Proposed Amendments to Regulations under the Medicines Act 1981
Report of the Analysis of Submissions and Final Decisions
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Introduction


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, 18 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 21 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 list of submissions is attached in Appendix One.

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) of the Medicines Act 1981 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. The majority of these submitters felt that the Environmental Risk Management Authority’s 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 20 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 Therapeutic Goods (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 the Medicines Act is amended.

**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 a non-prescription 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 non-prescription 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 retail 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), 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 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 no dosage instructions for children under two 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 (ie, a statement along the lines of ‘Although this medicine is unlikely to affect your ability to drive or operate machinery, a few people may be impaired and care should be taken’).

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, for example, from a paramedic or hospital emergency department, the medicine can be traced back to the original prescription. It may 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.

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.

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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.
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/healthcare 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 their 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 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\(^2\) 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.

\(^2\) The Researched Medicines Industry Association has changed its name to Medicines New Zealand.
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
- 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 a 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 and published.
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 responsible authorities 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 prescribed 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, these are broader concerns that relate to current policy under the HPCAA. Concerns were raised, for example, about the ability of pharmacists 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 opposed to five days’ supply plus five days’ repeat), as for all other authorised prescribers.

It is also proposed that provision be made for the Director-General of Health 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 12 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 12 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 DHBs, 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).

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<th>Change proposal 1.7: Restrict prescribing for patients who are not in New Zealand</th>
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<td>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.</td>
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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 six months, or aligning with Inland Revenue Department 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 electronic 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 (which is available on Medsafe’s website).

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<th>Change proposal 1.9: Amend the requirements for countersigning records of supply or administration of a medicine under a standing order</th>
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<td>It is proposed that the Medicines (Standing Order) Regulations 2002 be amended to require an authorised prescriber issuing a standing order(^3) to specify the arrangements for countersigning, including specifying:</td>
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\(^3\) Standing orders permit specified people (eg, paramedics) to administer and supply medicines under the overall authority of a prescriber, such as a doctor.
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 countersigning 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 per 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 of Health 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’s 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 will seek feedback on the draft guideline and will add new colouring substances when these have 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 percent 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 ‘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 five 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 do not have a permanent street address for their business and were uncomfortable providing a private address.

Outcome

It is intended to proceed as proposed and, in addition, make it a requirement for the physical street address (with an exemption for midwives who do not have a permanent business 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 where the information was not readily accessible (such as when a doctor is prescribing for a new patient after hours and does not have access to the patient’s National Health Index (NHI)). The Ministry of Health considers there are other ways to encourage the use of unique health practitioner and patient identifiers (such as through DHB contracts or as a data requirement for electronic transmission of prescriptions).

It is considered unnecessary to mandate a requirement for the weight of a child less than five years old to be on a prescription given that the Medical Council’s ‘Good Prescribing Practice’ statement 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 the Medicines Act and cannot be achieved through the planned amendments 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 the Medicines Act (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 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 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 the dose of medicine.
## Appendix One: List of Submissions

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization/Position</th>
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<tbody>
<tr>
<td>Dr Sharon L Kletchko</td>
<td>Nelson Marlborough DHB</td>
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<tr>
<td>Melville Killip</td>
<td>Biomed Ltd</td>
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<tr>
<td>Dr Alison Drewry</td>
<td>New Zealand Defence Force</td>
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<tr>
<td>Debbie Bassett-Clarke</td>
<td>Senior Lecturer, Faculty of Health and Environmental Science</td>
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<tr>
<td>Dr Robin Whyman</td>
<td>Accident Compensation Corporation</td>
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<td>M Mackenzie</td>
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<tr>
<td>Professor Robert M Love</td>
<td>Dental Council</td>
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<tr>
<td>Neil McDowall Stephen</td>
<td>Community Dental, Hutt Valley DHB</td>
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<tr>
<td>Alison Sherlock</td>
<td>Takapuna Grammar School</td>
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<td>William M Gaudie</td>
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<tr>
<td>Compass Health Wellington Trust</td>
<td>Starship Children’s Health</td>
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<tr>
<td>Janet Campbell</td>
<td>Chair, Nurse Practitioner Advisory Committee of New Zealand</td>
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<td>Helen Snell</td>
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<tr>
<td>Natalie Gauld</td>
<td>Midwifery Council of New Zealand</td>
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<tr>
<td>Sue Calvert</td>
<td>Sanofi-Aventis Pty Ltd</td>
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<td>Sean Duncan</td>
<td>BBG Fulfilment Ltd</td>
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<td>Bruce Gilbert</td>
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<tr>
<td>Dr Susan Shaw in consultation with: Prof Max Abbott, Assoc Prof Marion Jones, Dr Duncan Reid, Ms Naumai Smith, Dr Daniel Poratt and Ms Brenda Costa-Scorse</td>
<td>Faculty of Health and Environmental Sciences, Auckland University of Technology</td>
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<tr>
<td>Jan Adams</td>
<td>Albany Care Chemist Ltd</td>
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<td>Teresa Taylor</td>
<td>Pharmaco (NZ) Ltd</td>
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<tr>
<td>Mark Atkin</td>
<td>Fluoride Action Network NZ Inc</td>
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<td>Thuy Dang</td>
<td>Bayer Australia Ltd</td>
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<tr>
<td>Garth Wyllie</td>
<td>Cosmetic Toiletry and Fragrance Association of New Zealand Inc</td>
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<tr>
<td>Deborah Owen</td>
<td>Mylan New Zealand</td>
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<tr>
<td>Peter Pratt</td>
<td>Therapeutic Advertising Pre-vetting System</td>
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<tr>
<td>Kevin Sheehy</td>
<td>Researched Medicines Industry</td>
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<tr>
<td>Rob Ticehurst</td>
<td>Auckland City Hospital Pharmacy Department</td>
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<tr>
<td>Clare Kirk</td>
<td>Safe Medication Management Programme</td>
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<tr>
<td>David Mitchell</td>
<td>Pharmacy Partners Ltd</td>
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<tr>
<td>Jenny Carryer</td>
<td>College of Nurses, Aotearoa (NZ) Inc</td>
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<td>Tony Miller</td>
<td>Capital &amp; Coast DHB</td>
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<td>Family Planning</td>
<td>Family Planning</td>
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<td>Barbara Moore</td>
<td>Pharmacy Council</td>
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<td>Tim Roper</td>
<td>New Zealand Self-Medication Industry</td>
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<td>Philip Sussex</td>
<td>Nelson Marlborough DHB</td>
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<tr>
<td>Marilyn Crawley</td>
<td>Pharmacy and Therapeutics Committee, Waitemata DHB</td>
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<tr>
<td>Paul Barrett</td>
<td>Canterbury DHB</td>
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<tr>
<td>Matthew Brougham</td>
<td>PHARMAC</td>
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<tr>
<td>John Barnard</td>
<td>Waikato DHB</td>
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