Public Communication -
Health Canada Endorsed Important Information on
PrFLOLAN® (epoprostenol sodium)

April 24, 2013

Subject: **Updated Information – Potential for Glass-Related Particles in FLOLAN® (epoprostenol sodium) Sterile Diluent and the Essential Use of a Filter with the Administration of the Reconstituted Product**
(FLOLAN® 0.5 mg vial, DIN: 02230845; FLOLAN® 1.5 mg vial, DIN: 02230848; Sterile Diluent DIN: 02230857)

GlaxoSmithKline Inc., in consultation with Health Canada, is providing Canadians with updated information on the use of the pulmonary hypertension drug, FLOLAN®. Some vials of Sterile Diluent for FLOLAN® have been found to contain glass-related particles that may not be easily visible under normal lighting conditions . Studies indicate filtration through a 0.22 or 0.2 micron pore size filter is an effective means to remove these glass-related particles. The infusion tubing supplied by your Pharmaprix/Shoppers Drug Mart Specialty Pharmacy already incorporates a 0.2 micron filter.

There have been no reports of adverse events that could be definitively attributed to these glass-related particles in GlaxoSmithKline's safety database for FLOLAN®.

Based on this information, GlaxoSmithKline would like to advise you of the following:

- Some vials of Sterile Diluent for FLOLAN® have been found to contain glass-related particles
- When administering FLOLAN® you must only use the infusion tubing supplied to you by your Pharmaprix/ Shoppers Drug Mart Specialty Pharmacy. This tubing already incorporates a 0.2 micron filter.
- FLOLAN® Sterile Diluent and reconstituted FLOLAN® should be inspected for visible particles prior to use. Product containing visible particles should not be used

GlaxoSmithKline has sent a letter to healthcare professionals informing them of this safety information. A copy of that letter will be available on the Health Canada Website.

GlaxoSmithKline continues to search for improvements in the manufacturing process of the Sterile Diluent for FLOLAN® so that no vials will contain glass particles. Since the continued availability of this product is medically necessary for patients who require FLOLAN®, the use of a filter with the administration is essential for these patients.

For media inquiries, please contact GlaxoSmithKline Communications at (905) 819-3363.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any serious or unexpected side effects in patients receiving FLOLAN® should be reported to GlaxoSmithKline Inc. or Health Canada.

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You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, please contact Health Canada at:
Health Products and Food Branch Inspectorate
E-mail: DCVIU_UVECM@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

Sincerely,

Dr. Glenn Crater,
Vice-President, Medical and Chief Medical Officer
GlaxoSmithKline Inc.