Appendix M: What Do Pharmacists Want?

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Background

The Australian pharmacy profession should embrace the potential opportunity for selected Schedule 4 (S4) Prescription Only Medicines to be rescheduled to Schedule 3 (S3) Pharmacist Only Medicines, following the addition of Appendix M to the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). Appendix M relates to “additional controls or supply requirements for poisons included in Schedule 3 to allow them to be provided by a pharmacist”. This paper presents the views of Australian pharmacists surveyed on the potential to down-schedule specific S4 medicines. These findings provide important insights for policy makers and pharmacy organisations to inform the professional conversation and the associated Therapeutic Goods Administration (TGA) consultation.

Appendix M

Appendix M is intended to facilitate such down-scheduling “where, for example, there is a community need for access to a medicine that has previously only been accessible with a prescription, but where it is considered that additional controls and oversight by a dispensing pharmacist are needed, in the interests of protecting public health”. This suggests medicines that down-schedule to S3 Appendix M could be provided by a pharmacist without prescription, if specific controls are in place. Conceptually, Appendix M shares similarities with Appendix D in that it articulates additional controls required for the supply of medicines. While Appendix D specifies controls for certain S4 and Schedule 8 (S8) medicines, Appendix M will apply only to S3. For Appendix M, the objective is to articulate conditions for supply by pharmacists of substances which, while grouped under S3, carry additional risk to public safety that exceed the level considered acceptable for substances in this Schedule.

The Australian Health Ministers' Advisory Council (AHMAC) is responsible for scheduling policy and has agreed on the establishment of Appendix M. A Scheduling Working Group, comprising of state and territory representatives and industry, health professional and consumer representatives, has been tasked with identifying candidates for the new schedule and criteria for the use of Appendix M, which will include definitions for controls and oversights. These activities were informed by medicines reclassification globally and a 2018 Pharmaceutical Society of Australia (PSA) survey that identified the relative priorities of 211 pharmacists for potential down-scheduling to over-the-counter (OTC). The resulting list comprised seven medicines/medicine classes: oral contraceptives, triptans, melatonin, ondansetron, trimethoprim, adapalene and sildenafil. Additionally, the Australian Self Medication Industry (ASMI) identified a list of 18 medicines available OTC in other countries, that included all of the PSA list except ondansetron, and additional medicines such as oseltamivir, statins and azithromycin. While these substances give indication to potential additions to S3 in the revised SUSMP, the definition of the additional controls and oversight alluded to in Appendix M are, as yet, unconfirmed.

TGA Consultation

In February 2019, the TGA called for feedback on the proposed criteria for Appendix M. At present, the proposed criteria outline seven key aspects of Appendix M, three of which pertain to pharmacists’ responsibility to provide medication advice and counselling (patient education), the training that may be required and any additional conditions that may be imposed to ensure public safety. According to the TGA, these aspects of the new appendix could potentially be legislated for at the State and Territory level. The remaining four items relate to aspects of pharmacists’ competency...
that the TGA suggests could be managed by the profession’s governing bodies. These items pertain to pharmacists’ competency to assess the patients’ symptoms/needs, limitations on quantity/frequency of supply and need for formal diagnosis and/or review by medical practitioners to determine the suitability for supply as well as pharmacists’ duties pertaining to record keeping and information sharing. As the profession awaits the final decision that will undoubtedly have significant impact on the practice landscape, this paper offer insights from recent research that may contribute to the TGA consultation.

**OTC Medicines Research**

Researchers at Griffith University have been investigating the topic of OTC access to medicines for a number of years. The team has explored the literature to identify the range of medicines that were S4 in Australia but were available OTC overseas, in countries with similar health care systems. Of interest were the supply models that had been established to allow pharmacists to provide certain prescription medicines if specific criteria were met. The researchers conducted primary studies into Australian pharmacists’ and pharmacy staff opinions on consumers’ demand for OTC supply of S4 medicines and the perceived readiness for increased non-prescription availability of medicines. Of many countries, including New Zealand and the UK, the number of medicines available without prescription far exceeded that accessible in Australia. Using the UK and New Zealand as examples, exploration of the conditions for supply revealed the following information:

**UK Model**

In 2004, the UK reclassified simvastatin from a prescription only medicine (POM) to a pharmacy only ‘P’ medicine for people with a moderate risk of coronary heart disease, and in 2008 they reclassified azithromycin from POM to ‘P’ only for individuals with a positive test results for chlamydia. In 2010, tamsulosin became a ‘P’ medicine for the urinary symptoms of benign prostatic hyperplasia (BPH), and in 2017, sildenafil for erectile dysfunction and calcipotriol for psoriasis were reclassified to OTC access. In contrast, the UK had long debated the proposal for reclassification of trimethoprim to a ‘P’ medicine to treat uncomplicated urinary tract infection (UTI), but applications to reclassify trimethoprim and nitrofurantoin were ultimately withdrawn in 2010. UK pharmacists can now only provide non-prescription access to medicines such as trimethoprim under a Patient Group Directives (PGD). While pharmacist training is available for the OTC provision of the reclassified ‘P’ medicines, provision requirements are not as strict as the ‘controlled pharmacist-supply model’ that exists in New Zealand.

**New Zealand Model**

In contrast to the UK, New Zealand allowed ‘accredited’ pharmacists to supply trimethoprim for women aged 16 to 65 years for uncomplicated UTI from 2012. The antibiotic was, and still is, classified as a prescription medicine “except in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16-65 years for the treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists’ training in the treatment of urinary tract infections.” Accreditation involved completion of detailed training on trimethoprim and the appropriate management of UTIs. The intention behind the reclassification was to improve access to treatment for this common condition. Follow-up research identified that pharmacists were very satisfied with their training and that their provision of trimethoprim did not affect medical prescribing of antibiotics or increase the overall use of antibiotics. Other medicines available from
New Zealand pharmacists under the accreditation model include sildenafil,\textsuperscript{16} emergency contraception, triptans and oral contraceptives.\textsuperscript{13,15}

**Interview Research**

In 2015, the Griffith University research team undertook preliminary interview research with 15 community pharmacy staff (9 pharmacists, 4 dispensary technicians and 2 pharmacy assistants) which revealed that the pharmacists were keen for medicines rescheduling, supported by a desire to facilitate consumers’ management of minor illnesses and promote adherence by reducing treatment disruption to those on long-term therapies.\textsuperscript{6} Research participants identified a broad range of medicines as potential candidates for down-scheduling, with oral contraceptives, blood pressure and cholesterol-lowering medicines being the most dominant. Access to OTC oral contraceptives were linked to the desire to mitigate possible barriers to supply such as prescriber access or religious issues. They also suggested that OTC availability of erectile dysfunction medicines could save patients from embarrassment. Importantly, participants expressed their desire for the establishment of protocols and training resources to support their transition from the status quo. While the study provided new and insightful information about the opinions and readiness of pharmacists and support staff, it was acknowledged that the generalisability of the findings were limited by the small sample size and the confinement of the research to the Gold Coast region of Australia.\textsuperscript{6}

**Survey Research**

Informed by the 2015 interviews, the research team conducted a national survey of pharmacists in 2015 and 2016 on the perceptions of the profession regarding medicines down-scheduling.\textsuperscript{17} One aspect of the research asked Australian pharmacists for their opinions on the scheduling of 17 medicines/medicine classes, which had been defined from overseas OTC availability and from the interview results (Table 1). Survey participants were asked to:

1) indicate on a trichotomous scale (Yes/Yes with conditions/No) whether the medicine/medicine class should be available OTC. The conditions were: (a) continuing therapy only; (b) with established symptoms; and (c) with confirmed microbiology;

2) rate the importance of OTC access for each of the medicines on a 10-point scale (where 1 = not at all important and 10 = very important);

3) rate their confidence to supply each medicine OTC, on a 10-point scale (where 1 = not at all confident and 10 = very confident); and

4) select the OTC requirements that should apply for each of the 17 medicines, should they become available OTC. Participants could select all that applied from (i) Protocol, (ii) Training or (iii) Pharmacist Accreditation.

Institutional ethical clearance was obtained (Griffith University Human Research Ethics Committee Ref No: PHM/04/15/HREC). The findings are summarised below.
Table 1: Selected Medicines and Conditions for Potential Down-Scheduling

<table>
<thead>
<tr>
<th>Selected Medicines</th>
<th>Additional Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-nausea medicines, for conditions other than migraine</td>
<td>with established symptoms</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>with confirmed microbiology</td>
</tr>
<tr>
<td>Blood pressure medicines</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Calcipotriol</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Erectile dysfunction medicines</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Mebeverine</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Oseltamivir</td>
<td>with established symptoms</td>
</tr>
<tr>
<td>Other anti-infectives (except azithromycin, trimethoprim &amp; oseltamivir)</td>
<td>with established symptoms</td>
</tr>
<tr>
<td>Oxybutynin, transdermal</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Statins</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Steroids, inhaled</td>
<td>continuing therapy only</td>
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<tr>
<td>Steroids, dermal</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Tamsulosin</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Tranexamic acid</td>
<td>continuing therapy only</td>
</tr>
<tr>
<td>Trimethoprim for urinary tract infection</td>
<td>with established symptoms</td>
</tr>
<tr>
<td>Triptans</td>
<td>continuing therapy only</td>
</tr>
</tbody>
</table>

Survey Results

Two hundred and eight seven Australian pharmacists (126 male and 161 female) completed an online survey in 2015 and 2016. Pharmacists represented all Australian states and territories and a variety of practice contexts, including community, hospital, academia and consultant pharmacy.

Figure 1 summarises participants’ response to the question that asked whether the medicine/s should be available OTC (Yes/Yes with conditions/No). Results are sorted descending, from the highest percentage of positive responses to the least.

Figure 1: Pharmacist views on which medicines should be available without prescription
The majority of pharmacists agreed that anti-nausea medicines (for indications other than migraine), oral contraceptives and statins should be available without prescription. Although more than two thirds of pharmacists agreed that there should be OTC access to key therapeutic agents used in the management of migraines, asthma and hypertension, the majority preferred that this be under specified conditions, primarily for the purpose of continuing therapy. Agreement on increased consumer access to the anti-infectives azithromycin, trimethoprim and oseltamivir with established symptoms contrasted with less favourable views on expanding this to other anti-infectives.

Rating of the importance of OTC supply alongside pharmacists’ confidence to supply the medicines OTC are presented in Figure 2.

Figure 2: Mean Scales (from 1-10) of Importance of OTC Access and Confidence to Supply OTC

Trimethoprim (mean 8.73, SD 1.30) and inhaled corticosteroids (mean 8.63, SD 1.38) were the medicines that pharmacists considered most important to have available OTC and felt most confident to supply in this context (trimethoprim mean 8.90, SD 1.29; inhaled corticosteroids mean 8.76, SD 1.28). Oral contraceptives were ranked fourth in importance (mean 8.45, SD 1.60) and fourth in pharmacists’ confidence to supply (mean 8.71, SD 1.47). Calcipotriol was ranked least.
important for OTC access (mean 6.66, SD 1.94) and also the medicine pharmacists were least confident to supply OTC (mean 7.61, SD 1.92).

Figure 3 presents a frequency graph of participants’ suggested requirements for OTC provision of selected medicines (Protocol, Training or Pharmacist Accreditation), in which more than one option could be selected. Data are presented in descending order of total number of responses to each medicine/medicine class.

Figure 3: Suggested Requirements for OTC Provision of Selected Medicines
Protocols were the most frequently suggested requirement (1939 selections), with the highest suggestion of protocols reported for anti-nausea medicines (for indications other than migraine) by 185 (75.8%) of pharmacists, followed by oral contraceptives, with protocols suggested by 179 (74.0%) of pharmacists. Training was also frequently suggested (1839 selections), with the most frequently suggested medicine candidates for training being calcipotriol (n=120, 73.2%) and dermal corticosteroids (n=152, 73.1%). Pharmacist accreditation was the least often suggested requirement for OTC supply (1135 selections), with other anti-infectives (excluding azithromycin, oseltamivir and trimethoprim) the most frequently suggested medicines for pharmacist accreditation (n=36, 56.3%).

Discussion

This study provides valuable insights for policy makers and pharmacy organisations on the importance that Australian pharmacists place on increased consumer access to selected medicines and their associated confidence in managing OTC provision. The major findings of the research are an increased understanding of pharmacists’ opinions on the candidate medicines for potential down-scheduling, guided by their confidence to supply and judgement on the importance of OTC supply, which should help to guide further TGA consultation. While this research generated important commonalities with the candidate medicines lists provided by AHMAC and ASMI, there are also some significant differences (Figure 4). Additionally, this research gives voice to pharmacists’ opinions regarding the additional conditions, i.e. controls, that they feel are necessary to facilitate appropriate supply of down-scheduled medicines. These findings should guide the development of Appendix M and inform guidance and training development by the pharmacy organisations and educators.

Potential Candidates for Down-Scheduling

The commonalities and differences between the proposed candidate medicines of AHMAC/PSA, ASMI and the Griffith University research study are summarised in the Venn diagram (Figure 4).
Figure 4 highlights the common medicines proposed for down-scheduling and also some key differences between the ASMI and AHMAC/PSA priority lists. However, the Griffith University study, explored the views of pharmacists in relation to the majority of medicines on both lists. Exceptions include adapalene, estriol pessaries, melatonin, nitrofurantoin, oral cholera vaccine, proguanil, and varenicline. Both the convergence and divergence of priorities between the different organisations and the context of pharmacists’ views provided by this study emphasise the need for further investigation of the listed medicines (Figure 4) and beyond this.

Key medicines at the crux of the intersection of the three candidate lists include oral contraceptives, trimethoprim, sildenafil and triptans. The pharmacists in this Griffith University study considered oral contraceptives, trimethoprim and triptans important candidates for down-scheduling and pharmacists self-reported being confident to manage these. This was less evident for erectile dysfunction medicines, such as sildenafil, even though they are available without prescription in New Zealand. The New Zealand model of OTC sildenafil has been reported as a positive for both pharmacists and patients. Also at the centre of the intersected candidate lists are: statins,
calcipotriol and oseltamivir. This means these medicines are available OTC overseas and have been reported by Australian pharmacists as candidates but not an AHMAC priority. Participants of this Griffith University study rated oseltamivir and statins as both important to have OTC access and that they were confident to supply. Oseltamivir OTC provision in New Zealand did initially incur some barriers due to specific controls over supply, i.e. requirement to present in person to the pharmacy with symptoms of influenza, and these controls were amended over time as informed by grass-roots research with pharmacists. OTC simvastatin supply in the UK was also met with concerns related to the evidence base for the available 10 mg strength. While calcipotriol was also at the centre of the intersected candidate lists, in the Griffith University study it was rated least important with least pharmacist confidence to supply OTC. That said, many participants suggested protocols, training or accreditation to support any OTC provision of calcipotriol. Such protocols were developed to support the down-scheduling of calcipotriol in New Zealand. These reports of pharmacy related experiences overseas highlight how critical research with pharmacists pre and post down-scheduling is to facilitating application of appropriate yet practically feasible controls and guidance that builds pharmacist confidence to supply newly reclassified medicines within a quality use of medicines framework.

While there was commonality between the AHMAC/PSA and Griffith studies with regards ondansetron, the difference identified in both Griffith studies was that pharmacists were focused on a broader range of anti-nausea medicines, beyond just ondansetron. In the pilot study interviews pharmacists additionally identified domperidone, metoclopramide and prochlorperazine as potential candidates. The survey research revealed that anti-nausea medicines (for indications other than migraine) were the highest rated medicine class that should be available OTC. Whilst ranked 12th in importance to down-schedule pharmacists ranked them fifth in confidence to supply. This may be explained by the fact that pharmacists are already familiar with supplying metoclopramide and prochlorperazine as S3 medicines, for nausea associated with migraine. They are therefore more confident to extend that provision to non-migraine indications. The results of our research suggest that the TGA should consider a broader range of anti-nausea medications for Appendix M, in addition to ondansetron.

Even though ASMI did not identify combination preventer asthma inhalers as potential candidates, because they are not available OTC overseas, it is important to be aware that Australia is one of the few countries in which beta agonist reliever inhalers are available without prescription. Aligned with consumers’ needs to manage prevalent chronic conditions such as asthma, it is unsurprising that pharmacists identified corticosteroid inhalers as the second most important medicine class for OTC access. Likewise, they reported confidence in being able to supply these inhalers OTC. As with current S3 anti-nausea medicines, pharmacists are familiar with managing consumers’ asthma OTC through the provision of the S3 reliever inhalers. The Griffith University research was the only one to report pharmacists’ desire to see an extension of the available dermal corticosteroids OTC. Again, pharmacists are used to supplying S2 and S3 corticosteroids and expressed confidence in being able to supply more potent corticosteroids if they are down-scheduled.

While this paper has not suggested further investigation of antihypertensive medicines and drugs such as mebeverine, because they were not reported by either AHMA/PSA or ASMI, both were identified by pharmacists as candidates that should be available OTC. They expressed greater importance and confidence for blood pressure medicines than mebeverine. The pharmacists interviewed expressed their motivation to provide continuing therapy for chronic conditions, such as hypertension and hypercholesterolaemia, valuing the ability to assist their patients to manage such long-term conditions. Statins were identified by all three groups (Figure 4) but not considered a priority medicine by AHMAC. The fact that it sits at the crux of the intersection highlights the need for their consideration.
**Additional Controls/OTC Requirements**

Regardless of confidence to supply medicines OTC, the pharmacists in this study clearly expressed the desire for protocols, training and/or accreditation to guide down-scheduling of these medicines. Drawing on our current provision for S3 supply, pharmacists are entirely familiar with using protocols, including those published by the Pharmaceutical Society of Australia (PSA), exemplified by provisions for emergency contraception,\(^23\) oral famciclovir\(^24\) and ophthalmic chloramphenicol.\(^25\) Similarly, training is an expected part of a health professional’s continuous professional development and lifelong learning. On the other hand, pharmacist accreditation in Australia has traditionally been limited to those undertaking specialised forms of practice or cognitive services that are remunerated separately from medicines’ supply, such as home medicines reviews, through organisations, e.g. the Australian Association of Consultant Pharmacy.\(^26\) While accreditation was not the dominant OTC requirement selected, this option was identified by at least a third or more of those supporting the down-scheduling for every one of the 17 medicines surveyed. Accreditation as an option rated highest for oral contraceptives and blood pressure medicines. Pharmacist accreditation to supply certain medicines without prescription has long been a model of practice in New Zealand. This suggests that the New Zealand model might be appropriate to apply to medicines that populate Appendix M of the SUSMP in Australia.

**Conclusion**

Australian pharmacists are clearly ready to embrace OTC availability of a wide range of medicines, which reflects a person-centred approach to meet consumer needs through increased access in the context of quality use of medicines. Our findings provide critical context to inform lists of medicines proposed for down-scheduling to include perceived confidence of pharmacists and recommendations of conditions of supply and associated guidance and training. Participating pharmacists were asked to consider medicines beyond those identified by the AHMAC Working Group and ASMI lists,\(^5\) in a survey informed by the literature and previous research. The novelty of this research lies in the fact that it provides evidence of grass-roots pharmacist support for improved access to selected medicines alongside a road map of recommended guidance and training prior to down-scheduling.
References


