

## Report on New Patented Drugs - Gardasil

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's *Excessive Price Guidelines* (Guidelines) for all new active substances introduced after January 1, 2002.

**Brand Name:** Gardasil

**Generic Name:** (*quadrivalent human papillomavirus recombinant vaccine*)

**DIN:** 02283190 (0.5 mL dose)

**Patentee:** Merck Frosst Canada Ltd.

### Indication - as per product monograph:

Vaccine indicated in girls and women 9-26 years of age for the prevention of infection caused by Human Papillomavirus (HPV) types 6, 11, 16 and 18 and for the prevention of the following diseases associated with these HPV types: Cervical cancer, vulvar and vaginal cancer, genital warts (condyloma acuminata), cervical adenocarcinoma in *situ* (AIS), cervical intraepithelial neoplasia (CIN) grade 2 and grade 3, vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3, vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3, and cervical intraepithelial neoplasia (CIN) grade 1.

### Date of Issuance of First Patent(s)

**Pertaining to the Medicine:** September 20, 2005

**Notice of Compliance:** July 10, 2006

**Date of First Sale:** August 16, 2006

**ATC Class:** J07BM01  
Antiinfectives for Systemic Use; Vaccines; Viral Vaccines; Papillomavirus Vaccines

## APPLICATION OF THE GUIDELINES

### Summary

The introductory price of Gardasil was found to be within the Guidelines because the price in Canada did not exceed the median of the prices of the same drug in those countries listed in the *Patented Medicines Regulations, 1994* (Regulations) in which Gardasil was sold.

## Scientific Review

Gardasil is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Gardasil be classified as a category 2 new medicine. It is a breakthrough medicine as it is the first drug product sold in Canada that addresses effectively both the prevention of infections with HPV types 6, 11, 16 and 18 and the associated precancerous cervical, and external genital lesions.

The HDAP did not identify any comparators for Gardasil. There is no drug therapy or vaccine indicated or used for the prevention of HPV and its associated precancerous lesions.

## Price Review

Under the Guidelines, the introductory price of a new category 2 drug product will be presumed to be excessive if it exceeds the prices of all comparable drug products, based on a Therapeutic Class Comparison (TCC) test, and the median of the international prices identified in an International Price Comparison (IPC) test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines.

It was not possible to conduct a TCC test as the HDAP did not identify any comparator drug products. At introduction, the price of Gardasil was within the Guidelines as it did not exceed the median of the international prices identified in an IPC test.

### Introductory Period (August to December 2006)

Country	Price per Dose (CDN)
Canada	\$134.8894
France	\$170.4902
Germany	\$183.5870
Italy	n/a
Sweden	\$177.2312
Switzerland	\$187.7860
United Kingdom	\$181.8804
United States	\$152.1041
International Median	\$179.5558

Sources: Publicly available prices as per the *Regulations*

*Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the PMPRB Staff and the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.*

*The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.*

## References - Gardasil

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