

## 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: NZ Self Medication Industry Association (name)

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Organisation: (if applicable) NZSMI

Position: (if applicable) Executive Director

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:

4 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  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?

*Yes. Please note that Part 1.1 discusses “fluoride toothpastes and mouthwashes”, the subsequent change proposal only specifies “dentifrices” (powders or pastes used for cleaning teeth). We understand that the intent is to deregulate fluoride mouthwashes as well and would prefer to see this clearly stated. The new regulation under 105(1)(i) would need to account for liquids such as mouthwashes and non-liquids such as toothpastes and powders, preferably in alignment with the Australian schedules.*

*With respect to anti-dandruff preparations there needs to be a general statement that actives that are unscheduled can be used in anti-dandruff preparations, eg Ketoconazole <1%*

### 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.

*YES*

### 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?

*Many other products should be excluded from regulation under the Medicines Act. Particularly products that are considered devices overseas but are expected to be registered as Related Products or even Medicines in New Zealand. Attempts to try and register these types of products are met with significant and often insurmountable regulatory hurdles as these type of products are not regulated in the same way overseas. This issue is compounded by cases of such products being marketed without any regulatory approval as the need to register them is unclear in the guidelines.*

*We suggested the following products are suitable for exclusion from the Medicines legislation:*

*Tooth whitening systems*

*Head lice treatments*

*Anti-dandruff shampoo with Ketoconazole <1%*

*Eye lubricants (that are used on the eyelid but not in the eye)*

*Anti acne products with salicylic acid  $\leq$  2% for prevention & control of acne (sold as cosmetic in Australia)*

*Topical rubs such as liniments*

*Throat lozenges that contain unscheduled ingredients registered and others are not.*

*Barrier creams to seal out wetness (eg as used to prevent rather than treat nappy rash). We note that currently some of these are registered as lower risk medicines)*

*Medicated soaps*

*Products at the device / medicine interface such as*

*pregnancy test kits*

*saline nasal sprays*

*spermicidal condoms.*

## **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.

YES

## **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.

*Ensure the definition of single dose units is comprehensive enough, eg Labelling of individually wrapped dose units such as transdermal patches, single dose tablets, lozenges or capsules and sachets*

*The change needs to make it clear that the sachets, foil, wrapper or pouch is NOT the primary label, the outer carton is.*

*TGO 69 does not require the batch and expiry date to be added to the label of an individually wrapped dosage unit that are in unsealed protective cover, it is only required for individually wrapped goods if the single dose is sealed into an individual sachet or blister. Adopting the same requirements in NZ allows for greater harmonisation of labelling.*

*Proposed non-sedating antihistamine warning. RASML does not have an equivalent warning. Adding this warning to the NZ requirements removes any prospect of future harmonisation. The requirement for a warning needs to be removed for non-sedating antihistamines and not replaced with an alternate warning.*

*Accept TGO 69 for Foil labelling of Safety containers, ie one set of text per 2 blister positions*

*Consider changing reg 15 so that the PDP does not have to contain the quantities of the actives on the PDP. This would allow harmonisation with UK labelling where PDP's include the names of all actives but the quantities are on the back label*

*Amend 22(3) to make it clear that words to the same effect can be used for "Warning-Prolonged or excessive use can be harmful. Do not give to children under 2 years of age except on medical advice.", eg no dose instructions under X years and "Do not exceed the stated dose" are accepted by evaluators without question*

*Amend Reg 15(4) to remove the limits on the size of the PDP being 1/3 of the label for a cylindrical container. This is especially onerous for small containers*

*The number of actives required to be listed on the PDP should be harmonised with Australia where products with more than 4 actives can be listed on the back label.*

*Remove the limits of the size of a sample pack being 1/3 the size of the smallest commercial pack. This is impossible for single dose products and unworkable for many others where small packs are marketed*

*Sample packs currently require the dose to be included on the printed label. This can be very difficult for products with multiple indications or doses. Allowance for a blank space for the prescriber to add the dose would solve this problem.*

*Consider the issue of website addresses being included on labelling. There seems to be some variation on how this is evaluated / approved. Clearer guidelines would be helpful*

*Currently there is no provision to include the name of a second, complimentary product on the labelling of the first product without it being considered advertising. This should be allowed where the 2 products are clearly complimentary to each other and aid consumer awareness and compliance, eg athletes foot creams and powders.*

*Transparent packaging should not be considered labelling. Wrapping a product in a clear, transparent wrap may be done for security or other reasons and provided it does not obscure any registered labelling should be allowed without recourse to Medsafe. This change will also align with TGO 69*

## **Question 6**

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

## **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.

*The proposed Ad code submitted to Medsafe by the NZSMI is far more detailed than this – comments have been made on the marked up version as attached*

*Excluded advertisements need to be expanded to include sponsorships, reminders, brand names, logo or pictures providing they do not include a therapeutic claim – care is needed to provide details without restricting future changes ie is a branded car or bus excluded if no claims are made?*

*The requirement that there is a warning statement about any known serious adverse effects, or contra-indications in a known group of people is not clear. Does this mean that the current NSAID and analgesic warnings are no longer required (Stomach ulcers, incorrect use) or is it assumed that “Always read the label” is sufficient?*

***The following is taken from the current regulations, comments are highlighted***

### **8 Advertisements for medicines**

- (1) Subject to regulation 11(2) of these regulations, every advertisement for a medicine, other than a label or a price list or branded POS and promotional items without therapeutic claims, shall include the following:
  - (a) A statement of the quantities of the active ingredients in the medicine: **As requested - Revoke except for mail order direct mail or internet marketing**
  - (b) A statement of the authorised uses of the medicine: **As requested, Confirm that this deleted as it is deemed to be included in the pack shot?**
  - (c) A statement of the appropriate precautions to be taken in the use of the medicine: **Except for excluded ads and Internet/direct mail advertising**

- (d) A statement of any contra-indications to the use of the medicine: **Except for excluded ads and Internet/direct mail advertising**
- (e) A statement of the known or likely poisonous effects of, or adverse reactions to, the medicine. **Except for excluded ads and Internet/direct mail advertising**

(2) Every medical advertisement that refers to an ingredient of a medicine by name shall state the appropriate designation of the ingredient. Confirm applies only to **Internet or direct mail order etc??**

(3) Subject to subclause (4) of this regulation, every advertisement for any prescription medicine, restricted medicine, or pharmacy-only medicine shall include, conspicuously printed (in the case of a printed advertisement) or clearly spoken (in the case of an oral advertisement), the following words: **Is this being revoked except for RX ?**

*Need to confirm that the mandatories listed above are all that will be required going forward, ie Always read the label. Use as directed. If symptoms persist ....”*

*Please confirm if a consolidated Medsafe code will be published, on the website, in the NZRGM?*

*Name and address of advertiser is in Act, S59. However it seems an exemption can be granted in the Regs to this requirement. Please confirm “Always read the label” is deemed to cover this requirement*

*Act 62 (1) d, allows regulations to be made as required. No comment on Professional recommendation or testimonial, both are in Act S58 so difficult to change – what is Medsafe’s position on this?*

### **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*

### **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.

*No Objection*

### **Question 10**

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

*Yes*

### **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.

*No Comment*

### **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.

*Yes*

### **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 Comment*

### **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.

*Not Applicable*

### **Question 16**

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

*Yes*

### **Question 17**

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

*Minimal*

### **Question 18**

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

*Consideration of storage conditions, stock control, expiry dates and security. The contact number for the vending machine supplier needs to be prominently displayed so that any and all issues are directed to them in the first instance*

### **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.

*Yes*

### **Question 20**

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

*Yes, provided any changes proposed are first subject to consultation with industry*

### **Question 21**

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

*Yes*

### **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.

*Yes*

### **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.

*Yes provided any changes proposed are first subject to consultation with industry.*

*Please provide a positive and negative list of colouring substances. A negative list shows applicants that a colour has already been considered and rejected.*

*Please consider removing Tartrazine from the negative list. This colour is currently allowed in food in NZ and is also allowed in Europe*

### **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.

*Yes*

### **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.

*Yes*

### **Additional Points for Consideration**

Reg.35 (4) states that “Every container used in the packaging of a medicine and made of glass or plastic shall comply with the tests for that type of container (if any) specified in the United States Pharmacopeia”

Please confirm if the USP alone is still appropriate here? Should other pharmacopeia be included?

#### **37. Safety Containers**

Is it time this was reviewed to ensure that the list of medicines in safety containers is appropriate?

The term “safety containers” is outdated, should this definition be updated? Eg a blister pack/platform. Within the definition of safety containers we should include “Containers having child resistant closures”

#### **Reg 45-Hawkers Licences**

Clarify that Licences are not required for GSL medicines and that Company licences rather than individual licences can be granted