Drug approvals taking too long?

Health Canada, which takes an average of 2 years to review a licence application for a new drug, has "one of the worse performances in new medication approvals in developed countries," says Jacques Lefebvre, spokesperson for Canada's brand-name pharmaceutical lobby group, Rx&D.

However, the head of the department's Therapeutic Products Directorate (TPD) says the directorate is being unfairly maligned.

Dr. Robert Peterson argues that the TPD's results compare favourably with those from the US when it comes to issuing a notice of compliance (NOC) for new drugs that actually "fill a need within our health care system."

He says these "priority-review" drugs, aimed at illnesses for which other therapies are not available, are reviewed within a target range of about 200 days "with increasing frequency." A 355-day target for "nonpriority" drugs usually isn't met, but he says these drugs are often "the 10th, 12th or 20th member of a class for which there already are therapeutic products available on the market."

The US Food and Drug Administration (FDA) reports that 136 new medical products were approved last year, including 66 new drugs. Of the 66 new drugs, 10 "priority" ones were approved within a median time of 180 days. The remaining 56 were approved within 420 days.

However, other critics say Canada's performance is deteriorating. Pat Kelly, co-chair of the recent Best Medicines Second National Summit on Reform of the Drug Review System, says it took an average of 743 days to review a drug in 2000, or "152 days longer than in 1999."

Health Canada estimates that it approved 53 new drug and biologic submissions in 2001, as well as 75 abbreviated submissions from generic drug firms. Several drugs received approval in both Canada and the US, including imatinib mesylate, an oral treatment for chronic myeloid leukemia. However, the FDA approved several "breakthrough drugs" that aren't yet on the list of Canadian NOCs, including alemtuzumab (for treating B-cell chronic lymphocytic leukemia) and tenofovir (an antiviral drug for treating advanced HIV infection).

Peterson says these are apple-and-orange comparisons because companies don't apply for approvals at the same time in both countries. As well, the FDA's annual budget is US$700 million, while TPD's is about Can$70 million. Despite this funding disparity, he says the average number of approvals is "very similar. In 1999, Canada approved 37 new active substances, the FDA 39. [But] we are not in competition with the FDA," he added. "We are providing an approval process that is commensurate with the Canadian health care system."

A *CMAJ* study (2000;162[4]:501-4) determined that approval times in Canada (median 518 days) were significantly longer than in the US (median 369 days), but Peterson says Canada and the US pursue different strategies. The US goal is to approve all applications within a specified time, and it funds its system accordingly.

In Canada, "we prioritize in a sense that allows for us to get priority-review drugs out the door on performance target frequently."

But Lefebvre remains unimpressed, and says improvements will only come if more reviewers are hired to speed the process.

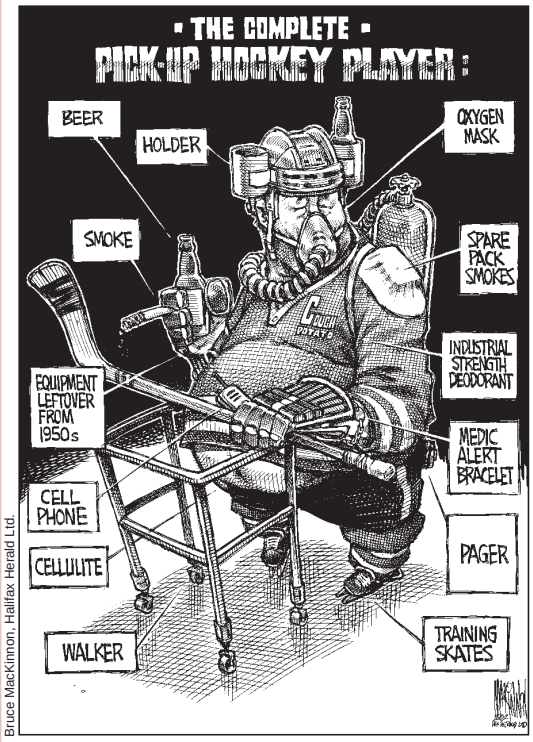
Increased funding, more transparency and improved postmarket surveillance were at the core of recommendations that emerged from a 1999 workshop on the TPD drug-review process and from a review conducted by a subcommittee of Health Canada's Science Advisory Board.

But Peterson indicates that federal budget allocations for drug-evaluation processes have fallen short in recent years and "one will not be able to meet performance requirements without having additional resources."

Health Canada may soon move to strengthen postmarket surveillance, Peterson adds. In April it will create a Marketed Health Products Directorate that will focus "on all postmarket activities that are federally regulated — drugs, biologics, medical devices, vaccines, natural health products."

To promote more transparency, TPD is now consulting on revisions to product monographs.

"We would hope to be looking at implementation of a much more open process, whereby the information contained in the monograph — safety issues, appropriate utilization, contraindications and patient information — would become freely available." — *Wayne Kondro*, Ottawa



A recent *CMAJ* article on the cardiovascular effects of adult recreational hockey (*CMAJ* 2002;166 [3]:303-7) struck a chord with *Halifax Chronicle-Herald* editorial cartoonist Bruce MacKinnon, who came up with this rendition of the type of person who plays in "oldtimer" leagues. The *Globe and Mail* also produced a cartoon on the subject.