

Report on New Patented Drugs - RotaTeq

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: RotaTeq
Generic Name: (*rotavirus vaccine, live, oral, pentavalent*)
DIN: 02284413 (2 mL / vial)
Patentee: Merck Frosst Canada Ltd.

Indication - as per product monograph:

For the prevention of rotavirus gastroenteritis caused by the serotypes G1, G2, G3, G4, and G-serotypes that contain P1[8] when administered to infants.

Date of Issuance of First Patent(s)

Pertaining to the Medicine: February 12, 2002

Notice of Compliance: August 1, 2006

Date of First Sale: October 16, 2006

ATC Class: J07BH01
Antiinfectives for Systemic Use; Vaccines; Viral Vaccines; Rotavirus diarrhea vaccines: Rotavirus, live, attenuated.

APPLICATION OF THE GUIDELINES

Summary

The introductory price of RotaTeq was found to be within the Guidelines because 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, 1994* (Regulations) in which RotaTeq was sold.

Scientific Review

RotaTeq is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that RotaTeq be classified as a category 2 new medicine. It is a breakthrough medicine as it is the first vaccine sold in Canada that prevents severe rotavirus gastroenteritis in children, a serious public health issue. RotaTeq also has a reassuring safety profile with respect to intussusception.

The HDAP did not identify any comparators for RotaTeq. There is no drug therapy or vaccine indicated or used for the prevention of human rotavirus infection.

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 price of all of the comparable drug products, based on a Therapeutic Class Comparison (TCC) test and if the price exceeds 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 RotaTeq was within the Guidelines as it did not exceed the median of international prices identified in an IPC test.

Introductory Period (October to December 2006)

Country	Price per mL (CDN)
Canada	\$27.5000
France	\$30.7957
Germany	\$32.3355
Italy	n/a
Sweden	n/a
Switzerland	n/a
United Kingdom	n/a
United States	\$40.3117
International Median	\$32.3355

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 - RotaTeq

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