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Pfizer Canada Inc.

IMPORTANT COMMUNICATION TO PRESCRIBERS

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 Healthcare 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

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- **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 DEPO-PROVERA 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,

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