Pharm World Sci (2009) 31:230–237
DOI 10.1007/s11096-008-9266-8

RESEARCH ARTICLE

National implementation of standards of practice for non-prescription medicines in Australia

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Received: 14 April 2008 / Accepted: 2 November 2008 / Published online: 2 December 2008

Abstract In Australia, there are two categories of non-prescription medicines: pharmacy medicines and pharmacist only medicines. Standards were developed to define and describe the professional activities required for the provision of these medicines at a consistent and measurable level of practice. *Objective* Our objective was to implement nationally a quality improvement package in relation to the Standards of Practice for the Provision of Non-Prescription Medicines. *Methods* Approximately 50% of Australian pharmacies ($n = 2{,}706$) were randomly selected by local registering authorities. Trained pharmacy educators audited each community pharmacy in the study three times, 7 weeks apart on Standards of Practice for the Provision of Non-Prescription Medicines, Visit 1 involved the educator explaining the project and conducting an assessment of the pharmacy's level of compliance. Behaviour of community pharmacists and their staff in relation to these standards was measured by conducting pseudo-patron visits. Pseudopatron visits were conducted at Visit 2, with the educator providing immediate feedback and coaching and a compliance assessment. Visit 3 involved a compliance assessment, and a second pseudo-patron visit for those pharmacies that had performed poorly at the first visit. *Results* At Visit 1, the lowest levels of compliance were to the standards relating to the documentation process (44%) and customer care and advice (46%). By Visit 2, more than 80% of pharmacies had met most criteria. At Visit 3, compliance had significantly improved compared to Visits 1 and 2 ($P < 0.001$). The lowest levels of compliance were to criteria which required written operating procedures for specific tasks, but these also improved significantly over time ($P < 0.001$). *Conclusions* Professional practice in relation to the handling of pharmacist only and pharmacy medicines improved considerably as measured by the auditing process, and the results indicate that Australian pharmacies are well-equipped to provide high quality service to consumers of these medicines. The acceptability of national implementation of these standards of practice in Australia indicates that such an approach could be taken internationally.

Keywords Australia · Community pharmacist · Implementation · Non-prescription · OTC · Quality improvement · Standards of practice · Training

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Impact of findings on practice

- Significant improvement in the quality of service delivery in the management of requests involving non-prescription medicines.
- Provision for the large scale implementation of commonly accepted and recognised standards and protocols for the management of requests involving non-prescription medicines incommunity pharmacy.

Introduction

In Australia, the classification of medicines provides for two categories of non-prescription medicines that can only

be purchased from a pharmacy, *pharmacy medicines* and *pharmacist only medicines*. This is a different system from the USA, for example, in which prescription-only or general sale are the only two categories of medicines. Classifying non-prescription medicines in this way is not unique to Australia. However, *Pharmacist only* and *pharmacy medicines* categories also exist in countries such as New Zealand and Canada, while in the UK and France, there is a *pharmacy only* category [1]. The purpose of these categories is to allow consumers to have reasonable access to effective medicines without a medical prescription. The underlying assumption of the regulation that restricts sales of these medicines to pharmacies is that pharmacists will monitor sales and intervene where necessary to ensure people use medicines safely, appropriately and effectively.

In Australia, the Industry Commission into the Pharmaceutical Industry (the industry includes manufacturers, wholesalers and community pharmacies) recommended that the current scheduling for *pharmacy* and *pharmacist only* medicines should only be retained, "pending further research into the role of the pharmacist counselling in ensuring improved health outcomes, and the monitoring of the extent of such counselling" [2].

A more recent inquiry recommended that for "over-the-counter medicines" (*pharmacy only* and *pharmacist only*), "consumers must have adequate information and understanding to enable them to select and use the most appropriate medicines for their condition and to use it safely and effectively, taking into account their health status" [3]. This same inquiry "accepted that some pharmacists do provide good service to consumers who obtain *pharmacy* and *pharmacist only* medicines from them, but that the standard is not generally high, nor do all pharmacists always provide proper care" [4]. Indeed, studies conducted in Australian and other countries support this assertion. These few studies indicate that standards of practice in relation to non-prescription medicines vary a great deal in community pharmacy. Whilst some pharmacies do provide quality services and advice, others do not [5–7].

The legal requirements in relation to *pharmacy only* and *pharmacist only* medicines and criticisms of the performance of community pharmacists in relation to the monitoring of these products has led to the development of comprehensive national standards of practice in relation to these products[8]. This represented a significant development in the area of standards for community pharmacy. Guidelines produced by the International Pharmaceutical Federation for standards of practice focus on the supply and use of prescription medicines [9], and while many countries have professional practice standards, few address the provision of non-prescription products, let alone have a separate set of standards dealing with these medicines [10].

Following consultation with key industry and consumer groups and selected community pharmacists, standards of practice were developed including protocols for the sales of *pharmacy* and *pharmacist only* medicines (Tables 1, 2) [8]. The Standards defined and described what professional activities are required in the provision of *pharmacist only* and *pharmacy* medicines at a consistent and measurable level of practice. These were in the areas of Resource Management; Professional Practice; Pharmacy Design and Environment; and Rights and Needs of Customers [8]. The Standards were followed by criteria, which are clearly defined process guides describing how each standard is achieved in practice. They described key components of the standard and specified the appropriate level of performance required by expressing what a competent professional would do in terms of observable "outputs". Each criterion was followed by a number of indicators that assisted in deciding the degree to which an individual criterion had been met. The development of the Standards of Practice has been reported elsewhere [8].

Initial testing process of the Standards demonstrated a significant improvement in the quality of service delivered by community pharmacies in the management of non-prescription medicines and led to a recommendation for the development and execution of a national implementation strategy [8].

Aim of the study

Following this recommendation, the current study aimed at implementing a quality improvement package in relation to the Standards in each State and Territory of Australia.

Method

Research design

Within-subjects (repeated measures) design was employed. Randomly selected pharmacies were coached on the implementation of the Standards of Practice for the Provision of Non-Prescription Medicines. Pre and post measurements of the level of adherence to the Standards were taken.

Sample size

The study was conducted from January 2000 to December 2002. Out of a total of approximately 5,000 pharmacies in Australia at the time, 2,706 pharmacies were selected by the local registering authority to take part in the study (Table 3). The randomisation procedure was not controlled by the researchers but conducted by the registering authorities.

Table 1 Standards of practice for *pharmacy* and *pharmacist only* medicines

Standard 1 Resource management is composed of three criteria
1.1.1 The workload in the pharmacy, its workflow procedures and staffing levels ensure that a pharmacist is available at all times for consultation on *pharmacist only* medicines and, when necessary, on *pharmacy* medicines.
1.1.2 The pharmacy has timely access to sources of expert advice on clinical matters for use by the pharmacist.
1.1.3 The pharmacy provides for customer access to pertinent information materials on *pharmacist only, pharmacy* and unscheduled non-prescription medicines, and the conditions for which they can be used.
Standard 2 Customer care and advice is composed three of three separate parts
Part one—supply
2.1.1 The pharmacy has a screening and referral system which ensures that customers who present with symptom-based requests receive appropriate care and advice.
2.1.2 *Pharmacist only* medicines are provided to customers with the direct involvement of the pharmacist and according to state legislative requirements.
2.1.3 Customers who request purchase of a *pharmacy* medicine receive appropriate advice and care.
2.1.4 Pharmacists are trained in the provision of advice on the management of symptoms and the appropriate selection of *pharmacist only* and *pharmacy* medicines.
2.1.5 Pharmacy staff is trained in the provision of advice on the appropriate selection of *pharmacy* medicines.
2.1.6 Customers whose medical condition warrants further investigation are referred to an appropriate health professional.
Part two—Indirect supply
2.2.1 Where supply of *pharmacist only* or *pharmacy* medicines is not made directly to the customer, customers receive appropriate professional service and advice to promote optimal health outcomes.
2.2.2 When a *pharmacist only* or *pharmacy* medicine is provided to a customer by way of a third party, the pharmacist ensures that the customer or their carer receives appropriate information and advice on its safe and effective use.
Part three—documentation
2.3.1 The pharmacy maintains a record management system for *pharmacist only* medicine consultations which conforms to relevant legislative requirements.
2.3.2 When a customer has a medication profile at the pharmacy, and with the customer's agreement, the purchase of *pharmacist only* medicines is recorded in the customer's file.
2.3.3 The pharmacy has a system for documenting inappropriate use of *pharmacist only* and *pharmacy* medicines.
Standard 3 Pharmacy design and environment is composed of two parts with criterion
3.1.1 *Pharmacist only* medicines are located in a secure area
3.1.2 *Pharmacy* medicines are located in a well-defined professional services area.
3.2.1 The pharmacy makes provision within the professional services area for private consultation with customers.
Standard 4 Rights and needs of customers is composed three criterion
4.1.1 Pharmacy staff provides respectful care at all times and under all circumstances.
4.1.2 Information concerning customers is handled by staff in ways that protect the confidentiality of the information.
4.1.3 Customers have the right to refuse treatment or advice and to seek alternative opinions.

Researchers contacted the registering authorities and requested that they provide a random sample of 50% of their community pharmacies. The sample size, determined by budgetary constraints was composed of approximately 50% of the total number of pharmacies in Australia. The randomisation procedure was used in every state and territory of Australia with the exception of pharmacies from the state of South Australia where the registering authority decided that they wished all pharmacies to participate in the program (389) and provided additional funding.

Recruitment

The selected pharmacies were firstly contacted by their local registering authority via a letter outlining the pharmacy's role, a description of the Quality Improvement (QI) cycle and a copy of the individual Standards of Practice. The letter also made the proprietor aware that a pharmacy educator from the project would be visiting the pharmacy within the following 2 weeks for the first of a series of three visits (Fig. 1).

Measures

Compliance with the standards was assessed via an auditing process. Educators went through the individual Standards of Practice and assessed whether or not they had been met. Practice behaviour, was monitored via pseudo-patron visits, also known as simulated patient visits. That is, confederates of the researchers were trained to go to the

Table 2 Protocols for the sales of *pharmacy* and *pharmacist only* products

Direct product request
• Check satisfaction with product
• Check other medication
• Check other health condition
• Refer if needed
• Provide information (verbal or written)
Symptom-based request
• Check symptoms
• Check length of symptoms
• Check other medication
• Check other health condition
• Refer if needed
• Provide information (verbal or written)

Table 3 Number of pharmacies visited at least once per location (State)

State	Number of pharmacies
New South Wales & Australian Capital Territory	958
Queensland	436
South Australia & Northern Territory	389
Tasmania	73
Victoria	599
Western Australia	251
Total	2,706

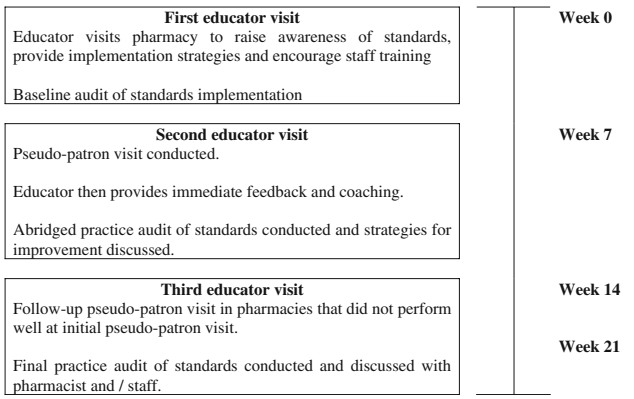

Fig. 1 Educator visit protocol

pharmacies in the study and enact particular scenarios. A trained educator provided feedback and coaching to the pharmacist immediately after the pseudo-patron visit. This training method had been previously shown to be effective in shaping practice behaviour of community pharmacists and their staff in relation to the provision of non-prescription medicines [5, 11–15]. The pseudo-patron method was critical in assessing standards of practice related to customer care and advice and resources management (Table 1). However, although the results pertaining to customer care and advice and resources management are reported, the current study will focus on the auditing process as results from pseudo-patron visits have been reported in detail elsewhere [16].

Visit process

At each visit point, assistance with the requirement of the Standards was an integral part of the educator's role. During the first visit, the pharmacy educator explained the project, answered questions and also conducted an assessment of the level of compliance with the Standards. At each visit point, assessment involved the measurement of all practice indicators (Table 4) with the exception of criteria 1.1.3, 2.1.1, 2.1.2, and 2.1.3 which relied on pseudo-patron visits for assessment.

A follow-up letter from the project was sent to the participating pharmacies after each visit point. The letter related to the assessment of the individual Standards of Practice highlighting the standards that had been met and providing suggestions and motivation to pursue the standards that had not yet been met. Twenty-one pharmacy educators were employed for the visit process.

Data analysis

Frequency distributions were used to compare compliance with the standards overtime and chi square analysis of proportions was used to test for significance.

Results

Pharmacy educators emailed data to the authors who for reliability and validity reviewed available paper data for accuracy of data entry. All 2,706 pharmacies in the study received the first educator visit, 2,534 pharmacies received the second educator visit and 2,371 pharmacies received the third and last educator visit. The most common reasons for attrition were pharmacy withdrawal from the study due to unforseen circumstances (e.g. pharmacy closure, sale), educators' omission to collect data, and educators' contradiction of study protocol and introduction of potential bias by delivering the second audit visit prior to the pseudo-patient visit.

Compliance with the standards

At each visit point, educators assessed the individual Standards of Practice (Table 1). This was accomplished by

Table 4 Example of one standard with accompanying criteria and indicators

Standard 1.1. The Pharmacy has adequate human, material and financial resources to promote the quality use of non-prescription medicines as part of a more general primary health care service

Criterion 1.1.1 The workload in the pharmacy, its workflow procedures and staffing levels ensure that a pharmacist is available at all times for consultation on *pharmacist only* medicines and, when necessary, on *pharmacy* medicines.

Indicators

☐ A. The pharmacy has written Standard Operating Procedures, that are accessible to staff and external auditors, which ensure that all customers have timely access to a pharmacist for advice on the treatment of symptoms and the appropriate selection of *pharmacist only* and *pharmacy* medicines (*direct observation*, *pharmacist interview*)

☐ B. All staff have been trained in the Standard Operating Procedures (*pharmacist interview*, *non-pharmacist staff interview*)

☐ C. All staff apply Standard Operating Procedures (*pseudo-patron visit*)

☐ D. Customers report that a pharmacist is available for consultation when necessary and is proactive in providing advice (*pseudo-patron visit*)

Assessment

Criterion met	Criterion not met	Not applicable
☐	☐	☐

Not Applicable—Reasons:

Table 5 Compliance rates for Visits 1, 2, and 3

No.	Short description of the criterion	1%	2%	3%	*P* value
1.1.1	Pharmacists are available at all times for consultation on *pharmacy* and pharmacist *only medicines*	55	74	91	0.0001
1.1.2	The pharmacy has timely access to sources of expert advice on clinical matters	96	99	100	0.0001
1.1.3	The pharmacy provides for customer access to pertinent information materials	79	83	96	0.0001
2.1.1	The pharmacy has screening and pharmacist referral system	54	72	91	0.000
2.1.2	Pharmacist only medicines are provided to customers with the direct involvement of the pharmacist	60	78	92	0.0001
2.1.3	Customer receive appropriate advice and care	55	73	90	0.0001
2.1.4	Pharmacist maintains continuing education training	88	91	95	0.0001
2.1.5	Staff is trained on the provision of advice	95	96	98	0.0001
2.1.6	Pharmacy has form protocol for customer referral to other health professional when appropriate	71	77	89	0.0001
2.2.1	When medicine is posted or delivered, the consumer receives appropriate information and advice	54	76	90	0.0001
2.2.2	When medicine is sold to third party, the pharmacist ensures patient receives information and advice	48	70	87	0.0001
2.3.1	State legislation require the recording of selected pharmacist only medicines	87	97	99	0.0001
2.3.2	It is recommended, with patient's consent, the recording of purchases of pharmacist only medicines	75	79	86	0.0001
2.3.3	The pharmacy has a system for documenting inappropriate use	63	82	92	0.0001
3.1.1	Regulations require the storage of *pharmacist only* medicines in a manner that consumer cannot self-select	99	100	100	0.0001
3.1.2	Pharmacy medications are located in a well-defined professional area	94	97	99	0.0001
3.2.1	Confidential conversations can be conducted in a location where they cannot be easily overheard	93	98	99	0.0001
4.1.1	Staff provide respectful care at all times and under all circumstances	93	98	100	0.0001
4.1.2	Confidentiality is maintained	75	88	94	0.0001
4.1.3	Customers have the right to refuse treatment or advice and to seek alternative opinions	94	98	100	0.0001

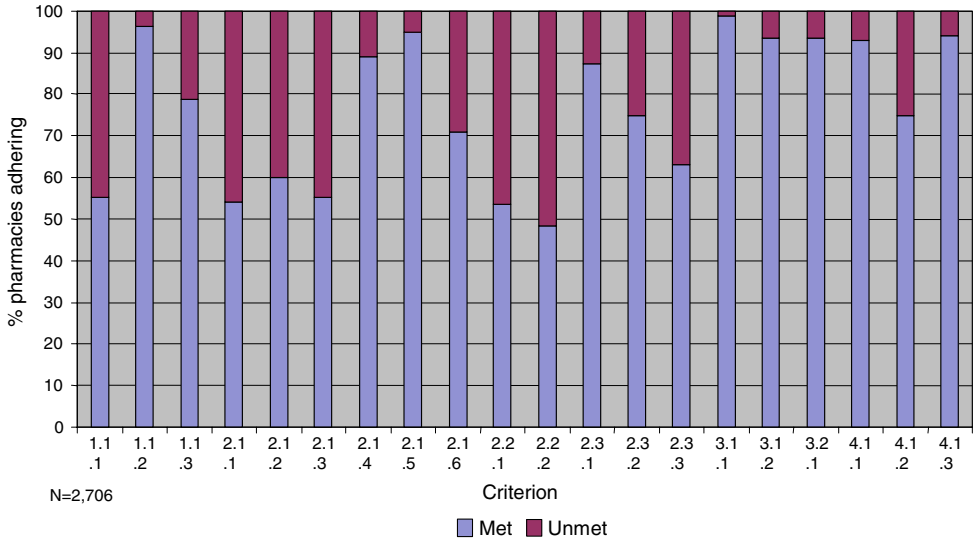

Fig. 2 National adherence to standards of practice at Visit 1

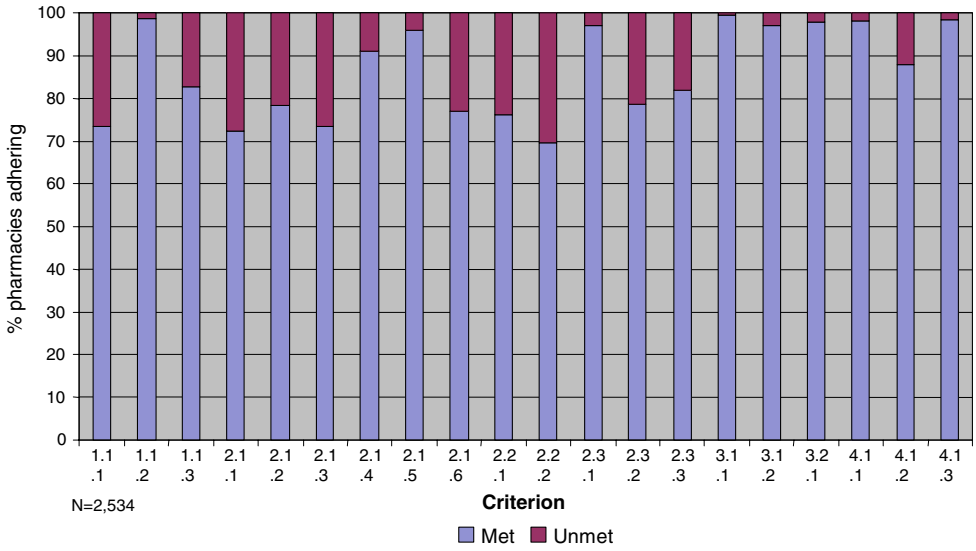

Fig. 3 National adherence to the standards of practice at Visit 2

determining whether or not individual criteria had been met. The proportion of criteria met (compliance rates) was calculated for each of the three visits (Table 5).

Figure 2, below, shows the national adherence to the Standards of Practice at Visit 1. At this point, the lowest levels of adherence were to documentation process (44%) and to Customer Care and Advice (46%).

Figure 3 shows compliance to Standards at Visit 2. At this visit, more than 80% of pharmacies had met most criteria. The lowest levels of compliance were to criteria 1.1.1, 2.1.1, 2.1.3 and 2.2.2, which required written operating procedure for specific tasks.

Figure 4 shows compliance to Standards at Visit 3. At this visit, compliance to most criteria had significantly improved compared to Visits 1 and 2. Consistent with previous visits, criteria related to documentation had the lowest levels of compliance.

Discussion

The current study represented the first attempt in Australia, and perhaps globally, to implement standards of practice specific for non-prescription medicines, at a large scale. The implementation strategies seemed to have been well accepted by participants and results indicate pharmacies across the country were better equipped to provide higher quality service to consumers of non-prescription medicines.

Results showed that the methodology had been effective in sensitising community pharmacists and staff to the importance of pharmacist counselling in the non-prescription area. However, it should be noted that the results presented in this paper might not represent true behavioural measurement of pharmacy performance, but indicators. Pharmacists and staff were aware of the impending pseudo-patron visits, which could have made performance reactive.

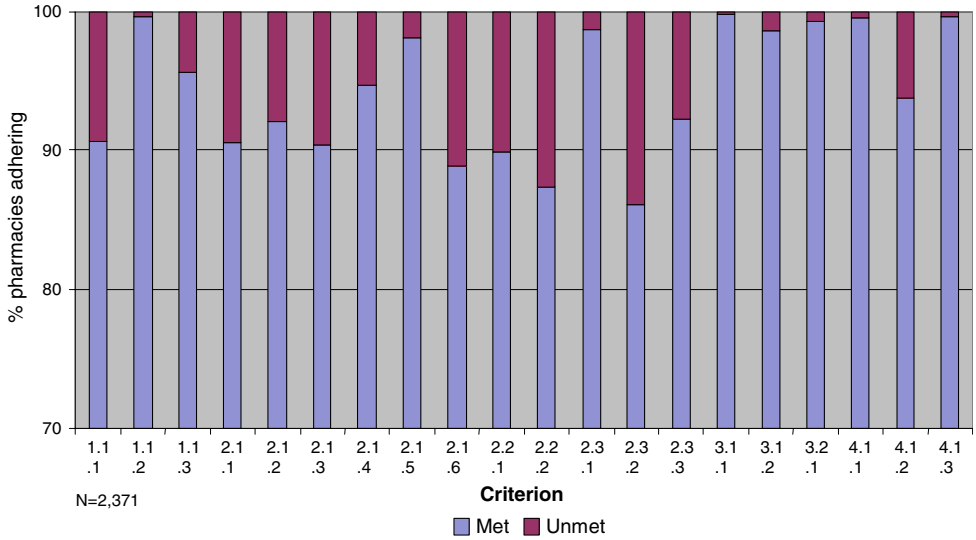

Fig. 4 National adherence to standards of practice at Visit 3

It is also noted that across the auditing visits the lowest level of compliance was observed for criteria related to documentation process. It seems reasonable to suggest that a belief that the keeping of consumer records constitutes extra professional duty and lack of mechanisms for recording patient details may at least partially explain these results. It is true that the successful implementation of sustainable behaviours in community pharmacy requires that pharmacies develop mechanisms to allow them to integrate documentation procedures into routine professional practice.

As one would expect, criteria related to behaviours where pharmacists already had in their repertoire which were also mandatory by legislation—such as storage of *pharmacist only* medicines in secure area, location of *pharmacy* medicines in a professional area—presented the highest levels of compliance throughout the study.

Also, it is noted that criteria related to *pharmacist only* medicines and those related to *pharmacy* medicines improved in parallel between Visit 1 and 3 but failed to reach significant different scores. A limitation of the study lies in the fact that researchers did not record who provided advice and care (criteria 2.1.3), consequently data obtained from pharmacists could not be compared to those obtained by pharmacy staff. It is not known whether or not scores obtained by pharmacists were higher than those obtained by other staff members. Further research is needed to assess appropriateness of advice and care in relation to who in the pharmacy team delivers the care.

Finally, attrition was spread proportionately across Australian states and territories with a total rate of 11.8% (318 pharmacies). Therefore, generalisation from the sample to the population of Australian pharmacies can be made with a high degree of confidence.

Conclusion

Community pharmacists across Australia responded favourably to the large-scale implementation of standards of practice for the provision of *pharmacy* and *pharmacist only* medicines. Professional practice in relation to the handling of these medicines improved considerably as measured by the auditing procedure. The good acceptability of large-scale implementation of these standards of practice in Australia indicates that such an approach could be taken beyond Australia. It should also be noted that the current study did not include a cost-benefit analysis. Such an analysis has been conducted in a separate study and reported elsewhere [1].

Acknowledgement The authors would like to acknowledge the support of the Pharmacy Boards and pharmacy staff in participating in the project.

Conflicts of interest We declare that Professor Benrimoj, Dr de Almeida Neto, and Dr Kelly have been involved with professional pharmacy organisations in Australia, which may have an interest in the development and implementation of standards of practice for the provision of non-prescription medicines.

Funding Funding for this project was from the Australian Government Department of Health and Ageing through the 3rd Community Pharmacy Agreement Research and Development Program.

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