CONSULTATION

PHARMAC
Pharmaceutical Management Agency

6 November 2013

Proposals to amend the Dispensing Frequency rule and add zopiclone to the Safety Medicines list

PHARMAC is seeking feedback on a proposal to amend the Pharmaceutical Schedule rules relating to the Dispensing Frequency rule. This would result in increased frequency of subsidised dispensing for some patients in residential care.

PHARMAC is also proposing to add zopiclone to the Safety Medicines list.

Feedback sought

PHARMAC welcomes feedback on these proposals. To provide feedback, please submit it in writing by **Friday, 6 December 2013** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on these proposals.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

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Background and summary of proposed changes

Amendment to the Dispensing Frequency Rule

The Dispensing Frequency rule was amended from 1 July 2012 to focus on enabling pharmacists to better manage dispensing frequency to meet patients' clinical needs. This amendment supported the strategic direction of the Community Pharmacy Services Agreement (CPSA).

During previous consultations PHARMAC indicated there would be an ongoing review of the Schedule rules throughout the transition phase of the CPSA to ensure the rules meet patient, prescriber, pharmacy and DHB requirements.

A working group comprised of prescribers and pharmacists reviewed the Dispensing Frequency rule in late 2012. Its conclusion was that the rule was working, but minor amendments were proposed to enhance its effectiveness.

The working group recommended amendments, some of which are included in this consultation. PHARMAC is continuing to review the Dispensing Frequency rule and may issue a further consultation on additional changes in the coming months.

Residential Care - more frequent subsidised dispensing for some medicines

PHARMAC is proposing two minor amendments to the Dispensing Frequency criteria for persons in residential care. This is for patients in a Residential Disability Care Institution[1] or an age related residential care (ARRC) facility. Pharmacy will continue to dispense monthly to the majority of its residential disability care institution patients.

PHARMAC has received feedback that the current minimum 10 day dispensing period for **Class B controlled drugs** to persons in residential care does not align well with pharmacy practice, as a 10 day dispensing period may fall due when pharmacy is closed. PHARMAC is proposing to allow subsidised dispensing of Class B controlled drugs to persons in residential care at a frequency of not less than 7 days. The current frequency of 10 day dispensing period may continue but PHARMAC is proposing to provide pharmacy with more flexibility through allowing 7 days supply to be dispensed for residential care patients.

PHARMAC recognises that there are issues with the 10 day dispensing period for Class B controlled drugs in the community generally as it doesn't align well to a specific day of the week. PHARMAC will be considering addressing this issue for community based patients separately to this proposal as it is part of other Schedule rules.

The second proposed amendment for persons in residential care is permitting more frequent dispensing for patients prescribed **clozapine** in accordance with the Clozapine Dispensing Protocol. Under the Clozapine Dispensing Protocol the frequency of blood monitoring will dictate the dispensing, generally in lots of 7, 14 or 28 days. For example, the first 18 weeks of treatment patients require close monitoring and must only receive sufficient quantities of clozapine for 7 days treatment. By allowing the dispensing of clozapine to residential care patients in weekly lots, it would reduce the administrative workload by the prescriber and the pharmacist.

[1] Residential Disability Care Institutions are funded by the Ministry of Health or a DHB; and defined in the Pharmaceutical Schedule with reference to the definition of residential disability care in the Health and Disability Services (Safety) Act 2001.

What is not changing?

This proposal is **not** seeking to make changes to the following:

- Pharmaceutical Supply Management;
- Section F: Part II Certified Exemptions and access exemptions to monthly dispensing; and
- Section F: Part III: Flexible and variable dispensing periods for pharmacy.

For the avoidance of doubt PHARMAC will continue to monitor the use of Dispensing Frequency.

Addition of zopiclone to Safety Medicines list

Requests have been received from prescribers and pharmacy to add zopiclone to the Safety Medicines list. We have considered these requests and are now proposing to add zopiclone to the Safety Medicines list. This would permit prescribers to determine the dispensing frequency of zopiclone without the patient having to meet other Dispensing Frequency criteria.

The prescriber would need to assess the clinical risk and if the patient requires frequent dispensing, the prescriber would specify the dispensing quantity and frequency. The prescriber does not need to endorse prescriptions for Safety Medicine.

Details of the proposal

PHARMAC is proposing to delete the current Dispensing Frequency rule and replace it with a new Dispensing Frequency rule outlined below. The order of the rule has been modified to improve the flow. Substantially new or amended items are identified in bold and deletions in strikethrough.

> Part IV
> Dispensing Frequency Rule
>
> The Pharmaceutical Schedule specifies, for community patients, a default period of supply for each Community Pharmaceutical (a Monthly Lot, 90 Day Lot, or for oral contraceptives 180 Day Lot). This Dispensing Frequency rule defines patient groups or medicines eligible for more frequent dispensing periods; and the conditions that must be met to enable any **pharmacy to** claim for payment of handling fees for the additional dispensings made. **For the avoidance of doubt this rule relates to the circumstances in which subsidy is payable. It does not override alternative dispensing frequencies as expressly stated in the Medicines Act, Medicines Regulations, Pharmacy Services Agreement, Pharmaceutical Schedule or under rule 4.3 Trial Periods or rule 4.4 Safety and Co Prescribed Medicines.**
>
> "Frequent Dispensing" means:
>
> - for a Community Pharmaceutical referred to in Section F Part I **(Stat rule)**, dispensing in quantities less than one 90 Day Lot (or for oral contraceptives, less than one 180 Day Lot); or
> - for any other Community Pharmaceutical, where any of the below of Part IV apply, dispensing in quantities less than a Monthly Lot.
>
> **There are 5 different ways to use the Dispensing Frequency Rule to gain more frequent dispensing periods for patients. These are, Frequent Dispensing for:**

1. **Long Term Condition (LTC) patients and Core patients, or**
2. **persons in residential care, or**
3. **trial periods, or**
4. **safety and co-prescribed medicines, or**
5. **Pharmaceutical Supply Management.**

~~NOTE patients who have had more frequent dispensings due to being "intellectually impaired, frail, infirm or unable to manage their medicines" will continue to receive the same frequency of dispensings until they are assessed to see if they are eligible for additional support under the Long-Term Condition (LTC) service. The structure of the remainder fee payment provides funding for pharmacy to continue to provide more frequent dispensings for patients until they are assessed.~~

4.1 Frequent Dispensing for Long Term Condition (LTC) patients and Core patients

4.1.1 If a Pharmacist considers more frequent dispensing is required, this can occur as follows:

a) For Long Term Condition (LTC) **registered** patients dispensing frequency can occur as often as the dispensing pharmacist deems appropriate to meet the patient's compliance and adherence needs;

b) For **Core (**non-LTC**)** patients the dispensing frequency should be no more often than monthly. **Pharmacists may authorise this monthly frequency on a Stat medicine without prescriber authority.** If dispensing more often than monthly is necessary for Core patients, prescriber approval is required. Verbal approval from the prescriber is acceptable, provided that it is annotated by the pharmacist on the Prescription and dated.

The repeats in each of these scenarios are **reimbursed to pharmacies according to the agreement with the DHBs** ~~paid as a handling fee only~~.

4.2 Frequent Dispensing for persons in residential care

4.2.1 Pharmaceuticals can be dispensed ~~in quantities of not less than 28 days~~ to:

- any person whose placement in a Residential Disability Care Institution is funded by the Ministry of Health or a DHB; or
- a person assessed as requiring long term residential care services and residing in an age related residential care **(ARRC)** facility;

on the request of the person, their agent or caregiver or community residential service provider via Frequent Dispensing, provided the following conditions are met:

a) the quantity or period of supply to be dispensed at any one time is not less than:

(i) **7 days' supply for a Class B Controlled Drug; or**

(ii) 7 days' supply for clozapine in accordance with the Clozapine Dispensing Protocol; or

(iii) 28 days' supply **for any other pharmaceutical** (except under conditions outlined in 4.3 **(Trial periods)** below); and

b) the prescribing Practitioner or dispensing pharmacist has

i) included the name of the patient's residential placement or facility on the Prescription; and

ii) included the patient's NHI number on the Prescription; and

iii) specified the maximum quantity or period of supply to be dispensed at any one time.

4.2.2 Any person meeting the criteria above who is being initiated onto a new medicine or having their dose changed is able to have their medicine dispensed in accordance with 4.3 **(Trial periods)** below.

4.3 Frequent Dispensing for Trial Periods

Trial period dispensing can occur when a ~~The~~ Community Pharmaceutical has been prescribed for a patient who requires close monitoring due to recent initiation onto, or dose change for, the Community Pharmaceutical (applicable to the patient's first changed Prescription only)and the prescribing Practitioner has:

- endorsed each Community Pharmaceutical on the Prescription clearly with the words "Trial Period", or "Trial"; and
- specified the maximum quantity or period of supply to be dispensed for each Community Pharmaceutical at any one time.

Patients who reside in Penal Institutions are not eligible for Trial Periods.

4.4 Frequent Dispensing for Safety and co-prescribed medicines

a) A **Safety Medicine** ~~Community Pharmaceutical~~ is any of the following:

i) a tri-cyclic antidepressant; or
ii) an antipsychotic; or
iii) a benzodiazepine; or
iv) a Class B Controlled Drug; or
v) codeine (includes combination products); or
vi) buprenorphine with naloxone; or
vii) zopiclone.

To be dispensed via Frequent Dispensing, all ~~All~~ of the following conditions must be met:

The **Safety Medicine** ~~Community Pharmaceutical~~ has been prescribed for a patient who is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in 4.2 above.

The prescribing Practitioner has:

- Assessed clinical risk and determined the patient requires increased Frequent Dispensing; and
- Specified the maximum quantity or period of supply to be dispensed for each Community Pharmaceutical at any one time.

b) **When a** ~~The~~ Community Pharmaceutical is co-prescribed with **a Safety Medicine** ~~one of the Community Pharmaceuticals~~ **(**listed in 4.4(a)**)** above and has been prescribed for a patient who is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in 4.2 above **and the** ~~. The~~ dispensing pharmacist has:

- Assessed clinical risk and determined the patient requires Frequent Dispensing of their co-dispensed medicines; and
- Annotated the Prescription with the amended dispensing quantity and frequency;

The Community Pharmaceutical may be dispensed at the same frequency as the Safety Medicine.

4.5 Frequent Dispensing for Pharmaceutical Supply Management

4.5.1 Frequent Dispensing may be required from time to time to manage stock supply issues or emergency situations. Pharmacists may dispense more frequently than the Schedule would otherwise allow when all of the following conditions are met:

a) PHARMAC has approved and notified pharmacists to annotate Prescriptions for a specified Community Pharmaceutical(s) "out of stock" without prescriber endorsement for a specified time; and

b) the dispensing pharmacist has:

i) clearly annotated each of the approved Community Pharmaceuticals that appear on the Prescription with the words “out of stock” or “OOS”; and

ii) initialed the annotation in their own handwriting; and

iii) has complied with maximum quantity or period of supply to be dispensed at any one time, as specified by PHARMAC at the time of notification.

Note – no claim shall be made to any DHB for subsidised dispensings under this rule where dispensing occurs more frequently than specified by PHARMAC to manage the supply management issue.