PHARMACEUTICAL INDUSTRY

Collaboration with the FDA promising but problematic

The recent Canada–US agreement to share pharmaceutical regulatory information may be a sensible way to pool resources but has some potential problems, says an expert in pharmacology.

Health Canada and the US Food and Drug Administration (FDA) signed a Memorandum of Understanding for Closer Collaboration in November that allows them to share pre- and postmarket information, including evaluations of efficacy and data on adverse reactions. The aim, according to a Health Canada statement, is to develop a more efficient therapeutic evaluation process and more rapid access to new therapies to "enhance [Health Canda's] regulatory performance."

Dr. Jim Wright, a specialist in pharmacology at the University of British Columbia, says that given Canada's relatively small population, it makes sense to share information — particularly evidence of adverse events — with other countries. "We're all trying to answer the same questions, so why not share the expertise?"

But Wright is concerned about the potential implications of the FDA's ties to the pharmaceutical industry. "Their whole review process is funded by the industry. If we're going to use [that data] then I have concerns."

However, if collaboration gives Canada more clout in requiring industry to do "proper postmarketing randomized controlled trials, I'd be in favour," he said. (See also *CMAJ* 2003; 169[11]:1170-1.)

In an interview with *CMAJ*, the director general of Health Canada's Therapeutic Products Directorate declined to elaborate on what collaboration would ultimately mean. However, Dr. Robert Peterson emphasized that a more cooperative regulatory environment would enhance and hasten the regulatory process "without compromising issues associated with safety."

The signing follows an infusion of $190 million into the directorate, to accelerate reforms. — *Louise Gagnon*, Ottawa, and *Barbara Sibbald*, CMAJ

ADDICTION MEDICINE

First injection site almost at capacity

Vancouver's much-anticipated safe injection site (SIS), the first in North America, was nearly at full capacity less than 3 months after opening Sept. 15. Site staff are supervising an average of 450 injections daily; full capacity is 600 visits (see *CMAJ* 2003; 169[8]:759-63). There are an estimated 4000 injection drug users in the city's Downtown Eastside.

Mark Townsend of the Portland Hotel Society, which runs the SIS with the Vancouver Coastal Health Authority, says initial fears that patrolling police officers and security cameras would deter drug users have proved unfounded. He also attributes the high usage to the experienced staff, extensive street-level and word-of-mouth publicity prior to the opening.

So far, 25 users have experienced adverse reactions on site and required assistance. At least 33 users have been referred to detoxification services. Nurses are also carrying out a lot of wound and other basic medical care.

Townsend says he hopes that the SIS's 3-year research project will answer questions about the site's early success. Meanwhile, in the short term, he would like to see extended hours, a second location and more detoxification facilities.— *Heather Kent*, Vancouver

Canpress

About 90% of injection drug users are still on the streets.