

Health System Action Plan: Injectable Sodium Bicarbonate Shortage and Recall

Health System Emergency Management Branch

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Background

On June 8, Pfizer Canada Inc., the sole Canadian manufacturer of injectable sodium bicarbonate, issued a backorder notification for this product. On June 14, following the back order notification, Pfizer Canada voluntarily recalled two lots of injectable sodium bicarbonate. These lots were distributed in Canada from February to June 2017 and have been used in patient care. There is no indication that the manufacturing issues that prompted the recall of sodium bicarbonate vials impacts sodium bicarbonate pre-filled syringes. Sodium bicarbonate pre-filled syringes are not within the scope of the recall.

The above-referenced voluntary recall is being conducted due to the remote possibility of microbial growth based on testing results from a simulated manufacturing process. The microorganisms identified during the simulated manufacturing process were two fungal organisms (*Penicillium chrysogenum* & *Doratomyces asperulus*) and a single bacterial organism (*Actinomadura oligospora*). To date, Pfizer has not received reports of any adverse events associated with the remote possibility of microbial growth in lots and the likelihood of patient exposure to the microorganisms is considered to be low; however Pfizer is recalling these lots out of an abundance of caution.

The backorder notification and recall together removed a significant proportion of product that health care providers in Ontario had available. The resulting shortage could affect patient care for a large number of patients and there is a possibility this shortage may last throughout the summer months and beyond.

Sodium bicarbonate is used in the treatment of a wide range of conditions including metabolic acidosis, in cardiac surgery, as an antidote to certain poisons, in cases of organ failure and in some types of cancer chemotherapy.

The Ministry of Health and Long-Term Care (ministry) has activated the Ministry Emergency Operations Centre and will work closely with health system partners across Ontario as well as its federal, provincial and territorial partners to understand and mitigate the impacts of this shortage.

This action plan outlines five areas of activity that the ministry and health system partners are undertaking in response to the shortage and recall: monitoring the situation and its impact, making best use of available product, identifying other sources and alternatives, modifying services, and communications.

Monitoring the Situation and its Impact

The ministry is working with partners to:

- monitor inventory levels in the province
- monitor impacts of the shortage
- monitor impacts of the recall

Monitor Inventory Levels

The ministry is working with LHINs on a reporting process for inventory levels and in various parts of the health system – particularly hospitals. This will help the ministry and LHINs to understand the criticality of the drug shortage across the province and to implement appropriate responses.

Assess Shortage Impacts

The reporting process for inventory levels described above also includes information on impact of the shortage to patient care in order to inform decision making. In addition, the ministry asks all health sector partners to flag any urgent situations related to the shortage as early as possible to the Health Care Provider Hotline at 1-866-212-2272.

Monitor Recall Impacts

Patients in Ontario have received product that was subsequently recalled. Patients and health professionals can report adverse reactions to Health Canada's [Canada Vigilance Program](#). Pfizer has advised that if a patient has received potentially impacted product, and has signs or symptoms of infection, the healthcare professional should seek the advice of an infectious disease specialist or other medical practitioner with experience in the treatment of fungal and bacterial infections regarding appropriate therapy.

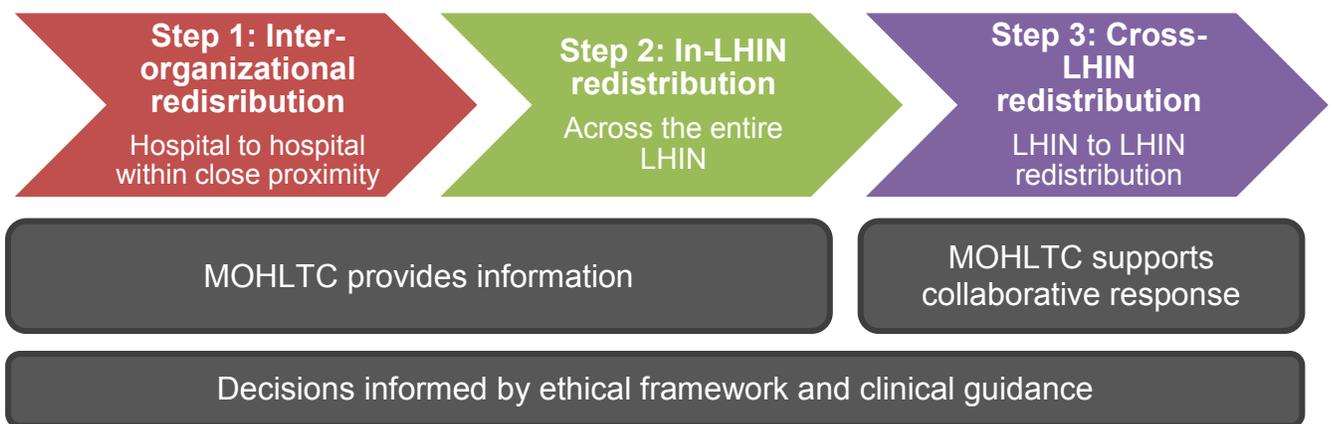
The ministry will work with Health Canada to monitor for any adverse reactions associated with recalled product.

Making Best use of Available Product

To support inventory management throughout the shortage, the ministry and health system partners are:

- implementing an inventory management framework
- promoting understanding of injectable sodium bicarbonate use to support decision making

Inventory Management Framework



The ministry and partners are using the above inventory management framework to guide decision making regarding redistribution of sodium bicarbonate within the province to support the most critical services.

Local partners should take immediate steps to refresh or establish redistribution processes at the organizational level (step 1) and the LHIN level (step 2). Activities undertaken in this framework can be informed by the ethical framework and clinical guidance regarding modification of services (see [Modifying Services](#) section).

While this framework emphasizes the role of hospitals, the ministry and LHINs are exploring opportunities to share inventory across other sectors.

Step 1: Local level redistribution (existing mechanisms where they exist)

- Hospitals coordinate redistribution decisions within their organizations, and share inventory within local areas using hospital best practices.

Step 2: LHIN level redistribution

- LHINs support the redistribution of products within their jurisdictions, which may also include redistribution between sectors.

Step 3: Cross LHIN redistribution - as possible

- LHINs and the ministry would support the redistribution of products across LHIN boundaries, where possible.
- The ministry would work with the LHINs to determine which geographical areas/LHINs are potential candidates to redistribute injectable sodium bicarbonate to other LHINs.
- Where no other LHIN can supply injectable sodium bicarbonate, providers can use the ethical framework to assist in decision making.

Promote Understanding to Support Decision Making

Decision makers may need to have an understanding of injectable sodium bicarbonate and the priority needs associated with it to make key decisions. The ministry is undertaking various activities to promote an understanding of injectable sodium bicarbonate and its uses within the health sector to support decision making throughout the response.

Identifying other Sources and Alternatives

The ministry will continue to collaborate with Health Canada and other federal/ provincial/ territorial partners to identify and assess options to address the shortage. Current exploratory measures being investigated include compounding the original product, filtration of product that has been recalled, sourcing products outside of Canada and sourcing new therapeutic alternatives.

Modifying Services

Health care providers are modifying services to conserve use of injectable sodium bicarbonate.

The ministry is supporting these difficult decisions in two ways:

- sharing an ethical framework to guide decision making
- facilitating discussions on service modification (focusing on conservation) across the health sector

Ethical Framework Development

The ministry has broadly shared the [Ethical Framework for Resource Allocation during the Drug Supply Shortage from the](#) Joint Centre for Bioethics (JCB) at the University of Toronto. JCB has confirmed that the ideas in this document apply well to this particular shortage. The JCB may develop additional and more specific guidance shortly which the ministry will also release and share broadly.

Facilitation of Service Modification Discussions

The ministry is encouraging and facilitating discussions with health sector partners to ensure coordinated approaches to service modifications within specific clinical care settings. This includes the collection of information on how frequently this product has been used and the identification of conservation strategies and currently available therapeutic alternatives to promote inventory availability where it is most needed. The ministry is also working with experts to identify and share resources that include strategies for conservation that are currently used across the system (e.g. the [guidance produced by the Society of Critical Care Medicine](#)).

Communications

The ministry is delivering and facilitating coordinated communication with health stakeholders and the general public and will work to coordinate public messaging and communications with the federal government, and health system partners.

Communication activities that are underway in the Ministry Emergency Operations Centre include:

- coordination teleconferences with LHINs
- information sharing teleconferences for key unions, regulatory colleges and health professional associations
- coordination teleconferences with healthcare shared service organizations
- federal/provincial/territorial teleconferences
- situation reports to external and internal partners (daily or as required)
- additional communications as may be required by the response (e.g. memos to the field, fact sheets, frequently asked questions, etc.)
- use of the Emergency Management Communications Tool (EMCT) to share resources with registered health organizations
- use of the 24/7 Health Care Provider Hotline as a single window phone number to the Ministry's Emergency Operations Centre