Health Canada Santé Canada

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Health Product InfoWatch

May 2017

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
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HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

Avastin (bevacizumab)
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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 150

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 April 2017 by Health Canada.

Avastin (bevacizumab) Summary Safety Review	This safety review evaluated the risk of non-mandibular osteonecrosis associated with Avastin (bevacizumab) in adult cancer patients. Health Canada's review concluded that there was not enough information to establish a definitive link. However, Health Canada has recommended that the manufacturer update the Canadian product monograph (CPM) to include information of the reports of non-mandibular osteonecrosis in adult cancer patients treated with Avastin. The current CPM only mentions this risk in children treated with Avastin. Health Canada will continue to monitor safety information involving Avastin.
Dipeptidylpeptidase-4 (DPP-4) inhibitors Summary Safety Review	This safety review evaluated the risk of arthralgia associated with dipeptidylpeptidase-4 (DPP-4) inhibitors. Health Canada's review concluded that there is a potential link between the use of DPP-4 inhibitors and the development of arthralgia. Health Canada is working with manufacturers to update the Canadian product monographs for all DPP-4 inhibitors to inform healthcare professionals and patients about the risk of developing arthralgia when DPP-4 inhibitors are used.
Direct-acting antivirals (DAAs) Summary Safety Review	This safety review evaluated the risk of liver cancer recurrence associated with direct-acting antivirals (DAAs). Health Canada's review concluded that there was not enough information to establish a link. Health Canada has requested additional safety information from DAA manufacturers regarding this risk as it becomes available.
EpiPen (epinephrine) Advisory	Pfizer Canada recalled one lot of EpiPen auto-injector (0.3 mg/dose) and one lot of EpiPen Jr. auto-injector (0.15 mg/dose). The recalled devices may contain a defective part that may result in the auto-injector failing to activate or requiring increased force to activate.
Erwinase (Erwinia L-asparaginase) Health Product Risk Communication	To help manage the impact of the ongoing shortage of Erwinase, some previously unreleased Erwinase vials from Batch CAMR-180 were made available. These vials should be used with a 5-micron filter due to the presence of particulate matter. If particulate matter is observed elsewhere other than on the underside of the stopper (e.g., on or in the product) before or after reconstitution, the product should not be administered and should be retained for collection.

Hospital beds Summary Safety Review Health Product Risk Communication	This safety review evaluated the risk of patient entrapment in hospital beds. Serious incidents of patient entrapment in hospital beds continue to be reported to Health Canada. Health Canada's review concluded that it is possible to improve the safety of hospital beds by increasing the awareness of the risk of patient entrapment. Healthcare professionals are encouraged to perform a patient assessment to determine if the use of bed rails is appropriate and to closely monitor patients for whom bed rails are used. Healthcare professionals and institutions are reminded of measures to reduce the risk of patient entrapment.
Iodinated contrast media Summary Safety Review Health Product Risk Communication	This safety review evaluated the risk of hypothyroidism with Iodinated contrast media (ICM). Health Canada's review concluded that there is a rare potential risk of hypothyroidism with the use of ICM in certain patients, mostly infants. Health Canada is working with manufacturers to update the Canadian product monographs for all ICM products to include this safety information. Health Canada has also communicated this information to healthcare professionals.
Unauthorized health product (Rhino Blitz Gold) Advisory	Testing confirmed that the unauthorized health product "Rhino Blitz Gold" contains undeclared sildenafil. The product, promoted for sexual enhancement, was seized from Stag Shop in Hamilton, Ontario.
Unauthorized health products promoted for sexual enhancement Advisory	Additional unauthorized products promoted for sexual enhancement were seized from 24 Hour Adult Mart in Toronto, Ontario.
Unauthorized health products sold online Advisory	Health Canada warned Canadians about unauthorized health products, including unauthorized prescription drugs, sold online at sarms.ca. The products were promoted for various uses, including fitness and bodybuilding.

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.

SAFETY BRIEF

Disposable plastic syringes - clarification of intended use

Safety reminder

All disposable plastic syringes in Canada regardless of manufacturer are licensed for immediate drug administration and fluid aspiration only. There is a potential risk of decreased medication potency if these syringes are used for storage of medication.

Action taken by Health Canada

Health Canada has previously communicated on this issue with regard to specific disposable syringes. Since then, Health Canada has been working with all manufacturers of disposable plastic syringes marketed in Canada to update their labelling to align with the intended use of these devices. Device labelling now contains directions such as: “for immediate use” or similar wording (e.g., “not for drug storage”). The updated wording may appear in the following locations:

- Syringe peel-away / pouch labels
- Syringe box labels
- Package insert

Syringes that are sold pre-filled with heparin, saline or any other drug product were not subject to this labelling update.

For more information

More information can be found on the Institute for Safe Medication Practices (ISMP) Web site. In addition, some individual manufacturers have also communicated directly to clients on this label update.

Report health or safety concerns

Health Canada encourages the reporting of reduced medication potency with the use of disposable plastic syringes to the Regulatory Operations and Regions Branch through the toll free hotline (1-800-267-9675). The adverse incident reporting form and guidelines can be found on the Health Canada Web site.

VACCINE SAFETY QUARTERLY SUMMARY

Report for July 1, 2016 to September 30, 2016

Post-market surveillance is essential to monitor the safety and effectiveness of vaccines and other health products. The monitoring of the safety of vaccines is a shared responsibility between Health Canada and the Public Health Agency of Canada (PHAC). Market authorization holders are required to report serious adverse events following immunization (AEFIs) to the Canada Vigilance Program in the Marketed Health Products Directorate at Health Canada. The Canada Vigilance Program also receives voluntary AEFI reports from healthcare professionals and consumers. Provincial and territorial public health authorities report AEFIs from publicly funded vaccine programs to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) in PHAC to monitor the safety of immunization programs.

This Vaccine Safety Quarterly Summary includes AEFI reports received by the Canada Vigilance Program between July 1, 2016 and September 30, 2016. To access reports published by CAEFISS, please visit the CAEFISS Web site.

- From July 1, 2016 to September 30, 2016, the Canada Vigilance Program received 73 reports* of adverse events following immunization (AEFIs) for which vaccines were the suspected cause.
- There were 45 (62%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.
- The largest proportion of reports (serious and non-serious) involved herpes zoster vaccine (33%) followed by pneumococcal vaccines (19%) and influenza vaccines (8%).
- The most frequently reported AEFIs (serious and non-serious) included pyrexia, injection site erythema, pain in the extremity, and drug ineffectiveness. Cases of drug ineffectiveness included those that lacked sufficient information for adequate assessment. The other AEFIs are common following vaccination and are captured in the respective Canadian product monographs.
- No new safety signals (potential safety issues) were identified during this period.
- The benefits of vaccines authorized in Canada continue to outweigh the risks.
- Health Canada, in collaboration with PHAC, will continue to closely monitor the safety of vaccines authorized in Canada.

For additional information, contact the Marketed Health Products Directorate.

Note that because of updated information received by the Canada Vigilance Program, there may be differences in the number of AEFI reports and adverse events retrieved at different dates.

* Glossary of Fields in the Canada Vigilance Adverse Reaction Online Database

This summary may contain duplicate reports. Duplicate reports are reports related to the same patient and event received from more than one source (e.g., pharmacist and consumer). Therefore, the sum of all reports in the line listing may exceed the total number of individual patient cases.

HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- Summary Safety Reviews
- 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

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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