Dear Health Care Provider,

The Product Monograph for Sativex® (delta-9-tetrahydrocannabinol 27mg/mL and cannabidiol 25mg/mL, buccal spray) has been recently updated. Two indications previously authorized under Health Canada's Notice of Compliance with conditions (NOC/c) policy, as set out below, have been removed. Sativex® remains indicated as an adjunctive treatment for symptomatic relief of spasticity in multiple sclerosis (MS), as set out below. Please refer to the updated Sativex® Product Monograph dated December 11, 2019 for full product information.

| From the Indications and Clinical Use section of the previous Sativex® Product Monograph | From the Indications and Clinical Use section of the current Sativex® Product Monograph |
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| • NOC SATIVEX® is useful as adjunctive treatment for symptomatic relief of spasticity in adult patients with multiple sclerosis (MS) who have not responded adequately to other therapy and who demonstrate meaningful improvement during an initial trial of therapy.<br>• NOC/c SATIVEX® may be useful as adjunctive treatment for the symptomatic relief of neuropathic pain in adult patients with multiple sclerosis. The physician who elects to use SATIVEX® for extended periods should periodically reevaluate the long-term usefulness of SATIVEX® for the individual patient.<br>• NOC/c SATIVEX® may be useful as adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain. | SATIVEX® (delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)) is indicated as:<br>• an adjunctive treatment for symptomatic relief of spasticity in patients with multiple sclerosis (MS) who have not responded adequately to other therapy and who demonstrate meaningful improvement during an initial trial of therapy. |

Authorization to sell a product in Canada under the Health Canada NOC/c policy may be granted for a drug product with promising evidence of clinical effectiveness providing it possesses an acceptable safety profile based on a benefit/risk assessment and is found to be of high quality. In

accordance with the NOC/c policy, GW Pharma conducted confirmatory studies to verify the clinical benefit of Sativex®. However, upon review, Health Canada determined that these studies were unable to provide sufficient evidence to maintain market authorization for the Sativex® indications authorized under the NOC/c policy.

There are no new safety signals that resulted in these updates. This is not a product withdrawal or recall. Sativex ® continues to be available to prescribing physicians in Canada and is authorized as an adjunctive treatment for symptomatic relief of spasticity in patients with multiple sclerosis (MS) who have not responded adequately to other therapy and who demonstrate meaningful improvement during an initial trial of therapy.

Bayer Inc. markets and distributes Sativex® in Canada under licence from GW Pharma. For access to the full product monograph, please go to www.bayer.ca.

If you have further questions, please contact Bayer Medical Information at 1-800-265-7382.

**Signed,**

Georgina Wells
Regulatory Affairs Manager