

VOLUNTARY COMPLIANCE UNDERTAKING
OF
BIOSYENT PHARMA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

- 1.1 Cysview (hexaminolevulinate hydrochloride) is an optical imaging agent indicated for use in the cryptoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy.
- 1.2 Health Canada issued a Notice of Compliance (NOC) for Cysview on January 23, 2015. BioSyent Pharma Inc. (BioSyent) began selling Cysview in Canada on November 26, 2015.
- 1.3 Canadian Patent No. 2,327,393 is the current Canadian patent that pertains to Cysview. The last patent pertaining to Cysview expires on April 22, 2019. BioSyent is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

- 2.1 The Human Drug Advisory Panel (HDAP) identified Cysview as a moderate improvement on primary factors.
- 2.2 At introduction, the National Average Transaction Price (N-ATP) of Cysview exceeded its Maximum Average Potential Price (MAPP) by an amount that triggered the investigation criteria. As of December 31, 2016 cumulative excess revenues totalled \$4,433.13 for Cysview.

3.0 Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by BioSyent that the price of Cysview is or was at any time since the date of first sale of the medicine excessive for purposes of the *Patent Act*.

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.



4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, BioSyent undertakes:

- 4.1. To agree that the National-Non-Excessive Average Prices (N-NEAPs) of Cysview are as follows:

| YEAR | NEAP |
|------|------------|
| 2015 | \$659.7069 |
| 2016 | \$672.9010 |
| 2017 | \$680.1578 |

- 4.2 To ensure the 2017 N-ATP of Cysview does not exceed the 2017 N-NEAP as outlined in 4.1 above and to ensure that the price in each market where Cysview is sold is within the Guidelines;
- 4.3 To make a payment to Her Majesty in right of Canada, within 30 days of acceptance of this VCU, to offset cumulative excess revenues received, up to December 31, 2016, in the amount of \$4,433.13; and
- 4.4 To ensure that the price of Cysview remains within the PMPRB's Guidelines in all future periods in which Cysview is under the PMPRB's jurisdiction.

Signature:

Name:

Position:

Patentee:

Date:

Tom CARSON

Dir. Business Development

BioSyent Pharma Inc.

08/16/17.

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