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Ref. No _____

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Chair
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Committee of New Zealand
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Dear Helen Snell

Changes to regulations under the Medicines Act 1981

Following public consultation the Government has agreed to a suite of amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. Amendments have been made to prescribing, labelling, advertising and dispensing requirements.

I would like to take this opportunity to highlight the key changes to the prescribing requirements.

Aligning prescribing rights (Reg 39 and 39A)
The current requirements for dentists to prescribe prescription medicines for dental treatment only and for midwives to prescribe prescription medicines for antenatal, intra-partum or postnatal care only has been removed. The regulations will stipulate that prescribers are required to prescribe in accordance with their scope of practice, as defined by their responsible authorities under the Health Practitioners Competence Assurance Act 2003, for patients under their care.

Concerns have been raised about the ability of pharmacists to verify whether prescriptions issued are in accordance with the prescriber's scope of practice. Pharmacists should continue to dispense prescriptions 'on their face', unless there is reason to believe that a prescription does not comply with legal requirements. If a pharmacist is concerned that the prescription is outside the prescriber's scope of practice, they should discuss this with the prescriber in the first instance.

From 1 December 2011 the 10 day limit on supply of a prescription medicine by a dentist will be removed and the period of supply aligned for all authorised prescribers at six months for oral contraceptives and three months for other prescription medicines. In addition, the Director-General of Health will have the ability to waive the limit on the period of supply in certain circumstances.

Requirements for prescriptions (Reg 41)
Requirements for a prescription, both its physical form and the information it must include, are specified in regulation 41 of the Medicines Regulations. Some of these requirements were very detailed, while other sensible requirements (such as including the printed name and telephone number of the prescriber) were not specified.

Regulation 41 has therefore been amended to:

- require the name of the prescriber to be included on the prescription, as well as the street address of their place of work (or the postal address if the prescriber does not have a fixed place of work), phone number and signature
- require inclusion of the given name(s) of the person for whose use the prescription is given
- require the prescriber to specify the total quantity of medicine or total period of supply, but no longer require the prescriber to specify in what portions or at what intervals the medicine should be dispensed.

Brand substitution (Reg 42(4))
Pharmacists will be allowed to substitute an alternative brand of a prescribed medicine provided:

- there are no clinical reasons why substitution should not occur
- the prescriber has not marked the prescription with a statement such as 'no brand substitution permitted'; and
- the pharmacist records details of the brand substitution on the prescription and informs the patient of the change of brand.

The decision by a pharmacist to substitute an alternative brand can only be made after the pharmacist has determined that there is no clinical reason that the substitution cannot be made, in the context of the clinical equivalence of the alternative brand, and the patient's treatment and circumstances. This will include consideration of relevant information from the medicine data sheet (which is available on Medsafe's website).

Dispensing requirements (Reg 42(3))
Provisions relating to the frequency of dispensing have been revoked and the requirements for recording dispensing details updated to reflect current practice. The amended regulations require the pharmacy name and address, date, quantity of medicine dispensed and prescription number to be recorded each time a prescription is dispensed. However, the way in which these details are recorded is not specified, which will allow for flexibility in the use of electronic technologies.

While there was some support from submitters for legal recognition of faxed prescriptions, the Ministry does not consider there are adequate safeguards to enable faxed prescriptions to be considered legitimate prescriptions not requiring prescriber verification. It is also envisaged that once secure electronic transmission of prescriptions is occurring there will no longer be a need for prescriptions to be faxed.

Medicines (Standing Order) Regulations

Standing orders permit specified people (eg, paramedics) to administer medicines under the overall authority of a prescriber. Currently the prescriber issuing a standing order is required to countersign the charted treatment or record every time a medicine is administered under the order. This requirement imposes a significant administrative burden in areas such as the ambulance service, where paramedics administer medicines under a standing order given by the medical director.

The regulations have been amended to remove the requirement for the issuing prescriber to countersign every administration or supply of a medicine under a standing order. In the future, the issuer of a standing order will be able to specify:

- when countersigning is and is not required
- who may supply and/or administer treatments under the order without countersigning being required on each occasion; and
- the interval at which the issuer of the order will review the practices of those working under the order.

To address concerns about a possible lack of oversight if countersigning is not mandatory, the regulations require, as a minimum, a documented monthly audit of a sample of the records of administration or supply under a standing order.

All other requirements for standing orders set out in the regulations will continue to apply.

The Regulations also:

- Exclude certain dentifrices, oral hygiene products, anti-dandruff preparations, anti-acne preparations, barrier creams and antibacterial skin products from regulation under the Medicines Act 1981, aligning the criteria for exclusion with those applied in Australia.

- Simplify advertising and labelling requirements, and better align them with Australian requirements, so as to minimise costs to companies associated with changing advertising material and relabelling products for the New Zealand market.

- Enable the Director-General of Health to issue a waiver to one or more regulatory requirements for a prescription to permit electronic transmission of prescriptions in specified situations.

- Remove the prescriptive content, format and publication requirements for medicines data sheets, and require data sheets to be submitted for publication within 10 days of approval of the medicine. The Ministry will, instead, publish guidelines on the content and format for data sheets.

- Remove the regulation which lists the colouring substances permitted in medicines and related products. The Ministry will, instead, publish and maintain an up-to-date list of acceptable colouring substances in guidelines.

- Allow the Director-General of Health to permit (by notice in the *New Zealand Gazette*) specified general sale medicines to be sold via vending machine.

- Provide greater clarity about those situations in which a prescription is not required by specifying that the medicine must be dispensed by a person who has been instructed by the prescriber and that the prescriber and dispenser must make a record in the patient's medical record.

- Update Schedule 1 of the Medicines Regulations 1984, which lists all classified medicines.

Most of the amendments will come into force on 1 August 2011. However, amendments to align prescribing rights (Regs 39 and 39A) and to the form of a prescription (Reg 41) will come into force on 1 December 2011. This will allow time for the necessary changes to be made to software systems.

The proposal to extend the period of supply from six months to 12 months for oral contraceptives, and from three months to six months for other prescriptions medicines has been put on hold. Extending the period of supply for prescription medicines has fiscal and software impacts. Further work is required to accurately quantify the impacts and determine how they are best managed.

The Medicines Amendment Regulations 2011 and the Medicines (Standing Order) Amendment Regulations 2011 are available from Bennetts or online at www.legislation.govt.nz.

For further information see *Proposed Amendments to Regulations under the Medicines Act 1981 – report of the analysis of submissions and final decisions* (www.moh.govt.nz/moh.nsf/indexmh/proposed-amendments-regs-medicines-act-submissions-report?Open). Alternatively, you can contact Sharon Woollaston, Senior Policy Analyst, Policy Business Unit (sharon_woollaston@moh.govt.nz).

Kind regards

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