Eliminating barriers to DTC advertising for OTCs and natural health products

Health Canada has proposed eliminating statutory barriers against direct-to-consumer (DTC) advertising of the purported health benefits from using natural health products (NHPs) and non-prescription drugs to treat serious diseases like cancer.

Proponents of the change claim it will have little impact other than an occasional advertisement for a very limited number of products, like the use of sunscreens to prevent skin cancer. But critics say it will launch a wave of misleading advertisements that will prey on the desperation of patients.

At issue are regulatory amendments published in *Canada Gazette* last November that will allow manufacturers of NHPs and over-the-counter drugs (OTCs) to make marketing claims of relief in 40 designated diseases and health conditions.

Since 1934, under regulations designed to prevent fraud, such claims have been prohibited under Schedule A of the Food and Drugs Act.

But Health Canada is proposing to allow health relief claims if they are consistent with the product monograph. Therein, however, lies the rub. The new licensing regime governing NHPs and non-prescription drugs allows manufacturers to make claims of therapeutic benefit based on "traditional" or extended use, which critics say results in products being approved even though their therapeutic efficacy hasn't been scientifically established (*CMAJ* 2005;172[8]:983).

Health Canada is conducting a second round of consultations. The deadline for submissions is May 31.

Many stakeholders believe the regulations "need to be modernized, one, to reflect scientific and medical advances, and two, to reflect the current health care context, which includes the prescription drug regime, pre-market review, universal health care, and the desire of the Canadian public to make decisions about their health care," says Health Canada spokesperson Christopher Williams.

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Echinacea, indiginous to North America, is a commonly used natural health product.

That rationale mystifies critics, like Dr. Lloyd Oppel, Vancouver-based emergency physician and UBC professor of statistics and experimental design, who argue the change will yield no public health benefits and may even lead to dire forms of mistreatment.

"There are a number of risks," Oppel says. "One, it may misinform people about matters to do with their health. ... It may cause people to believe they can treat these illnesses by themselves and cause delays in treatment. Or it may give people the impression the purveyors of these remedies are bonafide health professionals. In a sense, it may give credit where it's not due and it may divert from proper care and delay diagnosis."

Patients suffering from serious Schedule A diseases are "much more vulnerable" and potential harm through mistreatment is much greater, adds Barbara Mintzes, faculty associate with UBC's Centre for Health Services and Policy Research. "One of the risks would have to do with people substituting treatments for which there's less evidence of effectiveness for others, in which there's more evidence."

If patients aren't informed that the basis of a health claim is something as nebulous as traditional use, the potential for misleading advertising is even greater, Mintzes adds. "And what about a situation where you have a remedy that actually has been tried in a clinical trial and been found to be ineffective? As long as it was approved for that indication, it could still be advertised for it."

Consumer surveys indicate the mere act of licensing a product legitimizes it as a therapy, even though the scientific evidence of its efficacy or safety hasn't been properly established, argues Bill Jeffery, national co-ordinator of the Canadian Centre for Science in the Public Interest. "In the case of NHPs, the market authorization is often granted on the basis of skimpy to no evidence. . . . In some cases, it really amounts to no more than cataloguing medical lore." But Non-prescription Drug Manufacturers' Association President David Skinner argues it is unfair to preclude manufacturers from advertising information that's allowed on product labels.

The NHPs and OTCs met a "scientific test" when licensed by Health Canada, and manufacturers should be able to communicate that to consumers, Skinner says. "If you can provide the evidence that supports such a claim in a product that's appropriate for self-care, you should be allowed to do so."

Skinner also argues there's a public health benefit to such advertising. "If we are preventing people from being able to have access to products with labels that can describe what the product can be usefully used for, we're not doing the health system any favours whatsoever and it defies simple regulatory logic, let alone good science."

Skinner projects such advertising will be more in the vein of a trickle than a flood. "But if there are more products that are helping consumers to help themselves and keep them out of hospitals and so on, good."

Although Skinner dismisses the concern as unwarranted, Mintzes believes oversight of NHP and OTC advertising will be inadequate. She says a Health Canada review of non-Schedule A advertising of NHPs indicated that a majority of print ads and roughly one-third of broadcast ads presented inaccurate information.

But Health Canada says revised advertising guidelines (now in consultation phase) will establish that marketing claims must be consistent with evidence presented during a product's licensing stage.

"It has to be based on the Health Canada market authorization," says Ann Sztuke-Fournier, manager of Marketed Health Products Directorate's regulatory advertising and risk communications section.

"That's a roof built on a house of cards," Jeffery counters. "The adequacy of evidence accepted by Health Canada to approve health claims is so low the guidelines are doomed to fail public health."

Oversight of NHP and OTC advertising will continue to be vested with the not-for-profit industry body, Advertising Standards Canada, which will evaluate all ads before they can be shown to consumers. — Wayne Kondro, Ottawa

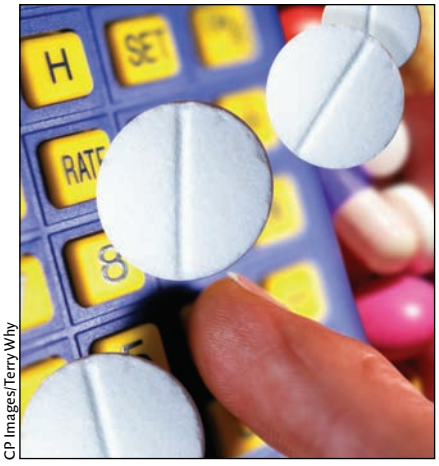
DOI:10.1503/cmaj.060506

Monitoring the price of new drugs

The tribunal in charge of regulating drug prices in Canada should more closely scrutinize the price of new drugs, rather than the annual price increases posted by manufacturers on already-marketed drugs.

That message was delivered to the Patented Medicines Prices Review Board in response to a discussion paper on drug price increases released by the board in March 2005.

"They said we had the wrong description of the problem," explained PMPRB executive director Barbara Ouellet. As result, the board has produced a new discussion paper, scheduled to be posted on its Web site this spring.



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Pricing of generic drugs in Canada under review.

Last year's discussion paper was prompted by concern that in 2004 prices increased for 35% of all patented drugs, an unusually high percentage.

Manufacturers have the option of increasing prices according to a formula based on the Consumer Price Index, and need only inform the board at their next reporting period, which could be up to a year later. The discussion paper outlined alternative approaches, such as a requirement that companies apply in advance for and justify any price increases.

However respondents identified the introductory price of drugs as a key problem. A major driver behind increased retail spending on drugs is the substitution of newer, more expensive medications for older, less expensive ones, Dr. Joel Lexchin, associate professor of health policy at York University, noted in a submission to the board.

This substitution is achieved in large part by intense promotional activities, he wrote.

Insurer Green Shield Canada argued that the PMPRB should take into account spending on drug promotion (marketing and sales) in its initial pricing reviews, as well as spending on comparative trials that demonstrate the value of a drug compared to others in the same therapeutic class. (The board is now limited, under the Patent Act, in the factors it can consider in reviewing price.)

Manufacturers, on the other hand, have argued that because the board only recognizes 3 categories of drugs, which have different pricing considerations, companies are limited in their ability to charge more for improvements made to existing drugs. (The 3 categories are new dosages of existing drugs, "me too" drugs that offer little or moderate improvement over an existing drug, and breakthrough drugs.)

Green Shield also pointed to problems created by tiered pricing and a consequent lack of stability and transparency in pharmaceutical pricing. For example, a drug listed for $1.90 on the Ontario Drug Benefit formulary in 2004 was sold to the Department of National Defence for 45 cents, it noted. As well, bulk buyers are sometimes offered rebates, and list prices are often higher than prices actually charged to larger pharmacy groups, the insurer noted.

Finally, some stakeholders argued that at the time of pricing of new patented drugs, the board should consider whether members of Rx&D, the association representing most trade name pharmaceutical companies in Canada, were meeting the commitment they made when they were granted patent extension to maintain a 10% research and development to sales ratio in Canada. In 2004, this ratio dropped to 8.3% for all patentees, the lowest ratio seen since 1989.

Meanwhile, this June the board will be posting the first quarterly report on pricing of generic drugs in Canada, Ouellet said.