FEDERAL POLICY

# Health Canada to seek public input on drugs

Health Minister Ujjal Dosanjh has promised to open up Canada's drug approval process to allow public comment on pharmaceutical company submissions and on postmarketing experiences.

The changes to Health Canada's drug approval process — which has long been criticized by public interest groups as being too closed — stem from the department's experience with rofecoxib (Vioxx) and other COX-2 inhibitors, Dosanjh said during a conference call with a few reporters on Feb. 15.

"Canadians have and must continue to have confidence in Health Canada to act in their best interests," Dosanjh said. "One of the means to accomplish this is to ensure opportunities for public interest before regulatory decisions are made.That means before approval and in the postmarket actions."

Dosanjh's proposed changes include creating a permanent advisory panel modelled on the one the US Food and Drug Administration (FDA) set up to review the safety of COX-2 inhibitors.

"I believe a uniquely Canadian model can be developed," Dosanjh said. "This model must take into account the needs of the patients [and] consumers, be supportive of the practitioners and be built on evidence and scientific expertise."

Dosanjh scheduled his conference the same day the FDA announced its new Drug Safety Oversight Board. That board, consisting of FDA and other government scientists, will consult with medical experts and patient groups to assess postmarketing safety data. The board was created in response to public criticism — and mounting lawsuits — alleging that the FDA ignored the warnings from its own scientists about the potential risks of rofecoxib and other drugs. Merck withdrew rofecoxib from sale in both Canada and the US on Sept. 30.

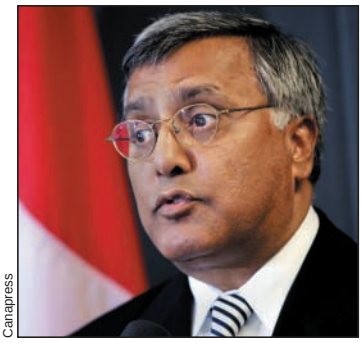
The FDA is also creating a Drug Watch Web page to post emerging data about new drugs as soon as potential risks are raised. instead of waiting for the FDA reaction.

In Ottawa, Dosanjh said he will ask the all-party Standing Committee on Health to advise the department on a new, more open process, and on a forum for public input. He also indicated he was not "unalterably opposed" to creating an independent agency to review drug safety.

The minister expressed surprise when reporters informed him they cannot currently get access to documents related to Health Canada's deliberations over rofecoxib and other COX-2 inhibitors.

"You don't have them now?" Dosnajh asked. He said that all the documents, except those that violate individual privacy or proprietary information, should be released.The FDA has posted comparable documents online.

The Canadian Health Coalition, a public-interest group that has been highly critical of Health Canada's secrecy, described Dosnjah's remarks as "encouraging."



Canapress

**Federal Health Minister Ujjal Dosanjh promises more transparency on drugs.**

"We have a minister who's not, I believe, captured by the industry," says executive director Mike McBane. "Can he wrestle the public agency back into [serving] the public interest? That's the political challenge we're facing."

The all-party Health Committee issued a report last winter pushing for more transparency. "The status quo is unacceptable," says McBane. "We have to end the secrecy and stop jeopardizing public health and people's lives."

In related news, the FDA's advisory panel on COX-2 inhibitors recommended that rofecoxib, celecoxib (Celebrex) and valdecoxib (Bextra) stay on the market, albeit with Black Box warnings about possible cardiac complications.

Ten Health Canada scientists and physicians in consultation with a panel of 9 external experts are conducting their own review of the COX-2 inhibitors. The results are due at the end of March. — *Laura Eggertson*, CMAJ

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