

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
HZNP Canada Limited
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1. Quinsair (levofloxacin) 240 mg/2.4 mL (100 mg/mL) (as levofloxacin hemihydrate) (DIN 02442302) is indicated for the management of cystic fibrosis (CF) in patients aged 18 years or older with chronic pulmonary *Pseudomonas aeruginosa* (*P. aeruginosa*) infections.
- 1.2. The last reported Canadian Patent (No. 2,773,033) pertaining to Quinsair was issued to HORIZON ORPHAN LLC on October 11, 2016, and will expire on September 3, 2030.
- 1.3. Health Canada issued a Notice of Compliance for Quinsair on June 9, 2015. Sales in Canada commenced December 12, 2016. Quinsair is currently marketed in Canada by HZNP Canada Limited (“HZNP”).
- 1.4. HZNP is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (“PMPRB”).

2.0 Application of the Excessive Price Guidelines

- 2.1 The Human Drug Advisory Panel recommended Quinsair be classified as a Slight/No improvement and identified TOBI (tobramycin solution for inhalation), TOBI Podhaler (tobramycin solution for inhalation) and Cayston (aztreonam for inhalation solution) as the most appropriate comparators.
- 2.2 In accordance with the PMPRB’s *Compendium of Policies, Guidelines and Procedures* (“*Guidelines*”), a Therapeutic Class Comparison (“TCC”) test and a Highest International Price Comparison (“HIPC”) test were conducted. The introductory National Average Transaction Price (“N-ATP”) of Quinsair exceeded its Maximum Average Potential Price (“MAPP”) triggering the investigation criteria in the *Guidelines*.

3.0 Position of Patentee

- 3.1 This Voluntary Compliance Undertaking (“VCU”) constitutes no admission by HZNP that the price of Quinsair is now, or was at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

Pursuant to this VCU, HZNP undertakes:

- 4.1 To agree that the MAPP for 2017 and projected National Non-Excessive Average Price (“N-NEAP”) for 2018 for Quinsair are as follows:

Year	MAPP/N-NEAP
2017	\$63.5984
2018	\$64.4887

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.

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- 4.2 To ensure the list price of Quinsair does not exceed \$64.4887 in each market where Quinsair is sold within 30 days of acceptance of the VCU
- 4.3 To ensure the July to December 2018 N-ATP of Quinsair does not exceed the calculated 2018 N-NEAP and to ensure that the price in each market where Quinsair is sold is within the thresholds set out in the *Guidelines*;
- 4.4 To ensure that the price of Quinsair remains within the PMPRB's *Guidelines* in all future periods in which Quinsair is under the PMPRB's jurisdiction.

Name: John Haslam
Position: General Manager
Patentee: HZNP Canada Limited
Date: June 8, 2018

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