October 2006

Report on New Patented Drugs - Fuzeon

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: Fuzeon

Generic Name: *(enfuvirtide)*

DIN: 02247725 3 mL/vial

Patentee: Hoffmann-LaRoche Limited

Indication - as per product monograph:

For the treatment of HIV-1 infection in antiretroviral experienced patients or patients with resistant virus.

Notice of Compliance: July 14, 2003

Date of First Sale: August 2003

Date of Issuance of First Patent(s) Pertaining to the Medicine: March 14, 2006

ATC Class: J05AX07
Antivirals for Systemic Use, Direct Acting Antivirals, Other Antivirals

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Fuzeon was found to be within the Guidelines in the introductory period (August to December 2003), as the price in Canada did not exceed the median of the prices of the same drug product in those countries listed in the *Patented Medicines Regulations* (Regulations) in which it was sold by an amount sufficient to trigger any of the investigation criteria under the *Compliance & Enforcement Policy.*

For information on the Criteria for Commencing an Investigation, please see Schedule 5 of the *Compendium of Guidelines, Policies and Procedures*, as posted on our Web site under Legislation, Regulations and Guidelines.

Scientific Review

Fuzeon is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Fuzeon be reviewed as a category 2 new medicine (provides a breakthrough or substantial improvement). Enfuvirtide represented the first drug of a new class of antiretroviral agents (fusion inhibitors) to be marketed in Canada.

The HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

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 of the comparable drug products based on a TCC test, and the median of the international prices identified in an International Price Comparison (IPC) test.

As no comparable drug products could be identified for purposes of conducting a TCC test, the introductory price of Fuzeon was considered within the Guidelines as it did not exceed the median of the international prices identified in the IPC test by an amount that triggered the investigation criteria. Fuzeon was sold in six of the seven countries listed in the Regulations.

Introductory period (August to December 2003)

Country	Price per vial (CDN$)
Canada	$39.7600
France	$37.1614
Germany	$39.3053
Sweden	$38.8904
Switzerland	$38.3194
United Kingdom	$45.5822
United States	$37.6958
International Median	$38.6049

Source: Publicly available prices as per the *Patented Medicines 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 – Fuzeon

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