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Email Address/Courriel: drugprogramsdelivery@ontario.ca

DATE: October 24th, 2017

MEMO TO: Drug Shortages Health Partners

FROM: David Schachow
Director, Drug Programs Delivery Branch
Ontario Public Drug Programs Division

RE: **Shortage of 50mL and 100mL intravenous solutions (Mini-Bags) of 0.9% Sodium Chloride and 5% Dextrose manufactured by Baxter Corporation.**
Anticipated shortage of 250mL and 500mL intravenous solutions manufactured by Baxter Corporation.

On October 13th, 2017, the Ministry became aware of a shortage of 50mL and 100mL intravenous (IV) solutions (Mini-Bags) manufactured by Baxter Corporation through a letter that was circulated to its customers dated October 11th, 2017 (See Appendix 1 and 2). Although Mini-Bags are not drugs, but rather, a diluent vehicle for drug administration, they are vitally important to the usual process of administering many drugs used within hospital and community settings where intravenous drugs are administered. A shortage of Mini-Bags has the potential to significantly impact patients and the appropriate delivery of drugs administered intravenously within hospitals and other health care settings.

Baxter supplies about 70% of the Mini-Bags used in Ontario while other suppliers (e.g. Hospira/Pfizer, Fresenius Kabi, and B Braun) supply the remaining 30%.

The Ministry has received information from Baxter that the shortage is primarily the result of the impact of Hurricane Maria on the electrical supply of their Puerto Rico plants which produce about 40% of the Canadian supply of Mini-Bags. The manufacturer has implemented alternate production processes to increase production to meet the demands of the Canadian market and is working in a number of ways to further improve supply. At this time, all customers are on 50% allocation and there is a 2 week Canadian supply that is available. Baxter is working in a number of ways to further improve supply and increase allocations.

This message is being sent to ensure that health care providers are aware of the situation and to advise that it may be prudent for suppliers, hospitals and pharmacies who use Mini-Bags to survey their actual supplies and to initiate immediate conservation measures to optimize the preservation and conservation of Mini-Bag supplies for more immediate patient needs. This will allow Baxter time to re-establish their Mini-Bag supplies over the next weeks to months. Through this evaluation, hospitals are advised to work with their pharmacies and health professionals to determine if their facility needs to initiate further changes to their intravenous drug delivery and administration processes.

Some of the immediate conservation measures may include:

- i) Limit or eliminate all regular batching activities of drugs in Mini-Bags for the purpose of future usage.
- ii) Work with materials management, hospital pharmacies, and other impacted hospital teams to move Mini-Bag supplies to a more centralized location where supplies, usage and wastage may be monitored.
- iii) Review current compounding and intravenous drug administration practices with subject matter experts (e.g. pharmacists, nurses, clinicians) within your organization to evaluate alternative methods to administer selected intravenous drugs to conserve the Mini-Bags for drugs that more urgently require administration in a 50mL and 100mL volume.
- iv) Work with suppliers to redistribute Mini-Bag supplies based on actual patient needs within the facility.
- v) Explore the availability for Mini-Bag supplies by an alternate manufacturer
- vi) Reserve small volume bags for medication preparation and use larger volumes (e.g. 500mL, 1L) for other uses such as starting IV lines, administering blood, or flushing.

At this time, Baxter has notified Health Canada of this shortage and provided further communication to its customers dated October 19th, 2017 (See Appendix 3). We appreciate your collaboration and attention to this evolving situation and will continue to notify you with information as we work together to avoid and/or minimize patient impacts resulting from the shortage of IV solutions manufactured by Baxter.

For further information regarding product allocation and supply availability, please contact Baxter directly.

You can contact your Local Health Integrated Network (LHIN) or the Ministry by emailing us at drugprogramsdelivery@ontario.ca.

Sincerely,



David Schachow, Director
Drug Programs Delivery Branch
Ontario Public Drug Programs Division

Appendix 1:



October 11, 2017

Dear Valued Baxter Customer,

As part of Baxter's Global manufacturing network, Baxter Canada is supplied by several plants in Puerto Rico. Baxter's plants that produce components of our 50 mL and 100 mL IV Solutions (Mini-Bags) were affected by Hurricane Maria.

At this time, Baxter teams on the ground in Puerto Rico are working on the implementation of our recovery plan. The infrastructure of the island has been significantly impacted which is affecting our ability to return to full production capacity. We continue to work on sourcing alternative production from other manufacturing plants in our network in order to meet the demand of the Canadian market.

As a consequence of Hurricane Maria, we currently do not have enough supply to meet normal demand requirements of the Canadian market. To protect Canadian supply and minimize disruption to patient care, Baxter has placed the following IV Solutions (Mini-Bags) on allocation:

Size	Description	Product Code	DIN
50mL	0.9% Sodium Chloride Injection, USP	JB1301P	00060208
100mL	0.9% Sodium Chloride Injection, USP	JB1302P	00060208
50mL	0.9% Sodium Chloride Injection, USP	JB1308M	00060208
100mL	0.9% Sodium Chloride Injection, USP	JB1309M	00060208
50mL	5% Dextrose Injection, USP	JB0081P	00060348
100mL	5% Dextrose Injection, USP	JB0082P	00060348
50mL	5% Dextrose Injection, USP	JB0088M	00060348
100mL	5% Dextrose Injection, USP	JB0089M	00060348

This shortage has been reported to the Drug Shortages Canada website.

We will continue to monitor orders within the allocation process on an ongoing basis, however please be advised that over the short term the allocation release amounts will be limited as we work to implement our alternate production plans. We encourage you to work with your clinical partners within your institution to source a portion of your demand with alternate product or implement an alternate mode of medication delivery where possible. Please note that our 0.9% Sodium Chloride Injection and 5% Dextrose Injection IV solutions in bags sizes of 250 mL or greater are produced in Canada and have not been impacted by Hurricane Maria.

Should you have any questions or concerns regarding product allocations, please reach out to your Baxter Territory Manager, or contact Baxter Customer Care at 1.888.719.9955 or by email at hospitalcare_ca@baxter.com.

We sincerely apologize for this disruption and thank you for your patience as we continue to work through the recovery from the recent Hurricanes. We will continue to provide additional updates as they become available.

Sincerely,

James Teaff

Baxter Corporation
7125 Mississauga Road
Mississauga, ON L5N 0C2
T 905.369.6000 / 1-800-387-8399

Appendix 2:



October 11, 2017

Dear Valued Baxter Customer,

As part of Baxter's Global manufacturing network, Baxter Canada is supplied by several plants in Puerto Rico. Baxter's plants that produce components of our 50 mL and 100 mL IV Solutions (Mini-Bags) were affected by Hurricane Maria.

At this time, Baxter teams on the ground in Puerto Rico are working on the implementation of our recovery plan. The infrastructure of the island has been significantly impacted which is affecting our ability to return to full production capacity. We continue to work on sourcing alternative production from other manufacturing plants in our network in order to meet the demand of the Canadian market.

As a consequence of Hurricane Maria, we currently do not have enough supply to meet demand requirements of the Canadian market. To protect Canadian supply and minimize disruption to patient care, Baxter has placed the following IV Solutions (Mini-Bags) on allocation:

- 50 mL and 100 mL - 0.9% Sodium Chloride Injection, USP
- 50 mL and 100 mL - 5% Dextrose Injection, USP

This shortage has been reported to the Drug Shortages Canada website.

We will continue to monitor orders on an ongoing basis, however please be advised that over the short term the allocation release amounts will be limited as we work to implement our alternate production plans. We encourage you to work with your clinical partners to source a portion of your demand with alternate product or implement an alternate mode of medication delivery where possible. Please note that our 0.9% Sodium Chloride Injection and 5% Dextrose Injection IV solutions in bags sizes of 250 mL or greater are produced in Canada and have not been impacted by Hurricane Maria.

Should you have any questions or concerns regarding product allocations, please reach out to your Baxter Territory Manager, or contact Baxter Customer Care at 1.888.719.9955 or by email at hospitalcare_ca@baxter.com.

We sincerely apologize for this disruption and thank you for your patience as we continue to work through the recovery from the recent Hurricanes. We will continue to provide additional updates as they become available.

Sincerely,

A handwritten signature in black ink, appearing to read 'James Teaff', is positioned above the printed name.

James Teaff

Baxter Corporation
7125 Mississauga Road
Mississauga, ON L5N 0C2
T 905.369.6000 / 1-800-387-8399

Appendix 3:

October 19, 2017



Dear Valued Baxter Customer,

We're writing to provide further information regarding the impact from Hurricane Maria to our facilities in Puerto Rico. This information is intended to help you understand Baxter's product supply, so you can make important clinical decisions.

As part of Baxter's Global manufacturing network, Baxter Canada is supplied by several plants in Puerto Rico. Multiple production days were lost of our 50 mL and 100 mL IV Solutions (Mini-Bags).

As we continue to work on increasing our available supply of Mini-Bags, please be advised of the following:

- Baxter has released 50% of all Mini-Bags orders placed on or before October 12th
- These releases are being shipped as per your normal delivery schedule
- The remaining portions of these orders have been cancelled
- The following is a list of the impacted codes:

Size	Description	Product Code
50mL	0.9% Sodium Chloride Injection, USP	JB1301P
100mL	0.9% Sodium Chloride Injection, USP	JB1302P
50mL	0.9% Sodium Chloride Injection, USP	JB1308M
100mL	0.9% Sodium Chloride Injection, USP	JB1309M
50mL	5% Dextrose Injection, USP	JB0081P
100mL	5% Dextrose Injection, USP	JB0082P
50mL	5% Dextrose Injection, USP	JB0088M
100mL	5% Dextrose Injection, USP	JB0089M

Please continue to submit your ongoing orders for Mini-Bags as per your usual process. The Baxter team is assessing all orders and available inventory on a daily basis and will be releasing additional Mini-Bags.

For any inquiries, please reach out to our Customer Care team at hospitalcare@baxter.com or by phone at 1.888.719.9955.

Thank you for your ongoing support.

Sincerely,

James Teaff

Baxter Corporation
7125 Mississauga Road
Mississauga, ON L5N 0C2
T 905.369.6000 / 1-800-387-8399