Essay

Prescription to over-the-counter deregulation in Canada: Are we ready for it, or do we need to be?

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Emergency contraception[1] is just the latest example in a long list of medications that are being shifted from prescription only to over-the-counter (OTC) status. More experience with other potent and effective prescription drugs and an increased understanding of their safety and efficacy in the management of complex and chronic diseases will inevitably result in the deregulation of additional prescription drugs to OTC status.

The momentum for the expansion of the OTC armamentarium, although encouraged by modern notions of individual responsibility and self-care, is also being driven by pharmaceutical companies seeking increased sales and the rapidly rising costs of maintaining prescription drug plans, both public and private.

Nonprescription drugs play a significant role in health care, generating in excess of $3 billion a year in sales in Canada in 2004.[2] To garner access to a larger market and increased sales, many pharmaceutical companies are encouraging regulators to allow for more prescription drugs to be reclassified as OTC, motivated in part by the expiration, or the pending expiration, of patents on lucrative prescription drugs.[3] Governments and private insurance companies may also benefit from deregulation under the guise of cost containment for formularies. Prescription drug costs are an increasingly large component of overall health care costs. For example, in 1999, the total cost of prescription-only medicines in Canada was $10.3 billion, of which about 34% was covered by private insurance plans, 44% by public insurance plans and the remaining 22% ($2.3 billion) directly by patients.[4] In 2004, the total cost increased to over $18 billion, with private and public insurance plans still covering about 34% and 44% of the cost respectively, and patients paying the remainder (close to $4 billion) out of pocket.[2] In 2002, in the United Kingdom, prescription drugs accounted for £5.5 billion of primary care spending, a £520 million increase over the previous year.[5]

Several countries are aggressively pursuing a move toward making more prescription drugs available OTC. In the United Kingdom, the National Health Service Plan, published in July 2000, committed the UK government to introduce a wider range of OTC medicines. This plan provided the impetus for the then Medicines Control Agency (now the Medicines and Healthcare products Regulatory Agency [MHRA]) to undertake a strategic review of prescription drugs for potential reclassification to OTC status in that country. The list of drugs to be reviewed included many indicated for the management of chronic diseases.[6] Candidate classes of drugs being proposed for reclassification included proton pump inhibitors, β-blockers, diuretics, calcium-channel blockers, angiotensin-converting-enzyme (ACE) inhibitors, HMG–coenzyme A (CoA) reductase inhibitors, inhaled corticosteroids, short- and long-acting β_2-adrenergic agonists, bisphosphonates and oral contraceptives; these drugs represent only a partial list of over 100 individual drugs.[7]

For many of these drugs, the MHRA has proposed that although the drugs would not be available strictly OTC — a physician would still be required to make the initial diagnosis and provide the first prescription — the ongoing drug therapy could be managed by the patient in consultation with another health care professional. The first of the proposed drugs to receive approval for OTC sale was simvastatin, which became available to the UK public without a prescription in July 2004. In Ontario, 8 prescription drugs (2 HMG–CoA reductase inhibitors, 1 proton pump inhibitor, 2 ACE inhibitors, 2 calcium-channel blockers and 1 corticosteroid) included on the MHRA list of candidates for reclassification accounted for $540 million (27%) of the total Ontario Drug Benefit Plan budget in 2001–02.[8] Similarly, 49 of the top 100 drugs covered by Pharmacare in British Columbia are on the MHRA list and accounted for $266 million (44%) of the $603 million of Pharmacare's drug expenditures (Andrew Shaw, Information Analyst, Knowledge Management and Technology Division, BC Ministry of Health: personal communication, 2003).

The extent of these expenditures and how they are apportioned becomes increasingly important when one considers the recent proposal for a national pharmacare program. Based on current drug scheduling, full coverage

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could result in an $8.1 billion increase in public spending on prescription drugs.[9] Within the drug reimbursement policies of most provincial drug plans and private insurance plans, the result of a change in the status of a substantial number of prescription drugs to OTC could mean that a considerable portion of drug costs would be passed on to patients, with reduced costs for private and public insurers. Conversely, because patients with drug plans are more likely to be prescribed a medication that is covered by their plan, the granting of OTC status could promote changes in therapy from older, less expensive drugs that have been granted OTC status (and subsequently become uninsured) to newer, more costly drugs that are available by prescription only. Thus, rather than a net saving, the result could be a net increase in costs to third-party payers.

The potential positive implications for provincial governments and private insurers are not without potential negative implications for both payers and patients. Because OTC drugs are not covered by most public and private drug plans, a greater financial burden could be shifted onto the patient. Increases in out-of-pocket treatment expenses will invariably result in more patients choosing not to treat, consequentially increasing the prevalence of undertreated chronic diseases (e.g., hypertension).[10–12] Furthermore, increasing the patient's responsibility in deciding whether to initiate or continue treatment will make patients' nonmedical characteristics (e.g., expected quality of life and health expectations, level of education, and health insurance coverage) much more salient in the decision-making process.[13] Because these factors correlate with socioeconomic class, a shift in responsibility for personal health (financial and otherwise) could result in further social inequities in health outcomes.[14]

Patients' perceptions may also influence the societal acceptance of a paradigm shift in chronic care. Traditionally, the physician has been the gatekeeper to the health care system, with almost exclusive control over access to most health care services, including drug therapy for chronic diseases. Removing the prescription requirement would eliminate the requirement of a physician visit, at least after the initial diagnosis and receipt of the first prescription. Because a visit to a physician and the ensuing receipt of a prescription can be psychologically reinforcing and potentially validate the patient's need for therapy, shifting the prescribing or the provision of medications for chronic diseases to other health care professionals may negatively affect the patient's perception of the need for therapy or of the effectiveness of a drug therapy. A Canadian study that evaluated the feasibility of pharmacist-directed strategies for drug therapy management found that both physicians and patients felt that the physician should be in primary control of drug therapy decisions.[15] Thus, although pharmacists and other allied health care providers may be capable of practising as primary care providers, the public's expectations of the pharmacist's role may not be consistent with a new, primary care role, and therefore there may be some reluctance to transferring the responsibility of chronic care from a physician to another health care professionals.

Although the movement to deregulate more prescription drugs to OTC status may result in an economic loss for pharmacists, owing to fewer prescriptions, it also creates a potential opportunity for gain by significantly broadening the scope of practice from primarily a dispensing role to a clinical, evaluative and consultative role, for which professional services could be reimbursed. This also raises the question of whether pharmacists should be, and need to be, granted prescribing authority, as is being pursued by the Alberta College of Pharmacists, or whether prescription drugs should merely be deregulated to nonprescription, behind-the-counter (no public access) status (e.g., emergency contraception), for which an interaction with a pharmacist is required. Although some previous nonscientific evaluations of pharmacists' involvement or intervention in the provision of nonprescription drugs have not been favourable,[16–18] the recently published experience of pharmacists prescribing emergency contraception[1] provides evidence of the feasibility and effectiveness of such a program with appropriate planning, infrastructure and remuneration.

Not requiring a physician visit on a continuing basis also has other economic implications. Although the shifting of some of the responsibilities for the care of chronic diseases from physicians to other health care providers may be a logical step in maintaining an acceptable level of health care given the current physician shortage, it will also probably increase the overall complexity of the conditions physicians will see.[19] More complex cases require more time, which will necessitate a concomitant change in how professional services are remunerated. In fact, the provision of professional services by other health care professionals will require that the current fee schedules for all health care providers be reviewed and revised, as has already been done for pharmacists in some jurisdictions.

The movement to deregulate more prescription drugs to OTC status for the management of chronic diseases may be seen as a logical step toward meeting the demands of today's health care environment and promoting the rights and health of patients. However, the overall objective of such a change must be improved health care provision and patient outcomes.

Given the sweeping changes that have already occurred and those being proposed in other jurisdictions in line with the Romanow report[20] as well as the need for further budget constraints, similar changes for Canada will be an inevitable consideration. Although in the short term physicians will probably maintain a primary role in choosing drug therapies regardless of the status of the drug, the roles and responsibilities of all health care providers will probably undergo further changes over the long term. The changes seen in making emergency contraception available OTC are merely the tip of the iceberg.[21] Now is the time to

consult with stakeholders, explicitly examine the potential benefits and risks, and begin the debate with the primary objective of developing a self-care policy specific to Canada to facilitate the planning that will be required, rather than blindly creating change that may not be warranted, required or desired.

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Clinical trial registration

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