
Developments in pharmacists' disciplinary processes and outcomes

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Pharmacy disciplinary processes and outcomes protect consumers by deterring pharmacists from unacceptable practices and maintaining the reputation and standing of the pharmacy profession. It is important that pharmacists are informed of disciplinary processes and outcomes in order to predict what is regarded as unacceptable behaviour and the potential consequences thereof. Disciplinary procedures and outcomes also play an important role in maintaining public trust in the pharmacy profession and it is therefore important that the public has confidence in the disciplinary structure. The outcomes of pharmacy disciplinary cases that reflect the patient care role of pharmacists are particularly important in helping to determine pharmacists' changed professional responsibility and potential legal liability in the provision of these patient care services.

INTRODUCTION

State and Territory legislation provides for the regulation of the pharmacy profession throughout Australia¹ through pharmacy registering authorities that act for the protection of the public.² The authorities have responsibility for the registration and discipline of registered pharmacists and have the ability to investigate allegations or suspicions of misconduct by registered pharmacists, and to take disciplinary action as they see fit. In addition to the disciplinary processes followed by the registering authorities, there are also health complaints commissions in every State and Territory which handle service complaints from the public. These commissions were established as part of a general move towards the recognition of greater consumer rights internationally.³ Complaints are managed between the relevant commission and registration board, and are dealt with by either body depending on the nature of the complaint.

Pharmacy errors can have serious consequences. It is therefore important that the public has confidence that the outcomes of disciplinary processes reflect the gravity and nature of the breach, and are consistent and transparent. Pharmacy disciplinary outcomes are, however, complicated by the changing role of pharmacists towards the provision of patient care services as their newer roles create a different set of responsibilities and legal liability.

This article provides a contemporary overview of pharmacy disciplinary outcomes in the context of these practice changes. In particular, an analysis of Queensland disciplinary decisions provides an understanding of the nature of errors that lead to disciplinary action, the process followed during disciplinary actions, and the disciplinary outcomes.

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¹ *Pharmacists Registration Act 2001* (Qld); *Health Practitioners (Professional Standards) Act 1999* (Qld); *Pharmacy Act 1964* (NSW); *Pharmacy Practice Act 2006* (NSW); *Health Professions Registration Act 2005* (Vic); *Pharmacists Act 1991* (SA); *Pharmacists Registration Act 2001* (Tas); *Pharmacy Act 1964* (WA); *Health Professions Act 2004* (ACT); and *Health Practitioners Act 2004* (NT).

² Pharmacists Board of Queensland, Pharmacy Board of New South Wales, Pharmacy Board of Victoria, Pharmacy Board of South Australia, Pharmacy Board of Tasmania, Pharmaceutical Council of Western Australia, Pharmacy Board of the Australian Capital Territory and Pharmacy Board of the Northern Territory.

³ Wilson W, "Health Complaints: What do Consumers Really Want?" (Summer 2006) *Health Issues* 40.

DISCIPLINARY DEFINITIONS AND ACTIONS

The provisions in the pharmacy legislation in each of the jurisdictions that identify the conduct or behaviour of a pharmacist that will generate disciplinary proceedings are not uniform. The conduct that will constitute a complaint is defined inconsistently throughout Australia, using varied terms such as “professional misconduct”,⁴ “unsatisfactory professional conduct”⁵ and “unprofessional conduct”.⁶ Although the intention of the legislation in the various jurisdictions seems to overlap, the inconsistent use of terminology can potentially impact on disciplinary outcomes, as was evident in the outcome of an appeal to the Supreme Court of Tasmania in *Adamson v Pharmacy Board (Tas)* [2004] TASSC 32. In this case a clear distinction was made between a pharmacist’s professional misconduct and unprofessional conduct, where the former was defined as “behaviour on the part of a member of a profession that would reasonably be regarded as disgraceful or dishonest by members of that profession of good repute and competency”, and the latter was defined as “conduct which may reasonably be held to violate, or fall short of, to a substantial degree, the standard of professional conduct observed or approved by members of the profession of good repute and competency”. Professional misconduct was therefore regarded as a more grave categorisation of misconduct than unprofessional conduct.

In the case of a pharmacist’s registration being cancelled or suspended by a registering authority due to disciplinary action, the authorities in other jurisdictions, whether interstate or overseas, may give effect to that order. The jurisdictions have similar stepwise processes in place whereby less serious breaches are managed through streamlined procedures and more serious breaches are referred to committees or panels. However, a significant difference exists between the powers of the various authorities to impose sanctions. In Queensland, Western Australia, Victoria, New South Wales and the Australian Capital Territory, the cancellation or suspension of registration is reserved for tribunals, presided over by a judge. In comparison, the Pharmacy Boards of South Australia, Tasmania and the Northern Territory have the power to both suspend registrations for up to three years and to cancel registrations. These inconsistencies potentially impact on disciplinary processes and outcomes and should be addressed, especially in the light of the Council of Australian Governments’ recommendations to introduce national registration of pharmacists and other health professionals.⁷

DISCIPLINARY DECISIONS

In general, disciplinary bodies are able to apply a broader range of penalties that are more remedial than are those available to a court.⁸ Disciplinary sanctions imposed on health professionals through regulatory authorities do not follow a punitive approach, but instead seek to protect the public by specific and general deterrence. Therefore, one of the aims of disciplinary actions is to deter other pharmacists from similar behaviour. Additionally, disciplinary outcomes also serve to maintain the reputation and standing of health professionals.⁹ These two outcomes need to be balanced. Weighing the interests of practitioners against the interests of the public may cause some difficulty. This is evident from the decisions of two disciplinary cases that have been appealed to the Supreme Court of Victoria following the imposition of sanctions by the Pharmacy Board of Victoria. Although the court upheld the board’s decisions in the two cases with regard to the pharmacists’ conduct, it did not support the penalties imposed by the board, as these were considered too severe, and less harsh penalties were subsequently imposed.

Mercer v Pharmacy Board (Vic) [1968] VR 72 dealt with a pharmacist who was absent from the pharmacy while it was open and professional services were provided. The court upheld the board’s

⁴ *Pharmacy Act 1964* (NSW), s 19A; *Health Professions Registration Act 2005* (Vic), s 3.

⁵ *Health Practitioners (Professional Standards) Act 1999* (Qld), Dictionary Schedule.

⁶ Pharmacy Board of South Australia, *Codes of Professional Conduct and Professional Practice* (effective 1 July 2006).

⁷ Hattingh HL, Smith NA, Searly J, King MA and Forrester K, “Regulation of the Pharmacy Profession Throughout Australia” (2007) 37 *JPPR* 174.

⁸ Forbes JRS, *Justice in Tribunals* (2nd ed, Federation Press, Sydney, 2002) p 160.

⁹ Freckelton I, “Regulation of Health Practitioners: Grappling with Temptations and Transgressions” (2004) 11 *JLM* 401.

finding that the pharmacist had been guilty of conduct discreditable to a pharmaceutical chemist, but found the cancellation of registration penalty imposed by the board too severe, and imposed a less harsh sanction. Pape J made the following comment in considering the board's penalty (at 93):

I am conscious of the fact that the Board, composed as it is of pharmaceutical chemists who are charged by statute with preserving discipline among pharmaceutical chemists, is infinitely better able to assess the appropriate penalty than I am, and I am not anxious to undermine their authority or discourage them from taking firm action in the interest of the public and the profession nor am I anxious to take any action which might be construed as an indication that I do not regard the conduct proved against the appellant as anything but most serious.

However (at 94):

There are, I think, a number of factors which would indicate that the penalty imposed by the Board (which is the most severe penalty that it could impose) was excessive in all the circumstances.

The court instead imposed a four-week suspension.

Of additional interest is the case of *Ha v Pharmacy Board (Vic)* 18 VAR 465; [2002] VSC 322, as this case did not directly involve the practice of pharmacy but rather, as stated by Gillard J (at [89]), was brought to "uphold the law". Mr Ha, a pharmacist, indecently assaulted two young females (14 and 20 years old) during their job interviews. In the Supreme Court of Victoria, Gillard J acknowledged (at [84]) that, in determining

the standard that one would expect of the reasonable competent pharmacist or the good character and reputation expected of a pharmacist, the members of the Board are usually in a better position than this Court to make an assessment of those matters, and in those circumstances, the Court should attach substantial weight to their findings.

Gillard J further observed (at [86]) that the inappropriate behaviour of the appellant

was not confined to the practice of pharmacy ... However, his conduct does have a connection with the practice of pharmacy in that he was able, by reason of his position as a pharmacist, to deceitfully induce the potential employees to go along with his investigation because, as a pharmacist, he was concerned about the theft of drugs.

He postulated that the Pharmacy Board had a joint focus, namely the protection of the public as well as the protection of the reputation of the profession itself. However, Gillard J considered the order of the board that the pharmacist's registration be suspended and concluded that, in this case, suspension was not necessarily to protect the public but rather to maintain the profession's standing. He held (at [84]):

[W]here the issues involve matters that do not depend upon the practice of pharmacy, then the Court is in as good a position as the Board to make its own assessment of the penalty.

Therefore, although the court upheld the board's finding of professional misconduct, it found the three months' suspension unreasonable considering the circumstances, and it imposed a less severe penalty. Mr Ha was instead fined \$1,500 and given a two-year community-based order to perform unpaid community work, and to undergo psychological or psychiatric treatment as directed.

As part of the disciplinary process is to maintain appropriate standards within the profession and to maintain public confidence in health professionals, it can be questioned whether the Supreme Court of Victoria's lighter sanctions in these two cases were in the best interest of the public, or whether they acted to deter other pharmacists. However, the court does not consistently impose less severe sanctions than the board. In *Loewy v Pharmacy Board (Vic)* [1991] VSC 11301 the court upheld the Pharmacy Board of Victoria's penalties and dismissed an appeal against a three-month suspension for Mr Loewy. This case dealt with the supply of huge quantities of ephedrine to customers. Hedigan J, in his decision as to whether the penalty was appropriate, held (at [32]):

With respect to penalty, the court ought to give weight to the views formed by the relevant professional body created by the Act of Parliament to exercise supervision over the conduct of the members of the relevant profession. Those views have been expressed by the Pharmacy Board and I take them into account.

Another interesting decision was the Supreme Court of Tasmania's decision to increase the penalty imposed on Mr Adamson in *Adamson v Pharmacy Board (Tas)* [2004] TASSC 32. This case

involved a dispensing error whereby the pharmacist dispensed Panafcortelone(r) 25mg instead of 5mg and thereafter incorrectly dispensed a repeat supply of the same tablets. The Pharmacy Board of Tasmania's order was to allow Mr Adamson to continue to practise but only under the supervision of another pharmacist. However, Mr Adamson was the owner of the pharmacy and the court indicated that it would therefore not be appropriate to make him work under the supervision of an employee. As Mr Adamson was already 80 years old, the court instead held that his name be removed from the register, but in order to enable the selling of his pharmacy, deferred the deregistration until a later date. Mr Adamson was not allowed to dispense medication during the deferral of his deregistration.

These cases demonstrate the consistent approach followed by courts with regard to the requirement that pharmacists need to follow legislative provisions that guide the practice of pharmacy and endorsed practice standards. They also demonstrate the important role of the pharmacy registering authorities with regard to disciplining pharmacists for breaches that do not directly relate to pharmacy practice but which impact on the reputation of the profession. However, the determination of appropriate sanctions is a complicated issue that will always be controversial: what may be an appropriate sanction in one case may not be so in another case involving a similar breach. The two outcomes that need to be achieved – namely the protection of the public and the maintenance of professional standards – must be carefully considered. These separate outcomes often complicate the disciplinary process.

PUBLICITY OF OUTCOMES

Another important function of professional disciplinary mechanisms is the publicity given to breaches.¹⁰ It is important that pharmacists are informed of disciplinary outcomes to enable them to predict the consequences of unprofessional conduct. However, New South Wales is the only jurisdiction that publishes all disciplinary case outcomes. In all other Australian jurisdictions only the more serious outcomes are published. This is an area that requires improvement as research has indicated that the publication of disciplinary decisions serves to educate other pharmacists regarding practice requirements and the disciplinary process.¹¹ An analysis of the impact of the publication of the Royal Pharmaceutical Society of Great Britain Statutory Committee's decisions in the *Pharmaceutical Journal* indicated that publication served to inform and deter other pharmacists from similar conduct and played a role in keeping the number of persistent offenders low.¹² Disciplinary outcomes should therefore be used as a tool to improve practice, and communication of pharmacy cases and outcomes to the profession should therefore be improved.

AN ANALYSIS OF QUEENSLAND PHARMACY DISCIPLINARY CASES

Although research has been published regarding New South Wales¹³ and Victorian¹⁴ pharmacy errors that led to disciplinary action, there is a dearth of information about pharmacy disciplinary processes. An analysis was therefore undertaken by the present authors that focused on Queensland pharmacy disciplinary procedures and outcomes.

In relation to the discipline of the pharmacy profession in Queensland, the *Health Practitioners (Professional Standards) Act 1999* (Qld) provides the structural framework within which the discipline of pharmacists takes place. This involves a stepwise approach, where complaints of a potentially serious nature are referred to a Professional Conduct Review Panel while cases involving offences of

¹⁰ Tito F, *Review of Professional Indemnity Arrangements for Health Care Professionals. Compensation and Professional Indemnity in Health Care: An Interim Report* (AGPS, 1994) p 366.

¹¹ Tullet J, Rutter P and Brown D, "A Longitudinal Study of United Kingdom Pharmacists' Misdemeanours – Trials, Tribulations and Trends" (2003) 25 *Pharmacy World & Science* 43.

¹² See Tullet, n 11 at 50: "Indeed, publication of each case in detail in the *Pharmaceutical Journal* may have played a part in this."

¹³ Kiel H, "Pharmacist Misconduct: The Pitfalls of Practice" (2005) 12 *JLM* 348.

¹⁴ Newgreen DB, Pressley JA and Marty SH, "A Survey of Dispensing Errors Reported to the Pharmacy Board of Victoria, July 1998 to December 2004" (2005) 24 *Australian Pharmacist* 644.

such a nature that the registrant could potentially be suspended, or have her or his name removed from the register, are referred to the Health Practitioners Tribunal.

Method

Thirty-six pharmacy disciplinary cases that were subject to disciplinary proceedings between January 2000 and October 2006 were analysed to obtain insight into the incidents that lead to disciplinary action, the processes and evidence used to assess conduct, and the penalties imposed on pharmacists.

Disciplinary case hearings are not open to the public but disciplinary case documentation is available to the general public in de-identified form.¹⁵ Written permission for access to case files was hence sought from the Pharmacists Board of Queensland and a contract subsequently signed with the board to access de-identified disciplinary case documentation. Ethical approval for the study was obtained from the Griffith University Human Research Ethics Committee.

Description of board processes: Evidence and standard of proof

The Act¹⁶ states the following regarding proceedings before the board, disciplinary committee, panel or tribunal:

- When conducting a hearing, a board or disciplinary committee/panel/tribunal –
- (a) must comply with natural justice; and
 - (b) must act quickly, and with as little formality and technicality, as is consistent with a fair and proper consideration of the issues before it; and
 - (c) is not bound by the rules of evidence and
 - (d) may inform itself of anything in the way it considers appropriate.

Therefore, the rules of evidence do not strictly apply in disciplinary proceedings involving health professionals in Queensland. Similar legislative provisions exist in all Australian jurisdictions in relation to the admission of evidence into disciplinary proceedings involving professionals.¹⁷ Therefore, the board, disciplinary committee, panel and even the tribunal may admit and inform itself of matters which, in the judicial adversarial process, would be excluded from consideration based on the inadmissibility of the content as evidence. The disciplinary body thereby has the potential to admit and consider a broader range of information or materials than that which may come before a court. The legislation entrusts the board with broad discretionary powers relating to the amount of evidence, the type of evidence, and the source of the evidence that may be admitted into the proceedings for consideration in determining the outcome of any matter. However, although the rules of evidence do not need to be followed in disciplinary proceedings, they generally provide guidance in terms of fairness and natural justice in the conduct of proceedings.¹⁸ As a general principle, the admissibility of evidence is determined initially on the relevance of the information to the facts in issue and then in weighing up the probative value of the information against its prejudicial impact on the determination.

Pharmacists' conduct was measured and assessed against professional practice standards. The common law test was used frequently in the form of "peer review" evidence, as defined by Priestley JA in *Qidwai v Brown* [1984] 1 NSWLR 100 at 105:

Whether the practitioner was in such breach of the written or unwritten rules of the profession as would reasonably incur the strong reprobation of professional brethren of good repute and competence.

In addition to the opinion of the pharmacists on the disciplinary committee or panel, opinion was also gathered in a dispensing error case caused by the pharmacist's misinterpretation of the prescription. This involved a small survey of nine community pharmacists working in Brisbane. Six of the pharmacists correctly identified the medicine, and while the other three interpreted it incorrectly, all stated they would have contacted the prescriber to clarify the dose. The opinion of an "expert community pharmacist" was also considered in one case.

¹⁵ *Health Practitioners (Professional Standards) Act 1999* (Qld), s 137.

¹⁶ *Health Practitioners (Professional Standards) Act 1999* (Qld), ss 136, 179, 219.

¹⁷ Forbes, n 8, p 173.

¹⁸ Forbes, n 8, p 174.

The standard of proof followed throughout the disciplinary process was the civil standard “on the balance of probabilities”, not the more onerous criminal standard of “beyond reasonable doubt”. This is in accordance with the *Briginshaw* test as defined in *Briginshaw v Briginshaw* (1938) 60 CLR 336, and is the standard followed in Australia with regard to all disciplinary proceedings. The rationale for this lower standard is that the jurisdiction is protective towards the public, and a professional may need to be excluded from practice in order to protect the public on the basis of facts that are impossible to prove beyond reasonable doubt. However, according to *Briginshaw*, the clarity of proof required to discharge the burden must reflect the seriousness of the charge.

Analysis

All of the analysed cases arose from initial complaints received by the board, and were subject to disciplinary inquiries on the grounds of “unsatisfactory professional conduct”.¹⁹ Cases pursued on health grounds that underwent health assessments and monitoring were excluded from the analysis. Cases were categorised into seven categories, as summarised in Table 1. Those cases with multiple breaches involving more than one category were grouped under the most prominent category. Although all of the cases were evaluated, the focus was to gather in-depth information about the four categories relating to a pharmacist’s professional competence to practise or manage the pharmacy, namely:

- dispensing errors;
- inappropriate supply of a Sch 3 medicine;²⁰
- inappropriate owner supervision; and
- excessive supply of pseudoephedrine.

These four categories were considered most likely to be categorised as professional negligence in cases of civil litigation.

TABLE 1 Categories of analysed disciplinary cases

Category	Number	Percentage
Dispensing errors	17	47.2
Fraud	7	19.4
Excessive supply of pseudoephedrine	4	11.1
Inappropriate owner supervision	3	8.3
Inappropriate supply of Sch 3 medicine	2	5.6
Illegal export	2	5.6
Practised without registration	1	2.8

¹⁹ Defined in the Dictionary Schedule of the *Health Practitioners (Professional Standards) Act 1999* (Qld) as: “(a) professional conduct that is of a lesser standard than that which might reasonably be expected of the registrant by the public or the registrant’s professional peers; (b) professional conduct that demonstrates incompetence, or a lack of adequate knowledge, skill, judgement or care, in the practise of the registrant’s profession; (c) infamous conduct in a professional respect; (d) misconduct in a professional respect; (e) conduct discreditable to the registrant’s profession; (f) providing a person with health services of a kind that are excessive, unnecessary or not reasonably required for the person’s wellbeing; (g) influencing, or attempting to influence, the conduct of another registrant in a way that may compromise patient care; (h) fraudulent or dishonest behaviour in the practice of the registrant’s profession; (i) other improper or unethical conduct.”

²⁰ Also referred to as “Pharmacist Only Medicines”. These medicines have been defined by the National Drugs and Poisons Scheduling Committee as “substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription”: see Commonwealth Department of Health and Ageing, *Standard for the Uniform Scheduling of Drugs and Poisons* (2007).

TABLE 1 continued

Category	Number	Percentage
Total	36	100

Dispensing errors

Dispensing errors represented a significant proportion of the cases, which is indicative of the percentage of time pharmacists are occupied with the activity of dispensing and the significance of the dispensing workload. Two of the cases involved incidents that led directly to the death of a person. The case of *Shay v Pharmacists Board (Qld)* (unreported, Brisbane Health Practitioners Tribunal, 2 November 2004, D2929/04) involved the death of a small child as a result of a methadone²¹ overdose: the pharmacist incorrectly dispensed 10 take-away methadone doses to a registered drug addict in a single bottle rather than in 10 separate bottles. Additionally, the pharmacist did not use a child-resistant cap on the bottle, or dilute the take-away doses as was required. The child accessed and swallowed the fatal quantity of methadone and died. This case was referred to the Health Practitioners Tribunal and Richards DCJ made the following comments regarding the responsibility of pharmacists to be vigilant in the dispensing of medicines (p 3):

On the 9th of June Sarah Alder, who was approximately 2 and a half years, died when she ingested the contents of the methadone that was given to Phillips by the Registrant. As I say it is graphic illustration of the need for people who administer dangerous drugs to be scrupulous, not only in their record keeping, but in the procedures that are followed in issuing such medicine. Otherwise tragic consequences such as this can follow.

The other case involved the death of a patient as a result of a Tramadol SR® (tramadol)²² overdose. The pharmacist dispensed the tramadol without affixing a label with proper usage instructions, and also did not provide any advice or a Consumer Medicine Information (CMI)²³ leaflet. Although the prescription did not include the required dosage instructions as specified in the *Health (Drugs and Poisons) Regulation 1996 (Qld)*, the pharmacist did not attempt to contact the prescriber to clarify the dosage. The patient subsequently took an overdose and died.

Three of the dispensing errors caused the patients to be admitted to hospital.²⁴ In the first case, the pharmacist dispensed Ledertrexate® (methotrexate) instead of letrozole.²⁵ Methotrexate is used in low doses, usually 2.5 mg weekly, while the usual dose of letrozole is 2.5 mg daily. Due to the patient incorrectly being dispensed methotrexate, the patient used the methotrexate daily in accordance to the instructions on the label. After two weeks of taking the methotrexate at the dosage level appropriate to letrozole, the patient was

suffering from loss of appetite, extreme fatigue, very painful mouth ulcers, and cellulitis of the leg. She was urgently referred to [a metropolitan teaching hospital] by her local doctor. She was found to be pancytopenic ... She required platelet transfusion and antibiotic treatment for the cellulitis.

The second case involved dispensing the incorrect strength of MS Contin® (morphine).²⁶ MS Contin® 100 mg was supplied instead of MS Contin® 10 mg. Subsequently, the patient took twice-daily doses of 130 mg (30 mg + 100 mg) instead of 40 mg (30 mg + 10 mg), and had to be admitted to hospital:

[S]he felt generally unwell being confused and delusional, extremely drowsy and with an incomplete memory of early hours of that day. She was seen by [the doctor] at his surgery and diagnosed with

²¹ Methadone is used as a substitute in opioid-dependent patients.

²² Tramadol is an opioid analgesic.

²³ Brand-specific, manufacturer-produced written information about drug products that conforms with special provisions set out in the *Therapeutic Goods Regulations 1990 (Cth)*, targeted at patients.

²⁴ Extracts from these cases are quoted with permission from the Pharmacists Board of Queensland.

²⁵ Methotrexate is an antifolate with cytotoxic, immunosuppressive and anti-inflammatory action and is mostly used in weekly doses. Letrozole is used daily in hormone receptor-positive breast cancer in post-menopausal women.

²⁶ Morphine is an opioid analgesic.

bronchitis with delusions secondary to hypoxia ... she was still delusional and had difficulty swallowing. She was taken to [a metropolitan private hospital] where she was found to be febrile and tachycardic and was diagnosed with a chest infection. She was admitted at 1100 hrs. During the admission the dose error with the MS Contin was noticed when the medicine was handed over to be locked in the controlled drugs safe in the ward.

The third hospitalised case involved the substandard labelling of methotrexate tablets. In this instance the pharmacist only labelled the secondary container (the box) and not the primary container (the bottle). The patient discarded the labelled box and used the methotrexate daily instead of weekly, and subsequently became seriously ill:

She was admitted for treatment of her ulcerated mouth and throat, diarrhoea and high temperature ... [The patient's] medical notes as supplied by [a health service district] confirmed that she was admitted ... from 16 March 2004 until 19 March 2004 and again on 22 March 2004 until 27 March 2004. On 16 March she was admitted with methotrexate toxicity and received ... After being discharged on 19 March 2004 she was readmitted on 22 March 2004 as she had difficulty in swallowing due to severe mouth ulceration.

The pharmacist failed to advise the patient regarding the side-effects, and did not provide written information. This case emphasises two practical difficulties: the fact that the methotrexate bottle is very small, and it is therefore difficult to attach a label to it; and the absence of an audit trail of the dispensing process due to dispensing software limitations. For example, software programs do not record how many labels were printed during the dispensing process and whether a Consumer Medicines Information leaflet was printed out.

The remainder of the dispensing errors resulted in less serious physical consequences for the patients. In all of the cases, good dispensing practice procedures were not followed. The errors occurred at various stages of the dispensing process, including selecting the wrong product from the shelf; typing the wrong product into the computer; dispensing the incorrect strength; incorrect labelling; supplying expired medication; unauthorised generic substitution; incorrect recording of Sch 8 medicines;²⁷ and the inappropriate storage of Sch 8 medicines. One complaint was the result of an extemporaneous compounding error.

Inappropriate supply of a Schedule 3 medicine

Two cases involved the inappropriate supply of Sch 3 medicines. One case involved the weight loss product Xenical® (orlistat). The incident occurred in July 2004, only months after the down-scheduling of Xenical® from a prescription product to a Sch 3 medicine by the National Drugs and Poisons Scheduling Committee. The pharmacist supplied the Xenical® to a 15-year-old girl without verifying her age. The supply was outside the provisions of the *Health (Drugs and Poisons) Regulation 1996* (Qld), which specifies a minimum age of 16 years for the supply of Sch 3 medicines. The pharmacist also failed to follow recommended practice guidelines regarding the information to be gathered, and assessment of the patient's body mass index before supply took place. Additionally, the pharmacist did not advise of any side-effects.

The fact that the inappropriate supply of Sch 3 medicines followed through to disciplinary action demonstrates the significance attached to the responsibility given to pharmacists in the supply of Sch 3 medicines.

Inappropriate owner supervision

Three cases involved the responsibilities of pharmacy owners who were not necessarily working on-site in their pharmacies. These cases emphasise that the responsibility of ownership extends to ensuring relevant protocols and procedures are in place in the pharmacy and that pharmacy owners need to provide satisfactory proof to the board if this function had been delegated to another pharmacist.

²⁷ Also referred to as "Controlled Drugs". These medicines have been defined by the National Drugs and Poisons Scheduling Committee as "substances [that] should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence": see Commonwealth Department of Health and Ageing, *Standard for the Uniform Scheduling of Drugs and Poisons* (2007).

Excessive supply of pseudoephedrine

In all four cases involving the excessive supply of pseudoephedrine, it was found that multiple packs were supplied to individuals at a frequency not therapeutically justifiable, or that the drug was for non-therapeutic purposes. Although the pharmacists were aware that pseudoephedrine is readily capable of abuse or misuse in the manufacture of amphetamines, it was supplied in quantities contrary to responsible pharmacy practice and without regard, or sufficient regard, to the risk to the public arising from the side-effects of abuse or misuse of the drug.

One case was determined by the panel, one was referred to the tribunal, and two were referred to the tribunal following the imprisonment of the offenders. In the latter two cases the disciplinary action was based on the provisions in the legislation that provide for disciplinary action following conviction of an indictable offence in a civil or criminal court. The very fact that pharmacists have been imprisoned for the illegal supply of pseudoephedrine indicates the significance of the responsibility placed on the profession to supply these products responsibly, and the expectation that pharmacists will follow the guidelines. Judge O'Brien in *Lim v Pharmacists Board (Qld)* (unreported, Brisbane Health Practitioners Tribunal, 11 December 2001, No 3562/01) stated (p 5):

[I]n the Tribunal's view ... the order made is one which is calculated to maintain public confidence in the profession and in the system of disciplinary administration. There is also the need to remind other practitioners of the consequences of such transgressions.

Regarding pharmacists' professional responsibility, Judge O'Brien in *Honke v Pharmacists Board (Qld)* (unreported, Brisbane Health Practitioners Tribunal, 14 December 2001, D2312 of 2001) stated (p 8):

Having consulted my assessors I have concluded that a pharmacist, entrusted with the responsibility of selling and dispensing drugs which are capable of such abuse, must exercise a greater level of care than that which was demonstrated by the registrant in this case. So much is expected by the public and by other members of the profession.

Judge Richards in *Lau v Pharmacists Board (Qld)* (unreported, Brisbane Health Practitioners Tribunal, 27 October 2003, No 1384/03) considered the seriousness of the breach of public trust in sanctioning the pharmacist (p 4):

[I]t is trite to say that a professional who uses his profession to supply drugs to people of whom he is aware are manufacturing illegal substances commits a very serious breach of the law and a serious breach of his professional standards. So a significant punishment must be imposed in the circumstances.

Other findings

The analysis also identified certain pharmacy practice aspects that need to be addressed.²⁸ These included various shortcomings in dispensing software programs in providing an audit trail and poor record-keeping by pharmacists, which is demonstrated by the following finding:

The prescription was dispensed. Most probably the label was placed on the outer box of methotrexate tablets and given to [the patient] ... (along with a number of other medicines) without any counselling by [the pharmacist] ... In this matter there is no evidence that either [the patient] ... or [the patient's wife] ... were provided with written advice about the dose, day and time of administration for methotrexate – other than the instructions on the label placed on the outer packaging.

A lack of consistency in the utilisation of endorsed practice standards and guidelines was identified; however, the evidence admitted did appear to comply with the requirement of being "logically probative".²⁹ Evidence supportive of registrants and indicating that appropriate procedures were followed was also admitted and considered:

The reason for the decision of the Pharmacists Board that a ground for disciplinary action is not established is that although the registrant did mistakenly dose the patient with 625 mg instead of 125 mg of methadone as a syrup, his actions subsequent to the event complied with the accepted procedures to follow in the case of a dispensing error. In addition he went to considerable lengths to

²⁸ Extracts in this section are quoted with permission from the Pharmacists Board of Queensland.

²⁹ Forbes, n 8, p 176.

find the patient and resolve any problems resulting from the overdose despite receiving incorrect information from the patient himself.

Therefore, evidence was gathered not only to support the complainant but also to ensure compliance with natural justice and hence a fair outcome for the registrant.

Sanctions imposed

The sanctions that may be imposed on pharmacists include the board or committee being empowered to advise, caution or reprimand and enter into undertakings with pharmacists; the panel being additionally empowered to impose conditions on a pharmacist's registration; and the tribunal also being empowered to suspend or cancel pharmacists' registration.³⁰ The analysed cases³¹ indicated that pharmacists were suspended by the tribunal for periods between nine months and two years, with various conditions imposed upon re-registration.

In two of the analysed cases the sanctions imposed seemed to have been inconsistent with previous case outcomes; that is, the sanctions deviated from those imposed in previous cases with similar facts. One case involved the excessive supply of pseudoephedrine. The pharmacist in this case was only required to enter into undertakings with the board, whereas all three pharmacists in similar pseudoephedrine supply breaches had their registrations suspended for between nine months and two years. One explanation for this light sanction could have been the lack of substantial evidence about the breaches before the board:

Although there is no direct evidence of either the supply of multiple packs of Sudafed 60 mg 90s to a particular person, or the supply to particular people of Sudafed 60 mg 90s at a frequency indicating that the usage was not therapeutically justifiable or was for non-therapeutic purposes, the purchasing records indicate a high level of sales, far higher than would normally be expected.

The other case that imposed a sanction inconsistent with the facts of similar cases involved the Tramal SR® (tramadol) dispensing error case which resulted in the death of the patient due to an overdose. The committee identified the following breaches:

1. The prescription for Tramal contained no directions about the use of Tramal or the dose to be taken or administered;
2. The customer [the patient] ... was not the person the prescription was written for;
3. There was no evidence available to the registrant that [the patient] had taken Tramal before; and
4. The Tramal prescribed was of the maximum available strength (200 mg) the registrant failed to affix any label containing directions about the use of Tramal (including the dosage of Tramal to be taken) to the box of Tramal before providing it to [the patient].

Despite these breaches, the pharmacist was merely reprimanded. The purpose of disciplinary proceedings is neither to punish an offending health care practitioner (unlike criminal proceedings), nor to recompense the patient or the patient's family who has suffered harm (unlike a tortious action). Accordingly, the patient outcome is not considered directly, as is the case with civil proceedings. However, part of the disciplinary process is to maintain appropriate standards within the profession and to maintain public confidence in health professionals. The pharmacist involved in this case made various errors in the dispensing of the Tramal SR® which were in breach of the *Health (Drugs and Poisons) Regulation 1996* (Qld), as well as not following the endorsed professional standards. Additionally, the safety of tramadol had been questioned in various professional publications since its registration in Australia in late 1998 with the Therapeutic Goods Administration. Of specific relevance is an article published in the *Australian Adverse Drug Reactions Bulletin* in February 2003,³² just months before the incident. It can therefore be argued that a reasonable pharmacist should have known about the safety risks at the stage of the incident, and should therefore have been particularly careful in the dispensing of Tramal SR®.

³⁰ *Health Practitioners (Professional Standards) Act 1999* (Qld), ss 165(2), 201(2)(b) and 241(2)(g).

³¹ Extracts from these cases are quoted with permission from the Pharmacists Board of Queensland.

³² Adverse Drug Reactions Advisory Committee, "Tramadol – Four Years' Experience" (2003) 22 *Australian Adverse Drug Reactions Bulletin* 2.

CONCLUSION

The disciplinary processes and outcomes followed by the pharmacy registering authorities are crucial in introducing and maintaining practice roles, as well as maintaining public trust in the pharmacy profession. The analysis of the disciplinary cases provides insight regarding the types of errors that lead to disciplinary action. It also highlights the Pharmacists Board of Queensland's approach towards pharmacists who do not comply with their responsibility in ensuring safe medication practices. The analysis supports claims of a changed relationship between the pharmacist and patient, a relationship which implies greater ethical responsibility from pharmacists. This expanded role of pharmacists as medication managers impacts on their potential legal liability.³³

Changes in the practice of pharmacy are partly the result of an increased emphasis on patient care services. Many of the newer roles required to be performed by pharmacists are less procedural in nature than the traditional compounding function and require professional judgment specific to the individual patient's needs.³⁴ These higher cognitive functions, such as the giving of medication advice or identifying medication interactions, therefore create challenges in determining a pharmacist's responsibility in a specific situation. The analysis indicated the many issues that need to be considered by disciplining bodies to ensure best patient outcomes.

The expansion of the judicial recognition of the responsibilities of pharmacists towards patient care services should not be seen as a threat but rather as a positive development, as it reflects an appreciation of the realities of current pharmacy practice. However, the changed role of pharmacists imposes an increased liability risk on them that needs to be managed, and many processes in pharmacy practice need to be reviewed in order to ensure that appropriate risk management practices are in place.

³³ Hattingh L, Forrester K, Smith N and Searle J, "Pharmacy Practice Developments: The Potential Impact on Pharmacists' Legal Liability" (2007) 14 JLM 397.

³⁴ Dwyer P, "A Pharmacist's Duty to Warn" (2003) 12(8) *Australian Health Law Bulletin* 103; Sweet BV, Tatro DS and Whitsett TL, *Pharmacy Law Digest* (Douglas-McKay, Milwaukee, 2004) p 254.