



Health Product InfoWatch

September 2023

CONTENTS

Monthly recap	2
Online pharmacies: Marketing of drugs and medical devices	3

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and biologics

- Amitriptyline
- Apo-Acyclovir
- Domperidone
- Keytruda (pembrolizumab)
- Sabril (vigabatrin)
- Tecentriq (atezolizumab)

Natural and non-prescription health products

- Cromolyn Eye Drops

Other

- Unauthorized health products

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: [Adverse Reaction and Medical Device Problem Reporting](#)
Telephone: 1-866-234-2345
Fax or mail: Form available online

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories electronically, subscribe to [MedEffect™ e-Notice](#) or to [MedEffect™ Canada RSS feeds](#).

This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of [health product advisories](#), [type I drug recalls](#) and [summaries of completed safety reviews](#) published in August 2023 by Health Canada.

Amitriptyline Type 1 drug recalls: Amitriptyline Apo-Amitriptyline Elavil Pms-Amitriptyline	Certain lots of amitriptyline tablets were recalled as the affected lots exceeded the interim acceptable intake limit for N-nitroso-nortriptyline (NNORT) or exceeded the acceptable cumulative intake limit for N-nitrosodimethylamine (NDMA) and NNORT.
Apo-Acyclovir Type 1 drug recall	Certain lots of Apo-Acyclovir tablets were recalled as the affected lots exceeded the concentration intake limit for NDMA.
Cromolyn Eye Drops Advisory	The Pendopharm Division of Pharmascience Inc. recalled all lots of the 10 mL format of Cromolyn Eye Drops due to the risk of microbial growth.
Domperidone Summary Safety Review: Domperidone Health Product InfoWatch: Domperidone	This safety review evaluated the risk of psychiatric withdrawal events following sudden discontinuation or tapering of domperidone used to stimulate lactation. Health Canada's review found a link, which was mostly observed in patients taking daily doses greater than the maximum recommended dose of 30 mg per day. Health Canada will work with the manufacturers to update the Canadian product monographs for domperidone-containing products to note that cases of psychiatric withdrawal events have been reported. Health Canada has also communicated this information to healthcare professionals.
Keytruda (pembrolizumab) and Tecentriq (atezolizumab) Summary Safety Review	This safety review evaluated the risk of aplastic anemia associated with Keytruda (pembrolizumab) or Tecentriq (atezolizumab). Health Canada's review found a link. The review also found that the risk applied to all members of the immune checkpoint inhibitor drug class. Health Canada is working with the manufacturers to update the Canadian product monographs for Keytruda and Tecentriq, as well as for the other products in the immune checkpoint inhibitor drug class that are not currently labelled for this risk.

<p>Sabril (vigabatrin)</p> <p>Advisory</p>	<p>Two lots of Sabril (vigabatrin) 500 mg powder for oral solution, in sachet format, were found to contain trace amounts of another prescription drug, tiapride. Health Canada has determined that the health risk of the trace contamination to patients is low. It is important that patients do not stop taking their Sabril as prescribed without consulting their physician, as the benefits of this drug are expected to outweigh its potential risks despite trace amounts of tiapride, unless patients have a severe allergy to tiapride.</p>
<p>Unauthorized health products</p> <p>Unauthorized health products seized from stores in the Greater Toronto Area</p> <p>Unauthorized health products seized from Yang Sheng Health Food and G&R Ginseng Trading stores in Richmond, B.C.</p> <p>Unauthorized sexual enhancement products</p> <p>Unauthorized skin lightening and skin treatment products</p>	<p>Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.</p>

Online pharmacies: Marketing of drugs and medical devices

In Canada, pharmacies and/or pharmacy owners are regulated by the pharmacy regulatory authority in the jurisdiction (province or territory) where the business is established. A legitimate pharmacy and/or pharmacy owner, including online pharmacies and owners of online pharmacies, will thus be licensed by the pharmacy regulatory authority in that province or territory.¹

Health Canada is the national regulatory authority for drug and medical device advertising and as such, is responsible for ensuring compliance with federal advertising legislation and regulations. Health Canada would like to remind healthcare professionals and online pharmacy owners that online pharmacies in Canada are subject to the Canadian federal legislation related to advertising of health products.

Health Canada’s [Stop Illegal Marketing of Drugs and Devices \(SIM-DD\) program](#) is a platform that provides support to healthcare professionals in understanding, identifying, and reporting illegal marketing of drugs and medical devices. The SIM-DD program also helps healthcare professionals and online pharmacy owners avoid engaging in illegal advertising when promoting health products and/or services to consumers.

Healthcare professionals are encouraged to [report](#) any suspected illegal online pharmacy advertising to Health Canada.

Health Canada encourages healthcare professionals to discuss the risks of purchasing drugs from illegal online sellers with their patients. The following links are provided to help identify and differentiate illegal websites selling drugs from licensed online pharmacies in Canada:

[Choosing a safe online pharmacy](#)

[Buying drugs over the internet](#)

[National Association of Pharmacy Regulatory Authorities](#)

[Alliance for Safe Online Pharmacies](#)

[National Association of Boards of Pharmacy](#)

Reference: 1. National Association of Pharmacy Regulatory Authorities. *Online Pharmacies*. Accessed July 3, 2023

Helpful links

- [MedEffect™ Canada](#)
- [Recalls and Safety Alerts Database](#)
- [New Safety and Effectiveness Reviews](#)
- [Canada Vigilance Adverse Reaction Online Database](#)
- [Drug Product Database](#)
- [Medical Devices Active Licence Listing](#)
- [Licensed Natural Health Products Database](#)
- [The Drug and Health Product Portal](#)
- [Drug Shortages Canada](#)
- [Medical device shortages: List of shortages and discontinuations](#)
- [Stop Illegal Marketing of Drugs and Devices](#)
- [List of drugs for exceptional importation and sale](#)
- [Coronavirus disease \(COVID-19\)](#)
- [Drug and vaccine authorizations for COVID-19](#)
- [COVID-19 vaccines and treatments portal](#)
- [Reported side effects following COVID-19 vaccination in Canada](#)

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at: infowatch-infovigilance@hc-sc.gc.ca

Health Product InfoWatch Editorial Team

Marketed Health Products Directorate, Health Canada

Address Locator 1906C, Ottawa ON K1A 0K9

Telephone: 613-954-6522 Teletypewriter: 1-800-465-7735 (Service Canada)

Copyright

© 2023 His Majesty the King in Right of Canada. This publication may be reproduced without permission provided the source is fully acknowledged. The use of this publication for advertising purposes is prohibited. Health Canada does not assume liability for the accuracy or authenticity of the information submitted in case reports.

Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Due to time constraints relating to the production of this publication, information published may not reflect the most current information.

ISSN: 2368-8025

Cat.: H167-1E-PDF

Pub.: 230000