



Pharmacists' views on the upscheduling of codeine-containing analgesics to 'prescription only' medicines in Australia

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Abstract

Background Codeine is the most commonly used opioid worldwide, and is available over-the-counter (OTC) in many countries. There is continual debate regarding the risk:benefit profile for OTC codeine. In Australia, codeine containing analgesics became 'prescription only medicine' from February 2018. However, there is currently limited knowledge on the views of community pharmacists on this upscheduling and the perceived impacts on clinical practice. **Objective** To investigate the views of community pharmacists on the recent codeine upscheduling in Australia. **Setting** Community pharmacists in Australia, predominately recruited from Victoria. **Method** A descriptive cross-sectional study was conducted using a pre-tested customised anonymous self-administered online questionnaire between March and May 2018. To capture a broad range of demographics, pharmacists were recruited via local industry contacts and the Pharmaceutical Society newsletter, with further recruitment through snowball sampling. **Main outcome measure** Pharmacists' opinions to targeted questions regarding the perceived advantages and disadvantages of the recent 2018 codeine rescheduling from both their perspectives and their perceived impact on patients. **Results** A total of 113 pharmacists completed the survey. Approximately 43% of pharmacists agreed/strongly agreed that they believed upscheduling will positively impact their ability to manage pain; while 30% were neutral. Approximately 54% of pharmacists agreed/strongly agreed that they believed upscheduling will positively benefit their patients; while 25% were neutral. Perceived advantages for codeine upscheduling included: increased pharmacist/patient engagement, and less codeine use leading to better overall risk:benefit outcome; while disadvantages included: fewer analgesic options, and increased burden for patients, General Practitioners, and the health system. **Conclusion** This study showed that the current views on the recent codeine upscheduling are quite mixed, with both advantages and disadvantages perceived. Improving education and up-skilling in this space is essential.

Keywords Australia · Codeine · OTC · Pharmacists' views · POM · Prescription-only · Upscheduling

Impacts on Practice

- Most pharmacists in Australia agree with the recent codeine upscheduling, although there is a high percentage of those who were neutral.
- Perceived or actual advantages and disadvantages of codeine upscheduling need to be addressed as it impacts on pharmacy practice.

- There is a need and a great potential for better education and training for pharmacists in the clinical pain management space.

Introduction

Codeine is the most commonly used opioid worldwide, and is available over-the-counter (OTC) in many countries, including previously in Australia [1]. Codeine is widely used as an analgesic in Australia, often in combination with products such as paracetamol or ibuprofen [2]. However, there has been substantial continual debate regarding the safety of OTC codeine with the misuse of codeine combination products (described through case series and data from various Drug and Alcohol units) appearing to be

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increasing in Australia [1]. Furthermore, the lack of efficacy, potential risks for toxicity and adverse effects, and addiction of OTC codeine has also been well documented and has generated substantial debates [3–6].

The Australian legislative framework for OTC is different to many other countries, with legal classification of non-prescription medicines being: ‘unscheduled’; ‘Pharmacy Medicines’ (Schedule 2—for sale only in pharmacies, may not have pharmacist involvement); or ‘Pharmacist Only’ Medicines (Schedule 3—pharmacist required in sale, cannot be self-selected) [1, 7, 8]. In 2010, OTC codeine underwent one round of upscheduling by the Australian Therapeutic Goods Administration (TGA, responsible for scheduling of medicines in Australia) to restrict codeine containing analgesics to ‘Pharmacist Only’ [1]. Previously some OTC codeine products were ‘Schedule 2’ and were available for purchase via self-selection from pharmacies often without pharmacist interaction [2]. The aim of this upscheduling to Schedule 3 is to encourage pharmacist involvement to better establish the therapeutic risks, benefits and need, and as means to reduce the misuse of these OTC codeine products [2]. However, evidence suggested that this limited rescheduling failed to substantially curb the rise in codeine abuse [1].

Consequently, in December 2016, the TGA announced that OTC codeine would undergo another round of upscheduling to become a ‘prescription only medicine’ (schedule 4) from 1st February 2018. The decision followed a consultation period and a review of the literature highlighting the unfavourable risk:benefit profile for OTC codeine [4, 5]. Furthermore, it has been suggested that its unfavourable risk:benefit profile means that the Australian rescheduling aligns with many other countries to minimise harm [5].

However, there is currently limited published literature on studies investigating the impacts of this further 2018 upscheduling, in particular the views of community pharmacists on this issue and how this latest upscheduling of all OTC codeine products to ‘prescription only’ may impact clinical practice. Given the important and direct role of pharmacists in patient education and medication supply, it is anticipated that this codeine upscheduling will have a direct impact to practice and outcomes.

Aim of the study

The aim of this exploratory study was to examine the views and perceptions of community pharmacists on the 2018 codeine upscheduling in Australia, in particular the perceived advantages and disadvantages of this change.

Ethics approval

This study was approved by the Human Research Ethics Committee of the study institution (Approval number: SEHAPP 99-17).

Methods

Study Participants

This study was designed as a descriptive cross-sectional study to capture the current views and perceptions of Australian practicing community pharmacists on the recent codeine upscheduling. Participation involved completing an anonymous online survey that took approximately 5–10 min to complete. This survey was open to all community pharmacists across Australia, although it is estimated that survey participants would mainly be pharmacists in Victoria, Australia, due to the recruitment. Data collection was conducted over approximately 8 weeks (March–May 2018) to capture as many responses as possible. Implied consent was obtained by completion of the survey by the participant. The investigators were responsible for the initial recruitment via the Pharmaceutical Society of Australia newsletter and local industry contacts, with further recruitment through snowball sampling. After the data collection period, additional recruitment was deemed not required as data saturation was established.

Questionnaire

An anonymous, self-administered online questionnaire was developed by the study team to collect a broad range of data from Australian community pharmacists. Qualtrics software was used to develop and deliver the questionnaire. Questionnaires are one of the most frequently used tools for health research, including pharmacy practice research, for collection information from a population [9]. Furthermore, there is value in both qualitative and quantitative methodologies for pharmacy practice research [10].

Questions were developed under several sections. To ensure that a broad range of pharmacist responses were captured, demographic data such as age, gender, employment, area of primary employment, tertiary qualifications, and approximate years of experience as an Australian registered pharmacist were obtained.

Further, the questionnaire asked two questions using a 5-point Likert scale (ranging from Strongly disagree to Strongly agree). The questions were:

- With the rescheduling of codeine containing products to prescription only, this will POSITIVELY impact my ability to manage pain for my patients.
- With the rescheduling of codeine containing products to prescription only, I believe my patients will POSITIVELY benefit from this restriction.

Pharmacists were also asked to insert free-text comments to elaborate on their responses to these questions to capture more specific additional views on codeine rescheduling. The pharmacists could comment on any aspect of codeine rescheduling in this open-ended free-text section, both positive and negative views.

The questionnaire underwent a series of pilot tests with a small group of pharmacists and pharmacy academics prior to final release. The survey was therefore preliminarily pre-tested for ease of use and to identify any technical or interpretative issues. Questions were then re-worded based on the feedback received, and a second round of pilot tests were conducted before the questionnaire was made available to Australian community pharmacists.

Data analysis

Statistical tests and descriptive statistics were conducted (using the statistical software package SPSS version 18) to assess responses to the survey. A Chi square goodness-of-fit analysis was also performed for age and gender distributions of the surveyed population compared with Pharmacy Board registrant data to assess sampling and external validity. A $p < 0.05$ is considered as statistically significant.

Qualitative responses for the free-text comments were categorised into themes based on the responses received. Two researchers independently analysed and manually coded the themes and sub-themes from all the responses. The data analysis process was frequently discussed and reviewed by the research team to reach validity and consistency, with the thematic analysis anchoring in grounded theory (to explore the pharmacists' perceptions) as the methodological approach.

Results

Demographics

Of the total of 149 pharmacists who attempted the survey, 36 incomplete submissions were excluded, with 113 completed responses used for this study. Table 1 describes the participant demographics. Registrant data (Tables 2, 3) was retrieved from the Pharmacy Board of Australia for the period 1 January–31 March 2018 [11]. The eligible

Table 1 Demographic distributions from survey

Characteristic	N (%)
a. Age	
20–24 years	15 (13.3)
25–35 years	62 (54.9)
36–45 years	15 (13.3)
46–55 years	9 (8.0)
56–65 years	7 (6.2)
65+ years	5 (4.4)
b. Gender	
Male	37 (32.7)
Female	76 (67.3)
c. Primary place of practice	
Metropolitan	78 (69.0)
Regional	25 (22.1)
Rural	10 (8.8)
d. Approximate years of experience as a pharmacist	
1–4 years	50 (44.2)
5–10 years	30 (26.5)
11–14 years	11 (9.7)
15–20 years	3 (2.7)
21–24 years	1 (0.9)
25+ years	18 (15.9)
e. Primary pharmacy qualification obtained in Australia	
Yes	103 (91.2)
No	10 (8.8)
f. Work status	
Full time	81 (71.7)
Part time	22 (19.5)
Casual/locum	10 (8.8)
g. Highest qualification	
Bachelor	73 (64.6)
Post grad cert/dip	19 (16.8)
Master	16 (14.2)
Doctorate	5 (4.4)

responses (113) were multiplied by the proportions of each category in the registrant data. The Chi square (χ^2) goodness-of-fit test showed a statistically significant difference in the age distribution between the survey and registrant data. Although there appears to be a similar trend between the proportions of the survey and registrant data, the proportions of the age groups under 34 years in the survey data appear to be over-represented, and the age groups over 35 years appear to be under-represented. However, there was no statistically significant difference in the distribution of gender between the registrant and survey data. This indicates that the survey sample distribution based on gender is a reasonable representative of the greater population of Australian pharmacists.

Table 2 Age distribution difference between registrant data and survey data

Age (years)	Registrant data			Survey	
	Number of registered pharmacists	Expected frequency	%	Observed frequency	%
Under 25	1254	5	4.4	15	13.3
25–34	11,517	46	40.7	62	54.8
35–44	7138	29	25.6	15	13.3
45–54	3900	16	14.2	9	8.0
55–64	2917	12	10.7	7	6.2
65+	1339	5	4.4	5	4.4
Total	28,065	113	100.0	113	100.0

Chi square value ($\chi^2=37.470$) was more than the critical value ($\chi^2=11.071$, at $df=5$, $\alpha=0.05$). $p < 0.05$

Table 3 Gender distribution difference between registrant data and survey data

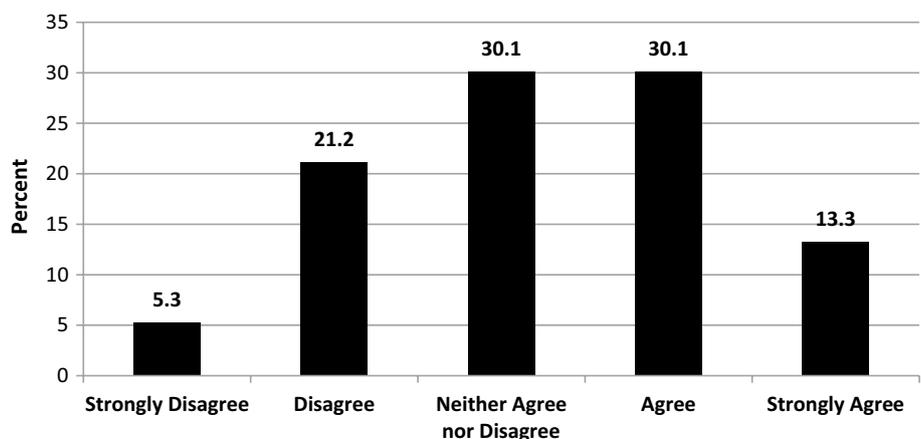
Gender	Registrant data			Survey	
	Number of registered pharmacists	Expected frequency	%	Observed frequency	%
Male	10,599	43	38.1	37	32.7
Female	17,466	70	61.9	76	67.3
Total	28,065	113	100.0	113	100.0

Chi square value ($\chi^2=1.351$) was less than the critical value ($\chi^2=3.841$, at $df=1$, $\alpha=0.05$). $p > 0.05$

Community pharmacist views on rescheduling of codeine

Overall, there were mixed views on the recent codeine rescheduling, with many pharmacists undecided on whether this change will be beneficial (Figs. 1, 2).

Fig. 1 Community pharmacists’ views to the statement “With the rescheduling of codeine containing products to ‘prescription only,’ this will POSITIVELY impact my ability to manage pain for my patients”. (n = 113)



Based on the free-text responses, key themes were identified and broadly divided into the pharmacists’ views on perceived advantages and disadvantages of codeine rescheduling. Thematic saturation was evident from the pharmacists’ free-text responses. The themes emerging from the data are reported below along with illustrative verbatim quotations.

Perceived advantages

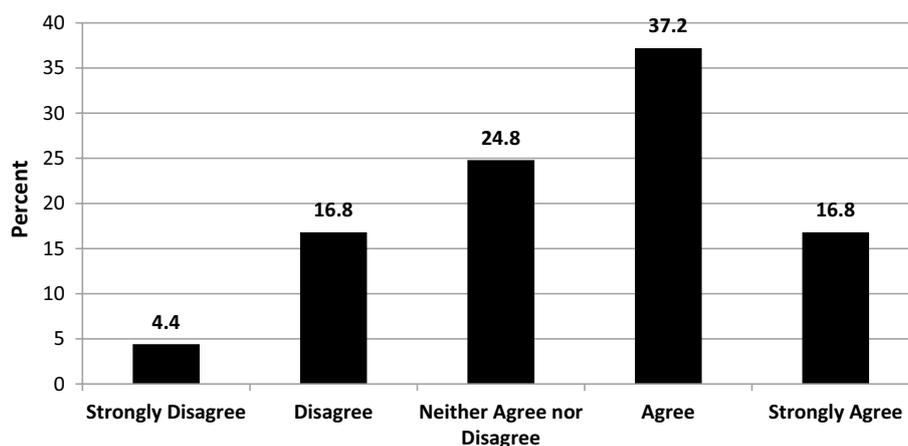
Many pharmacists viewed the codeine rescheduling as a positive move as the tighter restrictions to prescription only will now encourage the patients to be more willing to speak about their pain. Furthermore, this will further encourage the patients to come into the pharmacy to discuss the matter with a pharmacist (as OTC codeine is no longer available without assessment and referral), rather than simply come into the pharmacy for the OTC purchase then depart with limited consultation, as was the situation previously where many were not interested in discussing their pain prior to upscheduling:

It brought up some conversations with patients, they opened up so we can discuss their pain and what’s happening and most appropriate management. Previously, they wouldn’t tell the complete story about the history of pain.

Additionally, encouraging patients to discuss their pain provides better opportunities for pharmacists to get more involved with pain management discussions/strategies and to recommend alternative pain management strategies/other analgesics available. Furthermore, it was also quoted that the upscheduling facilitated more readily referrals to the General Practitioner (GP)/physician or consider more suitable alternatives:

Most of my patients will develop a pain management plan with their GP which we do not have the in depth prescribing capabilities to undertake in community

Fig. 2 Community pharmacists' views to the statement "With the rescheduling of codeine containing products to 'prescription only,' I believe my patients will POSITIVELY benefit from this restriction". (n = 113)



pharmacy. There is also the possibility of referral to a pain management specialist.

A positive benefit is possible for my patient with successful inter-professional collaboration between prescribing doctors, pharmacist, physiotherapist, chiropractors etc.

Extending on this, some pharmacists have also commented that codeine upscheduling also encouraged them to undertake additional up-skilling and seeking further education to better equip themselves (given that OTC codeine was no longer available) to manage and provide advice:

The rescheduling of codeine will help me further develop my skills and training to help patients find an alternative.

I have completed my Painwise training and am competent at providing these services to my patient but since the upscheduling patients are now more willing to listen to my advice before seeing a GP.

Many pharmacists also commented that codeine upscheduling was beneficial as many cited that they believed the codeine dose in OTC products was sub-therapeutic or ineffective and thus did not provide any extra effectiveness for pain, with the current evidence not supporting its use. Thus the upscheduling will mitigate codeine misuse and abuse. Extending on this, indeed many pharmacists also asserted that restricting codeine will lead to less addiction, codeine toxicity and thus will improve safety.

The dosage of codeine in the OTC pain relief is considered inadequate. However patients are still heavily reliant on these types of medications.

It is so commonly abused and lacks clinical evidence for most conditions for which patients request it OTC. To be able to honestly say I can't offer it as a choice is fantastic because it opens the door to provide treatments with much more clinical evidence

and fewer side effects that they probably wouldn't try if they could access codeine easily.

Perceived disadvantages

Many pharmacists also commented on several disadvantages of codeine upscheduling. Some pharmacists felt that the upscheduling of codeine does not solve the wider codeine misuse as the patients have simply gone from "pharmacist-shopping" to "doctor-shopping", and escalation to inappropriate use of other medicines or stronger opioids:

The main concern I would have is that patients who misuse codeine may start misusing even more potent opiates because as they are now going to the doctor, they may use that opportunity to request for a 'stronger' product rather than just codeine, or they may end up resorting to illegal opiates.

Some patients may find visiting their doctors more of a nuisance and become complacent in pain management plans and resort to other medications or drug/alcohol abuse.

However the main view supported by many pharmacists in this category was the opinion that the codeine upscheduling means there is now less OTC analgesic options (e.g. using OTC codeine as an additional step-up option) that pharmacists can provide to patients who would otherwise respond well to codeine-containing products for acute symptoms (e.g. short term management of acute migraines). It was noted by pharmacists that the patients are now disadvantaged, as well as the pharmacists' ability to recommend an appropriate codeine product was limited given that they felt paracetamol with or without NSAIDs (which are the only OTC options available now) are not sufficient in some cases, especially when patients are unable to take NSAIDs due to contraindications:

There are situations where it is a useful medication to be able to supply OTC (codeine) when there is a genuine clinical need. E.g. Dental pain or severe migraines. There certainly were some patients who did benefit from paracetamol/codeine combinations—despite trials claiming low-dose codeine is inferior. There is very little available for people who have contra-indications to NSAIDs. We will probably see more topical Diclofenac being used - especially in older patients.

An additional concern commented by many pharmacists was the added burden that is now shifted to the GP/physicians as patients now are forced to see their GPs for conditions that would have otherwise been managed prior to up-scheduling. Extending on this, the added burden (both practically and economically) now on the patients due to the codeine rescheduling was also noted by pharmacists in the survey:

GPs are not always available at short notice in rural areas. Also, there is now an added cost burden to the patient as the cost to dispense codeine prescriptions is added to the cost of the medication.

Clogs up the GPs when they are clogged up already. Extra financial burden on Medicare. Timely access to medicine now compromised.

Discussion

This study examined the views of community pharmacists with the 2018 codeine rescheduling, particularly assessing their opinions on the perceived benefits and disadvantages. Interestingly, the views in this study were quite diverse, with many agreeing with the codeine up-scheduling. However, it should be noted that it is perhaps too early to definitively conclude overwhelming support, or otherwise, for the rescheduling and its impact to practice. Given that codeine rescheduling only took place recently, it is not unexpected that there are currently limited published studies investigating the views of community pharmacists on this issue, particularly examining perceived advantages and disadvantages of the rescheduling.

In a recent study by McCoy et al. [4], it was reported that prior to the codeine up-scheduling announcement, majority of consumers, pharmacists, and a third of GP respondents opposed the codeine up-scheduling. In particular, it was identified that, on average, pharmacists were significantly more likely to indicate their opposition to the proposed change than GPs, for reasons similar to those identified in this study [4]. This is in contrast to this study whereby many of the pharmacists appear to support the up-scheduling. In a UK study of codeine prescribing health professionals (such as GPs, specialists and nurse prescribers), there were also substantial variations in their views and practices related

to prescribed codeine medicines, including differences in their perceived risks and benefits [12]. Furthermore, a recent ‘covert simulated patient’ community pharmacy study also reported that management and handling of non-prescription codeine combination analgesic requests were sub-optimal [13]. Although that study was not designed to specifically assess pharmacists’ opinion on codeine products, the results did indicate variability in their preference in ultimately whether the pharmacist chose to supply the codeine product or not [13]. It has been previously noted that many pharmacists have identified that the up-scheduling of OTC combination analgesics containing codeine had impacted their practice to varying degrees [2].

In this study, although approximately half of the surveyed pharmacists feel the patients will benefit from the up-scheduling, many pharmacists were neutral with the view that the rescheduling of codeine will positively benefit their patients or their ability to assist patients in their pain management. This could be due to that many pharmacists are still yet uncertain whether the up-scheduling is beneficial (both from their or the patient’s perspective), or it is perhaps too early to fully gauge the impact of the recent codeine up-scheduling to the practice of pharmacy in Australia, given that codeine has previously been available without a prescription for an extensive period of time. In this study, several key themes and issues were identified. In terms of perceived advantages and benefits, many agreed that the rescheduling will lead to harm reduction due to decreased codeine abuse and toxicities. Indeed concerns of OTC codeine misuse are high amongst codeine-prescribing healthcare professionals [12]. This is interesting given that a previous study identified that one of the pharmacists’ main concerns was questioning whether the up-scheduling would adequately address the harm reduction and codeine dependence issues [4]. In this study, there were also respondents who indeed questioned the harm minimisation effectiveness of codeine up-scheduling.

The issue of OTC codeine efficacy and dosage is contentious as OTC codeine products in Australia contains only 8–15 mg of codeine phosphate in fixed-dose combinations with other simple analgesics such as paracetamol, ibuprofen or aspirin, with patients often not reaching the 30 mg dose required for adequate analgesia [3, 5, 14]. Further, the maximum daily dosages allowed for these combination products are often limited by the paracetamol or ibuprofen component, rather than the codeine component. The current Australian Therapeutic Guidelines also indicates the recommended codeine dosage of 30–60 mg orally, 6-hourly as necessary for moderate acute pain [15]. Interestingly, the UK study of codeine prescribing health professionals (GPs, specialists and nurse prescribers) reported that many of them believed doses of 30 mg or less of codeine phosphate are effective [12].

However, it was also encouraging to note that many pharmacists were optimistic about the upscheduling as it now encourages more pharmacist up-skilling, patient engagement, and encourages the patient to discuss their pain management with the pharmacist. This supports the view that pharmacists are considered as a trusted primary healthcare professional where their pain management knowledge and skills should be more optimally utilised [3, 16, 17]. Recommending other pharmacological and non-pharmacological pain management options instead of OTC codeine is a role identified by many pharmacists [2]. Taken together, encouraging and enhancing pharmacists' engagement and up-skilling is a great opportunity for pharmacists to respond to, in and outside of the pain management context.

In contrast, many comments regarding the disadvantages of codeine upscheduling were also noted. In particular, the issues of disadvantaging the genuine patients, limiting the pharmacists' capacity in offering pain management, and increasing the GP's and the healthcare system's burdens were identified in this study and others [3]. This is also in agreement with the pre-codeine upscheduling study by McCoy et al. [4]. Further, given that pharmacists are medication experts with the knowledge and skills to assist in pain management, it has been questioned whether this upscheduling is justified [3]. Finally, the impact of codeine upscheduling encouraging the inappropriate use of other products (e.g. Non-steroidal anti-inflammatories), or patients "doctor-shopping" and seeking a prescription supply of higher strength codeine were also views shared in this and other studies [3].

There were a number of limitations to this study. Although a broad range of demographics were captured, the number of respondents is low and it is likely that the pharmacists participating in this study do not fully represent all pharmacists. Further, there was a difference in the age distribution between the survey and registrant data. A larger sample size will increase generalizability of the results. In an attempt to assess this, demographics data was compared with the Pharmacy Board registrant data. Furthermore, selection bias is possible; however this is unlikely to be significant given the mixed views from the pharmacists who participated. Whilst there are many advantages to using questionnaires, they do have recognised limitations in terms of potential issues such as non-sampling errors, validity, reliability, and constrained responses that may limit conclusions [9]. In an attempt to overcome this, open ended free-text questions were incorporated in the questionnaire. Furthermore, the results were only based on the perceived views of the pharmacists on this recent codeine upscheduling without the use of any specific patient or practice data, for example use of actual analgesic or codeine utilisation data. Lastly, it should be noted that it was not the intention of this exploratory study to conduct an extensive evaluation

of the recent 2018 codeine rescheduling and its impacts, but only to provide some initial insights.

To extend this research, it would be important to further explore the specific impacts this upscheduling has on pharmacy practice and to a pharmacist's role, for example conducting a larger study; examining the perceived risks and benefits of codeine rescheduling from the patient's perspectives; examining other key drivers for pharmacist's views and behaviours; as well as conducting a more thorough practice and economic analyses of codeine rescheduling.

Conclusion

In summary, many pharmacists in Australia support the latest codeine upscheduling change and are encouraged by the potential benefits, but there is still much uncertainty and there are many perceived disadvantages. However, results from this study provided insights and suggest a potential opportunity to further develop and support training/education/resources in the clinical pain management and codeine utilisation space for both pharmacists and patients.

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