

25 July 2008

## **Proposal to Amend the General Rules regarding Substitution and Alteration to Quantity Dispensed**

PHARMAC is seeking public feedback on a proposal to amend the restrictions and other general rules that apply to subsidies on community pharmaceuticals (the "General Rules"). This letter outlines the proposal and how you can provide your feedback on it.

### **Proposal Summary**

PHARMAC is proposing to amend the General Rules, Section A of the Pharmaceutical Schedule to include rules regarding:

- substituting and claiming for a subsidised brand when a non-subsided or partially subsidised brand has been prescribed; and
- where pharmacists alter the quantity dispensed.

The details of the proposed change are on page 3 of this consultation letter. It is proposed that these rules take effect from 1 September 2008.

We are also proposing to change the wording of the current Authority to Substitute letter published in the Pharmaceutical Schedule to reflect the amended rule. The details of the proposed changes are on page 4 of this consultation letter. Authority for substitution is given in the Medicines Regulations 1984 42 (4). We intend to make the Authority to Substitute letter available on the PHARMAC website [www.pharmac.govt.nz](http://www.pharmac.govt.nz) from 1 September and include it in the September 2008 issue of the Pharmaceutical Schedule Update, and further issues of the Update until it is published in the December 2008 Schedule.

### ***Why are we doing this?***

The proposed changes would clarify that it is appropriate to claim for a subsidised brand that has been substituted for a non-subsidised brand of the same medicine even if it means a cost to the Pharmaceutical Budget. The Authority to Substitute letter in the back of the Pharmaceutical Schedule would be updated to indicate this. What we are proposing would widen the scope of that letter and include a specific rule around this. Pharmacists may send the Authority to Substitute letter to Practitioners and request that they sign it to authorise the Pharmacist to dispense an alternate brand of medicine. Practitioners may also choose to sign the Authority to Substitute letter and send it to Pharmacists without such prompting.

The addition of the rule around alteration to quantity dispensed is an issue that we would like to address at the same time. This rule is similar to and in agreement with rule 4.11 that is set out in the Pharmacy Procedures Manual.

PHARMAC proposes to clarify that alterations to the quantity dispensed that may mean an increased cost to the DHB's may be authorised from time to time by PHARMAC, and in these cases the alteration is not required to be signed by the prescriber.

### **Feedback sought**

We welcome your feedback on this proposal. To provide feedback on this proposal please submit it in writing by **5pm, Friday 8 August 2008** to:

Linda Wellington      email: [linda.wellington@pharmac.govt.nz](mailto:linda.wellington@pharmac.govt.nz)  
Schedule Analyst  
PHARMAC                Fax; (04) 460 4995  
PO Box 10-254  
Wellington 6143

### **What will happen then?**

All of the submissions we receive before the deadline will be considered by PHARMAC's Board (or Chief Executive, acting under delegated authority) when making a decision on whether to implement this proposal.

If the proposal is approved, it is anticipated that the proposed changes would take effect from 1 September 2008.

## Details of the proposal

Proposed amendments to Part I Interpretations and Definitions of the Pharmaceutical Schedule are to insert a new definition as follows:

**“Authority to Substitute”** means an authority for the dispensing pharmacist to change a prescribed medicine in accordance with regulation 42(4) of the Medicines Regulations 1984. An authority to substitute letter which may be used by Practitioners is available on the final page of the Schedule.

Proposed amendments to Part IV Miscellaneous Provisions of the General Rules of the Pharmaceutical Schedule are to insert two new rules 4.7 and 4.8 as follows:

### 4.7 Substitution

Where a Practitioner has prescribed a brand of a Community Pharmaceutical that has no Subsidy or has a Manufacturer's Price that is greater than the Subsidy and there is an alternative fully subsidised Community Pharmaceutical available, a Contractor may dispense the fully subsidised Community Pharmaceutical, subject to:

- a) the Contractor having received a general Authority to Substitute from the Practitioner in relation to the particular medicine or medicines in general; or
- b) the Practitioner having indicated their Authority to Substitute on the prescription.

Such an Authority to Substitute is valid whether or not there is a financial implication for the Pharmaceutical Budget.

When dispensing a subsidised alternative brand, the Contractor must annotate and initial the prescription.

### 4.8 Alteration to Quantity Dispensed

A Contractor, when dispensing a Community Pharmaceutical, may alter the quantity dispensed but may not alter the total daily dose or frequency of dosing ordered by the Practitioner. If the change will result in additional cost to the DHBS, then:

- a) the Practitioner must authorise and initial the alteration; or
- b) in cases where PHARMAC has approved and notified in writing such a change in dispensing of a named Pharmaceutical due to an out of stock event or short supply, the Contractor must annotate and initial the alteration.

As a result of the two new rules (set out above) inserted into Part IV Miscellaneous Provisions of the General Rules of the Pharmaceutical Schedule the current rules 4.7 and 4.8 will be renumbered as rules 4.9 and 4.10 respectively as follows (deletions in strikethrough and insertions underlined):

#### **4.9 4.7 Amendment of the Schedule**

PHARMAC may amend the terms of the Schedule from time to time by notice in writing given in such manner as PHARMAC thinks fit, and in accordance with such protocols as agreed with the Pharmacy Guild of New Zealand (inc) from time to time.

#### **4.10 4.8 Conflict of Provisions**

If any rules in Sections B\_G of this Schedule conflict with the rules in Section A, the rules in Sections B-G apply.

Proposed amendment to the Authority to Substitute letter published in the back of the Pharmaceutical Schedule as follows (deletions in strikethrough and insertions underlined):

### **AUTHORITY TO SUBSTITUTE**

Dear Pharmacist

Where I refer in a prescription to a medicine by its trade mark or trade name (brand), or by the name of its manufacturer, I give authority to substitute an alternative brand of the same medicine in the following situations:

#### **Sole Supply Products**

Where PHARMAC has entered into sole supply arrangement for the medicine you may substitute the sole supply brand, except if the patient chooses to pay for the non-sole supply brand.

This includes repeat dispensings where the brand I have prescribed is no longer subsidised or is partly subsidised.

#### **~~Preferred brand (Preferred Supplier) Products~~**

~~You may substitute the preferred brand, except if the patient specifically requests the brand prescribed.~~

~~This includes repeat dispensings where the brand I have prescribed is no longer subsidised or is partly subsidised.~~

#### **Other subsidised products**

Where PHARMAC has listed more than one brand of the medicine on the Pharmaceutical Schedule (and the brand that I have prescribed is not listed or has a Manufacturer's Price that is greater than the Subsidy) you may substitute with a listed brand, except if the patient specifically requests the brand prescribed.

This includes repeat dispensings where the brand I have prescribed is no longer subsidised or is partly subsidised.

#### **Exceptions**

I do not want substitution to occur for the following chemical entities, unless I am contacted verbally in each specific case:

This authority to substitute replaces all previous authorities relating to these particular chemical entities which I may have provided previously.

This authority to substitute is valid unless I have indicated on the prescription an instruction not to substitute.

This authority is valid whether or not there is a financial implication for the Funder.

Please inform my patient that I have authorised substitution.

Name: \_\_\_\_\_ NZMC: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

*Authority for the dispensing pharmacist to change a prescribed medicine in this way is contained in regulation 42(4) of the Medicines Regulations 1984*

**A copy of this letter is available on the PHARMAC website [www.pharmac.govt.nz](http://www.pharmac.govt.nz)**