Important Safety Information on
CELEBREX *(celecoxib) capsules,
A Selective Cyclo-oxygenase-2 (COX-2) Inhibitor Non-Steroidal Anti-Inflammatory Drug (NSAID)

20 December 2004

Subject: **CELEBREX* (celecoxib) capsules**
Important Safety Information

Dear Healthcare Professional,

Pfizer Canada Inc., following discussions with Health Canada, would like to inform you of important new safety information for CELEBREX* (celecoxib) capsules

On December 16, 2004, Pfizer, Inc. received new information related to the cardiovascular safety of its COX –2 inhibitor Celebrex (celecoxib). This new information is based on an analysis of two long-term colon cancer prevention trials.

The Data Safety Monitoring Board reviewing these studies informed Pfizer that their review indicated one of the studies (the Adenoma Prevention with Celecoxib [APC] cancer prevention trial) demonstrated an increased cardiovascular risk when compared to placebo, while the other trial (the PreSAP cancer prevention trial) revealed no greater cardiovascular risk than placebo.

In the Adenoma Prevention with Celecoxib (APC) trial, patients taking 400mg and 800mg of CELEBREX daily had an approximately 2.5 and 3.4 fold increase, respectively, in their risk of experiencing a major fatal or non-fatal cardiovascular event compared to those patients taking placebo, according to the National Cancer Institute (NCI).

The information from these trials was received by Pfizer on the night of 16 December 2004 has been shared by the company with Health Canada, the U.S. FDA, as well as the EMEA.

Based on the statistically significant findings associated with the APC trial:

- **Dosing of CELEBREX has been suspended in both trials.** At this time, Pfizer does not have detailed access to the actual data and analyses upon which the decision of the Data Safety Monitoring Board have been based. Pfizer expects to receive these data shortly. Pfizer is taking immediate steps to fully understand the results and rapidly communicate new information to regulators, physicians and patients.

- **Health Canada has suspended the market authorization (Notice of Compliance with Conditions) for the use of CELEBREX to reduce the number of adenomatous colorectal polyps in patients with Familial Adenomatous Polyposis (FAP) for reasons related to safety as noted above.**

Pfizer therefore requests that physicians immediately contact all patients currently using CELEBREX in FAP and advise them to immediately discontinue the medication. Physicians should continue to observe these patients according to standard medical practice.

Physicians should consider this evolving information in evaluating the risks and benefits of CELEBREX in individual patients treated for OA, RA or acute pain. Factors to be considered include: this new information concerning long-term use; the existing body of data which currently exists for CELEBREX; and the risk of gastrointestinal ulcers and bleeding.

Additional information will be made available publicly as soon as possible.

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 CELEBREX* 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 CELEBREX* (celecoxib) 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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