



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 on
UNFRACTIONATED HEPARIN

November 25, 2009

To: Hospital Chief of Medical Staff

Please distribute to the relevant Departments of Surgery, Emergency Medicine, Pharmacy, Pediatrics, Anesthesia, Internal Medicine, Cardiology, Nephrology, Neurology, Nursing, Intensive Care and/or other Departments as required and other involved professional staff and **post this NOTICE** in your institution.

Subject: Decreased Potency of some Unfractionated Heparin Products as a Result of New United States Pharmacopeia (USP) Standards

Heparin products are widely used in the treatment of thrombotic conditions and to prevent the extension of clots and thromboembolic phenomena. They are also used prophylactically to prevent clotting during various procedures.

- **New manufacturing and testing requirements for unfractionated heparin manufactured according to USP standards will result in a decrease in potency of approximately 10%.**
- **There will be a transition period over the next 2 years where heparin products of both the old and new potency will be on the market simultaneously.**
- **Physicians should consider the possibility of decreased potency when administering unfractionated heparin and the potential need for dosage adjustments, especially in circumstances where achievement of a rapid or aggressive anticoagulated state is required.**
- **Patients may require closer monitoring of their coagulation parameters during this transition period.**
- **Lots of unfractionated heparin with the new USP standard will be shipped by as early as December, 2009 (please refer to table below).**

The United States Pharmacopeia (USP), an American organisation which develops standards for the quality of therapeutic products, has revised its monograph for unfractionated heparin, as part of ongoing efforts to reduce the risk of heparin contamination. At the same time, the USP took this opportunity to calibrate their new Unfractionated Heparin potency reference standard to the International Standard for Unfractionated Heparin issued by the World Health Organization, so that potency results of all heparin

products would be the same regardless of which standard is used. This will result in approximately a 10% reduction in potency for unfractionated heparin products relative to previous USP standards. Low molecular weight heparins will not be affected by this change.

At this time, dosage recommendations are not expected to change. However, some patients may require closer monitoring of their level of anticoagulation to ensure adequate heparinization. In circumstances where rapid or aggressive anticoagulation is desired, the difference in potency should be considered when determining the dose to be administered.

The manufacturers impacted by the change in the USP reference standard will be implementing measures to distinguish lots with the new standard from lots with the old standard. The following table provides the name of the manufacturer, the date when heparin lots with the new standard will be shipped, and the measures implemented to distinguish the lots:

<i>Affected Manufacturers</i>	<i>Date for first lots of products with new USP standard</i>	<i>How to Distinguish Products with New USP Standard</i>
B.Braun Medical, Inc.	December, 2009	“N” at the end of the lot number
	Additional Information can be found by contacting B.Braun Medical Inc. at: Tel: 1-800-854-6851 http://www.bbraunusa.com http://www.bbraunusa.com/index.cfm?uid=11CF153665B05CD0D14127904CE186FC	
Baxter Corporation (Canada)	December, 2009	“New Lot” on unit label
	Additional Information can be found by Contacting Baxter Corporation (Canada) at: Tel: 1-888-719-9955 Fax: 1-888-719-9986	
Hospira Healthcare Corporation	December, 2009	Lot number beginning with 82 or higher
	Additional Information can be found by contacting Hospira Healthcare Corporation at: Hospira Clinical Support Department Tel: 1-866-488-6088 Option 4	
Pharmaceutical Partners of Canada, Inc. (PPC)	March 1, 2010	“N” at the end of the lot number
	Additional Information can be found by contacting PPC Inc. at: Tel: 1-877-821-7724 or 1-905-770-3711 http://www.ppcdrugs.com	
Sandoz Canada, Inc.	January 10, 2010	“New USP Standard” on the boxes and “New” on unit label
	Additional Information can be found by contacting Sandoz Canada, Inc. at: Drug Information Tel: 1-800-343-8839 ext.4636	

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any cases of serious adverse reaction suspected to be related to the change in potency or other serious or unexpected adverse reactions in patients receiving unfractionated heparin should be reported to the relevant market authorization holder or Health Canada at the following addresses:

<p><u>B.Braun Medical, Inc.</u> Clinical and Technical Support Tel: 1-800-854-6851 http://www.bbraunusa.com/index.cfm?uuid=DBD50225D0B759A1E30E32DC7DCD70C8</p>	<p><u>Baxter Corporation (Canada)</u> Pharmacovigilance Department 4 Robert Speck Parkway Suite 700 Mississauga, Ontario L4Z 3Y4 Email: canada_pharmacovigilance@baxter.com Tel: 1-800-387-8399 ext.6626, 6622, 6526 (or state to receptionist that you are reporting an adverse event)</p>
<p><u>Hospira Healthcare Corporation</u> Complaint & Safety Department 1111 Dr. Frederik-Phillips, Suite 600 Saint-Laurent (Quebec) H4M 2X6 ProductcomplaintsCA@hospira.com Tel: 866-488-6088 Option 7 Fax: 877-906-0208</p>	<p><u>Pharmaceutical Partners of Canada, Inc</u> Medical Information 45 Vogell Road, Suite 200 Richmond Hill, Ontario L4B 3P6 Tel: 877-821-7724 or 905-770-3711 Fax: 905-770-4811</p>
<p><u>Sandoz Canada, Inc.</u> Pharmacovigilance General Contact Fax: 1-450-641-6408 Email: drugsafety.canada@sandoz.com</p>	

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: 613-954-6522
Fax: 613-952-7738