
Peak flow meters	Copper intra-uterine devices

These products are only available on a WSO, and are not subsidised on a prescription. We note that these products are either general sale medicines or medical devices, and that some of these are relatively large items.

Direct distribution

PHARMAC currently operates a system of direct distribution of medicines to patients (or to their clinician) for a small number of products. These products tend to be low volume, high priced products. In this case it has been considered practicable to operate a direct distribution mechanism outside of the regular delivery channels. At present imatinib mesylate, dasatinib, multiple sclerosis treatments (beta interferon, glatiramer acetate) and somatropin (growth hormone) are directly distributed; these products do not attract a patient co-payment.

Discussion

The delivery mechanisms and dispensing restrictions for community pharmaceuticals vary widely, and the current use of these mechanisms may not be the most efficient way of providing access to subsidised pharmaceuticals. PHARMAC is aware of the following issues; however there are likely to be others:

Variation between pharmacies

For a pharmacy to dispense a subsidised product with an HP1 or HP4 restriction, they need to have the relevant contract variation with the local District Health Board. Subsequently not all community pharmacies are able to dispense all subsidised community pharmaceuticals, and so patients may have to travel further to pick up some of their medicines.

High cost products

The average cost³ per subsidised dispensing in 2008 was slightly less than \$15; however many products exceed \$1,000 per dispensing.

For such high cost products under the current pharmacy payment structure, each dispensing incurs a 5% mark-up to be paid to the pharmacy, which is then fed through to wholesalers. For these products, the effect of wholesaler mark-ups greater than 5% could mean a substantial financial loss to the dispensing pharmacy.

The high cost of these products also means that if pharmacies are left with part-packs, it can be costly to them. Similarly, accumulation of unused product by patients can have a large financial impact. The mark-ups on these products also represent a large cost to District Health Boards – a \$5,000 product would have a \$250 mark-up in addition to the dispensing fee.

These facts have led to an increased use of direct distribution to patients. It is likely that the list of subsidised products with a similar cost structure will increase over time; however the optimal role of direct distribution to patients is uncertain, particularly in relation to higher volume products.

The restrictions applying to high cost products are variable – for example, the top 25 products in the Schedule by cost per dispensing in 2008, and their distribution restrictions are:

Retail pharmacy	
Adalimumab	Paraldehyde
Etanercept	

Hospital pharmacy [HP1]	
Dornase alfa	Imiglucerase
Enfuvirtide	Zidovudine [AZT] with lamivudine

Hospital pharmacy [HP3]	
Aminoacid formula without methionine	Octreotide (somatostatin analogue)
Aminoacid formula without phenylalanine	Pegylated interferon alpha-2a
Aminoacid formula without valine, leucine and isoleucine	Pegylated interferon alpha-2b with ribavirin
Colistin sulphomethate	Sirolimus
Interferon alpha-2a with ribavirin	Temozolomide
Metyrapone	

Direct distribution	
Glatiramer acetate	Interferon beta-1-alpha
Growth hormone biosynthetic human	Interferon beta-1-beta
Imatinib mesylate	Recombinant human growth hormone

While it may be desirable to take a common approach to all of these products, in some cases a wider view would need to be taken – it may, for example, be sensible for all antiretroviral products to have the same dispensing restriction, regardless of their pricing structure.

³All costs represent the pharmaceutical cost only, and are ex-manufacturer and exclusive of GST

Special foods

Special foods are all listed with an HP3 restriction, and are generally dispensed by community pharmacies. However, special foods are not classified as medicines, and so do not need to be dispensed by a pharmacist (although we note that some undergo further compounding before dispensing). In several cases these products are distributed directly to patients through agreements with the relevant DHB.

Many of these products are fairly bulky, consuming considerable space in community pharmacies, and can be difficult for some patients to collect, particularly when these products are used as a complete diet due to the volume and weight of product involved. We note that, as with high cost products, there can be discrepancies between the mark-ups that pharmacies are charged by wholesalers, and what they are reimbursed by DHBs.

Supply orders

While a relatively wide range of products are available on BSO and on rural PSO, for WSO and PSO, there is a defined list of products and maximum quantities that may be ordered.

Typically new listings in the Pharmaceutical Schedule do not get added to the list of products available on supply orders, in part because there is no clear intention behind the use of these mechanisms in preference to pharmacy dispensing, and also because new listings often have a Special Authority restriction, which prevents them from being accessed in this manner.

Having certain products available on a supply order can be more convenient for patients, as it results in products being immediately available to them, and could be considered appropriate for one-off treatments and for those treatments that require administration by a particular health professional. However, substantially increased use of supply orders may not be considered appropriate without adjustment to these mechanisms, as there is no patient co-payment payable for products provided on a supply order.

Feedback sought

PHARMAC is seeking feedback from interested parties on all of the issues raised in this paper. In particular, we would appreciate consideration of the particular questions highlighted below. Please do not limit your feedback to these specific matters as we invite all options and views relating to the overall theme of this review.

If you wish to provide feedback on any of the issues raised in this paper, please submit it in writing by Thursday, 24 December 2009 to:

Sean Dougherty

PHARMAC

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Generation of subsidies

Should health professionals without prescribing rights be able to generate a subsidy for a pharmaceutical (as broadly defined in this document) in their own right, and what do you consider would be the benefits and risks of such a change?

If so:

- Should this capability be limited to certain groups of health professionals?
- Should there be additional requirements, such as audit and compliance or further training or qualifications, be required in excess of standard practicing rules?
- Should this capability be limited to a defined formulary of products, or should it be for any product that the relevant health professional has the legal right to provide? If for a defined formulary, what do you consider should be the criteria for determining which products should be included in this formulary?
- Do you consider that such a change would result in decentralised provision of primary care, and if so, to what extent would this be an issue and how could this be addressed?

Delivery of subsidised pharmaceuticals

Should there be greater use of alternative delivery mechanisms for subsidised community pharmaceuticals, and if so, in what circumstances should these be employed?

- Should all community pharmacies be able to dispense medicines equally, or should the 'hospital pharmacy' (or similar) restrictions that limit subsidised dispensings to certain community pharmacies be retained? If this approach should be retained, what should be the basis for determining which products should be restricted in this way?
- For high cost products, what do you consider would be the preferred approach for distribution:
 - direct distribution to patients;
 - community pharmacies via wholesalers;
 - community pharmacies via direct distribution by manufacturers; or
 - dispensing of community pharmaceuticals from DHB hospital pharmacies?
- Is community pharmacy via wholesalers the optimal channel for distribution of special foods, or would other options be more appropriate?
- Under what circumstances should products be available for direct provision by a clinician, and for what reasons should they be available in this way?
 - In particular:
 - Is it appropriate that this mechanism is used for medications used on a chronic basis?
 - Should use of products under supply orders be exempt from co-payments?
 - Should prescribers (or PHOs) be able to claim a subsidy directly for usage of certain products, rather than obtaining them from a pharmacy?
 - Should medicines with restricted criteria, such as those under Special Authority, be available directly to prescribers?
 - Under what circumstances should private institutions be able to obtain publicly subsidised pharmaceuticals under a bulk supply order?
 - Should pharmaceuticals continue to be available through wholesale supply order, or should these instead be channelled through community pharmacy, either on prescription or practitioner's supply order?
- Are there delivery mechanisms other than those already in place that should be considered; if so, for what types of products would these be suitable, and why?
- Are there any other significant issues associated with delivery of subsidised community pharmaceuticals that you would like to comment on?