

- i. **Title:** Pharmacists subject to complaints: a national study of pharmacists reported to health regulators in Australia
- ii. **Running title:** Pharmacists subject to complaints
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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1002/JPPR.1633](https://doi.org/10.1002/JPPR.1633)

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iv. Statements:

a. Authorship Statement

MB developed the initial project and YT and MB did the analysis of the data and LH and MB the interpretation of the data. All authors had access to the data. LH drafted the manuscript and all authors provided input into the finalisation of the manuscript.

b. Head of Department Submission Confirmation

The Head of Department of the Centre for Health Policy, Melbourne School of Population and Global Health, Professor Terry Nolan, has given permission for this manuscript to be published.

c. Human Studies Statement

This research was covered under an ethics approval by the University of Melbourne's Human Ethics Sub-Committee (Ethics application 1543670 approved 17 March 2015).

d. Conflict of Interest Statement

No conflicts of interest declared.

e. Acknowledgements

The work was supported by an NHMRC Early Career Fellowship and an NHMRC Partnership Grant with the Australian Health Practitioner Regulation Agency. The authors acknowledge the support of Australian Health Practitioner Regulation Agency, the Health Professionals Councils Authority and Office of the Health Ombudsman for facilitating access to the data.

v. Word counts:

Counts

| | |
|-----------------------|-------------|
| Abstract: | 241 words |
| Article: | 3,107 words |
| Number of references: | 25 |
| Number of tables: | 4 |
| Panel: | 1 |

Article type : Research Article

Pharmacists subject to complaints: a national study of pharmacists reported to health regulators in Australia

ABSTRACT

Background

Complaints against pharmacists provide an opportunity for learning and improvement within the profession.

Aim

To describe the nature and prevalence of complaints about pharmacists in Australia and to identify factors associated with an increased risk of complaints.

Method

De-identified data on all pharmacists registered to practise in Australia between 1 January 2011 and 31 December 2016 were linked with complaints about pharmacists lodged with health regulators during the same period. Descriptive statistics describe the source, nature, outcome, and clustering of complaints. Regression analyses identify factors associated with complaints.

Results

Around 6% of pharmacists who were registered over the six-year study period were subject to at least one complaint to a regulator. Over half of these complaints resulted in regulatory action. Four-fifths of complaints related to five issues: accuracy and appropriateness of dispensing, lawfulness of supply, communication and interpersonal behaviour, records and information, and the health of the pharmacist. Fewer than 1% of pharmacists were the subject of two or more complaints: this group accounted for nearly a third of all complaints. Male

pharmacists and those aged 36 to 44 years were at increased risk of complaints compared with their peers.

Conclusion

A small group of pharmacists in Australia receive a disproportionate share of complaints. Complaints against pharmacists provide an opportunity for learning and improvement within the profession. Improved understanding of complaint patterns may assist in the development of programs to reduce risk to patients and support safe practice by pharmacists.

Keywords

Complaints, Disciplinary action, Medication safety, Notifications, Pharmacists, Risk regulation

INTRODUCTION

Pharmacists play a central role in improving health outcomes through the safe and effective use of medicines and provision of disease management services. Unfortunately, some pharmacists fail to provide the high standard of care that their clients rely on. Understanding complaints and disciplinary actions against pharmacists provides an opportunity to focus regulatory and educational interventions on areas of greatest concern.

Across Australia, over thirty thousand pharmacists are registered to practise pharmacy.[1] Over the last twenty years, the role of pharmacists has become broader and more complex. Pharmacists now provide a wide range of services in hospitals and community pharmacies, as well as other settings such as aged care facilities. They are increasingly expected to take direct responsibility for client outcomes through medication management, with the Pharmacy Board of Australia Guidelines for the dispensing of medicines stating that pharmacists need to exercise independent judgment to ensure medicines are safe and appropriate.[2] In parallel with these changes, there has been increasing awareness of the risk posed by medication-related problems.[3]

Regulation of the pharmacy profession is the principal means of ensuring public trust in the services provided by pharmacists. As far back as the 19th century, pharmacists in Australia have been subject to regulation – initially under the auspices of state and territory pharmacy registering authorities with diverse legislative frameworks and processes.[4] Since 2010, pharmacists across Australia have been regulated by the Pharmacy Board of Australia (the

Pharmacy Board), in partnership with the Australian Health Practitioner Regulation Agency (AHPRA) who oversee the regulation of 16 health professions.[2] As well as approving courses of pharmacy study, developing standards, codes and guidelines for the profession, and registering pharmacists and pharmacy students, the Pharmacy Board is responsible for managing notifications of concern about the health, conduct, or performance of pharmacists across Australia (hereafter referred to as “complaints”). Two States have co-regulatory arrangements with the Health Professionals Councils Authority (HPCA) in New South Wales and the Office of the Health Ombudsman (OHO) in Queensland. Collectively, we refer to AHPRA, HPCA, and OHO as “health regulators”. In addition to the requirements of the Pharmacy Board, pharmacists are bound by state-specific statutes and regulations which authorise the manufacture, sale or supply medicines, along with practice standards and a Code of Ethics for Pharmacists developed by the Pharmaceutical Society of Australia (PSA).[5] Together, these requirements form the regulatory foundations of Australian pharmacy practice, and serve as a frame of reference during disciplinary investigations.

Complaints about pharmacists can be made by a concerned individual through a range of avenues: directly to the pharmacist or their employer, through a health complaint commissioner, or to a health regulator. Notification is mandatory in situations where any registered practitioner, or an employer of a registered practitioner, forms a reasonable belief that another practitioner has engaged in notifiable conduct, such as a pharmacist practising while intoxicated by alcohol or drugs. Complaints lodged with health regulators are assessed and may be referred to the Pharmacy Board. The Board may decide that no further action is needed, require a pharmacist to undergo a health or performance assessment, or refer the matter to a tribunal.

The establishment of the national scheme provides a valuable opportunity to analyse and learn from complaints data. Previous work by Spittal et al. has shown that the rate of complaints about pharmacists is lower than for doctors, dentists, and chiropractors. However, when a complaint is made, the risk of regulatory action is higher, with pharmacists having three times higher odds of a complaint resulting in regulatory action compared to doctors.[6] To date, however, there has been little empirical analysis focused on understanding the prevalence and characteristics of pharmacists who are subject to complaints.

Aim of the study

The aim of this study was to describe the nature and distribution of complaints about pharmacists in Australia and to explore factors associated with being the subject of a complaint.

METHOD

This retrospective cohort study analysed registration and complaints data on all pharmacists registered to practise in Australia over a six-year study period. . It was part of a larger research partnership between AHPRA and the University of Melbourne aimed at identifying hotspots of complaint risk among health practitioners in Australia. The project received ethics approval from the University of Melbourne's Human Ethics Sub-Committee (Ethics application 1543670 approved 17 March 2015). Data were provided in a de-identified form under a strict data protection plan.

Study design

Using administrative data routinely collected by AHPRA, de-identified data on all pharmacists registered to practise in Australia between 1 January 2011 and 31 December 2016 were extracted. The extract consisted of variables indicating the period during which each pharmacist was registered, the pharmacist's age, sex, and practice location. All complaints about pharmacists lodged with health regulators during the same time periods were also identified, and information collected on the date of complaint, source of notification, primary issue raised, and outcome. The registration data was linked to the complaints data using anonymised, unique identifiers.

Measures

To ensure confidentiality, AHPRA provided pharmacists' birth dates in 5-year bands (e.g., 1970-1974). This variable was recorded to reflect each pharmacist's age group at the beginning of the study period. To calculate pharmacists' exposure time (the period each pharmacist could potentially receive a complaint), data on the dates when pharmacists became registered and unregistered with AHPRA were used. For pharmacists whose registration began and/or ended within the interval 1 January 2011 and 31 December 2016 (e.g. new graduates, retirees), the exposure time was adjusted based on the dates when they commenced and ceased registration with AHPRA. The estimated number of hours worked by pharmacists per week considering sex and age was obtained from the Health Workforce

Australia's 2015 Health Workforce Survey.[7] Pharmacists registered to an address outside of Australia were excluded from the analysis.

The primary issue raised by the complainant was coded by health regulators staff on receipt of the complaint. These codes were grouped into 11 complaint issue categories (Table 1) by two investigators.

Data analyses

Initially, frequency distributions were performed to describe the characteristics of notifications, including the reporting source, the primary issue raised by the complainant, and the number of notifications made against a pharmacist. Negative binomial regression was then performed to examine the factors associated with complaints including pharmacists' age, gender, area remoteness, jurisdiction and average hours worked weekly. All analyses were conducted using Stata 14.2 (College Station, Texas).

RESULTS

Sample characteristics

The data on complaints were analysed for 33,226 pharmacists registered with AHPRA at any time between 2011 and 2016. While most pharmacists were female (59.9%), nearly 60% of pharmacists with complaints were male (Table 1). Most pharmacists practised in metropolitan locations (79.0%), and over three-quarters lived in NSW, Victoria or Queensland. Pharmacists aged 36 to 45 years made up less than 18% of the practising pharmacists but accounted for more than a quarter of complaints.

Distribution and source of notifications

Over the study period, 2,374 notifications against pharmacists were received by regulators. A large majority of pharmacists (94.2%) had no complaints to health regulators during the study period. Around 300 pharmacists (0.9% of all pharmacists) were subject to two or more complaints accounting for over 31% of all complaints about pharmacists.

Over half (52.2%) of the complaints were made by a client or relative, 17.1% by another health practitioner, 9.1% by police or another government department (such as a drugs and poisons service), 8.6% by a health regulator, and the rest by another agency, employer or a self-notification from the pharmacists themselves. Whilst police and other government

departments lodged fewer than 10% of complaints overall, they were the source of nearly a quarter (23.4%) of concerns regarding the lawfulness of medicine supply ($p < 0.001$).

Over half of the notifications (51.0%) resulted in regulatory action against the pharmacist, such as a fine, undertaking, imposition of conditions or – in the most serious cases – suspension from practice (Table 2).

Notifications type

As shown in Table 3, more than half of the complaints involved medicines (59.8%). Within this medicines-related category, around 70% raised concerns about the accuracy or appropriateness of dispensing or supply. This category included errors in the drug, dose, quantity, person, or packaging. The remainder of the medicines-related complaints raised concerns about the lawfulness of dispensing or supply. This category included concerns about the illegal supply of drugs of addiction, supply for re-sale, and supply for non-therapeutic purposes.

One in ten complaints related to interpersonal behaviour or communication (10.3%). The most common concerns within this category were inadequate information about medication and disrespectful manner. Seven percent of complaints related to the health of the pharmacist and over half of these health-related complaints raised concerns about substance use by the pharmacist; the remainder related to the physical or mental health of the pharmacist. Use of client information was the primary issue in one in twenty complaints (5.5%). Within this category, the most common concerns were about inappropriate collection and disclosure of patient information.

Factors associated with notifications

After adjusting for age, sex, remoteness, jurisdiction, and number of weekly hours worked, the risk of complaints was highest amongst pharmacists aged between 36 to 45 years. Compared with pharmacists aged under 36 years of age, the risk of notifications was nearly 40% higher (IRR 1.37, 95% CI, 1.14-1.65) for the 36-45 age group (Table 4). Male pharmacists were found to be twice as likely as female pharmacists to be subject to notifications (IRR 2.09; 95% CI, 1.70-2.57). The risk of complaints did not appear to differ significantly between pharmacists working in metropolitan compared to those in regional/rural areas.

DISCUSSION

This national study of complaints to health regulators showed that around 6% of all pharmacists who were registered over a six-year period were subject to at least one complaint to a regulator and over half of the complaints resulted in regulatory action. Most of the complaints related to medicines, with concerns about inappropriate or unlawful prescribing or supply of medicines featuring highly. Male pharmacists, and those aged 36 to 45 years, were at highest risk of notifications. Less than 1% of pharmacists accounted for over 30% of complaints.

Our finding that male pharmacists were twice as likely as female pharmacists to be the subject of a complaint is consistent with previous research. A 2011 review of pharmacy disciplinary literature covering the United Kingdom (UK), United States of America (USA), Canada, Australia, New Zealand and Europe found that male pharmacists were more likely to experience performance problems.[8] Similar findings on increased complaint risk among male practitioners have also been found in studies of other health professions.[9, 10] However, the Royal Pharmaceutical Society of Great Britain's disciplinary case data showed no correlation between pharmacists' gender and disciplinary action.[11] Importantly, our study controlled for important confounders including age and average hours worked.

Our study showed that mid-career pharmacists, aged between 36 and 45 years, were at highest risk of notifications. This contrasts with research on doctors, which found that doctors over the age of 65 had the highest risk of complaints.[12] Previous research with pharmacists has not identified an association between age and performance[8] although concerns have been raised about younger pharmacists reporting high levels of workload stress.[13] In turn, workload stress and fatigue may contribute to dispensing errors as highlighted by two UK studies that linked errors to high dispensing volume, work overload and job characteristics.[14, 15] This is a topical issue, with regulators and professional organisations expressing concern about dispensing workload pressures in certain pharmacy settings.[16]

The clustering of complaints identified in this study is consistent with data from the Disciplinary Committee of the Royal Pharmaceutical Society of Great Britain, which showed approximately one-fifth of pharmacists meeting with the Disciplinary Committee had previously been disciplined by the Society.[11] Further work is needed to understand whether an intervention, such as mentoring following a first complaint, may help to reduce the risk of

further complaints. Research with doctors and medical students suggests that red flags for conduct issues may even arise during training, and that a long-term approach is required to avert careers of misconduct.[17, 18] Where misconduct has occurred, the practitioner's level of insight or understanding is an important factor in assessing what action needs to be taken.[19]

Over half of the complaints about pharmacists related to medicines (60%). Within this group, concerns about accuracy or appropriateness (e.g. dispensing errors) were twice as common as concerns about ethics or lawfulness (e.g. supply of drugs of abuse). This result is unsurprising. Dispensing of medicines is the core function of pharmacists in community pharmacy settings where most pharmacists are employed. The dispensing process has evolved over recent years into a complicated process involving cognitive, clinical and technical aspects with many risks for error if structured processes are not followed and barcode scanners not used. While dispensing errors can have serious consequences, including death, they are mostly unintentional and pharmacists with disciplinary action due to dispensing errors are typically cautioned (see Panel 1). A recent coronial inquest emphasised the responsibility of pharmacists to "prevent medication misadventure"[20] and the Pharmacy Board periodically reminds pharmacists to follow appropriate dispensing procedures, ensuring that all medicines are clearly labelled, including dose administration containers.[2]

One third of the complaints about medicines raised concerns about unlawful dispensing or supply of medicines. These complaints were significantly more likely to be lodged by police or other government agencies, compared with complaints about other issues. Such conduct is taken very seriously by the Pharmacy Board and tribunals, and several pharmacists have had conditions imposed on their registration or been deregistered, some with criminal convictions, due to the unlawful supply of medicines that could cause addiction and anabolic steroids (see Panel 1).

Communication or interpersonal conduct was the primary issue in one in ten complaints, with disrespectful communication and insufficient information featuring highly among these complaints. The need to communicate effectively with clients, healthcare team members and other healthcare professionals has grown with the changes in pharmacy practice and advanced communication skills are now integrated throughout pharmacy curricula. Communication and collaboration is one of the five domains of pharmacists' competency

standards; it is also embedded throughout the PSA Professional Practice Standards.[21] However, our data highlight a need for the profession to provide ongoing training in effective communication and professional interpersonal behaviour. This should include training on complaint resolution to reduce the risk of dissatisfied clients feeling ignored and subsequently escalating a complaint.

Concerns about records and use of client information was the primary issue in one in twenty complaints (5.5%). Research has highlighted privacy and confidentiality challenges in pharmacy practice settings, especially community pharmacy which is both a professional environment as well as a retail space.[22] Our findings highlight the need for staff education on privacy and confidentiality requirements. This is particularly important considering changes in scope of practice and the provision of new professional services that require pharmacists to collect sensitive information from clients and the recent national roll out of My Health Record with increased privacy protections.

In our sample, nearly 4% of all complaints related to substance use – a higher percentage than for health practitioners overall. Pharmacists are thought to be at heightened risk for drug misuse and addiction due to their ready access to potent drugs of abuse, a stressful working environment, a culture that unofficially condones medication diversion, lack of education related to addiction, and lack of support for individuals seeking treatment.[23] Despite the introduction of mandatory reporting laws, it is likely that our study significantly underreports rates of substance use among pharmacists in Australia. A US study estimated that more than half of pharmacists had used a non-prescribed prescription drug at least once in their lifetime.[24] Past-year prevalence of drug use was higher among pharmacists than other health professions (12.8%). Another US study found that around 40% of the pharmacists surveyed had, on at least one occasion, used some form of mind-altering or potentially addictive prescription drugs without first obtaining a prescription from a doctor, and about one-fifth of respondents reported repeated use.[25] Further research is needed to assess the prevalence of substance misuse among Australian pharmacists.

A key strength of this study was its breath, covering all registered pharmacists in every state and territory of Australia across a six-year period. We were also able to control for important confounders, such as average number of hours worked. Our study also had some limitations. While our complaints data came from a national dataset, our dataset did not include outcome

data for NSW notifications, which accounted for a third of all notifications. We did not have sufficient statistical power to assess the factors associated with a complaint with regulatory outcomes. This would be a useful area for further research. The generalisability of our findings to pharmacists outside Australia is not known. However, our findings regarding risk factors and clustering of complaints are consistent with previous work in Great Britain.[11] A second important limitation is that our study focused on complaints lodged with health regulators and did not include complaints lodged directly with pharmacists, employing organisations, or health complaints commissions. Third, complaints were coded at the time they were received by health regulators and our issue categories may therefore not reflect information gathered during subsequent assessment or investigation. The coding taxonomy was designed for use by all registered health professions and therefore lacked granularity around the exact nature of medicines-related complaints. We also note that complaints and adverse outcomes are imperfectly related: some complaints arise following appropriate care, and many clients who suffer serious preventable adverse events never complain. Furthermore, we were not able to measure certain practitioner-level variables that may be associated with an increased risk of complaints. These include client and dispensing volume, public or private practice setting, number of colleagues, country of training, and disciplinary history. Our measure of practice location was collected at the beginning of the study period and does not reflect pharmacists who may have moved during the study period, or who may have been practising in a location other than their principal practice at the time of the complaint.

CONCLUSION

This study describes the nature and distribution of complaints about all Australian pharmacist over a six-year period and the factors associated with being the subject of a complaint. Four-fifths of complaints related to five areas of concern: accuracy and appropriateness of medicines; lawfulness of medicines; communication and interpersonal behaviour; records and information; and the health of the pharmacist. Male pharmacists and those aged 36 to 45 years were at highest risk of complaints. A small group of pharmacists received a disproportionate share of complaints. Improved understanding of these complaint patterns may assist the Pharmacy Board of Australia and professional organisations in the development of programs to reduce risk to clients and support safe pharmacy practice.

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Table 1: Demographic characteristics of pharmacists registered between 2011 and 2016

| | Pharmacists with complaints (N = 1,936) | Total Pharmacists (N = 33,226) |
|--------------------|--------------------------------------------------------|-----------------------------------------------|
| | N (%) | N (%) |
| Age (years) | | |
| <36 | 854 (44.1) | 16817 (50.6) |
| 36-45 | 489 (25.3) | 6091 (18.3) |
| 46-55 | 278 (14.4) | 3959 (11.9) |
| 56-65 | 201 (10.4) | 3210 (9.7) |
| ≥66 | 114 (5.9) | 3149 (9.5) |
| Sex | | |
| Female | 784 (40.5) | 19915 (59.9) |
| Male | 1152 (59.5) | 13311 (40.1) |
| Remoteness | | |
| Metropolitan | 1523 (78.7) | 26251 (79.0) |
| Regional/Rural | 413 (21.3) | 6975 (21.0) |

Table 2: Sources and outcomes of complaints

| | Complaints (N=2,374) |
|--------------------------------------------------|---------------------------------|
| Source of complaint | |
| Client or relative | 1238 (52.2) |
| Employer | 107 (4.5) |
| Health practitioner | 406 (17.1) |
| Police, drugs and poisons, government department | 215 (9.1) |
| Health regulator | 204 (8.6) |
| Self-notification | 33 (1.4) |

| | |
|--------------------------------------------------------|----------------|
| Other | 171 (7.2) |
| Outcome¹ | |
| No regulatory action | 638 (49.0) |
| Referral to another body | 26 (2.0) |
| Caution, reprimand, fine, undertaking | 449 (34.5) |
| Conditions, suspension, cancellation | 188 (14.5) |
| Time to complaint resolution (days)² | 149 (79 – 313) |

¹Percentages were calculated with the number of available observations used as the denominator. Outcome data was not available for 62 cases with unknown outcome and 206 cases that were still open at the end of the study period. Excluded NSW complaints as outcome data from NSW not included in our dataset.

²Time to notification resolution median (IQR) calculated using observations from closed cases. Excluded NSW complaints as outcome data from NSW not included in our dataset.

Table 3: Complaints by issue type

| | Number | % |
|-----------------------------------------------------------|--------|------|
| Access / delays | 49 | 2.1 |
| Assessment / diagnosis / treatment / monitoring | 30 | 1.3 |
| Communication / interpersonal | 245 | 10.3 |
| Compliance with practice laws / registration requirements | 82 | 3.5 |
| Costs / honesty | 73 | 3.1 |
| Health of practitioner | 162 | 6.8 |
| Mental or physical health | 73 | 3.1 |
| Substance use | 89 | 3.7 |
| Medicines | 1419 | 59.8 |
| Accuracy and appropriateness | 992 | 41.8 |
| Lawfulness | 427 | 18.0 |
| Records / reports / use of information | 131 | 5.5 |
| Other | 183 | 7.7 |

Table 4: Factors associated with at least one complaint¹

¹ Adjusted for State and clinical hours worked

| Characteristic | IRR (95% CI) | p-value |
|--------------------|--------------------|---------|
| Age (years) | | |
| <36 | 1.00 (reference) | - |
| 36-45 | 1.37 (1.14 – 1.65) | 0.001 |
| 46-55 | 1.14 (0.89 – 1.46) | 0.227 |
| 56-65 | 1.14 (0.89 – 1.46) | 0.302 |
| ≥66 | 1.12 (0.67 – 1.87) | 0.659 |
| Sex | | |
| Female | 1.00 (reference) | |
| Male | 2.09 (1.70 – 2.57) | <0.001 |
| Remoteness | | |
| Metropolitan | 1.00 (reference) | |
| Regional/Rural | 1.02 (0.91 – 1.15) | 0.692 |

Panel 1: Case studies*

Medicines – appropriateness or accuracy

Dispensing error: A pharmacist made a dispensing error by dispensing medication different to that which had been prescribed but labelled as the prescribed medication. The pharmacist had not checked the product, had not used the barcode scanner, and had not checked the dispensed product when counselling the client. When the prescribing doctor queried the appearance of the medication, the pharmacist provided an inadequate and ill-considered response. The disciplinary panel acknowledged that since the incident, the pharmacist reviewed the stock in the dispensary monthly, used the bar code scanner at each dispensing, and confirmed client details against label at counselling. The pharmacist was cautioned.

Medicines – lawfulness

Drugs of addiction: A pharmacist illegally supplied over 800,000 tablets of

benzodiazepines and opiates from his pharmacy over a 5-year period. His registration was cancelled. A court sentenced him to 12 months imprisonment on each of twelve charges, to run concurrently.

Anabolic steroids, stimulants and growth hormones: A pharmacist admitted to professional misconduct by dispensing drugs for non-therapeutic reasons, despite knowing the risks of doing so. He had dispensed clomiphene to male clients when he knew that the medical practitioners who had written the prescriptions didn't have authority to do so. He had also dispensed anabolic androgenic steroids, stimulants and human growth hormone to clients in quantities and combinations which created a real risk of adverse effects, and a real risk of on-selling to others. His registration as a pharmacist was cancelled, and he was disqualified from applying for re-registration for 30 years.

Health – substance use

Opiate addiction: A pharmacist suffered a serious and long-standing addiction, primarily to opiates. At no point in his training, registration or annual re-registration had he notified the Pharmacy Board of his substance abuse issues, including previous hospital admissions for drug detoxification. He was recorded on CCTV footage removing boxes of section 8 medicines from the safe and taking them to an area unseen by CCTV cameras. Empty packets of OxyContin were found in a bin where old medications are discarded. Audit of the drug register showed discrepancies of hundreds of Oxycontin tablets between the number prescribed and the number dispensed. Mr O was deregistered and prohibited from reapplying for registration for three years. The Tribunal expressed concern about the “code of silence” under which his colleagues failed to notify the regulator of their concerns. The Tribunal noted that timely notification may have resulted in him receiving supervision, monitoring and treatment that could have helped him, and may even have prevented the events that ultimately led to these disciplinary proceedings.

* References available on request