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All authors devised the study and its methodology, created the questionnaire, sought ethics approval, recruited participants and collected questionnaires electronically. MK and DH performed statistical analyses. All authors had access to the data, contributed to all drafts of the paper and approved the final copy for publication.

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Abstract

Objectives Reclassification of medicines from prescription to non-prescription increases timely access to treatment, promotes self-management of minor ailments and relieves healthcare system burden. Previous research identified that Australia lagged behind the United Kingdom and New Zealand in medicines reclassification. This study aimed to identify Australian pharmacists' opinions on the current state of medicines reclassification; the prescription medicines consumers requested without prescription; the medicines pharmacists believed should and should not be considered for reclassification; and perceived barriers to reclassification.

Methods A 2016 national online survey that sought pharmacists' opinions on the state of reclassification, perceived barriers to reclassification and readiness of the profession for further reclassification. Pharmacists' comments were invited through open-ended questions.

Key findings Two hundred and thirty-five valid surveys were completed. Respondents practised in community, hospital, consultant and academic contexts, and the majority were female (58.7%, n=138). More than two thirds (70.66%, n=166) of pharmacists reported receiving daily or weekly requests for non-prescription access to prescription medicines. The majority of pharmacists (71.7%) agreed that the Australian pharmacy profession is ready for further medicines reclassification, guided by patient safety, harm minimisation and medication continuance. The most prominent barrier to further reclassification was opposition from other healthcare professionals.

Conclusions Australian pharmacists believe that their profession has the capacity to safely and effectively manage a wider range of non-prescription medicines through increased reclassification in the contexts of patient safety and risk mitigation. This study has contributed

to the global conversation on non-prescription medicines access, providing momentum for practice and policy change.

Key Words Australia; pharmacists; health policy; legislation, drug; non-prescription drugs.

Introduction

Community access to medicines without prescription can increase timely initiation of effective treatment, promote self-management of minor ailments, and encourage patient autonomy in health decision-making.[1,2] Responsible self-medication has also been shown to provide significant economic benefits, including improved productivity and cost savings.[2-4]

In Australia and countries with similar health systems, access to medicines is regulated through a classification system or *scheduling framework*, guided by a medicine's therapeutic purpose, potential for abuse, safety, toxicity and the need for access.[5] In Australia, unscheduled medicines are considered low risk and are available for general sale from retail outlets, while scheduled medicines are classified into progressively more restrictive schedules under the federal Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). Schedule 2 (S2) *Pharmacy Medicines* are available only from pharmacies and may be obtained without further necessary intervention; Schedule 3 (S3) *Pharmacist Only Medicines* are available only from pharmacies and require pharmacist involvement to determine appropriateness and advice to ensure proper use; Schedule 4 (S4) *Prescription Only Medicines* and Schedule 8 (S8) *Controlled Drugs* are available only on prescription. S8 medicines have the greatest degree of restriction to reduce potential abuse, misuse and dependence.[5]

An Australian study that reviewed medication access guided by the classification processes in six countries, i.e. Australia, New Zealand, Canada, France and the United Kingdom (UK), reported that the presence of pharmacy-specific schedules facilitated reclassification of medicines into less restrictive schedules, thereby broadening consumer access.[6] This contrasts with the United States of America (USA) where pharmacy-only schedules do not exist.[2] A range of other factors have been identified as either enablers or barriers to medicines reclassification.[7,8] Gauld *et al* showed that enablers included stakeholders' confidence in regulators and regulator support.[7] Barriers to reclassification included risk averseness, limited

trust by regulators in consumers and pharmacists, and 'patch protection' by other healthcare professionals, for example the Australian Medical Association has opposed reclassifications.[8] These articles identified that Australia had more barriers than enablers when compared with the UK[7] and New Zealand.[8]

Notwithstanding these significant barriers, Australian examples of medicines that have been reclassified from S4 to S3 include levonorgestrel for emergency contraception in 2004,[9] proton pump inhibitors for reflux from 2008,[10] ophthalmic chloramphenicol for bacterial conjunctivitis in 2010,[11] oral famciclovir for cold sores in 2012,[12] naloxone for opioid overdose in 2016[13] and ulipristal for emergency contraception in 2017.[14]

Medicines reclassification has also occurred in the direction of increased restriction, primarily due to concerns over medicines abuse, misuse or safety. For example, Australia reclassified flunitrazepam in 1997 and alprazolam in 2014, from S4 to S8,[15] and codeine-containing analgesics from S3 to S4 in 2018.[16] Additionally, Australia reduced pack sizes and reclassified non-prescription pseudoephedrine to S3 in 2006.[16] In New Zealand, pseudoephedrine was up-scheduled to prescription only in 2011,[17,18] and in the UK, oral diclofenac was reclassified from non-prescription to prescription-only in 2015, due to concerns over perceived cardiovascular risk.[19]

When compared with other countries with similar health systems e.g. the UK and New Zealand, Australia's reclassification appears to have fallen behind.[8,20,21,22] Despite the goal of regulatory harmonisation between Australia and New Zealand,[23,24] between 2003 and 2013, New Zealand allowed more drugs to be rescheduled than Australia,[21] including the provision of pharmacist only supply of sildenafil for erectile dysfunction, triptans for migraine, trimethoprim for urinary tract infection (UTI)[25] and oseltamivir for influenza.[8,17,20,26] These medicines are currently S4 in Australia, suggesting that consumers may face unnecessary barriers to timely access for some medicines.

There are additional medicines that have been reclassified in other countries that remain prescription only in Australia.[22,27,28] For example, New Zealand has recently approved selected oral contraceptives for non-prescription access from specially trained pharmacists[29] while Australia rejected applications for reclassification of oral contraceptives and has only allowed pharmacist provision of certain oral contraceptives under comparatively strict conditions of the Continued Dispensing Initiative.[30] Continued Dispensing occurs within the Pharmaceutical Benefits Scheme (PBS) and allows pharmacists to provide medication continuance of subsidised oral contraceptives and 'statins', without prescription once every 12 months if patients meet particular criteria.[30] This approach is similar to prescribing models such as the Chronic Medication Service in Scotland.[31]

Recent research to examine New Zealand pharmacists' views on reclassification of certain medicines indicated both motivation and readiness.[32] The extent of Australian pharmacists' perceived readiness for a greater role in providing increased consumer access to medicines that are presently prescription only is under explored. Pilot research indicated that pharmacists often received requests for non-prescription access to prescription medicines and supported reclassification, underpinned by motivation to facilitate consumers' self-management and medication adherence.[33] However, the small study sample involved only community pharmacy staff and may not be generalisable to all practice contexts. It is timely to more broadly explore Australian pharmacists' perspectives, particularly given the February 2019 introduction of Appendix M to the SUSMP by the Australian Therapeutics Goods Administration. Appendix M has been proposed as a mechanism to allow provision of selected S4 medicines by a pharmacist without prescription and will list S3 medicines with additional controls or supply requirements.[34]

The aim of this study was to explore and identify Australian pharmacists' opinions on the current state of medicines reclassification; the type of prescription medicines that consumers

request to access without prescription; the frequency of requests; the medicines that pharmacists think should and should not be considered for reclassification; the perceived barriers to reclassification; and the readiness of the profession for future reclassification of prescription to non-prescription medicines in Australia. The intended outcome was to inform the national and global conversations regarding consumer access to medicines.

Methods

A survey was developed, informed by the literature and pilot qualitative research.[33] The survey comprised three sections. Section 1 gathered demographic information (gender, length of practice, practice location, role and practice context), sought opinions on Australia's current state a medicines reclassification using 5-point Likert scale responses (1= strongly disagree and 5 = strongly agree) and asked how often participants were asked for non-prescription access to prescription medicines (daily, weekly, monthly, every few months, rarely or never). Section 1 also invited free-text responses for the most common medicines asked for, medicines the participant thought should be made available without prescription, and why. Section 2 sought opinions related to 17 different medicines/medicine classes that were available without prescription in countries with similar health systems to Australia. Data generated from Section 2 have been reported elsewhere[35] and will not be reported in this manuscript. Section 3 sought opinions on the readiness of the Australian pharmacy profession for reclassification, using a 10-point scale (1 = not at all ready and 10 = completely ready) used for assessing motivational readiness for change.[36] Section 3 also sought opinions on perceived barriers to change with a 5-point Likert scale and invited free-text responses on the classes of prescription medicines participants thought should never be considered for reclassification and why. The survey was piloted with pharmacists from an academic and/or community pharmacy background and items were reviewed for face and content validity.

The online JotForm survey was administered nationally between August and December 2016. The survey was promoted by a national pharmacy organisation via a continuing professional e-learning website. Strategies used to enhance response rates for online surveys included selection of a topical survey subject, official sponsorship via pharmacy industry channels, use of multiple online channels for recruitment, limiting the length of the survey and a prize draw to incentivise participation.[37] Institutional ethical clearance was obtained (PHM/04/15/HREC).

Data were exported to Microsoft Excel. Responses from non-pharmacist pharmacy staff (n=12, 4.9% of 247 responses) were excluded from data analysis as being poorly representative. Responses to free-text questions were coded thematically by two researchers and confirmed by a third. Pharmacists identified individual medicines or medicine classes as medicines that should or should not be reclassified and these were coded according to the Anatomical Therapeutic Chemical classification system hierarchy,[38] using the process outlined above. SPSS 22 was used to calculate means and medians of Likert scale responses, frequencies and percentages. Likert scale responses were either reported as aggregated into agree/strongly agree or neither agree or disagree, or disagree/strongly disagree, or as means and medians to provide an overview of level of agreement with particular statements.

Results

Results included 235 valid survey responses from pharmacists, working in community, hospital, consultant and academic practice contexts. Participants were predominantly female (Table 1). All Australian states and territories were represented.

Table 1: Participant Demographics

Demographic Characteristic		n	(%)
Gender (n=235)			
	Male	97	(41.3)
	Female	138	(58.7)
Length of Practice (n=235)			
	Less than 5 years	21	(8.9)
	6-10 years	62	(26.4)
	11-20 years	51	(21.7)
	21-30 years	30	(12.8)
	31-40 years	53	(22.6)
	41-50 years	8	(3.4)
	More than 51 years	10	(4.3)
State or Territory (n=235)			
	Australian Capital Territory	13	(4.5)
	New South Wales	97	(33.8)
	Northern Territory	4	(1.4)
	Queensland	96	(33.4)
	South Australia	10	(3.5)
	Tasmania	7	(2.4)
	Victoria	40	(13.9)
	Western Australia	19	(6.6)
Practice Role (n=231)			
	Student Pharmacist	2	(0.9)
	Intern Pharmacist	8	(3.4)
	Dispensing Pharmacist	80	(34.0)
	Forward Pharmacist	96	(40.9)
	Consultant Pharmacist	16	(6.8)
	Other (including academia)	29	(12.3)

Current state of medicines classification

Opinions on whether 'the current rate of down-scheduling limited consumers' access to medicines' (n=228) were polarised, with 95 participants (41.7%) indicating that they disagree or strongly disagree with the statement while 88 (38.6%) indicated that they agreed or strongly agreed with the statement. (NB the term *down-scheduling* indicates reclassification to less restrictive medicines access. It is commonly used by Australian health practitioners and can be used interchangeably with reclassification, providing directional context to reclassification.) Responses to the statement depicting the current scheduling as providing appropriate access to medicines (n=226) were also polarised, with 74 participants (32.7%) disagreeing or strongly disagreeing while 105 (46.5%) agreed or strongly agreed.

Requests for non-prescription supply of Prescription Only Medicines

Respondents indicated that they were often asked for non-prescription access to a wide range of prescription medicines, with 70.6% (n=166) indicating that they had been asked at least once weekly. The most commonly requested medicines were anti-infectives (25.8%, n=161, combining antibiotics, antivirals and antifungals), analgesics, oral contraceptives, corticosteroids (mainly topical and inhaled) and anti-emetics. Reported requests included both increased quantities and/or higher strengths of existing non-prescription analgesics, or access to prescription only analgesics, such as tramadol and celecoxib. Response to the statement 'Australia is aligned with down-scheduling in countries with similar health systems' (n=231), indicated many were neutral (n=84, 36.4%).

Medicines that should be down-scheduled

The majority of respondents (n=176, 74.9%) identified medicines that they considered should be down-scheduled. The remaining respondents considered reclassification unnecessary

(n=36, 15.3%), were uncertain (n=4, 1.7%) or did not answer (n=19, 8.1%). Table 2 summarises the medicines most frequently identified as potential candidates for down-scheduling and exemplar comments that justified these choices.

Table 2: Most Frequently Reported Prescription Medicine Classes for Down-Scheduling

Classification	**n**	**(%)***
Anti-infectives	112	(25.9)
Contraceptives	73	(16.9)
Corticosteroids	67	(15.5)
Lipid lowering agents	31	(7.2)
Antiemetics	29	(6.7)
Analgesics	21	(4.9)
Antihypertensives	19	(4.4)
Erectile dysfunction drugs	13	(3.0)
Proton pump inhibitors	13	(3.0)
Antimigraine drugs	8	(1.9)
Vaccines	6	(1.4)
Other	40	(9.3)

* A total of 432 medicines were reported

Exemplar Respondent Quotes Supporting Opinions for Down-Scheduling
Medication safety: *If the medication is safe; and treatment without regular review by a health professional is safe, then a change in schedule should be considered on its merits.* (ID 259)
Medicines continuance: *Up to weeks supply of most medication required for continued treatment in emergency when contact with prescriber is not possible. This would relieve pressure on emergency departments.* (ID 272)

Antibiotics were the most frequently proposed drug class, spanning topical, otic and selected systemic medicines. Justifications for potential down-scheduling included improved consumer access to medicines; the promotion of safe access to effective medicines for acute conditions; alignment with other countries; and consumer and healthcare cost savings. Some supported the concept of medication continuance without a new prescription for established medication regimens.

Only a small number of participants (3.0%, n = 13) identified erectile dysfunction drugs as having been requested by consumers and as potential candidates for reclassification, whereas tamsulosin for the urinary symptoms of benign prostatic hyperplasia was not identified. Respondents prioritised medicines that would facilitate medication continuance for ongoing chronic or stabilised conditions, such as asthma, e.g. inhaled corticosteroids, or hypertension, e.g. antihypertensives. Continuity of patient care was often discussed in qualifying text responses to support candidates for potential reclassification.

Medicines that should never be down-scheduled

Most respondents (n=207, 88.1%) provided detailed suggestions on medicines that should not be considered for reclassification and these reflected a wide range of drugs and drug classes (n=577 classifiable medicines), with one respondent listing 15 different classes of medicines. Table 3 summarises the medicines most frequently identified as never to be down-scheduled and associated exemplar comments.

Table 3: Most Frequently Reported Prescription Medicine Classes Not for Down-Scheduling

Classification	**n**	**(%)***
Psychotropic drugs	153	(26.5)
Cardiovascular drugs	105	(18.2)
Anti-infectives	86	(14.9)
Analgesics	85	(14.7)
Antineoplastics and immunomodulators	53	(9.2)
Neurologicals	36	(6.2)
Antidiabetic drugs	24	(4.2)
Endocrine drugs	17	(2.9)
Other	18	(3.1)

*A total of 577 classifiable medicines were reported

Exemplar Respondent Quotes Supporting Opinions Not for Down-Scheduling
Patient safety and scope of practice:
They require close doctor monitoring (e.g. efficacy, ADRs [adverse drug reactions], pathology). Pharmacists also do not get paid the same as doctors so should not shoulder the responsibility. (ID 76)
Pharmacists should have limited prescribing rights. That is the only way medicines can be down-scheduled safely and there is accountability in the system, whilst at the same time improving public access. (ID 195)
Antibiotic resistance:
Antibiotic resistance is a serious issue. Observing what has occurred in countries… where access to AB [antibiotics] is unrestricted is frightening…" (ID 257)

More than a third of respondents (36.6%, n=86), identified anti-infectives as a class of medicines that should never be down-scheduled, citing concerns of overuse and the development of resistance. Other key medicines identified as not suitable for reclassification included psychotropic drugs, e.g. antidepressants and antipsychotics; cardiovascular drugs; analgesics; and groups of medicines with specific attributes. These included drugs of addiction or dependence, e.g. opioid analgesics, benzodiazepines and psychostimulants; and medicines with a narrow therapeutic index. Respondents cited concerns for patient safety, possibly unveiling that pharmacists perceived themselves as having limited skills to diagnose and capacity to conduct therapeutic drug monitoring, and limited remuneration or financial viability as justification for their opinions. When naming analgesics (particularly opioids), as medicines

never to be considered for reclassification, pharmacists cited concerns for patient and public safety, underpinned by potential for overuse, misuse and abuse of the medicines. They were also concerned about the potential for antibiotic resistance, citing overseas experience to demonstrate potential negative outcomes of broadened access.

Readiness and barriers to change

Respondents identified the Australian pharmacy profession as ready for further down-scheduling. On the readiness for change scale (where 1=not at all ready and 10=completely ready) the majority of respondents (71.7%, n=137 of 191 replies) indicated between 6 and 10, compared to 28.3% (n=54) that indicated between 5 and 1. The majority (91.0%, n=212) agreed or strongly agreed that opposition from other health professional bodies was the main barrier to further down-scheduling (mean 4.52, median 5.00). Other commonly identified barriers related to legislation or the broader health system (Table 4) including lack of access to patient's medical records, risk averseness of the medicines scheduling committee and complexity of the application process. Less commonly reported barriers included pharmacists' training, confidence, financial viability and concerns over medicines efficacy.

Table 4: Factors Considered Barriers to Further Down-Scheduling

Factor	Mean	Median
Opposition from other health professional bodies	4.52	5.00
Lack of patient medical history	3.79	4.00
Risk averseness of the medicines scheduling committee	3.78	4.00
Complexity of reclassification application processes (i.e. red tape)	3.77	4.00
Concern over medicine misuse or abuse	3.70	4.00
Concern over inappropriate requests	3.68	4.00
Political conservatism	3.59	4.00
Concern over medicine safety	3.48	4.00
Lack of time for consultation	3.44	4.00
Lack of advocacy from peak pharmacy organisations	3.39	3.00
Inadequately trained support staff	3.28	3.00
Pharmacists are risk averse	3.24	3.00
Lack of training resources for pharmacists	3.08	3.00
Lack of pharmacist confidence in own ability	2.88	3.00
Current supply mechanisms are adequate*	2.83	3.00
Lack of financial viability	2.82	3.00
Concern over medicine efficacy	2.72	2.00

*This reflects satisfaction with the status quo

Discussion

Australian pharmacists believed their profession is ready for increased non-prescription medicines reclassification and that consumer access to selected medicines can be improved. Recommendations for less restrictive reclassification were guided by patient demand, safety and facilitating continuity of care in chronic illness. Opposition from other health professional bodies was perceived to the main barrier to reclassification.

This national cross-sectional study is the first to quantitatively and qualitatively explore Australian pharmacist perspectives on current and future reclassification. Key challenges of online surveys include more limited response rates than mail surveys[37] and limitations on use of standard response rates, particularly when multiple online channels are used for recruitment.[39] Researchers used varied strategies to increase response rate with promotion of the survey via a professional organisation being particularly effective.[37] However, sample size, and over and under-representation of pharmacist views for selected states may limit

generalisation of study findings. Self-reported data can be limited by respondent recall and social desirability bias and textual responses were included to capture perceptions beyond those possible with singular data collection methods.

Interestingly, pharmacist views were polarised which may highlight the contextual nature of medicines rescheduling. For example, antibiotics were frequently proposed class not to be down-scheduled, due to concerns over resistance, yet also the most frequently identified class for future reclassification. Suggestions for reclassification of antibiotics were commonly qualified in text as limited to short-course treatment of common infections, such as trimethoprim for uncomplicated UTI. This may reflect the New Zealand experience of reclassification of trimethoprim in 2012,[26] with reports of pharmacists acceptance of the supply model[25] and no associated reports of excessive antibiotic use or changes to usual prescribing practices.[40] However, efforts to reclassify trimethoprim in the UK from Prescription Only Medicines to Pharmacist Medicines were abandoned in 2010 after concerns about resistance.[41]

While antibiotics were the most polarised drug class, other examples occurred of medicines being proposed for both reclassification and not for reclassification. Cardiovascular drugs were the second most reported drug class not to be down-scheduled yet lipid lowering agents and antihypertensives were also suggested as candidates for possible down-scheduling, particularly in the context of medication continuance. Some respondents included lipid lowering agents and antihypertensives in their suggestions for not being down-scheduled, but the majority of drugs identified in this category were cardiac drugs and antithrombotics, with pharmacists suggesting that these patients needed greater medical oversight and monitoring. Analgesics also appeared on the frequently reported lists for both medicines to be down-scheduled and those not to be down-scheduled. Again, the contextual nature of these apparently opposing views was that suggestions for not down-scheduling applied to analgesics with potential for abuse and misuse, e.g. opioids, whereas suggestions for potential down-scheduling applied primarily to non-

steroidal anti-inflammatory drugs, which pharmacists considered safer and reported greater confidence in their provision.

Continuity of care was provided as a rationale for respondent recommendations of medicines to be reclassified. For example, oral contraceptives were prioritised by pharmacists and this aligns with global recommendations for non-prescription access to oral contraceptives, to prevent unintended pregnancies.[42] Although recent applications to down-schedule oral contraceptives in Australia have been unsuccessful,[43] selected oral contraceptives can be supplied without prescription under the PBS Continued Dispensing Initiative.[30,44] In New Zealand, oral contraceptives are available without prescription, under the pharmacist-supply model applied to trimethoprim, sildenafil and oseltamivir.[29]

Encouragingly, the addition of Appendix M to the SUSMP may facilitate adoption of a supply model similar to that used in New Zealand[45]and promote increased down-scheduling. Consultation for the proposed criteria of and medicines for inclusion in Appendix M is ongoing.[34,35,46] Anticipated medicines include trimethoprim for uncomplicated urinary tract infections, sildenafil for erectile dysfunction and triptans for migraine. It is expected that criteria might include additional pharmacist training and competency to be eligible to supply these medicines. Interestingly, medicines available overseas, such as sildenafil were not a priority for down-scheduling in Australia.

Patient safety was often provided as justification for why certain medicines should never be considered for down scheduling. The list of medicines or classes of medicines never to be consider for down scheduling included antibiotics and medicines that could be considered more high risk, e.g. psychotropic drugs; antineoplastic medicines and immunomodulators; and neurological drugs. Many suggested that pharmacists should not have a non-prescription supply role in any conditions that were considered complex, which might require close

monitoring or need assessment by a healthcare team. They cautioned against rescheduling medicines with a perceived potential for abuse, misuse or diversion.

The main barrier to reclassification perceived by respondents was opposition from other health professional bodies, which was consistent with pilot interviews[33] and previous Australian research that identified "patch protection" as a barrier to Australian reclassification.[7] This may be influenced by a perceived loss of income as Australian medical practitioners are paid on a fee for service model.[47] Respondents commonly agreed that other barriers included lack of patient medical history or risk averseness of the medicines scheduling committee. Additionally, risk averseness of pharmacists, lack of training and lack of confidence were apparent barriers, which has important implications for policy makers and training providers.

Participating pharmacists expressed overall support for policy change to enable the profession to better care for consumers with non-complex health conditions through greater access to medicines. The World Self-Medication Industry strongly supports international policy change that improves opportunities for self-care to contribute to improved health outcomes and more sustainable healthcare systems.[48] Perhaps it is time to consider more creative approaches to policy change with regards to medicines reclassification.[7] One creative approach to policy changes as exemplified by New Zealand, where non-sponsor stakeholders, such as pharmacy retail groups, were proactively involved in reclassification applications within models that balanced increased access with safety controls.[8] It has been argued that this enabler allowed for more progressive reclassifications.[8] Other identified enablers to reclassification might then be explored to facilitate further change.

To inform discussions on future policy change and goals toward medicines reclassification future research could investigate the preferred models of medicines provision and whether additional training or accreditation is sought or required,

Conclusion

Pharmacists are clearly ready for greater reclassification yet Australia appears to have lost momentum when compared to other nations in the reclassification of medicines. The pharmacists in this study believed that their profession has the capacity to safely and effectively manage a wider range of non-prescription medicines to enhance medicines access. Pharmacists recommendations for future reclassification were context-specific and underpinned by safety and quality considerations. Given the recent creation of new regulatory structures intended to promote reclassification this study provides timely insights for Australian and international policy makers, contributing to the global conversation on non-prescription medicines access, and providing impetus for practice and policy change.

Conflicts of Interest

The authors declare no conflicts of interest.

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