AUGUST 2006

newsletter

pharmacycouncil
OF NEW ZEALAND

Pharmacists Among Top Ten Trusted Professions

Pharmacists continue to be highly rated as trusted professionals according to a survey conducted by an independent market research company, the Leading Edge.

The commissioned 2006 survey considered a statistically representative sample of 500 adult New Zealanders and as with similar previous surveys, pharmacists have been listed in the top 10 along with other health professionals. These results are a reflection of the Council's mission to have pharmacy practitioners recognised as the trusted experts in medicines.

Following the publication of the results of the survey, Scoop Independent News stated on their website "Is it the uniform? Aussies and Kiwis agree that firefighters, ambulance officers, pilots, pharmacists, doctors and nurses deserve the top spots when it comes to most trusted professions." Full details of the survey appear in the Readers' Digest (NZ) June 2006.

Proposed New Process for Registration of Overseas Trained Pharmacists in New Zealand

The Pharmacy Council of New Zealand is proposing two new qualification routes for registration – one for pharmacists from the United Kingdom, Ireland, Canada and the USA, and another for graduates from Australia wishing to register as intern pharmacists in New Zealand. The Council is inviting submissions on these new prescribed qualifications from all registered pharmacists. The consultation package is now available on the web www.pharmacycouncil.org.nz/pharmacists/index.asp. The package consists of an invitation letter containing a list of the groups consulted, a background document explaining in detail the changes proposed, and a formal feedback form for you to fill in. To ensure that your feedback is included in the development of the processes please return the feedback form by 14 August 2006.

The Pharmacy Council of New Zealand has been established under the Health Practitioners Competence Assurance Act 2003 and has a duty to protect the public and promote good pharmacist practice.

IN THIS EDITION

STOP PRESS

Appointments to the Pharmacy Council

The Minister of Health is seeking nominations for two Health Practitioners for appointment to Council.

Ideally candidates should be experienced, actively involved in the pharmacy profession and have an understanding of the broad context of pharmacy practice and education in New Zealand. Experience at a governance level is desirable. Candidates should be registered and hold a current Annual Practising Certificate.

Expressions of interest can be emailed to:
enquiries@pharmacycouncil.org.nz by Friday 4th August.

Medicines Use Review (MUR) Competence standards released

As part of the Medicines Management competence framework, Council has finalized the first level of competence standards for MUR services and the College of Pharmacists is currently preparing a training course to assess these. These exciting new services align with the DHBNZ framework for pharmacists services and have been developed in consultation with pharmacists and key stakeholders. Council has now set up a Competence Advisory Group to develop the higher level competencies.

CONTACT US:

Phone: 04 495 0330 **Fax:** 04 495 0331 **Email:** enquiries@pharmacycouncil.org.nz
Address: PO Box 25137, 40 Johnston St, Wellington

A New Approach to Professional Discipline: The Health Practitioners Competence Assurance Act Two Years On

The Health Practitioners Competence Assurance Act 2003 (the HPCAA) came into force in September 2004. Two years later, and with the first disciplinary proceeding under the HPCAA behind us, it is appropriate to take stock of the differences between the new processes and those that used to apply under the Pharmacy Act 1970.

The Key Players at a Glance

- Health Practitioners Disciplinary Tribunal (the Tribunal). An independent statutory Tribunal to hear and determine complaints involving health practitioners. In the case of pharmacy, the Tribunal consists of three pharmacists (who cannot be Councillors of the Pharmacy Council), one layperson and a legally qualified Chair. Members are appointed by the Minister of Health.
- Professional Conduct Committee (PCC). An independent committee of the Pharmacy Council established to consider whether certain complaints against pharmacists require further action. The PCC consists of two pharmacists and a layperson. Members are appointed by the Pharmacy Council.
- The Pharmacy Council of New Zealand. The regulatory body for the profession of pharmacy. The Council has no role in hearing or determining complaints against pharmacists. It consists of six pharmacists and 2 lay people, all of whom are appointed by the Minister of Health

The HPCAA Disciplinary Regime

Under the Pharmacy Act, the profession was truly "self-regulatory" in the disciplinary arena. The Council of the Pharmaceutical Society, a majority of who were elected from the ranks of the profession, had primary responsibility for the maintenance of professional standards and discipline within the profession. Complaints about pharmacists were considered by a committee of the Society Council and recommendations as to appropriate action were made to the Society Council by that committee.

This is no longer the case. While the Pharmacy Council has an obligation to set standards of clinical, ethical and cultural competence for pharmacists and retains a role in both the competence and disciplinary processes, the Council is no longer the primary decision-maker in relation to disciplinary proceedings.

Under the HPCAA a new body, the Health Practitioners Disciplinary Tribunal, has responsibility for hearing professional disciplinary charges that are brought against all health practitioners, not just pharmacists. As a result, it is the Tribunal, not the Council, who hears charges of professional misconduct or other disciplinary offence that are brought against pharmacists and it is the Tribunal who determines whether those charges are found to be proven and, if so, what penalty is appropriate

The Tribunal is independent from all of the authorities that regulate the health professions and, indeed, members of the Pharmacy Council (or any other Council) are not eligible for membership of the Tribunal. The staff of the Pharmacy Council provide administrative assistance to the Tribunal, but the Council itself is not involved in the Tribunal's work.

The Complaints Process

Where complaints are made about the conduct of pharmacists to the Council, these complaints are initially dealt with in a similar manner to complaints under the Pharmacy Act. All complaints that suggest that the conduct of a pharmacist has affected a health consumer are referred to the Health and Disability Commissioner and the Pharmacy Council takes no further action on those complaints until the Commissioner's investigation is complete. The Commissioner has a number of options open to them in relation to complaints, the decision to bring charges before the Tribunal is but one of those options.

Complaints that do not involve health consumers, or that are referred to the Council by the Commissioner, are considered by the Council to determine whether they raise matters of competence or professional conduct:

- Competence issues are dealt with by the Council's Professional Standards Committee. It is important to note that this process is entirely separate from the disciplinary process. The focus in competence review is on working with practitioners to improve standards. The results of the review enable the Council to determine what "gaps" there may be in a pharmacist's practice, and direct the pharmacist to further education, assessment, counselling or mentoring
- Where a complaint, or other information known to the Council, raises issues of professional conduct the issue is referred to a Professional Conduct Committee (PCC). The PCC is a committee made up of a lay member and two senior pharmacists (any of whom can be members of the Council). Its role is to make an initial assessment of the material before it, including information provided by the practitioner concerned, and determine the appropriate course of action.

While PCCs are a committee of the Pharmacy Council, they have independent responsibilities under the HPCAA and it is the PCC, not the Pharmacy Council, who decides what the appropriate course of action in any particular case is. Like the Health and Disability Commissioner, the PCC has a number of options open to it in considering a complaint. The PCC can determine to refer the matter to the Council for appropriate action (for example a competence review or a review of the practitioner's scope of practice). The PCC can also determine to take no further action in relation to a complaint or that the matter should be referred to conciliation. Finally, the PCC has the power to determine that a charge is brought in the Tribunal against the practitioner.

Where a charge is laid before the Tribunal, either the Commissioner or the PCC, will be responsible for prosecuting that charge. After hearing the matter it is the Tribunal that determines what, if any, penalty is appropriate in the circumstances. The Tribunal, like the Society's Council before it, has a wide range of penalties that it can impose. These range from censuring or fining the practitioner through to suspension or, in serious cases, deregistration.

In the two years since the HPCAA came into effect, only one case involving a pharmacist has proceeded solely under the HPCAA through to the Tribunal. This reflects well on the profession and also reflects the new processes that are available under the HPCAA. Under the old Pharmacy Act, the options for the Society's Council in dealing with complaints against practitioners were limited. Under the HPCAA, far more flexibility exists to deal with issues in a way that both ensures that pharmacists receive the guidance and support they need and that the public can have confidence in the profession of pharmacy.

KensingtonSwan *LAWYERS

Excellent Response to Recertification

We are very pleased to advise that at the time of this publication over 90% of pharmacists who hold an Annual Practising Certificate have indicated that they are participating in recertification (ie Enhance) and are to be congratulated on their commitment to continuing competence. By now all pharmacists are expected to be participating and should have completed the Practice Review and be well on the way to planning and actioning some identified learning activities (i.e. CPD or Continuing Professional Development). Remember, you are required to achieve at least 4 outcome credits in the first year of participation, and a minimum of 12 credits in any 3 year period. You are only required to submit your CPD records when you are called up for audit. It is at that stage that you will be asked to demonstrate your competence and justify the outcome credits of your learning. Auditing will begin in 2007.

As it is a Council requirement that a Practice Review should be completed every 5 years, pharmacists who have been actively participating in recertification since its inception in 2001 should be starting to think about undertaking another practice review.

Technicians, Interns and Controlled Drugs

The Council has received several enquiries about whether it is legal for interns and pharmacy technicians to dispense controlled drugs. An amendment to (section 8(2)(b) of the Misuse of Drugs Act now permits "any person with the authority and under the immediate supervision of a pharmacist" to dispense controlled drugs. Technicians, interns, and pharmacy students are not specifically mentioned in this legislation, however, pharmacists are advised to restrict the dispensing of controlled drugs only to those who are currently permitted to dispense medicines under regulation 42(1), (1A) and 63 of the Medicines Act.

Pharmacist's "Own Remedies"

A TV3 Campbell Live programme in April this year ran an item about a pharmacy-manufactured topical head lice product containing Lindane (gamma benzene hexachloride) that did not conform to labelling requirements and was displayed for self-selection by customers alongside other proprietary brand medicines. The programme highlighted the risks for patients who buy Lindane, especially when they are not made aware of the directions for safe use and it emphasised the pharmacist's ethical and legal responsibilities.

Lindane (2% or less) solutions for topical use and other such products that are manufactured in the pharmacy may be sold by the pharmacist **only**.

These remedies must be prepared, stored and sold according to the requirements of regulation 23 of the Medicines Regulations and Part 3 of the New Zealand Code of Good Manufacturing Practice (see the Pharmacy Practice Handbook 2003 section 2.6). These regulations are in place to ensure that patients have the opportunity to receive individualised professional advice on how to use an unapproved medicine, and any safety information. The manufactured products must be kept in the dispensary until requested by a patient or recommended by the pharmacist for a particular patient. The patient's name must be included on the label.

ACC Pharmacist Reports of Treatment Injury

A treatment injury is a personal injury occurring in the context of treatment by a registered health professional. It used to be known as "medical misadventure". A treatment injury sustained by a patient is, by definition, one which is not a necessary part, or ordinary consequence of the treatment. Since 1 July 2005, following an amendment to the Injury Prevention, Rehabilitation, and Compensation Act 2001, ACC no longer reports individual medical error decisions and trends to the Health and Disability Commissioner (HDC), registration authorities and employers. However, where ACC determines that there is a risk of public harm the treatment injury event is reported to the appropriate authority responsible for patient safety. The Pharmacy Council has received two notifications from ACC of serious treatment injuries and they are summarised here because there is potential for similar dispensing errors. We hope that pharmacists may learn from others' mistakes:

- Aldara® (imiquimod) cream was prescribed for genital warts, to be applied to the perineal area three times weekly. The directions on the dispensed prescription were for three times daily. The patient suffered painful vulval chemical burns preventing work. She was unable to walk without assistance. Fortunately the burns caused only temporary dysfunction. The Council emphasises the need firstly, for a final pharmacist check of all prescriptions and secondly, to counsel all patients who receive a medicine for the first time. Technicians and pharmacists inputting prescription data must have a system in place that alerts the checking pharmacist that a medicine has not been used or taken by the person before. Counselling in this case should have reinforced the doctor's advice and the error could have been detected before the prescription left the pharmacy.
- A prescription for glacial acetic acid/propylene glycol ear drops was dispensed containing equal parts of the two components. The patient complained of burning in the ear and on examination the GP found inflamed external canals and chemical burns. Pharmacists are expected to be aware of, and use, their common sense regarding the dangers of glacial acetic acid applied to the skin in high concentrations. This prescription should have been clarified with the prescriber. The Council encourages all pharmacists to be proactive in questioning anomalies on prescriptions and to realise their professional responsibility to ensure that the prescription is suitable for the patient's needs/purpose.

Dangers of Combining OTC and Prescription Medicines

The following article is reprinted from *Australian Prescriber* Vol 29 No 3 with permission. The case highlights the risks of mixing over-the-counter medicines with prescription medicines. We encourage pharmacists to ensure that appropriate questions are asked when selling OTC medicines so that a safe and appropriate product may be offered to the customer.

Serotonin syndrome precipitated by an over-the-counter cold remedy

Prepared by Chris Cameron, Advanced trainee in general medicine, Hutt Hospital, Lower Hutt, New Zealand (Aust Prescr 2006; 29:71)

Case

A 46-year-old man presented to the emergency department with a three-day history of headache and vomiting, and one day of confusion and fevers. His medical history included an old spinal injury and his usual medications were methadone 70 mg daily, gabapentin 3.6 g daily and citalopram 40 mg daily. One week before admission he had a tooth extracted and two days later developed a 'head cold', from which he recovered.

At presentation the patient was febrile (39.1°C) and sweating. His pulse fluctuated between 80 and 140 beats/minute, and his blood pressure between 170/86 and 214/100 mm Hg. He had a score of 12 on the Glasgow Coma Scale and was unable to sustain conversation. His dental socket looked clean and there was no clinical evidence of infective endocarditis, but he had generalised abdominal tenderness. Neurological examination revealed dilated reactive pupils and no meningism, but he had increased tone in both legs, with brisk reflexes and clonus at both ankles. Investigations revealed a white cell count of 21.1 x 109, predominantly neutrophils, and a C-reactive protein of 15. Chest and abdominal X-rays and urine were normal.

The diagnosis was sepsis, probably from an intracerebral or abdominal source, so broad-spectrum antibiotics were started. However, the patient had a normal brain scan and the lumbar puncture found no evidence of infection. The patient's condition remained unchanged over the next 24 hours. An abdominal CT scan and an echocardiogram were ordered, but were normal.

On reviewing the history, the patient recounted taking 'Night and Day' capsules containing dextromethorphan as a cough suppressant for his head cold for two or three days before becoming unwell. A presumptive diagnosis of serotonin syndrome was made and the creatine kinase was found to be elevated (354 IU). After 48 hours without citalopram, the patient recovered fully.

Comment

Serotonin syndrome is a triad of mental-status changes, autonomic hyperactivity, and neuromuscular abnormalities[1], with a mortality of about 11%. It is caused by excessive stimulation of serotonin receptors, often as a result of interactions between serotonergic drugs.[2] Severe cases of serotonin syndrome can cause rhabdomyolysis, with raised creatine kinase and metabolic acidosis.[1]

Many drugs have been implicated, including monoamine oxidase inhibitors, selective serotonin reuptake inhibitors (SSRIs), opioid analgesics including tramadol, antimigraine treatments and antibiotics, for example linezolid. Over-the-counter cough and cold remedies have occasionally been implicated[3], but no case reports involving dextromethorphan and citalopram were found in a literature search.

Several mechanisms may have contributed to the development of serotonin syndrome in this patient. Firstly, dextromethorphan is a potent inhibitor of serotonin reuptake, similar to SSRIs.[4] The combination with citalopram would therefore be expected to markedly increase the concentration of serotonin at the synapse. Secondly, SSRIs act as cytochrome P450 2D6 inhibitors[5], and although citalopram is a weak inhibitor, this may have contributed to elevated concentrations of dextromethorphan, which is a substrate of CYP 2D6.[6] Finally, methadone increases brain serotonin in laboratory animals[7], but the patient had been taking methadone and citalopram for two years, without ill-effect.

Estimates from previous studies are that 85% of doctors may be unaware of serotonin syndrome as a clinical entity.[8] Some community pharmacists may also be unaware that serotonin syndrome can be precipitated by over-the-counter cold remedies. As it can cause significant morbidity and mortality, health professionals need to consider the possibility of serotonin syndrome. This case also shows the value of taking a thorough drug history, including over-the-counter preparations.

Acknowledgement: Dr Sisira Jayathissa

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Storage and Sales of Medicines with Abuse Potential

The Council reminds pharmacists to make sure that medicines with established abuse potential are not stored in the pharmacy where they may be self-selected by customers. Gee's Linctus (which contains morphine) should not be stored in the cough and cold section of the pharmacy. It is acceptable to store empty containers on the shop shelf with a sign explaining that the medicine is sold only on the advice of the pharmacist. Please reiterate to your staff that they must refer dubious or unfamiliar customers, and those who do not display or describe the expected symptoms, to the pharmacist. Medicines of current concern are Gee's Linctus, codeine-containing medicines and of course pseudoephedrine-containing medicines. People who have managed to obtain large quantities of codeine-based medicines from pharmacies have recently come to the attention of the Police again. To uphold and maintain the image of pharmacists as healthcare professionals we ask that you and your staff monitor sales carefully to ensure that, as far as possible, sales are only made to customers with a genuine therapeutic need for the medicine.

Owings and Partial Dispensings

The Council reminds pharmacists that identification of the pharmacist who takes final responsibility for a dispensed medicine must be able to be determined (Code of Ethics Obligation 3.9 Identifiers). This obligation includes the identification of the pharmacist who takes final responsibility for an owing or a partial dispensing.

A Health and Disability Commissioner's report, recently referred to the Council, highlighted a dispensing error in which failure to confirm whether an existing signature on the prescription related to an individual item caused the wrong strength of a medicine to be given out. Other items on the same script were available for dispensing but the out-of-stock medicine had to be ordered in. The pharmacy's procedure for partially dispensed scripts at the time was for each item to be ticked as it was completed and for the checking pharmacist to sign the pharmacy date stamp. This was done for the in-stock items. Later on, when dispensing the medicine that had been ordered, a technician selected the wrong strength and it was stored in the fridge until the patient returned. The prescription was given out with an assumption that it had also been checked.

The system whereby the pharmacy stamp is signed prior to all the items being checked is open to misinterpretation and is inadequate because it does not identify whether a pharmacist had checked all the individual items on a prescription. Pharmacists can learn from this mistake and we encourage you to review your procedures. To prevent such errors each and every individual item should be initialed by the checking pharmacist. A signature placed alongside the 3-part label would be ideal. As a suggestion, the dispenser could sign the left hand side and the checker could sign on the right. The checker could always use a different coloured pen (e.g. green). Particular care needs to be taken to ensure that refrigerated prescription medicines are checked before being packaged and stored. For owings the original script could be annotated with "owe …." and initialed by the pharmacist. When the owing is dispensed, either a second 3-part label for the item could be attached to the original and signed or a prescription copy of the owing printed and initialed when it is dispensed.

Advertising and Sales Practices

The Council has received reports from concerned pharmacists about some recent advertising practices. Pharmacists are reminded that comparative pricing of medicines is not permitted under Obligation 8.3 of the Code of Ethics, which states that "The Charge Pharmacist must use only those methods that are of a standard consistent with the professional image of pharmacy when advertising, promoting or offering as inducement to the public any services, interventions, medicine, complementary therapy, herbal remedy or other healthcare product". You can state, "Great value" or "Our price is…" but you cannot state a comparative price e.g. "Reduced from…." or "was $…" Incentives to purchase additional quantities are also deemed unprofessional and contravene Obligations 8.6 and 8.7 of the Code of Ethics. These two obligations require the pharmacist to sell only the quantity of medicine that is appropriate for the clinical needs of the patient and to ensure that advertisements do not promote "…misuse, injudicious or unsafe use or unnecessary sales or excessive use…"

Pharmacy web-sites that offer to sell Pharmacist Only Medicines should state clearly that a consultation with the pharmacist is required before sale is permitted, and have a mechanism for doing this (e.g. interactive questionnaire and/or pharmacist phone line). In addition, it is unethical to offer multiple packs for a single price. We have been concerned to see that Obligation 3.15 is being breached with discounted offers for medicines such as Nurofen Plus. Your obligation is to "exercise professional judgment to prevent the supply of any medicine, complementary therapy, herbal remedy or other healthcare product likely to constitute a hazard to health or the supply of unnecessary or excessive quantities of these, particularly those which the pharmacist knows or should reasonably be expected to realise are likely to cause or have potential for misuse, abuse or dependency."

Such breaches of the Code of Ethics are matters of professionalism and complaints may be brought before the Council's Professional Conduct Committee (PCC), which decides on the appropriate course of action (see article by Kensington Swan in this Newsletter for actions that may be taken by the PCC).

Access to Legislation in Pharmacies

Pharmacists must be able to demonstrate ready access to legislation as part of the audit requirements and the Council has received enquiries about whether internet access would fulfil the requirement. Medsafe has confirmed that www.legislation.govt.nz is an acceptable site BUT please note that this site does not provide email notification when new laws are introduced or when changes are made to existing legislation. The web-site is updated monthly. The material on the site is not endorsed by the New Zealand Government and repealed and revoked legislation is not available.

Pharmacists who decide to use the website must therefore also have a reliable method of ensuring they are aware of changes to the laws that affect the professional practice of pharmacy (see the front page of the Pharmacy Council Code of Ethics for a list of these Acts and Regulations). One of the best ways to keep up-to-date is through membership of the professional body, the Pharmaceutical Society of New Zealand, which publishes a regular newsletter, The Edge. The Pharmacy Council Newsletter also contains information about important regulatory changes that affect pharmacy practice.

"Lost" Pharmacists

Can you help us locate these people? They will be removed from the public register unless we receive their new address. If you know of these pharmacists' whereabouts, please email Susan McKibbin: s.mckibbin@pharmacycouncil.org.nz or phone 04 495 0333. Thank you.

Hui Sien Chin, Jacqueline Beth Christian, Azizah Ghazally, Sherif Zaher Youssef Hanna, Lucille Inn Fei Lam, James Cecil Mckay, Devinda Asoka Joseph Polonowita.

Pharmacist Changes since March 2006

Congratulations to the following intern pharmacists who have successfully complete the preregistration programme in 2006

Al-Kubaisy S, Al-Saudi B, Araba BA, Askevold HJ, Askevold RM, Breytenbach WP, Bhatti T, Cha E, Chieng NHL, Farhan S, Fereshtian S, Heeney CT, Hsieh Y, Huang C, Kamal Quillinchi BA, Kao MY, Kusel MLS, Lee W, Mackintosh VR, Man LYY, Makita H, Mathieson NF, Ng SHY, Petros K, Slaimankhel J

Total Registered Pharmacists and Interns

As at the 17th July, the public register numbers of pharmacists were:

Practising pharmacists who hold an APC	2810
Non practising pharmacists	1030
Interns	186
Total register	4026

Pharmacists registered from UK, Ireland and Australia

Almahdi M, Burgess PD, Daalman J, Davis SR, Dunlevy B, Earl LA, Fitzsimons MM, Hebron BS, Hibbert HF, Keown KJM, Knatt JM, Magee DM, Morris CJ, Munro WJD, O'Meara M, Phillips SJ, Redshaw J, Robertson AJ, Singh HK, Thomson EJB, Ubhi BS, Whibley JA, Wiseman DN

Pharmacists who have returned to practice in NZ

Al-Shakarchi M, Batchelor G, Choi SA, Collie GD, Kelman MS, Loh MS, McIlraith AK, Oliver CA, Payne SN, Sivarajan S, Taylor NM, Turnbull CM, Wakim SM, Wilkinson A, Williamson JK

Erratum – Special Authority Numbers

The March 2006 Newsletter contained an article about temporary Special Authority numbers which may have been misleading. We have been advised by HealthPAC that if a patient's Special Authority number has expired, and if the need is **urgent**, pharmacists may call HealthPAC to establish the status of the application. The number to call is 0800 243 666. If the patient fulfils HealthPAC criteria a "RISK" number will be issued to allow uninterrupted supply of the medicine. The criteria for a "RISK" number is outlined on page 25 of the Pharmacy Procedures Manual.

Please note the patient must fall into the category of 'Life Threatening Circumstance', or if the situation is an 'In Good Faith' dispensing. Please note HealthPAC reserve the right to decline a RISK if required pharmacy procedure is not followed.

It is always best practice to contact HealthPAC, if in doubt, **prior** to dispensing a Special Authority product, to ensure the patient's needs are met in the best possible manner.