Important Safety Information on BEXTRA* (valdecoxib) tablets, A Selective Cyclo-oxygenase-2 (COX-2) Inhibitor Non-Steroidal Anti-Inflammatory Drug (NSAID)

21 April 2005

Subject: BEXTRA* (valdecoxib) tablets
Serious Adverse Drug Reactions

Dear Healthcare Professional,

On 7 April 2005, Pfizer Canada Inc., following discussions with Health Canada, agreed to voluntarily suspend the sale and marketing of BEXTRA (valdecoxib) tablets in Canada pending the submission of BEXTRA's benefit/risk assessment. Health Canada's request to suspend the sale of BEXTRA is based on the risk of serious, potentially life threatening skin reactions associated with BEXTRA and its ongoing cardiovascular safety assessment of COX-2 inhibitors. Satisfactory safety evidence will need to be established with respect to the review of cardiovascular, gastro-intestinal and rare, but potentially life-threatening skin reactions events (Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), erythema multiforme).

As a further precautionary measure, and pending finalization of Health Canada's ongoing cardiovascular safety assessment of COX-2 inhibitors, on 8 April 2005 Pfizer Canada Inc. proceeded with a voluntary recall of all lots of BEXTRA (valdecoxib) oral tablets, 10 mg and 20 mg on the Canadian market.

Pfizer has also agreed to similar suspension of BEXTRA sales and marketing activities in the United States at the request of the Food and Drug Administration and in Europe at the request of the European Medicines Agency (EMEA). Furthermore, in the U.S., on 7 April 2005, FDA announced a series of important changes pertaining to the labeling and marketing of the NSAID group of drugs including COX-2 inhibitors.

Advice to Health Care Professionals

Prescribers are advised:

- Not to initiate treatment of new patients
- To switch patients to alternative therapy where appropriate

Pharmacists are advised:

- Not to dispense further prescriptions for BEXTRA
- To advise patients taking BEXTRA to return to their physicians to discuss discontinuing their current treatment with BEXTRA medication and to discuss alternative therapies.

After having consulted with a physician, consumers should return the product to their pharmacy. In order to avoid contaminating ground or municipal water systems, the product should not be flushed down the toilet or sink.

Health Canada is conducting an ongoing cardiovascular safety review of the COX-2 selective NSAIDs. Safety updates were recently communicated to healthcare professionals on the cardiovascular safety and warnings on serious skin reactions associated with BEXTRA as follows:

- On 10 December 2004, contraindications for patients undergoing CABG surgery and additional information and warnings on the occurrence of serious skin reactions were introduced (Dear Healthcare Professional Letter: http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/bextra2_hpc_e.html).

- This previous letter to health professionals outlined specific concerns regarding safety issues for patients undergoing coronary artery bypass graft (CABG) surgery, patients using BEXTRA in any peri- and/or post-operative settings, and serious skin reactions associated with BEXTRA, and advised caution in prescribing BEXTRA to patients with a history or risk of cardiovascular disease.

- BEXTRA received market authorization in Canada in December 2002, as a selective COX-2 inhibitor, indicated for the symptomatic treatment of osteoarthritis, rheumatoid arthritis and primary dysmenorrhoea.

- The original Product Monograph included information regarding the occurrence of rare cases of serious skin reactions and cases of hypersensitivity reactions in patients with or without a history of allergic-type reaction to sulfonamides. A Dear Healthcare Professional Communication was also issued upon introduction of BEXTRA on the Canadian market in order to advise healthcare profesionnals of the occurrence of rare cases of serious skin reactions and cases of hypersensitivity reactions in patients with and without a history of allergic-type reactions to sulfonamides (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/bextra_e.html).

Pfizer is continuing to monitor the safety of the COX-2 selective NSAIDs, and will review all new data as it becomes available and continue its dialogue with Health Canada. Pfizer will explore options under which the company might be permitted to resume making BEXTRA available to physicians and patients.

Health Canada continues to evaluate the safety of all COX-2 selective NSAIDs in light of recent concerns regarding cardiovascular risk associated with the use of these agents.

The identification, characterization, and management of drug-related adverse events are dependent on the active participation of health care professionals in adverse drug reaction reporting programmes. Healthcare professionals are asked to report any suspected adverse reactions in patients receiving BEXTRA* to the following addresses:

Pfizer Canada Inc.
Drug Safety
P.O. Box 800
Pointe-Claire- Dorval, Quebec
H9R 4V2
1 800 463-6001

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
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
cadrmp@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/hpfb-dgpsa/tpd-dpt/adverse_e.html>
<http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html>

Your professional commitment in this regard has an important role in protecting the well-being of your patients by contributing to early signal detection and informed use of drugs.

If you require any further information on BEXTRA please contact Pfizer Medical Information at 1-800-463-6001.

Sincerely,

Bernard Prigent, M.D.
Vice-President and Medical Director
Pfizer Canada Inc.

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