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Health Product InfoWatch

March 2019

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

CONTENTS

Announcements

Comparative effectiveness and safety of biosimilar drugs	2
Program launch: Help Stop Illegal Marketing of Drugs and Devices	3
Public access to clinical information on drugs and medical devices	3

Monthly recap	4
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New information

- *Notice of market authorization with conditions*

Lorbrena (lorlatinib)	5
-----------------------	---

Pharmaceuticals and Biologics

Cough and cold products containing opioids
 Ferriprox (deferiprone)
 Gilenya (fingolimod)
 Lorbrena (lorlatinib)
 Proscar and Propecia (finasteride)

Medical devices

Breast implants

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.



ANNOUNCEMENTS

Comparative effectiveness and safety of biosimilar drugs

Health Canada is collaborating with the Drug Safety and Effectiveness Network (DSEN) on a project that aims to compare the safety and effectiveness of biosimilar drugs to the reference biologic drug.

The Canadian Network for Advanced Interdisciplinary Methods for comparative effectiveness research (CAN-AIM) team, which is part of the DSEN, is undertaking this work.

CAN-AIM will study patients across Canada with inflammatory rheumatic diseases and inflammatory bowel disease (IBD) who are taking biologic drugs. The primary focus is on patients without a previous history of biologic drug use. CAN-AIM will also study patients switching to a biosimilar drug from a reference biologic drug. The study will measure how long patients stay on treatment, if they require new treatment, if their disease control improves, and the occurrence of adverse reactions that could be related to these drugs. The study has a 5 year duration with annual deliverables. Patients are currently being recruited from both rheumatology and IBD cohorts and retrospective data is being analyzed.

For further information and protocol, please visit [CAN-AIM's Web Page](#).

Did you know?

Biologic drugs come from living organisms or from their cells, and are often made using biotechnology¹. A **biosimilar** is a drug demonstrated to be highly similar to a biologic drug that was already authorized for sale. Biosimilars are approved based on a thorough comparison to a reference drug and may enter the market after the expiry of reference drug patents. Biosimilars are not the same as generic drugs. Generic drugs are small molecules that are chemically synthesized and contain identical medicinal ingredients to their brand name reference products. Due to the size, complexity and natural variability of biologic drugs, and because biologic drugs are made in living cells rather than with chemicals, a biosimilar and its reference biologic drug can be shown to be similar, but not identical.

Reference

1. [Fact Sheet: Biosimilars](#). Ottawa (ON): Health Canada; 2017 August 3. (accessed 2019 February 1).

Program launch: Help Stop Illegal Marketing of Drugs and Devices

Health Canada is pleased to announce the launch of the “[Stop Illegal Marketing of Drugs and Devices](#)” program. This program is intended to help healthcare professionals identify and report illegal marketing of drugs and devices to Health Canada.

Inappropriate marketing or advertising related to drugs or medical devices should be reported to drug-device-marketing@canada.ca. Please include as much detail as possible related to the suspected inappropriate marketing activity or advertising material, including any pictures or scanned copies of the advertisements. Personal information in the reports is protected under the provisions of the [Privacy Act](#).

Help stop illegal marketing of drugs and devices

PRESCRIPTION
DRUGS



OPIOIDS AND OTHER
CONTROLLED SUBSTANCES



NATURAL
HEALTH PRODUCTS



YOU REPORT • YOU PROTECT

Public access to clinical information on drugs and medical devices

On March 20, 2019, Health Canada published final regulations that allow for the public release of clinical information on drugs and medical devices. Clinical information will be made available to Canadians through Health Canada’s new [Clinical Information Portal](#). To find out more, consult the [News Release](#).

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 February 2019 by Health Canada.

<p>Breast implants Information Update</p>	<p>Health Canada is in the process of updating its safety review of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) following an increase in reports of Canadian cases. As of January 1, 2019, Health Canada has received reports of 22 confirmed and 22 suspected Canadian cases of BIA-ALCL. In its initial safety review in 2017, Health Canada found that the rate of BIA-ALCL cases was low, with 5 confirmed Canadian cases of BIA-ALCL reported by Canadian manufacturers in the last 10 years. Increased awareness by healthcare professionals and the public about BIA-ALCL is believed to be contributing to the increased reporting of cases of BIA-ALCL to Health Canada.</p>
<p>Cough and cold products containing opioids Information Update Summary Safety Review</p>	<p>This safety review evaluated the risk of opioid use disorders and related harms in children and adolescents associated with cough and cold products containing opioids (including codeine, hydrocodone or normethadone). Health Canada's safety review found that there is limited evidence to support the effectiveness of these products in children and adolescents (under 18 years of age). In addition, the review found that early use of opioids may be a factor in problematic substance use later in life. Health Canada will notify manufacturers to update the Canadian product monographs of opioid-containing cough and cold products to limit the indication to adults only. Health Canada has also communicated this information to Canadians.</p>
<p>Ferriprox (deferiprone) Summary Safety Review</p>	<p>This safety review evaluated the risk of neurological disorders associated with Ferriprox (deferiprone). Health Canada's review concluded that there may be a link between Ferriprox and neurological disorders in children treated at recommended doses and not only at higher doses as currently referenced in the Canadian product monograph. Health Canada will notify the manufacturer to update the safety information for Ferriprox.</p>
<p>Gilenya (fingolimod) Health Product InfoWatch Summary Safety Review</p>	<p>This safety review evaluated the risk of multiple sclerosis rebound (return of disease activity) after Gilenya (fingolimod) discontinuation. Health Canada's review concluded that there may be a link. The Canadian product monograph for Gilenya has been updated to inform Canadians and healthcare professionals about this potential safety issue. Health Canada has also communicated this information to healthcare professionals.</p>

Proscar and Propecia (finasteride)

Summary Safety Review

This safety review evaluated the risk of suicidal ideation associated with Proscar and Propecia (finasteride). Health Canada's review concluded that there may be a link. Health Canada has notified the manufacturer to update the Canadian product monographs on this potential safety issue.

Unauthorized health products

Advisory - Kobayashi Aibon/
Eyebon Eyewash

Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

NOTICE OF MARKET AUTHORIZATION WITH CONDITIONS

A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the nature of authorization granted.

Healthcare professionals are encouraged to [report to Health Canada](#) any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada, in accordance with the NOC/c Policy. For the most up-to-date information, consult Health Canada's [NOC database](#).

Lorbrena (lorlatinib): Authorization with conditions

Health Canada has issued a Notice of Compliance under the Notice of Compliance with Conditions policy for Lorbrena (lorlatinib), oral tablets, 25 and 100 mg. Lorbrena is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on crizotinib and at least one other ALK inhibitor, or patients who have progressed on ceritinib or alectinib. Patients should be advised about the conditional market authorization for this indication.

For the complete prescribing information and information available for the patients/caregivers, please consult the Lorbrena Canadian product monograph. The product monograph can be accessed through Health Canada's [Drug Product Database](#), the [Pfizer Canada ULC Web site](#) or by contacting Pfizer Canada ULC at 1-800-463-6001. Contact the company for a copy of any references, attachments or enclosures.

HELPFUL LINKS

- [MedEffect™ Canada](#)
- [Recalls and Safety Alerts Database](#)
- [New Safety 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

Health Canada
Marketed Health Products Directorate
Address Locator 1906C
Ottawa ON K1A 0K9
Telephone: 613-954-6522
Fax: 613-952-7738

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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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