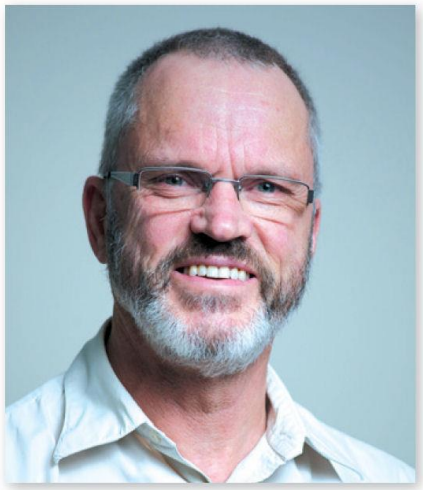
Dr Samantha King

Medical Protection Society



Dr Tim Cookson

Medical Protection Society

Sunday, June 11, 2017

7:15 - 8:10 Medical Protection Society Breakfast Session

GP CME ROTORUA 2017

UPDATES ON MEDICOLEGAL MATTERS

Dr Samantha King, MPS Medical Adviser
Dr Tim Cookson, MPS Medical Consultant
Mr Murray Grant, Senior Associate, DLA Piper

Today's topics

1. Your risks when signing prescriptions for patients importing medicines from overseas.
2. Brief updates on other MCNZ statements.
3. Medical Council Statement on treating those close to you.

Patients Importing Medicines.

Scenario 1

Mr Smith has ED and sources Viagra from India as it is much cheaper than sourcing it in NZ. He asks you to sign a prescription and the Medsafe forms to bring 500 pills through customs.

Scenario 2

Mrs Wong has Hepatitis C and does not qualify for Pharmac funding. She cannot afford to pay for the drug in NZ and wants to source it from Australia. She cannot speak English very well and asks if you would help her by applying to get the medication on her behalf.

Scenario 3

Mr Jones is at risk of contracting HIV and would like to order PrEP for prophylaxis from Australia. He asks you to sign the forms for him.

The Medicines Act 1981

Under s43 an individual can import medicine into NZ if they have a ‘reasonable excuse’ which includes:

- Holding a prescription for themselves or another person who is a patient
- Necessary or incidental to use by the individual or patient
- Not for sale or supply

The Medicines Regulations 1984

Regulations 39 and 39A of the regulations limit prescriptions:

- For treatment of a patient under their care.
- Within their scope of practice.
- Must not be more than a 3 month supply (6 months for contraceptives).

The Medicines Act 1981

Practitioners can prescribe any medication:

- Approved.
- Unapproved (all imported medication).
- Unapproved use (off label).
- This includes experimental.

The Medical Council of New Zealand

You may prescribe medication or treatment, including repeat prescriptions, only when you:

- Have adequate knowledge of the patient's health.
- Are satisfied that the medication or treatment are in the patient's best interests.

Good Medical Practice

The Medical Council of New Zealand

Before prescribing any medicine for the first time to a patient, Council expects you to have an **in-person** consultation with the patient. [emphasis added]

Good Medical Practice

The Medical Council of New Zealand

> You may prescribe on the instructions of a senior colleague or a practice colleague … as long as you are confident that the medicines or treatment are **safe** and **appropriate** for that patient and the patient has given his or her **informed consent**. Medicines or treatment must not be prescribed for your own convenience or simply because patients demand them. [emphasis added]

The Medical Council of New Zealand

> Be familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the medicines that you prescribe.

The Medical Council of New Zealand

Prescribing **unapproved** medicines or **off label:**

- You must take responsibility for overseeing the patient's care, including monitoring and any follow-up treatment.
- You must document your reasons for prescribing any unapproved medicines.
- You must document patient's informed consent: any risks, adverse effects, costs or benefits any other available options.
- You must work within your scope of practice.
- Should consult with a senior colleague before prescribing them.

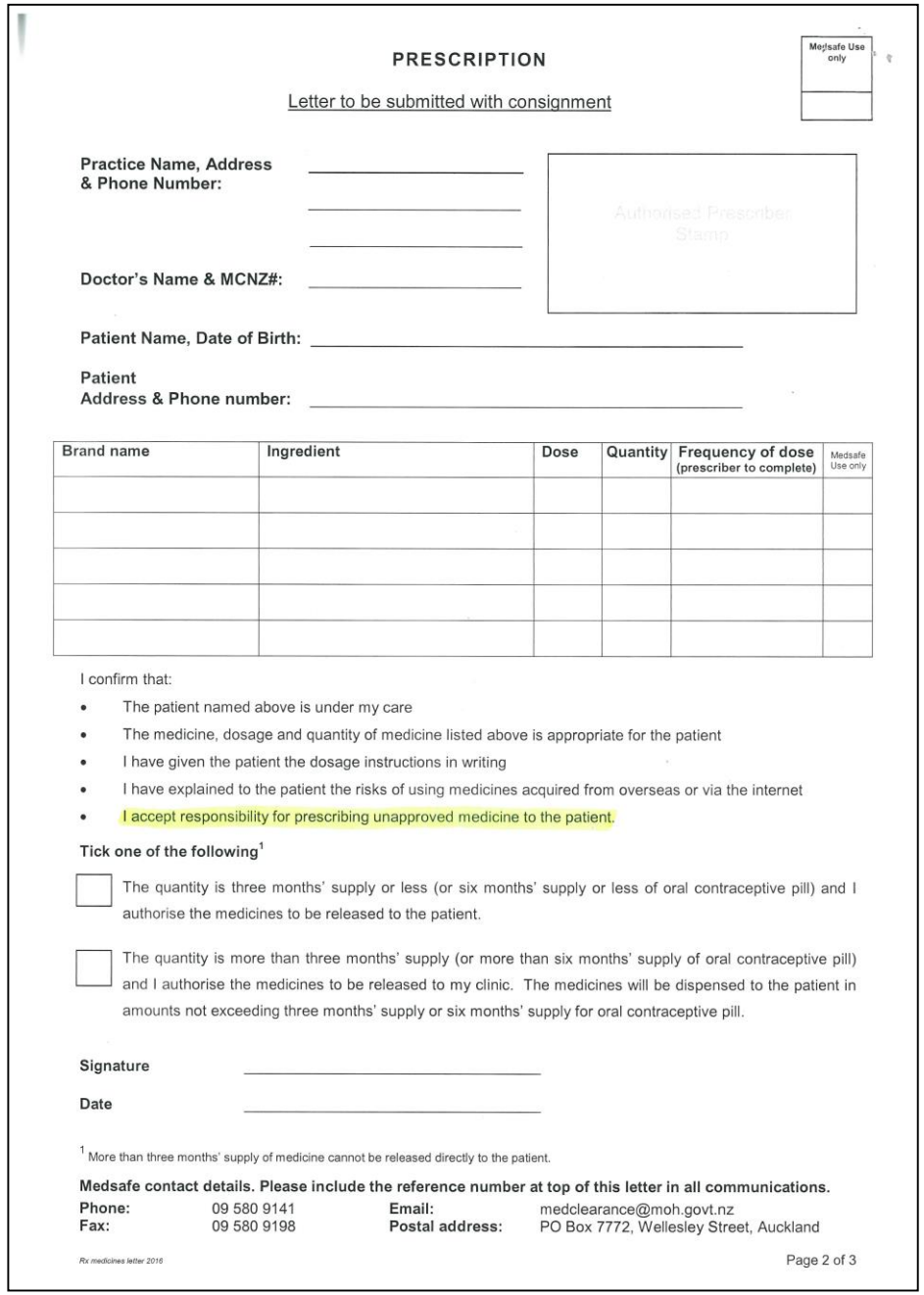
The Code of Patient Rights

Code: right s 4,6 and 7

- 4: Right to services of an appropriate standard.
- 6: Right to be fully informed.
- 7: Right to give informed consent.

Medsafe

New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.



PRESCRIPTION

Medsafe Use only

Letter to be submitted with consignment

Practice Name, Address & Phone Number: _____

Doctor's Name & MCNZ#: _____

Authorised Prescriber Stamp

Patient Name, Date of Birth: _____

Patient Address & Phone number: _____

Brand name	Ingredient	Dose	Quantity	Frequency of dose (prescriber to complete)	Medsafe Use only

I confirm that:

- The patient named above is under my care
- The medicine, dosage and quantity of medicine listed above is appropriate for the patient
- I have given the patient the dosage instructions in writing
- I have explained to the patient the risks of using medicines acquired from overseas or via the internet
- I accept responsibility for prescribing unapproved medicine to the patient.

Tick one of the following[1]

☐ The quantity is three months' supply or less (or six months' supply or less of oral contraceptive pill) and I authorise the medicines to be released to the patient.

☐ The quantity is more than three months' supply (or more than six months' supply of oral contraceptive pill) and I authorise the medicines to be released to my clinic. The medicines will be dispensed to the patient in amounts not exceeding three months' supply or six months' supply for oral contraceptive pill.

Signature _____

Date _____

[1] More than three months' supply of medicine cannot be released directly to the patient.

Medsafe contact details. Please include the reference number at top of this letter in all communications.

Phone: 09 580 9141 **Email:** medclearance@moh.govt.nz
Fax: 09 580 9198 **Postal address:** PO Box 7772, Wellesley Street, Auckland

Rx medicines letter 2016

Page 2 of 3

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Prescription medicines obtained over the internet - advice for prescribers

Website: August 2009 Revised 13 June 2013
Prescriber Update 2009;30(3):17

The internet has now become a significant resource for patients to obtain supplies of prescription medicines from overseas. When these medicines are held at the New Zealand border prescribers are usually asked to provide a prescription to enable their release.

Prescribers are reminded to consider the following prior to providing a prescription for medicines obtained from an overseas source:

- Is this patient under your care?
- Is the medicine, dose and quantity appropriate for the patient?
- Is the patient aware of the risks of using medicines purchased over the internet?
- Are you willing to take on the responsibility for prescribing your patient an unapproved medicine that is likely to be of unknown quality and origin?

Patients who order medicines online commonly believe they are importing genuine branded medicines from countries with highly regulated systems such as Canada or the USA. These websites, which may be linked to spam emails, are sophisticated and misleading as the website may be based in a country different to where it appears to be hosted. A recent study conducted by the FDA of medicines ordered from websites claiming to be Canadian found only 15% of the medicines inspected actually originated in Canada.[1]

Several websites offer medicines for sale without a prescription or in some cases require an online questionnaire to be completed. It is usually not clear whether a healthcare professional is involved in the process.

Medicines coming into New Zealand are intercepted by New Zealand Customs and passed to Medsafe for inspection. Last year approximately 11,000 parcels containing 17,000 medicines were inspected by Medsafe; it is estimated that up to 30% of these medicines may have been ordered over the internet. Medsafe's experience is that many of the prescription medicines crossing the border are of poor quality and may be adulterated or counterfeit. For example, recent testing revealed four undeclared active ingredients in one product ordered over the internet.

The New Zealand medicines legislation requires anyone who imports, distributes, sells or possesses a prescription medicine to have a 'reasonable excuse'. A patient will have a reasonable excuse if a New Zealand registered prescriber has prescribed the medicine. If a prescriber provides a prescription for a medicine that has been intercepted at the border they take on all the responsibilities of prescribing, including responsibility for the quality and appropriateness of the medicine for that patient. Without a prescription a patient is unlikely to have a reasonable excuse and would be in breach of this provision.

In addition to quality concerns, Medsafe is also concerned about the dangers of self-medication. Individuals may not have seen a medical professional, had an adequate diagnosis made, or received information on the risks and benefits of using a particular medicine.

Medsafe advises prescribers to carefully consider these issues before agreeing to authorise supply of a medicine purchased over the internet.

Reference

[1] FDA (2005). FDA operation reveals many drugs promoted as "Canadian" products really originate from other countries. Accessed 3/7/09 from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108534.htm

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To minimise your risk

1. Is the patient under your care?
2. Has an adequate diagnosis been made?
3. Is the medicine, dose and quantity appropriate for the patient?
4. Have you provided the patient with written instructions on the appropriate dose and quantity?

To minimise your risk

5. Have you clearly explained to the patient the risk that the medicine(s) may be of poor quality, not conform to label (ingredient and dosage), be contaminated with harmful substances and/or be counterfeit?

6. Have you weighed up the patient's rights under the Code?

7. Have you explained to the patient you are not in a position to take responsibility for the quality, safety or efficacy of any medicine?

To minimise your risk

8. Have you explained to the patient you recommend obtaining approved medication in New Zealand rather than obtaining it overseas?

9. Have you put in place a monitoring programme with your patient to assess and monitor them closely while they are on such medication?

10. Do you have clear and accurate documentation including a robust informed consent process? We advise you obtain a signed form from the patient outlining the above discussions/risks.

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MCNZ Updates

MCNZ recent Statements activity since November 2016

- Good Medical Practice (Dec 2016)
- Good Prescribing Practice (Nov 2016)
- Performance Enhancing Drugs (Feb 2017)
- Internet & Electronic Communications (Dec 2016)
- Telehealth (Dec 2016)
- Advertising (Nov 2016)
- Treating Family & Friends (Nov 2016)

Significance of MCNZ Statements

- Expectation that all doctors in NZ will read and follow these.
- Most contain the warning ‘This statement may be used by the HPDT, the Council, and the HDC as a standard by which your conduct is measured.’
- Regularly updated and feedback is sought from interested parties.

Good Prescribing Practice

- Confirmation of previous statement.
- You are not permitted to prescribe for anyone not under your care.
- Faxed prescriptions original to chemist within 7 days, controlled drugs 2 days.
- First prescription in-person consult. If not possible in exceptional circumstances consider video consultation.
- Notify CARM if allergic, severe, uncommon or unanticipated reaction.
- Drugs with misuse potential remember Medicines Control as resource.
- Patients abroad > 3/12 need to register with local doctor for next script.

Doctors and Performance Enhancing Medicines in Sport

- Responsibility of athletes to inform their doctor of their status as a listed athlete. Usually have card from Drug Free Sport NZ.
- Need to check any prescription against the WADA Prohibited list (www.wada-ama.org), links in the NZ Formulary.
- Resist pressure to prescribe or advising on access to substances for the deliberate purpose of enhancing performance.
- Supplements may be problematic.
- Doping starts at school age & gyms are prime source of supply.

Use of the Internet and Electronic Communication

- Caution when sending emails – wrong address, shared computers etc.
- Keep records of any HI sent in by patient via email etc. & of any advice given.
- Personal social media use – beware causing distress to colleagues, patients and their families.
- Exercise restraint in using social media to seek information about your patients – get consent.
- ‘Social Media & the Medical Profession’ – joint NZMA/NZMSA document.
- Publishing information on the net – comply with Health on the Net Foundation code www.hon.ch

Telehealth

- Beware of the inherent risks in providing treatment when a physical examination is not possible.
- If a physical examination is likely to add critical information you should not treat or refer till this is done.
- Remember the ‘exceptional circumstances’ requirement before prescribing without an in-person consult.
- Obvious tension here between the direction medicine is heading (patient portals/ Waikato initiative) and the MCNZ position.

Advertising

- Includes, but is not limited to, any public communication using television, radio, motion picture, newspaper, billboard, list, display, the internet or directory, and includes business cards, announcement cards, office signs, letterhead, telephone directory listings, professional lists, professional directory listings and similar professional notices.
- Does not include clinical information given to patient during a consult.
- Adverts must be truthful & balanced, should not encourage excessive use of health resources, avoid testimonials, and care with before & after photos.

Advertising continued

- Must not advertise by visiting, emailing or phoning prospective patients.
- Doctors are not permitted to endorse medicines, medical products or medical treatments.
- Not appropriate to offer medical treatments as prizes or gifts where this is done to promote a commercial service or for financial gain.
- If you are worried about an planned advert consult the Therapeutic Advertising Pre-Vetting Service (TAPS).

Treating Family & Friends

> The man who is his own lawyer has a fool for a client.

Attributed to Abraham Lincoln (amongst others!)

A fool for a client?

- Does this apply to doctors and other health professionals?
- What about treating family, friends, work colleagues?
- A brief history, the international perspective and the evidence behind this philosophy.
- Does MCNZ have the balance right?
- Does it matter? HPDT hearing

Case – Personal and family prescribing

- Dr AB, DHB specialist aged early 50’s.
- Reported by the MOH to MCNZ in 2016 under memorandum of understanding.
- Over 14 years prescribed over 200 items for personal use.
- Included medication for long-term conditions, antibiotics and medication available OTC such as antihistamines.
- Also prescribed antidepressant to family member on around 8 occasions.
- Has own GP and family have own GPs.

Case (cont.)

- Fulsome letter of acknowledgement of actions sent back to MCNZ, but no apology.
- Promise never to self-prescribe or prescribe for family again.
- Fully supports MCNZ position of not prescribing in such circumstances.
- Has now had opportunity to review 2013 Statement.
- Thanked MCNZ for bringing matter to their attention.

Case (cont.)

- Considered by Complaints Triage Team (CTT)
- Consists of Chairperson, Deputy Chair, CEO, Registrar, Deputy Registrar, General Manager – Core Services, Senior Policy Analyst and Medical Advisers.
- Decided not to take any further action.
- Appreciated honest response and noted that will not do this again.

In addition CTT would like you to note that self-prescribing medicines that are available over the counter for economic reasons may be considered a misuse of your standing as (sic) medical professional.

Should the Council receive concerns of a similar nature in the future, it will be taken very seriously.

Complaints Triage Team (CTT)

Is this doctor unusual?

- Do you know other doctors who have done similar things?
- Self-prescribing OTC for economic reasons ‘misuse of standing as medical professional’ – comments.
- Therefore OK to buy but not self-prescribe.
- If I ask my GP to prescribe omeprazole for me is that a ‘misuse of my standing as medical professional’?
- Any logic gap here?

History

- The first code of ethics drafted by the AMA in 1847 recommended against physicians treating family members –

  'the natural anxiety and solicitude which the physician experiences at the sickness of a wife, a child … tend to obscure his judgement, and produce timidity and irresolution in his practice.'

- The concern has been present in some jurisdictions for a long time.

Theoretical concern about treating family and friends

- Emotional involvement may reduce clinical objectivity, producing bias which we may not be aware of.
- Overtreatment and under-treatment are both possible outcomes.
- It may be less likely that the full relevant history is obtained, assumptions may be made about depth of knowledge of patient, and some potentially relevant questions and examinations may not be done.

Theoretical concern about treating family and friends

- Family or friends may place you under specific pressures regarding management that would not apply with usual patients.
- ‘Corridor consultations’ are less likely to be adequately recorded, and information less likely to be passed on to the usual GP.

There is a substantial gap between the MCNZ statement and what many doctors actually do

- Confirmed both by surveys and our own experience.
- MCNZ says it is getting regular and frequent notifications from ACC and the MOH.
- Significant variation in the positions of regulatory authorities around the world.
- If this is such an important principle, why is there such variation?

NZ history

- 2007 statement replaced 2001 statement.
- The following are specific situations when treating yourself, family members, people you work with and friends should be avoided – includes:
    1. Prescribing drugs of dependence & psychotropics
    2. performing surgery & providing psychotherapy.
- Inappropriate in most other clinical situations.

Exceptions

1. Prescribing for a continuing condition & GP monitoring. Retired doctors could still get APC allowing this activity.

2. Emergencies and working in small communities.

2013 statement

- MCNZ ceased to issue APC to retired doctors which would allow them to treat themselves and family – only 4 years ago.
- Changes - The following are specific situations when you **must not** treat yourself, family, friends etc –
    1. Prescribing drugs of dependence and psychotropics.
    2. Performing invasive procedures (unless an appropriate referral process has been followed)
- Removed section allowing doctors to prescribe for themselves etc. for continuing condition, with GP monitoring.

2016 Statement – much more detailed

New definitions –

- Family member – anyone with both a familial connection & personal or close relationship which could reasonably be expected to affect professional and objective judgement.

- Includes but is not limited to - spouse or partner, parent, child, sibling, members of extended family, members of partner’s extended family.

2016 Statement – much more detailed

New definitions and changes –

- Care – anything that is done for a diagnostic, preventative, palliative, cosmetic, therapeutic or other health-related purpose.
- Urgent situation – treatment of illnesses or injuries that require immediate attention.
- Surgery – now changed to must not perform invasive procedures.
- The reference to not treating those you work with has now been removed. It is now limited to treating yourself, family members or those close to you.

Other jurisdictions

- The UK, Australia, Canada and the US have similar philosophies, but none is so proscriptive.
- The GMC states *'wherever possible you should avoid providing medical care'* to those close to you. Also – *'you should not treat yourself.'*
- 'Must not' is now used in NZ where 'should not' was the term previously used and the one used in many of these – semantics?

USA

- AMA – physicians generally should not treat themselves or immediate family members.

  'Not always inappropriate to undertake self-treatment or treatment of immediate family members'

  'There are situations in which routine care is acceptable for short-term, minor problems'

- In NZ the wording is 'exceptional circumstances' and 'will not . . . in the vast majority of clinical situations.'

Australia and Canada

- Australia states *'Whenever possible, avoid providing medical care to anyone with whom you have a close personal relationship.'*

- The Canadian Medical Association code of ethics states – *'Limit treatment of yourself or members of your immediate family to minor or emergency services and only when another physician is not readily available; there should be no fee for such treatment.'*

Singapore

'You may provide self-care or care to those close to you when –

1. *repeat prescribing for stable conditions*
2. *treating simple minor conditions*
3. *there is an emergency or urgent need to act to avoid serious deterioration.*
4. *there is need to alleviate otherwise unbearable pain.'*

'If you choose to provide significant care to those close to you, such as major surgery, you have an obligation to make sure your objectivity etc is not compromised.'

Germany

- Germany –

‘Physicians may dispense with all or part of the fee in the case of family members, colleagues, their family members and destitute patients.’

Other NZ Organisations

- Dentists – *'should not prescribe medicines and controlled drugs for themselves and should not prescribe for family members or friends, unless they are patients and the medicine relates to dental treatment requirements.'*

- *Psychologists – 'Psychologists should seek to avoid dual relationships where that might present a conflict of interest. A dual relationship is where the psychologist has a personal and professional relationship with a patient'.*

The evidence

- Coles states – *'Be committed to autonomous maintenance and improvement in your clinical standards in line with best evidence-based practice.'*
- Do the same standards apply to MCNZ??
- What is the evidence of harm when treating self, family or those close to you?
- I could find no study that showed that outcomes were significantly different when comparing treating someone close to you compared with a patient who was not close.
- In the absence of evidence of harm, what limitations are justifiable?

- New Zealand has what seem to be the ‘tightest’ statement in international terms on treating family & friends.

- Statements have also chopped & changed – surgery is allowed with suitable referral then not allowed; people you work with are put in the same category as friends and family and then removed; until only 4 years ago, retired doctors could treat family within the guidance at that time; the definition of family is now very broad.

- Does this all matter?

- What are the penalties anyway?

- Review of MPS files shows that most transgressors get an educational letter similar to the one I started with.

- Disciplinary action is generally reserved for prescribing narcotics to family, particularly if it is intended for personal use, and treating close family with mental health issues and no external overview.

- One case though of prescribing antidepressants for 3 years to a spouse who then attempted suicide resulted in a 6 month recertification program.

- Is the MCNZ bark worse than its bite? Current HPDT case.

Where to from here?

- Medical profession in NZ needs to be aware our regulatory authority has the tightest restrictions in the world regarding treating family and friends.
- There is a significant gap between what is in the statement and what doctors are still doing.
- There is a lack of any firm evidence of harm arising from doctors treating family and friends, though the philosophy does appear sound.
- There is significant risk of harm to doctors who breach the statement.

Is it fair?

- MCNZ gets reports from ACC & MOH. Only relates to prescribing and certificates.
- Otherwise MCNZ relies on notifications from HDC or direct complaints to MCNZ
- Care – anything that is done for a diagnostic, preventative, palliative, cosmetic, therapeutic or other health-related purpose.
- Is this any less significant than prescribing?
- What if your family member has a different surname?
- Is how doctors are treated by the regulator equitable?

Where to from here?

- There is also an assumption that we don't get close to our patients, whereas the reality is that we do and this could affect our judgement.
- What about cultural expectations?
- Is there a better way that MCNZ could manage this issue?
- Does this 'must not' approach reflect a broader philosophy that MCNZ has towards doctors in NZ?
- Do we in the medical profession accept this ideology from our regulator if it is clearly different from what many of us do and lack of evidence of harm?

MORE THAN DEFENCE

Medical Protection Society is the world’s leading protection organisation for doctors, dentists and healthcare professionals

As a not-for-profit, mutual organisation, we protect and support the professional interests of more than 300,000 members around the world

Membership provides access to expert advice and support together with the right to request indemnity for complaints or claims arising from professional practice

Our philosophy is to support safe practice in medicine and dentistry by helping to avert problems in the first place

Further support and information is offered on our website, in addition to our publications, booklets, factsheets and case studies.

medicalprotection.org