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Direct-to-consumer prescription drug ads getting bolder

Canada's pharmaceutical companies appear to be pushing the envelope in a bid to pitch their wares directly to Canadian consumers.

Officially, Canada's Food and Drug Act prohibits this direct-to-consumer advertising (DTCA). Although a 1996 Health Canada policy paper defines DTCA as an activity "with the primary aim of stimulating product sales," advertisements for products such as birth-control pills and erectile-dysfunction drugs now appear regularly in Canadian magazines and on the country's TV screens. They join the cross-border barrage of ads from the US, where DTCA is legal.

Critics aren't amused by the move toward made-in-Canada ads. "I think what's happened, for reasons that aren't entirely clear, is that Health Canada has reinterpreted the law," says Joel Lexchin, a Toronto doctor who comments frequently on the pharmaceutical industry. "But in a strict reading of the law, these advertisements are illegal."

Existing legislation prohibits DTCA involving prescription drugs because these drugs cannot be compared with other consumer items, explains Ross Duncan, Health Canada's policy adviser on DTCA. But most of the ads currently appearing on TV, at movie theatres and in magazines is legal, he says.

A 1978 amendment, designed to allow pharmacists to post comparative prices, allows DTCA as long as "the person shall not make any representation other than with respect to the brand name, proper name, price and quantity of the drug."

Duncan says this means that providing "information" is not illegal, and Health Canada has taken the position that "help-seeking" ads — those that describe a medical condition such as erectile dysfunction and then direct consumers to a doctor, telephone number or Web site — are legal. More controversial are "reminder" or "branded" advertisements, which mention the brand name of the drug but don't say what condition it treats. While critics say they are clearly prohibited advertising, Health Canada maintains that they are legal.

Indeed, Health Canada says the only real problem is mentioning the brand name and the therapeutic use of a drug in the same advertisement. Advertisers have tried to push the envelope, and federal officials did cry foul when Wyeth-Ayerst Canada aired branded television ads for a birth-control pill, Alesse, and then, a few weeks later, aired unbranded ads with the same actors. But it took Health Canada 6 months to inform the company that the campaign "is considered to contravene the Food and Drug Regulations." No penalties were suggested in the letter, but there was a friendly warning to take this decision in account "when developing future advertisements." Wyeth-Ayerst subsequently opted to air only advertisements that did not name the product.

Health Canada wrote a stronger letter to Glaxo Wellcome (now GlaxoSmithKline) when advertisements for bupropion (Zyban) ran on TV just after New Year's 2000. "These commercials violate section c.01.044(1) of the regulations. We ask you to immediately suspend broadcast of these commercials until a full review of this activity can be completed," stated the letter, sent 7 weeks after the first ad was aired.

A defiant GlaxoSmithKline responded that the advertising had in fact been informational programming by CTV — an antismoking vignette about a successful smoking-cessation experience — followed by a "sponsorship statement." A slightly revised version of the same advertisement/vignette aired on CTV in January 2001. This prompted another Health Canada investigation, but as of mid-May officials would say only that the investigation is "ongoing."

Advertising prescription drugs directly to consumers "gets in the way of treatment," says Saskatoon urologist Peter Barrett, the CMA's past president. Drug companies should show doctors why their products are useful, he said in an interview, but pitching drugs directly to patients puts an extra strain on doctors, who must take time to explain why the advertised drugs may be inappropriate.

Meanwhile, the drug and advertising industries are lobbying hard to loosen existing restrictions on DTCA, a move that the CMA opposes. The Food and Drug Act is being opened up for "legislative renewal," and new draft legislation is expected soon. DTCA is one of the most controversial areas, Duncan says, and one of the few points that has been agreed upon is that there be mandatory pre-clearance of such ads.

As yet there is no official body vetting DTCA before it appears, since such advertising, at least officially, does not exist. — *Ann Silversides*, Toronto

Drug advisory: famotidine (Pepcid)

The US Food and Drug Administration and Health Canada have issued a warning to change the dose and dosing intervals of famotidine in patients with severe **or moderate** renal failure. Famotidine, a histamine H_2 receptor antagonist used mainly to treat peptic ulcer disease, is excreted almost exclusively by the kidneys. On Mar. 23, 2001, the FDA issued a warning to physicians treating patients with renal failure, including moderate renal failure (creatinine clearance < 50 mL/minute), to use the drug with care. Health Canada issued a similar warning July 10, 2001. Adverse effects to the central nervous system include psychiatric disturbances, insomnia, somnolence, anxiety and depression, among others. For other adverse effects, consult the product monograph. Famotidine is marketed in Canada under the following names: Alti-famotidine, Apo-famotidine, Gen-famotidine, Riva-famotidine, Pepcid, Novo-famotidine, Nu-famotidine, Penta-famotidine, Famotidine and Rhoxal-famotidine.

What to do

The dose should be reduced by half or the dosing interval extended to 36 or 48 hours in patients with moderate or severe renal insufficiency. Previous recommendations were to reduce the dose only for severe renal insufficiency (creatinine clearance < 10 mL/minute). Renal function should be monitored in elderly patients using this drug. — *CMAJ*