Proposals to Amend Aspects of New Zealand's Medicines Law
Foreword

This discussion document seeks your input on proposals to amend aspects of New Zealand's medicines law. Medsafe has held preliminary discussions with some sector groups to obtain advice to inform the development of this document, but now seeks formal feedback from the wider sector.

This project is a component of Medsafe’s work on a proposed joint New Zealand Australia Agency to regulate therapeutic products. This document concentrates on parts of New Zealand’s existing medicines law that would not form part of any joint regulatory arrangement if the joint agency proposal is advanced.

However, it should be noted that even if the JTA proposal is not advanced, there is still likely to be an opportunity to make suitable amendments to update the existing medicines law.

I encourage you to give full consideration to the proposals contained in this paper and provide informed comment to help develop appropriate New Zealand-specific medicines legislation.

Susan Martindale
JTA Project Team Leader
Medsafe
November 2002
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Proposals to amend aspects of New Zealand’s Medicines Law
How to Make a Submission

Submissions should be received by 20 December 2002. If meeting this timeline would cause difficulties, please discuss this with the project team leader, Susan Martindale.

Where possible, your submission should contain relevant evidence to support your views. Please also indicate if you are making the submission on your own behalf or on behalf of an organisation.

Under the Official Information Act 1982, submissions may be publicly released. Any information that you do not wish to be made public should be sent separately and clearly marked CONFIDENTIAL, although such information will still be subject to the provisions of the Official Information Act 1982.

Addresses to send submissions, or to request further information, are:

<table>
<thead>
<tr>
<th>JTA Project Team Leader</th>
<th><a href="mailto:becci_slyfield@moh.govt.nz">becci_slyfield@moh.govt.nz</a></th>
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<tr>
<td>Medsafe</td>
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<tr>
<td>Ministry of Health</td>
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<tr>
<td>PO Box 5013</td>
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<tr>
<td>Wellington</td>
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<td><a href="mailto:susan_martindale@moh.govt.nz">susan_martindale@moh.govt.nz</a></td>
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This document is available on the following websites:

www.medsafe.govt.nz
www.moh.govt.nz

Further copies can also be obtained on request from the project team at the address given above.
Introduction

Proposed Joint New Zealand Australia Therapeutic Products Regulatory Agency

The New Zealand and Australian Governments have agreed in-principle to progress a proposal to establish a joint New Zealand Australia therapeutic products regulatory agency (JTA). In June 2002 a comprehensive discussion paper was released in New Zealand and Australia, detailing the JTA proposal and seeking public feedback (that paper can be accessed on the following website: www.jtaproject.com). The Government will make a decision on whether to proceed after considering a report from officials on the views of stakeholders and the details of the proposals.

It is proposed that the JTA would regulate therapeutic products in both countries - including medicines, medical devices and complementary healthcare products. The joint regulatory scheme would focus on ensuring the safety, quality and effectiveness of therapeutic products through a mix of pre- and post-market controls. It would not cover those aspects of medicines law that relate to activities occurring along the distribution chain for medicines (e.g. prescribing, dispensing and wholesaling activities). The regulation of such activities is the subject of this discussion paper and would be covered in New Zealand-specific medicines law.

What is New Zealand-Specific Medicines Law?

This discussion document seeks your input on proposed changes to New Zealand-specific medicines law. New Zealand’s medicines law is over twenty years old and it is important to note that even if the proposed JTA does not eventuate, there is still likely to be an opportunity to update New Zealand’s existing medicines law.

In general terms, the split between the law to be administered by the proposed JTA and New Zealand-specific medicines law can be represented as follows:

<table>
<thead>
<tr>
<th>Areas of medicines law proposed to be administered by the JTA</th>
<th>Areas of NZ-specific medicines law</th>
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<tr>
<td>• Law to regulate the market entry of therapeutic products via a product licensing system</td>
<td>• Law covering aspects of the distribution chain after manufacture of products. For example</td>
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<td>• Law covering a range of pre- and post-market requirements for therapeutic products, including:</td>
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<tr>
<td>➢ Setting standards</td>
<td>➢ Prescribing</td>
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<tr>
<td>➢ auditing and licensing of manufacturers and packers</td>
<td>➢ Dispensing &amp; labelling of dispensed products</td>
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<td>➢ post-market monitoring and testing of products</td>
<td>➢ Activity Licensing (e.g. Wholesale Licences)</td>
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<td>➢ enforcement activities, such as advertising controls</td>
<td>➢ Information / record keeping requirements</td>
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<td></td>
<td>➢ Medicines Control functions &amp; Misuse of Drugs Act issues</td>
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<tr>
<td></td>
<td>➢ Miscellaneous issues.</td>
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NB: other related New Zealand law will also still apply (e.g. proposed Health Practitioners Competence Assurance Bill)
Existing Medicines Law in New Zealand

The existing New Zealand law for medicines comprises a number of Acts and Regulations. This discussion document focuses primarily on the:

- Medicines Act 1981 & Medicines Regulations 1984

There is also some other related law that may be indirectly affected by the outcomes of this project. This law includes:

- Hazardous Substances and New Organisms Act 1996
- Agricultural Compounds and Veterinary Medicines Act 1997.

Scope of Change Envisaged by this Discussion Paper

It is envisaged that most of the existing New Zealand-specific medicines law will be rolled over into any new legislation enacted with minor, if any, change – especially if the current law is working well. The underlying thrust of this paper is to update New Zealand-specific medicines law where this is necessary and, where appropriate, to make the law more enabling so new developments can be readily implemented or further developed (e.g. robotic dispensing, electronic prescribing). It does not seek to initiate significant new policy reviews, consider significant policy issues being developed in other contexts, or revisit policy decisions recently implemented.

For example, the Health Practitioners Competence Assurance Bill (the HPCA Bill), currently before Parliament, would amend certain New Zealand-specific medicines law provisions. These amendments are therefore outside the scope of this discussion document. For a summary of the HPCA Bill see Appendix I.

Principles Underpinning the Proposed Amendments

In developing potential amendments to New Zealand-specific medicines law Medsafe has been guided by the following principles.

- There are potential risks associated with the use of therapeutic products. Medicines law must protect public health and safety first and foremost, but it should also endeavour to manage these risks without imposing excessive compliance costs on the sector or unduly restricting consumer choice.

- Legislative changes should be enabling where possible, so appropriate future developments (e.g. technological developments) can be readily incorporated down the track.

- If the current law is working well, it should not be changed unnecessarily.
The law should not be unnecessarily prescriptive or impose unnecessary administrative requirements.

Where possible, opportunities to consolidate or make the law more consistent should be taken.

Amendments should be consistent with the Code of Good Regulatory Practice

The law must ensure safe and effective prescribing, dispensing, and labelling practices.

The interfaces between medicines law and other relevant law need to be clearly defined – e.g. the Misuse of Drugs Act, the Agricultural Compounds and Veterinary Medicines Act, and the Hazardous Substances and New Organisms Act.

The law also needs to give effect to New Zealand’s international obligations – (for example, United Nation’s requirements to help prevent diversion of medicines for non-medical or non-scientific purposes).

Layout of this Paper

This discussion paper discusses the various issues under six main headings:

- Prescribing issues
- Dispensing & labelling issues
- Licensing issues
- Information requirements/record keeping issues
- Medicines Control & Misuse of Drugs Act issues
- Miscellaneous issues.

To prompt comment on the proposals in this document, Medsafe is asking a range of questions, which are in shaded boxes. We welcome your feedback in response to these questions, or other issues you wish to raise.
Prescribing Issues

**Issue: Clarity of Prescribing Rights**

It is important that the law is clear as to which health professionals are authorised to prescribe particular medicines. This issue has become more complex in recent years because new classes of prescribers have become authorised to prescribe certain medicines within their respective scopes of practice (e.g. nurses, midwives etc).

**Current Law**

Part 2 of the Medicines Act 1981 generally places restrictions and controls on dealings with medicines and medical devices. Prescribing is enabled within the Act under a series of exemptions for authorised prescribers (practitioners, registered midwives, designated prescribers) [s.25], pharmacists [s.26] and veterinarians and opticians [s.27]. The Medicines Regulations 1984 further set out the conditions under which the prescription of medicines can occur by medical practitioners, dentists, veterinary surgeons, and registered midwives [regulation 39]. Additionally, other regulations also exist which authorise specific prescribers to prescribe certain medicines – for example, nurse prescribing is covered by the Medicines (Designated Prescribers: Nurses Practising in Aged Care and Child Family Health) Regulations 2001.

Section 8 of the Misuse of Drugs Act 1975 also authorises some prescribers to prescribe controlled drugs (e.g. medical practitioners). The Act also empowers the Minister of Health to prohibit the prescribing of controlled drugs [s.23]. The Misuse of Drugs Regulations 1977 set out restrictions on, and requirements for, the prescription of controlled drugs [regulations 20, 21, 24, 29, 30, & 31].

**Discussion**

This paper does not discuss which health professions should be allowed to prescribe particular medicines. Such issues are considered by the Minister of Health’s New Prescribers Advisory Committee using the process outlined in figure 1 below. However, the paper does propose a new method for medicines law to clearly state:

- which health professionals are entitled to prescribe medicines
- what restrictions or exceptions relate to such prescribing rights (e.g. period of supply, emergency supply of prescription medicines, whether supervision is required etc)
- what types of medicine each specific prescriber can prescribe.

The issue of prescribing rights for health professionals needs to be considered in conjunction with the Ministry of Health’s work on the proposed Health Practitioners Competence Assurance Bill (HPCA Bill), which is currently before Parliament.

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1 NB: This issue is concerned with the legal right to prescribe and how that is expressed in the law and not the recognition of a prescription for the purpose of access to subsidies for medicines.
The HPCA Bill effectively proposes a new, uniform, framework for the regulation of the various types of health professionals. It proposes to establish registration authorities for each profession regulated under the Bill and these authorities will be responsible for, among other things, authorising scopes of practice for their registered health professionals. A ‘scope of practice’ refers to the range of services a practitioner is competent to provide and the parameters within which such services can be offered. Such scopes of practice will cover a range of issues - including appropriate prescribing rights for practitioners (at least, for those professions that are authorised to prescribe).

Consistent with this approach Medsafe is proposing that the Medicines Act only needs to contain a general provision empowering all “authorised prescribers” to prescribe any medicine that is scheduled in the Medicines Regulations. The definition of “authorised prescriber” would be specified in regulations made under the Act and would cover those prescribers currently authorised to prescribe medicines under existing Medicines Regulations 1984 (e.g. medical practitioners, dentists, registered midwives etc).²

This approach would not empower those professions who are currently not allowed to prescribe medicines to unilaterally give themselves the right to prescribe, or enable those who are allowed to prescribe to increase their existing prescribing rights. There are existing processes for such decisions (see Figure 1 below). However, for those health professionals allowed to prescribe (to various extents), their relevant registering authorities, established under the HPCA Bill (e.g. the Nursing Council for nurses), would then be responsible for developing, maintaining and publishing, prescribing scopes of practice appropriate for their members. Such registering authorities would also be responsible for audit functions and for disciplining members who breach the agreed prescribing scopes of practice. The registering authority for each profession that is authorised to prescribe medicines could then decide if its members needed different levels of prescribing rights according to different levels of skills and training etc.

Such an approach is consistent with the legislative scheme of the HPCA Bill. Under the HPCA Bill, each scope of practice established by each health professional authority will be published in the New Zealand Gazette and any amendment will need to be Gazetted. The content of each scope of practice will need to cover issues such as prescribing rights for each profession.

Like the Bill, further work on the specifics would be required to implement such a policy approach. For example, clearly defining the respective roles of various stakeholders and developing robust processes to disseminate information etc.

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² It should be noted that the Medicines (Designated Prescriber: Nurses Practising in Aged Care and Child Family Health) Regulations 2001 also empower nurses practising in the areas of aged care and child family health to prescribe certain prescription medicines.
A: Process for obtaining authority to prescribe (retain existing process)\(^3\)

Registering authority for a profession prepares a submission to the New Prescribers’ Advisory Committee (NPAC) → NPAC consider submission → advice to Minister of Health → Cabinet → Change to regulations made under Medicine Act 1981

B: Process for defining and specifying an authority to prescribe (proposed new framework)

- General empowering provision in Medicines Act 1981 for “authorised prescribers” to prescribe medicines
- Definition of “authorised prescriber” specified in Medicines Regulations
- If HPCA Bill is enacted, then the registering authorities for each profession will develop, maintain, and publish scopes of practice for their members (which will include prescribing rights for their members – e.g. which medicines can be prescribed within their scope(s) of practice, under what conditions etc).

NB: Such scopes of practice will be secondary to legislation. Professions will not be able to unilaterally increase their existing prescribing rights. This will require the normal policy development process by the Ministry of Health, in consultation with stakeholders, and appropriate legislative or regulatory amendment.

Question 1: Subject to the enactment of the HCPA Bill, do you agree that the lists of medicines that can be prescribed by each profession should be disseminated by the professional bodies rather than maintained as Schedules to the Medicines Act?

Issue: Dental Prescribing Rights

The Ministry of Health is currently communicating with a number of dental bodies\(^4\) about potential amendments to restrictions on the prescribing rights of dentists. The following issues are being considered:

- Dentists prescribing of medicines is currently limited to 5 days supply (with a possible repeat of 5 days to give a maximum of 10 days supply), which is markedly shorter that the time for other prescribing groups.
- Dentists can only prescribe medicines for “dental treatment” of patients under their care.
- If dentists prescribing time frames are extended, a related issue is whether the prescribed medicine will be subsidised or funded. Such decisions are detailed in the Pharmaceutical Schedule, maintained by PHARMAC. The Pharmaceutical Schedule

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\(^3\) For more detail on the process, please refer to the Ministry of Health website: www.moh.govt.nz

\(^4\) Including: the New Zealand Dental Association, the Dental Council of New Zealand, the New Zealand Society of Hospital and Community Dentistry, & the Australia & New Zealand Association of Oral and Maxillofacial Surgeons.
restricts the funding of some medicines to defined ‘specialists’, but does not recognise
dental specialists, and the associated extent of their clinical responsibility.

Current law
Regulation 39(4) of the Medicines Regulations imposes the 5 days supply (or 10 days supply
with a repeat) restriction on dentist prescribing. For subsidy purposes, such time frames are
effectively mirrored in Section A: General Rules, Part 3.3.1 of the Pharmaceutical Schedule.
Regulation 39(3) contains the restriction on prescribing for “dental treatment” only.

Discussion
Regulations governing prescribing by dentists were gazetted almost 20 years ago. Since that
time there have been changes in the practice of dentistry and the availability of medicines
useful in dental treatment. The groups of health professionals entitled to prescribe have also
increased over that time and the regulations governing the new prescriber groups are less
restrictive than those governing dentists.

The 5-day (or 10-day including repeat) supply limitation can make the management of some
long term conditions difficult. The Ministry has requested advice from dental bodies about
what they consider to be appropriate prescribing time restrictions, and for which medicines.
This will feed into policy development.

If the prescribing time limits in the Regulations are amended as described above, there may
be a case for also amending the subsidy time limits in the Pharmaceutical Schedule to be
consistent with any law change in dental prescribing rights. PHARMAC would of course
have to assess the implications of any potential change to the Pharmaceutical Schedule.

Dental bodies are concerned about the situations where a prescription medicine is prescribed
for dental treatment and may have an adverse effect that could be mitigated by another
medicine that is not normally prescribed for dental treatment in the narrow sense. A
restrictive interpretation of the regulation would effectively prohibit the dentist from
prescribing another medicine (e.g. to relieve a stomach condition caused by the initial
prescription) in situations when the dentist may be the most appropriate prescriber and has a
detailed case knowledge of the patient.

A balance needs to be reached between ensuring the law does not condone prescribing
practices that are outside the scope of the class of prescriber in question, but also is not being
unduly restrictive in cases where the prescriber is acting within their scope of practice. The
Ministry has asked dental bodies to work together to draft a document that sets out what they
consider ‘dental treatment only’ should mean. This will feed into the policy development
process and could lead to possible wording change to clarify Regulation 39(3) or the
development of appropriate guidelines to supplement interpretation of the regulation. It may
be that the “dental treatment” provision is not required if the HPCA Bill is enacted. The key
objective will be ensuring dentists are working and prescribing in accordance with their
scopes of practice developed by the dental registering authority.
Question 2: Do you agree that dentists’ prescribing timeframes should be extended and brought into line with other prescribers?

Question 3: Do you think the prescribing for ‘dental treatment only’ caveat is too restrictive on dentists? If so, how should ‘dental treatment’ be defined (if such a caveat is needed at all)?

**Issue: Internet Sales of Prescription Medicines**

Some stakeholders have expressed continuing concern about domestic sales of prescription medicines over the Internet in circumstances where there is inadequate medical supervision. For example, Regulation 44(g) authorises a prescription medicine to be sold or dispensed by a practitioner, registered midwife, veterinarian, or designated prescriber without prescription to a patient under his or her care. It could be argued that a patient who provided a brief medical history to a practitioner via an Internet form could be held to have been ‘under the practitioners care’. See also the discussion on electronic prescribing in the next section of the paper.

There is also concern about export sales over the Internet in situations where the medicines are being supplied to customers who are not authorised to possess prescription medicines by the regulatory authority of the destination country.

**Current law**

Regulation 39 (1) of the Medicines Regulations 1984 prohibits practitioners from prescribing a prescription medicine otherwise than to treat a patient under the prescriber’s care. Regulation 44C of the Medicines Regulations prohibits the export of a prescription medicine, unless it is under a prescription given by a practitioner, registered midwife, or designated prescriber. This provision is intended to limit the sale and supply of prescription medicines under the authority provided by section 33(b) of the Medicines Act.

**Discussion**

Stakeholders have generally advised Medsafe that the opportunity should be taken to ensure medicines law is ‘water-tight’ in respect of Internet sales of prescription medicines. Medsafe agrees and is proposing to confirm and clarify what is meant by the current requirement for the patient to be under the care of the prescriber in any new law passed.

Additionally, Medsafe is proposing to include provision in any New Zealand-specific Medicines law to prohibit the exportation of prescription medicines (including over the Internet) unless the exporter is licensed and the sale is consistent with the conditions of the licence (refer also to the wholesale licence discussion on page 19).

**Question 4:** Do you agree that Internet sales of prescription medicines should be prohibited, unless pursuant to a licence issued under the Medicines Act?
Issue: Electronic Prescribing

Electronic prescribing is also an emerging issue for New Zealand and other countries.

Current law

The Medicines Act does not specifically mention electronic prescribing as technology to allow this was not available when the Act was passed. The Electronic Transactions Act 2002 recently passed by Parliament aims to facilitate the use of electronic technology. However, regulations 41 & 42 (regarding the form of prescriptions and dispensing of prescription medicines) of the Medicines Regulations 1984 are exempted from the scope of the Act.

Discussion

Electronic prescribing could entail, for example, a prescriber sending an electronic copy of a prescription, for a named patient, to a pharmacist who could then dispense the medicine for the patient from the pharmacy. Electronic prescribing could also be used in a hospital setting as it is merely an alternative method of conveying a prescription from the prescriber to the dispenser.

HealthPAC is progressing some project work in this area. With appropriate procedures and safeguards, electronic prescribing could increase efficiency and decrease compliance costs and so is supported by some sector stakeholders. It could also confer other advantages, such as the prescriber being able to confirm that the medicine they prescribed was actually dispensed to their patient.

However, issues such as patient privacy and security also need to be considered. Some people have also expressed concern about inappropriate practices that could occur with electronic technology.

Although, further policy work is required on this issue, the Ministry of Health considers that new medicines law should enable electronic prescribing, provided appropriate safeguards are met. Guidelines or standards could be developed to determine when electronic prescribing is appropriate, and cover issues such as when a patient is ‘under a prescribers care’

The Medical Council of New Zealand, for example, has already issued guidelines for doctors using the Internet, which cover prescribing issues. The Guidelines should be read as a whole, but point 12 states that no doctor should prescribe medication to a patient unless the patient has had a face-to-face consultation with the doctor or another medical practitioner who can verify the physical data and identity of the patient. Such guidelines would provide a good basis for work in this area, which could be expanded to cover all prescribers.

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5 These are available on the Medical Council of New Zealand’s website www.mcnz.org.nz
**Question 5:** Do you agree that New Zealand’s medicines law should enable electronic prescribing?

**Question 6:** Under what circumstances should electronic prescribing be allowed? What are the risks and benefits, and what safeguards are needed (e.g. secure identification procedures)?

**Question 7:** What sorts of issues need to be covered in any definition or guidelines about what constitutes ‘being under the care’ of a prescriber?

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**Issue: Information Requirements for Prescriptions**

When prescribers issue a prescription, certain information is required by law to be recorded on the prescription. Different parties need such information for various reasons – for example, pharmacists need specific information about the medicine to be able to dispense it correctly, Ministry staff may need information for funding or policy purposes, and HealthPAC need information to process applicable payments/claims owed to providers etc.

**Current law**

Regulations 40 and 41 of the Medicines Regulations 1984 require written prescriptions (in most circumstances) and specify the form of prescriptions - including a list of specific requirements (eg, the address of the prescriber, some details of the patient, etc). Regulation 44 specifies the situations where a written prescription is not required.

If the medicine concerned is also a Controlled Drug, then Regulations 29 and 30 of the Misuse of Drugs Regulations 1977 also specify a list of requirements (many of which mirror the sort of information for prescription medicines that is required to be included on a prescription under Regulation 41 of the Medicines Regulations).

**Discussion**

An appropriate balance between safety and efficiency must be found. The Ministry of Health considers that the level of detail in the current law does not pose significant problems, although some amendments are required. It is proposed to roll over most of the current requirements regarding the information required on a prescription into any new law.

Specific information requirements proposed to be required under new law include:

- Appropriate prescriber identification information – registration number, full name of the prescriber (not just signature), address and contact details, and health professional group.
- Existing codes in the sector and existing specifications for claims data (e.g., for subsidies). In addition, codes could also be used on prescriptions to distinguish between different categories of prescribers and between different scopes of practice within a prescriber group.
- Appropriate patient identification information (e.g., NHI number, first name, middle initial, last name, date of birth, and address). While use of the NHI number is mandated through many contracts with prescribers, it is proposed that it should be a
legislative requirement providing all prescribers are able to access the numbers. This is not the case at the moment. It is proposed that the requirement for salutations such as Mr, Ms etc [Regulation 41(d)(1)] should not be incorporated into new legislation.

- Appropriate information about the medicine being prescribed (e.g. name, strength, dose form, dose, frequency of dose, total amount to be dispensed etc).
- A mechanism to flag when the prescription is for a young person. However, there is an anomaly in the specification of the age of young patients between the Medicines Regulations (under 13 years as per regulation 41(d)(ii)) and the Misuse of Drugs Regulations (under 12 years as per regulation 29(1)(f)). It is proposed to make the law consistent.

In some situations medicines are prescribed and dispensed in the same environment (e.g. in hospitals) and the patient is not given a hard copy of a prescription to take to a pharmacy. Hospitals have their own procedures for such situations – e.g. using in-patient charts to record information to comply with the law. However, the Ministry of Health would be interested in feedback as to whether the current law about the form and content of a prescription adequately covers all prescribing situations.

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<thead>
<tr>
<th>Question 8: Are there any aspects of the information requirements for prescriptions discussed above that you do not agree with?</th>
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<tr>
<td>Question 9: Are there other information requirements you think are necessary for prescriptions, or requirements in the existing law that are unnecessary and should not be rolled over?</td>
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<td>Question 11: Does the current law about the form of a prescription (including the regulation 44 exemptions from having written prescriptions) adequately cover all prescribing situations (e.g. prescribing in hospitals)?</td>
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<tr>
<td>Question 12: What age should be chosen to reconcile regulation 41(d)(ii) of the medicines Regulations and regulation 29(1)(f) of the Misuse of Drugs Regulations?</td>
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Issue: Veterinarians using Human Medicines

It is proposed that section 27 of the Medicines Act should be rolled over into new law, but the opportunity should be taken to improve the wording because it is currently too rigid.

Current law

Part 2 of the Medicines Act 1981 generally places restrictions and controls on dealings with medicines. Section 27 provides an exception for veterinarians to manufacture, sell, supply, or administer a medicine for the treatment of an animal.

Discussion

Veterinarians currently use many human medicines to treat animals, subject to appropriate safeguards and risk management provisions in law administered by the New Zealand Food Safety Authority (NZFSA). It is essential that an enabling mechanism is retained in any new medicines law to allow this to continue. The NZFSA considers the current enabling mechanism, section 27, needs to be modified. For example, the definition of “administer” in the Act is restricted “to a human being” and does not include animals.

Section 27 was also enacted before the most recent animal remedies legislation (the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997) was passed. This Act contains the legislative framework to control veterinarians using veterinary medicines on animals.

The New Zealand Food Safety Authority and Medsafe agree that the Medicines Act should recognise the ACVM Act as the most appropriate Act to regulate veterinarians’ use of medicines for animals – subject to maintaining the current requirement for appropriate consultation with the Director-General of Health for all applications to NZFSA to approve veterinary medicines containing active ingredients that are also used in prescription-only human medicines.

Question 13: Do you agree that the current section 27 of the Medicines Act 1981 should be retained, but amendments should clearly state that veterinarians can administer prescription medicines to animals?

Question 14: Do you agree that the ACVM Act is the most appropriate mechanism to regulate veterinarians’ use of human medicines in animals (subject to appropriate consultation with the Ministry of Health)?
Dispensing Issues

Issue: General Dispensing Law

Preliminary feedback from some sector stakeholders has indicated that there is general satisfaction with the dispensing requirements under current legislation - although some changes have been proposed.

Current law

Section 18 of the Medicines Act 1981 specifies the circumstances by which prescription, restricted and pharmacy-only medicines may be sold by retail. Section 26 authorises pharmacists to manufacture, pack, label, sell and supply any medicine in certain circumstances (e.g. pursuant to a prescription) and sets out when a pharmacist can sell or supply medicines that they compound to suit the needs of specific people.

Regulation 42 covers the dispensing of prescription medicines. Regulation 42(1) & (2) specify the type of people that are allowed to dispense (e.g. pharmacists, veterinary surgeons (or their agents in some instances), dispensary technicians, registered midwives). Regulation 42(3) then lists a set of requirements for dispensing prescription medicines.

Regulation 23 specifies the requirements for labels on containers of medicines sold by practitioners or pharmacists.

The Misuse of Drugs Act 1975 contains a provision empowering the Minister to prohibit the supply of controlled drugs [section 22]. The Misuse of Drugs Regulations 1977 set out the restrictions on supplying controlled drugs [regulations 22, 24 & 28].

Discussion

The Ministry of Health proposes to roll over the majority of current general dispensing law. Some amendments could be made to reflect technological developments. For example, the Regulation 42(3)(h) requirement that dispensers must stamp their pharmacy name and address, and the date, on the back of the prescription when issuing repeats could be modernised to take account of computer recording and printouts commonly used instead of stamping.

Initial stakeholder feedback has also emphasised that labelling requirements for dispensers under any new regulatory regime should be as non-prescriptive as possible – provided heath and safety considerations are satisfied. It should also be noted that labelling and receipt requirements could also be covered by contractual arrangements, should District Health Boards require further information to be supplied as part of dispensing practice.

6 It should be noted that the HPCA Bill proposes to repeal the Pharmacy Act 1970 and introduce a new regulatory regime to ensure the public have ready access to medicines in a safe environment. The Bill proposes to make a number of amendments to the Medicines Act and Regulations (e.g., it has provisions relating to the ownership of pharmacies, the definition of a pharmacy, licensing of pharmacies, pharmacy-related offences and penalties etc.). A copy of the Bill is available on the Ministry’s website: www.moh.govt.nz
Issue: Substitution of Medicines

Some stakeholders have argued that the current law is too restrictive on pharmacists who are competent to substitute, in appropriate circumstances, equivalent medicines, to those specified on a prescription by a prescriber. Central to this question is the issue of accountability for prescribing or for the substitution: should it be entirely on the prescriber or should the dispenser share some accountability? Currently, pharmacists can have in place a written agreement with individual prescribers to enable substitution of branded medicines.

Current law

Regulation 42(4) requires pharmacists to dispense medicines specified on a prescription if the prescriber has identified it by a trade name, manufacturer name etc, unless certain limited exceptions are met.

Discussion

Some stakeholders have suggested that the current wording in regulation 42(4) is too restrictive. This can cause problems, for example, when prescribers specify out-of-date brand names or discontinued medicines on the prescription, or prescribe medicines that that are not on the Pharmaceutical Schedule.

The pharmacist must seek the approval of the prescriber to dispense an equivalent medicine. The prescription then has to be returned to the prescriber for counter-signing unless the pharmacist has a substitution agreement with the prescriber.

Matters of convenience must be secondary to the primary imperative of ensuring public safety. Therefore, before any change is progressed in respect of substitution, consideration needs to be given to factors such as bio-equivalence, allergies to components of multi-source medicines, industry viewpoints, price concerns, accurately tracing brands for recalls etc.

However, Medsafe currently publishes a list of inter-changeable multi-source medicines (IMM). Some stakeholders argue that if pharmacists could substitute an appropriate subsidised IMM for a brand name medicine they could save the patient money and themselves administrative work. Additionally, prescribers could also direct the pharmacist to “not substitute” an interchangeable medicine for a specific brand name medicine in cases where they specifically want a particular brand to be prescribed.

Medsafe is currently examining the IMM list in the context of the JTA project, and so this approach to defining interchangeability may change. In the interim, Medsafe considers that New Zealand’s medicines law should enable regulations or codes of practice to be developed, after appropriate consultation with prescribers, pharmacists and other stakeholders, which set out when and where substitution is appropriate. One option is to develop/confirm a schedule.
of medicines that can be substituted, and/or guidelines specifying when it is appropriate to substitute medicines, and the processes required to be followed by each party. For instance, for any given set of circumstances:

- prescribers could clearly state “no substitution” on the prescription
- a pharmacist could be able to annotate a prescription and dispense another brand of a medicine after discussing the matter with the prescriber
- it may be appropriate for a pharmacist to substitute a generic IMM medicine without discussing the issue with the prescriber
- the consumer should be informed of the substitution.

Question 17: Do you agree that medicines legislation should enable regulations or guidelines to be developed so that pharmacists could substitute medicines in certain circumstances?

Question 18: If so, in what circumstances should this be allowed?

Issue: Standing Orders

Some stakeholders have sought clarification on when it is appropriate for authorised prescribers to issue Standing Orders – a written instruction by an authorised prescriber, which allows a delegate to administer a medicine in the prescribers absence. The particular issue of veterinarians issuing Standing Orders authorising non-veterinarians to administer human medicines to animals has also been raised.

Current law

Section 19 of the Medicines Act 1981 enables the making of regulations regarding the use of Standing Orders. Such regulations can include minimum requirements to ensure the safe and consistent use of Standing Orders.

Discussion

The Ministry of Health’s Sector Regulation group is working on draft regulations, proposing to establish minimum requirements that must be met when Standing Orders are issued by medical practitioners and dentists. Medsafe considers that this is the appropriate forum to consider the issuing of Standing Orders, and accordingly proposes to roll current law over consistent with this work.

Veterinarians are not covered by this work. The provisions of the Medicines Act are sufficiently broad to enable regulations to be made authorising veterinarians to issue Standing Orders which authorise non-veterinarians to administer a human medicine to an animal. However, the Ministry of Health and the New Zealand Food Safety Authority (NZFSA) consider that the issue of veterinarians issuing Standing Orders should be regulated under law administered by the NZFSA (the Agricultural Compounds and Veterinary Medicines Act 1997) - providing appropriate linkages between that Act and the Medicines Act are
developed and agreed. For example, a code of practice could be developed that veterinarians have to comply with when administering a human medicine to an animal.

**Question 19**: Do you agree that veterinarians’ use of Standing Orders for human medicines being used on animals should be regulated under the NZFSA administered law, with appropriate linkages to medicines law?

### Issue: Infected Persons Handling Medicines

The Ministry considers that Regulations 27 and 28 of the Medicines Regulations should be repealed because they are unduly restrictive. Regulation 26 could also be expanded.

**Current law**

Regulation 26 contains a generic requirement about those handling or coming into contact with medicines in the dispensing process to maintain their clothing and person in a “state of cleanliness”. Regulation 27 prohibits people with communicable diseases (within the meaning of the Health Act 1956), or who are carriers (within the meaning of that Act), or who are suffering from a condition causing a discharge of pus or exudate, to engage in or be employed in the sale, manufacture, packaging, labelling, storage, or supply for sale of medicines etc. Regulation 28 empowers the Medical Officer of Health, to serve written notice on any person who has been in contact with a person to whom regulation 27 applies to prohibit the person served from engaging or being employed in the sale of medicines etc.

**Discussion**

Medsafe is proposing to expand Regulation 26 to also require that any open lesions be appropriately covered. The Ministry considers Regulations 27 and 28 are unduly restrictive in proportion to the risk they were originally enacted to counteract. The transmission of infection through the dispensing of medicine is rarely reported. However, the Ministry considers that some restrictions are still warranted. For example, people who have an infectious disease readily transmissible by the faecal-oral route (e.g. hepatitis A) should be excluded from work during the period they are infectious as a precautionary measure.7

Medsafe will also be looking to review its *New Zealand Codes of Good Manufacturing Practice for the Manufacture and Distribution of Therapeutic Goods* to ensure they are consistent with any new medicines law. More detail can be included in these publications.

**Question 20**: Is it appropriate to expand Regulation 26 as outlined?

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7 It should also be noted that the proposed Public Health Bill, being developed by the Ministry of Health, has a provision allowing the Ministry of Health to restrict or attach conditions to employment for persons whose disease status poses a risk to others. This would apply to handlers of medicines, as any other occupation. It would also be a back-up to more specific law governing the worker in question.
Issue: New Developments Relating to Dispensing

New medicines law should enable uptake of appropriate developments in technology and best practice (e.g. robotic dispensing, or recognising new classes of dispensers) through the adoption of future Regulations or Codes of Practice.

Current law
Dispensing-related medicines law does not specifically mention robotic dispensing.

Discussion
Medsafe has been working with those developing and implementing robotic dispensing, (which is becoming a viable option for situations such as unit dose dispensing of medicines used in rest homes) to ensure that patient health and safety is not at risk.

Initial sector feedback indicated general agreement that any new medicines legislation should enable robotic dispensing in appropriate circumstances. However, thought needs to be given to issues such as where liability lies for dispensing errors. There are also technical issues to consider. For example some prescriptions may require doses of ½ tablets to be dispensed and the dispensing machinery may not be able to do this.

Some stakeholders have suggested extending dispensing rights to some new dispensing providers in specified circumstances– for example, public health staff (to allow the supply of prophylactic medicines directly to clients with infectious diseases).8

Question 22: Do you support enabling legislation to allow robotic dispensing in appropriate circumstances?

Question 23: In what circumstances do you think robotic dispensing would be appropriate? What safeguards would be needed?

Question 24: Should dispensing rights be extended to other health providers? If so who, and should there be restrictions on the medicines or the circumstances of their supply?

8 NB a proposed amendment to the medicines regulations regarding dispensing technicians dispensing rights is currently being progressed by the Ministry.
Licensing Issues

Issue: General Licensing Law not Covered by the Joint Agency Proposal

Manufacturers’, packers’ and product licences would be dealt with by the proposed joint agency and hence are outside the scope of this discussion paper9. However, several domestic licences are likely to remain in the New Zealand-specific legislation (e.g. wholesale and retail licences).10

Current law

The Medicines Act requires that medicine manufacturers, packers, and wholesalers are licensed [section 17 & 34]. Part 3 of the Act specifies provisions relating to the application for, granting of, effect of, duration of, display of, and register of licences [sections 50-55]. Part VIII of the Medicines Regulations [Regulations 45-49] provides details of the licensing regime including the application process, the form and conditions of licences and the surrender of licences. Regulation 48 sets out the licensing conditions applicable to the hawking of medicines. The Second Schedule to the Medicines Act specifies the application form for licences, which is broken down into sections for applications for manufacturing, packing, wholesale, retail, and hawking licences.

The provision of controlled drugs through licences is enabled under section 14 of the Misuse of Drugs Act. Other sections of this Act also permit dealing, possession or holding of controlled drugs pursuant to licences [eg, section 6]. Licences are held subject to conditions set out in the Misuse of Drugs Regulations. Regulation 3 relates to the application and issuing of controlled drug licences. Dealers’ licences are set out under regulations 4-6 and licences to possess controlled drugs are set out under Regulation 10. The position of private hospitals with respect to controlled drugs is dealt with under Regulation 15.

Discussion

The Ministry is proposing to roll over much of the current licensing legislation that will not be covered by the joint agency project - although some possible changes have been suggested by some stakeholders.

9 See JTA discussion paper for the proposed product licence regime for therapeutic products (pages 22-25). It is proposed that therapeutic products could only be imported/exported or supplied by, or with the approval of, the holder of a product licence issued by the proposed JTA.

10 The HPCA Bill proposes to amend provisions of the Medicines Act regarding Pharmacy licences. Such issues are not covered in this paper.
Wholesale licences

Medsafe considers that the Medicines Act should enable different categories of wholesale licence, which could be specified in regulations. Wholesalers could decide to apply for one or more of the specified categories of licence. The categories would include:

- Export only
- National distribution only (i.e. sell to pharmacies or other wholesalers in New Zealand)
- Both.

Hawker Licences

Medsafe is seeking feedback as to whether stakeholders consider that it is necessary for all individual hawkers to be licensed. An alternative would be for companies employing hawkers to be responsible for maintaining a record of all staff engaged in hawking activities, ensuring that these people had met the required competency standards, and maintaining a record of the medicines hawked by its sales force. Such companies already require a licence to wholesale medicines and are therefore subject to an annual audit. The obligations with respect to hawkers would be specified on the wholesale licence and compliance would be assessed during the annual audit. Those holding hawker licences would need to be employed by a New Zealand-registered entity as a condition of their licence. This is needed in circumstances such as the serving of documents etc.

Licences Authorising Controlled Drugs to be held by Organisations such as Research and Teaching Agencies

Any New Zealand-specific medicines legislation licensing regime will need to cover research and teaching organisations who seek permission to hold and use controlled drugs for specific purposes. However, there has not yet been in-depth consideration of issues such as:

- How can assurance be given that conditions of the licence are adhered to and the drugs are not used for purposes outside the scope of the licence?
- Where should the drugs be stored? Should they be in only one secure area within the institution? What assurances need to be given about the level of security and the number of people who have access to the drugs?

Medsafe is proposing to licence Heads of Departments of such organisations. A condition of the licence would be that the Head of Department is responsible for their staff complying with any conditions on the licences.

Import / Export Licences for Controlled Drugs

New Zealand has obligations under the United Nations international drug control framework, which aims to restrict the use of Controlled Drugs, some of which are used as medicines, to medical and scientific uses. New Zealand currently has licensing procedures in place to help restrict, and track, movements of Controlled Drugs to achieve this aim. Such licences would be retained in any New Zealand-specific medicines legislation.
Issue: Definition and Role of the Licensing Authority under the Medicines Act

Medsafe is proposing that the Director-General or her delegate becomes the sole licensing authority under New Zealand Medicines Law. This would require removal of references to the Medical Officer of Health (the current licensing authority for some purposes). The proposal is consistent with the direction being taken in the Health Practitioners Competence Assurance Bill, currently before Parliament, in which “licensing authority” is defined as the Director-General of Health, or her delegate for the licensing activities within the scope of the Bill.

Current law

Under the current definition of licensing authority in section 2, the Director-General is the licensing authority for manufacturers licences, while for wholesale, retail, and packing licences the licensing authority is defined as the Medical Officer of Health in the health district within which the medicines are proposed to be sold or packed. Section 50 of the Medicines Act requires applicants to submit licence applications to their closest Medical Officer of Health.

Likewise, applications for Controlled Drug licences can be made to the Director-General of Health on a form provided, or with the approval of the Medical Officer of Health, otherwise in writing [Regulation 3]. In practice all Controlled Drug licence applications are processed by Medsafe. Medsafe also keeps a register containing the particulars of each controlled drug licence.

Regulation 31 of the Medicines Regulations empowers the Medical Officer of Health to serve a written notice on an occupier or owner of a premise, if they consider the premise is such a condition that medicines may be exposed to contamination or taint, or may deteriorate or become dirty. The notice can prohibit the use of the premise for manufacture, storage, or packing medicines etc.

Discussion

The HPCA Bill proposes to remove reference to Medical Officers of Health from some of the licensing provisions in the current medicines law (for example Section 50, 53(1)). Medsafe considers that the New Zealand-specific elements of the Medicines Act and the Misuse of Drugs Act should require all licence applications to be sent directly to the Director-General of Health or her delegate for processing.

Likewise, Medsafe proposes that the Director-General of Health, or her delegate, should fulfil the functions of the Medical Officer of Health under the current Regulation 31.
Information Requirements/Record Keeping Issues

Issue: Accommodating New Developments and Documenting Processes

Since New Zealand’s current medicines law was introduced, there have been significant technological developments (e.g. electronic communication, record keeping). Overall, initial feedback from the sector is that there is general satisfaction with information and record keeping requirements under current legislation. However, there is a need to ‘modernise’ the law so ensure technological developments can be utilised – in particular the law should recognise the widespread use of computers for business administration.

Current law

Section 45 of the Medicines Act requires that persons involved in the manufacturing, packing, selling or supplying of any medicine must keep records and make these available on request to certain authorities. Part XI of the Medicines Regulations deals with records, including the keeping of medicine registers and records of prescription medicines and sales by retail, wholesale, or hawking [Regulations 54A-58]. Regulation 42(3)(l) outlines requirements for the retention of prescriptions by dispensers.

Specific regulations also deal with the requirement to retain prescriptions and keep appropriate records for Controlled Drugs [regulations 33-49A of the Misuse of Drugs Regulations].

Discussion

The following issues are raised for consideration.

Electronic Records and Controlled Drug Books

Misuse of Drugs law requires those authorised to hold and deal in Controlled Drugs to maintain a hard copy controlled drug register and prescription book - as opposed to an electronic form of record-keeping [regulation 37]. Most pharmacies currently use both systems. Written records allow errors and changes to be identified and tracked easily, but electronic registers may also have ‘audit trail’ components. Medsafe is requesting feedback as to whether the law should give those authorised to possess, handle, and deal in Controlled Drugs the option to use an appropriate computer record keeping system – for their own record-keeping purposes as well as for reporting, auditing obligations etc. Medsafe considers that such systems must be designed with certain basic safeguards (e.g. errors can be corrected but not deleted to enable an audit trail to be kept and hard copies are printed off where necessary etc).
Retention of Prescriptions

Regulation 42(3)(l)(i) of the Medicines Regulations regarding the retention of prescriptions, was inadvertently revoked in October 2001. The Director-General of Health issued a waiver to address the revocation, but this will be tidied up in any new law introduced.

Another issue is the responsibility for retaining prescription forms after claims have been lodged and processed by HealthPAC. Currently, pharmacies have to retain hard copies for medicines that are Controlled Drugs under the Misuse of Drugs Act and non-subsidised medicines prescriptions. However, HealthPAC has been storing the majority of hard copy scripts sent to them by pharmacies when they make their claims. Prescription medicine scripts are retained for 3 years after being dispensed, while Controlled Drug scripts are retained for 4 years. Whoever has responsibility for storing scripts, therefore, has a compliance cost to bear.

In the modern environment of electronic claiming, pharmacies send electronic records of prescriptions dispensed to HealthPAC. However, HealthPAC considers that the pharmacist should be responsible for retaining and storing all hard copies of scripts where this is necessary to meet legal requirements. (There is no requirement for prescription forms to be submitted to HealthPAC with payment claims, other than for audit and compliance purposes, which can be managed on a case-by-case basis).

Question 28: Are there parts of the current law regarding information requirements or record keeping that you consider need to be modernised – e.g. electronic record keeping allowed? Are there situations where this is not appropriate? Why is this?

Question 29: Who should be responsible for retaining and storing hard copies of prescriptions after HealthPAC has processed claims?

Medicines Control and Misuse of Drugs Act Issues

Issue: Penalty Provisions

The Medicines Act and Misuse of Drugs Act are both over twenty years old and the Ministry of Health considers that the penalty provisions for various offences to be included in the New Zealand specific legislation are out-dated and need reviewing.
The Medicines Act specifies a range of offences with associated penalties that range from $500 to $100,000, depending on the offence and whether an individual or body corporate is convicted of that offence. The offences can be broadly split into three categories:

1. General Offence penalty (set out in section 78), which has as potential penalties: 3 months imprisonment, or a fine not exceeding $500, or fine not exceeding $50 per day for a continuing offence
2. Listed minor offences, which have associated penalties of 6 months imprisonment or fines not exceeding $1000
3. Listed major offences, which have associated penalties of 6 months imprisonment, individuals fined up to $20,000, and body corporates fined up to $100,000.

Discussion

Medsafe considers that the penalties associated with categories 1 and 2 above need reviewing and that changes are likely to be necessary. Examples of offences and penalties in the Medicines Act include:

- Sections 17 and 18 relating to licensing of manufacturers, wholesalers, retailers, and packers of medicines
- Section 20 relating to the sale and supply of new medicines.

The HPCA Bill, currently before Parliament, proposes to increase the monetary penalties for sections 17 and 18 offences from $500 to $40,000.

Medsafe will consider other offences in New Zealand-specific medicines law (including those relating to the licensing of Controlled Drugs in the Misuse of Drugs Act) to ensure consistency with any changes made to the Medicines Act by the HPCA Bill.

Question 30: Are there any penalty provisions in the Medicines Act that you consider need reviewing?

Issue: Some Misuse of Drugs Issues

Some specific issues have been raised in relation to the Misuse of Drugs Act 1975.

Pharmacy Technicians

Medsafe is proposing to extend pharmacy technicians' dispensing rights to include Class C controlled drugs, while under the supervision of the pharmacist. To achieve this, amendments to section 8 of the Misuse of Drugs Act 1975 would be required.
Inconsistencies between Medicines Law and the Pharmaceutical Schedule

There are some inconsistencies between the Misuse of Drugs Regulations and the Pharmaceutical Schedule regarding the amounts of controlled drugs able to be prescribed, and timeframes. PHARMAC and Medsafe will be considering these issues.

Question 31: Do you wish to comment on the issues identified?

Miscellaneous Issues

Issue: General Feedback about New Zealand-Specific Medicines Law

Medsafe welcomes feedback about parts of the existing New Zealand-specific medicines law that you think currently work well and should be rolled over into any new medicines law with minor if any change.

Alternatively, you might have other issues not discussed in this document that you wish to raise.

Question 32: What parts of the existing New Zealand-specific medicines law do you think currently work well and should be rolled over into any new medicines law with minor if any change (please identify specific provisions of the Acts or Regulations)?

Question 33: If you have a New Zealand-specific medicines law issue not covered in this document, please give specific details of the issue, relevant law and any proposed solution.

Issue: Clearly Defining the Relationship between Medicines Law and other Legislation

The relationship between medicines law and other legislation – including the Agricultural Compounds and Veterinary Medicines Act, the Misuse of Drugs Act 1975, the Customs and Excise Act 1996, and the Hazardous Substances and New Organisms Act 1996 etc need to be clear. For example, some medicines and Controlled Drugs are also registered animal remedies.

Officials will be working together to develop appropriate information packages about the interface between the medicines law and other related legislation. Such work will be published on the respective government agencies websites when developed.
Question 34: Are there any issues you would like clarified relating to the interface between New Zealand-specific medicines law and other legislation? If, so please provide details.

**Issue: Some Immunisation Provisions in the Medicines Regulations**

The Medicines Regulations currently contain a number of references to immunisation matters. Medsafe is seeking comment about whether the Medicines Regulations are in fact the most appropriate place for such provisions, or would it be more appropriate for such provisions to be incorporated into the proposed Public Health Bill, being developed by the Ministry of Health, which also proposes to cover immunisation matters?

For example, Regulation 2 defines “approved immunisation programme”. In addition, Regulation 44A deals with “administration of vaccines in approved immunisation programmes” and provides, for example, for the Director-General of Health or the Medical Officer of Health to authorise persons to administer vaccines.

Question 35: Do you think the Medicine Regulations should contain such immunisation-related provisions, or would these be more appropriately included with the immunisation-related provisions in the proposed Public Health Bill?

**Issue: Regulation of Human and Animal Tissue used for a Therapeutic Purpose**

The Ministry of Health is currently considering the best way to regulate human and animal tissue used for therapeutic purposes. Although New Zealand has the Human Tissues Act 1964, there is an argument that provisions relating to the use of human and animal tissues for therapeutic purposes should be covered by the Medicines Act. Australia is also considering this issue. Once the Ministry has developed proposals, a separate consultation exercise will occur for this issue.
Appendix I: The Health Practitioners Competence Assurance (HPCA) Bill

The HPCA Bill was introduced into Parliament by the Minister of Health, Hon. Annette King, on 11 June 2002. The Bill impacts on New Zealand-specific medicines law. It proposes a new framework for the regulation of the different types of health practitioners (e.g. doctors, nurses, dentists, pharmacists, podiatrists, etc) and includes mechanisms to assure the public that a health practitioner, who is registered under the Bill, is competent to practise. The Bill will:

- provide a uniform approach to all health professions, with changes applying automatically to all professions;
- be flexible enough to meet changing skill sets, roles, diagnostic regimes and treatments;
- be transparent so that practitioners and the public can easily see which professions are regulated and how;
- provide a supportive environment for health practitioners to maintain their competence;
- provide a process for new professions to be regulated under the Act by Order in Council;
- provide consistent, co-ordinated, fair and transparent processes for handling complaints against health practitioners;
- provide a safe regulatory environment for the distribution of medicines.

The Bill proposes to repeal 11 existing regulatory statutes in respect of health practitioners (e.g. the Medical practitioners Act 1995, Nurses Act 1977, Pharmacy Act 1977, etc). Consequent to the repeal of the Pharmacy Act 1970, a new regulatory regime will be introduced to ensure that the public have ready access to medicines in a safe environment.

The Bill also proposes amendments to the Medicines Act. A new regulatory regime for the distribution of medicines is proposed that is based on the existing licensing regime in the Medicines Act for the manufacture, wholesale, and packing or labelling medicines. Some of these amendments are also New-Zealand-specific legislation issues are therefore not repeated in detail in this discussion paper. These include:

- providing new definitions of authorised prescriber, dispensing, pharmacy, pharmacy practice and licensing authority
- inserting new provisions relating to the regulation of pharmacies (e.g. provisions about ownership, licensing and operation of pharmacies)
- amending some of the offence and penalty provisions in the Medicines Act - for various offences relating to licensing of manufacturers, wholesalers, retailers, and packers of medicines (currently contained in sections 17 and 18 of the Medicines Act).
For more detail about these issues, copies of the HPCA Bill are available at any Government Bookshops or on the Ministry of Health’s website: www.moh.govt.nz. Information on the proposals contained in the Bill is also available on the Ministry of health website.