PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on Fluoroquinolone antibiotics (AVELOX®, CIPRO®, CIPRO® XL, and LEVAQUIN®)

Bayer HealthCare

janssen PHARMACEUTICAL COMPANIES OF Johnson&Johnson

March 14, 2012

Subject: **Association of fluoroquinolone antibiotics (AVELOX®, CIPRO®, CIPRO® XL, and LEVAQUIN®) with worsening of symptoms of myasthenia gravis in patients with myasthenia gravis**

The manufacturers of the fluoroquinolone antibiotics (Bayer Inc. and Janssen Inc.) in consultation with Health Canada would like to inform you of important updates to the labelling for fluoroquinolone antibiotics (AVELOX®, CIPRO®, CIPRO® XL, and LEVAQUIN®).

Fluoroquinolone antibiotics are a class of prescription drugs used to treat certain types of bacterial infections in adults, such as respiratory tract infections, skin infections and urinary tract infections.

Healthcare professionals, patients and their caregivers should be aware of the following information:

- Patients should tell their healthcare provider about all their medical conditions, including myasthenia gravis.
- Worsening of myasthenia gravis symptoms can present as muscle weakness or breathing problems.
- Fluoroquinolone antibiotics should be avoided in patients with a known history of myasthenia gravis.

Exacerbation of symptoms of myasthenia gravis was already included as an undesirable effect in earlier versions of the Product Monographs of Avelox®, Cipro®, Cipro® XL and LEVAQUIN®. To reinforce the warning, the Canadian Product Monographs (PMs) for the fluoroquinolone antibiotics have been updated in January 2012 to reflect potential for worsening of symptoms of myasthenia gravis in patients with myasthenia gravis. The corresponding generic Product Monographs are in the process of being updated to reflect these warnings. Myasthenia gravis is a rare, chronic (long-lasting and recurring) disease that causes progressive muscle weakness. Activity makes the muscle weakness worse, and symptoms generally improve with rest.

Managing marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally

presumed to underestimate the risks associated with health product treatments. Any case of worsening of myasthenia gravis in patients with myasthenia gravis or other serious or unexpected adverse reactions in patients receiving fluoroquinolone antibiotics should be reported to the manufacturer (Bayer Inc. or Janssen Inc.) or Health Canada.

For AVELOX®, CIPRO® and CIPRO® XL:
Bayer Inc.
77 Belfield Road
Toronto, Ontario
M9W 1G6
Toll-free telephone: 1-800-265-7382
E-mail: Canada.medinfo@bayer.com

For LEVAQUIN®:
Janssen Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9
Toll free at telephone: 1-866-825-7122
E-mail to dsscan@joica.jnj.com
Fax to 1-866-767-5865

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

For other health product inquiries related to this communication, please 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,

Shurjeel Choudhri, MD FRCPC
Senior Vice President & Head,
Medical & Scientific Affairs
Bayer HealthCare Pharmaceuticals

Cathy Lau, PhD.
Vice President,
Regulatory and Quality
Janssen Inc.