CMAJ NEWS

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Health Canada to improve drug recall process

Health Canada says it will respond to drug recalls more quickly and clearly in response to an independent review analyzing how it handled a recent birth control pill recall.

The government-commissioned review, conducted by Ottawa, Ontario-based Risk Sciences International, found that Health Canada followed all of its existing procedures properly. Nonetheless, the review suggested that these procedures should change to reflect the speed of modern communication and public expectations that Health Canada effectively regulate drug distribution.

"Health Canada will engage health care practitioners and health care associations to increase their understanding of the different roles Health Canada and industry have in health product recalls," Blossom Leung, a communications officer for the federal agency, writes in an email.

By mid-2014, she adds, the "department will also develop plain-language communication products to better explain these differences to stakeholders, the media and the public."

The review showed several problems with the recall process for Alysena 28, a birth control pill distributed by Apotex. It noted, for instance, that Apotex's initial recall notice on Apr. 3 "stated that the recall was being conducted in collaboration with Health Canada, which was not the case as Health Canada was not notified of the recall until late on the following day, Thursday April 4."

When asked to comment, Apotex stated it was "reviewing the report in detail," according to a response sent to *CMAJ* by Elie Betito, director of public and government affairs for the company.

"We are eager to cooperate and work proactively with Health Canada in assessing the recommendations in the report, with the overall objective of improving communications among all stakeholders in the Canadian health care system with respect to drug recalls," the statement continued.

The independent review also listed "problematic actions by Health Canada." The top item in the list was that "personnel did not act on the opportunity to issue a public communication of the recall of the drug on the

afternoon of Friday April 5, to respond to the social concern associated with unplanned pregnancies."

According to the review, Apotex received a complaint with a photograph of a faulty package on Mar. 20. The package had two rows of active pills (pink) and two rows of placebo pills (white). There should have been only one row of placebos. It wasn't until Mar. 28, the Thursday before the Easter long weekend, that the company decided to recall the affected lot. The notice of recall, however, wasn't sent to wholesalers, distributors and retailers until the following Wednesday (Apr. 3).

Apotex assessed the risk level for the recall as type II, meaning that users might experience temporary adverse health consequences.

On Friday, Apr. 5, Health Canada reassessed the risk. It determined it was still type II for the general population but type I (reasonable chance of death or serious health problems) for "vulnerable populations." These were identified as women who should not get pregnant for medical reasons or were using contraindicated therapy. But the department waited until after the weekend to release a public communication about the recall.

The media and the public, however, heard the news before Monday. The drugstore chain London Drugs posted the recall notice on its blog on Saturday, Apr. 6. The blog post "was not anticipated and is not standard, but it shone a spotlight on the absence of Health Canada notification," states the review.

Over the weekend, media picked up the story based on the available information, which was limited and unclear. The review cites this as evidence that "traditional models of communications no longer apply." In the 24-7, Internet era, Health Canada should develop "greater agility in preparing and providing information."

Health Canada received heavy criticism, mainly for not doing its job as a pharmaceutical regulator, but also for not recognizing the psychosocial importance of an unplanned pregnancy. The review recommends that Health Canada employees involved with drug recalls receive training about "social sensitivities" of some drugs, including contraceptives, and about risks unrelated to physical health.

The review also notes, however, that Health Canada has no legal powers to order recalls and little means to compel drug companies to more quickly notify it of recalls. The public response to the Alysena 28 recall suggests that Canadians

have high expectations for Health Canada as a drug regulator "that are not achievable with the present legislative and regulatory provisions," states the review.

Health Canada publishes information about drug recalls, monitors drug recalls as they occur and can request drug recalls, but does not conduct recalls. The United States' Food and Drug Administration serves a similar role, but also has legal authority to order a drug recall. — Catherine Cross, *CMAJ*

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