

# Are we ready for prescriptive authority?

## Lessons from the self-care example

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The year 2004 has been a benchmark for pharmacists advocating to expand prescriptive authority, as pharmacists in British Columbia, Quebec, and Saskatchewan received authority to prescribe emergency contraception.<sup>1</sup> Certainly this is one category that seems to follow a win-win strategy: fulfilling pharmacists' potential to be positioned as drug experts while demonstrating significant value — in cost, access, and safety — to the public.

While acknowledging the rationale for the role of pharmacists in emergency contraception, it is timely to consider whether the record of pharmacists to date bears out the premise that expanded prescriptive authority is good for the public and the profession (as mentioned in the Romanow Report,<sup>2</sup> for instance).

An arena that invites comparison is self-care or over-the-counter (OTC) drugs, and in particular, Schedule II products. Do pharmacists have a track record in supervising self-care product delivery that demonstrates readiness to tackle prescriptive authority for prescription products?

We suggest that it is timely to reflect upon how OTC medicines are regulated in this country, how well the profession is managing the use of these agents, and how the argument for pharmacist prescribing authority may be inextricably linked to pharmacist performance with Schedule II OTCs.

### Schedules II and III

In Canada, where and how medicines can be acquired is dictated by a series of drug schedules. Schedule I drugs require a written prescription prior to dispensing. If Health Canada declares that an agent no longer requires a prescription, the National Drug Scheduling Advisory Committee determines the retail location — and thus the professional requirements — for its sale. OTC drugs may be classified as Schedule II (pharmacist-only or no public access), Schedule III (pharmacy-only), or

Unscheduled. The required level of professional intervention lessens as a product moves down through these schedules, to the point where unscheduled medications can be sold from any retail outlet.

Canadian health officials believe that while Schedule II medicines do not require a prescription, product selection by the public still carries certain health risks that can be mitigated with professional (in this case, pharmacist) involvement. Schedule II drugs therefore require that a pharmacist be in a position to monitor product selection and use in order to minimize inappropriate therapy or adverse events. Schedule III dictates that the product is to be available only from pharmacies, but not from a restricted area; therefore, any interaction will likely be initiated by the consumer when assistance is required.

Schedules II and III were adopted under the premise that either the *mandatory participation* or *consultative availability* of a pharmacist facilitates more appropriate drug use and improves patient outcomes. Accordingly, provincial regulatory authorities follow standards of practice that stipulate a certain level of patient care when providing a drug from a specific schedule. Unfortunately, evidence suggests that the frequency of pharmacist intervention (and thus the overall impact on OTC use) is somewhat limited, even for pharmacist-only OTC medicines. This may not bode well during a general call for greater pharmacist control, especially as agents such as proton pump inhibitors, statins, and inhaled corticosteroids face deregulation to OTC status in various countries.

The extension of any prescribing authority to pharmacists can be viewed as a significant breakthrough for the profession. However, to justify the authority to prescribe, no matter how limited, pharmacists need to display a high level of competency. It would seem advisable, therefore, to restrict prescribing to duly qualified practitioners similar to the model adopted for the Emergency Contraceptive Program<sup>3</sup> or as outlined in a proposal for independent prescribing by Alberta pharmacists.<sup>1</sup>

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## 'Mystery shopper' data

Some of the evidence not in favour of pharmacists has originated in Canada. Using disguised shoppers, a public affairs television program found that 36 of 70 pharmacists failed to ask any questions or give warnings when providing terfenadine (when it was still on the market) following its move to Schedule II for safety reasons.<sup>4</sup> The program noted that while pharmacists may have been physically involved in the sale, clinical assessment of product appropriateness was generally considered negligible. Similar findings (although now dated) have been identified in the United Kingdom, where consumer groups found that pharmacist-only medications were being sold without any attempt to determine the reason for use or were being sold by pharmacy assistants (at times with no pharmacist on the premises).<sup>5-7</sup>

Concerns have also been raised in the US,<sup>8</sup> where the OTC legislative landscape is such that all nonprescription drugs can be sold from any retail outlet. Although numerous pharmacy organizations have argued for a pharmacist-only class of OTC medicines (similar to Schedule II in Canada), the lack of evidence of any clear benefit has hindered progress. Florida's Pharmacist Prescribing Law, for example, permitted pharmacists to "prescribe" certain prescription-only agents (the majority of which were available without prescription in other countries at the time). With the law in effect for approximately 18 months, program evaluation revealed that pharmacists often failed to obtain any information deemed critical to case assessment.<sup>9</sup> Fewer than 17% of pharmacists inquired about current medical conditions, allergies, or concurrent drug therapy; only 5% asked about the onset, duration, or frequency of symptoms.

Later, the pharmacist lobby was set back again by a government report's conclusion that there was no value in granting pharmacists greater control of the sale of OTC medicines in the US.<sup>10</sup>

## Walk first, then run

The pharmacy profession has not fared entirely well in reports from around the world concerning medicines that, for all intents and purposes, could be considered as *phar-*

*macist prescribed*. Workload, competing time demands,<sup>11</sup> time pressures on consumers and pharmacists alike,<sup>12</sup> and lack of professional fee may all contribute to less-than-ideal pharmacist involvement in OTC transactions.

It might be argued that we neglect self-care categories precisely because we view them as deserving or requiring less of our attention. Indeed, given the variety of agents in Schedule II, pharmacists may disagree on the level of intervention required for a given agent and on which agents should, in fact, be placed behind the counter.<sup>13</sup>

That said, there is great potential for the expansion of professional activities in assisting patients who require Schedule II medicines. The array of drugs being considered for deregulation to OTC status is vast, putting pharmacists in an ideal position to properly assess, counsel, and monitor patients who require these agents. It is likely that most of any deregulated agents will be legislated (at least initially) into this "prescribing category" of OTCs.

## Drug experts

As pharmacists we often refer to ourselves as the "drug experts." If true, this assertion should apply to all medicines, regardless of their assigned schedule. By applying standards similar to those developed for emergency contraception to an expanding array of Schedule II medicines, pharmacists could greatly improve the quality of care provided while enhancing our professional image among patients and other health care disciplines. Indeed, with emergency contraception being reclassified as *merely* Schedule II, it would seem a reasonable expectation that the same current level of care will be taken when providing it to the patient.

In conclusion, focusing our energy on improving our standard of care in the area of over-the-counter medicines before striving to become prescribers may be a reasonable strategy for the profession. At a minimum, improving practice habits for current Schedule II OTC agents will strengthen our professional foundation, ensure our preparedness for future OTC switches, and pave the way to expanded professional responsibilities. ■

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