September 2006

Report on New Patented Drugs - Reyataz

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 in Canada after January 1, 2002.

Brand Name: Reyataz

Generic Name: *(atazanavir sulfate)*

DIN: 02248610 150 mg capsule
02248611 200 mg capsule

Patentee: Bristol-Myers Squibb Canada Inc.

Indication - as per product monograph:

In combination with other antiretroviral agents for the treatment of HIV-1 infection.

Notice of Compliance: December 5, 2003

Date of First Sale: January 9, 2004

Date of Issuance of First Patent(s) Pertaining to the Medicine:

November 2, 2004

ATC Class: J05AE08
Antiinfectives for systemic use, Antiviral for systemic use, Direct acting antivirals, Protease inhibitors

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Reyataz were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing comparable medicines in the therapeutic class comparison or did not do so by an amount sufficient to trigger the investigation criteria under the Compliance and Enforcement Policy. Further, the prices of Reyataz did not exceed the range of prices in other comparator countries where Reyataz was sold.

Scientific Review

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

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 selection of the Guidelines and the policies on TCCs.

The HDAP identified Agenerase (*amprenavir*), Crixivan (*indinavir*), Fortovase (*saquinavir*), Invirase (*saquinavir*), Kaletra (*lopinavir/ritonavir*), and Viracept (*nelfinavir*) as comparable medicines for Reyataz. These medicines share the same 4th level ATC class and are indicated for the treatment of HIV-1 infection.

Since Reyataz has been studied with or without Norvir SEC (*ritonavir*) and is available in two dosage strengths, separate dosage regimens were recommended for the available strengths of Reyataz.

The 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 Reyataz 150 mg capsule with Norvir SEC and the comparators are based on the U.S. Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents for Treatment-experienced patients. The recommended comparable dosage regimens for Reyataz 200 mg capsule and the comparators are based on the approved monographs and the DHHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents for Treatment-naïve patients.

Price Review

Under the Guidelines, the introductory price of a new category 3 medicine will be presumed to be excessive if it exceeds the range of the prices of the comparable medicines in a TCC test, or if it exceeds the range of the prices of the same medicine sold in the countries listed in the *Patented Medicines Regulations (*Regulations*)* based on an International Price Comparison (IPC) test.

The introductory price of Reyataz 150 mg capsule exceeded the Guidelines as the daily cost of therapy exceeded the cost of therapy with the comparable

medicines but did not trigger the investigation criteria under the Compliance and Enforcement Policy[1].

Reyataz 150 mg capsule – Introductory Period (January to June 2004)

Name	Strength	Dosage Regimen	Unit Price[2]	Cost per Day
Reyataz and Norvir SEC	150 mg capsule and 100 mg capsule	2 capsules and 1 capsule	$9.9000 and $1.3354	$21.1354
Agenerase and Norvir SEC	150 mg capsule and 100 mg capsule	8 capsules and 2 capsules	$ 1.9200 and $1.3354	$18.0308
Crixivan and Norvir SEC	400 mg capsule and 100 mg capsule	4 capsules and 2 capsules	$2.6933 and $1.3354	$13.4440
Crixivan and Norvir SEC	400 mg capsule and 100 mg capsule	4 capsules and 4 capsules	$2.6933 and $1.3354	$16.1148
Fortovase and Norvir SEC	200 mg capsule and 100 mg capsule	4 capsules and 8 capsules	$1.0200 and $1.3354	$14.7632
Fortovase and Norvir SEC	200 mg capsule and 100 mg capsule	10 capsules and 2 capsules	$1.0200 and $1.3354	$12.8708
Invirase and Norvir SEC	200 mg capsule and 100 mg capsule	4 capsules and 8 capsules	$1.8200 and $1.3354	$17.9632
Invirase and Norvir SEC	200 mg capsule and 100 mg capsule	10 capsules and 2 capsules	$1.8200 and $1.3354	$20.8708
Kaletra	133.3 mg capsule and 33.3 mg capsule	6 capsules	$3.2944	$19.7664

Note 1: The unit price of Reyataz 150 mg capsule and the comparable drug products are derived from the Ontario Drug Benefit Formulary/Comparative Drug Index of January 30, 2003.

The introductory price of Reyataz 200 mg capsule was within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparable medicines.

Reyataz 200 mg capsule – Introductory Period (January to June 2004)

Name	Strength	Dosage Regimen	Unit Price[3]	Cost per Day
Reyataz	200 mg capsule	2 capsules	$9.9000	$19.8000
Crixivan and Norvir SEC	400 mg capsule and 100 mg capsule	4 capsules and 2 capsules	$2.6933 and $1.3354	$13.4440
Crixivan and Norvir SEC	400 mg capsule and 100 mg capsule	4 capsules and 4 capsules	$2.6933 and $1.3354	$16.1148
Fortovase and Norvir SEC	200 mg capsule and 100 mg capsule	4 capsules and 8 capsules	$1.0200 and $1.3354	$14.7632
Fortovase and Norvir SEC	200 mg capsule and 100 mg capsule	10 capsules and 2 capsules	$1.0200 and $1.3354	$12.8708

[1] Board Staff will commence an investigation into the price of a new patented drug product when any of the following criteria are met: (1) introductory price is 5% or more above the maximum non-excessive price; (2) excess revenues in the introductory period are $25,000.00 or more; or (3) complaints with significant evidence.

Invirase and Norvir SEC	200 mg capsule and 100 mg capsule	4 capsules and 8 capsules	$1.8200 and $1.3354	$17.9632
Invirase and Norvir SEC	200 mg capsule and 100 mg capsule	10 capsules and 2 capsules	$1.8200 and $1.3354	$20.8708
Kaletra	133.3 mg capsule and 33.3 mg capsule	6 capsules	$3.2944	$19.7664
Viracept	250 mg tablet	10 tablets	$1.8200	$18.2000

Note 2: The unit price of Reyataz 200 mg capsule and the comparable drug products are derived from the Ontario Drug Benefit Formulary/Comparative Drug Index of January 30, 2003.

In 2004, Reyataz 150 mg and 200 mg capsules were being sold in five of the seven countries listed in the Regulations, namely France, Germany, Sweden, United Kingdom, and the United States. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries. They were the lowest.

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 – Reyataz

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