



The Health Products and Food Branch (HPFB) posts on the Health Canada Web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

NOTICE TO HOSPITALS
Health Canada Issued Important Safety Information Update
on the Risk of Entrapment of Patients in Hospital Beds

August 10th, 2012

To: Hospital, Long-Term Care Facility and Nursing Home Staff

Please distribute to all relevant departments and other involved professional staff and **post this NOTICE** in your institution.

Subject: Risk of entrapment of patients in hospital beds (update)

Health Canada continues to receive reports of serious incidents resulting from bed entrapment. Twelve (12) additional incidents including 3 deaths have been reported to Health Canada since the issuance of a Notice to Hospitals in October 2009. Eight (8) out of the 12 cases (67%) occurred in nursing homes or long-term care facilities while the remaining incidents happened in hospitals (3) or at home (1).

- **Incidents of bed entrapment continue to be reported to Health Canada, some of them leading to serious injuries or death.**
- **To reduce the risk of bed entrapment in health care facilities, Health Canada is reminding institutions of the following recommendations:**
 - **Institutions should consult the previous Notice to Hospitals as well as the guidance document and the Fact Sheet issued by Health Canada on this issue.**
 - **Institutions should contact manufacturers for advice on reducing entrapment hazards when using beds manufactured prior to the year 2000. Some manufacturers have developed covers or side rails upgrade kits to reduce the risk of bed entrapment.**
 - **Institutions should verify and ensure that replacement mattresses are the correct size for the bed frame.**

Health Canada issued in October 2009, a Notice to Hospitals (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2009/hospital_bed-lit_hospital_nth-aah-eng.php) to inform health care professionals of the importance of assessing the safety of hospital beds by properly identifying high risk zones of potential hazards. Prior to that, Health Canada published in March 2008 a guidance document entitled *Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demanded/guide-ld/md_gd_beds_im_ld_lits-eng.php). This document was intended to reduce life-threatening entrapment associated with hospital bed systems and to provide recommendations to assist health care facilities in assessing side rail latching reliability and other potential hazards. In addition, a Fact Sheet was also issued in June 2008 *Bed rails in hospitals, nursing homes and home health care* (http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/fs-fi/bedrail_fs_fd_cotedelit-eng.php).

Bed-related incidents can be reported to Health Canada using the *Bed-related Entrapment and Fall Report Form*, available on Health Canada's website: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/md_im_form_beds_lits_e.pdf. Forms can be sent to the address mentioned below.

Managing marketed health product-related adverse incidents depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse incidents are generally presumed to underestimate the risks associated with health product treatments. Any cases of serious incident of bed entrapment or other serious or unexpected adverse incidents in patients using hospital beds or side rails should be reported to Health Canada at the following addresses:

Any suspected adverse incident can be reported to:

Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9
Telephone: The Inspectorate Hotline: 1-800-267-9675

The [Medical Devices Problem Report Form and Guidelines](#) can be found on the Health Canada Web site.

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php>

For other medical device inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: mhpd_dpssc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738