Public Communication -
Health Canada Endorsed Important Safety Information for tablets and suppository formulations of diclofenac-containing medicines including VOLTAREN® / VOLTAREN® SR (diclofenac sodium), VOLTAREN RAPIDE® (diclofenac potassium), ARTHROTEC® (diclofenac sodium/misoprostol)

October 6, 2014

Subject: **Update to heart and stroke related safety information and decrease in the maximum recommended daily dose for tablets and suppository formulations of diclofenac-containing medicines including VOLTAREN®/VOLTAREN® SR (diclofenac sodium), VOLTAREN RAPIDE® (diclofenac potassium), ARTHROTEC® (diclofenac sodium/misoprostol).**

Novartis Pharma Canada Inc. ("Novartis Canada") and Pfizer Canada Inc. ("Pfizer Canada"), in collaboration with Health Canada, would like to inform you about safety and dosing information for diclofenac-containing tablets or suppositories, which include VOLTAREN/VOLTAREN SR (diclofenac sodium), VOLTAREN RAPIDE (diclofenac potassium), ARTHROTEC (diclofenac sodium/misoprostol) and other diclofenac containing tablets or suppositories. Diclofenac is a medicine used for relieving pain and inflammation.

This safety update does not refer to topical formulations of diclofenac, such as gel or eye drops.

Patients should be aware of the following safety labelling information:

- Diclofenac tablets and suppositories, particularly at high dose (150 milligrams (mg) per day) are associated with an increased risk of a heart attack or stroke.
- Treatment with diclofenac tablets and suppositories is not recommended in patients with a history of, or risk factors for heart disease, stroke or uncontrolled high blood pressure.
- The recommended maximum daily dose is now 100 milligrams (mg) per day. Please contact your health care professional if your current dose of diclofenac tablets and suppositories is more than 100 mg per day.

As recommended in the Product Monograph, it is important to take the lowest dose of *diclofenac* that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk of side effects on the heart and blood vessels as small as possible.

Use of NSAID such as diclofenac tablets and suppositories (including VOLTAREN SR, VOLTAREN RAPIDE or ARTHROTEC) can result in increased blood pressure and/ or worsening of congestive heart failure.

If, at any time while taking any of these products you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, you should contact your healthcare professional immediately.

It is important to take these medicines as directed by your health care professional. You should not take more of it, take it more often or take it for a longer period of time than recommended by your health care provider.

A Health Professional Communication to inform your healthcare professional of this new safety information has also been posted on Novartis Canada, Pfizer Canada and Health Canada websites. To see this communication, please visit www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php.

The Product Monographs for diclofenac-containing systemic medicines, including the *Health Professional Information* which is the reference document that healthcare professionals use when prescribing medications and the *Consumer Information*, have been revised.

Please refer to the VOLTAREN / VOLTAREN SR and VOLTAREN RAPIDE Product Monographs at the following link for complete details:
http://www.novartis.ca/en/products/pharmaceuticals/index.shtml

Please refer to the ARTHROTEC Product Monographs at the following link for complete details:
http://www.pfizer.ca/en/our_products/

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious or unexpected adverse reactions in patients receiving tablets and suppositories of VOLTAREN / VOLTAREN SR (diclofenac sodium), or VOLTAREN RAPIDE (diclofenac potassium), ARTHROTEC (diclofenac sodium/misoprostol) and the generic versions of diclofenac-containing tablets and suppositories should be reported to Novartis Canada, Pfizer Canada, the appropriate generic company or Health Canada.

Contact information for manufacturer of VOLTAREN / VOLTAREN SR and VOLTAREN RAPIDE
Novartis Pharma Canada Inc.
385 Bouchard Blvd., Dorval, (QC) H9S 1A9
Phone: 1-800-363-8883 (Medical Information)

Contact information for manufacturer of ARTHROTEC
Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5
Telephone: 1-800-463-6001

Health Canada contact
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, contact Health Canada at:

Marketed Health Products Directorate
E-mail: mhpd_dpsc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Original signed by

Jean Godin, M.D.
Vice-President and Chief, Scientific Affairs
Novartis Pharma Canada Inc.

Vratislav Hadrava M.D., Ph.D.
Vice-President and Medical Director
Pfizer Canada Inc.