Submission : Consultation on Proposed Amendments to Regulations under the Medicines Act 1981

MARCH 2010

Submission to:
Regulations under the Medicines Act 1981 Consultation
Policy Unit
Health and Disability Systems Strategy Directorate
Ministry of Health
PO Box 5013
Wellington 6145

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Executive Director - Professor Jenny Carryer, RN, PhD, FCNA (NZ), MNZM

This submission was prepared on behalf of the College of Nurses, Aotearoa (NZ) Inc.
The College is a professional body of New Zealand nurses from all regions and specialities. It provides a voice for the nursing profession and professional commentary on issues which affect nurses, and also the health of the whole community. Its aim is to support excellence in clinical practice, research and education and to work with consumers to influence health policy. The College is committed to the Treaty of Waitangi and the improvement of Maori health. This commitment is reflected in the bicultural structure of the organisation.

Submission Booklet: *Consultation on Proposed Amendments to Regulations under the Medicines Act 1981*

Submissions close on **26 March 2010.**

You do not have to answer all the questions or provide personal information if you do not want to.

This submission was completed by:		Dr Jill Wilkinson *(name)*
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Organisation:	*(if applicable)*	College of Nurses, Aotearoa
Position:	*(if applicable)*	On behalf of broader consultation with College members

Are you submitting this as:
(Tick one box only in this section)

an individual (not on behalf of an organisation) ☐
on behalf of a group or organisation ☒

other *(please specify)*.....

Other *(please specify)*.....

Please send your submission to:

Regulations under the Medicines Act 1981 Consultation
Policy Unit
Health and Disability Systems Strategy Directorate
Ministry of Health
PO Box 5013
Wellington, 6145

Or

email: medregs@moh.govt.nz

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under the legislation of the Act, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☐ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Do you wish to receive a copy of the summary of submissions? Yes **X**☐ No ☐

Submission Questions

There are eight questions in total.

Question 1

Do you agree that fluoride dentifrices and anti-dandruff preparations should no longer be regulated as related products under the Medicines Act? If not, why not?

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No view expressed .....

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Question 2

Do you think compliance with the Cosmetic Products Group Standard provides adequate assurance about the safety of these products? If not, what alternative would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

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No view expressed .....

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Question 3

Are there any other types of products you consider should be excluded from regulation under the Medicines Act? If so, why should they be excluded and how should they be regulated instead? What would be the impact of excluding these products?

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No view expressed .....

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Question 4

Do you support each of the proposed changes to the labelling requirements? If not, why not? What alternative changes would you prefer to see? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

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No view expressed .....

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Question 5

Are there other changes you consider should be made to labelling requirements for medicines and related products? Please detail the changes, your reasons for supporting those changes and the impacts of the changes you are suggesting.

No view expressed.....

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Question 6

Do you support the proposed changes to advertising requirements? If not, why not?

No view expressed.....

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Question 7

Are there other changes you consider should be made to the advertising requirements? Please detail the changes, give reasons for supporting those changes and describe the impacts of the changes you are suggesting.

No view expressed.....

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Question 8

Do you support the proposed amendments to regulation 43, coupled with the development of clear criteria and standard requirements for the issue of waivers, as a way to enable electronic transmission of prescriptions to proceed in the short term, until more extensive provisions can be included in primary legislation? If not, why not? What alternative mechanism would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

Yes. However, removing mention of the form of prescription and the need for waiver arrangements would require a change to the primary legislation and highlights the need for a proper re-write of the Medicines Act to bring it up to date.

Should this proposal go ahead as described, when conditions are being determined for when the Director-General will issue a waiver for electronic prescribing, all prescribers should be treated equally (designated and authorised).

Question 9

Do you agree that the Regulations should be amended so that prescribing rights for medical practitioners, dentists and midwives are aligned and are governed by the practitioner's scope of practice? If not, why not? What alternative changes (if any) would you suggest? Please detail the changes, give reasons for supporting those changes and describe the impacts of the changes you are suggesting.

Yes. We agree that a prescriber should be able to prescribe anything determined to be necessary provided it is within the prescriber's scope of practice.

Our expectation is (when the Medicines Act is finally updated) that nurse practitioners and any future nurse prescribers will be able to operate in the same fashion, that is not have to prescribe to a schedule of medicines, but rather to their scope of practice.

The statement of impact advanced by the Ministry in support of this amendment serves also as justification for nurse practitioner prescribers becoming authorised prescribers.

Question 10

Do you agree that dentists' prescribing timeframes should be extended and brought into line with other prescribers? If not, why not?

No view expressed.....
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Question 11

Do you agree that it would be appropriate to extend the limits on supply of prescription medicines in the proposed circumstances? If not, why not?

Yes.

Question 12

Are there other circumstances in which you think the period of supply should be extended beyond three months (or six months for an oral contraceptive)? Please specify the circumstances and the impact of the changes you are suggesting.

Yes. When the condition for which a medication is required is clinically stable and a self-care management plan is in place, (i.e with nurse case management in place) the cost of going to the GP for a repeat prescription would be reduced and medication 'lapses' would be reduced. Patients are inclined to view returning to the GP for a repeat prescription for something they take and use all the time as a costly and an unnecessary inconvenience.

Question 13

Do you support the requirement for the patient to be in New Zealand when prescription medicines are prescribed for them (or normally resident in New Zealand but temporarily overseas)? If not, what alternative measures (if any) do you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

No view expressed .....

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Question 14

Do you agree that substitution should be allowed under the proposed conditions? If not, why not and what alternative provision for substitution would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

No view expressed .....

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Question 15

Do you agree with the proposal to allow the issuer of a standing order to determine the circumstances in which countersigning of administration records is required? If not, why not? What alternative (if any) would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

Yes: The relaxation of countersigning requirements for standing orders as described does make sense. There is concern, however, about the growing use of standing orders amongst *all levels of experience* of registered nurses. There is an expectation that professional judgement will be exercised by the nurse as to whether or not the standing order is appropriate for a particular patient episode. Whilst supply and/or administration under a standing order is not prescribing, the decision to use a prescription medicine still requires a sound knowledge base. Specifying who may supply and/or administer treatments under the order with countersigning on each occasion and a robust system for review of practice seem important safeguards.

Ideally, standing orders should be used less often. A change to the current primary legislation to allow registered nurses to prescribe in a collaborative relationship with an authorised prescriber (nurse practitioner and medical practitioner) is a safer way to improve timely access to medicines than this quick-fix solution to relax the requirements for countersigning standing orders.

Question 16

Do you agree that unscheduled medicines should be able to be sold by vending machine? If not, why not?

The College of Nurses has only one comment to make regarding the sale of unscheduled medicines being sold in vending machines and that is that Nicotine Replacement Therapy should be able to be purchased from a vending machine and *not cigarettes*.

Question 17

What do you consider would be the impact on businesses of allowing unscheduled medicines to be sold by vending machine?

No view expressed .....

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Question 18

Are there any particular limitations you consider should be placed on vending machine operators? Please specify.

No view expressed.....
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Question 19

Do you support the proposed changes to the Regulations in relation to data sheets to bring them into line with current practice? If not, why not? What alternative would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

No view expressed.....
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Question 20

Do you agree that the content and format of data sheets should be specified in guidelines rather than in Regulations?

No view expressed.....
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Question 21

Do you support the above changes to definitions relating to pharmacy qualifications? If not, why not?

No view expressed.....
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Question 22

Are there any other definitions in regulation 2 that you think should be updated? Please provide details, give reasons why you think the changes are necessary and describe the impact of those changes.

No view expressed.....
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Question 23

Do you agree that regulation 6 should be revoked and a list of acceptable colouring substances incorporated into regulatory guidelines published on the Medsafe website? If not, why not? What alternative would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

No view expressed.....

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Question 24

Do you support the proposed changes to the information required to be included on a prescription? If not, why not? What alternative (if any) would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

No view expressed.....

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Question 25

Do you support the proposed changes to remove outdated requirements relating to the dispensing of prescriptions? If not, why not? What alternative (if any) would you suggest? Please detail your alternative, give reasons for supporting that alternative and describe the impacts of the alternative you are suggesting.

No view expressed.....

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