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Health Product InfoWatch

March 2015

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REPORTING ADVERSE REACTIONS

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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

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Olanzapine
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Medical Devices

Small bore (Luer) connectors

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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

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of health product advisories as well as summaries of completed safety reviews published in February 2015 by Health Canada.

Cefazolin for Injection USP 1 g Health Product Risk Communication	Two lots of Cefazolin for Injection USP 1 g, manufactured by Hospira and distributed in Canada by Apotex Inc., are being voluntarily recalled due to the potential presence of foreign particulate matter. Inadvertent injection of foreign particulate matter and the potential that sterility has been compromised for these lots could result in risks to health.
Mycophenolates (Cellcept and Myfortic) Summary Safety Review	This safety review evaluated the potential risk of bronchiectasis in patients taking mycophenolates. It also evaluated the risk of hypogammaglobulinemia, which may occur together with bronchiectasis. The current evidence suggests that bronchiectasis, with or without hypogammaglobulinemia, may occur while taking products containing mycophenolates. The prescribing information for Cellcept and Myfortic has been updated to include this safety information. Manufacturers of generic versions will also update their prescribing information.
Olanzapine Health Product Risk Communication	Eleven lots of olanzapine distributed by Pharmascience Inc., Pro Doc Limitée and Laboratoire Riva Inc. are being voluntarily recalled. There is a possibility that bottles from the recalled lots may contain tablets of a different drug, ondansetron.
Pradaxa (dabigatran) and Multaq (dronedarone) or Cordarone (amiodarone) - Drug-Drug Interaction Summary Safety Review	This safety review evaluated the available information on the interaction between dabigatran and dronedarone or amiodarone. This possible interaction can raise the blood level of dabigatran and potentially increase bleeding risk. The current evidence suggests that bleeding related side effects may be associated with the drug-drug interaction. The prescribing information for Pradaxa, Multaq and Cordarone has been updated to include this safety information. The prescribing information for applicable generic amiodarone products is also being updated.
Risperidone Health Product Risk Communication	The indication for risperidone in dementia has been restricted to the short-term symptomatic management of aggression or psychotic symptoms in patients with severe dementia of the Alzheimer type. The indication no longer includes the treatment of other types of dementia.
Tecfidera (dimethyl fumarate) Dear Healthcare Professional Letter Public Communication	New important safety information regarding Tecfidera and the risk of progressive multifocal leukoencephalopathy (PML) is being communicated to healthcare professionals and to the public. The prescribing information will be updated to include the risk of PML and additional recommendations on lymphocyte monitoring.

Unauthorized health products Advisory	Two unauthorized health products that may pose serious health risks were removed from sale by Health Canada. These products, "MRM DHEA" and "Altimate Fat Burner Maximum Burn" were being sold by Nature's Source in Vaughan, Ontario.
Zelboraf (vemurafenib) Information Update Summary Safety Review	This safety review evaluated the potential risk of pancreatitis associated with Zelboraf. The current evidence suggests an association between Zelboraf and the occurrence of pancreatitis. This may be due, in part, to the fact that the drug may stimulate the proliferation of cells leading to obstructive pancreatitis. The prescribing information for Zelboraf has been updated to include this safety information. Health Canada has also communicated this risk to Canadians.
Zenhale (mometasone furoate/formoterol fumarate dihydrate inhalation aerosol) Health Product Risk Communication	A recall of certain lots of Zenhale has been initiated due to the possibility of device malfunction after 24 months of shelf-life. This could result in the potential for a patient to receive a lower dose than expected, leading to potential increased asthma symptoms and worsening asthma control.

No foreign product alerts (FPAs) were issued in the previous month by Health Canada. Previously issued FPAs can be accessed on the Recalls and Safety Alerts Database.

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.

REVIEW ARTICLE

Tubing misconnection errors and the anticipated redesign of small bore (Luer) connectors

Key points

- A medical tubing misconnection error occurs when a tube or catheter is unintentionally connected to the wrong connector or device, potentially resulting in patient harm.

Medical tubing is used in a large number and variety of medical interventions, including during the delivery or removal of fluids or gasses and the support or assessment of physiological functions in patients.[1] A medical tubing misconnection error (or wrong-route administration) occurs when a tube or catheter is unintentionally connected to the wrong connector or device.[2] These errors can result in gas-gas misconnections, liquid-liquid misconnections, or gas-liquid misconnections.[3] The patient consequences of a tubing misconnection error can include serious injury and death.

Key points (continued)

- A series of International Organization for Standardization (ISO) standards are expected to guide the design of new small bore connectors that are meant to be incompatible between devices used for different clinical applications.
- For timelines and more information regarding connector device changes and availability, healthcare facilities are encouraged to contact their medical device suppliers and refer to available resources.

In 2014, a potentially serious incident involving an infant was reported to Health Canada. An enteral feed extension tube was inadvertently connected to a closed suction system instead of the naso-oro gastric tube. As a result of the misconnection error, expressed breast milk was infused into the endotracheal tube. The error was noticed immediately and the breast milk was suctioned from the endotracheal tube, thereby preventing potentially serious patient harm. Similar incidents have been documented in safety publications.[4]

Tubing misconnection errors have been described as a systems failure with human factors.[5] Several publications describe how the design features of current tubes, catheters, and connectors can facilitate an inadvertent connection between devices that are intended to be incompatible.[5-8] In particular, small bore connectors can allow unrelated medical device systems to be connected to one another.[5-8] A small bore connector has been defined as a connector with an inner diameter of less than 8.5 mm that is used to link or join medical devices, components, and accessories for the purposes of delivering fluids or gases (e.g., a Luer connector).[9]

In response to this risk, the development of a series of International Organization for Standardization (ISO) standards is anticipated to guide the design of new small bore connectors that are meant to be incompatible between devices used for different clinical applications.[10] The first standard, ISO 80369-1:2010, provides general requirements for connectors for liquids and gases in healthcare applications and establishes a framework for testing connectors to ensure non-interconnectability of unrelated delivery systems. Each additional standard in the series will focus on connectors for a specific clinical application and will be released as it is completed. Overall, it is expected that there will be new ISO standards for several device types:[11]

- breathing systems and driving gases applications;
- enteral applications;
- urethral and urinary applications;
- limb cuff inflation applications;
- neuraxial applications; and
- intravascular or hypodermic applications.

Available timelines suggest that the new enteral-specific connector design will be marketed in Canada in 2015.[10] Other connector designs are anticipated to be phased into the Canadian market subsequent to ISO standard development. As healthcare facilities transition to the use of the new connector designs, there may be an impact on the preparation, dispensing and administration of health products, which could affect healthcare professionals, caregivers and patients. To minimize potential disruptions to supply and clinical practice, it has been described that temporary transition sets for enteral-specific applications will fit both current connectors and new ISO standard connectors through the use of a dual compatible adapter.[10] In preparation for the anticipated changes to connector devices, healthcare facilities are encouraged to contact their medical device suppliers for details about timelines and refer to available resources for more information.[10]

Health Canada will continue to conduct post-market surveillance of medical devices on the Canadian market. Incidents related to tubing misconnection errors are suspected to be greatly underreported.[6,12-15] Healthcare professionals are encouraged to report to Health Canada any incidents of tubing misconnection errors or near-misses that occur with current or new devices.

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HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- Summary Safety Reviews
- Canada Vigilance Adverse Reaction Online Database
- Drug Product Database
- Canadian Drug Shortage Database
- The Drug and Health Product Register

Suggestions?

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