OFF THE PRESCRIPTION PAD AND OVER THE COUNTER: THE TREND TOWARD DRUG DEREGULATION GROWS

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In Brief • En bref

In the future, regulatory agencies may authorize the switch of more drugs from prescription-only to over-the-counter status. This could have the double effect of reducing the number of doctor visits and cutting drug costs. Although some physicians worry about the escape of reasonably potent drugs from medical surveillance, pharmacists are assuming a more significant counselling and medication-tracking role. This article looks at the negative and positive sides of drug deregulation from the perspectives of the physician, pharmacist and patient.

Des organismes de réglementation pourraient autoriser plus souvent le remplacement de médicaments prescrits par des médicaments en vente libre. Ce remplacement pourrait avoir le double effet de réduire les visites chez les médecins et d'éviter les coûts des médicaments prescrits. Alors que certains médecins craignent que des médicaments assez puissants n'échappent à la surveillance médicale, les pharmaciens jouent un rôle plus important de conseil et de suivi des médicaments. Dans cet article, on aborde les avantages et les préoccupations qui ont trait à la déréglementation des médicaments des points de vue du médecin, du pharmacien et du patient.

The volume of over-the-counter drugs sales is huge, which is not surprising given that some 30% of North Americans will use some type of nonprescription medicine in the next 2 days. If these medicines were available only by prescription, the cost to the health care system would be intolerable.

Regulatory agencies around the world, bent on reducing health care costs, are trying to ensure that the opposite happens. The idea is simple: authorizing switches from prescription-only to over-the-counter (OTC) status eliminates doctor visits. An economist estimated that Americans saved more than $1 billion from 1980 to 1982 simply because hydrocortisone ointment was switched to nonprescription status.

The pressure to switch comes from large pharmaceutical companies. Despite the disadvantages — smaller profit margins and higher promotion costs for OTC drugs — drug marketers know how to sell to the public and hunger for volume sales, and this obviously increases overall drug costs.

Gerald McDole, president of Astra Pharma Inc., paints the commercial picture in broad strokes: "If you have a product you are promoting through a nonprescription status, you have a much better chance of maintaining customer loyalty. Customers making a decision are influenced by whatever influences [you set up]. Patients at the moment are still relying on what their doctors are recommending."

Physicians are already worrying about the escape of reasonably potent drugs like ibuprofen from medical surveillance. In medical school they are imprinted with a distrust of self-medication, and recite the hazards of self-diagnosis and self-treatment: misdiagnosis, overdosing, inappropriate treatment, masking of serious symptoms, drug interactions, delay of definitive diagnosis and habituation.

However, those responsible for making regulatory decisions don't seem as obsessed with the risks. Health Canada's Jan Pound, manager of the Drug Regulatory Affairs Program at the Drugs Directorate, Health Protection Branch (HPB), stresses the great body of experience that accumulates with a drug before it receives OTC status. "After a certain length of time there is a track record for the product and a greater assessment of safety is possible. The manufacturers have a body of data that will enable [us and] them to assess whether or not it is appropriate to let it go to a nonprescription status."

The process of approving a switch, administered by the Bureau of Nonprescription Drugs, is detailed: "They have a clinical division — the product-evaluation division — which looks at the safety and efficacy picture. There is also a pharmaceutical-chemistry review area in case there is any change in the manufacturing data and they have a product-regulation division where people look at the con-

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sumer labelling that has been proposed for a drug."

Although there may not be enough information on how people use OTC medications, there is some support for the populist view that most people are careful about their use of pills and capsules purchased at a drugstore. Ten years ago a survey found that only a fraction of medical problems were brought to the attention of physicians in the US. In 35% of cases, respondents used OTC drugs to deal with a problem on their own; 90% of them stopped taking the drugs when the problem disappeared, 4% stopped taking the medicine because of some concern, and 92% reported satisfaction with the result (Vickery DM. A medical perspective. *Drug Info J* 1985; 19:155–158). Since then, everyone has agreed that patients are becoming more sophisticated as they demand more control over their health care.

Elie Betito, director of public and government affairs for Apotex, a generic drug firm, reiterates the conventional wisdom: "I think what we really have to do is look at the needs of the consumers in the system, and I think the trend is to give back a little of the decision making [to them]."

Representatives of the medical profession are only a little more reserved on this point. Dr. Mark Berner, assistant professor of family medicine at McGill University and a member of the CMA's Subcommittee on Drugs and Therapeutics, hopes that "if we have an intelligent population that can diagnose conditions for which these drugs are available, can read and understand the warnings on the label and will not use [the drugs] longer than they are supposed to, then in fact [the trend] might be a good thing."

Even if drugs that are moved to OTC status are relatively safe, patients have to diagnose accurately and monitor the progress of treatment for conditions that were once considered serious enough to warrant medical attention. Here the pharmacist often steps into the physician's shoes, quizzing potential customers about symptoms, making recommendations and even carrying out routine follow-up telephone calls. Contact with the pharmacist is required for new OTC drugs if the legislation that delists them requires "no public access" or pharmacist-monitored status, since in these cases the drugs are kept behind the pharmacy counter. Leroy Fevang, executive director of the Canadian Pharmaceutical Association, which represents more than 10 000 pharmacists, sees this as part of a trend in which pharmacists become more active partners on the health care team. He characterizes the pharmacist's role as "a trend we see in health care to move the decision-making process further down the pipeline to other levels that are less costly."

The cost effectiveness of the pharmacist-monitored drug category, and even the readiness of most pharmacists to carry out this role, remain to be proven. Dr. Anne Carter, the CMA's associate director of health care and promotion and staff liaison for the Subcommittee on Drugs and Therapeutics, says "we are willing to give it a chance to prove itself. We don't feel there is any evidence that proves a pharmacist-monitored category is cost effective. [But] we are willing to accept the possibility that it might be."

Berner also concedes that the pharmacist-controlled schedule has potential benefits, but is concerned that private insurance companies and governments may not pay for needed drugs that gain this status. And he worries that once pharmacists are in the position of being able to steer a client toward a specific drug, potential profits could cause them to suggest a more expensive or extensive treatment.

Dr. George Carruthers, professor and head of the Department of Medicine at Dalhousie University and a member of the Subcommittee on Drugs and Therapeutics, goes further. "Pharmacists gain rights, but they also gain important responsibilities. . . . They must not send everyone to the doctor on a knee jerk — they have to develop the skill to sift between the people who are just coming back because they have a little more heartburn, and the person who [continues] to have significant pain or discomfort or is showing evidence of weight loss, which may indicate an underlying [pathology], cancer, or something [else]."

Carruthers' message for the public is that even though a drug may now be available on an OTC basis, it can't be taken as casually as other nonprescription drugs that have been available for years. "This is not milk of magnesia. Just because you can get a nonsteroidal [product] over the counter doesn't make it any safer than when you had to get it through a prescription. You still run the risk of getting ulcers or kidney problems."

David Windross, a pharmacist who is director of government and professional affairs at Novopharm, suggests that pharmacists could be reimbursed for giving information so they do not have to rely solely on sales for profits. "I think that as we go more and more to nonprescription drugs we have to start moving toward a fee-schedule model for pharmacists, one that recognizes what pharmacists can do and how they are trained."

In Canada and most developed countries, a "good" switch to OTC status involves continued collaboration between the manufacturer and government regulatory agency. Decisions are usually handed down faster than in the case of new drug applications. Mary Carman, director of the Bureau of Nonprescription Drugs, says the rejection rate is about 10%; most companies that are discouraged by HPB staff in their initial approaches to the bureau do not file formal applications. In its initial and middle stages the evaluation process is secretive: the names of the drugs coming down the pipeline are held confidential for proprietary reasons, as they would be for a new product application. In Canada, the HPB releases the information about the proposed switch when it determines that the application is ready for public debate. It is listed in the Canada Gazette and the notice is sent to groups such as the Consumers' Association of Canada and the CMA.

The CMA had adequate opportu-

nity to discuss one switch, the delisting of the antifungal compounds clotrimazole, miconazole and tioconazole. Carter says the CMA subcommittee was satisfied with the inclusion of the antifungal products in nonprescription topical creams, shampoos and vaginal preparations. However, it says the use of vaginal and topical antifungal products should be monitored by pharmacists and counselling should occur with every purchase. The subcommittee also thinks pharmacists should recommend that a patient consult a physician before first use of the product and after a significant number of uses.

In some provinces vaginal antifungal products have to be monitored by pharmacists, but it remains to be seen whether women will be willing to discuss and receive advice of such a personal nature in the nonconfidential confines of a drugstore.

In a letter to Health Canada, Carter noted that "overall health care costs may actually increase as a result of this regulatory change if there is an increase in the proportion of patients who self-treat inappropriately with antifungals and subsequently require a physician consultation and the provision of additional appropriate therapy."

The challenge created by diverse regulations has led to a thrust toward drug harmonization. Berner represents the CMA on the Canadian Drug Advisory Committee, the national group charged with recommending uniform prescription and nonprescription schedules among all provinces and territories. The group is considering recognizing a hierarchy: prescription medications would be on top, followed by pharmacist-monitored drugs, pharmacy-only drugs and, finally, unrestricted medications.

Carter dismisses the pharmacy-only category. "It increases cost and decreases patient access, but it doesn't add any value. What does it matter if you can walk in, pick [a drug] off the drugstore shelf, walk over to a cash counter, pay some clerk and walk out again? Why couldn't you do that in a convenience store?"

Dr. Jacques Messier, vice-president of regulatory affairs for Novopharm, disagrees: "There is a difference between putting [a drug] on the counter beside some Certs, and in having it where a professional still does have an interface with the consumer."

Carruthers thinks pharmacy-restricted sales offer the consumer "an environment where patients can ask for and receive information about the medication if they want it." In many instances, the pharmacist may also be familiar with the patient's medical history and prescriptions, he adds.

Bringing the pharmacist and medical team closer always seems to appear as the solution to concerns about the switch to OTC drugs. "One of things we feel would contribute to our support of [the pharmacist-monitored category] would be that pharmacists be required to record all drugs dispensed under the category," says Carter. They would add this information to the records they already keep for prescription drugs. It is often difficult for physicians to ascertain exactly which products patients have purchased and are using. "If the doctor could phone a pharmacist and find out it might be pretty useful at times," adds Carter.

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Practicing physicians may be troubled by the expanding role of pharmacists. Carruthers thinks some doctors will fear a loss of power, worrying that pharmacists will "take their patients off the streets." He does not see this as a win-win situation, noting that "as some people become empowered, then by definition others lose power."

Nevertheless, he finds the advantages of increased pharmacist participation appealing: "There are some pharmacists who have very aggressively promoted their role in the new order, who would check your blood pressure when you come into the pharmacy. I have no concern with this. . . . If the blood pressure is fine, that is new information that will be useful, and if the blood pressure is too high, then I would like the patient to be advised to see me sooner than the 6-months-away appointment that is currently booked."

Most medical situations are far more complex than the diagnosis of hypertension, however — there is also a potential epidemiologic problem. When the prescription (and perhaps the patient) escape the physician's scrutiny, the only news doctors will hear about drugs added to the OTC list will be bad: patients experiencing side effects and victims of therapeutic misadventures will report in, but the physician will have no sense of the number of patients using the preparation safely and benefiting from it. This could lead to an over-reporting of adverse effects.

Canadian physicians will likely be bothered by more than the lack of information on the therapeutic results of switches to the OTC category — the enthusiastic commercialization of drugs also will gall. Whatever physicians may feel about the way drugs are advertised in medical journals, many will get a jolt when they see a former prescription medication advertised during a sitcom.

As pharmaceutical rules change, Canada's pharmacists and their professional organizations will face a major challenge in establishing professional information services that will benefit the patient and respect the physician–patient relationship, and at the same time sell pharmaceutical products through acceptable marketing practices. ■