**Public Communication -**
**Health Canada-Endorsed Important Safety Information on ZITHROMAX®/ZMAX SR® (azithromycin)**

May 16, 2013

**Subject: ZITHROMAX® /ZMAX SR® (azithromycin) and the Risk of potentially Fatal Irregular Heart Beats**

Pfizer Canada Inc., in collaboration with Health Canada, would like to inform you of additional safety information regarding the risk of potentially fatal irregular heartbeats with the two marketed medicines ZITHROMAX and ZMAX SR.

Both ZITHROMAX and ZMAX SR contain azithromycin, an antibiotic used to treat many types of infections. The consumer information document for both medicines now includes additional information regarding the risk of this specific, rare heart beat abnormality. This risk mainly affects patients who are at a higher baseline risk for cardiovascular events.

Before you use Zithromax/Zmax SR, talk to your doctor or pharmacist if:

- you have a known prolonged heart cycle (interval) (QT prolongation);
- you are currently taking medication known to prolong QT interval (prolong the heart cycle) such as antiarrhythmics (drugs to regulate the heart beat such as class IA: quinidine, procainamide and class III; dofetilide, amiodarone, sotalol); antipsychotic agents; antidepressants; and fluoroquinolones (a class of antibiotics);
- you have constantly low levels of potassium or magnesium;
- you have a history for heart problems such as bradycardia (slow heart rate), cardiac arrhythmia (irregular heart beat) or cardiac insufficiency (the heart has a hard time pumping blood to your body).

These conditions may put you at an increased risk of having irregular heartbeats associated with this medicine.

A small increase in the risk of cardiac deaths was observed in a recent study by Ray et al.[1] in patients taking azithromycin. Information regarding risk factors for irregular heartbeats was included in the consumer information document.

Pfizer is committed to patient safety and, as with all Pfizer products; the safety profile of azithromycin is continually monitored.

Patients who are currently prescribed ZITHROMAX or ZMAX SR should talk to their doctors or healthcare providers if they have questions regarding their treatment.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious side effects involving a heart rhythm abnormality or other serious or unexpected side effects in patients receiving ZITHROMAX/ZMAX SR should be reported to Pfizer Canada Inc. or Health Canada.

If you have an inquiry of a medical nature related to ZITHROMAX and ZMAX SR, please contact our Medical Information Services as per the contact information below.

Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5
1-800-463-6001.

This notice can be found on Pfizer Canada's website: www.pfizer.ca

You can report any suspected side effect 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@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

***Original signed by***

Bernard Prigent, MD, MBA
Vice-President and Medical Director
Pfizer Canada Inc.

***References:***

1. Ray WA, Murray KT, Hall K, Arbogast PG, Stein CM. Azithromycin and the Risk of Cardiovascular Death. The New England Journal of Medicine 2012;366:1881-90.