Initial confusion after massive Allerject recall

A broad recall of all Allerject-brand epinephrine auto-injectors in North America on Oct. 28 appears to be well underway after some initial confusion.

Sanofi in Canada and the United States decided to recall the device, used for emergency treatment of serious anaphylactic reactions, following 26 reports of suspected malfunction that could affect delivery of the required dose, including nine reports in Canada. As well, the contract manufacturer of the device noted problems that could lead to underdosing.

Since Allerject came on the market in January 2013, 492 000 devices have been dispensed in Canada (many patients have more than one).

The malfunction reports and manufacturing problems were still under investigation as of Nov. 2 and were not confirmed. It is also unclear whether all products or only certain lots are affected, according to Sanofi.

"The recall is really a precautionary step in the spirit of patient safety," said Franca Mancino, vice-president of medical and regulatory affairs for Sanofi Canada.

The announcement late on Oct. 28 led to some short-term confusion. Mancino said Sanofi tried to contact all physicians and pharmacists in Canada directly, as well as through professional and patient associations, hospitals, emergency departments and social media. However, Dr. Sandy Kapur, an allergist in Halifax, says that on the morning of Oct. 29, "I was inundated with phone calls from patients and pharmacists. Most pharmacists were still not aware of it and we were getting a lot of faxes from pharmacists to do the switch-over to EpiPen."

In the recall, patients were asked to visit their pharmacy to exchange an Allerject device for an EpiPen (manufactured by Pfizer), a competitor auto-injector that delivers epinephrine in the same doses. Sanofi had arranged with Pfizer for Allerject devices to be exchanged one-for-one for an EpiPen, without a prescription and at no cost to the patient; Sanofi is covering costs to the pharmacies for exchanges. However, the exchange plan led to a run on EpiPen devices, with some pharmacies running short, according to local news reports.

Sanofi

Allerject users can exchange their device for an EpiPen at no cost.

A spokesperson for Pfizer Canada confirmed that it has shipped its entire inventory of EpiPen products to wholesalers, and has ordered five times its usual stock of EpiPen and EpiPen Jr to meet the unexpected demand.

Kapur gives both companies credit for cooperating on this issue. He is also president of the Canadian Society of Allergy and Clinical Immunology, one of the associations that received the recall announcement, along with the Canadian Paediatric Society, Food Allergy Canada and others. He says associations contacted their members, and physicians contacted their patients. However, he suspects many physicians and patients found out about the recall through news media. Information was also made available through Health Canada's MedEffect alerts and on Sanofi, Health Canada and association websites.

"It's a big recall, a lot of devices, a lot of people," said Kapur. "The plan is reasonable; it's just the communication of getting that plan out. It would have been helpful even if I had got the message earlier in the day. We were

scrambling to get the message out to our members."

Allerject's market share in the US, where it is called Auvi-Q, has been estimated at 10% against EpiPen's 90%, but Kapur thinks it is higher in Canada, thanks to a more explanatory brand name and wider adoption in Canada's allergy community. "Allerject is a bit smaller to carry, and it has a voice modulator module that talks you through using the device."

He said the voice module is popular for use in children, whose parents may not be present to help with using the device in an emergency. "The devices are different in how they inject," Kapur explained. "The EpiPen injects into the muscle and the needle stays extended. When the device is withdrawn, a safety cover slides over the needle and covers it. With the Allerject, the needle injects and retracts automatically." In his practice, he presents both devices to patients and their parents, and family preference is the deciding factor.

Kapur calls Allerject and EpiPen "life insurance" in case of serious anaphylaxis. "The majority of patients never use them, but a significant proportion do. For most people, they end up expiring and they return them to the pharmacy."

Kapur and Sanofi Canada both stress that, in case of anaphylaxis, patients should use their Allerject device if they have not yet exchanged it. Physicians with further questions are encouraged to call Sanofi's toll-free information line (855 405-4321). — Carolyn Brown, Ottawa, Ont.

***CMAJ* 2015. DOI:10.1503/cmaj.109-5194**