Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Health Product InfoWatch

September 2019

CONTENTS

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.

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

Hormonal birth control products

Other

Unauthorized health products
Vaping products

ANNOUNCEMENTS

Mandatory reporting by hospitals begins December 16, 2019

New regulations requiring hospitals to report serious adverse drug reactions (ADRs) and medical device incidents (MDIs) to Health Canada will come into force on December 16, 2019.

Mandatory reporting is intended to improve the quality and increase the quantity of serious ADRs and MDIs reported to Health Canada to help identify emerging safety issues with health products on the Canadian market, and allow Health Canada to act quickly in the interest of public safety. If you suspect a serious ADR or MDI, report! Every report counts, together they tell a story.

Continued on page 2

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.

Canada

Mandatory reporting by hospitals begins December 16, 2019 (cont.)

A poster designed to raise awareness of the new reporting requirements is available for download from the Health Canada Web site.

You can also order the poster through the Canada Vigilance Program: hc.canada.vigilance.sc@canada.ca

Learn about what and how to report at: Canada.ca/drug-device-reporting

For more information: hc.canada.vigilance.sc@canada.ca

Phone: 1-866-234-2345 | Fax: 1-866-678-6789

Reporting of pulmonary disease associated with vaping products

Following recent cases of severe pulmonary disease and death in the United States (U.S.) reportedly associated with the use of vaping products, Health Canada has advised Canadians who use vaping products to monitor themselves for symptoms of pulmonary illness (e.g., unexplained cough, shortness of breath, chest pain) and to seek medical attention promptly if they have concerns about their health. Some cases in the U.S. have also reported gastrointestinal (e.g., nausea, vomiting, diarrhea, abdominal pain) and constitutional symptoms (e.g., fever, fatigue). Symptoms developed over a few days to several weeks.

The U.S. reports include people who vaped tetrahydrocannabinol (THC) and/or nicotine-containing products. However, at this time no specific product, substance, or device has been linked to all of the cases in the U.S.

Healthcare professionals are asked to report severe adverse reactions or incidents related to vaping products (including nicotine or cannabis) to Health Canada.

For more information, please see:

- Health Canada Information Update - Health Canada warns of potential risk of pulmonary illness associated with vaping products
- U.S. Centers for Disease Control and Prevention Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping
- Health Canada About vaping web page

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories, type I recalls as well as summaries of completed safety reviews published in August 2019 by Health Canada.

Hormonal birth control products Summary Safety Review	This safety review evaluated the risk of suicidality associated with hormonal birth control products (including oral contraceptive pills, transdermal patch, vaginal ring, intrauterine contraceptive device [IUD], and injectable contraception). Health Canada's review concluded that there was not enough evidence to support a direct link between the use of hormonal birth control products and the risk of suicidality. The current Canadian labelling of hormonal birth control products includes a warning about the risk of depression/mood changes. Suicidality is specifically labelled for Depo-Provera.
Unauthorized health products Colloidal Solutions colloidal metal products Multiple unauthorized health products Products from Aphrodite Aesthetic Clinic	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

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 Register
- Drug Shortages Canada
- Annual trends for adverse reaction case reports and medical device problem incidents
- Stop Illegal Marketing of Drugs and Devices

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.ca

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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.

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