Bayer HealthCare
Pharmaceuticals

Health Canada Endorsed Important Safety Information on MIRENA®

June 15, 2010

Dear Health Care Professional,

Subject: **Association of MIRENA® (Levonorgestrel-releasing Intrauterine System) with the potential risk of uterine perforation**

Bayer Inc., in collaboration with Health Canada, would like to remind you of important safety information regarding reports of uterine perforation in women treated with MIRENA®. MIRENA® is approved for conception control up to a maximum of 5 years and for treatment of idiopathic menorrhagia following appropriate diagnostic investigation in women accepting the contraceptive effect of MIRENA®.

Uterine perforation is a rare, but serious complication associated with intrauterine contraceptive devices, and occurs at a rate between 1/1,000 and 1/10,000 insertions. Bayer Inc. continues to receive post-market reports of uterine perforation associated with the use of MIRENA®. Some cases of uterine perforation were not detected during or immediately after the insertion. The risk of perforation may be increased with use in the post-partum period, during lactation, and in women with an atypical uterine anatomy (such as fixed retroverted uterus). Uterine perforation may occur with MIRENA® at the time of insertion or after the insertion with limited clinical symptoms. In order to minimize the risk of complications associated with the use of MIRENA®, Health Care Professionals are encouraged to:

- Ensure they are familiar with and/or trained on the correct insertion technique for MIRENA®, and carefully review the insertion instructions included in the labelling.
- Consider performing ultrasound or X-ray imaging in case of a difficult insertion, if patients complain of pain, or if there is suspicion that the system may not be correctly positioned.
- Follow up patients 4 to 12 weeks after insertion, and once a year thereafter or more frequently, as required.
- Inform patients before the procedure about the risk of uterine perforation, especially in the post-partum period and during lactation, and educate them on possible signs of this complication, including, but not limited to: severe low abdominal pain, which may be associated with bleeding after the procedure. Advise the patient how to self-check the removal threads of MIRENA®.

The reporting rate of uterine perforation with MIRENA® has remained stable in Canada since 2001, however the absolute number of incident reports has increased in accordance with the increased use. Bayer continues to emphasize the importance of training healthcare professionals on the correct insertion technique for MIRENA®, and of patient follow-up.

Bayer Inc., in collaboration with Health Canada, issued a letter to patients informing them of this important safety information. A copy of that letter is available on the Health Canada web site (http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/_2010/index-eng.php).

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For additional information on educational material for healthcare professionals and patients, please refer to the Bayer website at http://www.bayer.ca/?q=en/node/62. The current Canadian Product Monograph (May 11, 2010) includes this safety information as well as guidance to prevent uterine perforation.

Managing marketed health product-related adverse reactions depends on health care 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 uterine perforation or other serious or unexpected adverse reactions in patients receiving MIRENA® should be reported to Bayer Inc. or Health Canada at the following addresses:

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

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
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
CanadaVigilance@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/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Tel: 613-954-6522
Fax: 613-952-7738

Sincerely,

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

References:

1. MIRENA Product Monograph, May 11, 2010.