



Regulatory Operations and Regions Branch
Health Product Compliance Directorate
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18-001587-254

Dr. Douglas B. DuVal
President
Canadian Anesthesiologists' Society
1 Eglinton Avenue East, Suite 208
Toronto, Ontario M4P 3A1

Dear Dr. DuVal:

This is in response to your letter of March 7, 2018 addressed to the Honourable Ginette Petitpas Taylor, Minister of Health, regarding the availability of local anesthetics in Canada, such as bupivacaine and ropivacaine. Your correspondence has been forwarded to Health Canada's Regulatory Operations and Regions Branch, Health Product Compliance Directorate (HPCD). HPCD is Health Canada's focal point on drug shortages and is responsible for compliance and enforcement activities related to health products in Canada.

Health Canada recognizes that drug shortages can have a significant impact on patients and health professionals and we are committed to doing our part to address them when they occur.

Addressing the complex issue of drug shortages is a multi-stakeholder responsibility requiring collaborative action from provinces and territories, manufacturers, distributors, practitioners, and the federal government. For its part, when a critical national shortage occurs, Health Canada works with stakeholders across the drug supply chain to coordinate information sharing and identify mitigation strategies.

With respect to shortages of local anesthetic products in Canada, by working closely with companies, Health Canada obtained up-to-date information on product supply for 43 local anesthetic product formulations. We have been in regular contact with our partners in the provinces and territories, and provided updates on February 9, 2018, February 16, 2018, and March 19, 2018 to share information on supply, allocation, and resupply timelines to help mitigate the impact on the healthcare system. We have also engaged directly with the Québec Ministry of Health on the supply of local anesthetic products in the province of Québec. Moving forward, we will continue to engage with our provincial and territorial partners to facilitate information-sharing on this issue.

Timely notification and communication is an essential part of managing drug shortages. This is why, on March 14, 2017, Health Canada launched a new website, www.drugshortagescanada.ca, to support new mandatory reporting regulations that require industry to publicly report drug shortages and discontinuances within a specified timeframe.

While several local anesthetic products are currently reported on www.drugshortagescanada.ca to be in shortage in Canada, a number of products remain in regular supply. As you may be aware, the shortage of Marcaine Spinal (bupivacaine) was reported by Pfizer Canada Inc. to be resolved as of March 20, 2018. Sensorcaine 0.25% with epinephrine, a bupivacaine product manufactured by Aspen Canada Inc., is not currently reported to be in shortage and Health Canada's understanding is that it is in regular supply.

Concerning marketed products containing ropivacaine, all Naropin products are reported to be in shortage or anticipated shortage, except Naropin® 10mg/mL 5x10mL SU Polyamp® Duofit®, as its shortage was reported to be resolved in October 2017. Additionally, Ropivacaine Hydrochloride Injection, USP (DIN2347830) is currently in shortage, which is expected to be resolved by the end of October 2018. The shortage of the other Ropivacaine Hydrochloride Injection, USP product (DIN 2347822) was reported to be resolved on March 7, 2018. The reason for all of these shortages is reported to be due to an increase in demand or a manufacture disruption.

Provinces and territories have informed Health Canada that supply is currently being managed through the implementation of conservation measures, use of alternatives when available, and through compounding when possible.

Manufacturers are the best source of information regarding the supply of a drug and you may wish to contact them directly for more information about these shortages:

- Pfizer Canada Inc., the manufacturer of Marcaine Spinal and Ropivacaine Hydrochloride Injection, USP, can be contacted by phone at 1-800-387-4974 or 1-800 387-4974.
- Aspen Canada Inc., the manufacturer of Naropin, can be contacted by phone at 1-844-330-1213 or by e-mail at hello@aspenpharma.ca.

With respect to the Special Access Programme (SAP), the programme considers requests for access to non-marketed drugs from practitioners treating patients with serious or life-threatening conditions when conventional treatments have failed, are unsuitable or unavailable. Requests to the SAP are practitioner initiated and considered on a case-by-case basis taking into consideration the severity of the condition, therapeutic alternatives, data supporting the use of the drug and availability from the manufacturer. A drug is not accessible via the SAP when marketed alternatives are available in Canada, unless the drug requested offers some unique clinical advantage.

The SAP is not intended as a default mechanism to address shortages or discontinuations. However, in exceptional circumstances, the SAP has been used as an interim mechanism to assist practitioners to access medically necessary drugs on a case-by-case basis when alternatives are not available.

Additional information about the SAP is available at the following website:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html>.

Physicians and the general public are encouraged to refer to drugshortagescanada.ca or contact companies directly to obtain the most up to date information on the supply status of a specific product.

Thank you for taking the time to share your concerns about this issue, and I hope that this information is helpful.

Yours sincerely,



Stefania Trombetti
Director General