Report on New Patented Drugs – Alertec

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Under its transparency initiative, the Board publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's Price Guidelines for all new active substances introduced after January 1, 2002. The Board also reserves the ability to publish additional reports if warranted.

Brand Name:	Alertec
Generic Name:	Alertec (modafinil)
DIN:	02239665 100mg tablet
Patentee:	Draxis Health
Indication (as per product monograph):	For the symptomatic treatment of excessive daytime sleepiness in patients with narcolepsy
Notice of Compliance:	February 26, 1999
Date of First Sale:	May 1999
Date of First Patented Sale:	December 10, 2002
ATC Class:	N06BA07 *Psychostimulants and Nootropics* *Centrally acting sympathomimetics*

Application of the Guidelines

Summary:

The introductory price of Alertec was found to be within the Guidelines because the price in Canada did not exceed the median of the international prices identified in an International Price Comparison (IPC) Test. The Canadian price was and continues to be less than half the lowest international price. Although Alertec has been sold in Canada since 1999, it only came under the PMPRB's jurisdiction with the issuance of the first patent on December 10, 2002.

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The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the Anatomical, Therapeutic, Chemical (ATC) System that are clinically equivalent in addressing the approved indication. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

Scientific Review:

Alertec is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Alertec (modafinil) be reviewed as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

Other agents in the same 4th level ATC class available on the Canadian market, include dextroamphetamine (Dexedrine spansules) and methylphenidate (Ritalin and Ritalin SR). Dextroamphetamine and methylphenidate are indicated both for the treatment of narcolepsy and ADHD, whereas modafinil is indicated solely for the treatment of narcolepsy. The American Academy of Sleep Medicine published updated guidelines for the treatment of narcolepsy in 2000. This publication included modafinil, methylphenidate, and dextroamphetamine in their practice parameters.

Narcolepsy is not a common disease with population estimates ranging between 10 to 26 per 100,000 people (Finnish and US data). ADHD represents a larger patient population, approximately 5 % of children, with 18-30 % of these children carrying the disease to adulthood.

The HDAP recommended that Dexedrine spansules (dextroamphetamine), Ritalin (methylphenidate) and Ritalin SR (methylphenidate) be included in the TCC.

The PMPRB's Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for modafinil and the comparators are based on their respective product monographs and supported by clinical literature. See table in price test section below.

Price Review:

Under the Guidelines, the introductory price for a new category 3 drug product will be presumed to be excessive if it exceeds the price of all of the comparable drug products based on the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*. The Guidelines further state that when it is inappropriate or impossible to conduct a TCC Test, the Board will give primary weight to the median of the

international prices identified in an IPC Test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines.

As shown in Table 1, the cost of treatment of Alertec is significantly higher than the cost of its comparators. However, it was considered inappropriate to rely on the TCC in this instance for a number of reasons. The comparators are older drugs and, although used in the treatment of nacolepsy, are not primarily used for this indication. The Canadian price of $1.2000 per tablet was and still is less than half the lowest international price. At the time of its introduction in Canada in 1999, Alertec was only available in three countries, France, Germany and the U.K. The lowest international price was Germany at $3.1624. When Alertec became patented in December 2002, it was sold in all seven comparator countries. The lowest international price at that time was Switzerland at $2.4201.

Under the circumstances, primary weight was given to the median IPC Test. The Canadian price of Alertec was found to be within the Guidelines as it did not exceed the median of the prices for the same drug in those countries in which it was being sold.

Table 1

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
Alertec	100 mg/tablet	400 mg	$1.2000/tab	$4.8000
Ritalin	20 mg tablet	60 mg	$0.4420/tab	$1.3260
Ritalin SR	20 mg tablet	60 mg	$0.4806/tab	$1.4418
Dexedrine	15 mg capsule	60 mg	$0.4836/cap	$1.9344
pms-methylphenidate	20 mg	60 mg	$0.3536	$1.0608
Ratio-methylphenidate	20 mg	60 mg	$0.3536	$1.0608
Phl-methylphenidate	20 mg	60 mg	$0.3536	$1.0608

Source: Liste de médicaments du Québec, October 2003

Table 2

Country	Price per tablet/capsule (Can$)
Canada	$1.2000
Germany	$2.8321
France	$3.7277
Italy	$3.0344
Sweden	$3.8725
Switzerland	$5.5946
United Kingdom	$4.3060
United States (incl. FSS)	$5.3794
International Median	$3.8725

Sources: Canada: Liste de médicaments du Québec, October 2003
Germany: Rote Liste, December 2002
France: Sempex, December 2002
Italy: L'informatore farmaceutico, December 2002
Sweden: Prislista, December 2002
Switzerland: Medwin, December 002
United Kingdom: Mims, December 2002
United States: Average prices of US Red Book, December 2002 and prices available on the US Department of Veterans Affairs website.

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. ■

Evidence/ References:

The references are available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs; Alertec.

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