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. However, the Board is not prevented from publishing the results of other reviews. In light of the interest expressed regarding the price review of Sustiva and Ziagen, as well as complaints received regarding their prices, here are the summary reviews of those two drug products which have recently been concluded.

Report on New Patented Drugs — Sustiva

Brand Name (generic):	SUSTIVA (*efavirenz*)
DIN:	02239886 50mg capsule 02239887 100mg capsule 02239888 200mg capsule
Patentee:	Bristol-Myers Squibb Pharmaceutical Group (previously Dupont Pharma)
Indication (as per product monograph):	For the treatment of HIV-1 infection in combination with other antiretroviral agents. This indication is based on analysis of plasma HIV-RNA levels and CD4 cell counts in controlled studies of up to 24 weeks duration.
Notice of Compliance:	March 19,1999
Date of First Sale:	March 1999 In most cases, patents are issued before the drugs come to market. In this case, the first patent pertaining to Sustiva was issued on August 28, 2001 and it came under the PMPRB's jurisdiction at that time.
ATC Class:	J05AG03 *Antiretrovirals for systemic use:* *non-nucleoside reverse transcriptase inhibitors (NNRTI)*

Application of the Guidelines

Summary:

The introductory prices of Sustiva at the date of first sale were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the prices did not exceed the range of prices in other comparator countries where Sustiva was sold. These prices continued to be within the Guidelines in 2001 when Sustiva came under the PMPRB's jurisdiction.

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Sustiva be reviewed 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. The Guidelines provide that it may, however, be appropriate to include products from other ATC classes if they are clinically equivalent for the appropriate indication to the drug product under review. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

Members of the same 4th level ATC class as Sustiva include Rescriptor (delavirdine) and Viramune (nevirapine).

Like other drugs for HIV infections, Sustiva is ordinarily used in combination with other drugs. The *Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents* maintained by the HIV/AIDS Treatment Information Service (ATIS) in the U.S. (published online: **http://www.hivatis.org/trtgdlns.html#Adult**) includes Sustiva, in combination with other drugs in the list of "strongly recommended" treatments including the non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs). The *British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy* (July 2001) identify Sustiva, PIs and NNRTIs to be used in combination with dual nucleoside reverse transcriptase inhibitors (NRTIs) background therapy.

In light of the evidence that Sustiva is used in combination with two NRTIs as an alternative to a PI-based regimen, other NNRTI-based regimens or a Ziagen-based regimen in patients with HIV, the HDAP recommended NNRTIs and PIs as appropriate TCC comparators for Sustiva.

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 maintenance adult daily dose identified in individual product monographs and supported by clinical literature was recommended for comparison purposes. 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, and if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicine Regulations, 1994*.

The following TCC was established for Sustiva 200 mg capsule. It should be noted that although Rescriptor and Agenerase would have been appropriate TCC comparators from the scientific perspective, they have not been included as these drug products were under review at the time of Sustiva's review. The exclusion of these drugs does not affect the outcome of the price review.

Name	Strength	Dosage Regimen	Unit Price[1]	Cost Per Day[2]
Sustiva (efavirenz)	200 mg capsule	600mg daily	$4.43	$13.29
Viramune (nevirapine)	200 mg tablet	200 mg twice daily	$4.65	$9.30
Crixivan (indinavir)	400 mg capsule	800 mg three times daily	$2.69	$16.14
Viracept (nelfinavir)	250 mg tablet	1250 mg twice daily	$1.82	$18.20
Norvir (ritonavir)	100 mg capsule	600 mg twice daily	$1.34	$16.08
Fortovase (saquinavir)	200 mg capsule	1200 mg three times daily	$1.02	$18.36
Ziagen (abacavir)	300 mg tablet	300 mg twice daily	$6.25	$12.50

1 Ontario Drug Benefit Formulary, 2001
2 This medication is administered on a chronic base, therefore the cost per day was used as the basis for cost comparison with the comparators.

A Reasonable Relationship Test was conducted for Sustiva 50 mg capsule and 100 mg capsule because these presentations of the medicine are intended for paediatric use and the comparators identified above are not approved for use in paediatric patients. The prices of Sustiva 50 mg ($1.11) and 100 mg ($2.22) were considered to be within the Guidelines because they bear a reasonable relationship to the price of Sustiva 200 mg. These prices appear in the Ontario Drug Benefit Formulary 2001.

The prices of all strengths of Sustiva did not exceed the price of the same drug products sold in Germany, Switzerland, the United Kingdom and the United States and therefore were determined to be within the Guidelines relative to the highest price component of the International Price Comparison Test. The Canadian prices of Sustiva were the lowest of these countries. ■

Evidence/ Reference considered by HDAP:

There are 17 references.

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