Health Canada Endorsed Important Safety Information on DEPO-PROVERA* (medroxyprogesterone acetate)

November 18, 2004

Subject: **Important Safety Update: Potential Effect of DEPO-PROVERA* (medroxyprogesterone acetate) on Bone Mineral Density (BMD) changes in adults and adolescents**

Dear Health Care Professional,

Pfizer Canada Inc. would like to inform you of important updated safety information, currently under evaluation by Health Canada for DEPO-PROVERA (medroxyprogesterone acetate suspension for injection) indicated for the prevention of pregnancy in women of child-bearing potential and treatment of endometriosis. As a result of new clinical studies, one with adults and one with adolescents, we now have clinical data regarding the use of Depo-Provera and its associated effect on bone mineral density (BMD). The data suggest that women who use DEPO-PROVERA Contraceptive Injection may lose significant BMD. Bone loss is greater with increasing duration and may not be completely reversible. It is unknown if use of DEPO-PROVERA during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture in later life.

Pfizer is currently working in collaboration with Health Canada to revise the Product Monograph. The proposed update to the DEPO-PROVERA labeling will affect the following section:

• **INDICATIONS and CLINICAL USE**: Addition of a Risk-Benefit statement stating that loss of BMD in women of all ages, and the impact on peak bone mass in adolescents, should be considered, along with the decrease in BMD that occurs during pregnancy and/or lactation, for women who use Depo-Provera long term

• **WARNINGS**: Addition of statements regarding loss of bone mineral density in adults and adolescents females

• **DOSAGE AND ADMINISTRATION**: Addition of a cautionary statement about the use of DEPO-PROVERA Contraceptive Injection in adolescence and early adulthood

• **ADVERSE REACTIONS**: Addition of a statement based on post-marketing experience regarding rare cases of osteoporosis including osteoporotic fractures reported

Patient information labeling is also being updated to reflect the BMD results from the above studies. The proposed revised text is also under evaluation by Health Canada.

We are committed to working with Health Canada towards ensuring that DEPOPROVERA is used safely and effectively and to working in collaboration with you for the safety and well being of all patients receiving Depo-Provera. Should you have any questions, please contact Pfizer Canada's **Medical Information at 1 800 463-6001**. Further communications will be issued as soon as the product Monograph discussions are finalized with Health Canada.

Sincerely,

original signed by

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

The identification, characterization, and management of marketed health product-related adverse reactions are dependent on the active participation of health care professionals in adverse reaction reporting programmes. Any occurrences of serious and/or unexpected adverse reactions in patients receiving DEPO-PROVERA* (medroxyprogesterone acetate) should be reported to Pfizer Canada Inc. or Health Canada at the following addresses:

Pfizer Canada Inc.
P.O. Box 800 / C.P. 800
Pointe Claire / Dorval (Québec)
Tél: (514) 695-0500
Fax/Téléc: (514) 693-4118

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

For other inquiries: please refer to contact information.

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