Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
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Canada

2019-11-18
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Ms. Ann McAlduff
Senior Compliance Officer
GMP Inspection - Central
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. McAlduff:

Re: Further to the Responses to the Health Canada Inspection of Wholesale Activities at St. John's Operations
2019-03-27

The following are the actions taken by Canadian Blood Services in response to the Health Canada letter dated 2019-09-27, requesting additional information for observations to the Exit Notice for Health Canada's Inspection of Wholesale Activities at St. John's Operations.

C.02.015 - Quality control department

1. **The guidelines and/or procedures were inadequate in ensuring storage and/or transportation conditions would maintain the quality and safe distribution of the drug.**
b) A verification of the delivery time of the shipment was not being recorded. Therefore, there was a lack of documented evidence that cold chain shipments were delivered within their qualified timeframe. The time of receipt was being visually noted but not being recorded.
As per 05 127, Managing Shipments Designated for Temperature Monitoring, shipments are designated for temperature monitoring in January and July. These shipments have temperature monitoring devices included in each shipment. This monitoring process was established to provide an on-going mechanism to evaluate the current shipping process, and to demonstrate that required shipping temperatures and maximum shipping times are met. In addition, Canadian Blood Services works closely with our hospital customers when determining delivery times, routes and mode of transportation. Based on the agreed upon delivery times, Canadian Blood Services schedules our staff accordingly to ensure the shipments are not packed far in advance of the shipping times, keeping in mind the expected duration of the shipment.

In addition, as communicated to customers the previous Customer Letter 2018-21 "Qualification Information – New Insulated Shipping Containers for Hospital Deliveries" (2018-05-28), customers are asked to confirm upon receipt the packing time to time of receipt ≤ 27 hours.
We will consider the need for documented evidence that shipments are delivered within their qualified timeframe as part of future opportunities to improve this process.

Health Canada Follow-up letter dated 2019-09-27:

Please provide further detail on how the time data from the temperature monitoring devices is being recorded permanently. These devices typically have a short-term memory before data is over-written. Please note it is a GMP requirement to ensure that records are complete, accurate, and contemporaneously completed and retained for their required retention period. It has not been demonstrated to date, how shipment length (i.e. delivery times) is being recorded.

Canadian Blood Services Response:
A temperature monitoring device is included in every designated shipment used to verify the continued validated state of the shipping boxes. The device, at the time of packing the shipping container, is activated by Canadian Blood Services and placed in the box. Upon receipt, the hospital customer stops the temperature recording of the temperature monitoring device and completes the Monitored Shipment Receipt Confirmation form, which includes the date and time the shipping container was opened and returns the Monitored Shipment Receipt Confirmation form to Canadian Blood Services. Once received, all information, including the downloaded temperature profiles from the temperature monitoring device are forwarded to Quality Assurance for review to ensure the shipment has met all requirements. All information including the temperature profiles are maintained by Quality Assurance.

As to the shipment time being recorded, a potential solution to capture this information is under consideration. We will follow up by November 15th, 2019.

Canadian Blood Services Response follow-up response:
We are examining the feasibility of a manual system of recording delivery times (accuracy, can it be scaled, data searches, etc.). We will also test various solutions available via our Descartes Shipping Management System currently in use in other Canadian Blood Services' sites as well as explore alternate systems such as driver PDAs. We expect to have these activities and assessments completed by June 2020.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please refer to the above control number in all correspondence.**

Sincerely,

for

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affair
Fax Number: 613-739-2505

cc: Ms. Joy Bregg
Regulatory Operations and Regions Branch