

19 August 2011

Proposal to amend the General Rules in the Pharmaceutical Schedule

PHARMAC is seeking feedback on a proposal to amend the General Rules in the Pharmaceutical Schedule. The intention of this proposal is to reduce some of the administrative requirements for pharmacists and practitioners.

In summary, from 1 November 2011 this proposal would result in:

- Pharmacists being able to annotate a prescription where they have evidence that the patient is eligible for subsidy, without requiring a counter signature or endorsement from the prescriber.
- Pharmacists being able to alter the presentation of the pharmaceutical dispensed, without requiring a signature from the prescriber only when not practicable to dispense the presentation prescribed.
- Removal of Part II 2.2 in the General Rules. This will result in certain pharmaceuticals having restrictions on what uses they will not be subsidised for.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 9 September 2011** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

The following Definitions of Part I, Section A: General Rules of the Pharmaceutical Schedule would be amended from 1 November 2011 (additions in bold, deletions in strikethrough):

“Annotation” means written annotation of a prescription by a dispensing pharmacist in the pharmacist’s own handwriting following confirmation from the Prescriber if required, and “Annotated” has a corresponding meaning. The annotation must include any required endorsement, the date the prescriber was contacted (if applicable) and be

initialled by the dispensing pharmacist. An electronic record must be kept on the patient's electronic file for audit purposes.

“Hospital Pharmacy-Specialist” means that the Community Pharmaceutical is not eligible for Subsidy unless it is supplied by a hospital or pharmacy contracted to the Funder to dispense as a hospital pharmacy **either**:

- a) to an Outpatient; and
- on a Prescription signed by a Specialist; or
- b) if the treatment of an Outpatient with the Community Pharmaceutical has been recommended by a Specialist, on the Prescription of a Practitioner **which is either**:**
 - i) endorsed with the words “recommended by [name of specialist and year of authorisation]” and signed by the Practitioner, **or**
 - ii) **Annotated by the dispensing pharmacist following verbal confirmation from the Practitioner of the name of the Specialist and date of recommendation, and endorsed with the words “recommended by [name of specialist and date of authorisation], confirmed by [practitioner]”. Where the Contractor has an electronic record of such an Endorsement or Annotation from a previous prescription for the same Community Pharmaceutical written by a prescriber for the same patient, they may annotate the prescription accordingly.**

“As recommended by a Specialist” to be interpreted as:

- a) follows a substantive consultation with an appropriate Specialist;
- b) the consultation to relate to the Patient for whom the Prescription is written;
- c) consultation to mean communication by referral, telephone, letter, facsimile or email;
- d) except in emergencies consultation to precede annotation of the Prescription; and
- e) both the specialist and the General Practitioner must keep a written record of the consultation.

For the purposes of the definition it makes no difference whether or not the Specialist is employed by a hospital.

“Retail Pharmacy-Specialist” means that the Community Pharmaceutical is only eligible for Subsidy if it is

- a) supplied on a Prescription or Practitioner's Supply Order signed by a Specialist, or,**
- b) in the case of treatment recommended by a Specialist, **supplied on** a Prescription or Practitioner's Supply Order and **either****
 - i) endorsed with the words “recommended by [name of Specialist and year of authorisation]” and signed by the Practitioner, or

ii) **Annotated by the dispensing pharmacist following verbal confirmation from the Practitioner of the name of the Specialist and date of recommendation, and endorsed with the words “recommended by [name of specialist and year of authorisation], confirmed by [practitioner]”. Where the Contractor has an electronic record of such an Endorsement or Annotation from a previous prescription for the same Community Pharmaceutical written by a prescriber for the same patient, they may annotate the prescription accordingly.**

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- a) follows a substantive consultation with an appropriate Specialist;
- b) the consultation to relate to the Patient for whom the Prescription is written;
- c) consultation to mean communication by referral, telephone, letter, facsimile or email;
- d) except in emergencies consultation to precede annotation of the Prescription; and
- e) both the Specialist and the General Practitioner must keep a written record of consultation.

Part II of the General Rules of the Pharmaceutical Schedule would be amended as follows from 1 November 2011 (additions in bold, deletions in strikethrough):

2.1 Community Pharmaceuticals eligible for Subsidy include every medicine, therapeutic medical device or related product, or related thing listed in Sections B to G of the Schedule, ~~and every preparation (having an inert base) of any of them, is hereby declared to be a~~ Community Pharmaceutical for the purposes of the Schedule, subject to:

2.1.1 ~~clauses 2.2 and 2.23~~ of the Schedule; and

2.1.2 clauses 3.1 to 4.4 of the Schedule; and

2.1.3 the conditions (if any) specified in Sections B to G of the Schedule;

~~2.2 The following medicines, therapeutic medical devices, or related products or related things are not eligible for Subsidy:~~

~~2.2.1 substances, or combinations of substances, ordered for any purpose other than:~~

~~a) treatment of a patient’s medical or dental condition; or~~

~~b) pregnancy tests; or~~

~~c) the prevention of sexually transmitted disease; or~~

~~d) contraception.~~

~~2.2.2 substances and combinations of substances packed under pressure in aerosol cans or other similar devices, unless it is specified in Sections B to G of the Schedule that they may be so packed;~~

~~2.2.3 electrode jellies;~~

- ~~2.2.4 eye drops packed in single dose units, unless it is specified in Sections B to G of the Schedule that they may be so packed;~~
- ~~2.2.5 insect repellents and similar preparations;~~
- ~~2.2.6 oral preparations in long-acting form, unless it is specified in Sections B to G of the Schedule that they may be in such a form;~~
- ~~2.2.7 substances or combinations of substances in lozenge or similar form, unless it is specified in Sections B to G of the Schedule that they may be in such a form;~~
- ~~2.2.8 machine spread plasters;~~
- ~~2.2.9 preparations prescribed as foods, unless they are specified in Section D of the Schedule;~~
- ~~2.2.10 substances, combinations of substances, or articles, in the form of proprietary medicines or proprietary articles, unless they are deemed or declared to be Pharmaceuticals elsewhere in the Schedule;~~
- ~~2.2.11 shampoos, other than extemporaneously prepared medicated shampoos, or shampoos specified in Sections B to G of the Schedule intended for the treatment of a patient's medical condition;~~
- ~~2.2.12 toilet preparations;~~
- ~~2.2.13 tooth pastes and powders;~~
- ~~2.2.14 lubricating jellies and catheter lubricants;~~
- ~~2.2.15 sterile diluents for nebulising solutions;~~
- ~~2.2.16 substances in a form intended to enable delivery by transdermal diffusion or osmosis or by the insertion of any solid object or substance into the eye cavity, unless it is specified in Sections B to G of the Schedule that they may be in such a form;~~
- ~~2.2.17 substances in a form intended for intravenous delivery (other than by injection), unless it is specified in Sections B to G of the Schedule that they may be in such a form;~~
- ~~2.2.18 substances packed in pre-loaded syringes known as Min-I-Jets, unless it is specified in Sections B to G of the Schedule that they may be so packed;~~
- ~~2.2.19 Community Pharmaceuticals prescribed as cough mixtures, unless they are specified in Sections B to G of the Schedule otherwise than in combination with other ingredients;~~
- ~~2.2.20 vitamin preparations in capsule form, unless they are specified in Sections B to G of the Schedule;~~
- ~~2.2.21 substances prescribed for use as irrigating solutions, unless it is specified in Sections B to G of the Schedule that they may be prescribed for such use.~~
- 2.2.23 No claim by a Contractor for payment in respect of the supply of Community Pharmaceuticals will be allowed unless the Community Pharmaceuticals so supplied:

- 2.23.1 comply with the appropriate standards prescribed by regulations for the time being in force under the Medicines Act 1981; or
- 2.23.2 in the absence of any such standards, comply with the appropriate standards for the time being prescribed by the British Pharmacopoeia; or
- 2.23.3 in the absence of the standards prescribed in clauses 2.23.1 and 2.23.2, comply with the appropriate standards for the time being prescribed by the British Pharmaceutical Codex; or
- 2.23.4 in the absence of the standards prescribed in clauses 2.23.1, 2.23.2 and 2.23.3, are of a grade and quality not lower than those usually applicable to Community Pharmaceuticals intended to be used for medical purposes.

As a consequence of removing general rule 2.2 of Section A, there would be changes to the listing of some pharmaceuticals in Section B of the Pharmaceutical Schedule with effect from 1 November 2011, as outlined below. We note that these proposed specific restrictions are currently in force under the general rule 2.2 of Section A, and so this proposal would not result in any further restriction or access for these products.

Dexamethasone sodium phosphate

Dexamethasone sodium phosphate injection would have a new restriction specifying that it would not be subsidised for oral use.

Eye preparations

Eye preparations would have a restriction specifying that they would be funded only for use in the eye. The exception to this would be pilocarpine, which would also be subsidised for oral use pursuant to the Standard Formulae.

Midazolam

The change to the general rules would mean that the note permitting intranasal use of funded midazolam injection would no longer be required, and so would be removed.

Phytomenadione

The change to the general rules would mean that the note permitting oral use of funded phytomenadione injection would no longer be required, and so would be removed.

Poloxamer

Poloxamer oral drops would have a new restriction specifying that they would not be funded for use in the ear

Sodium chloride

All parenteral sodium chloride preparations would have an additional restriction specifying that they are "not subsidised for use as a nasal drop or for use in a nebuliser". Note that this restriction would not apply to sodium chloride 7% nebuliser solution.

The following Sections of Part IV, Miscellaneous Provisions, of the General Rules of the Pharmaceutical Schedule would be amended from 1 November 2011 (additions in bold, deletions in strikethrough):

4.7 Alteration to Presentation of Pharmaceutical Dispensed

A Contractor, when dispensing a Community Pharmaceutical, may alter the presentation of a Pharmaceutical dispensed but may not alter the total daily dose. **This may occur when it is not practicable for the contractor to dispense the requested presentation.** If the change will result in additional cost to the DHBs, then **Annotation by the dispensing pharmacist must occur stating the reason for the change, and the Contractor must also keep an additional electronic record as to the reason for the change for the purposes of Audit.**

~~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.~~

4.8 Amendment of 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.~~

PHARMAC is proposing to rely on the consultation and notice obligations set out in section 49 of the NZPHD Act

Minor consequential changes would be made elsewhere in the Schedule as required to give effect to the changes set out in the proposal.