MANATŪ HAUORA
MINISTRY OF HEALTH

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19 December 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022017600

Tēnā koe s 9(2)(a)

**Response to your request for official information**

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 25 November 2022 for information regarding amendments to the Medicines Act. You requested:

> *Manatū Hauora / The Ministry of Health has a document from 2010 on the Proposed Amendments to Regulations under the Medicines Act 1981 [1]. Change proposal 1.6: Extend the period of supply of prescription medicines states for its outcome that:*
> *"As a result of submitter feedback, it is intended that the period of supply on a prescription be extended to 12 months for oral contraceptives and six months for other prescription medicines"*
> *This outcome does not appear to have been implemented in the Medicines Regulation 1984 in the 12 years since this was intended in 2010.*
> *For context, I am seeking to understand why:*
> ** this change proposal (1.6) was made*
> ** the outcome (quoted above) was intended*
> ** the status quo was rejected in favour of the outcome at the time*
> ** the outcome was not implemented at the time*
> ** the status quo was preserved despite the outcome at the time*
> ** there appears to be no information given on why the outcome was not implemented*
> ** the outcome remains not implemented at the present time*
> *I seek all information on this particular matter.*

On 8 December 2022, you were contacted in accordance with section 18B of the Act as your request, as it was worded, encapsulated a very large volume of information. On 9 December 2022 you accepted a refinement to official correspondence only concerning the seven topics you identified in your request.

On 9 December we also provided you with two links to publicly available information within the scope of your request. For your convenience I have provided these to you again:

- www.moh.govt.nz/notebook/nbbooks.nsf/0/ddbe0f6c0c8b81c6cc2576d8007a3222/$FILE/consultation-proposed-amendmentsmedact-feb10-feb10.pdf
- www.health.govt.nz/publication/proposed-amendments-regulations-under-medicines-act-1981

Manatū Hauora has identified twelve documents within scope of this part of your request. All documents are itemised in Appendix 1 and copies of the documents are enclosed. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Steve Waldegrave
**Associate Deputy Director-General**
**Strategy, Policy and Legislation | Te Pou Rautaki**

**Appendix 1: List of documents for release**

| # | Date | Document details | Decision on release |
|---|---|---|---|
| 1 | June 2010 | Briefing – Feedback on consultation on medicines regulations changes | Some information withheld under the following sections of the Act:<br>• Section 9(2)(a), to protect the privacy of natural persons; and<br>• Section 9(2)(g)(i) to maintain the effective conduct of public affairs through the free and frank expression of opinions by or between or to Ministers and officers and employees of any public service agency. |
| 1A | June 2010 | Draft report of the analysis of submissions and final decisions on proposed amendments to regulations under the Medicines Act 1981 | Some information withheld under section 9(2)(a) of the Act. |
| 2 | September 2010 | Briefing – Approval to implement changes to medicines regulations | |
| 2A | September 2010 | Cabinet Social Policy Committee – Approval to implement changes to several regulations under the Medicines Act 1981 | Released in full. |
| 2B | September 2010 | Report of the analysis of submissions and final decisions on proposed amendments to regulations under the Medicines Act 1981. | Some information withheld under section 9(2)(a) of the Act. |
| 2C | September 2010 | Regulatory impact statement | Released in full. |
| 3 | June 2011 | Briefing – Extending the period of supply for prescription medicines | Some information withheld under section 9(2)(a) of the Act. |
| 4 | June 2011 | Briefing – Approval to submit medicines regulations changes to Cabinet Legislation Committee | |
| 4A | June 2011 | Draft Medicines Amendment Regulations 2011 | Released in full. |
| 5 | December 2011 | Briefing – Extending the period of supply for prescription medicines – report back | Some information withheld under section 9(2)(a) of the Act. |

| # | Date | Document details | Decision on release |
|---|---|---|---|
| 6 | January 2012 | Letter to sector groups | Released in full. |
| 6A | January 2012 | Recipient list for letter to sector groups. | Some information withheld under section 9(2)(a) of the Act. |

MINISTRY OF HEALTH
MANATŪ HAUORA

**Health Report number:** 20100766

**Action required by:** **routine**

**Date sent to Minister:** **29 June 2010**

**Minister's reference:** **not applicable**

**File number:** **HC19-02-9-2**

## To: Hon Tony Ryall

**cc: Hon Peter Dunne**

## Title: Feedback on consultation on medicines regulations changes

## Executive summary

i. In February 2010, the Ministry released a consultation document on proposed amendments to regulations under the Medicines Act 1981. Eighty four submissions were received from a wide cross section of stakeholders. For the most part, submitters supported the proposals, and in some cases, they suggested additional useful changes.

ii. This report briefly describes the level of support and issues raised by submitters in relation to each of the original proposals, highlights some changes and some new proposals that have come out of the consultation process, and seeks your agreement on a set of recommendations for progressing the final set of proposals.

iii. Within two weeks of your decisions on this report, we will prepare a Cabinet paper, which seeks agreement to the final proposals for medicines regulation changes, and also seeks agreement to issue drafting instructions and release a summary of the analysis of submissions. We envisage the medicines regulation changes to be in effect by mid-December.

## The Ministry recommends that you:

a) **Agree** to the following recommendations as originally proposed (and broadly supported by submission): Yes / No

i) To exclude fluoride dentifrices and anti-dandruff preparations from regulation under the Medicine Act

ii) To remove the requirement for a consumer information panel on medicines for over-the-counter sale

iii) To change the advertising requirements for medicines so that they are better aligned with those in Australia, incorporating, where appropriate, submitters' suggested refinements to the proposals

iv) To amend the medicines regulations to enable a waiver to be issued that would permit electronic transmission of prescriptions in specified situations

v) To align the prescribing rights for medical practitioners, dentists, and midwives, requiring all prescribers to prescribe within their scope of practice

vi) To remove the 10 day limit on period of supply for dentists, thus aligning the period of supply for all prescribers

vii) To allow the Director-General of Health to waive the limit on period of supply of prescription medicines, either for an individual or a class of persons, in certain circumstances

viii) To tighten up the regulations, so that prescribers can only prescribe prescription medicines for the treatment of patients under their care, who are normally resident in New Zealand

ix) To allow pharmacists to substitute an alternative brand of a medicine

x) To change regulations setting out the content, format and publication requirements for data sheets, and require approved data sheets to be submitted for publication within 10 days of approval of the medicine

xi) To remove the regulation, which lists the colouring substances permitted in medicines and related products, and, instead, publish an up-to-date list of acceptable colouring substances in guidelines

xii) To remove prescriptive requirements relating to the dispensing of prescriptions and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice.

b) **Indicate** whether you agree to the following recommendations as changes to the original proposals:

i) **Exclude** the following products from regulation, using the approach taken in the Australian Excluded Goods Order to limit content, claims and presentation for use: Yes / No

- anti-acne preparations (such as cleansers, scrubs, masks)
- barrier creams for preventing nappy rash
- medicated soaps
- antibacterial skin products
- oral hygiene products

ii) **Proceed** with proposed amendments to labelling requirements and, in addition: Yes / No

- rationalise the requirements for labelling of strip packed medicines (including safety containers) and small containers
- remove prescriptive requirements that do not enhance patient safety (such as the requirement relating to the size of the Principal Display Panel)
- rationalise the requirements for labelling of medicines used by practitioners

iii) **Remove** label warning statements for non-sedating antihistamines from the regulations and, instead, place these in guidelines Yes / No

iv) **Require** the label on a dispensed medicine to include an identifying code linking the dispensed item back to the original prescription Yes / No

v) **Add** a new regulation setting out the requirements for labels on compliance[1] packaging Yes / No

vi) **Extend** the maximum period of supply on a prescription from 6 months to 12 months for an oral contraceptive, and from 3 months to 6 months for any other prescription medicine Yes / No

vii) **Proceed** as proposed with changes to the counter-signing requirements for standing orders, with an additional requirement that in situations where counter-signing of each administration or supply under a standing order is not occurring, there is a monthly (or more regular) review, by the issuer of the order, of a sample of records of administration or supply Yes / No

[1] Compliance packaging is a term used to describe a patient-specific pack of dispensed medicines. The pack comprises one or more strips of sealed pockets, each of which contains all the dispensed medicines that need to be taken at the day/time stated on the seal above each pocket.

viii) **Add** a new regulation allowing the Director-General of Health to permit (by notice in the *New Zealand Gazette*), specific general sale medicines to be sold via a vending machine in accordance with any conditions specified in the notice — Yes / No

ix) **Proceed** as proposed with changes to definitions relating to pharmacy qualifications and, in addition, remove a redundant sub-clause from the definition of 'pharmacy technician' — Yes / No

x) **Proceed** as proposed with changes to the requirements for prescriptions and, in addition, require inclusion of the prescriber's street address and phone number on a prescription — Yes / No

xi) **Amend** the regulation regarding circumstances in which a prescription is not required, to clarify its intent — Yes / No

xii) **Include** an update to the First Schedule, which lists all classified medicines, in the planned amendment to the Medicines Regulations. — Yes / No

Deborah Roche

**Deputy Director-General**

**Health and Disability Systems Strategy**

**Minister's Signature**

**Date:**

**Ministry of Health Contacts:**

| | | | |
|---|---|---|---|
| Therese Egan<br>Manager, Policy Unit | | Michael Hampl<br>Principal Analyst | |
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MINISTRY OF HEALTH
MANATŪ HAUORA



## Advice

1. In February 2010, the Ministry released a consultation document on proposed amendments to regulations under the Medicines Act 1981 [Health report 2010046, CAB Min (10) 5/2 and SOC Min (10) 1/1 refer]. The amendments aim to reduce unnecessary costs, remove barriers to innovation, and improve access to medicines. Submissions closed on 26 March 2010. Eighty four submissions were received from a wide cross section of stakeholders. A draft summary of the analysis of submissions is attached (see Appendix 1). It is drafted on the basis that you agree with the Ministry's recommendations, and will be amended to reflect your final decisions.
2. This report provides you with the Ministry's advice following analysis of the submissions received. It is recommended that many of the amendments should be progressed as proposed. Modifications to some of the proposals have been recommended in light of submitters' comments. It is also recommended that a small number of additional amendments should be progressed, including an update to the First Schedule to the Medicines Regulations.
3. We estimate the implementation date for the amended regulations will be mid-December 2010, based on the following:

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| Cabinet approval to issue drafting instructions | Late July/early August |
| PCO drafting and Ministry review process | August to October |
| Cabinet Committee (LEG) approval | By mid-November |
| In force (after 28-day period) | Mid-December |

4. We will keep stakeholders informed of progress.

### Proposals to reduce unnecessary costs, remove barriers to innovation and improve access to medicines

***Excluding certain products from regulation under the Medicines Act***

5. The proposal to exclude fluoride dentifrices containing 0.15 percent or less of elemental fluoride, and many anti-dandruff preparations, from regulation under the Medicines Act was strongly supported by submitters. The majority felt the Cosmetics Group Standard would provide adequate protection for consumers.
6. Many submitters provided examples of other products they considered should be excluded from regulation under the Medicines Act. Submitters also suggested that, in the interests of potential trade and consumer benefits, the approach to setting limits on content, claims and presentation of excluded products should be aligned with that used in Australia.
7. The Ministry recommends that you agree to:

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| Proceed as proposed to exclude fluoride dentifrices and anti-dandruff preparations from regulation under the Medicine Act. |

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| Also exclude the following products, using the approach taken in the Australian Excluded Goods Order to limit content, claims and presentation for use:<br>• anti-acne preparations (such as cleansers, scrubs, masks)<br>• barrier creams for preventing nappy rash<br>• medicated soaps<br>• antibacterial skin products<br>• oral hygiene products. |

***Labelling requirements for medicines***

8. The proposal to remove the requirement for certain information to be placed in a specific "consumer information panel" on the label of a medicine intended for retail sale without a prescription was well supported by submitters.
9. Proposed amendments to the labelling requirements were also well supported, with submitters suggesting further changes that would better align New Zealand labelling requirements with those applying in Australia. The Ministry supports such changes.
10. Submitter feedback in relation to the warning statement for non-sedating antihistamines has highlighted the need to redesign the way appropriate warning statements on product labels are included. The Ministry now recommends that label warning statements for non-sedating antihistamines be removed from the regulations and, instead, be placed in guidelines. Compliance would be ensured through the product approval process.
11. Two additional changes relating to the labelling requirements for dispensed medicines were also identified as desirable by submitters and are supported by the Ministry.
12. The Ministry recommends that you agree to:

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| Proceed as proposed with removal of the requirement for a consumer information panel on medicines for over-the-counter sale. |
| Proceed with proposed amendments to labelling requirements and, in addition:<br>• rationalise the requirements for labelling of strip packed medicines (including safety containers) and small containers<br>• remove prescriptive requirements that do not enhance patient safety (such as the requirement relating to the size of the Principal Display Panel)<br>• rationalise the requirements for labelling of medicines used by practitioners. |
| Remove label warning statements for non-sedating antihistamines from the regulations and, instead, place these in guidelines. |

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| Require the label on a dispensed medicine to include an identifying code linking the dispensed item back to the original prescription. |
| Add a new regulation setting out the requirements for labels on compliance[2] packaging. |

### *Advertising requirements*

13. The majority of submitters who responded supported the proposed changes to advertising requirements, with some suggesting refinements to the proposals or further changes they would like to see (eg, greater clarity about any differences in advertising requirements for prescription and non-prescription medicines). Those opposed to the suggested changes generally wanted more, rather than less, information in advertisements and were concerned that consumers would not have access to adequate information on the benefits and risks of the medicine if the requirements were relaxed. The Ministry does not consider that these concerns are valid, since an advertisement is not an effective way of conveying detailed information to consumers.

14. The Ministry recommends that you agree to:

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| Proceed with the proposed changes to advertising requirements for medicines so that they are better aligned with those in Australia, incorporating, where appropriate, submitters' suggested refinements to the proposals. |

### *Electronic transmission of prescriptions*

15. The majority of submitters who responded to this proposal supported the concept of allowing the Director-General of Health to issue waivers on a case-by-case basis to enable electronic transmission of prescriptions. Some expressed a wish to be involved in the development of the criteria for the waiver.

16. Some submitters stressed the need for careful consideration to be given to the development of the criteria to be met by those seeking a waiver. Some considered the waiver should be setting-specific (eg, District Health Board hospitals). The Ministry agrees that the criteria for granting a waiver need to be specific enough to ensure the integrity of the prescribing process. Use of a waiver mechanism means that the Director-General will have the ability to change the criteria as the sector's readiness for electronic prescribing progresses.

17. The Ministry recommends that you agree to:

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| Proceed with the proposed amendment to enable a waiver to be issued that would permit electronic transmission of prescriptions in specified situations. |

### *Aligning prescribing rights*

18. The proposal to align prescribing rights for medical practitioners, dentists and midwives was generally well supported. This would mean the regulations would stipulate that all these practitioners must prescribe in accordance with their scope of practice, as set by their responsible authorities, under the Health Practitioners Competence Assurance Act.

[2] Compliance packaging is a term used to describe a patient-specific pack of dispensed medicines. The pack comprises one or more strips of sealed pockets, each of which contains all the dispensed medicines that need to be taken at the day/time stated on the seal above each pocket.

19. Some pharmacy organisations and pharmacists, however, raised concerns about pharmacists' ability to verify whether prescriptions issued by dentists and midwives are in accordance with their scopes of practice. The Ministry does not consider that the proposed amendment would introduce any additional requirements for pharmacists. Previous Ministry legal advice is that pharmacists may dispense a prescription "on its face" provided he or she acts in "good faith". If the pharmacist has any concerns about the legitimacy or validity of a prescription, it should be referred to the prescriber. Provided the pharmacist dispenses a prescription in "good faith", the pharmacist will receive payment. If it is subsequently identified that the prescriber was working outside their scope of practice, this would be dealt with by the appropriate responsible authority.
20. The Ministry proposes to write to pharmacy organisations to reiterate this advice. At the same time, we will write to responsible authorities to remind them of their obligations to ensure that their health practitioners prescribe according to best practice guidelines and competencies for their respective scopes of practice. The Ministry will also copy pharmacy organisations in to this correspondence.
21. The Ministry recommends that you agree to:

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| Proceed with the proposal to align prescribing rights for medical practitioners, dentists, and midwives, requiring all prescribers to prescribe within their scope of practice. |

***Extending the period of supply of prescription medicines***

22. The proposal to remove the 10 day limit on the period of supply of a prescription medicine able to be prescribed by a dentist was well supported.
23. PHARMAC raised a concern about the potential fiscal impact of aligning dentists' prescribing rights and periods of supply with those of other prescribers. The Ministry expects that any increase in prescribing by dentists will be offset by a decrease in prescribing by medical practitioners, since patients will no longer need to be referred to a medical practitioner in order to obtain a prescription for extended treatment. Access and convenience for patients is likely to improve.
24. The proposal to allow the Director-General to waive the limit on period of supply in certain circumstances was also generally supported, particularly in relation to prescribing for armed forces personnel.
25. Many submitters supported an extension of the period of supply of prescription medicines for patients with chronic conditions who are stabilised on a treatment regime. Some submitters, however, pointed out that such an approach could lead to concerns about the safety of patients who stockpile their medicines, and the potential for wastage, if changes need to be made to a patient's treatment.
26. The Ministry proposes extending the period of supply on a prescription from 6 months to 12 months for oral contraceptives, and from three months to six months for other prescription medicines, at the prescriber's discretion. It is recommended, however, that measures are put in place to ensure that not more than three months' supply of a subsidised medicine is dispensed at one time to reduce the potential for wastage, and address the safety concerns associated with patients who stockpile their medicines. This could be achieved through the Pharmaceutical Schedule.

27. The Ministry recommends that you agree to:

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| Proceed with the proposal to remove the 10 day limit on period of supply for dentists, thus aligning the period of supply for all prescribers. |
| Proceed with the proposal to allow the Director-General of Health to waive the limit on period of supply of prescription medicines, either for an individual or a class of persons, in certain circumstances. |
| Extend the maximum period of supply on a prescription from 6 months to 12 months for an oral contraceptive, and from 3 months to 6 months for any other prescription medicine. |

***Restricting prescribing for patients who are not in New Zealand***

28. The majority of submitters who responded to the proposal to restrict prescribing for patients who are not in New Zealand supported it. Those involved in internet prescribing and dispensing prescriptions for overseas patients opposed the proposal because it would potentially put them out of business.

29. s 9(2)(g)(i) [redacted]

30. The Ministry recommends that you agree to:

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| Proceed with the proposal to tighten up the regulations, so that prescribers can only prescribe prescription medicines for the treatment of patients under their care, who are normally resident in New Zealand. |

***Allowing pharmacists to substitute alternative brands of medicines.***

31. There was strong support for the proposal to allow pharmacists 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 "no brand substitution permitted", and the pharmacist records details of the brand substitution on the prescription.

32. Some submitters suggested that Medsafe should maintain a list on its website of medicines that are interchangeable at a population level. Medsafe does not support this approach because the decision to substitute an alternative brand is a clinical one that should be made by the pharmacist, in the context of the particular patient's treatment and circumstances. Information is available in the medicine data sheet to help inform the decision.

33. The Ministry recommends that you agree to:

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| Proceed with the proposal to allow pharmacists to substitute an alternative brand of a medicine. |

***Changing counter-signing requirements for standing orders***

34. The proposal to allow the issuer of a standing order to specify when counter-signing of every administration and supply of the medicine is not required, who may supply and/or administer treatments under the standing order without counter-signing on each occasion, and the interval at which the issuer of the order will review the practices of those working under the order, was well supported by those who responded to it.

35. There was, however, a concern about lack of oversight of standing orders if the counter-signing requirement is removed. To address this concern, we recommend that the regulation must stipulate, in instances where counter-signing of every administration and supply is not required, that the standing order must require the issuer to conduct, at a minimum, a monthly audit of a sample of the records of administration or supply, under the standing order.

36. Concern was also raised that, presently, standing orders are only monitored during certification audits in hospitals and rest homes. This means that there is no monitoring of standing orders in the primary care setting. If this proposal proceeds, the Ministry will write to the responsible authorities to remind them of the responsibilities of issuers of standing orders, particularly where standing orders are being used outside the hospital and rest home setting.

37. The Ministry recommends that you agree to:

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| Proceed as proposed with changes to the counter-signing requirements for standing orders, with an additional requirement that in situations where counter-signing of each administration or supply under a standing order is not occurring, there is a monthly (or more regular) review, by the issuer of the order, of a sample of records of administration or supply. |

***Allowing sale of general sale medicines by vending machine***

38. Of those who responded to the proposal to permit sale of general sale medicines by vending machine, just over a third opposed it and raised concerns about the public safety risks of vending machines. Concerns included suicide risks with medicines such as paracetamol, the likelihood of children accessing machines, and vandalism. Submitters suggested controls on where vending machines could be located, what they could contain, and the volume of product to be dispensed at one time.

39. Based on submitter feedback, the Ministry proposes that, rather than a blanket permission for general sale medicines to be sold by vending machine, a new regulation is made to allow the Director-General of Health to permit (by notice in the *New Zealand Gazette*), specific general sale medicines to be sold via a vending machine in accordance with any conditions specified in the notice. The conditions would be those that were considered necessary to ensure the integrity of the medicines or as a safeguard against inappropriate access.

40. The Ministry recommends that you agree to:

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| Add a new regulation allowing the Director-General of Health to permit (by notice in the *New Zealand Gazette*), specific general sale medicines to be sold via a vending machine in accordance with any conditions specified in the notice. |

## Updating technical requirements

### *Data sheets*

41. The proposed changes to the content, format and publication requirements for medicines data sheets were strongly supported. A number of submitters commented on the timing of publication of the data sheet, with suggestions ranging from submission for publication within 10 days of the medicine being approved (which the Ministry supports), to publication on or before the date the medicine is placed on the market, to publication within a month of the medicine being approved.

42. The Ministry recommends that you agree to:

> Proceed as proposed with changes to the regulations setting out the content, format and publication requirements for data sheets, and require approved data sheets to be submitted for publication within 10 days of approval of the medicine.

### *Definitions relating to pharmacy qualifications*

43. The proposed amendments to definitions relating to pharmacy qualifications were well supported. Submitters also suggested removing a redundant sub-clause from the definition of 'pharmacy technician' because it is no longer needed and refers to the Council of the Pharmaceutical Society, which no longer exists. The Ministry does not consider that any of the other changes or additional definitions put forward by submitters should proceed.

44. The Ministry recommends that you agree to:

> Proceed as proposed with changes to definitions relating to pharmacy qualifications and, in addition, remove a redundant sub-clause from the definition of 'pharmacy technician'.

### *Colouring substances*

45. The proposal to remove the regulation, which lists the colouring substances permitted in medicines and related products and, instead, publish an up-to-date list of acceptable colouring substances in guidelines, was well supported. Submitters highlighted the need for the list of suitable colouring substances to be readily accessible.

46. The Ministry recommends that you agree to:

> Proceed with the proposal to remove the regulation, which lists the colouring substances permitted in medicines and related products, and, instead, publish an up-to-date list of acceptable colouring substances in guidelines.

### *Requirements for prescriptions*

47. Proposals to amend prescription requirements were well supported. Submitters suggested a number of other specific pieces of information they considered should be included on a prescription (eg, patient and prescriber identifiers, prescriber's street address and phone number).

48. While the Ministry strongly supports the inclusion of unique patient and prescriber identifiers on prescriptions, regulation is not considered the optimal mechanism for achieving this and could disadvantage prescribers, pharmacists and patients in situations (such as when a

doctor is prescribing for a new patient after hours), where the information was not readily accessible. The Ministry supports the inclusion of the prescriber's street address and phone number.

49. It was suggested that the weight of a child under five should be included on a prescription. Since the Medical Council already requires under its *Good Prescribing Practice* that a practitioner include the weight of a child on a prescription, if this information would affect dosage, the Ministry does not consider there would be any benefit in making this a regulatory requirement.

50. The Ministry recommends that you agree to:

> Proceed as proposed with changes to the requirements for prescriptions and, in addition, require inclusion of the prescriber's street address and phone number on a prescription.

### *Dispensing requirements*

51. Proposed changes to remove prescriptive dispensing requirements and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice, were strongly supported. Some submitters suggested additional requirements, including the recognition of faxed prescriptions without the need for a paper copy, and the need for original prescriptions (not just computer records) to be viewed when a repeat is dispensed. 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.

52. The Ministry recommends that you agree to:

> Proceed as proposed with amendments to remove prescriptive requirements relating to the dispensing of prescriptions and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice.

## Other issues raised through the consultation process

53. A request was made to clarify the intent of the regulation regarding circumstances in which a prescription is not required. It currently reads as a blanket exemption from the need for a prescription. Its purpose is to remove the requirement for a prescription to be written in a situation where a prescriber wishes a patient under his care to receive a dose of a medicine, and gives verbal instructions to that effect to the person who is going to supply or administer the dose of medicine.

54. The Ministry recommends that you agree to:

> Amend the regulation regarding circumstances in which a prescription is not required, to clarify its intent.

55. Some submitters requested changes that could not be achieved through an amendment to the Medicines Regulations but would require amendment to primary legislation (eg, altering the prescribing framework, amending labelling requirements for controlled drugs, banning direct-to-consumer advertising of prescription medicines, extending requirements for child-resistant packaging). Such changes will be considered by the Ministry in the context of work

on a Medicines Amendment Bill and a Natural Health Products Bill [Health Report 20100278 refers].

### Update to the First Schedule to the Medicines Regulations

56. The First Schedule to the Medicines Regulations comprises a list of individual medicines that are classified as Prescription Medicines, Restricted Medicines or Pharmacy Only Medicines. Classifications for new medicines and changes to the classification of existing medicines are given immediate effect through a time-limited notice in the *New Zealand Gazette*. Periodically, it is therefore necessary to update the First Schedule to include recent additions and changes. This is typically done every 12 to 18 months and is regarded as a technical change that does not require a policy approval from Cabinet because consultation has already occurred, and the update does not actually change the classification of any medicine.

57. It would be efficient to include drafting instructions for the next update to the First Schedule in tandem with the other proposals set out in this paper.

58. The Ministry recommends that you agree to:

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| Include an update to the First Schedule, which lists classified medicines, in the planned amendment to the Medicines Regulations. |

### Preparation of a Cabinet paper

59. Based on your decisions on these proposals to amend medicines regulations, we will prepare a Cabinet paper which seeks agreement to the final proposals (including the issuing of drafting instructions), and the release of a summary of the analysis of submissions. We anticipate that we will have a Cabinet paper ready for submission to Cabinet by late July/early August 2010. Subject to Cabinet approval, and drafting time, we anticipate that the new regulations will be passed and come into force around the end of the year.

## Minister's feedback

| | Very poor | Poor | Neutral | Good | Very Good |
|---|---|---|---|---|---|
| Quality of advice | 1 | 2 | 3 | 4 | 5 |
| Writing style | 1 | 2 | 3 | 4 | 5 |
| Quality of analysis | 1 | 2 | 3 | 4 | 5 |
| Completeness of information | 1 | 2 | 3 | 4 | 5 |

Comments:

**ENDS.**

Document 1A

DRAFT (June 2010)

# Report of the Analysis of Submissions and Final Decisions

# on

# Proposed Amendments to Regulations under the Medicines Act 1981

[Month] 2010

# INTRODUCTION

In February 2010 the Ministry of Health released a consultation paper *Consultation on Proposed Amendments to Regulations under the Medicines Act 1981* describing a set of proposals designed to modernise provisions in the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. Feedback on the proposals was sought by 26 March 2010.

The Ministry of Health received 84 submissions on the proposals from a wide cross-section of affected stakeholders. Seventeen submissions were received from District Health Board (DHB) employees, four from government agencies, eighteen from companies involved in the manufacture or supply of medicines, related products or cosmetics and six from organisations representing those suppliers. Groups representing or regulating health professionals provided twenty-one submissions, five submissions were received from individual health professionals, and four from organisations delivering healthcare services. Five submissions were received from consumer groups and one submission from the advertising sector.

A summary of the feedback received on each proposal, and the Government's decisions following consideration of the feedback, is provided below.

# Part 1: Proposals to reduce unnecessary costs, remove barriers to innovation and improve access to medicines

| *Change proposal 1.1* | *Exclude some fluoride dentifrices and some anti-dandruff products from regulation under the Medicines Act 1981* |
|---|---|

*It is proposed that a new regulation be made under section 105(1)(i) declaring that:*

- *dentifrices containing fluoride below the 0.15 percent level specified in Part 3 of the First Schedule to the Medicines Regulations 1984, and for which only general fluoride claims are made*

*and*

- *anti-dandruff shampoos that do not contain a scheduled medicine and for which only dandruff treatment claims are made*

*are not related products for the purposes of the Act.*

*Dentifrices containing higher levels of fluoride or other active ingredients, or that make claims other than fluoride claims, would continue to be regulated as related products or medicines, as they are at present.*

*Anti-dandruff products containing scheduled medicines or intended for the treatment of scalp conditions other than dandruff would continue to be regulated as medicines, as they are at present.*

## Feedback received

This proposal was almost universally supported by the submitters who commented on it and the majority of these also felt that the Cosmetic Products Group Standard would provide adequate protection about the safety of such products. Two submitters expressed concern about the toxicity of fluoride and its widespread use.

Around twenty submitters provided examples of other product types they considered should also be excluded from regulation under the Medicines Act 1981. A common theme in these submissions was that the exclusion list should be developed to align with the approach taken in Australia to define the cosmetic/therapeutic goods boundary because of the potential trade and consumer benefits of a harmonised approach. Submitters therefore recommended exclusion of products such as anti-acne skin care products, barrier creams for preventing nappy rash, and a broad range of oral hygiene products for the care of the teeth and the mouth. They also asked that cut-off levels for ingredients in those products and permissible claims for the excluded products be harmonised with Australia.

A few submitters asked that products such as pregnancy tests, medicated condoms and saline nasal irrigations that are regulated in Australia as medical devices be excluded from the Medicines Act.

## Outcome

The planned amendment will be progressed (with the level of fluoride in excluded dentifrices being set at 0.15% or less of elemental fluoride).

In addition, the following product types will be excluded from regulation under the Medicines Act using the approach taken in the Australian Excluded Goods Order to limit content, claims and presentation for use:

- anti-acne preparations (such as cleansers, scrubs, masks)
- barrier creams for preventing nappy rash
- antibacterial skin products
- oral hygiene products.

Some of these products may be covered by the Cosmetic Products Group Standard if they contain substances which meet the hazardous substances threshold, otherwise they will no longer be regulated.

Pregnancy tests can not be excluded from the Medicines Act by regulation as they are included in the definition of "medicine" in the Act. Similarly, products which are regulated as medicines in New Zealand but as medical devices in other countries will remain so until new primary legislation is developed.

| ***Change proposal 1.2*** | ***Amend the labelling requirements for medicines and related products*** |
|---|---|

*The following amendments to the labelling provisions in the Regulations are proposed.*

- *Revoke regulation 20, thereby removing the requirement for certain information to be placed in a specific 'consumer information panel' on the label of a medicine intended for retail sale without a prescription. The requirement for a label on an over-the-counter medicine to include a statement of the purpose for which the medicine is recommended would be retained.*
- *Insert a new regulation allowing medicines that are supplied as individually wrapped dosage units such as lozenges, pessaries, single doses of a powder or liquid, or a patch to be labelled just with the name of the medicine, the name and quantity of each active ingredient, the batch number and expiry date, provided the box enclosing the individual dosage units is fully labelled in accordance with the Regulations.*
- *Amend regulation 22(1) so that it only applies to medicines containing a sedating antihistamine, and add a new subclause specifying an appropriate warning statement for medicines containing non-sedating antihistamines.*

## Feedback received

The proposed changes to labelling requirements were well supported.

There was a call for harmonisation with Australian labelling requirements and labelling terminology, with a number of submitters requesting that the requirements set out in the Australian Therapeutic Goods Order No.69 *General Requirements for Labels of Medicines* be adopted in New Zealand. This would mean, for example, that information could appear over two blisters rather than over each blister in a blister pack; the size of the principal display panel (PDP) would depend on legibility rather than be a proportion of overall label size; and the PDP would not be required to list all the active ingredients for multi-ingredient products. Automatic acceptance of labelling changes already approved in Australia was also suggested.

A number of pharmaceutical industry submitters felt a class warning statement for non-sedating antihistamines was not appropriate and considered that the need for a sedation warning should be determined on a case-by-case basis. Use of a statement to the effect that the product was rarely associated with drowsiness was suggested.

A small number of submitters did not support removal of the requirement for a Consumer Information Panel on over the counter (OTC) medicines, believing this could result in consumers failing to read important information.

Other suggested changes to the labelling requirements were:

- Removing the requirement for the New Zealand-specific classification statement and distributor details to appear on the label
- Reducing the labelling requirements for small containers that are supplied within another fully-labelled container.
- Removing the requirement for a statement of purpose on labels of non-prescription medicines used by health professionals (eg saline injections), thereby avoiding the need for labelling exemptions to be granted for such products
- Ensuring dosage information for different age groups is included on medicines for OTC sale
- Requiring visual differentiation between different products produced by the same company to reduce dispensing and administration errors
- Mandating the inclusion of a barcode on product labels (or down to individual dose unit), the barcode being consistent with internationally recognised standards
- Mandating the use of the Pharmacode on product labels
- Permitting reference to a second ‘companion’ product on a label without this being considered to be an advertisement
- Requiring medicines to be produced in dispensing packs (to avoid repackaging and re-labelling) and mandating provision of Consumer Medicine Information (CMI) by pharmacists
- Amending regulation 22(3) so that the label of a product containing aspirin or paracetamol is not required to include the current warning statement provided the label includes an instruction not to exceed the stated dose and there are not dosage instructions for children under 2 years of age
- Ensuring labelling requirements for cosmetics such as anti-wrinkle creams are aligned with requirements in other jurisdictions (e.g. Australia)

- Prohibiting use of the acronym 'POM' as an alternative expression of "Prescription Only Medicine" on labels
- Developing a more flexible approach to labelling of medicines with low sales volumes
- Permitting website addresses on labels
- Requiring more anti-cholinergic warning statements on products containing prochlorperazine
- Requiring more storage information on products requiring refrigeration
- Not requiring transparent outer packaging to be labelled
- Not restricting the size of sample packs
- Changes to the labelling of controlled drugs.

## Outcome

The planned revocation of regulation 20 (removal of the Consumer Information Panel) will proceed as proposed. As a consequence, regulation 13 will be amended to require that the label of a non-prescription medicine includes a statement about the purpose of use of the medicine. Where the small size of a container makes it impractical to use the label to convey all the required information, the option of printing the required consumer information on an enclosed leaflet rather than the label will be retained.

In relation to amendments to regulation 13, submitter comments suggesting further changes to align labelling requirements as far as possible with those applying in Australia have been accepted. It is therefore planned to amend the regulations to achieve the proposed changes to labelling of individually wrapped dosage units and in addition:

- rationalise the requirements for labelling of strip packed medicines (including safety containers) and small containers
- remove prescriptive requirements that do not enhance patient safety (such as the requirement relating to the size of the PDP)
- rationalise the requirements for labelling of medicines used by practitioners
- require the names and strengths of active ingredients to be on the PDP.

Submitter feedback in relation to the warning statement for antihistamines has highlighted the need to change the way in which the inclusion of appropriate warning statements on product labels is achieved. It is therefore intended to revoke regulation 22 and include all warning statements in guidelines, with compliance ensured through the approval of the label as part of the product approval process. This would enable a case-by-case approach to be taken to the warning statements, in line with the Australian approach. In the case of non-sedating antihistamines, and in contrast to the situation in Australia, the guidelines will require a warning statement that will reflect the previous advice of the Medicines Adverse Reactions Committee.

Two additional changes to the labelling of dispensed medicines have been identified as desirable and will be progressed. The first involves amending regulation 23 to require the label on a dispensed medicine to include an identifying code linking the dispensed item back to the original prescription. This requirement would also cover compliance packaging. It will ensure that if there are queries relating to a labelled dispensed medicine from a paramedic or hospital emergency department, the medicine can be traced back to the original prescription. It will also be of assistance

with the introduction of electronic prescribing, where a unique identifier relating the medicine to a specific patient, from a specific prescriber, dispensed by a specific pharmacy will be paramount for public safety. The second change is a requirement to include on the label the date of dispensing. This will assist patients in determining how old a medicine is and whether it is out of date and is still safe to use. Other suggestions were considered, but will not be progressed.

### *Change proposal 1.3 Amend the advertising requirements*

*It is proposed that regulation 8 be amended in order to:*

- *expand the current set of types of advertisements that do not require mandatory information ('excluded advertisements') by adding point-of-sale advertisements (such as shelf-talkers) and promotional items (such as pens), providing they do not include a therapeutic claim*
- *specify that the mandatory requirements for advertisements (other than excluded advertisements) are:*
  - *the statement 'Always read the label' or words of similar meaning*
  - *the statement 'Use only as directed' or words of similar meaning*
- *specify that advertisements (other than excluded advertisements) for pharmacist-only medicines include the statement 'Your pharmacist's advice is required' or 'Available only from your pharmacist'*
- *specify that advertisements (other than excluded advertisements) for non-prescription medicines must also include:*
  - *the statement 'If symptoms persist see your doctor / health care professional' or words of similar meaning*
  - *a warning statement about any known serious adverse effects, or contra-indications in a known group of people*
- *specify that advertisements for prescription medicines (other than excluded advertisements) must also include:*
  - *the words "Prescription Medicine" or words of similar meaning*
  - *advice that this medicine has risks and benefits*
  - *appropriate and prominent warning statements about the contra-indications and major risks associated with use of the medicine − these should be stated in a manner that is relevant to, and easily understood by, the consumer*
  - *advice on how consumers can access more detailed information about the risks and benefits of the medicine*
- *retain the requirement that advertisements for the supply of medicines by mail order, direct mail or the internet include the name and quantity of each active ingredient.*



## Feedback received

Around 60% of submitters responded to the proposals and around half of these suggested other changes they would like to see made to the advertising requirements.

The majority of those who responded supported the proposed changes. Those opposed to the suggested changes generally wanted more, rather than less,

information in advertisements and were concerned that consumers would not have access to adequate information on benefits and risks of the medicine if requirements were relaxed.

Submitters sought greater clarity about any differences in requirements for prescription and non-prescription medicines (including a request for two separate regulations), expansion of the list of 'excluded advertisements', and full alignment with Australian advertising requirements.

Two bodies representing pharmacists considered that adopting the proposed approach could lead to pharmacists unintentionally breaching the Code of Ethics by using an advertisement that failed to meet the mandatory requirements.

A number of submitters took the opportunity to express their opposition to Direct To Consumer Advertising (DTCA) for prescription medicines.

Other suggestions included:

- requiring advertisements to state, where applicable, that the medicine is only available on prescription
- requiring risk benefit information to be provided in advertisements to consumers (not just a reference to where such information can be found)
- requiring advertisements in pharmacy trade magazines to include all the information required by health professionals
- allowing a reference to the Medsafe website as a source of further information
- requiring the names of active ingredients to be shown on point-of-sale advertisements
- ensuring the exemptions for point-of-sale advertising apply only where the advertisement is placed with the product (ie not to window posters)
- permitting short reminder advertisements to health professionals (consistent with the Researched Medicines Industry Association (RMI) code)
- not requiring the company name or logo on promotional items (consistent with Australian rules)
- maintaining a flexible approach to what constitutes an excluded advertisement
- requiring a statement to the effect that a pharmacist's advice is required, rather than "only available from your pharmacist"
- not requiring the statement "This medicine has risks and benefits" to be included
- requiring internet advertising for prescription medicines to include full regulation 8 information
- requiring an advertisement to direct the consumer to talk to their health professional
- requiring advertisements to include advice on adverse event reporting
- considering modern communication technologies used by advertisers when designing advertising controls.

## Outcome

The amendments to regulation 8 will proceed as proposed, recognising the need to:

- clearly define the types of advertisements that are excluded from requiring the mandatory statements; and
- clearly specify the mandatory statements that apply to particular types of advertisement.

Other suggestions were considered, but will not be progressed.

## *Change proposal 1.4 Enable electronic transmission of prescriptions*

*It is proposed that, in order to facilitate implementation of electronic transmission of prescriptions, regulation 43 should be amended to remove the term 'in special circumstances'. Regulation 43(a) would then be amended to state that the form of prescription authorised under the waiver could include (but would not be limited to) an electronic form.*

*This would enable a set of criteria for applicants and a standard set of requirements to be established, and waivers to be granted to applicants who met those criteria and could demonstrate an ability to fulfil the specified requirements. The requirements could include, for example, compliance with a specified standard.*

*This would provide transparency for applicants and reduce the complexity of the task of considering waiver applications on a case-by-case basis. The criteria and requirements could be published (and therefore be readily accessible to prospective applicants) and could be updated as necessary (eg, as new standards are developed or new systems implemented).*

### Feedback received

Around half of the submitters responded to this question with the majority of those supporting the proposal. A number of submitters took the opportunity to make comments on electronic prescribing generally and the need for a new national standards system for electronic prescribing. A few submitters asked to be consulted during the development of the new standards and the criteria for the waiver proposal. Some felt that waivers may need to be specific to particular settings (eg a DHB hospital). Others expressed concern about the need for the waiver criteria to be clear and unambiguous and about costs involved for the sector.

### Outcome

It is recognised that stakeholders are seeking a more comprehensive package of provisions relating to electronic prescribing. However, given that this cannot be implemented through regulation change alone, the proposed amendment to regulation 43 will proceed as an interim measure.

Criteria for granting a waiver will need to be developed in consultation with affected parties.

## *Change proposal 1.5 Align prescribing rights for medical practitioners, dentists and midwives*

*It is proposed that the 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 be removed, and that medical*

*practitioners, dentists and midwives be required to prescribe within their scope of practice as defined by their councils established under the Health Practitioners Competence Assurance Act..*

### Feedback received

The majority of submitters who responded to this question supported the proposal. However, a number of submitters were concerned about using the concept of 'scope of practice' in the regulations and whether there was a requirement for pharmacists to have to verify whether a particular medicine was within a prescriber's scope of practice. There seemed to be a general lack of understanding and awareness of the provisions of the Health Practitioners Competence Assurance Act (HPCAA) and misunderstanding around the proposal. Several submitters asked for clear guidelines on what would fall within each scope of practice.

### Outcome

The proposal to align prescribing rights for medical practitioners, dentists and midwives will proceed as planned. The proposal will make it clear that a prescribing right for a scope of practice applies to the treatment of patients under the prescriber's care.

While some groups expressed concerns about operational matters (such as a belief that a pharmacist would be expected to verify a prescriber was prescribing within their scope of practice), these are broader concerns that relate to current policy under the HPCAA. Concerns were raised, for example, about pharmacists ability to verify whether prescriptions issued by dentists and midwives are in accordance with their scopes of practice. Pharmacists may dispense a prescription "on its face" provided he or she acts in "good faith". The Ministry of Health will contact the bodies representing pharmacists and responsible authorities to provide clarification on such matters.

## *Change proposal 1.6 Extend the period of supply of prescription medicines*

*It is proposed that regulation 39(4) be amended to allow dentists to prescribe treatment for a period of three months, as for all other authorised prescribers.*

*It is also proposed that provision be made for the Director-General to waive the three-month limit in special circumstances.*

### Feedback received

The majority of submitters who responded to the question on aligning the period of supply for dentists with authorised prescribers supported the proposal. A small number supported the proposal with conditions, such as extending the period of supply to 10 or 30 days only, or requiring dentists to collaborate with medical practitioners prior to prescribing long term treatment.

Two submitters opposed the proposal. One submitter pointed out that consideration would need to be given to amending the Pharmaceutical Schedule to align prescribing and subsidy rules.

Most of those who commented on the proposal to allow the three-month prescribing limit to be waived in certain circumstances supported it. Two submitters felt that such a waiver should not apply to prescribing by dentists and midwives. One submitter felt strongly that a three month review was important, but if the proposal did go ahead it should only be extended to six months (or twelve months in the case of an oral contraceptive).

Many submitters supported extension of the period of supply of prescription medicines for patients with chronic conditions who are stabilised on a treatment regime. Some submitters, however, pointed out that such an approach could lead to concerns about the safety of patients who stockpile their medicines, and the potential for wastage, if changes need to be made to a patient's treatment.

Other issues raised included the need for pharmacists to be able to verify the existence of a waiver when presented with a prescription, and the potential for increased antibiotic resistance due to increased use. It was also suggested that an increased period of supply should be considered on a case by case basis with a maximum of six months, and only for New Zealand residents when a New Zealand registered prescriber has noted that the patient is stable.

### Outcome

As a result of submitter feedback, it is intended that the period of supply on a prescription be extended to twelve months for oral contraceptives and six months for other prescription medicines. This would apply to all authorised prescribers, including dentists.

It is also intended to proceed with the proposal to allow the Director-General of Health to waive the limit on period of supply (beyond the extended limits), either for an individual or for a class of persons, in certain circumstances

Concerns about possible safety concerns and wastage associated with stockpiling medicines could be dealt with by limiting the quantity dispensed on each occasion to no more than three months' supply. For subsidised medicines this could be achieved through the Pharmaceutical Schedule. Lead-in time will be required to allow PHARMAC time to amend the Pharmaceutical Schedule. In relation to unsubsidised medicines, the Ministry of Health will contact responsible authorities to remind them of their role in encouraging good prescribing practice. This includes not prescribing excessively or indiscriminately.

## *Change proposal 1.7 Restrict prescribing for patients who are not in New Zealand*

*It is proposed that, in addition to the requirement for a patient to be 'under the care' of the prescriber, there is a requirement for the patient to be in New Zealand at the time the prescribing occurs, or normally resident in New Zealand but temporarily overseas at the time the prescribing occurs.*

### Feedback received

Just over half of all submitters responded to this proposal. Most supported or strongly supported the concept of only permitting prescribing where the patient is in New Zealand or normally lives in New Zealand but is temporarily out of the country.

Submitters highlighted the need for defence force and other New Zealand personnel working overseas to have medicines prescribed for up to six months, and suggested that prescribing for residents of the Cook Islands, Tokelau and Niue should be permitted. It was also suggested that a medical practitioner in New Zealand should be able to prescribe for a patient who is temporarily overseas if an overseas doctor is able to carry out an examination and provide the necessary information to the prescriber.

One submitter felt it was desirable for the medicines to also be dispensed in New Zealand. Another considered that it would be inappropriate for a midwife to prescribe for women or their babies while they are overseas.

Some considered that "temporarily" or "normally resident" would need to be defined. Setting a maximum period of absence of 6 months, or aligning with the IRD definitions, were suggested.

Adherence to the Medical Council's rules in relation to prescribing (including the definition of "under the care") was suggested as an additional requirement.

One submitter felt that the issue of prescribing for people in other countries would need to be reviewed if a point was reached where telemedicine enabled physical examination of the patient to occur.

It was suggested there should be an additional requirement for a face-to-face consultation and/or physical examination of the patient to have been undertaken at some point.

Four submitters rejected the proposal. These submitters supported internet prescribing and export of dispensed medicines, considering it an innovative business that supported other New Zealand businesses. These submitters said there was no evidence of medicine shortages as a result of medicines being sent overseas, and supply of medicines to patients in other countries could be stopped if a supply shortage was to develop in New Zealand. They indicated that they were obtaining a significant proportion of the medicines they used from overseas, rather than using the New Zealand supply chain and they considered the safeguards in place to ensure verification of prescriptions from overseas doctors were adequate. Other points raised included:

- internet prescribing may lead to reduced prices in a small country like New Zealand as a result of economies of scale
- the proposed restriction on prescribing may be incompatible with New Zealand's free trade agreements
- the service being provided from New Zealand is of significant benefit to people such as United States citizens who have no health insurance and find United States medicine prices too high
- supply of medicines between countries in the European Union is permitted and the Federal Drug Administration permits importation of up to 90 days' supply of medicine for personal use
- the threat of parallel importation of medicines by individuals or organisations involved in internet prescribing will tend to keep down prices for patented medicines.

## Outcome

This proposal was generally well supported based on the safety, ethical and trade issues that it raises. The Government, however, has asked officials to explore

whether the potential risks of internet pharmacy businesses could be managed through additional safeguards in the regulations. It has therefore asked the Ministry of Health to meet with the submitters who expressed concern about the impact of the proposal on their businesses to discuss the possibility of developing acceptable protocols around their business to address concerns such as safety and security of supply.

| ***Change proposal 1.8*** | ***Allow pharmacists to substitute an alternative brand of a medicine in certain circumstances*** |
|---|---|

*It is proposed that regulation 42(4) be amended to allow a pharmacist to substitute an alternative brand of a prescribed medicine (but not a different 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.*

### Feedback received

Almost all of those who responded to this question supported the proposal.

However, a number of submitters included caveats such as:

- requiring or not requiring the use of specific words such as "no brand substitution permitted"
- not permitting substitution where medicines require dose titration or have a narrow therapeutic range
- requiring the prescriber to be notified of each substitution
- allowing substitution only when the medicine is no longer available in New Zealand or is not funded
- requiring patient consent to be obtained
- not allowing substitution where multiple brands are subsidised.
- providing a list of interchangeable medicines for pharmacists.

Several submitters recommended allowing substitution even when the prescriber has specified no substitution, in circumstances where the medicine is longer available in New Zealand or the patient has given informed consent. One submitter expressed concern that products may not be bioequivalent and different pack layouts for some medicines mean patients need to be given special instructions. One submitter did not support annotation of the script as it was counter to an e-environment and a less permanent record.

### Outcome

This proposal was well supported and will proceed as proposed. It is not considered that any further caveats are required.

Publication of a list of interchangeable medicines is not supported because the decision to substitute an alternative brand is a clinical one that should be made by

the pharmacist, in the context of the patient's treatment and circumstances, taking into consideration relevant information from the medicine data sheet.

| ***Change proposal 1.9*** | ***Amend the requirements for countersigning records of supply or administration of a medicine under a standing order*** |
|---|---|

*It is proposed that the Medicines (Standing Order) Regulations 2002 be amended to require an authorised prescriber issuing a standing order to specify the arrangements for countersigning, including specifying:*

- *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.*

### Feedback received

The majority of those who responded to this question supported the proposal (just under half of all submitters). It was suggested that:

- the issuer should review the records as well as the practices of the standing order
- countersigning could still be required but with a longer timeframe
- there should be a requirement for a timely review and sign-off and Ministry of Health guidelines on what this should be
- there should be monitoring by the Ministry of Health.

Reasons for opposing the proposal were that it may allow de-facto prescribing by non-prescribers and that counter-signing is a key safeguard. A suggestion was made that instead of operating under standing orders, paramedics be regulated under the HPCAA to give them prescribing rights and a scope of practice.

### Outcome

The proposal to remove the requirement for countersigning of every supply or administration of a medicine under a standing order will proceed. However, in order to address concerns about a possible lack of oversight if countersigning is not mandatory, it is intended to add a requirement that, as a minimum, there is a monthly audit of a sample of the records of administration or supply under a standing order. The Ministry of Health will write to responsible authorities to remind them of the responsibilities of issuers of standing orders.

| ***Change proposal 1.10*** | ***Allow sale of general sale medicines by vending machine*** |
|---|---|

*It is proposed that regulation 59 be revoked and a new regulation made to permit the sale of unscheduled (general sale) medicines by vending machine. This would*

*continue the permission for the sale of chemical contraceptives by vending machine (because they are general sale medicines), but they would no longer need to be supplied with condoms.*

### Feedback received

Of those who responded to this question, just over a third opposed the proposal. A number of submitters were concerned about the possible safety issues with some medicines such as paracetamol due to suicide risk and the likelihood of children accessing machines. There were also concerns about vandalism and about access to multiple packs. Several submitters suggested that not all general sales medicines should be able to be sold in this way and a list of permitted medicines should be developed. It was suggested that ibuprofen should not be available in this way.

Most felt that the proposal was unlikely to have a significant impact on other businesses. Several commented that it would be a new business opportunity. Other issues raised were about security of the medicines, and the costs of repackaging medicines to make them suitable for putting in vending machines. A licensing scheme for vending machine operators was suggested.

Suggestions made regarding limitations on vending machine operators included requirements for:

- adequate stock control and expiry date checking
- appropriate storage conditions, including temperature/humidity controls on machines
- adequate controls on access by children
- product information to be visible on packs before purchase
- limits on products, product mixes, pack sizes, number of packs in machine and number of packs able to be accessed at one time
- quality control standards
- a system to handle customer complaints
- products to be supplied in original packs
- safety monitoring and security of machines
- product recall, if necessary.

### Outcome

While the concept of allowing some medicines to be sold by vending machine was generally supported, many submitters considered there needed to be controls on where vending machines could be located, what they could contain, and the volume of product that could be dispensed at one time. Given these concerns, it is intended that provision be made for the Director-General to permit specified medicines to be sold by vending machine and to set appropriate controls to ensure the integrity of the medicines and to safeguard against inappropriate access.

# Part 2: Updating technical requirements

| ***Change proposal 2.1*** | ***Amend requirements for data sheet content, format and publication*** |
|---|---|

*It is proposed that:*

- *regulation 51 be amended to define 'data sheet' as the prescribing information relating to a particular medicine and to remove reference to a data sheet compendium*
- *regulation 52 be replaced with a regulation that requires the approved data sheet for a medicine to be submitted to Medsafe, in the format required for publication on the Medsafe website, not less than 10 working days before the medicine (whether a new or changed product) is placed on the market*
- *regulations 53 and 54 and Schedule 3 be revoked, and guidance on the content and layout of data sheets be provided in guidelines published by Medsafe.*

## Feedback received

The proposal to amend the requirement for data sheets to bring them into line with current practice and allow flexibility regarding the format of data sheets was strongly supported.

A number of submitters commented on the timing of publication of the data sheet, with suggestions ranging from publication within 10 days of the medicine being approved (regardless of whether the product is marketed), to publication on or before the date the medicine is placed on the market, to publication within a month of the medicine being approved.

One submitter suggested that data sheets could be published more quickly if companies were able to upload them directly, thus removing Medsafe processing time. Another suggested that data sheets should be required to include a photograph of the medicine.

Most of those who commented supported the proposal to specify data sheet content and format in guidelines. A number highlighted the need for consultation with industry in developing the guidelines.

A small number of submitters were concerned that using guidelines may mean the requirements were not enforceable and felt it was important to ensure that a standardised set of information was available.

## Outcome

It is intended to proceed as proposed, but to require that an approved data sheet be submitted for publication within 10 days of notification of approval of the new or changed medicine in the *New Zealand Gazette*. This should expedite the approval process.

| ***Change proposal 2.2*** | ***Amend definitions relating to pharmacy qualifications*** |
|---|---|

*It is proposed that definitions in regulation 2 be amended as follows:*

- *dispensary technician − a person who holds a certificate issued by the Pharmaceutical Society of New Zealand before 18 September 2004 that classifies the holder as a dispensary assistant, or records that the person has completed the requirements of the Pharmacy Technician's Certificate*
- *pharmacy graduate – a person who is not a pharmacist, but who has a qualification prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003 as a qualification necessary to practise in the profession of pharmacy and who is actively taking steps towards registration with the Pharmacy Council as a pharmacist under the Health Practitioners Competence Assurance Act 2003.*
- *pharmacy student – a person who is undertaking, but has not yet completed the course or examinations leading to, a qualification of a kind stated by the Pharmacy Council, for the purposes of section 12(2)(a) or (b) of the Health Practitioners Competence Assurance Act 2003.*

*It is proposed that the definition of approved school be removed from regulation 2 as this term will no longer be used in other definitions and will therefore be redundant. It is also proposed that the definition of Dispensary Assistant's Certificate be removed as this certificate is no longer issued or relevant, making the definition redundant.*

### Feedback received

The proposal to amend the definitions relating to pharmacy qualifications was strongly supported. A number of submitters considered that the term 'pharmacy graduate' should be replaced by 'pharmacy intern' since this is the terminology used by the Pharmacy Council when defining scopes of practice.

The following new definitions or amendments to existing definitions were suggested:

- Remove subclause (b) from the definition of *pharmacy technician* because the Council of the Pharmaceutical Society referred to in the definition no longer exists and no person has ever had an overseas qualification recognised in this way
- Update the definition of *poison bottle*
- Add definitions for *dispense*, *prescription assessment*, and *pharmacy practice*.

### Outcome

It is intended to proceed as proposed with changes to definitions.

In addition, the definition of *pharmacy technician* will be amended to remove subclause (b). No new definitions are considered necessary.

| ***Change proposal 2.3*** | ***Revoke the regulation on colouring substances permitted to be used in medicines*** |
|---|---|

*It is proposed that regulation 6 be revoked. Medsafe would instead maintain an up-to-date list of acceptable colouring substances in regulatory guidelines published on the Medsafe website.*

### Feedback received

This proposal was well supported. Submitters highlighted the need for consultation with industry when the guidelines are being developed and for the list of suitable colouring substances to be readily accessible. It was felt there should be a clear mechanism for colouring substances to be added to the list, and there was a request for publication of a list of colouring substances that had been assessed and found not to be suitable for use in medicines.

It was suggested that colouring substances permitted to be used in medicines in other countries should to be allowed to be used here provided they met the appropriate specifications. A review of the status of tartrazine in medicines was requested, since it is permitted in foods here and in medicines in the European Union.

### Outcome

It is intended to proceed as proposed. Medsafe would seek feedback on the draft guideline and would add new colouring substances when these had been evaluated as part of a new medicine application and found acceptable.

| ***Change proposal 2.4*** | ***Update requirements for prescriptions*** |
|---|---|

*It is proposed that regulation 41 be amended to:*

- *require the name of the prescriber to be included on the prescription, as well as their address and signature*
- *require inclusion of the given name(s) of the person for whose use the prescription is given (instead of the title and initials)*
- *replace subclauses (f) and (i) with a requirement for the prescriber to specify the total quantity of medicine or total period of supply (removing reference to the number of dispensings and the interval between dispensings)*
- *require inclusion of the given name(s) of the owner of an animal to be included on a prescription relating to the treatment of an animal (instead of the title and initials).*

### Feedback received

The proposed changes were generally supported by the 50% of submitters who commented on this proposal. One submitter rejected the proposal, suggesting instead that the requirements for the content of prescriptions should be aligned with those set out in the Medical Council's statement on Good Prescribing Practice.

A number of submitters considered that specific pieces of information should be required to be on a prescription, including:

- unique identifiers for the patient (NHI number) and the prescriber (NPI number)
- name and physical practice address for the prescriber
- the contact telephone number for the prescriber
- the weight of a child under 5 years of age.

One submitter highlighted the need for electronic or scanned signatures to be acceptable, while another was concerned about security if electronic signatures were permitted. Another highlighted the fact that computerised prescribing systems would need to be changed before new requirements could be effectively implemented.

One submitter advocated placing the rules for content of prescriptions in the Pharmaceutical Schedule, while another suggested that the quantity of medicine to be dispensed should be set by the prescriber specifying an end date for the treatment, enabling pharmacists to dispense appropriate quantities taking into account the amount the patient already has on hand.

Midwifery groups expressed a concern that many midwives to not have a permanent street address for their business.

### Outcome

It is intended to proceed as proposed and, in addition, make it a requirement for the street address (with an exemption for midwives who do not have a permanent business street address) and phone number of the prescriber to be shown on the prescription.

While the Ministry of Health strongly supports the inclusion of unique patient and prescriber identifiers on prescriptions, mandating their inclusion is not considered the optimal mechanism for achieving this and could disadvantage prescribers, pharmacists and patients in situations (such as when a doctor is prescribing for a new patient after hours and does not have access to the patient's NHI) where the information was not readily accessible. The Ministry of Health considers there are other ways (such as through District Health Board contracts or as a data requirement for e-transmission of prescriptions) to encourage the use of unique health practitioner and patient identifiers.

It is considered unnecessary to mandate a requirement for the weight of a child less than 5 years old to be on a prescription given that the Medical Council's statement on *Good Prescribing Practice* requires a practitioner to also include the weight of a child on a prescription if this information would affect dosage.

### *Change proposal 2.5 Update dispensing requirements*

*It is proposed that the provisions relating to the frequency of dispensing in regulation 42(3)(a) to (e) be revoked and the requirements for recording dispensing details in regulation 42(3)(g) to (i) be updated to reflect current practice.*

*It is proposed that the pharmacy name and address, date, quantity of medicine dispensed and prescription number be recorded each time a prescription is dispensed. However, the way in which these details are recorded would not be specified, so that it could be done by, for example, attaching a computer-generated label to the prescription.*

### Feedback received

Proposed changes to the dispensing requirements were strongly supported. Specific comments provided by submitters included the following:

- There should be alignment between the regulations and the requirements specified in the Pharmaceutical Schedule, and the requirements should be practicable
- Annotations should be made in the electronic record of the dispensing, rather than on the paper prescription
- The original prescription, not just the computer record, must be viewed when a repeat is dispensed
- Faxed prescriptions should be recognised as legitimate prescriptions without the need for a paper copy to be supplied. Alternatively, they could be treated in the same way as an urgent supply, requiring an original signed copy of the prescription to be supplied within seven days.
- Security could be improved by requiring the prescriber to certify on the prescription that it is being faxed to a named pharmacy
- Computerised dispensing systems will need to be changed before new requirements can be effectively implemented.

### Outcome

It is intended to proceed as proposed.

It is not considered 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.

## *Other issues*

Some submitters requested changes that would require an amendment to primary legislation and cannot be achieved through the planned amendment to regulations. These included such matters as changing the prescribing status of designated prescribers, extending prescribing rights, changing labelling requirements for controlled drugs and banning direct to consumer advertising of prescription medicines. Such changes will be able to be considered in the course of updates to other legislation.

A number of inter-related changes to the requirements for child-resistant packaging were also requested, some of which would require changes to primary legislation (e.g. setting standards for child-resistant closures). Reform in this area needs to be considered carefully and achieved using an integrated package of measures.

An amendment to change the meaning of “mortgagee in possession” provided in Form 1B in Schedule 2 of the Medicines Regulations was requested, to match the change already made to Form 1A in the same Schedule. It is intended that this be progressed.

It is also intended to progress an amendment to clarify that the intent of regulation 44, where prescriptions are not required for prescription medicines. Regulation 44 (h), for example, reads as a blanket exemption from the need for a prescription, but its intent is to remove the requirement for a prescription to be written in a situation where a prescriber wishes a patient under his care to receive a dose of a medicine, and gives verbal instructions to that effect to the person who is going to supply or administer the dose of medicine.

## Appendix One: List of submissions

| | |
|---|---|
| s 9(2)(a) | NMDHB |
| | Biomed Limited |
| | New Zealand Defence Force |
| | Senior Lecturer, Faculty of Health and Environmental Science |
| | |
| | ACC |
| | |
| | Dental Council |
| | Community Dental Hutt Valley DHB |
| | Takapuna Grammar School |
| | |
| | |
| | Starship Children's Health |
| | Chair, Nurse Practitioner Advisory Committee of New Zealand |
| | |
| | Midwifery Council of New Zealand |
| | Sanofi-Aventis Pty Ltd |
| | BBG Fulfilment Ltd |
| | Faculty of Health and Environmental Sciences, AUT |
| | Albany Care Chemist Ltd |
| | Pharmaco (NZ) Ltd |
| | Fluoride Action Network NZ Inc. |
| | Bayer Australia Limited |
| | Cosmetic Toiletry and Fragrance Association of New Zealand Inc. |
| | Mylan New Zealand |
| | TAPS |
| | RMI |
| | Auckland City Hospital Pharmacy Department |
| | Safe Medication Management Programme |
| | Pharmacy Partners Ltd |
| | The College of Nurses, Aotearoa (NZ) inc. |
| | CCDHB |
| | Family Planning |
| | Pharmacy Council of NZ |
| | New Zealand Self-Medication Industry |
| | Nelson Marlborough DHB |
| | |
| | Canterbury DHB |
| | PHARMAC |
| | Waikato DHB |
| | Waikato DHB |
| | New Zealand Dental Association |
| | New Zealand Nurses Organisation |
| | Pharmacy Guild of New Zealand |

**DRAFT (June 2010)**

| | |
|---|---|
| s 9(2)(a) | Australian Self-Medication Industry Inc |
| | The Paediatric Society of New Zealand |
| | Colgate-Parmolive |
| | Medical Council of New Zealand |
| | CSL Biotherapies (NZ) Ltd |
| | The Royal New Zealand College of General Practitioners |
| | Safekids New Zealand |
| | Canterbury Community Pharmacy Group |
| | Reckitt Benckiser |
| | Oral Health - Sector Capability and Innovation MOH |
| | GlaxoSmithKline NZ Ltd |
| | Johnson & Johnson (New Zealand) Ltd |
| | Community Dental Service, Canterbury DHB |
| | Canterbury Community Pharmacy Group |
| | Pegasus Health |
| | Counties Manakau DHB |
| | Federation of Woman's Health Councils Aotearoa |
| | Consumer Advisory Committee |
| | Novo Nordisk Pharmaceuticals |
| | Unilever Australasia |
| | Pharmacybrands Ltd |
| | Procter & Gamble |
| | Pharmaceutical Society of New Zealand Inc |
| | ESR |
| | New Zealand Food & Grocery Council |
| | New Zealand Medical Association |
| | New Zealand College of Mental Health Nurses (Inc) |
| | South Island Nurse Executives |
| | South Island Shared Service Agency Ltd |
| | Woman's Health Action Trust |
| | Red Seal Natural Health Ltd |
| | ACCORD |
| | CCDHB |
| | 3M |
| | New Zealand Hospital Pharmacists' Association (Inc) |
| | GlaxoSmithKline |
| | New Zealand National Board of the Royal Australian College of Surgeons |
| | Pharmacy Department of the Taranaki |
| | Audit & Compliance MOH |
| | Nursing Council of New Zealand |

Document 2

MINISTRY OF HEALTH
MANATŪ HAUORA

**Health Report number:** 20101372

(B/grd papers filed not scanned)

**Action required by:** **10.00am 16 September**

**Date sent to Minister:** **15 September 2010**

**Minister's reference:** **not applicable**

**File number:** **HC18-02-9-2**

## To: Hon Tony Ryall

## Title: Approval to implement changes to medicines regulations

## Advice

1. In February 2010, the Ministry released a discussion document proposing a number of changes to regulations under the Medicines Act 1981. These changes were designed to: update technical matters; reduce barriers to innovation in the health sector; reduce unnecessary costs for the Crown, industry, health service providers and consumers; and address some health and safety risks.
2. You have now agreed to proceed with these changes, and some additional proposals suggested during the consultation. The Ministry has drafted the attached Cabinet Paper, Submission Summary and Regulatory Impact Statement, for consideration by the Cabinet Social Policy Committee (SOC). Once decisions are taken on these proposals, the Ministry will issue drafting instructions to the Parliamentary Counsel Office.
3. If these papers are submitted to the Cabinet Office by 10.00am on Thursday 16 September, they could be considered by SOC on 22 September and Cabinet on 4 October.

## The Ministry recommends that you:

a) **Sign** the attached Cabinet Paper and CAB 100 — Yes / No

b) **Forward** the Cabinet Paper, Submission Summary and Regulatory Impact Statement to the Cabinet Office by 10.00am on Thursday 16 September. — Yes / No

D Roche

Deborah Roche
**Deputy Director-General**
**Strategy and System Performance Directorate**

Ryall

**Minister's Signature**

**Date:** 15 9 10

## Ministry of Health Contacts:

| | | | |
|---|---|---|---|
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| Cellphone: | [redacted] | Cellphone: | [redacted] |

copy to Mr Dunne

MINISTRY OF HEALTH
MANATŪ HAUORA

**Health Report number:** 20101372

## Minister's feedback

| | Very poor | Poor | Neutral | Good | Very Good |
|---|---|---|---|---|---|
| Quality of advice | 1 | 2 | 3 | 4 | 5 |
| Writing style | 1 | 2 | 3 | 4 | 5 |
| Quality of analysis | 1 | 2 | 3 | 4 | 5 |
| Completeness of information | 1 | 2 | 3 | 4 | 5 |

Comments:

**END.**

Office of the Minister of Health

Cabinet Social Policy Committee

# Approval to implement changes to several regulations under the Medicines Act 1981

## Proposal

1. Agreement is sought to issue drafting instructions to the Parliamentary Counsel Office to implement proposals discussed in the recent *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981.*

## Executive Summary

2. The regulatory framework for medicines is in need of updating. Earlier this year, the Government agreed to consult on a suite of amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002, in order to: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; address some health and safety risks; and update technical matters. Changes were recommended to labelling, advertising, dispensing, and prescribing requirements.

3. Having considered the submissions received, it is proposed to proceed with the original proposals (as set out in the *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981),* and in some cases, make some further amendments arising out of submitter feedback. The Minister of Health will issue drafting instructions to the Parliamentary Counsel Office to give effect to these changes. These drafting instructions will also include the next periodic update of Schedule 1 of the Medicines Regulations 1984.

## Background

4. In New Zealand, medicines and medical devices are regulated by the Medicines Act 1981 and associated regulations, most notably the Medicines Regulations 1984. This legislative framework is in need of updating, to ensure it safeguards consumers while not creating unnecessary barriers to innovation.

5. Many of the problems in the current medicines legislative framework can only be addressed through changes to the Medicines Act itself. While this is likely to happen during the current parliamentary term, it is likely to take some time to implement a new Act, and some improvements can be made in the mean time through amendments to regulations.

6. Accordingly, the Ministry of Health was directed to progress amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. The proposed amendments: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; address some health and safety risks; and update technical matters.

7. In February 2010, Cabinet noted the release of the *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981* [SOC Min (10) 1/1, recommendation 6 refers]. The Consultation Paper was released on 26 February 2010 and submissions closed on 26 March 2010. Eighty-four submissions were received. The Ministry has now summarised the submissions and provided advice on the issues they raise. A *Report of the Analysis of Submissions and Final Decisions* is attached as Appendix One.

## Comment

8. Most of the original proposals amendments were widely supported by submitters, and should proceed. Some submitters suggested additional useful amendments, and it proposed that these also proceed. The following sections briefly describe the proposals and main areas of submitter comment. The submission summary in Appendix One provides a more detailed analysis.

### *Excluding certain products from regulation under the Medicines Act*

9. A number of products are currently regulated as "related products" under the Medicines Act. This results in an overly rigorous assessment of products that are relatively low risk. There was strong support for excluding low risk fluoride dentifrices (ie, pastes, liquids or powders used for oral hygiene purposes) and many anti-dandruff preparations from regulation under the Medicines Act. Most people felt that the Cosmetic Products Group Standard (administered by the Environmental Risk Management Agency) would adequately protect consumers.

10. Submitters suggested also removing from the Medicines Act anti-acne preparations, barrier creams for preventing nappy rash, antibacterial skin products, and oral hygiene products. Submitters also suggested that, in the interests of potential trade and consumer benefits, the approach to setting limits on content, claims and presentation of excluded products should be aligned with that used in Australia. It is proposed to implement these additional proposals.

### *Labelling requirements*

11. A number of proposals were suggested to simplify labelling requirements, and better align them with other countries, so as to minimise costs to companies associated with relabelling products for the New Zealand market.

12. A proposal to remove the requirement to place certain information on non-prescription medicines in a specific "consumer information panel" on the label was well supported by submitters. Instead, the regulations will require consumer information on the purpose of a non-prescription medicine to be included on the label for the medicine. The option of printing the required consumer information on an enclosed leaflet rather than the label will be retained.

13. Submitters also suggested further changes that would better align New Zealand labelling requirements with those applying in Australia, and reduce the cost of relabelling, without risking consumer safety. It is proposed to adopt these changes.

14. Submitter feedback in relation to the warning statement for non-sedating antihistamines has highlighted the need to change the way in which we ensure that labels contain appropriate warning statements. It is now proposed to remove all warning statements on labels from the regulations and, instead, place them in guidelines, which would more easily allow a case-by-case approach to be taken (as

in Australia, for example). Compliance with guidelines would be ensured through the product approval process.

15. The Ministry of Health has made an additional proposal, to require medicine labels to have both the date of dispensing and a unique identifying code linking a dispensed item back to the original prescription. This will ensure that if there are queries relating to a labelled dispensed medicine from a paramedic or hospital emergency department, the medicine can be traced back to the original prescription. It will also assist patients to determine how old a medicine is and whether it is still safe to use.

***Advertising requirements***

16. A number of proposals were suggested to simplify advertising requirements, and better align them with other countries, so as to minimise costs to companies associated with changing advertising material for the New Zealand market.

17. The majority of submitters who responded supported the proposed changes to advertising requirements (eg, specifying mandatory information such as *'Use only as directed'*), with some suggesting refinements to the proposals or further changes (eg, greater clarity about any differences in advertising requirements for prescription and non-prescription medicines). Those opposed to the suggested changes generally wanted more, rather than less, information in advertisements and were concerned that consumers would not have access to adequate information on the benefits and risks of the medicine if the requirements were relaxed. These concerns are not considered valid, since advertisements are not the primary mechanism to convey detailed information to consumers.

***Enabling electronic transmission of prescriptions in some cases***

18. It is not generally legal to electronically transmit prescriptions, but the Director-General of Health may issue waivers, on a case-by-case basis, to enable electronic transmission in "special circumstances". It was proposed that a set of criteria would be developed to establish greater transparency about when waivers would be granted. Most submitters who responded to this proposal supported it.

19. Some submitters stressed the need for careful consideration to be given to the development of the criteria (and some expressed a wish to be involved in the development of the criteria for the waiver). Some considered the waiver should be setting-specific (eg, District Health Board hospitals). Use of a waiver mechanism means that the Director-General will have the ability to change the criteria as the sector's readiness for electronic prescribing progresses.

***Aligning prescribing rights of all authorised prescribers***

20. The proposal to align prescribing rights for medical practitioners, dentists and midwives (who are all authorised prescribers under the Medicines Act) was generally well supported. The regulations would stipulate that these practitioners must prescribe in accordance with their scope of practice (for patients under their care), as set by their responsible authorities (ie, the Medical, Dental and Midwifery Councils), under the Health Practitioners Competence Assurance Act 2003.

21. Some pharmacy organisations and pharmacists raised concerns about pharmacists' ability to verify whether prescriptions issued by dentists and midwives

are in accordance with their scopes of practice. It is proposed that pharmacists should be able to dispense a prescription "on its face" provided he or she acts in "good faith". The Ministry will contact bodies representing pharmacists and responsible authorities to clarify these matters.

***Extending period of supply of prescription medicines***

22. The proposal to remove the 10 day limit on supply of a prescription medicine by a dentist was well supported. The majority of submitters considered that dentists should be able to prescribe the same quantities (ie, the same number of days worth) as medical practitioners and midwives, within their scope of practice.

23. Concerns were raised about the potential fiscal impact of aligning dentists' prescribing rights and periods of supply with those of other prescribers. However, it is expected that any increase in prescribing by dentists will be offset by a decrease in prescribing by medical practitioners, since patients will no longer need to be referred to a medical practitioner in order to obtain a prescription for extended treatment. Access and convenience for patients is likely to improve.

24. The proposal to allow the Director-General to waive the limit on period of supply in certain circumstances was also generally supported, particularly in relation to prescribing for armed forces personnel deployed overseas. Many submitters supported a more general extension of the period of supply, to cover, for example, situations where patients had chronic conditions that had been stabilised on a treatment regime.

25. It is proposed to extend the period of supply on a prescription from six months to twelve months for oral contraceptives, and from three months to six months for other prescription medicines, at the prescriber's discretion. Some submitters, including ACC, pointed out that such an approach could create safety issues if patients stockpile their medicines, and the potential for wastage if changes need to be made to a patient's treatment or patients stop taking their medication.

26. It is considered that this risk can be appropriately managed for subsidised medicines by PHARMAC, which sets the rules for subsidised dispensing of these medicines. PHARMAC, in discussion with District Health Boards, will carefully consider the appropriate period of dispensing (ie, the amount that can be provided to a patient by a pharmacist from a prescription) for a given medicine, to ensure that dispensing more than three months supply at a time only occurs where appropriate (ie, when it is safe and cost effective). In relation to unsubsidised medicines, the Ministry of Health will write to responsible authorities to remind them of their role in encouraging good prescribing practice (eg, not prescribing excessively or indiscriminately).

***Brand substitution by pharmacists***

27. There was strong support for the proposal to allow pharmacists 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 "no brand substitution permitted", and the pharmacist records details of the brand substitution on the prescription. This proposal will save considerable time for prescribers and pharmacists, and allow many patients to have their medicines dispensed more quickly.

28. Some submitters suggested that Medsafe should maintain a list on its website of medicines that are interchangeable at a population level. Information is already available in the Medicine Data Sheet that companies provide to Medsafe to help inform the decision of the pharmacist, based on the patient's treatment and the circumstances.

***Relaxing countersigning of standing orders***

29. Standing orders permit specified people (eg, paramedics) to administer medicines under the overall authority of a prescriber, such as a doctor. At present, every time a medicine is administered in this way, it needs to be countersigned by the prescriber. The proposal to allow the issuer of a standing order to specify the appropriate standing order arrangements (including when countersigning of administration and supply of the medicine is required) was well supported by those who responded to it.

30. There was, however, a concern about lack of oversight of standing orders if the counter-signing requirement is removed. To address this concern, it is proposed that where countersigning is not required in every case, the standing order must require the issuer to conduct, at a minimum, a documented monthly audit of a sample of the records of administration or supply under the standing order.

31. Concern was also raised that, presently, standing orders are only monitored during certification audits in hospitals and resthomes. This means that there is no monitoring of standing orders in the primary care setting. It is proposed that the Ministry write to the responsible authorities to remind them of the responsibilities of issuers of standing orders, particularly where standing orders are being used outside the hospital and resthome setting.

***Sale of medicines through vending machines***

32. Allowing the sale of low risk medicines through vending machines could potentially make these medicines more accessible. However, several submitters raised potential risks (eg, suicide risks with medicines such as paracetamol, the likelihood of children accessing machines, vandalism). Submitters suggested controls on where vending machines could be located, what they could contain, and the volume of product to be dispensed at one time.

33. Accordingly it is proposed that, rather than providing a blanket permission for general sale medicines to be sold by vending machine, a new regulation is made to allow the Director-General of Health to permit (by notice in the *New Zealand Gazette*) specific general sale medicines to be sold via a vending machine in accordance with any conditions specified in the notice. The conditions would be those that were considered necessary to ensure the integrity of the medicines or as a safeguard against inappropriate access (eg, locating machines in visible public spaces, limiting pack size for medicines, requiring temperature control).

***Medicines Data Sheets***

34. Pharmaceutical companies are required to provide to Medsafe a Medicines Data Sheet, which contains detailed prescribing information for that medicine. Proposed changes to update the content, format and publication requirements for Medicines Data Sheets were strongly supported. A number of submitters commented on the

timing of publication of the data sheet. It is proposed that data sheets be submitted for publication within 10 days of approval of the medicine to expedite the approval process.

***Definitions relating to pharmacy qualifications***

35. Proposed amendments to update definitions relating to pharmacy qualifications were well supported. Submitters also suggested removing a redundant subclause from the definition of "pharmacy technician", because it is no longer needed and refers to the Council of the Pharmaceutical Society, which no longer exists.

***Colouring substances***

36. The proposal to remove the regulation which lists the colouring substances permitted in medicines and related products, and instead, publish an up-to-date list of acceptable colouring substances in guidelines, was well supported. The list will be readily accessible, as requested by submitters.

***Requirements for prescriptions***

37. Proposals to amend prescription requirements were well supported. Submitters suggested a number of other specific pieces of information they considered should be included on a prescription (eg, patient and prescriber identifiers, prescriber's street address and phone number).

38. While the inclusion of unique patient and prescriber identifiers on prescriptions could have merit, regulation may not be the optimal mechanism to achieve this and could disadvantage prescribers, pharmacists and patients in situations where this information was not readily accessible (eg, when a doctor is prescribing for a new patient after hours). It is proposed that the prescriber's street address and phone number be included, with an exception made on the street address requirement for those midwives who do not have a permanent business address (and would have to provide a home address). This will address privacy concerns raised by the Midwifery Council.

***Dispensing requirements***

39. Proposed changes to remove prescriptive dispensing requirements and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice, were strongly supported. Some submitters suggested additional requirements, including the recognition of faxed prescriptions without the need for a paper copy.

40. 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 there is secure electronic transmission of prescriptions, there will no longer be a need for prescriptions to be faxed.

***Additional proposals by the Ministry of Health***

41. Regulation 44 provides for cases where a prescription is not required (eg, where a prescriber wishes a patient under his or her care to receive a dose of a medicine, and gives verbal instructions to that effect to the person who is going to supply or

administer it). It has been interpreted by some as providing a blanket exemption from prescribing. The Ministry of Health proposes that the wording of Regulation 44 be amended to remove any doubt about when prescriptions are not required.

42. The Ministry of Health also proposes to include drafting instructions for the next update to Schedule 1 along with the other proposals set out in this paper, for the sake of efficiency. Schedule 1 of the Medicines Regulations comprises a list of individual medicines that are classified as Prescription Medicines, Restricted Medicines or Pharmacy Only Medicines. Classifications for new medicines and changes to the classification of existing medicines are given immediate effect through a time-limited notice in the *New Zealand Gazette*. Typically, Schedule 1 is updated every 12-18 months to include recent additions and changes. This is a technical change that does not require policy approval from Cabinet, as consultation has already occurred, and the changes notified in the *New Zealand Gazette*.

## Consultation

43. The following Government agencies were consulted in the development of this Cabinet paper: The Treasury; the Ministries of Consumer Affairs, Economic Development, Foreign Affairs and Trade and Justice; the Ministry for the Environment; the Environmental Risk Management Authority, the Accident Compensation Corporation; and PHARMAC. Their comments have been noted in the paper. The Department of Prime Minister and Cabinet were provided with a copy of the paper.

44. The Ministry of Health received 84 submissions on the proposals from a wide cross-section of affected stakeholders, including: District Health Boards; government agencies; companies involved in the manufacture or supply of medicines, related products or cosmetics; organisations representing those suppliers; the advertising sector; groups representing or regulating health professionals; individual health professionals; organisations delivering healthcare services; and consumer groups. There was also a final brief round of consultation with organisations representing pharmacists (eg, Pharmacy Guild, Pharmaceutical Society) and prescribers (eg, Medical Council, College of General Practitioners, Midwifery Council).

## Financial Implications

45. Costs associated with drafting and implementing the new regulations will be met from within Vote Health baselines.

## Legislative Implications

46. Drafting instructions will be issued to the Parliamentary Counsel Office to give effect to the changes through amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002.

## Human Rights and Gender Implications and Disability Perspective

47. The proposed changes have no human rights, gender or disability implications.

## Regulatory Impact Analysis

### *Regulatory Impact Analysis Requirements*

48. The Regulatory Impact Analysis Requirements apply in this case, and a Regulatory Impact Statement (RIS) is attached.

### *Quality of the Impact Analysis*

49. The Ministry of Health's Internal Cabinet Paper Committee has reviewed the RIS prepared by the Ministry of Health, and considers that the information and analysis summarised in the RIS meets quality assurance criteria.

### *Consistency with Government Statement of Regulation*

50. I have considered the analysis and advice of my officials, as summarised in the attached RIS and I am satisfied that, aside from the risks, uncertainties and caveats already noted in this Cabinet paper, the regulatory proposals recommended in this paper: are required in the public interest; will deliver the highest net benefits of the practical options available; and are consistent with the commitments in the Government Statement on Regulation.

## Publicity

51. Once Cabinet has made decisions on these proposals, the Ministry of Health will publicly release a *Report of the Analysis of Submissions and Final Decisions on Proposed Amendments to Regulations under the Medicines Act 1981* (attached as Appendix One), subject to any amendments to reflect Cabinet's final decisions.

## Recommendations

52. It is recommended that Cabinet Social Policy Committee:

    1. **Note** that in February 2010, a consultation document was released on a set of proposed amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002.

    2. **Note** that 84 submissions were received on the proposed amendments, most of which were supportive, and some of which proposed further useful changes.

    3. **Agree** to amend the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002 to:

        a) exclude low risk fluoride dentifrices, anti-dandruff preparations, anti-acne preparations, barrier creams for preventing nappy rash, antibacterial skin products and oral hygiene products, from regulation under the Medicines Act 1981, and align with Australia on limits content, claims and presentation for use for such products

        b) remove the requirement for a consumer information panel on medicines for over-the-counter sale, and align some other labelling requirements with Australia

c) remove warning statements on labels from the regulations, and instead place these in guidelines

d) require the label on a dispensed medicine to include an identifying code linking the dispensed item back to the original prescription, and the date of dispensing

e) change the advertising requirements for medicines so that they are better aligned with those in Australia

f) enable a waiver to be issued that would permit electronic transmission of prescriptions in specified situations

g) align the prescribing rights for medical practitioners, dentists, and midwives, requiring all prescribers to prescribe within their scope of practice for patients under their care

h) remove the 10 day limit on period of supply for dentists, thus aligning the period of supply for all prescribers

i) allow the Director-General of Health to waive the limit on period of supply of prescription medicines, either for an individual or a class of persons, in certain circumstances

j) extend the maximum period of supply on a prescription from 6 months to 12 months for an oral contraceptive, and from 3 months to 6 months for any other prescription medicine

k) allow pharmacists to substitute an alternative brand of a medicine where there are no clinical reasons why substitution should not occur, the prescriber has not marked the prescription with "no brand substitution permitted", and the pharmacist records the details of the brand substitution on the prescription

l) allow the issuer of a standing order to specify conditions of a standing order (including how often counter-signing is required), subject to a documented monthly (or more regular) review, by the issuer of the order, of a sample of records of administration or supply

m) change regulations setting out the content, format and publication requirements for data sheets, and require approved data sheets to be submitted for publication within 10 days of approval of the medicine

n) remove the regulation, which lists the colouring substances permitted in medicines and related products, and, instead, publish an up-to-date list of acceptable colouring substances in guidelines

o) remove prescriptive requirements relating to the dispensing of prescriptions and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice

p) allow the Director-General of Health to permit (by notice in the *New Zealand Gazette*) specific general sale medicines to be sold via vending machine subject to any conditions specified in the notice

q) amend definitions relating to pharmacy qualifications, and remove a redundant sub-clause from the definition of 'pharmacy technician'

r) require prescriptions to include the name of the prescriber, their street address (with an exception for midwives who do not have a permanent business address), and phone number, and the name of the person (or in the case of an animal, the owner) for whose use the prescription is given, and the quantity of medicine or total period of supply

s) clarify circumstances in which a prescription is not required

t) include an update to Schedule 1, which lists all classified medicines, in the planned amendment to the Medicines Regulations.

4. **Invite** the Minister of Health to issue drafting instructions to Parliamentary Counsel Office to give effect to recommendation 3 above.

5. **Agree** that the Ministry of Health publish the attached *Report of the Analysis of Submissions and Final Decisions on Proposed Amendments to Regulations under the Medicines Act 1981.*

6. **Authorise** the Ministry of Health to make minor editorial changes to the text of the report in recommendation 5 before the document is released.

Hon Tony Ryall
**Minister of Health**

15 9 10
**Date:**

Document 2

# Consultation on Cabinet and Cabinet Committee Submissions

## Certification by Department:

Guidance on consultation requirements for Cabinet/Cabinet committee papers is provided in the CabGuide (see Procedures: Consultation): http://www.cabguide.cabinetoffice.govt.nz/procedures/consultation

**Departments/agencies consulted:** The attached submission has implications for the following departments/agencies whose views have been sought and are accurately reflected in the submission:

Ministries of Consumer Affairs, Economic Development, Foreign Affairs and Trade and Justice; Ministry for the Environment; The Treasury; the Environmental Risk Management Authority; the Accident Compensation Corporation; PHARMAC

**Departments/agencies informed:** In addition to those listed above, the following departments/agencies have an interest in the submission and have been informed:

Department of Prime Minister and Cabinet

**Others consulted:** Other interested groups have been consulted as follows:

Royal NZ College of General Practitioners; NZ Medical Association; Medical Council; Pharmacy Guild; Pharmaceutical Society; Pharmacy Council; Midwifery Council; Dental Council; Nursing Council

**Name, Title, Department:** Deborah Roche, Deputy Director-General, Ministry of Health

| **Date:** 15/9/2010 | **Signature** |
|---|---|

## Certification by Minister:

Ministers should be prepared to update and amplify the advice below when the submission is discussed at Cabinet/Cabinet committee.

**The attached proposal:**

| | |
|---|---|
| *Consultation at Ministerial level* | ☐ **has been** consulted with the Minister of Finance *[required for all submissions seeking new funding]*<br>☑ **has been** consulted with the following portfolio Ministers: Dunne<br>☐ **did not need** consultation with other Ministers |
| *Discussion with National caucus* | ☐ **has been** or ☐ **will be** discussed with the government caucus<br>☑ **does not need** discussion with the government caucus |
| *Discussion with other parties* | ☐ **has been** discussed with the following other parties represented in Parliament:<br>☐ Act Party ☐ Maori Party ☐ United Future Party<br>☐ Other [specify]<br>☐ **will be** discussed with the following other parties represented in Parliament:<br>☐ Act Party ☐ Maori Party ☐ United Future Party<br>☐ Other [specify]<br>☑ **does not need** discussion with other parties represented in Parliament |

| **Portfolio** | **Date** | **Signature** |
|---|---|---|
| Health | 15/9/10 | Ryan |

Office of the Minister of Health

Cabinet Social Policy Committee

# Approval to implement changes to several regulations under the Medicines Act 1981

## Proposal

1. Agreement is sought to issue drafting instructions to the Parliamentary Counsel Office to implement proposals discussed in the recent *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981*.

## Executive Summary

2. The regulatory framework for medicines is in need of updating. Earlier this year, the Government agreed to consult on a suite of amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002, in order to: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; address some health and safety risks; and update technical matters. Changes were recommended to labelling, advertising, dispensing, and prescribing requirements.

3. Having considered the submissions received, it is proposed to proceed with the original proposals (as set out in the *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981),* and in some cases, make some further amendments arising out of submitter feedback. The Minister of Health will issue drafting instructions to the Parliamentary Counsel Office to give effect to these changes. These drafting instructions will also include the next periodic update of Schedule 1 of the Medicines Regulations 1984.

## Background

4. In New Zealand, medicines and medical devices are regulated by the Medicines Act 1981 and associated regulations, most notably the Medicines Regulations 1984. This legislative framework is in need of updating, to ensure it safeguards consumers while not creating unnecessary barriers to innovation.

5. Many of the problems in the current medicines legislative framework can only be addressed through changes to the Medicines Act itself. While this is likely to happen during the current parliamentary term, it is likely to take some time to implement a new Act, and some improvements can be made in the mean time through amendments to regulations.

6. Accordingly, the Ministry of Health was directed to progress amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. The proposed amendments: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; address some health and safety risks; and update technical matters.

7. In February 2010, Cabinet noted the release of the *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981* [SOC Min (10) 1/1, recommendation 6 refers]. The Consultation Paper was released on 26 February 2010 and submissions closed on 26 March 2010. Eighty-four submissions were received. The Ministry has now summarised the submissions and provided advice on the issues they raise. A *Report of the Analysis of Submissions and Final Decisions* is attached as Appendix One.

## Comment

8. Most of the original proposals amendments were widely supported by submitters, and should proceed. Some submitters suggested additional useful amendments, and it proposed that these also proceed. The following sections briefly describe the proposals and main areas of submitter comment. The submission summary in Appendix One provides a more detailed analysis.

### *Excluding certain products from regulation under the Medicines Act*

9. A number of products are currently regulated as "related products" under the Medicines Act. This results in an overly rigorous assessment of products that are relatively low risk. There was strong support for excluding low risk fluoride dentifrices (ie, pastes, liquids or powders used for oral hygiene purposes) and many anti-dandruff preparations from regulation under the Medicines Act. Most people felt that the Cosmetic Products Group Standard (administered by the Environmental Risk Management Agency) would adequately protect consumers.

10. Submitters suggested also removing from the Medicines Act anti-acne preparations, barrier creams for preventing nappy rash, antibacterial skin products, and oral hygiene products. Submitters also suggested that, in the interests of potential trade and consumer benefits, the approach to setting limits on content, claims and presentation of excluded products should be aligned with that used in Australia. It is proposed to implement these additional proposals.

### *Labelling requirements*

11. A number of proposals were suggested to simplify labelling requirements, and better align them with other countries, so as to minimise costs to companies associated with relabelling products for the New Zealand market.

12. A proposal to remove the requirement to place certain information on non-prescription medicines in a specific "consumer information panel" on the label was well supported by submitters. Instead, the regulations will require consumer information on the purpose of a non-prescription medicine to be included on the label for the medicine. The option of printing the required consumer information on an enclosed leaflet rather than the label will be retained.

13. Submitters also suggested further changes that would better align New Zealand labelling requirements with those applying in Australia, and reduce the cost of relabelling, without risking consumer safety. It is proposed to adopt these changes.

14. Submitter feedback in relation to the warning statement for non-sedating antihistamines has highlighted the need to change the way in which we ensure that labels contain appropriate warning statements. It is now proposed to remove all warning statements on labels from the regulations and, instead, place them in guidelines, which would more easily allow a case-by-case approach to be taken (as

in Australia, for example). Compliance with guidelines would be ensured through the product approval process.

15. The Ministry of Health has made an additional proposal, to require medicine labels to have both the date of dispensing and a unique identifying code linking a dispensed item back to the original prescription. This will ensure that if there are queries relating to a labelled dispensed medicine from a paramedic or hospital emergency department, the medicine can be traced back to the original prescription. It will also assist patients to determine how old a medicine is and whether it is still safe to use.

***Advertising requirements***

16. A number of proposals were suggested to simplify advertising requirements, and better align them with other countries, so as to minimise costs to companies associated with changing advertising material for the New Zealand market.

17. The majority of submitters who responded supported the proposed changes to advertising requirements (eg, specifying mandatory information such as *'Use only as directed'*), with some suggesting refinements to the proposals or further changes (eg, greater clarity about any differences in advertising requirements for prescription and non-prescription medicines). Those opposed to the suggested changes generally wanted more, rather than less, information in advertisements and were concerned that consumers would not have access to adequate information on the benefits and risks of the medicine if the requirements were relaxed. These concerns are not considered valid, since advertisements are not the primary mechanism to convey detailed information to consumers.

***Enabling electronic transmission of prescriptions in some cases***

18. It is not generally legal to electronically transmit prescriptions, but the Director-General of Health may issue waivers, on a case-by-case basis, to enable electronic transmission in "special circumstances". It was proposed that a set of criteria would be developed to establish greater transparency about when waivers would be granted. Most submitters who responded to this proposal supported it.

19. Some submitters stressed the need for careful consideration to be given to the development of the criteria (and some expressed a wish to be involved in the development of the criteria for the waiver). Some considered the waiver should be setting-specific (eg, District Health Board hospitals). Use of a waiver mechanism means that the Director-General will have the ability to change the criteria as the sector's readiness for electronic prescribing progresses.

***Aligning prescribing rights of all authorised prescribers***

20. The proposal to align prescribing rights for medical practitioners, dentists and midwives (who are all authorised prescribers under the Medicines Act) was generally well supported. The regulations would stipulate that these practitioners must prescribe in accordance with their scope of practice (for patients under their care), as set by their responsible authorities (ie, the Medical, Dental and Midwifery Councils), under the Health Practitioners Competence Assurance Act 2003.

21. Some pharmacy organisations and pharmacists raised concerns about pharmacists' ability to verify whether prescriptions issued by dentists and midwives

are in accordance with their scopes of practice. It is proposed that pharmacists should be able to dispense a prescription "on its face" provided he or she acts in "good faith". The Ministry will contact bodies representing pharmacists and responsible authorities to clarify these matters.

***Extending period of supply of prescription medicines***

22. The proposal to remove the 10 day limit on supply of a prescription medicine by a dentist was well supported. The majority of submitters considered that dentists should be able to prescribe the same quantities (ie, the same number of days worth) as medical practitioners and midwives, within their scope of practice.

23. Concerns were raised about the potential fiscal impact of aligning dentists' prescribing rights and periods of supply with those of other prescribers. However, it is expected that any increase in prescribing by dentists will be offset by a decrease in prescribing by medical practitioners, since patients will no longer need to be referred to a medical practitioner in order to obtain a prescription for extended treatment. Access and convenience for patients is likely to improve.

24. The proposal to allow the Director-General to waive the limit on period of supply in certain circumstances was also generally supported, particularly in relation to prescribing for armed forces personnel deployed overseas. Many submitters supported a more general extension of the period of supply, to cover, for example, situations where patients had chronic conditions that had been stabilised on a treatment regime.

25. It is proposed to extend the period of supply on a prescription from six months to twelve months for oral contraceptives, and from three months to six months for other prescription medicines, at the prescriber's discretion. Some submitters, including ACC, pointed out that such an approach could create safety issues if patients stockpile their medicines, and the potential for wastage if changes need to be made to a patient's treatment or patients stop taking their medication.

26. It is considered that this risk can be appropriately managed for subsidised medicines by PHARMAC, which sets the rules for subsidised dispensing of these medicines. PHARMAC, in discussion with District Health Boards, will carefully consider the appropriate period of dispensing (ie, the amount that can be provided to a patient by a pharmacist from a prescription) for a given medicine, to ensure that dispensing more than three months supply at a time only occurs where appropriate (ie, when it is safe and cost effective). In relation to unsubsidised medicines, the Ministry of Health will write to responsible authorities to remind them of their role in encouraging good prescribing practice (eg, not prescribing excessively or indiscriminately).

***Brand substitution by pharmacists***

27. There was strong support for the proposal to allow pharmacists 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 "no brand substitution permitted", and the pharmacist records details of the brand substitution on the prescription. This proposal will save considerable time for prescribers and pharmacists, and allow many patients to have their medicines dispensed more quickly.

28. Some submitters suggested that Medsafe should maintain a list on its website of medicines that are interchangeable at a population level. Information is already available in the Medicine Data Sheet that companies provide to Medsafe to help inform the decision of the pharmacist, based on the patient's treatment and the circumstances.

***Relaxing countersigning of standing orders***

29. Standing orders permit specified people (eg, paramedics) to administer medicines under the overall authority of a prescriber, such as a doctor. At present, every time a medicine is administered in this way, it needs to be countersigned by the prescriber. The proposal to allow the issuer of a standing order to specify the appropriate standing order arrangements (including when countersigning of administration and supply of the medicine is required) was well supported by those who responded to it.

30. There was, however, a concern about lack of oversight of standing orders if the counter-signing requirement is removed. To address this concern, it is proposed that where countersigning is not required in every case, the standing order must require the issuer to conduct, at a minimum, a documented monthly audit of a sample of the records of administration or supply under the standing order.

31. Concern was also raised that, presently, standing orders are only monitored during certification audits in hospitals and resthomes. This means that there is no monitoring of standing orders in the primary care setting. It is proposed that the Ministry write to the responsible authorities to remind them of the responsibilities of issuers of standing orders, particularly where standing orders are being used outside the hospital and resthome setting.

***Sale of medicines through vending machines***

32. Allowing the sale of low risk medicines through vending machines could potentially make these medicines more accessible. However, several submitters raised potential risks (eg, suicide risks with medicines such as paracetamol, the likelihood of children accessing machines, vandalism). Submitters suggested controls on where vending machines could be located, what they could contain, and the volume of product to be dispensed at one time.

33. Accordingly it is proposed that, rather than providing a blanket permission for general sale medicines to be sold by vending machine, a new regulation is made to allow the Director-General of Health to permit (by notice in the *New Zealand Gazette*) specific general sale medicines to be sold via a vending machine in accordance with any conditions specified in the notice. The conditions would be those that were considered necessary to ensure the integrity of the medicines or as a safeguard against inappropriate access (eg, locating machines in visible public spaces, limiting pack size for medicines, requiring temperature control).

***Medicines Data Sheets***

34. Pharmaceutical companies are required to provide to Medsafe a Medicines Data Sheet, which contains detailed prescribing information for that medicine. Proposed changes to update the content, format and publication requirements for Medicines Data Sheets were strongly supported. A number of submitters commented on the

timing of publication of the data sheet. It is proposed that data sheets be submitted for publication within 10 days of approval of the medicine to expedite the approval process.

***Definitions relating to pharmacy qualifications***

35. Proposed amendments to update definitions relating to pharmacy qualifications were well supported. Submitters also suggested removing a redundant subclause from the definition of "pharmacy technician", because it is no longer needed and refers to the Council of the Pharmaceutical Society, which no longer exists.

***Colouring substances***

36. The proposal to remove the regulation which lists the colouring substances permitted in medicines and related products, and instead, publish an up-to-date list of acceptable colouring substances in guidelines, was well supported. The list will be readily accessible, as requested by submitters.

***Requirements for prescriptions***

37. Proposals to amend prescription requirements were well supported. Submitters suggested a number of other specific pieces of information they considered should be included on a prescription (eg, patient and prescriber identifiers, prescriber's street address and phone number).

38. While the inclusion of unique patient and prescriber identifiers on prescriptions could have merit, regulation may not be the optimal mechanism to achieve this and could disadvantage prescribers, pharmacists and patients in situations where this information was not readily accessible (eg, when a doctor is prescribing for a new patient after hours). It is proposed that the prescriber's street address and phone number be included, with an exception made on the street address requirement for those midwives who do not have a permanent business address (and would have to provide a home address). This will address privacy concerns raised by the Midwifery Council.

***Dispensing requirements***

39. Proposed changes to remove prescriptive dispensing requirements and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice, were strongly supported. Some submitters suggested additional requirements, including the recognition of faxed prescriptions without the need for a paper copy.

40. 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 there is secure electronic transmission of prescriptions, there will no longer be a need for prescriptions to be faxed.

***Additional proposals by the Ministry of Health***

41. Regulation 44 provides for cases where a prescription is not required (eg, where a prescriber wishes a patient under his or her care to receive a dose of a medicine, and gives verbal instructions to that effect to the person who is going to supply or

administer it). It has been interpreted by some as providing a blanket exemption from prescribing. The Ministry of Health proposes that the wording of Regulation 44 be amended to remove any doubt about when prescriptions are not required.

42. The Ministry of Health also proposes to include drafting instructions for the next update to Schedule 1 along with the other proposals set out in this paper, for the sake of efficiency. Schedule 1 of the Medicines Regulations comprises a list of individual medicines that are classified as Prescription Medicines, Restricted Medicines or Pharmacy Only Medicines. Classifications for new medicines and changes to the classification of existing medicines are given immediate effect through a time-limited notice in the *New Zealand Gazette*. Typically, Schedule 1 is updated every 12-18 months to include recent additions and changes. This is a technical change that does not require policy approval from Cabinet, as consultation has already occurred, and the changes notified in the *New Zealand Gazette*.

## Consultation

43. The following Government agencies were consulted in the development of this Cabinet paper: The Treasury; the Ministries of Consumer Affairs, Economic Development, Foreign Affairs and Trade and Justice; the Ministry for the Environment; the Environmental Risk Management Authority, the Accident Compensation Corporation; and PHARMAC. Their comments have been noted in the paper. The Department of Prime Minister and Cabinet were provided with a copy of the paper.

44. The Ministry of Health received 84 submissions on the proposals from a wide cross-section of affected stakeholders, including: District Health Boards; government agencies; companies involved in the manufacture or supply of medicines, related products or cosmetics; organisations representing those suppliers; the advertising sector; groups representing or regulating health professionals; individual health professionals; organisations delivering healthcare services; and consumer groups. There was also a final brief round of consultation with organisations representing pharmacists (eg, Pharmacy Guild, Pharmaceutical Society) and prescribers (eg, Medical Council, College of General Practitioners, Midwifery Council).

## Financial Implications

45. Costs associated with drafting and implementing the new regulations will be met from within Vote Health baselines.

## Legislative Implications

46. Drafting instructions will be issued to the Parliamentary Counsel Office to give effect to the changes through amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002.

## Human Rights and Gender Implications and Disability Perspective

47. The proposed changes have no human rights, gender or disability implications.

## Regulatory Impact Analysis

### *Regulatory Impact Analysis Requirements*

48. The Regulatory Impact Analysis Requirements apply in this case, and a Regulatory Impact Statement (RIS) is attached.

### *Quality of the Impact Analysis*

49. The Ministry of Health's Internal Cabinet Paper Committee has reviewed the RIS prepared by the Ministry of Health, and considers that the information and analysis summarised in the RIS meets quality assurance criteria.

### *Consistency with Government Statement of Regulation*

50. I have considered the analysis and advice of my officials, as summarised in the attached RIS and I am satisfied that, aside from the risks, uncertainties and caveats already noted in this Cabinet paper, the regulatory proposals recommended in this paper: are required in the public interest; will deliver the highest net benefits of the practical options available; and are consistent with the commitments in the Government Statement on Regulation.

## Publicity

51. Once Cabinet has made decisions on these proposals, the Ministry of Health will publicly release a *Report of the Analysis of Submissions and Final Decisions on Proposed Amendments to Regulations under the Medicines Act 1981* (attached as Appendix One), subject to any amendments to reflect Cabinet's final decisions.

## Recommendations

52. It is recommended that Cabinet Social Policy Committee:

    1. **Note** that in February 2010, a consultation document was released on a set of proposed amendments to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002.

    2. **Note** that 84 submissions were received on the proposed amendments, most of which were supportive, and some of which proposed further useful changes.

    3. **Agree** to amend the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002 to:

        a) exclude low risk fluoride dentifrices, anti-dandruff preparations, anti-acne preparations, barrier creams for preventing nappy rash, antibacterial skin products and oral hygiene products, from regulation under the Medicines Act 1981, and align with Australia on limits content, claims and presentation for use for such products

        b) remove the requirement for a consumer information panel on medicines for over-the-counter sale, and align some other labelling requirements with Australia

c) remove warning statements on labels from the regulations, and instead place these in guidelines

d) require the label on a dispensed medicine to include an identifying code linking the dispensed item back to the original prescription, and the date of dispensing

e) change the advertising requirements for medicines so that they are better aligned with those in Australia

f) enable a waiver to be issued that would permit electronic transmission of prescriptions in specified situations

g) align the prescribing rights for medical practitioners, dentists, and midwives, requiring all prescribers to prescribe within their scope of practice for patients under their care

h) remove the 10 day limit on period of supply for dentists, thus aligning the period of supply for all prescribers

i) allow the Director-General of Health to waive the limit on period of supply of prescription medicines, either for an individual or a class of persons, in certain circumstances

j) extend the maximum period of supply on a prescription from 6 months to 12 months for an oral contraceptive, and from 3 months to 6 months for any other prescription medicine

k) allow pharmacists to substitute an alternative brand of a medicine where there are no clinical reasons why substitution should not occur, the prescriber has not marked the prescription with “no brand substitution permitted”, and the pharmacist records the details of the brand substitution on the prescription

l) allow the issuer of a standing order to specify conditions of a standing order (including how often counter-signing is required), subject to a documented monthly (or more regular) review, by the issuer of the order, of a sample of records of administration or supply

m) change regulations setting out the content, format and publication requirements for data sheets, and require approved data sheets to be submitted for publication within 10 days of approval of the medicine

n) remove the regulation, which lists the colouring substances permitted in medicines and related products, and, instead, publish an up-to-date list of acceptable colouring substances in guidelines

o) remove prescriptive requirements relating to the dispensing of prescriptions and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice

p) allow the Director-General of Health to permit (by notice in the *New Zealand Gazette*) specific general sale medicines to be sold via vending machine subject to any conditions specified in the notice

q) amend definitions relating to pharmacy qualifications, and remove a redundant sub-clause from the definition of 'pharmacy technician'

r) require prescriptions to include the name of the prescriber, their street address (with an exception for midwives who do not have a permanent business address), and phone number, and the name of the person (or in the case of an animal, the owner) for whose use the prescription is given, and the quantity of medicine or total period of supply

s) clarify circumstances in which a prescription is not required

t) include an update to Schedule 1, which lists all classified medicines, in the planned amendment to the Medicines Regulations.

4. **Invite** the Minister of Health to issue drafting instructions to Parliamentary Counsel Office to give effect to recommendation 3 above.

5. **Agree** that the Ministry of Health publish the attached *Report of the Analysis of Submissions and Final Decisions on Proposed Amendments to Regulations under the Medicines Act 1981*.

6. **Authorise** the Ministry of Health to make minor editorial changes to the text of the report in recommendation 5 before the document is released.

Hon Tony Ryall
**Minister of Health**

**Date:**

**APPENDIX ONE**

# Report of the Analysis of Submissions and Final Decisions

# on

# Proposed Amendments to Regulations under the Medicines Act 1981

**September 2010**

# INTRODUCTION

In February 2010 the Ministry of Health released a consultation paper *Consultation on Proposed Amendments to Regulations under the Medicines Act 1981* describing a set of proposals designed to modernise provisions in the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. Feedback on the proposals was sought by 26 March 2010.

The Ministry of Health received 84 submissions on the proposals from a wide cross-section of affected stakeholders. Seventeen submissions were received from District Health Board (DHB) employees, four from government agencies, eighteen from companies involved in the manufacture or supply of medicines, related products or cosmetics and six from organisations representing those suppliers. Groups representing or regulating health professionals provided twenty-one submissions, five submissions were received from individual health professionals, and four from organisations delivering healthcare services. Five submissions were received from consumer groups and one submission from the advertising sector.

A summary of the feedback received on each proposal, and the Government's decisions following consideration of the feedback, is provided below.

# Part 1: Proposals to reduce unnecessary costs, remove barriers to innovation and improve access to medicines

| ***Change proposal 1.1*** | ***Exclude some fluoride dentifrices and some anti-dandruff products from regulation under the Medicines Act 1981*** |
|---|---|

*It is proposed that a new regulation be made under section 105(1)(i) declaring that:*

- *dentifrices containing fluoride below the 0.15 percent level specified in Part 3 of the First Schedule to the Medicines Regulations 1984, and for which only general fluoride claims are made*

*and*

- *anti-dandruff shampoos that do not contain a scheduled medicine and for which only dandruff treatment claims are made*

*are not related products for the purposes of the Act.*

*Dentifrices containing higher levels of fluoride or other active ingredients, or that make claims other than fluoride claims, would continue to be regulated as related products or medicines, as they are at present.*

*Anti-dandruff products containing scheduled medicines or intended for the treatment of scalp conditions other than dandruff would continue to be regulated as medicines, as they are at present.*

## Feedback received

This proposal was almost universally supported by the submitters who commented on it and the majority of these also felt that the Cosmetic Products Group Standard would provide adequate protection about the safety of such products. Two submitters expressed concern about the toxicity of fluoride and its widespread use.

Around twenty submitters provided examples of other product types they considered should also be excluded from regulation under the Medicines Act 1981. A common theme in these submissions was that the exclusion list should be developed to align with the approach taken in Australia to define the cosmetic/therapeutic goods boundary because of the potential trade and consumer benefits of a harmonised approach. Submitters therefore recommended exclusion of products such as anti-acne skin care products, barrier creams for preventing nappy rash, and a broad range of oral hygiene products for the care of the teeth and the mouth. They also asked that cut-off levels for ingredients in those products and permissible claims for the excluded products be harmonised with Australia.

A few submitters asked that products such as pregnancy tests, medicated condoms and saline nasal irrigations that are regulated in Australia as medical devices be excluded from the Medicines Act.

## Outcome

The planned amendment will be progressed (with the level of fluoride in excluded dentifrices being set at 0.15% or less of elemental fluoride).

In addition, the following product types will be excluded from regulation under the Medicines Act using the approach taken in the Australian Excluded Goods Order to limit content, claims and presentation for use:

- anti-acne preparations (such as cleansers, scrubs, masks)
- barrier creams for preventing nappy rash
- antibacterial skin products
- oral hygiene products.

Some of these products may be covered by the Cosmetic Products Group Standard if they contain substances which meet the hazardous substances threshold, otherwise they will no longer be regulated.

Pregnancy tests can not be excluded from the Medicines Act by regulation as they are included in the definition of "medicine" in the Act. Similarly, products which are regulated as medicines in New Zealand but as medical devices in other countries will remain so until new primary legislation is developed.

| ***Change proposal 1.2*** | ***Amend the labelling requirements for medicines and related products*** |
|---|---|

*The following amendments to the labelling provisions in the Regulations are proposed.*

- *Revoke regulation 20, thereby removing the requirement for certain information to be placed in a specific 'consumer information panel' on the label of a medicine intended for retail sale without a prescription. The requirement for a label on an over-the-counter medicine to include a statement of the purpose for which the medicine is recommended would be retained.*
- *Insert a new regulation allowing medicines that are supplied as individually wrapped dosage units such as lozenges, pessaries, single doses of a powder or liquid, or a patch to be labelled just with the name of the medicine, the name and quantity of each active ingredient, the batch number and expiry date, provided the box enclosing the individual dosage units is fully labelled in accordance with the Regulations.*
- *Amend regulation 22(1) so that it only applies to medicines containing a sedating antihistamine, and add a new subclause specifying an appropriate warning statement for medicines containing non-sedating antihistamines.*

## Feedback received

The proposed changes to labelling requirements were well supported.

There was a call for harmonisation with Australian labelling requirements and labelling terminology, with a number of submitters requesting that the requirements set out in the Australian Therapeutic Goods Order No.69 *General Requirements for Labels of Medicines* be adopted in New Zealand. This would mean, for example, that information could appear over two blisters rather than over each blister in a blister

pack; the size of the principal display panel (PDP) would depend on legibility rather than be a proportion of overall label size; and the PDP would not be required to list all the active ingredients for multi-ingredient products. Automatic acceptance of labelling changes already approved in Australia was also suggested.

A number of pharmaceutical industry submitters felt a class warning statement for non-sedating antihistamines was not appropriate and considered that the need for a sedation warning should be determined on a case-by-case basis. Use of a statement to the effect that the product was rarely associated with drowsiness was suggested.

A small number of submitters did not support removal of the requirement for a Consumer Information Panel on over the counter (OTC) medicines, believing this could result in consumers failing to read important information.

Other suggested changes to the labelling requirements were:

- Removing the requirement for the New Zealand-specific classification statement and distributor details to appear on the label.
- Reducing the labelling requirements for small containers that are supplied within another fully-labelled container.
- Removing the requirement for a statement of purpose on labels of non-prescription medicines used by health professionals (eg saline injections), thereby avoiding the need for labelling exemptions to be granted for such products.
- Ensuring dosage information for different age groups is included on medicines for OTC sale.
- Requiring visual differentiation between different products produced by the same company to reduce dispensing and administration errors.
- Mandating the inclusion of a barcode on product labels (or down to individual dose unit), the barcode being consistent with internationally recognised standards.
- Mandating the use of the Pharmacode on product labels.
- Permitting reference to a second ‘companion’ product on a label without this being considered to be an advertisement.
- Requiring medicines to be produced in dispensing packs (to avoid repackaging and re-labelling) and mandating provision of Consumer Medicine Information (CMI) by pharmacists.
- Amending regulation 22(3) so that the label of a product containing aspirin or paracetamol is not required to include the current warning statement provided the label includes an instruction not to exceed the stated dose and there are not dosage instructions for children under 2 years of age.
- Ensuring labelling requirements for cosmetics such as anti-wrinkle creams are aligned with requirements in other jurisdictions (eg, Australia).
- Prohibiting use of the acronym ‘POM’ as an alternative expression of “Prescription Only Medicine” on labels.
- Developing a more flexible approach to labelling of medicines with low sales volumes.
- Permitting website addresses on labels.

- Requiring more anti-cholinergic warning statements on products containing prochlorperazine.
- Requiring more storage information on products requiring refrigeration.
- Not requiring transparent outer packaging to be labelled.
- Not restricting the size of sample packs.
- Changes to the labelling of controlled drugs.

## Outcome

The planned revocation of regulation 20 (removal of the Consumer Information Panel) will proceed as proposed. As a consequence, regulation 13 will be amended to require that the label of a non-prescription medicine includes a statement about the purpose of use of the medicine. Where the small size of a container makes it impractical to use the label to convey all the required information, the option of printing the required consumer information on an enclosed leaflet rather than the label will be retained.

In relation to amendments to regulation 13, submitter comments suggesting further changes to align labelling requirements as far as possible with those applying in Australia have been accepted. It is therefore planned to amend the regulations to achieve the proposed changes to labelling of individually wrapped dosage units and in addition:

- rationalise the requirements for labelling of strip packed medicines (including safety containers) and small containers
- remove prescriptive requirements that do not enhance patient safety (such as the requirement relating to the size of the PDP)
- rationalise the requirements for labelling of medicines used by practitioners
- require the names and strengths of active ingredients to be on the PDP.

Submitter feedback in relation to the warning statement for antihistamines has highlighted the need to change the way in which the inclusion of appropriate warning statements on product labels is achieved. It is therefore intended to revoke regulation 22 and include all warning statements in guidelines, with compliance ensured through the approval of the label as part of the product approval process. This would enable a case-by-case approach to be taken to the warning statements, in line with the Australian approach. In the case of non-sedating antihistamines, and in contrast to the situation in Australia, the guidelines will require a warning statement that will reflect the previous advice of the Medicines Adverse Reactions Committee.

Two additional changes to the labelling of dispensed medicines have been identified as desirable and will be progressed. The first involves amending regulation 23 to require the label on a dispensed medicine to include an identifying code linking the dispensed item back to the original prescription. This requirement would also cover compliance packaging (but only apply to the header of the blister pack). It will ensure that if there are queries relating to a labelled dispensed medicine from a paramedic or hospital emergency department, the medicine can be traced back to the original prescription. It will also be of assistance with the introduction of electronic prescribing, where a unique identifier relating the medicine to a specific patient, from a specific prescriber, dispensed by a specific pharmacy will be paramount for public safety. The second change is a requirement to include on the label the date of dispensing. This will assist patients in determining how old a medicine is and

whether it is out of date and is still safe to use. Other suggestions were considered, but will not be progressed.

### *Change proposal 1.3 Amend the advertising requirements*

*It is proposed that regulation 8 be amended in order to:*

- *expand the current set of types of advertisements that do not require mandatory information ('excluded advertisements') by adding point-of-sale advertisements (such as shelf-talkers) and promotional items (such as pens), providing they do not include a therapeutic claim*
- *specify that the mandatory requirements for advertisements (other than excluded advertisements) are:*
  - *the statement 'Always read the label' or words of similar meaning*
  - *the statement 'Use only as directed' or words of similar meaning*
- *specify that advertisements (other than excluded advertisements) for pharmacist-only medicines include the statement 'Your pharmacist's advice is required' or 'Available only from your pharmacist'*
- *specify that advertisements (other than excluded advertisements) for non-prescription medicines must also include:*
  - *the statement 'If symptoms persist see your doctor / health care professional' or words of similar meaning*
  - *a warning statement about any known serious adverse effects, or contra-indications in a known group of people*
- *specify that advertisements for prescription medicines (other than excluded advertisements) must also include:*
  - *the words "Prescription Medicine" or words of similar meaning*
  - *advice that this medicine has risks and benefits*
  - *appropriate and prominent warning statements about the contra-indications and major risks associated with use of the medicine − these should be stated in a manner that is relevant to, and easily understood by, the consumer*
  - *advice on how consumers can access more detailed information about the risks and benefits of the medicine*
- *retain the requirement that advertisements for the supply of medicines by mail order, direct mail or the internet include the name and quantity of each active ingredient.*

## Feedback received

Around 60 percent of submitters responded to the proposals and around half of these suggested other changes they would like to see made to the advertising requirements.

The majority of those who responded supported the proposed changes. Those opposed to the suggested changes generally wanted more, rather than less, information in advertisements and were concerned that consumers would not have access to adequate information on benefits and risks of the medicine if requirements were relaxed.

Submitters sought greater clarity about any differences in requirements for prescription and non-prescription medicines (including a request for two separate regulations), expansion of the list of 'excluded advertisements', and full alignment with Australian advertising requirements.

Two bodies representing pharmacists considered that adopting the proposed approach could lead to pharmacists unintentionally breaching the Code of Ethics by using an advertisement that failed to meet the mandatory requirements.

A number of submitters took the opportunity to express their opposition to Direct To Consumer Advertising (DTCA) for prescription medicines.

Other suggestions included:

- requiring advertisements to state, where applicable, that the medicine is only available on prescription
- requiring risk benefit information to be provided in advertisements to consumers (not just a reference to where such information can be found)
- requiring advertisements in pharmacy trade magazines to include all the information required by health professionals
- allowing a reference to the Medsafe website as a source of further information
- requiring the names of active ingredients to be shown on point-of-sale advertisements
- ensuring the exemptions for point-of-sale advertising apply only where the advertisement is placed with the product (ie not to window posters)
- permitting short reminder advertisements to health professionals (consistent with the Researched Medicines Industry Association (RMI) code)
- not requiring the company name or logo on promotional items (consistent with Australian rules)
- maintaining a flexible approach to what constitutes an excluded advertisement
- requiring a statement to the effect that a pharmacist's advice is required, rather than "only available from your pharmacist"
- not requiring the statement "This medicine has risks and benefits" to be included
- requiring internet advertising for prescription medicines to include full regulation 8 information
- requiring an advertisement to direct the consumer to talk to their health professional
- requiring advertisements to include advice on adverse event reporting
- considering modern communication technologies used by advertisers when designing advertising controls.

## Outcome

The amendments to regulation 8 will proceed as proposed, recognising the need to:

- clearly define the types of advertisements that are excluded from requiring the mandatory statements; and

- clearly specify the mandatory statements that apply to particular types of advertisement.

Other suggestions were considered, but will not be progressed.

## *Change proposal 1.4 Enable electronic transmission of prescriptions*

*It is proposed that, in order to facilitate implementation of electronic transmission of prescriptions, regulation 43 should be amended to remove the term 'in special circumstances'. Regulation 43(a) would then be amended to state that the form of prescription authorised under the waiver could include (but would not be limited to) an electronic form.*

*This would enable a set of criteria for applicants and a standard set of requirements to be established, and waivers to be granted to applicants who met those criteria and could demonstrate an ability to fulfil the specified requirements. The requirements could include, for example, compliance with a specified standard.*

*This would provide transparency for applicants and reduce the complexity of the task of considering waiver applications on a case-by-case basis. The criteria and requirements could be published (and therefore be readily accessible to prospective applicants) and could be updated as necessary (eg, as new standards are developed or new systems implemented).*

### Feedback received

Around half of the submitters responded to this question with the majority of those supporting the proposal. A number of submitters took the opportunity to make comments on electronic prescribing generally and the need for a new national standards system for electronic prescribing. A few submitters asked to be consulted during the development of the new standards and the criteria for the waiver proposal. Some felt that waivers may need to be specific to particular settings (eg a DHB hospital). Others expressed concern about the need for the waiver criteria to be clear and unambiguous and about costs involved for the sector.

### Outcome

It is recognised that stakeholders are seeking a more comprehensive package of provisions relating to electronic prescribing. However, given that this cannot be implemented through regulation change alone, the proposed amendment to regulation 43 will proceed as an interim measure.

Criteria for granting a waiver will need to be developed in consultation with affected parties.

## *Change proposal 1.5 Align prescribing rights for medical practitioners, dentists and midwives*

*It is proposed that the 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 be removed, and that medical practitioners, dentists and midwives be required to prescribe within their scope of*

*practice as defined by their councils established under the Health Practitioners Competence Assurance Act.*

### Feedback received

The majority of submitters who responded to this question supported the proposal. However, a number of submitters were concerned about using the concept of 'scope of practice' in the regulations and whether there was a requirement for pharmacists to have to verify whether a particular medicine was within a prescriber's scope of practice. There seemed to be a general lack of understanding and awareness of the provisions of the Health Practitioners Competence Assurance Act (HPCAA) and misunderstanding around the proposal. Several submitters asked for clear guidelines on what would fall within each scope of practice.

### Outcome

The proposal to align prescribing rights for medical practitioners, dentists and midwives will proceed as planned. The proposal will make it clear that a prescribing right for a scope of practice applies to the treatment of patients under the prescriber's care.

While some groups expressed concerns about operational matters (such as a belief that a pharmacist would be expected to verify a prescriber was prescribing within their scope of practice), these are broader concerns that relate to current policy under the HPCAA. Concerns were raised, for example, about pharmacists ability to verify whether prescriptions issued by dentists and midwives are in accordance with their scopes of practice. Pharmacists may dispense a prescription "on its face" provided he or she acts in "good faith". The Ministry of Health will contact the bodies representing pharmacists and responsible authorities to provide clarification on such matters.

## *Change proposal 1.6 Extend the period of supply of prescription medicines*

*It is proposed that regulation 39(4) be amended to allow dentists to prescribe treatment for a period of three months, as for all other authorised prescribers.*

*It is also proposed that provision be made for the Director-General to waive the three-month limit in special circumstances.*

### Feedback received

The majority of submitters who responded to the question on aligning the period of supply for dentists with authorised prescribers supported the proposal. A small number supported the proposal with conditions, such as extending the period of supply to 10 or 30 days only, or requiring dentists to collaborate with medical practitioners prior to prescribing long term treatment.

Two submitters opposed the proposal. One submitter pointed out that consideration would need to be given to amending the Pharmaceutical Schedule to align prescribing and subsidy rules.

Most of those who commented on the proposal to allow the three-month prescribing limit to be waived in certain circumstances supported it. Two submitters felt that such

a waiver should not apply to prescribing by dentists and midwives. One submitter felt strongly that a three month review was important, but if the proposal did go ahead it should only be extended to six months (or twelve months in the case of an oral contraceptive).

Many submitters supported extension of the period of supply of prescription medicines for patients with chronic conditions who are stabilised on a treatment regime. Some submitters, however, pointed out that such an approach could lead to concerns about the safety of patients who stockpile their medicines, and the potential for wastage, if changes need to be made to a patient's treatment.

Other issues raised included the need for pharmacists to be able to verify the existence of a waiver when presented with a prescription, and the potential for increased antibiotic resistance due to increased use. It was also suggested that an increased period of supply should be considered on a case by case basis with a maximum of six months, and only for New Zealand residents when a New Zealand registered prescriber has noted that the patient is stable.

### Outcome

As a result of submitter feedback, it is intended that the period of supply on a prescription be extended to twelve months for oral contraceptives and six months for other prescription medicines. This would apply to all authorised prescribers, including dentists.

It is also intended to proceed with the proposal to allow the Director-General of Health to waive the limit on period of supply (beyond the extended limits), either for an individual or for a class of persons, in certain circumstances

It is considered that wastage and safety risks can be appropriately managed for subsidised medicines by PHARMAC, which sets the rules for subsidised dispensing of these medicines. PHARMAC, in discussion with District Health Boards, will carefully consider the appropriate period of dispensing (ie, the amount that can be provided to a patient by a pharmacist from a prescription) for a given medicine, to ensure that dispensing more than three months supply at a time only occurs where appropriate (ie, when it is safe and cost effective). In relation to unsubsidised medicines, the Ministry of Health will write to responsible authorities to remind them of their role in encouraging good prescribing practice (eg, not prescribing excessively or indiscriminately).

| ***Change proposal 1.7*** | ***Restrict prescribing for patients who are not in New Zealand*** |
|---|---|

*It is proposed that, in addition to the requirement for a patient to be 'under the care' of the prescriber, there is a requirement for the patient to be in New Zealand at the time the prescribing occurs, or normally resident in New Zealand but temporarily overseas at the time the prescribing occurs.*

### Feedback received

Just over half of all submitters responded to this proposal. Most supported or strongly supported the concept of only permitting prescribing where the patient is in New Zealand or normally lives in New Zealand but is temporarily out of the country.

Submitters highlighted the need for defence force and other New Zealand personnel working overseas to have medicines prescribed for up to six months, and suggested that prescribing for residents of the Cook Islands, Tokelau and Niue should be permitted. It was also suggested that a medical practitioner in New Zealand should be able to prescribe for a patient who is temporarily overseas, if an overseas doctor is able to carry out an examination and provide the necessary information to the prescriber.

One submitter felt it was desirable for the medicines to also be dispensed in New Zealand. Another considered that it would be inappropriate for a midwife to prescribe for women or their babies while they are overseas.

Some considered that “temporarily” or “normally resident” would need to be defined. Setting a maximum period of absence of 6 months, or aligning with the IRD definitions, were suggested.

Adherence to the Medical Council’s rules in relation to prescribing (including the definition of “under the care”) was suggested as an additional requirement.

One submitter felt that the issue of prescribing for people in other countries would need to be reviewed if a point was reached where telemedicine enabled physical examination of the patient to occur.

It was suggested there should be an additional requirement for a face-to-face consultation and/or physical examination of the patient to have been undertaken at some point.

Four submitters rejected the proposal. These submitters supported internet prescribing and export of dispensed medicines, considering it an innovative business that supported other New Zealand businesses. These submitters said there was no evidence of medicine shortages as a result of medicines being sent overseas, and supply of medicines to patients in other countries could be stopped if a supply shortage was to develop in New Zealand. They indicated that they were obtaining a significant proportion of the medicines they used from overseas, rather than using the New Zealand supply chain and they considered the safeguards in place to ensure verification of prescriptions from overseas doctors were adequate. Other points raised included:

- internet prescribing may lead to reduced prices in a small country like New Zealand as a result of economies of scale
- the proposed restriction on prescribing may be incompatible with New Zealand’s free trade agreements
- the service being provided from New Zealand is of significant benefit to people such as United States citizens who have no health insurance and find United States medicine prices too high
- supply of medicines between countries in the European Union is permitted and the United States Food and Drug Administration permits importation of up to 90 days’ supply of medicine for personal use
- the threat of parallel importation of medicines by individuals or organisations involved in internet prescribing will tend to keep down prices for patented medicines.

## Outcome

It is not proposed to proceed with this proposal at this time. The Ministry of Health will do further policy work on this issue.

| ***Change proposal 1.8*** | ***Allow pharmacists to substitute an alternative brand of a medicine in certain circumstances*** |
|---|---|

*It is proposed that regulation 42(4) be amended to allow a pharmacist to substitute an alternative brand of a prescribed medicine (but not a different 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.*

## Feedback received

Almost all of those who responded to this question supported the proposal.

However, a number of submitters included caveats such as:

- requiring or not requiring the use of specific words such as "no brand substitution permitted"
- not permitting substitution where medicines require dose titration or have a narrow therapeutic range
- requiring the prescriber to be notified of each substitution
- allowing substitution only when the medicine is no longer available in New Zealand or is not funded
- requiring patient consent to be obtained
- not allowing substitution where multiple brands are subsidised
- providing a list of interchangeable medicines for pharmacists.

Several submitters recommended allowing substitution even when the prescriber has specified no substitution, in circumstances where the medicine is longer available in New Zealand or the patient has given informed consent. One submitter expressed concern that products may not be bioequivalent and different pack layouts for some medicines mean patients need to be given special instructions. One submitter did not support annotation of the script as it was counter to an e-environment and a less permanent record.

## Outcome

This proposal was well supported and will proceed as proposed. It is not considered that any further caveats are required.

Publication of a list of interchangeable medicines is not supported because the decision to substitute an alternative brand is a clinical one that should be made by the pharmacist, in the context of the patient's treatment and circumstances, taking into consideration relevant information from the medicine data sheet.

| ***Change proposal 1.9*** | ***Amend the requirements for countersigning records of supply or administration of a medicine under a standing order*** |
|---|---|

*It is proposed that the Medicines (Standing Order) Regulations 2002 be amended to require an authorised prescriber issuing a standing order to specify the arrangements for countersigning, including specifying:*

- *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.*

### Feedback received

The majority of those who responded to this question supported the proposal (just under half of all submitters). It was suggested that:

- the issuer should review the records as well as the practices of the standing order
- countersigning could still be required but with a longer timeframe
- there should be a requirement for a timely review and sign-off and Ministry of Health guidelines on what this should be
- there should be monitoring by the Ministry of Health.

Reasons for opposing the proposal were that it may allow de-facto prescribing by non-prescribers and that counter-signing is a key safeguard. A suggestion was made that instead of operating under standing orders, paramedics be regulated under the HPCAA to give them prescribing rights and a scope of practice.

### Outcome

The proposal to remove the requirement for countersigning of every supply or administration of a medicine under a standing order will proceed. However, in order to address concerns about a possible lack of oversight if countersigning is not mandatory, it is intended to add a requirement that, as a minimum, there is a documented monthly audit of a sample of the records of administration or supply under a standing order. The Ministry of Health will write to responsible authorities to remind them of the responsibilities of issuers of standing orders.

| ***Change proposal 1.10*** | ***Allow sale of general sale medicines by vending machine*** |
|---|---|

*It is proposed that regulation 59 be revoked and a new regulation made to permit the sale of unscheduled (general sale) medicines by vending machine. This would continue the permission for the sale of chemical contraceptives by vending machine (because they are general sale medicines), but they would no longer need to be supplied with condoms.*

## Feedback received

Of those who responded to this question, just over a third opposed the proposal. A number of submitters were concerned about the possible safety issues with some medicines such as paracetamol due to suicide risk and the likelihood of children accessing machines. There were also concerns about vandalism and about access to multiple packs. Several submitters suggested that not all general sales medicines should be able to be sold in this way and a list of permitted medicines should be developed. It was suggested that ibuprofen should not be available in this way.

Most felt that the proposal was unlikely to have a significant impact on other businesses. Several commented that it would be a new business opportunity. Other issues raised were about security of the medicines, and the costs of repackaging medicines to make them suitable for putting in vending machines. A licensing scheme for vending machine operators was suggested.

Suggestions made regarding limitations on vending machine operators included requirements for:

- adequate stock control and expiry date checking
- appropriate storage conditions, including temperature/humidity controls on machines
- adequate controls on access by children
- product information to be visible on packs before purchase
- limits on products, product mixes, pack sizes, number of packs in machine and number of packs able to be accessed at one time
- quality control standards
- a system to handle customer complaints
- products to be supplied in original packs
- safety monitoring and security of machines
- product recall, if necessary.

## Outcome

While the concept of allowing some medicines to be sold by vending machine was generally supported, many submitters considered there needed to be controls on where vending machines could be located, what they could contain, and the volume of product that could be dispensed at one time. Given these concerns, it is intended that provision be made for the Director-General to permit (by notice in the *New Zealand Gazette*) specified medicines to be sold by vending machine and to set appropriate controls to ensure the integrity of the medicines and to safeguard against inappropriate access.

# Part 2: Updating technical requirements

| *Change proposal 2.1* | *Amend requirements for data sheet content, format and publication* |
|---|---|

*It is proposed that:*

- *regulation 51 be amended to define 'data sheet' as the prescribing information relating to a particular medicine and to remove reference to a data sheet compendium*
- *regulation 52 be replaced with a regulation that requires the approved data sheet for a medicine to be submitted to Medsafe, in the format required for publication on the Medsafe website, not less than 10 working days before the medicine (whether a new or changed product) is placed on the market*
- *regulations 53 and 54 and Schedule 3 be revoked, and guidance on the content and layout of data sheets be provided in guidelines published by Medsafe.*

## Feedback received

The proposal to amend the requirement for data sheets to bring them into line with current practice and allow flexibility regarding the format of data sheets was strongly supported.

A number of submitters commented on the timing of publication of the data sheet, with suggestions ranging from publication within 10 days of the medicine being approved (regardless of whether the product is marketed), to publication on or before the date the medicine is placed on the market, to publication within a month of the medicine being approved.

One submitter suggested that data sheets could be published more quickly if companies were able to upload them directly, thus removing Medsafe processing time. Another suggested that data sheets should be required to include a photograph of the medicine.

Most of those who commented supported the proposal to specify data sheet content and format in guidelines. A number highlighted the need for consultation with industry in developing the guidelines.

A small number of submitters were concerned that using guidelines may mean the requirements were not enforceable and felt it was important to ensure that a standardised set of information was available.

## Outcome

It is intended to proceed as proposed, but to require that an approved data sheet be submitted for publication within 10 days of notification of approval of the new or changed medicine in the *New Zealand Gazette*. This should expedite the approval process.

| ***Change proposal 2.2*** | ***Amend definitions relating to pharmacy qualifications*** |
|---|---|

*It is proposed that definitions in regulation 2 be amended as follows:*

- *dispensary technician − a person who holds a certificate issued by the Pharmaceutical Society of New Zealand before 18 September 2004 that classifies the holder as a dispensary assistant, or records that the person has completed the requirements of the Pharmacy Technician's Certificate*
- *pharmacy graduate – a person who is not a pharmacist, but who has a qualification prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003 as a qualification necessary to practise in the profession of pharmacy and who is actively taking steps towards registration with the Pharmacy Council as a pharmacist under the Health Practitioners Competence Assurance Act 2003*
- *pharmacy student – a person who is undertaking, but has not yet completed the course or examinations leading to, a qualification of a kind stated by the Pharmacy Council, for the purposes of section 12(2)(a) or (b) of the Health Practitioners Competence Assurance Act 2003.*

*It is proposed that the definition of approved school be removed from regulation 2 as this term will no longer be used in other definitions and will therefore be redundant. It is also proposed that the definition of Dispensary Assistant's Certificate be removed as this certificate is no longer issued or relevant, making the definition redundant.*

## Feedback received

The proposal to amend the definitions relating to pharmacy qualifications was strongly supported. A number of submitters considered that the term 'pharmacy graduate' should be replaced by 'pharmacy intern' since this is the terminology used by the Pharmacy Council when defining scopes of practice.

The following new definitions or amendments to existing definitions were suggested:

- remove subclause (b) from the definition of *pharmacy technician* because the Council of the Pharmaceutical Society referred to in the definition no longer exists and no person has ever had an overseas qualification recognised in this way
- update the definition of *poison bottle*
- add definitions for *dispense*, *prescription assessment*, and *pharmacy practice*.

## Outcome

It is intended to proceed as proposed with changes to definitions.

In addition, the definition of *pharmacy technician* will be amended to remove subclause (b), because it is no longer needed and refers to the Council of the Pharmaceutical Society, which no longer exists. No new definitions are considered necessary.

## *Change proposal 2.3 Revoke the regulation on colouring substances permitted to be used in medicines*

*It is proposed that regulation 6 be revoked. Medsafe would instead maintain an up-to-date list of acceptable colouring substances in regulatory guidelines published on the Medsafe website.*

### Feedback received

This proposal was well supported. Submitters highlighted the need for consultation with industry when the guidelines are being developed and for the list of suitable colouring substances to be readily accessible. It was felt there should be a clear mechanism for colouring substances to be added to the list, and there was a request for publication of a list of colouring substances that had been assessed and found not to be suitable for use in medicines.

It was suggested that colouring substances permitted to be used in medicines in other countries should be allowed to be used here provided they met the appropriate specifications. A review of the status of tartrazine in medicines was requested, since it is permitted in foods here and in medicines in the European Union.

### Outcome

It is intended to proceed as proposed. Medsafe would seek feedback on the draft guideline and would add new colouring substances when these had been evaluated as part of a new medicine application and found acceptable.

## *Change proposal 2.4 Update requirements for prescriptions*

*It is proposed that regulation 41 be amended to:*

- *require the name of the prescriber to be included on the prescription, as well as their address and signature*
- *require inclusion of the given name(s) of the person for whose use the prescription is given (instead of the title and initials)*
- *replace subclauses (f) and (i) with a requirement for the prescriber to specify the total quantity of medicine or total period of supply (removing reference to the number of dispensings and the interval between dispensings)*
- *require inclusion of the given name(s) of the owner of an animal to be included on a prescription relating to the treatment of an animal (instead of the title and initials).*

### Feedback received

The proposed changes were generally supported by the 50% of submitters who commented on this proposal. One submitter rejected the proposal, suggesting instead that the requirements for the content of prescriptions should be aligned with those set out in the Medical Council's statement on Good Prescribing Practice.

A number of submitters considered that specific pieces of information should be required to be on a prescription, including:

- unique identifiers for the patient and the prescriber

- name and physical practice address for the prescriber
- the contact telephone number for the prescriber
- the weight of a child under 5 years of age.

One submitter highlighted the need for electronic or scanned signatures to be acceptable, while another was concerned about security if electronic signatures were permitted. Another highlighted the fact that computerised prescribing systems would need to be changed before new requirements could be effectively implemented.

One submitter advocated placing the rules for content of prescriptions in the Pharmaceutical Schedule, while another suggested that the quantity of medicine to be dispensed should be set by the prescriber specifying an end date for the treatment, enabling pharmacists to dispense appropriate quantities taking into account the amount the patient already has on hand.

Midwifery groups expressed a concern that many midwives to not have a permanent street address for their business.

## Outcome

It is intended to proceed as proposed and, in addition, make it a requirement for the street address (with an exemption for midwives who do not have a permanent business street address) and phone number of the prescriber to be shown on the prescription.

While the Ministry of Health strongly supports the inclusion of unique patient and prescriber identifiers on prescriptions, mandating their inclusion is not considered the optimal mechanism for achieving this and could disadvantage prescribers, pharmacists and patients in situations (such as when a doctor is prescribing for a new patient after hours and does not have access to the patient's NHI) where the information was not readily accessible. The Ministry of Health considers there are other ways (such as through District Health Board contracts or as a data requirement for e-transmission of prescriptions) to encourage the use of unique health practitioner and patient identifiers.

It is considered unnecessary to mandate a requirement for the weight of a child less than 5 years old to be on a prescription given that the Medical Council's statement on *Good Prescribing Practice* requires a practitioner to also include the weight of a child on a prescription if this information would affect dosage.

### *Change proposal 2.5 Update dispensing requirements*

*It is proposed that the provisions relating to the frequency of dispensing in regulation 42(3)(a) to (e) be revoked and the requirements for recording dispensing details in regulation 42(3)(g) to (i) be updated to reflect current practice.*

*It is proposed that the pharmacy name and address, date, quantity of medicine dispensed and prescription number be recorded each time a prescription is dispensed. However, the way in which these details are recorded would not be specified, so that it could be done by, for example, attaching a computer-generated label to the prescription.*

### Feedback received

Proposed changes to the dispensing requirements were strongly supported. Specific comments provided by submitters included the following:

- there should be alignment between the regulations and the requirements specified in the Pharmaceutical Schedule, and the requirements should be practicable
- annotations should be made in the electronic record of the dispensing, rather than on the paper prescription
- the original prescription, not just the computer record, must be viewed when a repeat is dispensed
- faxed prescriptions should be recognised as legitimate prescriptions without the need for a paper copy to be supplied. Alternatively, they could be treated in the same way as an urgent supply, requiring an original signed copy of the prescription to be supplied within seven days.
- security could be improved by requiring the prescriber to certify on the prescription that it is being faxed to a named pharmacy
- computerised dispensing systems will need to be changed before new requirements can be effectively implemented.

### Outcome

It is intended to proceed as proposed.

It is not considered 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.

## *Other issues*

Some submitters requested changes that would require an amendment to primary legislation and cannot be achieved through the planned amendment to regulations. These included such matters as changing the prescribing status of designated prescribers, extending prescribing rights, changing labelling requirements for controlled drugs and banning direct to consumer advertising of prescription medicines. Such changes will be able to be considered in the course of updates to other legislation.

A number of inter-related changes to the requirements for child-resistant packaging were also requested, some of which would require changes to primary legislation (eg, setting standards for child-resistant closures). Reform in this area needs to be considered carefully and achieved using an integrated package of measures.

An amendment to change the meaning of “mortgagee in possession” provided in Form 1B in Schedule 2 of the Medicines Regulations was requested, to match the change already made to Form 1A in the same Schedule. It is intended that this be progressed.

It is also intended to progress an amendment to clarify that the intent of regulation 44, where prescriptions are not required for prescription medicines. Regulation 44 (h), for example, reads as a blanket exemption from the need for a prescription, but its intent is to remove the requirement for a prescription to be written in a situation where a prescriber wishes a patient under his care to receive a dose of a medicine, and gives verbal instructions to that effect to the person who is going to supply or administer the dose of medicine.

## Appendix One: List of submissions

| | |
|---|---|
| s 9(2)(a) | Nelson Marlborough District Health Board |
| | Biomed Limited |
| | New Zealand Defence Force |
| | Senior Lecturer, Faculty of Health and Environmental Science |
| | |
| | Accident Compensation Corporation |
| | |
| | Dental Council |
| | Community Dental, Hutt Valley District Health Board |
| | Takapuna Grammar School |
| | |
| | |
| | Starship Children's Health |
| | Chair, Nurse Practitioner Advisory Committee of New Zealand |
| | |
| | Midwifery Council of New Zealand |
| | Sanofi-Aventis Pty Ltd |
| | BBG Fulfilment Ltd |
| | Faculty of Health and Environmental Sciences, Auckland University of Technology |
| | Albany Care Chemist Ltd |
| | Pharmaco (NZ) Ltd |
| | Fluoride Action Network NZ Inc. |
| | Bayer Australia Limited |
| | Cosmetic Toiletry and Fragrance Association of New Zealand Inc. |
| | Mylan New Zealand |
| | Therapeutic Advertising Pre-vetting System |
| | Researched Medicines Industry |
| | Auckland City Hospital Pharmacy Department |
| | Safe Medication Management Programme |
| | Pharmacy Partners Ltd |
| | The College of Nurses, Aotearoa (NZ) inc. |
| | Capital and Coast District Health Board |
| | Family Planning |
| | Pharmacy Council |
| | New Zealand Self-Medication Industry |
| | Nelson Marlborough District Health Board |
| | |
| | Canterbury District Health Board |
| | PHARMAC |
| | Waikato District Health Board |
| | Waikato District Health Board |
| | New Zealand Dental Association |
| | New Zealand Nurses Organisation |
| | Pharmacy Guild of New Zealand |

**DRAFT (September 2010)**

| | |
|---|---|
| s 9(2)(a) | Australian Self-Medication Industry Inc |
| | The Paediatric Society of New Zealand |
| | Colgate-Palmolive |
| | Medical Council of New Zealand |
| | CSL Biotherapies (NZ) Ltd |
| | The Royal New Zealand College of General Practitioners |
| | Safekids New Zealand |
| | Canterbury Community Pharmacy Group |
| | Reckitt Benckiser |
| | GlaxoSmithKline NZ Ltd |
| | Johnson & Johnson (New Zealand) Ltd |
| | Community Dental Service, Canterbury District Health Board |
| | Canterbury Community Pharmacy Group |
| | Pegasus Health |
| | Counties Manukau District Health Board |
| | Federation of Women's Health Councils Aotearoa |
| | Consumer Advisory Committee |
| | Novo Nordisk Pharmaceuticals |
| | Unilever Australasia |
| | Pharmacybrands Ltd |
| | Procter & Gamble |
| | Pharmaceutical Society of New Zealand Inc |
| | ESR |
| | New Zealand Food & Grocery Council |
| | New Zealand Medical Association |
| | New Zealand College of Mental Health Nurses (Inc) |
| | South Island Nurse Executives |
| | South Island Shared Service Agency Ltd |
| | Women's Health Action Trust |
| | Red Seal Natural Health Ltd |
| | ACCORD |
| | Capital and Coast District Health Board |
| | 3M |
| | New Zealand Hospital Pharmacists' Association (Inc) |
| | GlaxoSmithKline |
| | New Zealand National Board of the Royal Australian College of Surgeons |
| | Pharmacy Department of the Taranaki |
| | Nursing Council of New Zealand |

# Regulatory Impact Statement:

**Proposed Amendments to Regulations under the Medicines Act 1981**

**Agency Disclosure Statement**

This Regulatory Impact Statement has been prepared by the Ministry of Health.

It provides an analysis of options to: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; and address some health and safety risks. Some of the proposed amendments address technical matters that will have little impact, and which are exempt from the regulatory impact analysis requirements (see Appendix 1). The proposed amendments make changes to labelling, advertising, dispensing and prescribing requirements for medicines and related products.

The proposals cover issues that have been identified by the Ministry of Health and the health sector over many years as irritants. The proposed changes would simplify overly rigorous or bureaucratic processes. A discussion document outlining the proposals was released earlier in the year, and some of the comments from submitters have been addressed in follow-up discussions. Not all of the proposals suggested by submitters will be progressed – at this stage, the focus is on changes considered to be of highest priority, and with widespread support.

The Ministry of Health received 84 submissions on these proposals, from a range of stakeholder groups. There was only a small response from consumer groups. Nevertheless, the Ministry is confident that the proposals will not compromise consumer safety or the information available to them, while also potentially increasing the available selection of some products.

None of these policy proposals will impair private property rights, market competition, or the incentives on health care providers to innovate and invest, or override fundamental common law principles.

Deborah Roche

Deputy Director-General, Strategy and System Performance

Ministry of Health

[Signature of person] [Date]

## Status quo and problem definition

1. In New Zealand, medicines and medical devices are regulated by the Medicines Act 1981 (the Act) and the regulations that sit under it, most notably the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. This legislative framework is nearly 30 years old and is in need of updating to ensure that it safeguards consumers while not placing unnecessary barriers in the way of innovation in the health sector.

2. While many of the problems in the current medicines legislative framework can only be addressed through changes to the Medicines Act itself, it is likely to take some time to develop and implement a new Act, and some improvements can be made in the meantime through amendments to medicines regulations.

3. Earlier this year, the Government issued a discussion document *Consultation Paper on Proposed Amendments to Regulations under the Medicines Act 1981*. The document contained a suite of proposed amendments to regulations under the Medicines Act 1981. The Ministry received 84 submissions on the proposals, from a range of stakeholders (more detail is provided in the Consultation section).

## Objectives

4. The objectives of these proposed amendments, as described in the discussion document, were to:

   - reduce unnecessary costs for the Crown, industry, health service providers and consumers
   - reduce barriers to innovation in the health sector
   - address health and safety risks
   - update technical matters.

## Regulatory impact analysis

5. The following section presents an analysis of each of the proposed amendments, organised under the objectives above. The technical amendments, which are expected to have minimal impact and are exempt from the requirement to carry out a Regulatory Impact Analysis, are described in Appendix 1.

**Reducing unnecessary costs for the Crown, industry, providers and consumers**

***Excluding some products from regulation as related products under the Medicines Act***

*Issue*

6. Part 7 of the Act (sections 94 to 96) provides for cosmetics, dentifrices or foods that have a therapeutic purpose to be regulated as *related products* (as defined in the Act) and specifies that certain provisions apply to *related products* as if they were medicines.

7. Most fluoride toothpastes and mouthwashes fall within the definition of *related product* in section 94 of the Act because they are primarily used for cosmetic purposes (cleaning the teeth) but also have a therapeutic purpose (preventing dental decay), and do not contain any scheduled medicines. Other types of products that may meet the criteria for regulation as *related products* include some anti-dandruff shampoos and conditioners, antibacterial and anti-acne skin cleansers, and oral hygiene products.

8. Cosmetics that contain a hazardous substance are covered by a Cosmetic Products Group Standard under the Hazardous Substances and New Organisms (HSNO) Act 1996, which was last updated in July 2009. Many of the products regulated as *related products* under the Medicines Act are also covered by the Cosmetic Products Group Standard. Given the low-risk nature of these products, compliance with the Group Standard is considered to provide adequate assurance about safety.

9. Pre-market approval of new products and notification of changes to existing products is required for related products. Product manufacturers and distributors find the requirements onerous, particularly given the low-risk nature of the products, the number of different variants marketed and the rapidity with which changes are made.

10. Regulation under therapeutic product legislation is not the norm in other jurisdictions, so companies have to put together an application package specifically for New Zealand. In Australia, certain cosmetic-type products are excluded from regulation as therapeutic goods, with specified limits on allowable content and therapeutic claims made for excluded goods.

11. The impacts of regulating cosmetic-type products as related products include:

    - increased compliance costs (preparing and submitting applications for approval of new and changed products) and regulatory costs (application fee $5,500 for a new product and a range of lesser fees for changes to existing products). These costs are made more significant for New Zealand suppliers because such applications are not required in other countries, including Australia. The industry has estimated that the regulatory process can cost firms around $70-100K per product (an estimate based on staff time, consultant costs and regulatory fees).

    - increased product prices when regulatory and compliance costs are passed on to consumers.

    - delays in new products reaching the market because of the time taken for the application and approval process to be completed.

    - a reduced range of products on the New Zealand market if companies choose not to go through the approval process (eg, for products expected to have lower sales volumes).

    - increased workload for the regulator, with no significant impact on public health and safety.

12. The regulation-making powers in section 105(1)(i) of the Act enable the making of a regulation to declare that something is not a related product for the purposes of the Act. A declaration of this type means that such products are not subject to any of the requirements of the Act or Regulations.

*Option 1: Exclude certain fluoride dentifrices and anti-dandruff preparations from regulation as related products under the Medicines Act*

13. Under this option, certain fluoride dentrifrices and anti-dandruff preparations (the two related product categories that represent the largest numbers of individual products) would be excluded from regulation under the Medicines Act. Limits would be set for the allowable content and therapeutic claims for these products to be excluded. The excluded products would be covered by the Cosmetic Products Group Standard.

14. Other cosmetic-type related products would continue to be regulated as related products, and dentifrices and anti-dandruff preparations currently regulated as medicines would continue to be regulated in this way.

15. Exclusion of fluoride dentifrices and anti-dandruff preparations would increase regulatory alignment between Australia and New Zealand to some extent and result in decreased costs and increased product ranges for those two product categories.

*Option 2: Exclude a wider range of product types from regulation as related products under the Medicines Act (PREFERRED OPTION)*

16. Under this option, in addition to fluoride dentifrices and anti-dandruff preparations, the following products would also be excluded from regulation as related products under the Medicines Act:

- anti-acne preparations (such as cleansers, scrubs, masks)
- barrier creams for preventing nappy rash
- antibacterial skin products
- oral hygiene products.

17. Limits would be set for the allowable content and therapeutic claims for excluded products, with these limits aligned with those applied in Australia. The excluded products would be covered by the Cosmetic Products Group Standard.

18. Products such as toothpastes containing active ingredients other than fluoride or skin preparations containing ingredients that are scheduled medicines would continue to be regulated as related products or medicines, as they are at present.

19. This broader set of exclusions was requested by many submitters during consultation. It would provide significant alignment of New Zealand's regulatory controls with those in Australia. Anticipated positive impacts include significantly reduced regulatory and compliance costs for distributors, rapid market entry for new products, increased product choice, and reduced prices for consumers.

***Labelling***

*Issue*

20. Regulations 12 to 25 of the Medicines Regulations 1984 set out the requirements for the labelling of medicines, related products, and medical devices. These regulations contain many prescriptive requirements relating to matters such as the position of certain statements or the size of a particular panel on a label.

21. These prescriptive requirements are often not aligned with labelling requirements in other jurisdictions. Since the New Zealand market is small and most medicines are sourced from overseas, such labelling requirements can lead to additional costs (associated with having product specifically labelled for the New Zealand market, or obtaining an exemption from a labelling requirement) or restrict the range of medicines able to be marketed in New Zealand (because it is not possible or too expensive to get product labelled to meet our specific requirements).

22. Some of the labelling requirements set out in the regulations are outdated (eg, the medicines listed as requiring warning statements represent only a small proportion of those for which warning statements are now considered necessary) and other requirements do not reflect current best practice (eg, the requirements for the labelling of strip packed and individually wrapped medicines are not well covered).

*Option 1:* *Amend some specific labelling requirements for medicines and related products*

23. Under this option, the Regulations would be amended to achieve the following:

- remove the requirement for certain information to be placed in a specific "consumer information panel" on the label of a medicine intended for retail sale without a prescription (the information would still be required on the label)
- specify the labelling requirements for individually wrapped dosage units such as lozenges, pessaries, trans-dermal patches and single-dose sachets, allowing reduced information on the individual units provided they are enclosed in a fully-labelled packet
- permit use of an appropriate warning statement on non-sedating antihistamines, rather than requiring all antihistamine labels to include the sedation warning currently set out in the regulations.

24. The changes are expected to benefit medicine suppliers through increased efficiency and reduced costs as a result of better alignment between Australian and New Zealand labelling requirements. Suppliers will no longer need to have product labelled specifically for the New Zealand market or obtain an exemption from specific labelling requirements in order to use labels that are acceptable in other jurisdictions. The regulator's (Medsafe) workload would reduce as there would be fewer requests for labelling exemptions.

25. During consultation on the proposed changes to the Regulations there was some concern about the proposal to add a "class" warning statement for non-sedating antihistamines, largely based on a belief that decisions on the use of warning statements should made on a case-by-case basis. The other proposed labelling changes were strongly supported, but many considered they did not go far enough in aligning New Zealand's labelling requirements as closely as possible with those applying in Australia.

*Option 2:* *Substantially align labelling requirements with those applying in Australia for manufactured medicines, and add some requirements for labels on dispensed medicines (PREFERRED OPTION)*

26. Under this option, the Regulations would be amended to:

- remove prescriptive requirements relating to the size of label panels or the position of certain information on a label, including removing the requirements for a specific "consumer information panel" on the label of a medicine intended for retail sale without a prescription
- align with Australia, to the greatest extent possible, the requirements for labelling of individually wrapped dosage units (such as lozenges, pessaries, trans-dermal patches and single-dose sachets) and strip or blister packs (including those used as 'safety containers').

- remove all specified warning statements from the Regulations and instead set them out in guidelines, with compliance ensured through the approval of the label as part of the product approval process.

27. This broader amendment would update and clarify the labelling requirements for manufactured medicines. It was strongly supported during consultation on amendments to the Regulations.

28. The result would be much greater alignment with current Australian labelling requirements, leading to reduced regulatory and compliance costs for distributors and a reduced workload for the regulator.

29. In addition to the above changes in relation to labels on manufactured medicines, two further amendments intended to enhance patient safety would be made. These would be:

- requiring the label on a dispensed medicine to include a unique identifying code linking the dispensed item back to the original prescription

- requiring a label on dispensed medicine to include the date of dispensing.

30. Requiring an identifying code linking a dispensed item back to the original prescription would ensure that if there are queries relating to a labelled dispensed medicine (eg, from a paramedic or hospital emergency department), the medicine can be traced back to the original prescription. It would also be of assistance with the introduction of electronic prescribing, where a unique identifier relating the medicine to a specific patient, from a specific prescriber, dispensed by a specific pharmacy, will be important for public safety. This proposal would also apply to compliance packaging[1].

31. Requiring the inclusion on the label of the date of dispensing will assist patients in determining how old a medicine is, and whether it is out of date or still safe to use.

32. The impact of these changes would be marginal. Pharmacists already include a prescription number on the label of a dispensed medicine and almost all dispensing is done by pharmacists, rather than by the prescriber. Adherence to best practice ensures that most compliance packs are adequately labelled. However, where medicines are not currently being adequately labelled, patient safety is compromised, and patients could benefit from regulation in this area.

***Advertising of medicines***

*Issue*

33. Regulation 8 of the Medicines Regulations requires every advertisement for a medicine (other than a label or a price list) to include specified mandatory information about the active ingredients and uses of the medicine and its precautions, contra-indications and adverse reactions. These requirements are not harmonised with those that have been adopted in Australia for advertising of non-prescription medicines. This means that companies marketing products in both countries face additional costs associated with developing separate advertising copy for each country. In addition, the current rules are

[1] Compliance packaging is a term used to describe a patient-specific pack of dispensed medicines. The pack comprises one or more strips of sealed pockets, each of which contains all the dispensed medicines that need to be taken at the day/time stated on the seal above each pocket.

not practical for small advertisements such as point of sale material or for advertisements displayed for a limited time on television.

*Option 1: Amend some specific advertising requirements*

34. Under this option, Regulation 8 would be amended to simplify the mandatory information requirements for non-prescription medicines so they are harmonised with Australian requirements.

35. This would make it easier for companies to use the same advertising copy in New Zealand and Australia, for a greater range of advertisements than at present, thus reducing the costs of tailoring advertising copy to meet different New Zealand requirements. The proposal goes some way towards recognising the practical realities of different sorts of advertising media (ie, full blown written adverts compared to radio and TV or internet advertising) and limits the mandatory requirements to that information a consumer could reasonably be expected to "absorb" from an advertisement in a particular context (eg, alerting them to the fact that there are side effects and contraindications rather than listing them in a spoken advertisement). It will also allow shelf talkers (advertising material on display shelves alongside products) to have only minimal information, provided the product referred to is right there on the shelf with the advertisement (since the detailed information is available on the label of the product).

36. The proposal does not, however, address barriers to harmonisation that arise from prescriptive requirements in the Medicines Act, such as the prohibition on the use of testimonial adverts in section 58(1)(c)(iii).

37. The changes are not likely to impact on patient safety and were supported by the majority of submitters who responded to them during consultation.

*Option 2: Amend the advertising requirements more substantively to achieve the greatest possible alignment with those applying in Australia (PREFERRED OPTION)*

38. During consultation, submitters sought greater clarity about any differences in requirements for prescription and non-prescription medicines (including a request for two separate regulations), expansion of the list of "excluded advertisements" that do not require all the mandatory information normally required in an advertisement, and full alignment with Australian advertising requirements.

39. Therefore, this option involves progressing the changes proposed in Option 1 as well recognising the need to:

- clearly define the types of advertisements that are excluded from requiring the mandatory statements (including eg, shelf talkers, advertising on moving or stationary objects such as billboards, cars, yacht sails etc)

- more clearly specify the differing requirements for mandatory statements that are required for advertisements directed at consumers and those required for advertisements directed at health professionals. In addition, clearly specify the differing requirements for advertisements for each of the different classes of medicine (Prescription, Pharmacist-Only or Pharmacy-Only) – eg, in the case of pharmacist-only medicines the requirement for the statement *"Available only from your pharmacist".*

39. This will ensure greater alignment with Australian requirements (noting that in Australia it is not permissible to advertise any prescription medicine directly to consumers) and clarity for companies.

***Allowing pharmacists to substitute an alternative brand of a medicine in certain circumstances***

*Issue*

40. Regulation 42(4) requires a pharmacist to dispense the brand of medicine specified by the prescriber, unless the prescriber sanctions substitution of another brand. Prescribers are permitted to issue substitution authorities to allow pharmacists to substitute in specified circumstances. While some prescribers choose to do this, many do not, with the consequence that the pharmacists must seek their authority to substitute a different brand whenever a substitution is required.

41. There are a number of circumstances in which substitution may be required or potentially beneficial, such as where a discontinued or temporarily unavailable brand of medicine has been prescribed or where changes to subsidy rules mean that a patient would otherwise have to pay the full cost of the prescribed brand, but could get a cheaper, generic version of the prescribed medicine instead. Prescribing of non-subsidised brands is common (because computer systems have not been updated to show changes in subsidy rules), but is usually not intentional. Seeking authority to substitute on a case-by-case basis is inefficient for both the pharmacist and prescriber, and not substituting can be costly for the patient.

42. In certain circumstances, a prescriber (or patient) may wish a particular brand to be supplied. This could be catered for by allowing a prescriber to mark the prescription to indicate that substitution is not authorised, and ensuring that the pharmacist substitutes with a patient's approval.

43. Some people express concerns about the safety or efficacy of generic medicines. Consideration of the efficacy of generic medicines is part of the pre-market approval process for manufactured medicines and is generally established by reference to the innovator product or market leader. If a new generic medicine is not considered to be inter-changeable with another brand, this must be stated on the Medicine Data Sheet, providing pharmacists with the information they need to determine whether it would be safe to make a substitution without seeking authorisation from the prescriber.

*Option 1: Allow pharmacists to substitute an alternative brand of a medicine in certain circumstances (THE PREFERRED OPTION)*

44. This option provides for Regulation 42(4) to be amended to allow a pharmacist to substitute an alternative brand of a prescribed medicine (but not a different 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"
- the pharmacist records details of the brand substitution on the prescription and informs the patient of the change of brand.

45. The proposed change would improve efficiency for prescribers and pharmacists and convenience for patients by enabling pharmacists to make a substitution without seeking authorisation from the prescriber where a discontinued or temporarily unavailable brand has been unintentionally prescribed, or where dispensing the prescribed brand would result in a significant cost to the patient and a cheaper brand is able to be supplied without any risk to patient safety. Patient safety would be enhanced by allowing prescribers to specify a particular brand and prevent substitution where there were particular circumstances peculiar to that patient that would make substitution unsafe. However, there is a risk that some prescribers may choose to mark all prescriptions as "no substitution permitted" even when there is no clinical reason for it.

46. There was strong support from submitters who commented on this proposal during consultation on the Regulation changes.

*Option 2: Substitution at pharmacist's discretion regardless of the wishes of the prescriber*

47. This option would be substitution entirely at the discretion of the pharmacist with no ability for prescribers to prevent it. The disadvantage of this proposal would be that prescribers would have no say if they felt there was a particular reason why substitution would be unsafe, and this would cut across the prescriber's clinical judgment. Also, a pharmacist could make substitution decisions for commercial reasons, for example, based on which brand they had the most stock of at the time, or would be likely to make the most money from.

***Relaxing countersigning of records of supply or administration of a medicine under a standing order***

*Issue*

48. Under the Medicines (Standing Order) Regulations 2002, a prescriber is able to authorise specified people to supply or administer a medicine under specified conditions. These arrangements, or "standing orders", are often used in hospital or ambulance settings, where the authorising health practitioner may not always be physically present when a medicine needs to be administered. As a safeguard, Regulation 8 of the Medicines (Standing Order) Regulations specifies that the issuer of a standing order is required to countersign the record of every supply or administration of a medicine occurring under that order. This requirement is seen as particularly problematic in areas such as the ambulance service, where paramedics administer medicines frequently under a standing order given by the medical director and countersigning creates an unnecessary administrative burden.

49. Currently, there is no ability for an issuer of a standing order to tailor countersigning requirements to fit the circumstances in which the order will be used (eg, to have different requirements depending on experience and qualifications of the person acting under the order, or some other circumstance relevant to the situation). It may also be an inefficient use of the issuer's time, which would be better spent considering (on a frequent basis) how and when the order is being used and whether it needs refining to improve patient safety. An issuer is more likely to spot a problem actively reviewing a sample of records than just "blindly" signing all the records.

50. Consultation undertaken in 2006 by the Ministry of Health indicated that there was strong support for introducing more flexibility around this requirement. At that time, stakeholders considered that the need for countersigning should be at the discretion of

the person issuing the standing order and should be specified in the order, provided there was regular monitoring of the practices of all persons working under the order.

*Option 1:* *Amend the requirements for countersigning records of supply or administration of a medicine under a standing order so that the issuer of the order determines the circumstances in which countersigning is required*

51. This option would amend the regulations to require an authorised prescriber issuing a standing order to specify the arrangements for countersigning including:

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

52. This change would be likely to significantly reduce the time taken by the issuer of a standing order to countersign a potentially large number of records of administration or supply under the order.

*Option 2:* *Option 1 plus a requirement for a minimum monthly audit (PREFERRED OPTION)*

53. Option 1 was well supported during consultation, although there was concern about lack of oversight of standing orders if the countersigning requirement was removed. To address this concern, Option 2 proposes that the Regulations stipulate, in instances where countersigning of every administration and supply is not required, that the standing order must require the issuer to conduct, at a minimum, a documented monthly audit of a sample of the records of administration and supply, under the standing order.

54. Concern was also raised that, presently, standing orders are only monitored during certification audits in hospitals and rest homes. This means that there is no monitoring of standing orders in the primary care setting. The Ministry will write to responsible authorities to remind them of the responsibilities of issuers of standing orders, particularly where standing orders are being used outside the hospital and rest home setting.

## Reducing barriers to innovation in the health sector

### *Enabling electronic transmission of prescriptions*

*Issue*

55. Electronic prescribing is not currently legally permitted, and will not be generally possible until changes are made to the Medicines Act. However, Regulation 43(a) enables the Director-General to issue a waiver in respect of compliance with the requirements of Regulation 41 (governing the form of a prescription) in special circumstances, subject to any requirements the Director-General thinks fit. This process can be used to enable electronic transmission of prescriptions in specified cases.

56. Applications for the granting of a waiver under Regulation 43(a) need to be considered on a case-by-case basis, to assess the nature of the special circumstances and

determine any other requirements that should apply. This can be a complex and lengthy process.

*Option 1: Specify criteria and requirements that would have to be met for a waiver (PREFERRED OPTION)*

57. It is proposed that Regulation 43 be amended to remove the term "in special circumstances". Regulation 43(a) would then be amended to state that the form of prescription authorised under the waiver could include (but would not be limited to) an electronic form.

58. This would enable a set of criteria for applicants and a standard set of requirements to be established, and waivers to be granted to applicants who met those criteria and could demonstrate an ability to fulfil the specified requirements. The requirements could include, for example, compliance with a specified standard.

59. It would provide transparency for applicants and reduce the complexity of the task of considering waiver applications on a case-by-case basis. The criteria and requirements could be published (and therefore be readily accessible to prospective applicants) and could be updated as necessary (eg, as new standards were developed or new systems implemented).

60. The proposal is expected to enable a mechanism to be developed that will reduce the amount of time applicants need to spend preparing an application for a waiver that will allow them to progress initiatives that involve electronic transmission of prescriptions between prescribers and pharmacists.

61. There would be some costs associated with becoming familiar with the application process and requirements and preparing applications. However, this should be more than offset by the time saved in preparing applications and the reduced waiting time for a decision to be made on a waiver application compared with the time currently taken for case-by-case consideration. This may lead to earlier implementation of electronic prescribing initiatives that can improve efficiency for prescribers and pharmacists.

*Option 2 Maintain current waiver process*

62. It could be argued that the current process works, as it has been successfully used to grant waivers. However, the process seems unnecessarily cumbersome, and provides no assurance to applicants that they are doing what is necessary to achieve a waiver. Maintaining the status quo would maintain a barrier to innovative practice. There was no support from submitters to continue with the current process.

***Extending the period of supply of prescription medicines***

*Issue*

63. Regulation 39 of the Medicines Regulations permits medical practitioners, midwives, nurse practitioners and optometrists to prescribe up to 3 months' supply of a prescription medicine at a time (or up to 6 months' supply in the case of an oral contraceptive). A dentist may prescribe for a total period of 10 days (5 days, with a repeat of 5 days). There are two issues relating to the limitations on period of supply in Regulation 39.

64. Firstly, there are some circumstances in which the 3-month supply limit is problematic for prescribers and patients. For example, when missionaries or armed forces

personnel are travelling to remote areas for extended periods there is currently no provision for the 3-month limit to be waived so that patients can lawfully obtain adequate supplies of the prescription medicines they require during their period of absence from New Zealand. Some prescribers get round this by (unlawfully) writing multiple prescriptions for the patient to take to different pharmacies.

65. Secondly, given that dentists, like medical practitioners and midwives, are authorised prescribers, and the Health Practitioners Competence Assurance Act 2003 requires that dentists (like all health practitioners) must prescribe within their scope of practice, there appears to be little justification for maintaining this difference in the Regulations.

*Option 1:* *Align the period of supply for dentists with that of other authorised prescribers and allow the Director-General to waive the 3-month limit in special circumstances.*

66. This option would provide for the Director-General to waive the 3-month/6-month limit in special circumstances. This proposal is expected to benefit people travelling to remote areas and those prescribing for them, as it will provide a proper mechanism for obtaining adequate quantities of medicines they require for ongoing conditions.

67. This option would also amend Regulation 39(4) to allow dentists to prescribe treatment for a period of 3 months, as for all other authorised prescribers. This proposal may have a positive impact for the small number of people who require an extended period of treatment for a dental condition. Currently, either the patient is referred to a medical practitioner for the medicine to be prescribed, or the dentist issues multiple prescriptions to cover the required period of treatment. In either case, this results in additional costs for the patient (paying the consultation fee for the doctor, having already paid to see the dentist, or paying multiple prescription fees and dentist consultation fees) and the health system (subsidising the doctor's visit or paying for multiple dispensings). Under the proposal, there would be fewer prescriptions to be issued, dispensed and collected, without any increase in the total amount of medicine used.

68. These changes were supported by most submitters during consultation.

69. The proposal will mean more work for the Ministry of Health when dealing with waiver requests. Care will be needed in deciding the circumstances in which the waiver is appropriate – it is not intended for people simply going on long holidays, for instance. Also a policy decision still needs to made on how long extended treatment should be for and whether it will be subsidised or at the patient's expense.

*Option 2:* *Changes in Option 1 plus extension of period of supply for all authorised prescribers (THE PREFERRED OPTION)*

70. In addition to the changes proposed in Option 1, this option includes a proposal to extend the maximum period of supply on a prescription from 6 months to 12 months for an oral contraceptive, and from 3 months to 6 months for any other prescription medicine. Submitters were asked whether there were circumstances in which the period of supply should be extended and this general extension was suggested by some submitters.

71. The impact of this additional measure will be greater convenience for patients. It is most likely that it will be good for prescribers as they currently don't have a lawful way of ensuring that a patient going to a remote area has an adequate supply of medicines they need for chronic conditions.

72. Some submitters pointed out that such an approach could create safety issues if patients stockpile their medicines, and the potential for wastage if changes need to be made to a patient's treatment or patients stop taking their medication. It is considered that this risk can be appropriately managed for subsidised medicines by PHARMAC, which sets the rules for subsidised dispensing of these medicines. PHARMAC, in discussion with District Health Boards, will carefully consider the appropriate period of dispensing (ie, the amount that can be provided to a patient by a pharmacist from a prescription) for a given medicine, to ensure that dispensing more than three months supply at a time only occurs where appropriate (ie, when it is safe and cost effective). In relation to unsubsidised medicines, the Ministry of Health will write to responsible authorities to remind them of their role in encouraging good prescribing practice (eg, not prescribing excessively or indiscriminately).

***Allowing sale of medicines by vending machine***

*Issue*

73. Section 18(4) of the Medicines Act prohibits the sale of medicines by means of an automatic vending machine except as permitted by regulations made under the Act. Regulation 59 allows chemical contraceptives, which are general sale medicines, to be sold via vending machines when they are supplied with condoms.

74. There have been no regulations made to permit vending machine sales of other general sales medicines. However, such medicines are commonly sold from outlets such as supermarkets, dairies, petrol stations and other mixed-merchandise stores where there is no special supervision of the storage or sale of the medicines.

75. They can also be placed in locations such as lobbies, workplace restrooms or cafeterias, or waiting areas where there is no retailer operating, thus improving consumer access to general sale medicines. Vending machines can provide storage that is out of reach of young children and make it more difficult for a consumer to buy multiple packs of a medicine than over the counter.

76. The risk arising from the supply of medicines from appropriately located vending machines, which are securely sealed units dispensing one pack of medicine at a time, is likely to be less than the risk arising in retail outlets where storage and sale are unsupervised, leaving the stock vulnerable to tampering or access by young children when packs are stored on lower shelves.

*Option 1: Permit the sale of all general sale medicines by vending machine*

77. This option involves revoking Regulation 59 and making a new regulation to permit the sale of unscheduled (general sale) medicines by vending machine. This would mean those medicines currently able to be sold from retail outlets such as dairies and service stations could also be sold from a vending machine. The provision would continue the permission for sale of chemical contraceptives (because they are general sale medicines), but they would no longer be required to be supplied with condoms.

78. This option would benefit consumers by providing for access to commonly used general sale medicines at a wider range of locations. It would also benefit vending machine operators who have for some time sought to extend the range of products they can offer to include a small range of medicines. Sales from retail outlets such as supermarkets may reduce slightly, although this is likely to remain a convenient way for consumers to purchase medicines. If vending machines were placed in public areas of hospitals and medical centres, this could reduce sales of general sale medicines

through pharmacies. The extent to which vending machine sales replace sales from other retailers would likely depend to a large extent on product price and on factors such as the quantity of medicine able to be obtained from a vending machine.

79. It is unlikely that vending machine operators would put vending machines in remote areas, so the proposal is unlikely to improve access for those living a long way from retail outlets. However, they could provide instant access to a dose or two of a medicine in the middle of the night (eg, for shift workers in a factory that had a vending machine, or in places like hotel lobbies). The concerns submitters raised during consultation about safety could be dealt with by limiting pack sizes to the amount a person might need to tide them over until retail shops open.

*Option 2: Permit the sale of specific general sales medicines to be sold via vending machine with appropriate conditions (PREFERRED OPTION)*

80. Just over a third of submitters opposed the proposal during consultation, and raised concerns about the public safety risks of medicines in vending machines. As a result, Option 2 proposes that, rather than a blanket permission for general sale medicines to be sold by vending machine, a new regulation is made to allow the Director-General of Health to permit (by notice in the Gazette) specific general sale medicines to be sold via vending machine in accordance with any conditions specified in the notice. The conditions would be those that were considered necessary to ensure the integrity of the medicines or as a safeguard against inappropriate access.

81. This modification to the proposal would result in benefits to consumers whilst ensuring safety.

82. This options will potentially create some additional work for the Ministry of Health, but this is not considered to be significant.

**Address health and safety risks**

***Restricting prescribing for patients who are overseas***

*Issue*

83. Regulation 39 (1) permits medical practitioners to prescribe prescription medicines for the treatment of patients under their care. The Regulations do not define what "under the care" of the medical practitioner means in this context.

84. This permits prescribing to New Zealand residents temporarily overseas and foreign nationals being treated while in New Zealand. It has also been interpreted by some New Zealand prescribers as allowing them to prescribe to non-New Zealand patients overseas on the basis of details provided electronically (ie, without any physical examination of the patient by the prescriber). Sourcing medicines through New Zealand is an attractive proposition for patients in other countries because in many cases prices are lower in New Zealand. However, arguably overseas patients can not be "under the care" of a New Zealand doctor.

85. Whilst this may be putting the health of the overseas patient at risk, it is the role of regulatory authorities in their own country to control access to medicines, including those coming into the country by post. However, this activity would pose a risk to New Zealand patients if large volumes of a particular product were used to fill prescriptions in other countries, thereby resulting in a shortage of supply in New Zealand. It can also be argued that these medicines are intended for the New Zealand market at the

negotiated price, not for other markets where medicine funders have not been able to negotiate such prices.

86. The Ministry of Health, like other regulators, has had concerns around the practices involved in Internet prescribing and distance-dispensing. International Internet pharmacy operations have a poor track record of corrupt or unethical practices involving supply of counterfeit medicines and supplying prescription medicines to patients who are not under the care of the prescribing doctor. It has been difficult to monitor the practice in the past and it has been seen as unethical by most medical and pharmacy councils around the world and many governments.

*Option 1: Prohibit prescribing for patients who are overseas and are not New Zealand residents (PREFERRED OPTION)*

87. This option provides that, in addition to the current requirement for a patient to be "under the care" of the prescriber, there is a requirement for the patient to be in New Zealand at the time the prescribing occurs, or normally resident in New Zealand but temporarily overseas at the time the prescribing occurs.

88. It is expected that prescribers and consumers would benefit from reduction in the risk of products being lost from the New Zealand market. Doctors and pharmacists currently providing medicines intended for the New Zealand market to overseas patients not under their care would no longer be able to do so lawfully.

89. The majority of submitters who responded on this issue during consultation supported the proposal to restrict prescribing in this way. Three submitters involved in Internet prescribing and dispensing prescriptions for overseas patients opposed the proposal because it would potentially put them out of business.

*Option 2: Permit prescribing for patients who are overseas with controls and monitoring*

90. This option would expressly permit prescribing for overseas people with appropriate controls and monitoring of the activity. It came, in part, out of the submission of one company currently involved in this practice.

91. It could allow exports to be stopped if a medicine was in short supply here and would permit the Ministry of Health access to protocols, records etc to look for illegal or corrupt practices.

92. However, given that such Internet pharmacy operations internationally have a track record of medically dangerous and commercially corrupt practices, including the supply of counterfeit product, there would be extensive work and ongoing cost involved in setting up a scheme to permit and oversee the practice. Therefore, this option is not supported by the Ministry.

## Consultation

93. The proposals were initially tested with, and endorsed by, the Pharmacy Guild, Pharmacy Council and the Pharmaceutical Society, as key stakeholders.

94. A discussion paper entitled *Consultation on Proposed Amendments to Regulations under the Medicines Act 1981* was circulated to a number of industry organisations, other stakeholders, and Government agencies and was published on the Ministry of Health website. The discussion paper was released in February 2010, with submissions closing at the end of March.

95. The Ministry received 84 submissions on the proposals from a wide cross-section of affected stakeholders. Seventeen submissions were received from District Health Board employees and four from government agencies. Eighteen submissions were from companies involved in the manufacture or supply of medicines, related products or cosmetics, six from organisations representing those suppliers, and one from the advertising industry. Groups representing or regulating health professionals provided twenty-one submissions, five submissions were received from individual health professionals and four from organisations delivering healthcare services. Five submissions were received from consumer groups.

96. Most comments received were supportive of the intent to update and improve the regulations. A number of further suggestions were made by submitters, particularly around the issues of exempting products from the related product requirements of the Medicines Act, advertising and labelling. Those comments and suggestions were considered and in many cases the suggestions have been incorporated into the proposals.

97. At the Minister of Health's request, groups representing pharmacists and prescribers were consulted further on specific aspects of the proposals in late July 2010. Some of the points from this further consultation are reflected in the options presented.

98. A number of submitters asked to be consulted further about aspects of the proposals. It is intended that the Ministry of Health will continue to consult with affected parties on the detail of regulations. This is considered important due to the technical nature of the regulations and because the wording can have significant implications for industry.

## Conclusions and recommendations

99. The proposed amendments are part of a larger project to modernise the regulatory framework for therapeutic products to ensure that there are adequate safeguards for consumers of therapeutic products while reducing barriers to innovation in the health sector and reducing unnecessary costs for the Crown, industry, health service providers and consumers.

100. It is recommended that the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002 are amended to:

- exclude fluoride dentifrices, anti-dandruff preparations, anti-acne preparations (such as cleansers, scrubs, masks), barrier creams for preventing nappy rash, antibacterial skin products and oral hygiene products, from regulation under the Medicines Act 1981, and use the approach taken in Australia to limit content, claims and presentation for use
- remove the requirement for a consumer information panel on medicines for over-the-counter sale
- rationalise the requirements for labelling of strip packed medicines (including safety containers) and small containers
- remove prescriptive labelling requirements that do not enhance patient safety (such as the requirement relating to the size of the Principal Display Panel)
- remove warning statements on labels for non-sedating antihistamines from the regulations and, instead, place these in guidelines

- require the label on a dispensed medicine to include an identifying code linking the dispensed item back to the original prescription
- require the label on a dispensed medicine to include the date of dispensing
- change the advertising requirements for medicines so that they are better aligned with those in Australia
- amend the Medicines Regulations to enable a waiver to be issued by the Director-General that would permit electronic transmission of prescriptions in specified circumstances
- align the prescribing rights for medical practitioners, dentists, and midwives, requiring all prescribers to prescribe for patients under their care, within their scope of practice
- remove the 10 day limit on period of supply for dentists, thus aligning the period of supply for all prescribers
- allow the Director-General of Health to waive the limit on period of supply of prescription medicines, either for an individual or a class of persons, in certain circumstances
- extend the maximum period of supply on a prescription from 6 months to 12 months for an oral contraceptive, and from 3 months to 6 months for any other prescription medicine
- tighten up the regulations, so that prescribers can only prescribe prescription medicines for the treatment of patients under their care, who are foreigners temporarily in New Zealand or those who are temporarily overseas but normally resident in New Zealand
- allow pharmacists to substitute an alternative brand of a medicine where there are no clinical reasons why substitution should not occur, the prescriber has not marked the prescription with “no brand substitution permitted”, and the pharmacist records the details of the brand substitution on the prescription
- amend the counter-signing requirements for standing orders, to allow the issuer of a standing order to specify when counter-signing of every of administration and supply is not required, who may supply and administer treatments under the standing order without counter-signing on each occasion, and require in situations where counter-signing of each administration or supply under a standing order is not occurring, that there is a documented monthly (or more regular) review, by the issuer of the order, of a sample of records of administration or supply
- change regulations setting out the content, format and publication requirements for data sheets, and require approved data sheets to be submitted for publication within 10 days of approval of the medicine
- remove the regulation, which lists the colouring substances permitted in medicines and related products, and, instead, publish an up-to-date list of acceptable colouring substances in guidelines

- remove prescriptive requirements relating to the dispensing of prescriptions and replace them with more flexible requirements, which allow for electronic technologies and reflect current dispensing practice

- add a new regulation to allow the Director-General of Health to permit (by notice in the *New Zealand Gazette*) specific general sale medicines to be sold via a vending machine in accordance with any conditions specified in the notice

- amend definitions relating to pharmacy qualifications, and remove a redundant sub-clause from the definition of 'pharmacy technician'

- require prescriptions to include the name of the prescriber, their street address (with the exception of midwives who do not have a permanent business address), and phone number, and the name of the person (or in the case of an animal, the owner's name) for whose use the prescription is given, and the quantity of medicine or total period of supply

- amend the regulation regarding circumstances in which a prescription is not required, to clarify its intent.

## Implementation

101. These proposals will be given effect through amendment regulations. It is expected that the changes will be in effect early in 2011.

102. It is unlikely that there will be any implementation risks as the proposed amendments either align the law with current practice or have been requested by industry.

103. Similarly the compliance costs will be minimal, as in most cases the changes remove restrictive requires that impose costs, and align Australian and New Zealand requirements.

## Monitoring, evaluation and review

104. Officials are in regular contact with stakeholders and will recommend amendment of the regulations if this is considered necessary to ensure that they continue to meet their objectives.

## Appendix 1: Technical proposals with little or no regulatory impact

| Technical Updates | | |
|---|---|---|
| **Description of issue** | **Proposed amendment** | **Impacts** |
| *Regulation 2 – Interpretation*<br><br>There are a number of definitions in regulation 2 of the Medicines Regulations that are outdated or refer to qualifications held by people in pharmacy-related practice areas that no longer exist. | It is proposed that these definitions be amended to refer to current qualifications and current practice. | The proposed changes would remove some redundant definitions and align other definitions with current terminology for pharmacy-related qualifications. This will provide clarity and align the Regulations with current practice, but is not expected to have any impact in practical terms. |
| *Regulation 6 – Colouring substances*<br><br>Regulation 6 lists the colouring substances that are permitted to be used in medicines and related products. It also allows other colours to be used if the colour has been considered as part of the medicines approval process. The list is outdated and does not reflect current international practice regarding the use of colouring substances.<br><br>Consideration of the safety of a colouring substance is part of the pre-market approval process for manufactured medicines. | It is proposed that regulation 6 is revoked and that Medsafe maintains a list of acceptable colouring substances in guidelines published on its website so that the list can be updated easily. | This change will align the law with current international practice. The chance of a pharmacist using an inappropriate colouring when compounding a medicine is considered to be minimal given the low volume of compounded medicines, the small number of patients treated with such medicines, and the difficulty in obtaining colouring substances other than those in common use. |
| *Regulation 39 – Prescribing of prescription medicines*<br><br>Regulation 39 specifies the conditions under which prescription medicines may be prescribed.<br><br>A practitioner's 'scope of practice' refers to the range of services the practitioner is competent to provide and the parameters within which such services can be offered. Under the Health Practitioners Competence Assurance Act 2003 (HPCAA), health professionals are required to operate within their particular scope of practice. This includes prescribing where they are permitted by law to prescribe prescription medicines.<br><br>The conditions under which the different groups of prescribers may prescribe prescription medicines are framed differently in the Regulations because some pre-date the 'scope of practice' concept and have not been updated since the Regulations came into force in 1984. For medical practitioners, there is no reference to a scope of practice in the Regulations. For dentists, the restriction is to prescribing 'for dental treatment only', and for midwives, the reference is to 'antenatal, intrapartum and post natal care'.<br><br>Given that scopes of practice for these three groups are defined by the Medical Council, Dental Council and Midwifery Council respectively, each of which is established under the HPCAA, it would be sensible for the Regulations to also require each group to prescribe | It is proposed that the requirements for dentists to prescribe prescription medicines for dental treatment only and for midwives to prescribe prescription medicines for antenatal, intrapartum or postnatal care only are removed, and that medical practitioners, dentists and midwives are required to prescribe within their scope of practice (for patients under their care) as defined by their councils established under the HPCAA. | Consumers may benefit from this proposal if using the scope of practice to define prescribing rights results in dentists or midwives being able to prescribe medicines that would currently have to be prescribed by a medical practitioner. If this were to be the case, patients would benefit by having to pay only one consultation fee and having their overall treatment managed by a single health practitioner. This could result in an increase in the number of items prescribed by dentists and/or midwives. However, this should be offset by a corresponding decrease in items prescribed by medical practitioners. |

| | | |
|---|---|---|
| 'within their scope of practice'.<br><br>This would align the way in which prescribing conditions for medical practitioners, dentists and midwives are expressed in the Regulations, as well as aligning the Regulations with the HPCAA. | | |
| *Regulation 41 – Prescription requirements*<br><br>Regulation 41 of the Regulations specifies the requirements for a prescription – both its physical form and the information it must include. Some of these requirements are very detailed, while other sensible requirements (such as including the printed name of the prescriber) are not specified. | It is proposed that regulation 41 is amended to:<br><br>• Require the name of the prescriber to be included on the prescription, as well as the street address (with the exception of midwives who do not have a permanent business address), phone number and signature;<br><br>• Require inclusion of the given name(s) of the person for whose use the prescription is given (instead of the title and initials);<br><br>• Replace subclauses (f) and (i) with a requirement for the prescriber to specify the total quantity of medicine or total period of supply (removing reference to the number of dispensings and the interval between dispensings); and<br><br>• Require inclusion of the given name(s) of the owner of an animal to be included on a prescription relating to the treatment of an animal (instead of the title and initials) | The impact of this proposal is likely to be minimal as the changes would align the Regulations with usual practice in the current environment. An exemption is proposed for midwives who do not have a permanent business address. This exemption would address concerns raised by the Midwifery Council. |
| *Regulation 42 – Dispensing requirements*<br><br>Regulation 42(3) of the Regulations includes a number of prescriptive requirements relating to the way in which prescriptions must be dispensed and marked at the time of dispensing.<br><br>Paragraphs (a) to (f) relate to the number of repeats that may be dispensed and the time that must elapse between repeats, while paragraphs (g) to (i) specify the information that must be marked on a prescription when it is dispensed.<br><br>Such prescriptive requirements have become outdated and are at odds with current practice. Claiming and subsidy rules now govern matters such as frequency of dispensing and the number of repeats dispensed. In addition, use of computers in pharmacies has changed the way prescriptions are handled so that requiring the dispenser to stamp the back of the prescription and record the details of repeats dispensed is no longer appropriate. This regulation therefore needs updating. | It is proposed that the provisions relating to frequency of dispensing in regulation 42(3)(a) to (e) are revoked and the requirements for recording dispensing details in regulation 42(3)(g) to (i) are updated to reflect current practice.<br><br>It is proposed that the pharmacy name and address, date, quantity of medicine dispensed and prescription number should be recorded each time a prescription is dispensed. However, the way in which these details are recorded would not be specified, so that it could be done by, for example, attaching a computer-generated label to the prescription. | The impact of this proposal is likely to be minimal as the changes would align the Regulations with usual practice in the current environment. |

| | | |
|---|---|---|
| *Regulation 44 – Circumstances in which a prescription is not required*<br><br>Regulation 44 describes situations where a prescription is not required. There are concerns that, as worded, it is insufficiently clear. For example, Regulation 44(h) currently reads as a blanket exemption from the need for a prescription when its purpose is to remove the requirement for a prescription to be written in a situation where a prescriber wishes a patient under his care to receive a dose of a medicine, and gives verbal instructions to that effect to the person who is going to supply or administer the dose of medicine | It is proposed that Regulation 44 is amended to clarify the situations where a prescription is not required. | This amendment will close a potential loophole in the regulations that could allow for a blanket exemption for the requirement for a prescription. This will in turn ensure patient safety. |
| *Regulations 51 – 54 Datasheets*<br><br>The requirements for data sheets are based on the concept of paper documents that may be published into a compendium. Regulation 54 and Schedule 3 to the regulations specify the physical format and content for a data sheet, which is specific to New Zealand. Current practice is for data sheets to be distributed electronically and published on the Medsafe website, and for the headings and content used internationally to be accepted. | It is proposed that Schedule 3 is revoked and regulations 51 to 54 amended to:<br><br>• remove reference to paper documents, loose sheet format and a data sheet compendium;<br><br>• remove reference to submission of paper copies for distribution to interested persons;<br><br>• require approved data sheets to be submitted for publication within 10 days of approval of the medicine. | This change will align the law with current (non-compliant) practice. |

Document 3

MINISTRY OF HEALTH
MANATŪ HAUORA

RECEIVED
13 JUN 2011
MINISTER'S OFFICE

**Health Report number:** 20110660

Ministry of Health
13 JUN 2011
DISPATCHED

**Action required by:** routine

**Date sent to Minister:**

**Minister's reference:** not applicable

**File number:** AD10-29-2

**To: Hon Tony Ryall**

# Extending the Period of Supply for Prescription Medicines

## Executive summary

i. PHARMAC has written to you outlining the fiscal and pharmacy software implications of the proposed change to the period of supply for prescription medicines. PHARMAC estimates the fiscal impact in terms of reduced patient co-payments on the pharmaceuticals budget to be between $10 million and $12 million per year. The Ministry considers the impact on patient co-payments would be significantly less, however further work would be required to accurately quantify impacts and determine how to manage them.

ii. Given PHARMAC's concern about reduced co-payments, the Ministry has considered four options for implementing the change, and recommends extending the period of supply, with one $3 co-payment, but deferring the implementation until 1 July 2012. This would preserve existing policy on patient co-payments, but allow DHBs time to make allowances for the budget impact. The alternative option is to hold extending the period of supply, pending further advice. We have assumed a general increase in co-payments is not a feasible option.

## The Ministry recommends that you:

a) **EITHER:**

Extend the period of supply with a single $3 co-payment at the first dispensing but delay the implementation until 1 July 2012. Yes / No

**OR**

Hold the extension of the period of supply pending further advice on impacts Yes / No

By 31 December 2011
How did MOH miss the financial implications of this proposal?

Barbara Phillips

**Acting Deputy Director-General**
**Policy Business Unit**

**Minister's Signature**

**Date:**

## Ministry of Health Contacts:

| | |
|---|---|
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MINISTRY OF HEALTH
MANATŪ HAUORA



## Background

1. The intended amendment to the Medicines Regulations to extend the period of supply for prescription medicines will allow prescribers, at their discretion, to issue a 12 month prescription (currently six months) for an oral contraceptive, and a six month prescription (currently three months) for any other prescription medicine. The intent of the policy was to remove the inconvenience and financial cost ($10 to over $20) to patients of obtaining a prescription for medication(s) taken on a long-term basis, where there is no need for a nurse or GP consultation. It is expected that medicines will not be dispensed in amounts greater than three months supply, to address issues of wastage and safety.

## Impact of the change to the period of supply

2. At present, patients make one co-payment per prescription item, regardless of the period of supply. Patients are likely to expect that repeat dispensings from a single prescription will be treated in the same way as they currently are: a $3 co-payment per prescribed medication on the first dispensing; and no further co-payments on subsequent dispensings. This was the case with the introduction of three month dispensing (no increase in co-payment) and is the case with six month prescriptions for contraceptive pills now. The co-payment relates to the prescription of a medicine, rather than the dispensing – one co-payment per prescription item, regardless of the number of times the item is dispensed over the prescription period.

3. PHARMAC has estimated that pharmaceutical co-payments will be reduced by $10 to $12 million with the increase in supply periods. It assumes a loss of half the co-payment – ie every three month prescription would become a six month prescription. The actual loss of patient co-payments is very difficult to quantify. It is likely to vary markedly between regions due to demographics and between general practices due to doctor preference and practice.

4. In addition, there are minor to significant pharmaceutical software changes required to implement the extended period of supply. The extent and cost of the software changes depend on whether there is a single co-payment at the first dispensing only or two co-payments, one for each dispensing on the prescription. The implementation date for the change to the period of supply was always intended to be later than most of the other Medicines Regulation changes to allow the software vendors time to amend the pharmaceutical software.

## Options

5. The Ministry has considered the following options:

| | Option | Advice |
|---|---|---|
| 1. | Extend the period of supply with $3 co-pay at the first dispensing and no co-pay at subsequent dispensings. Delay implementation till 1 July 2012. | The Ministry recommends this option because it is consistent with current policy, imposes less cost on patients, and requires minimal and cheap software changes. The delayed implementation would allow the DHBs to include the cost of this change in their 2012/13 budgets. |
| 2. | Extend the period of supply with $3 | As above, but there would be a negative reaction from |

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**Health Report number:** 20110660

| | | |
|---|---|---|
| | co-pay at the first dispensing and no co-pay at subsequent dispensings. Implement on 1 December 2011. | DHBs who have already set their 2011/12 budgets. |
| 3. | Extend the period of supply with $3 co-pay at the first dispensing and $3 co-pay at the second dispensing. (Assuming two dispensings of three months supply at a time) | This would require Cabinet's agreement to amend the co-pay to $6 per medication per prescription for patients issued six month prescriptions. Likely to be viewed by patient groups as an increase in patient costs. Significant pharmaceutical software changes required. |
| 4. | Hold the decision to extend the period of supply, pending further work on impacts. | Would need to be noted in the Cabinet Legislation Committee paper seeking authorisation to submit the Medicines Amendment Regulations to the Executive Council. The decision was made public in the Medicines Regulations Analysis of Submissions document which is on the Ministry website, and in response to ministerial letters, though not with a specific date. May be some public reaction. |

6. PHARMAC's letter notes that in effect, six-monthly dispensing already occurs when doctors write two three-monthly prescriptions for a patient, post-dating the second. The Ministry understands this does occasionally occur, for example when a patient is intending to travel for an extended period. However, this practice is not consistent with Medicines Regulations which set out limits on the quantity of prescription medicine that a prescriber can prescribe on any occasion. In addition, this practice raises safety and wastage issues associated with patients being able to fill both prescriptions at the same time.

7. A decision about implementation of the amendment to the period of supply is required to enable the Medicines Regulations Changes to be submitted to Cabinet Legislation Committee for approval. The Parliamentary Counsel Office advises us they can make required changes in time for the paper to be submitted to the 23 June LEG meeting, which would allow the regulations to start to come into effect on 1 August 2011, as planned.

## Minister's feedback

| | Very poor | Poor | Neutral | Good | Very Good |
|---|---|---|---|---|---|
| Quality of advice | 1 | 2 | 3 | 4 | 5 |
| Writing style | 1 | 2 | 3 | 4 | 5 |
| Quality of analysis | 1 | 2 | 3 | 4 | 5 |
| Completeness of information | 1 | 2 | 3 | 4 | 5 |

Comments:

**END.**

Document 3

PHARMAC
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7 June 2011

Hon Tony Ryall
Minister of Health
Parliament Buildings
WELLINGRON

Dear Minister

**Operational implications of proposed changes to Medicine Regulations**

PHARMAC has recently convened a working group to provide detailed operational policy advice to the Ministry of Health regarding a proposed change to enable six-monthly prescribing. This working group includes pharmacy software vendors as well as various Ministry operational staff (IT, Sector Services, Audit and Compliance). The proposed changes would require changes to the Pharmaceutical Schedule, pharmacy dispensing and Ministry claiming systems.

A key issue that has come to our attention is the question of patient co-payments and it is clear that further policy analysis would be required to resolve this. I have briefly outlined below the main issues we have identified relating to two dispensings within the six-monthly prescription (effectively 90 days and a repeat):

- $3 at first dispensing and $3 at second dispensing would require very significant programming changes in pharmacy software – this is effectively a rebuild of the software as prescription numbers are linked to a single copayment
- $6 at first dispensing would provide a similar level of patient contribution as at present, but relatively easy to programme although initial Ministry advice is that all co-payments would then shift to $6 –whether this is desirable would need to be resolved
- $3 at first dispensing only – this is consistent with the current policy setting (as is the case for oral contraceptives). However, our analysis shows that with such a change, patients would contribute between $10 million and $12 million less per annum, pharmacists would continue to be reimbursed, and the full cost would shift to DHBs.

The latter option is the one favoured by the Ministry due to its consistency with current policy, although there would be significant, unanticipated fiscal pressure on DHBs. Additionally, we do not consider that the drug budget is the appropriate vehicle to pick up this shortfall in patient contributions.

The data used to support our analysis of the fiscal burden are attached. We have taken a conservative approach and extracted only data where patients have collected a medicine in all three 4-month periods of 2009/10. Three four-month periods are used instead of four three-month periods to allow people some leeway around script collection time and still be counted.





Investing in Health

We have assumed that these patients would most likely shift to a six-monthly dispensing and that they would pay two co-payments instead of four. However, it is possible that the size of the potential shift is much greater.

Patient co-payments amount to around $65 million per annum private contribution. We consider that a reduction in this contribution of around 15 percent per annum represents a significant, unintended, policy shift. It does highlight that there is a broader question to explore in respect to co-payments generally, such as the level at which they are set and when they might be applied, along with other payment options, and PHARMAC would be pleased to participate in more detailed policy analysis of this question outside the immediate proposal concerning medicine regulations.

It may also be useful to revisit the policy intent of the changes proposed to enable six-monthly prescribing. We note that, in effect, six-monthly prescribing already occurs in the system: doctors write out two 3-monthly prescriptions, post-dating the second. On these occasions, the second script is treated like the first and a second co-payment is charged.

I would be pleased to discuss these matters in greater detail should that be required.

Yours sincerely

Matthew Brougham
**Chief Executive**

| Sum of CopayAdj | | | | | |
|---|---|---|---|---|---|
| FormType | 1 July 2009 to 31 October 2009 | 1 November 2009 to 28 February 2010 | 1 March to 30 June 2010 | Total | |
| Antipsychotics | No collection | No collection | Collection | $80,331 | |
| | | Collection | Collection | $88,724 | |
| | | | No collection | $28,590 | |
| | Collection | No collection | Collection | $12,252 | |
| | | | No collection | $44,738 | |
| | | Collection | Collection | $465,267 | |
| | | | No collection | $43,164 | |
| Benzodiazapines | No collection | No collection | Collection | $144,377 | |
| | | Collection | Collection | $92,799 | |
| | | | No collection | $85,036 | |
| | Collection | No collection | Collection | $37,592 | |
| | | | No collection | $104,936 | |
| | | Collection | Collection | $523,518 | |
| | | | No collection | $51,705 | |
| ClassB | No collection | No collection | Collection | $14,892 | |
| | | Collection | Collection | $16,655 | |
| | | | No collection | $3,756 | |
| | Collection | No collection | Collection | $3,756 | |
| | | | No collection | $8,523 | |
| | | Collection | Collection | $146,560 | |
| | | | No collection | $8,836 | |
| Month | No collection | No collection | Collection | $4,495,014 | |
| | | Collection | Collection | $1,545,609 | |
| | | | No collection | $2,817,534 | |
| | Collection | No collection | Collection | $1,049,259 | |
| | | | No collection | $3,652,865 | |
| | | Collection | Collection | $4,981,260 | $2,490,630 |
| | | | No collection | $1,156,316 | |







Investing in Health

| | | | | | | |
|---|---|---|---|---|---|---|
| Stat | No collection | No collection | Collection | $5,503,230 | | |
| | | Collection | Collection | $3,233,357 | | |
| | | | No collection | $3,359,427 | | |
| | Collection | No collection | Collection | $1,821,545 | | |
| | | | No collection | $4,166,968 | | |
| | | Collection | Collection | $18,503,205 | $9,251,602 | $11,742,232 |
| | | | No collection | $2,149,190 | | |
| Tricyclic antidepressa | No collection | No collection | Collection | $106,687 | | |
| | | Collection | Collection | $73,795 | | |
| | | | No collection | $41,498 | | |
| | Collection | No collection | Collection | $14,185 | | |
| | | | No collection | $65,553 | | |
| | | Collection | Collection | $447,749 | | |
| | | | No collection | $42,577 | | |
| Unknown | No collection | No collection | Collection | $47,738 | | |
| | | Collection | Collection | $13,157 | | |
| | | | No collection | $29,297 | | |
| | Collection | No collection | Collection | $9,269 | | |
| | | | No collection | $37,840 | | |
| | | Collection | Collection | $32,250 | | |
| | | | No collection | $9,825 | | |
| Grand Total | | | | $61,412,202 | | |

Document 4

MINISTRY OF HEALTH
MANATŪ HAUORA

**Health Report number:** 20110362



**Action required by:** urgent

**Date sent to Minister:**

**Minister's reference:** not applicable

**File number:** HC18-02-9-2

**To:** Hon Tony Ryall (Minister of Health)

**Title:** Approval to Submit Medicines Regulations Changes to Cabinet Legislation Committee

## Advice

1. In October 2010, Cabinet agreed to changes to the Medicines (Standing Order) Regulations 2002 and the Medicines Regulations 1984 to: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; address some health and safety risks; and update technical matters. Changes include exclusion of certain low risk products from regulation under the medicines legislation and amendments to labelling, advertising, dispensing and prescribing requirements.

2. One of the proposed changes to prescribing requirements has been the subject of last minute review within the Ministry and with Pharmac. The concern was about pharmacists claiming subsidies they weren't entitled to. However, after further review, in consultation with Pharmac, the Ministry considers the subsidy rules in the Pharmaceutical Schedule are sufficient to prevent this happening.

3. Your decision to put the proposed extension to the period of supply for prescription medicines on hold (HR 20110660) is noted in the attached Cabinet paper. The Ministry has advised the NZMA, the GP Leaders Forum and the Royal College of GPs (who were consulted on this proposal) that the extension to the period of supply will not go ahead at this time.

4. The Ministry has drafted the attached Cabinet paper for consideration at Cabinet Legislation Committee (LEG). The Cabinet paper seeks authorisation for the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 to be submitted to the Executive Council. A copy of the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 are attached to the Cabinet paper for your information. The final certified copies of the Regulations will be submitted directly to Cabinet Office by the Parliamentary Counsel Office.

5. If the LEG paper and attached Order in Council are submitted to the Cabinet Office by 10.00am on Monday 4 July 2011 they can be considered by LEG on Thursday, 7 July and Cabinet and the Executive Council on Monday, 11 July. To allow the majority of the amended Regulations to come into force on 1 August 2011, a waiver to the 28 day rule is sought. The LEG paper seeks a waiver to the 28 day Rule on the grounds that the changes confer only benefits on the public. The amended provisions of the Regulations that require changes to advertising and labelling of medicines have transition provisions until 1 February 2012 and 1 September 2012 respectively. Note that Regulations 14, 15 and 18 require changes to software systems and will come into force on 1 December 2011.

MINISTRY OF HEALTH
MANATŪ HAUORA

**Health Report number:** 20110362

## The Ministry recommends that you:

a) **Sign:** the attached Cabinet Legislation Committee paper seeking the Committee's authorisation to submit the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 to Executive Council — Yes / No

b) **Sign:** the Order in Council recommending that the Governor-General make the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 — Yes / No

c) **Forward:** the Cabinet Legislation paper and the Order in Council to the Cabinet Office by 10.00am Monday, 4 July 2011. — Yes / No

Barbara Phillips
**Deputy Director-General (Acting)**
**Policy Business Unit**

**Minister's Signature**

**Date:**

## Ministry of Health Contacts:

| | | | |
|---|---|---|---|
| Oliver Poppelwell<br>Manager (Acting), Sector & Services, Team 4 | | Sharon Woollaston<br>Senior Policy Analyst | |
| Phone: | s 9(2)(a) | Phone: | s 9(2)(a) |
| Cellphone: | | Cellphone: | |

## Minister's feedback

| | Very poor | Poor | Neutral | Good | Very Good |
|---|---|---|---|---|---|
| Quality of advice | 1 | 2 | 3 | 4 | 5 |
| Writing style | 1 | 2 | 3 | 4 | 5 |
| Quality of analysis | 1 | 2 | 3 | 4 | 5 |
| Completeness of information | 1 | 2 | 3 | 4 | 5 |

Comments:

**In Confidence**

Office of the Minister of Health

Cabinet Legislation Committee

**Approval to implement changes to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002**

## Proposal

1 This paper seeks authorisation to submit the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 to the Executive Council.

## Policy

2 The purpose of the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 is to update aspects of the regulatory framework for medicines in order to: reduce unnecessary costs for the Crown, industry, health service providers and consumers; reduce barriers to innovation in the health sector; address some health and safety risks; and update technical matters. Changes include exclusion of certain low risk products from regulation under the medicines legislation and amendments to labelling, advertising, dispensing and prescribing requirements.

3 In line with previous Cabinet decisions [SOC Min (10) 23/1], the Medicines Amendment Regulations 2011 and Medicines (Standing Order) Amendment Regulations 2011 will:

a) Exclude low-risk fluoride dentifrices, anti-dandruff preparations, anti-acne preparations, barrier creams for preventing nappy rash, antibacterial skin products and oral hygiene products, from regulation under the Medicines Act 1981 and align the requirements on contents, claims and presentation for use for such products with Australian requirements.

b) 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.

c) Enable the Director-General of Health to issue a waiver to permit electronic transmission of prescriptions in specified situations. Use of a waiver mechanism means that the Director-General will have the ability to change the criteria as the sector's readiness for electronic prescribing progresses.

d) Align prescribing rights for medical practitioners, dentists and midwives (who are all authorised prescribers under the Medicines Act), enabling all prescribers to prescribe in accordance with their scope of practice for patients under their care.

e) Remove the 10 day limit on period of supply for prescription medicines for dentists (to align the period of supply with all other authorised prescribers); and allow the Director-General of Health to waive the limit on period of supply in certain circumstances.

f) Allow pharmacists to substitute an alternative brand of a medicine where there are no clinical reasons why substitution should not occur, the prescriber has not marked the prescription with "no brand substitution", and the pharmacist records the details of the brand substitution on the prescription.

g) Allow the issuer of a standing order to specify the arrangements for their countersigning of any administration or supply of the medicine under the order (including that countersigning may not be required, provided a monthly audit of treatments under the standing order is carried out).

h) Remove the prescriptive requirements for the 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, and enable the Minister to prescribe new requirements for the form of data sheets.

i) 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).

j) Update the requirements for information that must be provided on a prescription.

k) Remove prescriptive dispensing requirements and replace them with more flexible requirements, to allow for electronic technologies and reflect current dispensing practice.

l) 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.

m) Update pharmacy qualification definitions and remove references to old legislation.

n) Clarify when a prescription is not required.

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

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

**Regulatory impact analysis**

5. A Regulatory Impact Statement was submitted to Cabinet with the original policy proposals [SOC Min (10) 23/1].

**Timing and 28-day rule**

6. Regulations 14, 15 and 18 will come into force on 1 December 2011. This will allow time for the necessary changes to be made to software systems. A waiver to the 28-day rule is sought to allow the remainder of the regulations to come into force on 1 August 2011. The amendments will confer only benefits to the public.

**Compliance**

7. The Regulations comply with:

   a) the principles of the Treaty of Waitangi
   b) the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993
   c) the Privacy Act 1993
   d) relevant international standards and obligations
   e) *Legislative Advisory Committee Guidelines: Guidelines on Process and Content*.

**Regulations Review Committee**

8. There are no grounds for the Regulations Review Committee to draw the regulations to the attention of the House under Standing Order 310.

**Certification by Parliamentary Counsel**

9. The draft regulations were certified by parliamentary counsel as being in order for submission to Cabinet.

**Publicity**

10. The *Report of the analysis of submissions and final decisions on proposed amendments to Regulations under the Medicines Act 1981* was published on the Ministry of Health website in November 2010. In addition, the Ministry of Health included information about the key changes to the regulations in the March edition of its publication *Prescriber Update*. The Ministry of Health will also write to responsible authorities and other organisations with an interest in

the changes to update them on the changes, including the decision not to proceed with the change to the period of supply for prescription medicines. Medsafe will also publish information about the changes affecting industry on its website and in its regular communications with industry groups.

**Consultation**

11. The following Government agencies were consulted on the development of the policy: The Treasury; the Ministries of Consumer Affairs, Economic Development, Foreign Affairs and Trade and Justice; the Ministry for the Environment; the Environmental Risk Management Authority, the Accident Compensation Corporation; and PHARMAC. The Department of Prime Minister and Cabinet was informed.

12. In addition, the Ministry of Health received 84 submissions on its consultation document, *Consultation on Proposed Amendments to Regulations under the Medicines Act 1981,* from a wide cross-section of affected stakeholders. Feedback from this consultation was incorporated into the final policy proposals.

**Recommendations**

13. The Minister of Health recommends that the Cabinet Legislation Committee

1 **Note** that Cabinet agreed to make a number of changes to the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002 that sit under the Medicines Act 1981 to exclude certain low risk products from regulation under the Medicines legislation and to amend labelling, advertising, dispensing and prescribing requirements [SOC Min (10) 23/1]

2 **Note** that the proposed extension to the period of supply has fiscal and pharmacy software implications and has been put on hold.

3 **Note** that the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 give effect to the decision referred to in recommendation 1 above.

4 **Note** that a waiver of the 28-day rule is sought:

4.1 So that the Medicines (Standing Order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011 can come into force on the 1 August 2011, with the exception of regulations 14, 15 and 18 of the Medicines Amendment Regulations 2011, which will come into force on 1 December 2011.

4.2 On the grounds that the changes confer only benefits to the public

5. **Agree** to waive the 28-day rule so that the regulations can come into force on 1 August, with the exception of regulations 14, 15 and 18 of the Medicines Amendment Regulations 2011, which will come into force on 1 December 2011.

6. **Authorise** the submission to the Executive Council of the Medicines (Standing order) Amendment Regulations 2011 and the Medicines Amendment Regulations 2011

Hon Tony Ryall
**Minister of Health**

Date: 30 June 2011

# Consultation on Cabinet and Cabinet Committee Submissions

## Certification by Department:

Guidance on consultation requirements for Cabinet/Cabinet committee papers is provided in the CabGuide (see Procedures: Consultation): http://www.cabguide.cabinetoffice.govt.nz/procedures/consultation

**Departments/agencies consulted:** The attached submission has implications for the following departments/agencies whose views have been sought and are accurately reflected in the submission:

The following Government agencies were consulted on the development of the policy: The Treasury; the Ministries of Consumer Affairs, Economic Development, Foreign Affairs and Trade and Justice; the Ministry for the Environment; the Environmental Risk Management Authority, the Accident Compensation Corporation; and PHARMAC.

**Departments/agencies informed:** In addition to those listed above, the following departments/agencies have an interest in the submission and have been informed:

The Department of Prime Minister and Cabinet was informed.

**Others consulted:** Other interested groups have been consulted as follows:

The NZ Medical Association, GP Leaders Forum and the Royal College of GPs were consulted on the change to the period of supply for prescription medicines.

**Name, Title, Department:** Barbara Phillips, Deputy Director-General (Acting), Ministry of Health

| **Date:** 29 / 6 / 11 | **Signature** |
|---|---|

## Certification by Minister:

Ministers should be prepared to update and amplify the advice below when the submission is discussed at Cabinet/Cabinet committee.

**The attached proposal:**

| | |
|---|---|
| *Consultation at Ministerial level* | ☐ **has been** consulted with the Minister of Finance *[required for all submissions seeking new funding]*<br>☐ **has been** consulted with the following portfolio Ministers:<br>☑ **did not need** consultation with other Ministers |
| *Discussion with National caucus* | ☐ **has been** or ☐ **will be** discussed with the government caucus<br>☑ **does not need** discussion with the government caucus |
| *Discussion with other parties* | ☐ **has been** discussed with the following other parties represented in Parliament:<br>☐ Act Party ☐ Maori Party ☐ United Future Party<br>☐ Other [specify]<br>☐ **will be** discussed with the following other parties represented in Parliament:<br>☐ Act Party ☐ Maori Party ☐ United Future Party<br>☐ Other [specify]<br>☑ **does not need** discussion with other parties represented in Parliament |

| **Portfolio** | **Date** | **Signature** |
|---|---|---|
| Health | 30 / 6 / 11 | |

Document 4

# In Executive Council

*His Excellency the Governor-General is recommended to*

Sign the attached Order in Council making the
Medicines Amendment Regulations 2011

Hon Tony Ryall
**Minister of Health**

*Approved in Council*

*Clerk of the Executive Council*

Document 4

# Office of Hon Tony Ryall

Minister of Health
Minister of State Services

4 JUL 2011

His Excellency, the Honourable Sir Anand Satyanand, GNZM, QSO
Governor-General
Government House
Wellington

Your Excellency

**MEDICINES AMENDMENT REGULATIONS 2011**

These regulations are made under sections 62 and 105 of the Medicines Act 1981 ("the Act") and amend the Medicines Regulations 1984 ("the principal regulations").

Several of the regulations require statutory prerequisites to have been met.

Section 62(1)(a) of the Act, allows for the making of regulations to regulate the insertion in medical advertisements of information or warnings concerning any unwanted, incidental or untoward effects of effects of medicines and statements of the precautions to be taken by the user of the medicine.

Section 62(2) of the Act requires that regulations may only be made under section 62(1)(a):

- on the recommendation of the Minister after consultation with such organisations or bodies as the Minister considers likely to be substantially affected by the regulations (s 62(2)(a)); and
- if the regulations are designed to achieve a fair and balanced indication of the potential effects of the medicine (s 62(2)(b)); and
- if the regulations do not require the disclosure of information that may reasonably be regarded as confidential, or that cannot reasonably be expected to be in the possession of the person on whose behalf the advertisement is published or the inclusion of which in the advertisement is otherwise impractical (s 62(2)(c)).

I have carried out the consultation required. I am also satisfied that the regulations, as amended, achieve a fair and balanced indication of the potential effects of the relevant medicines and do not require the disclosure of information that is prohibited.

Section 61(c) of the Act requires that, before advising you to make any regulations under that regulation, I consult with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations. I have carried out such consultation.



Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand. Telephone 64 4 817 6804 Facsimile 64 4 817 6504

Section 105 of the Act requires that, before advising you to make any regulations under that regulation, I consult with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations. I have carried out such consultation.

The requirements have therefore been met.

Yours sincerely

Hon Tony Ryall
**Minister of Health**

Document 4

# In Executive Council

*His Excellency the Governor-General is recommended to*

Sign the attached Order in Council making the
Medicines (Standing Order)
Amendment Regulations 2011

Hon Tony Ryall
**Minister of Health**

*Approved in Council*

*Clerk of the Executive Council*

Document 4

# Office of Hon Tony Ryall

Minister of Health
Minister of State Services

4 JUL 2011

His Excellency, the Honourable Sir Anand Satyanand, GNZM, QSO
Governor-General
Government House
Wellington

Your Excellency

**MEDICINES (STANDING ORDER) AMENDMENT REGULATIONS 2011**

These regulations are made under section 105 of the Medicines Act 1981 ("the Act") and amend the Medicines (Standing Order) Regulations 2002 ("the principal regulations").

The regulations amend the requirements for counter-signing of standing orders issued under the principal regulations.

Section 105 of the Act requires that, before advising you to make any regulations under that section, I consult with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations. I have carried out such consultation.

The requirement has therefore been met.

Yours sincerely

Hon Tony Ryall
**Minister of Health**



Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand. Telephone 64 4 817 6804 Facsimile 64 4 817 6504

PCO 14905/29.2
Drafted by Leah Pickup

**IN CONFIDENCE**

# Medicines Amendment Regulations 2011

Governor-General

## Order in Council

At Wellington this day of 2011

Present:
in Council

Pursuant to sections 62 and 105 of the Medicines Act 1981, His Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations or bodies appearing to the Minister to be representative of persons likely to be substantially affected, and acting on the advice and with the consent of the Executive Council, makes the following regulations.

### Contents

## Regulations

**1 Title**

These regulations are the Medicines Amendment Regulations 2011.

**2 Commencement**

(1) These regulations, except regulations 14, 15, and 18, come into force on 1 August 2011.

(2) Regulations 14, 15, and 18 come into force on 1 December 2011.

**3 Principal regulations amended**

These regulations amend the Medicines Regulations 1984.

**4 Interpretation**

(1) Regulation 2(1) is amended by revoking the definitions of **approved school**, **colouring substance**, and **Dispensary Assistant's Certificate**.

(2) Regulation 2(1) is amended by revoking the definition of **dispensary technician** and substituting the following definition:

"**dispensary technician** means a person who holds a certificate issued by the Pharmaceutical Society of New Zealand before 18 September 2004 that—

"(a) classifies the holder as a dispensary assistant; or

"(b) records that the person has completed the requirements of the Pharmacy Technician's Certificate".

(3) Regulation 2(1) is amended by inserting the following definition in its appropriate alphabetical order:

"**general sale medicine** has the meaning given to it by section 99(2) of the Act".

(4) Regulation 2(1) is amended by inserting the following definition in its appropriate alphabetical order:

"**Pharmacy Council** means the Pharmacy Council established by section 114(5) of the Health Practitioners Competence Assurance Act 2003".

(5) Regulation 2(1) is amended by revoking the definitions of **pharmacy graduate**, **pharmacy student**, and **pharmacy technician** and substituting the following definitions in their appropriate alphabetical order:

"**pharmacy graduate** means a person who is not a pharmacist, but who—

"(a) has 1 or more of the qualifications prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003 for registration as a pharmacist; and

"(b) is actively taking steps towards registration as a pharmacist

"**pharmacy student** means a person who is undertaking, but has not yet completed, the course and examinations leading to a qualification of a kind prescribed by the Pharmacy Council under section 12(1) of the Health Practitioners Competence Assurance Act 2003

"**pharmacy technician** means any person who has a National Certificate in Pharmacy (Technician)".

**5 Regulation 6 revoked**

Regulation 6 is revoked.

**6 New regulation 8 substituted**

Regulation 8 is revoked and the following regulation substituted:

"**8 Advertisements for medicines**

"(1) Every advertisement for a prescription medicine must include—

"(a) the words 'Prescription medicine' or words of a similar meaning; and

"(b) the name of each active ingredient; and
"(c) the appropriate quantitative particulars of each active ingredient; and
"(d) a statement of the purpose for which the medicine is intended to be used; and
"(e) a statement that the medicine has risks and benefits; and
"(f) a statement about how to find further information on the risks and benefits of the medicine.

"(2) Every advertisement for a restricted medicine must include—
"(a) the following statements, or statements with a similar meaning:
"(i) 'Available only from your pharmacist.'; and
"(ii) 'If symptoms persist, see your doctor or health professional.'; and
"(iii) 'Use only as directed.'; and
"(b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:
" 'Always read the label.'; and
"(c) a statement of the purpose for which the medicine is intended to be used; and
"(d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

"(3) Every advertisement for a pharmacy-only medicine or a general sale medicine must include—
"(a) the following statements, or statements with a similar meaning:
"(i) 'If symptoms persist, see your doctor or health professional.'; and
"(ii) 'Use only as directed.'; and
"(b) the name of each active ingredient, or the following statement, or a statement with a similar meaning:
" 'Always read the label.'; and
"(c) a statement of the purpose for which the medicine is intended to be used; and
"(d) any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

"(4) Every advertisement for a medicine to be supplied by mail order, direct marketing, or via the Internet must—
"(a) include the name of each active ingredient; and

"(b) include the appropriate quantitative particulars of each active ingredient; and

"(c) comply with the following, to the extent they are applicable:

"(i) subclause (1)(a), and (d) to (f):

"(ii) subclause (2)(a), (c), and (d):

"(iii) subclause (3)(a), (c), and (d).

"(5) A statement required by this regulation must be—

"(a) clearly printed; or

"(b) clearly spoken.

"(6) A statement that is required by this regulation may be both clearly printed and clearly spoken.

"(7) This regulation does not apply to—

"(a) an advertisement for a medicine that does not refer to a therapeutic purpose:

"(b) an advertisement (not being an advertisement of the kind described in subclause (4)) that is—

"(i) located at the point of sale; and

"(ii) positioned immediately above, below, or next to the medicine to which it relates:

"(c) labels:

"(d) price lists.

"(8) An advertisement for a prescription, restricted, pharmacy-only, or general sale medicine that is subsequently reclassified must be treated as compliant with this regulation if—

"(a) the advertisement was compliant with every applicable requirement in this regulation immediately before the medicine was reclassified; and

"(b) not more than 3 months have elapsed since the medicine was reclassified.

"(9) In any proceedings for an offence against section 57 of the Act, it is for the defendant to prove that subclause (8) applies."

**7 Regulation 11 substituted**

Regulation 11 is revoked and the following regulation substituted:

"**11 Advertisements intended for health professions**

"(1) This regulation applies—

"(a) to advertisements intended for members of the medical, dental, pharmaceutical, and related professions; and

"(b) in addition to the requirements in regulations 7, 9, and 10 (but not regulation 8).

"(2) Every advertisement for a medicine must—

"(a) include—

"(i) the classification of the medicine; and

"(ii) the name of each active ingredient; and

"(iii) the appropriate quantitative particulars of each active ingredient; and

"(iv) a statement of the purpose for which the medicine is intended to be used; and

"(v) a statement of the appropriate precautions to be taken in the use of the medicine; and

"(vi) information on the effectiveness and limitations of the medicine; and

"(vii) a statement of any restriction imposed on distribution; and

"(viii) the dosage regime and mode of administration, or method of use, of the medicine; and

"(ix) a statement of any contraindications to the use of the medicine; and

"(x) information on the likely potentiating effects and interactions with other substances, medicines, or environmental influences; and

"(xi) a statement of the known or likely poisonous effects of, or adverse reactions to, the medicine; but

"(b) not include—

"(i) a statement (based on the citation of a report) relating to the effectiveness or safety of the medicine that omits relevant parts of the report, or quotes from the report in such a way that another meaning to that intended by the report is conveyed; or

"(ii) an unsubstantiated comparison with other medicines; or

"(iii) data, previously considered valid, but made obsolete or false by subsequent findings; or

"(iv) a statement of the use of the medicine, or the dosage of the medicine, that contravenes any condition of a consent given under section 20, 23 or 24 of the Act.

"(3) Nothing in subclause (2)(a)(iii) or (vi) to (xi) applies to an advertisement that—

"(a) is intended to provide a practitioner with details of—

"(i) a major therapeutic indication of a medicine; or

"(ii) the listing of a medicine in the pharmaceutical schedule (within the meaning of section 6(1) of the New Zealand Public Health and Disability Act 2000); or

"(iii) a new or changed strength of a medicine; and

"(b) does not enable the practitioner to reach a prescribing decision.

"(4) Every advertisement for a related product or medical device must include—

"(a) a statement of any restriction imposed on distribution; and

"(b) the dosage regime and mode of administration, or method of use, of the related product or medical device; and

"(c) information on the effectiveness and limitations of the related product or medical device."

**8 New regulations 13 to 16 substituted**

Regulations 13 to 16 are revoked and the following regulations substituted:

"**13 Labelling of medicines**

"(1) Every container of a medicine must, unless otherwise provided by these regulations, bear a label containing the following information:

"(a) the trade name of the medicine or, if there is no trade name, the appropriate designation of the medicine:

"(b) the name of each active ingredient:

"(c) the appropriate quantitative particulars of each active ingredient:

"(d) a description of the medicine, including dose form, or presentation, that indicates the true nature of the medicine:

"(e) a statement of the net weight or volume or number of the contents of the container, as the case may require:

"(f) in the case of a prescription medicine,—

"(i) the words 'PRESCRIPTION MEDICINE' or words of a similar meaning; or

"(ii) the words 'PRESCRIPTION-ONLY MEDICINE' or words of a similar meaning; or

"(iii) the acronym 'POM':

"(g) in the case of a restricted medicine,—

"(i) the words 'RESTRICTED MEDICINE'; or

"(ii) the words 'PHARMACIST-ONLY MEDICINE':

"(h) in the case of a pharmacy-only medicine,—

"(i) the words 'PHARMACY-ONLY MEDICINE' or words of a similar meaning; or

"(ii) the words 'PHARMACY MEDICINE' or words of a similar meaning:

"(i) any warning statement required by these regulations for the medicine:

"(j) in the case of a medicine other than a prescription medicine, a statement of the purpose for which the medicine is intended to be used:

"(k) in the case of a medicine sold, or intended for sale, for external use,—

"(i) a statement of directions for use and frequency of use; and

"(ii) the words 'Caution: not to be taken', or 'For external use only', or words of a similar meaning:

"(l) in the case of a medicine sold, or intended for sale, for internal use,—

"(i) the dose recommended; and

"(ii) the frequency of that dose:

"(m) the words 'Batch Number' or 'Lot Number', or the word 'Batch' or 'Lot', or the letter 'B' (either alone or inside a circle) followed by the batch or lot number of the medicine:

"(n) the words 'Use by' or 'Use before', or words of a similar meaning, followed by the expiry date (being in no case later than 5 years after the date of manufacture of the medicine) appropriate to the stability of the medicine:

"(o) where appropriate, a statement of the recommended storage conditions:

"(p) the name and address of—

"(i) the manufacturer or seller of the medicine; or

"(ii) the owner of the rights of manufacture; or

"(iii) the agent of any person who comes within subparagraph (i) or (ii).

"(2) For the purposes of subclause (1)(p),—

"(a) an address at a post office is not sufficient:

"(b) the name and address of a person not ordinarily resident in New Zealand are not sufficient unless the medicine is wholly manufactured and packed outside New Zealand:

"(c) in the case of a body corporate registered in New Zealand, the name of the town in which the body corporate has its registered office is sufficient.

"(3) In the case of a medicine intended for administration only in accordance with the directions of a practitioner, it is sufficient compliance with subclause (1)(l) to indicate the dose by a range if the container is accompanied by a more specific statement relating to each usage.

"(4) In the case of a prescription medicine, compliance with the requirements of subclause (1)(k) or (l) is required only at the time at which that medicine—

"(a) is sold by retail; or

"(b) is supplied in circumstances corresponding to retail sale; or

"(c) is supplied by way of gift or sample for the purpose of promoting a sale.

"(5) Subclause (1)(l) does not apply in the case of a medicine intended to be administered by or under the supervision of a practitioner, in circumstances where the dosage is to be dependent on concurrent skilled observation.

"(6) Every container of a medicine that is prepared for injection into the human body and that contains an antiseptic or preser-

vative must be labelled with a statement of the nature and amount of the antiseptic or preservative.

"(7) Every container of a medicine that is a biochemical preparation must, in addition to the other requirements in this regulation, bear a label containing the following:

"(a) a statement of the potency of the preparation; and

"(b) a statement of the nature and amount of every antiseptic or preservative (if any) used in the medicine.

"(8) Where it is impractical to put all of the information required by this regulation on a label because the container is too small, it is sufficient compliance with this regulation to print the information required by subclause (1)(i), (j), and (o) on a separate information sheet, in the same manner as that information would be required by these regulations to be printed on a label, and to supply that sheet to the customer with the medicine.

"(9) This regulation is subject to regulations 15 and 23.

**"14 Labelling of related products**

"(1) Every container of a related product must, unless otherwise provided by these regulations, bear a label containing the following information:

"(a) the trade name of the related product or, if there is no trade name, the appropriate designation of the related product:

"(b) the name of each active ingredient:

"(c) the appropriate quantitative particulars of each active ingredient:

"(d) a description of the related product that indicates the true nature of the related product:

"(e) a statement of the net weight or volume or number of the contents of the container, as the case may require:

"(f) any warning statement required by these regulations for the related product:

"(g) in the case of a related product sold, or intended for sale, for external use,—

"(i) a statement of directions for use and frequency of use; and

"(ii) the words 'Caution: not to be taken', or 'For external use only', or words of a similar meaning:

"(h) in the case of a related product sold, or intended for sale, for internal use,—

"(i) the dose recommended; and

"(ii) the frequency of that dose:

"(i) the words 'Batch Number' or 'Lot Number', or the word 'Batch' or 'Lot', or the letter 'B' (either alone or inside a circle) followed by the batch or lot number of the related product:

"(j) where appropriate, an expiry date:

"(k) the name and address of—

"(i) the manufacturer or seller of the related product; or

"(ii) the owner of the rights of manufacture; or

"(iii) the agent of any person who comes within subparagraph (i) or (ii).

"(2) For the purposes of subclause (1)(k),—

"(a) an address at a post office is not sufficient:

"(b) the name and address of a person not ordinarily resident in New Zealand are not sufficient unless the related product is wholly manufactured and packed outside New Zealand:

"(c) in the case of a body corporate registered in New Zealand, the name of the town in which the body corporate has its registered office is sufficient.

**"15 Exemptions from regulations 13 and 14**

"(1) Nothing in regulation 13 (except subclause (1)(a), (b), (c), (m), and (n)) and nothing in regulation 14 (except subclause (1)(a), (b), (c), (i) and (j)) applies to—

"(a) a container that—

"(i) contains a single dose of a medicine or related product; and

"(ii) is made of sheet material; and

"(iii) is not attached to another container; and

"(iv) is contained in a package that complies with regulation 13 or 14 (as the case requires); and

"(v) is not intended for sale other than in that package:

"(b) a container that—

"(i) contains a single dose of a medicine or related product; and
"(ii) is not made of sheet material; and
"(iii) has a volume of 20 millilitres or less; and
"(iv) is contained in a package that complies with regulation 13 or 14 (as the case requires); and
"(v) is not intended for sale other than in that package:

"(c) a container (other than an aerosol container) that—
"(i) contains a medicine or related product that is a gas; and
"(ii) is of a kind commonly used for storing or transporting gases in compressed, liquefied, or dissolved form; and
"(iii) has a capacity not exceeding 250 litres water capacity:

"(d) a container of a remedy that is, or is described as, homeopathic.

"(2) Nothing in regulation 13 or 14 applies to a strip of containers that—
"(a) is made of sheet material; and
"(b) bears the information required by—
"(i) regulation 13(1)(m) and (n), or regulation 14(1)(i) and (j) (as the case requires) at least once on the strip; and
"(ii) regulation 13(1)(a), (b), and (c) or regulation 14(1)(a), (b), and (c) (as the case requires)—
"(A) at least once in relation to every two containers, if the containers are easily detached from the strip; and
"(B) at least once on the strip in any other case; and
"(c) is contained in a package that complies with regulation 13 or 14 (as the case requires); and
"(d) is not intended for sale other than in that package.

"(3) In this regulation, **strip of containers** means a series of containers that each contain a single dose of a medicine or related product and that together form a strip.

"(4) Nothing in regulation 13(1)(f), (g), or (h) applies to a prescription medicine, restricted medicine, or pharmacy-only

medicine, held for sale by a manufacturer or wholesaler, for the period of 3 months immediately following the date on which it becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) if, at that date, the medicine was part of the existing stock-in-trade in New Zealand of the manufacturer or wholesaler.

"(5) Nothing in regulation 13(1)(f), (g), or (h) applies to a prescription medicine, restricted medicine, or pharmacy-only medicine, held for sale by a retailer, for the period of 6 months immediately following the date on which it becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) if, at that date, the medicine was part of the existing stock-in-trade in New Zealand of the retailer.

"(6) For the purposes of subclauses (4) and (5), any goods purchased before the date on which a substance becomes a prescription medicine, restricted medicine, or pharmacy-only medicine (as the case may be) for importation into New Zealand are deemed to be part of the purchaser's stock-in-trade in New Zealand.

"(7) In any proceedings for an offence against section 44 of the Act in respect of any container that does not comply with regulation 13(1)(f), (g), or (h), the onus is on the defendant to prove that the relevant paragraph does not apply by virtue of subclause (4) or (5) of this regulation.

**"16 Principal display panel**

"(1) The principal display panel of the label of a medicine must contain—

"(a) the information required by regulation 13(1)(a), (d), and (e); and

"(b) the information required by regulation 13(1)(b) and (c), but only if the medicine contains 3 or fewer active ingredients.

"(2) Subclause (1) is subject to regulation 23.

"(3) The principal display panel of the label of a related product must contain—

"(a) the information required by regulation 14(1)(a), (d), and (e); and

"(b) the information required by regulation 14(1)(b) and (c), but only if the related product contains 3 or fewer active ingredients.

"(4) Nothing in subclause (1) or (3) prevents the inclusion in the principal display panel of any other matters required by these regulations to appear on a label of any medicine or related product.

"(5) Subclause (4) is subject to regulation 19."

**9 Labelling of prescription medicines, restricted medicines, and pharmacy-only medicines**

Regulation 19 is amended by omitting "Subject to regulation 37(3) of these regulations, where" and substituting "Where".

**10 Regulation 20 revoked**

Regulation 20 is revoked.

**11 New regulation 22 substituted**

Regulation 22 is revoked and the following regulation substituted:

"**22 Warning statements for medicines and related products**

"(1) Every container of a medicine or related product must include on its label any warning statement that may be required by guidelines issued from time to time by the Ministry of Health.

"(2) A warning statement is additional to any other statement or information that is required by these regulations to be shown on a label.

"(3) Subclause (1) is subject to regulation 23."

**12 Labels on containers of medicines sold by authorised prescribers or pharmacists**

(1) Regulation 23 is amended by omitting "regulation 15(1)" and substituting "regulation 16(1)".

(2) Regulation 23 is amended by revoking paragraph (a) and substituting the following paragraph:

"(a) the name of, or a description of the nature of, the contents; and".

(3) Regulation 23 is amended by adding "; and" and also by adding the following paragraphs:

"(f) a unique identifying number or code for the prescription or record of supply; and

"(g) the date on which the medicine was packed, sold, or supplied."

**13 Safety containers**

Regulation 37(3) is revoked.

**14 New regulation 39 substituted**

Regulation 39 is revoked and the following regulation substituted:

"**39 Conditions under which authorised prescribers and veterinarians may prescribe prescription medicines**

"(1) An authorised prescriber (including a designated prescriber) may only prescribe a prescription medicine if the authorised prescriber—

"(a) is prescribing the prescription medicine—

"(i) for the treatment of a patient under the authorised prescriber's care; and

"(ii) within, and in accordance with all conditions (if any) stated in, the authorised prescriber's scope of practice, as determined by an authorisation granted under section 21 of the Health Practitioners Competence Assurance Act 2003 by the authority responsible for the registration of the authorised prescriber; and

"(b) is not prohibited by a notice under section 48(1) of the Act from prescribing that prescription medicine or any prescription medicines of a class or description that includes that prescription medicine.

"(2) An authorised prescriber who is a designated prescriber may only prescribe a prescription medicine if—

"(a) the prescription medicine is of a class or description that the designated prescriber is authorised to prescribe by regulations made under the Act; and

"(b) the requirements specified in or imposed under those regulations are satisfied.

"(3) A veterinarian may only prescribe a prescription medicine that is for the treatment of an animal under the veterinarian's care.

"(4) Subclause (1) does not apply to an authorised prescriber who is acting in the course of his or her employment by the Crown."

**15 New regulation 39A inserted**

The following regulation is inserted after regulation 39:

"**39A Limit on period of supply of prescription medicines**

"(1) An authorised prescriber may not on any occasion prescribe for any patient a quantity of any prescription medicine that exceeds—

"(a) 6 months' supply in the case of an oral contraceptive; or

"(b) 3 months' supply in any other case.

"(2) However, the Director-General may, at his or her discretion, authorise—

"(a) an authorised prescriber to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b):

"(b) a class of authorised prescribers to prescribe for any patient, or any specified class or classes of patients, a quantity of a prescription medicine exceeding the period of supply in subclause (1)(a) or (b)."

**16 Prescriptions to comply with regulations**

Regulation 40(1) is amended by omitting "veterinary surgeon" and substituting "veterinarian".

**17 Urgently required prescriptions of prescription medicines may be communicated orally if later confirmed in writing**

Regulation 40A is amended by omitting "veterinary surgeon" in each place where it appears and substituting in each case "veterinarian".

**18 Form of prescription**

(1) Regulation 41 is amended by revoking paragraph (c) and substituting the following paragraph:

"(c) set out the following information in relation to the prescriber:

"(i) the prescriber's full name; and

"(ii) the full street address of the prescriber's place of work or, in the absence of the prescriber having a place of work, the postal address of the prescriber; and

"(iii) the prescriber's telephone number; and".

(2) Regulation 41(d) is amended by revoking subparagraph (i) and substituting the following subparagraph:

"(i) the surname, each given name, and the address of the person for whose use the prescription is given; and".

(3) Regulation 41 is amended by revoking paragraph (f) and substituting the following paragraph:

"(f) indicate the total amount of medicine that may be sold or dispensed, or the total period of supply; and".

(1) Regulation 41 is amended by revoking paragraph (i).

(4) Regulation 41(j) is amended by revoking subparagraph (i) and substituting the following subparagraph:

"(i) set out the surname, each given name, and the address of the owner of the animal; and".

**19 Dispensing of prescription medicines**

(1) Regulation 42 is amended by omitting "veterinary surgeon" in each place where it appears and substituting in each case "veterinarian".

(2) Regulation 42 is amended by revoking subclauses (3) and (4) and substituting the following subclauses:

"(3) Every person dispensing a prescription relating to a prescription medicine must comply with the following requirements:

"(a) if the prescription has been communicated orally under regulation 40A(1), the prescription must not be dispensed on more than 1 occasion before the pharmacist

has received the written confirmation of the prescription, as required by regulation 40A(2):

"(b) the following information must be recorded on the prescription:

"(i) the name and address of the proprietor of the business at which the prescription is dispensed; and

"(ii) the date on which the prescription is dispensed; and

"(iii) the quantity of medicine dispensed; and

"(iv) a unique identifying number or code for the prescription:

"(c) a prescription for a medicine other than an oral contraceptive must not be dispensed on any occasion after 6 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:

"(d) a prescription for a medicine that is an oral contraceptive must not be dispensed on any occasion after 9 months have elapsed from the date on which it was printed or, if given under regulation 40A(1), communicated orally:

"(e) every prescription must be retained for a period of 3 years by the pharmacist on the premises on which it was dispensed or at a place approved by the Medical Officer of Health and must be kept in an orderly and consecutive manner so as to be readily available for inspection.

"(4) If an authorised prescriber or a veterinarian refers in a prescription to a medicine by its trade mark or trade name, or by reference to the name of its manufacturer, a pharmacist may supply an alternative brand of medicine, provided that—

"(a) the authorised prescriber or veterinarian has not marked the prescription 'No brand substitution permitted' or with words of similar meaning; and

"(b) the substituted brand contains the same active ingredient or active ingredients, and no other active ingredients; and

"(c) the substituted brand is in the same dose form and strength as the prescribed brand; and

"(d) there is no clinical reason why the substituted brand should not be supplied; and

"(e) the pharmacist records the brand substitution on the prescription; and

"(f) the pharmacist signs and dates the prescription; and

"(g) the pharmacist informs the patient of the brand substitution.

"(5) This regulation is subject to regulation 43."

**20 New regulation 43 substituted**

Regulation 43 is revoked and the following regulation substituted:

**"43 Director-General may waive certain requirements**

"(1) Despite the requirements in regulations 41 and 42, the Director-General may, at his or her discretion,—

"(a) authorise a form of prescription that does not comply with all or any of the requirements in regulation 41, but that is subject to any other requirements that he or she thinks fit; and

"(b) authorise the dispensing of prescription medicines in a manner that does not comply with all or any of the requirements in regulation 42, but that is subject to any other requirements that he or she thinks fit.

"(2) A form of prescription that may be authorised under subclause (1)(a) includes, but is not limited to, an electronic form of prescription."

**21 Prescriptions for prescription medicines not required in certain cases**

(1) Regulation 44(f) is amended by omitting "veterinary surgeon" and substituting "veterinarian".

(2) Regulation 44 is amended by revoking paragraph (h) and substituting the following paragraph:

"(h) a patient under the care of an authorised prescriber, provided that—

"(i) the medicine is administered by a person who has been instructed by the authorised prescriber (either verbally or in writing) to do so; and

"(ii) the person administering the medicine records the administration in the patient's medical record; and

"(iii) the authorised prescriber records the instruction under subparagraph (i) in the patient's medical record; or".

(3) Regulation 44(m) is amended by omitting "(except a dentist)".

(4) Regulation 44(n) is amended by omitting "veterinary surgeon" in each place where it appears and substituting in each case "veterinarian".

**22 New regulations 51 to 53 substituted**

Regulations 51 to 54 are revoked and the following regulations substituted:

"**51 Interpretation**

In this Part, unless the context otherwise requires, **data sheet**, in relation to a medicine, means a document containing information relating to the safe and effective use of the medicine.

"**52 Approval of data sheets for new medicines**

"(1) A person who applies under section 20 or 23 of the Act for the consent of the Minister to the distribution of a prescription medicine or restricted medicine (an **applicant**) must include with his or her application a proposed data sheet for the medicine in such form as may be required by guidelines issued from time to time by the Ministry of Health.

"(2) On receipt of the proposed data sheet, the Minister may—

"(a) approve the data sheet; or

"(b) require the data sheet to be resubmitted for approval after such changes have been made to it as the Minister considers appropriate.

"(3) Within 10 days after the Minister's consent to the distribution of a prescription medicine or restricted medicine has been notified in the *Gazette*, the applicant must send to the Director-General for publication an electronic copy of the approved data sheet for that medicine.

"**53 Approval of data sheets for changed medicines**

"(1) An importer or manufacturer who gives to the Director-General a notice under section 24(1) of the Act describing a material change to a prescription medicine or restricted medicine must include with the notice a proposed revised data sheet for the medicine in such form as may be required by guidelines issued from time to time by the Ministry of Health if a revision of the data sheet is necessary or desirable because of the material change.

"(2) On receipt of the proposed revised data sheet, the Director-General may—

"(a) approve the revised data sheet; or

"(b) require the revised data sheet to be resubmitted for approval after such changes have been made to it as the Director-General considers appropriate.

"(3) After the Director-General has approved a revised data sheet, the Director-General must give written notice of the approval to the importer or manufacturer.

"(4) Within 10 days after receiving a notice of approval under subclause (3), the importer or manufacturer must send to the Director-General for publication an electronic copy of the approved revised data sheet."

**23 New regulation 58A inserted**

The following regulation is inserted above regulation 59:

"**58A Substances that are not medicines or related products for purposes of Act**

"(1) The following classes of substances are not medicines or related products for the purposes of the Act:

"(a) dentifrice products, provided that—

"(i) the dentifrice product does not contain a medicine specified in Schedule 1; and

"(ii) the dentifrice product is not claimed to be for use in relation to any therapeutic purpose other than 1 or both of the following:

"(A) preventing dental decay:

"(B) improving oral hygiene:

"(b) anti-dandruff hair products, provided that—

"(i) the hair product does not contain a medicine specified in Schedule 1; and

"(ii) the hair product is not claimed to be for use in relation to any therapeutic purpose except controlling dandruff; and

"(iii) the hair product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the scalp and not through any other process:

"(c) anti-acne skin care products, provided that—

"(i) the skin care product does not contain a medicine specified in Schedule 1; and

"(ii) the skin care product is not claimed to be for use in relation to any therapeutic purpose except preventing acne; and

"(iii) the skin care product is claimed to be effective through cleansing, moisturising, exfoliating, or drying the skin and not through any other process:

"(d) barrier cream products, provided that—

"(i) the barrier cream product does not contain a medicine specified in Schedule 1; and

"(ii) the barrier cream product is not claimed to be for use in relation to any therapeutic purpose except preventing nappy rash; and

"(iii) the barrier cream product is claimed to be effective through providing a barrier to the transmission of moisture and not through any other process:

"(e) anti-bacterial skin products, provided that—

"(i) the product does not contain a medicine specified in Schedule 1; and

"(ii) the product is not claimed to be for use in relation to any therapeutic purpose except preventing the spread of bacteria (but not a named bacterium); and

"(iii) the product is not presented as being for use in connection with—

"(A) any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or

"(B) either of the procedures specified in subclause (2); and

"(iv) the product is not recommended for use in connection with the provision of health services (as defined in section 2 of the Health and Disability Commissioner Act 1994).

"(2) The procedures referred to in subclause (1)(e)(iii)(B) are—

"(a) piercing the skin or mucous membrane for any purpose; and

"(b) venipuncture, or the delivery of an injection."

**24 New regulation 59 substituted**

Regulation 59 is revoked and the following regulation substituted:

"**59 General sale medicines may be sold by vending machine**

"(1) The Director-General may, by notice in the *Gazette*,—

"(a) approve the sale of a general sale medicine by means of a vending machine:

"(b) specify any conditions to which an approval under paragraph (a) is subject:

"(c) withdraw an approval given under paragraph (a):

"(d) vary or revoke any conditions specified under paragraph (b), or specify additional conditions, to which an approval under paragraph (a) is subject.

"(2) A notice given under subclause (1) takes effect on the day after the date of notification."

**25 Offences**

(1) Regulation 64(1)(a) is amended by omitting "39(1), 39(2), 39(3), 39(4), 39(5), 39(7), 39(8)" and substituting "39, 39A(1)".

(2) Regulation 64(1)(c) is amended by omitting "52(1), 52(2), 52(5)" and substituting "52(3), 53(4)".

**26 New regulation 65A inserted**

The following regulation is inserted after regulation 65:

"**65A Transitional provision arising from enactment of Medicines Amendment Regulations 2011**

"(1) Until 1 February 2012, it is sufficient compliance with the advertising requirements of regulations 8 and 11 to comply with regulations 8 and 11 as in force immediately before 1 August 2011.

"(2) For medicines and related products manufactured or imported before 1 September 2012, it is sufficient compliance with the labelling requirements of regulations 13 to 16, 19, 22, 23, and 37 to comply with regulations 13 to 16, 19, 20, 22, 23, and 37 as in force immediately before 1 August 2011."

**27 New Schedule 1 substituted**

Schedule 1 is revoked and the Schedule 1 set out in the Schedule of these regulations substituted.

**28 Form 1B of Schedule 2 amended**

Form 1B of Schedule 2 is amended by omitting "section 2 of the Property Law Act 1952" and substituting "section 4 of the Property Law Act 2007".

**29 Schedule 3 revoked**

Schedule 3 is revoked.

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Clerk of the Executive Council.

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Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette*:
These regulations are administered by the Ministry of Health.

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PCO 14906/10.0
Drafted by Leah Pickup

**IN CONFIDENCE**

# Medicines (Standing Order) Amendment Regulations 2011

Governor-General

## Order in Council

At Wellington this day of 2011

Present:
in Council

Pursuant to section 105 of the Medicines Act 1981, His Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations and bodies appearing to the Minister to be representative of persons likely to be substantially affected, and acting on the advice and with the consent of the Executive Council, makes the following regulations.

## Contents

## Regulations

**1 Title**

These regulations are the Medicines (Standing Order) Amendment Regulations 2011.

**2 Commencement**

These regulations come into force on 1 August 2011.

**3 Principal regulations amended**

These regulations amend the Medicines (Standing Order) Regulations 2002.

**4 Interpretation**

Regulation 3(1) is amended by inserting the following definition in its appropriate alphabetical order:

"**countersigning** means the issuer signing the charted treatment of a patient to whom medicine has been administered or supplied under a standing order

**5 What standing order must contain**

Regulation 5 is amended by revoking paragraph (j) and substituting the following paragraphs:

"(j) specify whether countersigning is required; and

"(ja) if countersigning is required, specify—

"(i) the period within which the issuer must countersign the charted treatment; and

"(ii) any other requirements for countersigning that the issuer considers appropriate; and

**6 New regulation 6A inserted**

The following regulation is inserted after regulation 6:

"**6A Periodic audit of charted treatments in certain cases**

If a standing order does not require the countersigning of charted treatments, or requires countersigning less frequently than once each month, the issuer must, at least once each month, audit a sample of the charted treatments of patients to whom medicines have been administered or supplied under the standing order.

**7 Obligations of issuer**

Regulation 8 is revoked and the following regulation substituted:

"**8 Functions of issuer**

The issuer has the following functions:

"(a) to ensure that—

"(i) the standing order clearly sets out the expectations of the parties; and

"(ii) the provisions of regulations 5 to 7 are complied with; and

"(iii) if countersigning is required, he or she countersigns the charted treatment within the period specified in the standing order, and in accordance with any other requirements for countersigning specified in the standing order; and

"(iv) in addition to the audit required by regulation 6A and the review required by regulation 7, there is a process in place for monitoring and reviewing the correct operation of the standing order and, in particular, any adverse incidents that occur; and

"(v) the standing order is made available to every person permitted to supply or administer a medicine under the standing order, an employer of any practitioner or practitioner who is not an issuer, any person affected by the standing order, and, on request to the Director-General or any person authorised by the Director-General, any member of the public.

"(b) to impose any requirements for countersigning in the standing order that he or she considers appropriate.

**8 New Schedule substituted**

Schedule 1 is revoked and the Schedule set out in the Schedule of these regulations is substituted.

**9 Transitional provision**

Regulations 4 to 7 do not apply to standing orders issued before the commencement of these regulations, and the principal regulations continue to apply to those standing orders as if these regulations had not been made.

## Schedule

r 8

## New Schedule substituted

## Schedule

r 3(1)

## Registration authorities

Chiropractic Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Dental Council (established by section 114(2) of the Health Practitioners Competence Assurance Act 2003)

Dietitians Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Medical Council of New Zealand (being the Council continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Medical Sciences Council of New Zealand (formerly known as the Medical Laboratory Science Board which was the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Medical Radiation Technologists Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Midwifery Council (established by section 114(3) of the Health Practitioners Competence Assurance Act 2003)

Schedule —*continued*

Nursing Council of New Zealand (being the Council continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Occupational Therapy Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Optometrists and Dispensing Opticians Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Osteopathic Council (established by section 114(4) of the Health Practitioners Competence Assurance Act 2003)

Pharmacy Council (established by section 114(5) of the Health Practitioners Competence Assurance Act 2003)

Physiotherapy Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Podiatrists Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Psychologists Board (being the Board continued by section 114(1) of the Health Practitioners Competence Assurance Act 2003)

Psychotherapists Board (established by the Health Practitioners Competence Assurance (Designation of Psychotherapy Services as Health Profession) Order 2007)

Clerk of the Executive Council.

## Explanatory note

*This note is not part of the regulations, but is intended to indicate their general effect.*

These regulations come into force on 1 August 2011.

These regulations amend the Medicines (Standing Order) Regulations 2002, which set minimum requirements for the content, development, and use of standing orders. The amendments—

- require a standing order to specify whether countersigning of a charted treatment is required and, if so, the requirements for countersigning; and
- provide that, if countersigning is not required, or is required less frequently than once each month, the issuer must carry out a monthly audit of a sample of charted treatments; and
- substitute a new schedule with an updated list of registration authorities, consequential on the enactment of the Health Practitioners Competence Assurance Act 2003.

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Issued under the authority of the Acts and Regulations Publication Act 1989
Date of notification in *Gazette*:
These regulations are administered by the Ministry of Health.

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Document 5

MINISTRY OF HEALTH
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Ministry of Health
21 DEC 2011
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**Health Report number: 20111364**

Action required by: **routine**

File number: **AD10-29-2**

**To: Hon Tony Ryall (Minister of Health)**

# Extending the Period of Supply for Prescription Medicines – Report Back

## Executive summary

As part of the 2011 Medicines Regulations amendments, the Ministry proposed extending the period of supply for prescription medicines to 12 months for oral contraceptives (currently six months) and six months for any other prescription medicines (currently three months). The intent was to remove the inconvenience and financial cost (GP fee of approximately $16) to patients of obtaining a prescription for medication taken on a long-term basis for a stabilised condition when there is no need for a GP or nurse consultation.

This proposal to extend the period of supply could be implemented with a single pharmaceutical co-payment per prescription item (current practice), which would impact on the DHB pharmaceutical budget, or with two co-payments per prescription item (one for each dispensing of three months supply or six months for oral contraceptives), which would not impact on the pharmaceutical budget.

Regardless of how the proposal is implemented the cost of the pharmacy software modifications is significant i.e. $720,000 to $935,000 (combined software vendor and Ministry costs). In the Ministry's view, the savings to each individual patient of extending the period of supply, approximately $16 per six months, do not justify the software implementation costs, and the uncertain, but substantial, impact on the Community Pharmaceutical Budget.

## The Ministry recommends that you:

a) **Note** that the Ministry does not consider the savings for individual patients justify the significant implementation costs associated with this proposal — Yes / No

b) **Agree** that the proposal to extend the period of supply for prescription medicines does not proceed. — Yes / No

Jackie Fawcett
**Acting Deputy Director-General**
**Policy Business Unit**

**Minister's Signature:**

**Date:**

## Ministry of Health Contacts:

| | | | |
|---|---|---|---|
| Oliver Poppelwell<br>Manager, Sector and Services Policy | | Sharon Woollaston<br>Senior Policy Analyst | |
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MINISTRY OF HEALTH
MANATŪ HAUORA



# Advice

## Background

1. As part of the 2011 Medicines Regulations amendments the Ministry proposed extending the period of supply for prescription medicines. In June 2011, this amendment was put on hold pending further advice on the fiscal and software implications.

2. The proposal was to allow prescribers, at their discretion, to issue a 12 month prescription (currently six months) for an oral contraceptive, and a six month prescription (currently three months) for any other prescription medicine (though not drugs controlled under the Misuse of Drugs Act 1975). The intent of the proposal was to remove the inconvenience and financial cost (GP fee of approximately $16) to patients of obtaining a prescription for medication taken on a long-term basis, where there is no need for a nurse or GP consultation.

3. To address issues of wastage and safety implementation of this proposal would comply with the current dispensing rules: a maximum of six months supply of oral contraceptives to be dispensed at one time and; a maximum of three months supply of any other prescription medicine. This would mean that each prescription for an extended period of supply would require two separate dispensings from the pharmacy.

4. Earlier this year, the Ministry sought feedback on the proposal from the New Zealand Medical Association, the Royal College of GPs and the GP Leaders Forum. Two of the three organisations expressed concern about the proposal, primarily that it would intensify pressure on GPs to issue scripts for longer periods of time than is clinically safe or warranted. The GP Leaders Forum was generally supportive of the proposal but considered prescriber discretion to be essential.

### Impact of extending the period of supply on the DHB pharmaceutical budget

5. At present, patients make one co-payment per prescription item, regardless of the period of supply and regardless of the number of repeat dispensings on the prescription. If patients move to six month prescriptions (12 months for oral contraceptives) with a single co-payment per prescription item PHARMAC has estimated that pharmaceutical co-payments will be reduced by $10 to $12 million per annum. PHARMAC's estimate is based on all patients who received three monthly prescriptions over four consecutive quarters of a year moving onto six monthly prescriptions.

6. The Ministry's view is that the impact on the DHB pharmaceutical budget would be significantly less than $10 to $12 million. The Ministry does not consider that all patients who are currently on three month prescriptions for medication taken on a long-term basis would be suitable to move to six month prescriptions. For example, patients who are currently seen by the doctor or nurse every three months to monitor their clinical progress and/or to ensure they are managing their conditions appropriately would not be issued six month prescriptions. The actual loss of patient co-payments is very difficult to quantify. It is likely to vary markedly between regions due to demographics and between general practices due to doctor preference and practice.

### Impact of extending the period of supply on patients

7. The benefit for individual patients would be saving the approximately $16 fee that is currently paid for a prescription when no GP or nurse consultation is required (GP charges for this service range from $10 to over $20). If the period of supply change was implemented with a single co-payment option the savings to patients would be greater ie, an additional $3 per prescription item (for patients enrolled with PHOs). For example, if the patient had a

prescription for one item the saving would be $19 ($16 GP fee + $3 co-payment at second dispensing) per six months: if two prescription items, the saving would be $22 per six months.

8. Based on first and second quarter 2011 data on the number of prescriptions and the number of dispensed items, the Ministry estimates that extending the period of supply could produce a $16 million total saving to patients per annum. Note this figure is based on a number of assumptions and should be treated as indicative only.

**Impact of extending the period of supply on pharmacy software systems**

9. There are significant pharmaceutical software changes required to implement the extended period of supply across all the implementation options. The Ministry has obtained high-level costing and time-frame estimates from the pharmaceutical software vendors. Detailed costings would require significant input from the vendors at a cost to the Ministry. The estimated cost for software vendors has a range of $570,000 to $650,000 with an implementation timeframe of 18 to 24 months. The fiscal impact for the Ministry to modify our systems and to project manage the software vendor changes has a range of $100,000 to $350,000.

**Advice**

10. The Ministry has considered two options for implementing an extended period of supply (see table below). The assessment criteria are:

    - whether it achieves the policy intent of the proposal
    - impact on the DHB pharmaceutical budget
    - impact on the pharmacy software systems
    - consistency with current co-payment policy and implications for related policies/initiatives (such as e-prescribing projects, reducing pressure on the DHB pharmaceutical budgets).

**Table 1: Options for extending the period of supply** (assumes two dispensings of three months at a time)

| | Option | Impact |
|---|---|---|
| 1 | Extend the period of supply with $3 co-payment at the first dispensing and no co-payment at subsequent repeat dispensings | • Patients would save on average $16 in GP fees per six months and $3 on pharmaceutical co-payments per prescription item per six months<br>• PHARMAC estimates pharmaceutical co-payments will be reduced by $10 to $12 million per annum.<br>• Significant pharmacy software modifications required - $720,000 to $935,000 (combined software vendor and Ministry costs)<br>• Consistent with the current patient co-payment policy of a single contribution per item per prescription regardless of the number of repeat dispensings. |

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MANATŪ HAUORA



| | | |
|---|---|---|
| 2 | Extend the period of supply with $3 co-payment at the first dispensing and $3 co-payment at the second dispensing | • Patients would save approximately $16 in GP fees per six months<br>• There would be no impact on DHB pharmaceutical budgets.<br>• Significant pharmacy software modifications required - $720,000 to $935,000 (combined software vendor and Ministry costs)<br>• Could be implemented in a way that was either consistent (second dispensing treated as an "initial" dispensing) or inconsistent (second dispensing treated as a "repeat" dispensing). Note: software vendors have advised there are additional risks and complications for the system if second dispensing is treated as an "initial" dispensing. |

11. The Ministry does not recommend implementing an extension to the period of supply in a way that would impact on the DHB pharmaceutical budget. Arguably the approximately $1billion DHB annual pharmaceutical budget should be able to absorb the impact of reduced patient co-payments resulting from extending the period of supply. However, this budget is under significant pressure.

12. Any option for implementing the proposal has significant costs for software vendors, and to a lesser degree, for the Ministry of Health's IT Services Group. In addition, the changes would absorb significant resources and have implications for other Ministry and health sector IT initiatives (eg e-prescribing). The Ministry has concluded that the benefits of the proposal for individual patients do not justify the significant IT implementation costs.

13. Although the Ministry considers the policy intent of extending the period of supply at the prescriber's discretion has merit it is recommended that no change is made at this time.

| **Minister's feedback on quality of report** | | | | |
|---|---|---|---|---|
| Very poor (1) | Poor (2) | Neutral (3) | Good (4) | Very Good (5) |

END.

Document 6

20 January 2012

«Name»
«Organisation»
«Address»

Dear «Salu»

**Period of supply for prescription medicines will not be extended**

Following a number of enquiries from sector groups, I am writing to clarify that the maximum period of supply for prescription medicines will not be changed at this time.

As part of the 2011 Medicines Regulations amendments, the Ministry proposed extending the period of supply for prescription medicines to 12 months for oral contraceptives (currently six months) and six months for any other prescription medicines (currently three months). The intent was to remove the inconvenience and financial cost to patients of obtaining a prescription for medication taken on a long-term basis when there is no need for a GP or nurse consultation.

The Ministry has undertaken further analysis of the proposal and reviewed a number of options for implementation. An extension to the period of supply would create administrative complexity and significant IT system costs. In addition, the changes would absorb significant resources and have implications for other Ministry and health sector IT initiatives (eg, e-prescribing).

The Minister of Health has agreed that the benefits of the proposal for individual patients do not justify the significant costs at this stage. Accordingly, the period of supply limits set out in 39A of the Medicines Regulations 1984 will not be changed.

I am aware of the interest that this proposal has generated within the sector. I would be grateful if you could inform your colleagues and, where applicable, membership group of the decision not to extend the period of supply.

Yours sincerely

David Wood
**Acting Deputy Director-General**
**Policy**

Document 6A

| Name | Organisation | Address | Salu |
|---|---|---|---|
| s 9(2)(a) | Toniq Limited | PO Box 8831<br>Riccarton<br>CHRISTCHURCH, 8440 | s 9(2)(a) |
| | HealthSoft NZ | PO Box 37 831<br>AUCKLAND | |
| | Dental Council | PO Box 10 448<br>The Terrace<br>WELLINGTON, 6143 | |
| | Medical Council of New Zealand | PO Box 11 649<br>WELLINGTON, 6142 | |
| | Midwifery Council | PO Box 24 448, Manners Street<br>WELLINGTON, 6142 | |
| | Nursing Council of New Zealand | PO Box 9644, Marion Square<br>WELLINGTON, 6141 | |
| | Optometrists and Dispensing Opticians Boards | PO Box 10 140<br>WELLINGTON, 6143 | |
| | Pharmacy Council | PO Box 25 137<br>WELLINGTON, 6146 | |
| | DHBNZ | PO Box 5535<br>WELLINGTON, 6145 | |
| | Nurse Practitioner Advisory Committee of New Zealand | PO Box 2128<br>WELLINGTON, 6140 | |
| | Safe Medication Management Programme | Hutt Valley District Health Board<br>Private Bag 31 907<br>LOWER HUTT, 5040 | |

| | | | |
|---|---|---|---|
| s 9(2)(a) | College of Nurses, Aotearoa (NZ) Inc | PO Box 1258<br>PALMERSTON NORTH, 4440 | s 9(2)(a) |
| | Family Planning | PO Box 11 515, Manners St<br>WELLINGTON, 6142 | |
| | NZ Defence Force | Private Bag 39997<br>WELLINGTON, 5045 | |
| | NZ Society of Anaesthetists | PO Box 10-691<br>WELLINGTON SOUTH, 6143 | |
| | New Zealand Dental Association | PO Box 28 084, Remuera<br>AUCKLAND, 1541 | |
| | New Zealand Association of Optometrists | PO Box 1978<br>WELLINGTON, 6140 | |
| | New Zealand Nurses Organisation | PO Box 2128<br>WELLINGTON, 6140 | |
| | Pharmacy Guild of New Zealand | PO Box 27 139<br>WELLINGTON , 6141 | |
| | The Royal New Zealand College of General Practitioners | PO Box 10 440<br>WELLINGTON, 6143 | |
| | General Practice New Zealand | PO Box 8082, The Terrace<br>WELLINGTON, 6143 | |
| | Canterbury Community Pharmacy Group | PO Box 31348<br>Milford<br>AUCKLAND, 0741 | |
| | Council of Medical Colleges New Zealand | PO Box 10 028<br>WELLINGTON , 6143 | |
| | Royal New Zealand College of | PO Box 10 611 | |

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|---|---|---|---|
| s 9(2)(a) | Obstetricians and Gynaecologists | WELLINGTON, 6143 | s 9(2)(a) |
| | Royal Australasian College of Physicians | PO Box 10 601, The Terrace<br>WELLINGTON | |
| | Royal Australian and New Zealand College of Psychiatrists | PO Box 10 669<br>WELLINGTON, 6143 | |
| | Royal Australian and New Zealand College of Radiologists | PO Box 10 424<br>WELLINGTON, 6143 | |
| | Royal Australian and New Zealand College of Ophthalmologists | PO Box 156<br>WELLINGTON | |
| | Australasian College for Emergency Medicine | PO Box 22 234<br>WELLINGTON, 6441 | |
| | New Zealand College of Anaesthetists | PO Box 25 506, Panama Street<br>WELLINGTON SOUTH, 6146 | |
| | College of Midwives | PO Box 21 106, Edgeware<br>CHRISTCHURCH, 8143 | |
| | Pegasus Health | PO Box 741<br>CHRISTCHURCH, 8140 | |
| | Pharmaceutical Society of New Zealand Inc | PO Box 11 640<br>WELLINGTON, 6142 | |
| | New Zealand Medical Association | PO Box 156<br>WELLINGTON, 6140 | |
| | New Zealand College of Mental Health Nurses (Inc) | PO Box 83 111, Edmonton Road<br>WAITAKERE, 0652 | |
| | South Island Nurse Executives | PO Box 36126 | |

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|---|---|---|---|
| s 9(2)(a) | | Merivale<br>CHRISTCHURCH | s 9(2)(a) |
| | New Zealand Hospital Pharmacists' Association (Inc) | PO Box 11640, Manners Street<br>WELLINGTON, 6142 | |
| | New Zealand National Board of the Royal Australasian College of Surgeons | PO Box 7451<br>Newtown<br>WELLINGTON, 6242 | |
| | Pharmacy Department of the Taranaki DHB | Private Bag 2016<br>NEW PLYMOUTH, 4342 | |
| | New Zealand Society of Hospital and Community Dentistry | PO Box 28084<br>Remuera<br>AUCKLAND, 1541 | |
| | Veterinary Council of New Zealand | PO Box 10 563<br>WELLINGTON, 6143 | |