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We saw that over-the-counter medicines were positioned to potentially play larger roles in the management of chronic diseases and felt that national feedback was needed to better understand the area.

Nous avons constaté que les médicaments en vente libre pourraient jouer un plus grand rôle dans la prise en charge de maladies chroniques et nous avons jugé nécessaire d'obtenir une rétroaction nationale pour mieux comprendre cette question.

Results of a national survey on over-the-counter medicines, Part 1: Pharmacist opinion on current scheduling status

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Abstract

Background: OTC medicines make up an important part of the community pharmacy world. As with most aspects of practice, however, hurdles exist that prevent an optimal level of care.

Objective: To gauge pharmacist agreement on the scheduling status of various OTC medicines.

Methods: Pharmacists across Canada were surveyed by mail.

Results: Of the 5037 surveys mailed, 2403 were returned, with 2305 being usable for analysis (response rate of 49.4%). Across 25 agents, phar-

macists tended to support existing control for pharmacies (such as Nix crème rinse and minoxidil topical solution) and returning control to pharmacies for unscheduled agents (such as ranitidine 75 mg tablets and nicotine patches).

Conclusions: Pharmacists generally favour tighter control of OTC agents, especially those that are unscheduled. This hopefully reflects pharmacist desire to ensure their proper selection and use. *Can Pharm J* 2012;145:40-44.

Background

Advising consumers on the selection and proper use of over-the-counter (OTC) medicines is a key component of pharmacy practice. Canadian pharmacist involvement in this aspect of practice has been documented and has proven to be noteworthy.¹⁻⁴ Indeed, most community pharmacists will attest to the impact they can have in fielding questions on OTC medicines.

There is also room for improvement, however. Possible barriers to pharmacists' provision of this service are that pharmacists do not have time for it; are not getting paid for it; perceive minimal consumer demand for it; are not confident in this area; and/or disagree with legislators on what level of care is needed for certain agents.⁵⁻¹²

Accordingly, we set out to gather feedback on some of these issues. The work is based on a national survey covering a variety of matters regarding the sale and distribution of OTC medicines in Canada. It addressed factors that may impact pharmacist propensity to engage in medicine management involving OTC agents. This article represents the first of 3 in upcoming issues of the journal and addresses the overall methodology and results of the first section of the survey.

Pharmacists are respected health care professionals with very stressful, demanding roles in caring for the public. They are still often asked to find ways to do things better.¹³ This call to action should by default include greater involvement in OTC medicine management. But with so much

attention needed to help ensure appropriate medicine use in diabetes, asthma, hypertension, etc., finding the time to advise on OTC products can be frustrating. It may be a question of priorities.

Whether or not pharmacists find the time to consult on OTC medicines may hinge on the importance they attribute to this role. In other words, do pharmacists consider managing OTC medications to be as important as managing prescription medications?¹⁴ Along similar lines, if pharmacists feel certain agents are *overcontrolled* (an agent holds behind-the-counter status when it is felt unscheduled status would suffice, for example), then clinical interventions may be minimal (again, through a conscious choice to prioritize to more important matters).

The objective of the first component of the survey was to ascertain pharmacist agreement on the scheduling status of various OTC medicines.

Methods

The study design was cross-sectional in nature. Data were obtained via mail-out questionnaire to a large sample of Canadian pharmacists.

Questionnaire content for all sections was guided by the literature, but where none existed, items were created by drawing on researcher experience. There were 5 components to the survey: 1) agreement on the current scheduling status of OTC medicines; 2) perceptions of public expectations for clinical interaction involving such agents; 3) assessment of the professional skills required when involving Schedule II (pharmacy-only or behind-the-counter) agents¹⁵; 4) perspectives on the potential deregulation of 3 agents¹⁶⁻¹⁸; and 5) demographics.¹⁹ OTC agents under scrutiny were chosen by the researchers.

The mail-out sequence involved an advance letter (sent a week prior to main mailing), the main mailing (questionnaire), 2 follow-ups encouraging participation and a card mailed to gather brief information on nonresponders.

Sampling procedures

We sought to survey practising community pharmacists across Canada. The majority of the nearly 30,000 licensed pharmacists (NAPRA, circa 2006) were primarily working in community pharmacies. For a study population of this size, to attain $\pm 3\%$ sampling error, a sample of approximately 900 was needed. Briefly, we contacted provincial regulatory bodies and/or government agencies to obtain lists of community pharmacists. We used a weighted sampling by provincial population. The numbers of surveys sent were as follows: Newfoundland (n

= 99), Saskatchewan (n = 203), Manitoba (n = 155), Quebec (n = 1392), Ontario (n = 1843), Alberta (n = 767) and British Columbia (n = 578), for a total of 5037 (pharmacist information was unavailable from other provinces or territories). Surveys were sent out between April 2007 and March 2009. Further details on our sampling methods are available from the corresponding author.

Ethical approval was obtained by the institutional review bodies of the University of Saskatchewan and the Centre de Santé et de Services Sociaux de Laval.

Results

Response rate

Of the 5037 surveys mailed out from April 2007 to March 2009, 259 came back undelivered for various reasons, such as an inaccurate address. A total of 2403 completed surveys were returned. Fifteen documents were removed because major sections were left unanswered by respondents; this left 2388 cases. Another 83 were removed for a variety of reasons, including hospital-based practice, veterinary-based pharmacy, government pharmacist, consultant, prescribing physician or retired from practice. This left 2305 as the number of usable surveys.

The 83 cases mentioned above were removed for calculation of the response rate, along with the undelivered surveys, while the 15 incompletes were left in. This led to a response rate of 49.4%. The following results are based on 2305 surveys.

Demographics

The average age of responding pharmacists was 46.8 years ($SD \pm 14.3$, n = 2274). The majority were female (57.6%, n = 1316). Employment status and primary location of community practice appears in Table 1.

The distribution of rural and urban pharmacy settings can be found in Table 2 (for those who provided data). The information was obtained by asking responders to indicate the first 2 letters/numbers of their postal code. Codes where a zero followed a letter were categorized as rural, in accordance with the Canada Post guidelines.²⁰

Key Points

- Pharmacists generally favour tighter control of OTC agents, perhaps feeling that some moves to unscheduled status have been too aggressive.
- Pharmacist control of pseudoephedrine received strong support, as did the unscheduled status for acetaminophen 325 mg.
- 1 in 5 pharmacists supported a move to prescriptive status for OTC codeine-containing analgesics.

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Agreement on current scheduling status

Pharmacists were asked whether they agreed with the current scheduling status of various agents. For this, the current schedule for each was stated (as defined by NAPRA, circa 2006). Respondents then indicated how they believed the agent should be scheduled (i.e., prescription, Schedule II, Schedule III or unscheduled). Numbers provided here are based on number of responses for each agent (Table 3).

While Polysporin drops are available as an ophthalmic/otic combination, the agent was listed twice according to how the drops would be used. This allowed pharmacists the ability to differentiate responses along therapeutic lines.

Three agents changed status during the course of the survey — ibuprofen 400 mg moved to unscheduled status (November 2007), Plan B moved to Schedule III in May 2008 and benzoyl

peroxide 5% became unscheduled at the same time. However, surveys were not revised for provinces yet to receive them, affecting pharmacists in 3 provinces. Consideration was given to removing these agents from analysis, but they were retained because the question wording asked pharmacists to identify how they felt it *should be* categorized, which could be done independent of its existing status.

Nonresponders

Pharmacists unable or unwilling to complete the survey were eventually sent a small card designed to collect a minimum of demographic information. This was then compared to that of the main sample to help assess for nonresponse bias. Of the total number of cards sent ($n = 2687$), 329 were returned.

While the numbers were low, the data appeared to be reasonably concordant with the demographic parameters of the main sample, suggesting nonresponders shared similar demographic characteristics.

Discussion

Nonprescription medications are important products for the management of minor ailments. In the current climate, where OTC products are subject to less regulation, the opinions of front-line community pharmacists are of high relevance. This national survey should add to our understanding of the professional dynamics involving OTC medicines and is the first of its kind in Canada, to the best of our knowledge. Overall, it shows that pharmacists generally favour tighter control of OTC agents, particularly those that are currently unscheduled. These findings have important implications for community pharmacy practice: they signal that pharmacists consider OTC products, and the care that goes along with their selection and proper use, to be deserving of our attention.

The data may therefore reflect a potential disconnect between regulators — those deciding how OTCs should be legislatively categorized in Canada — and front-line pharmacists. It may suggest that Canadian pharmacists feel some deregulating actions taken to date have been too aggressive. By the same token, one would also have to ask whether clawing some (or all) disputed agents back to pharmacy status would automatically lead to enhanced patient safety, given that OTC medicines are not always given high priority by pharmacists.

We cannot conclusively rule out that pharmacists' call for greater regulation is profit-driven, where pharmacy has exclusive rights to retail sale.

TABLE 1 Demographic information for responders

Employment status ($n = 2217$)	n	Percent
Staff pharmacist	1436	64.8
Relief pharmacist	238	10.7
Dispensary manager	248	11.2
Owner	231	10.4
Other	64	2.9
Primary practice site ($n = 2216$)	n	Percent
Grocery or department store	356	16.1
Independent	467	21.1
Chain	458	20.7
Franchise (≤ 1200 sq ft)	125	5.6
Franchise (> 1200 sq ft)	600	27.1
Medical building	183	8.3
Other	27	1.2

TABLE 2 Distribution of rural and urban pharmacists

Province	Rural, n (%)	Urban, n (%)	Total contribution by province, n (%)
British Columbia	31 (12.9)	209 (87.1)	240 (11.2)
Alberta	60 (15.8)	320 (84.2)	380 (17.8)
Saskatchewan	31 (24.8)	94 (75.2)	125 (5.9)
Manitoba	14 (17.7)	65 (82.3)	79 (3.7)
Ontario	88 (15.4)	482 (84.6)	570 (26.7)
Quebec	110 (15.7)	591 (84.3)	701 (32.8)
Newfoundland	17 (41.5)	24 (58.5)	41 (1.9)
Total	351 (16.4)	1785 (83.6)	2136 (100)

However, based upon the nature of the products in question, we believe that pharmacists are identifying products with potential for misuse. Also, only about one-fifth of respondents were pharmacy owners; the rest of respondents would presumably not directly profit from these products being sold only in pharmacies.

Our finding that pharmacists generally favoured more regulation of products is interesting. In particular, pharmacists felt that many unscheduled products should be moved to Schedule III. Also, some pharmacists felt that a number of Schedule III products should be moved to Schedule II. This may be due to their concern over the inappropriate use (sometimes abuse) or need for education about these products. If so, this signals pharmacists' feelings of "ownership" in this area and willingness to take responsibility for the selection and appropriate use of these products.

The switch from Schedule II to Schedule III

for Plan B occurred while the survey was ongoing. The majority of pharmacists favoured a Schedule II designation for this product (likely because of the education needed for its appropriate use). Elsewhere, dimenhydrinate and Polysporin drops for ophthalmic use received significant support for a move to Schedule II. Several hundred pharmacists suggested making codeine-containing OTC products available by prescription only. As a reflection of the move made to help counteract crystal meth abuse, strong support was shown for Schedule II status of pseudoephedrine.

While our data present some perspective on OTC scheduling in Canada, the process of prescription-to-OTC switches is an area that has received considerable attention by researchers and policy-makers. This has included discussion about the actual pros and cons of deregulation.²¹⁻²⁶ With pharmacists in our survey leaning towards greater control, they may be highlighting the cons of self-

TABLE 3 Agreement on current scheduling status for select OTC medicines

Agent	Current status*	What status should it be in your opinion?			
		Rx	Sched II	Sched III	Unsched
Plan B tabs	II	466	1645	93	9
ASA 81 mg tablets	III	18	369	1598	233
Nix creme rinse	II	72	1496	576	85
Senna tablets	U	4	289	1381	560
DM syrup (small bottle)	U	6	299	1551	389
Dimenhydrinate tablets	III	10	1272	913	61
Nicotine 21 mg patch	U	17	541	1358	343
Acetaminophen/cafeine/codeine 8 mg	II	461	1731	39	6
Ferrous sulfate 300 mg tablets	II	145	1678	383	32
Pseudoephedrine 60 mg tablets	II	94	1680	444	20
Ibuprofen 200 mg tablets	U	7	169	1466	625
Ibuprofen 400 mg tablets	III	27	590	1350	289
Codeine-containing cough syrup	II	356	1822	39	12
Acetaminophen 325 mg tablets	U	2	34	963	1242
Loratadine 10 mg adult tablets	U	3	83	1446	717
Minoxidil topical solution	III	53	770	1238	199
Ranitidine 75 mg tablets	U	7	177	1581	505
Hydrocortisone 0.5% cream	III	2	185	1748	306
Tetrahydrozoline eye drops	U	11	278	1414	555
Miconazole foot cream	U	3	87	1475	704
Loperamide 2 mg capsules	U	3	272	1573	428
Clotrimazole 6-day vaginal cream	III	3	212	1878	151
Polysporin drops (if ophthalmologic)	III	16	1220	948	78
Benzoyl peroxide 5% lotion	III	8	366	1634	221
Polysporin drops (if otic)	III	11	888	1186	162

* At the time the survey was created.

Points clés

- Dans l'ensemble, les pharmaciens sont en faveur d'un resserrement du contrôle des produits en vente libre, estimant peut-être que certains retraits des annexes de médicaments ont été trop audacieux.
- Le contrôle par les pharmaciens de la pseudoéphédrine a été bien accueilli, tout comme le statut de médicament non inscrit pour l'acétaminophène 325 mg.
- Un pharmacien sur cinq est en faveur d'une modification du statut des analgésiques en vente libre qui contiennent de la codéine, afin que ceux-ci soient inclus dans les médicaments sur ordonnance.

medication.

Australia has a legislative system similar to Canada's, and one small Australian report has also shown pharmacist concern over the deregulation process, specifically for such agents as ibuprofen and nicotine replacement therapy attaining unscheduled status.²⁷ Pharmacists disagreed with the notion of combining Schedule II- and III-type agents into a single schedule, stating that the current system provided guidance on how

much involvement was needed for a given medicine. As would be hoped, Australian pharmacists have also been found to provide a higher level of service for a pharmacist-only product than for 2 agents just requiring sale from a pharmacy.²⁸

In the United Kingdom (circa 1996), pharmacists were supportive of some aspects of the switch process, but support varied by agent²⁹ (as was the case for our survey). UK physicians are on record as having favoured the reclassification of medicines for acute illness, but were opposed to medicines being available to treat chronic illness.³⁰ In the USA, 248 Ohio pharmacists indicated their support (or lack thereof) for deregulating 25 prescription drugs to behind-the-counter status.³¹ It is difficult to fully compare reports, however, because agents are often classified differently in other countries.

Limitations

Our survey, while extensive, was not truly national in scope, because not all provinces were able to participate. Further, differing response rates from individual provinces may have led to under- or overrepresentation within the data for those that did participate.

All limitations inherent to survey research are in play. For example, while the level of agreement (or disagreement) in scheduling status likely influences actual practice behaviour, our survey was limited to simply gauging opinion.

The survey could be considered very time-consuming and asked a lot of questions; responder fatigue could have affected the data.

Another limitation was in the handling of hospital pharmacists on our lists. Requests made to

provincial associations for mailing lists asked that only community pharmacists be included, but it became clear when mailing lists were received that hospital pharmacists were included as well. Trying to remove hospital pharmacists from lists before mailing the surveys had inherent risk. It may have been more appropriate to send surveys to all potential respondents (regardless of list quality) and then simply cull hospital practitioners afterward, but doing so would have added considerable cost to the initial mailing.

The choice of agents given to pharmacists for consideration was an important issue. Because the list was predetermined, responders were ushered into providing selective feedback. Conversely, pharmacists could have been allowed to identify agents they felt were problematic in an unprompted manner. Thus, the agents identified here should not be viewed as the most glaring examples of agreement and disagreement in Canada; important agents could have been missed.

Finally, we recognize that pharmacists' opinions are only one aspect of the consideration to switch a product from prescription to OTC. Other reasons — such as consumer demand, desire to improve access and reduce health care system costs — are also factors.

Conclusions

In this large national survey of community pharmacists, we found that pharmacists generally favoured greater regulation of OTC products, especially for those currently unscheduled. This may indicate pharmacists' acknowledgement of the importance of their involvement in the selection and use of OTC medications, and needs to be explored further in light of the move towards patient-centred care. ■

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