Health Canada targets postmarket surveillance of drugs

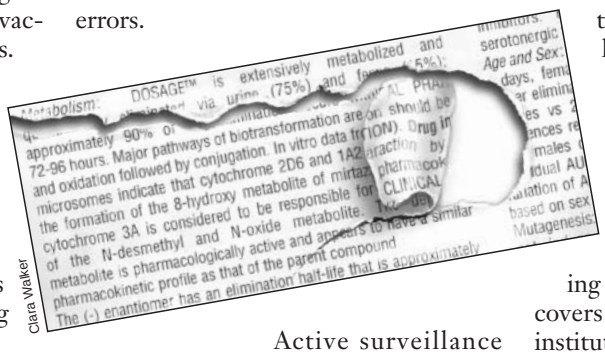
After years of complaints about inconsistent approaches to follow-up and surveillance once a drug has been marketed, Health Canada has created a Marketed Health Products Directorate (MHPD) to provide postmarket monitoring of products ranging from drugs and vaccines to foods that make health claims.

Proponents say the MHPD will bring all surveillance under one roof, allowing for a consistent approach and an expanded mandate. The ultimate goal is to make it easier to report adverse events and identify trends. "People here are very passionate about this," says Dr. Christopher Turner, the acting director general.

But Dr. Michelle Brill-Edwards, formerly the senior physician responsible for drug approvals at Health Canada, says the MHPD is merely a reshuffling of the deck, and the regulatory function — the power to withdraw approval or ask drug companies to issue warning letters to doctors — stays with the pertinent directorate. "There's no power here," she says.

However, it will offer something new because it has the money to build programs and hire 50 staff, with $6 million having been added to the existing $4.5-million set aside for postmarket surveillance. "The difficulty before was the relatively limited resources," says Turner.

The new directorate also has a broad mandate to incorporate postmarket surveillance across 3 Health Canada branches, and it takes on 2 additional roles — active surveillance and reducing the number of medication errors.



Clara Walker

Active surveillance goes beyond reporting adverse events to studying the postmarket effectiveness of health products. Many of these initiatives will involve collaboration with existing programs. For example, a pilot project involving reporting of severe adverse reactions in pediatric patients with HIV/AIDS is now under way. The MHPD is also considering using pilot sentinel sites to assess certain products.

Turner says the key to improved surveillance is a simpler reporting system. A pilot project will study the use of handheld computers to deliver drug advisories, and attempts are being made to produce more user-friendly information. Turner acknowledges that the usefulness of material being presented today is "extremely variable." A Therapeutic Products Directorate project, in which the MHPD is involved, aims to provide product monographs that everyone can use. "We're promoting conditions that allow Canadians to make healthy, informed choices," says Turner. He says this represents a "culture shift" because the emphasis used to be solely on health care professionals.

The MHPD will also help the Canadian Coalition on Medication Incident Reporting and Prevention. Medication error covers a lot of ground, from systemic, institutional problems to professionals' mistakes, but Health Canada's response is limited to areas such as confusing drug packaging and look-alike, sound-alike drug names that might cause prescribing mistakes. The goal is to bring all potential causes of error under one umbrella.

The new federal initiatives aren't enough for Terrence Young, whose 15-year-old daughter, Vanessa, died in 2000 after being prescribed cisapride (see *CMAJ* 2001;164[9]:1269). He says the new directorate is a far cry from the jury recommendations that emerged from the inquest into her death: 14 of them were aimed at Health Canada, and 1 called for mandatory reporting of adverse events. — *Barbara Sibbald*, CMAJ

Town ignores MD's advice, rejects chlorinated water

Erickson, BC, has become the first municipality in Canada to fight successfully to keep chlorine out of its water supply. The town of 2000 in the East Kootenays had battled bureaucrats for 4 years before residents voted against chlorine in a January referendum. This paved the way for an alternative ultraviolet radiation water-treatment system.

Since 1930, Erickson residents have used untreated water from a local creek. In 1992, new provincial regulations required municipalities to disinfect their water. The town was also issued a boil-water advisory. About 300 of BC's 3500 water-supply systems are on permanent boil-water advisories; the average sewage and water-filtration system is 37 years old. By 1998, Erickson still hadn't started treating its water, and 4 years of confrontations with water-supply regulators began.

Elvin Masuch, chair of the Erickson Improvement District and a 65-year resident of the town, says opposition to chlorine is based on health risks, which he says are "well documented."

Dr. Andrew Larder, the community's medical health officer at the time, disagrees. He says the risks posed by chlorinated water are "negligible because the water has very low organic levels. I truly believe that there has been an underestimation of the risks associated with drinking untreated water and an overestimation of the risks associated with drinking chlorinated water."

Don Corrigal, the manager of health protection for the East Kootenay region, says *Cryptosporidium* poses the main risk in Erickson. He says the primary disinfection in the town will be via microfiltration and ultraviolet light radiation. Instead of chlorine, the secondary disinfection system will employ a double barrier to prevent backflow from agricultural and commercial-water connections. A chlorine injector will be available for emergencies. The secondary system adds $1 million to the system's $9-million cost, which will be paid through an $85 surcharge on municipal tax bills. — *Heather Kent*, Vancouver