



Patented Medicine  
Prices  
Review Board

Since 1987

# PMPRB COMMUNIQUE

**OTTAWA, October 27, 2009**

## **The Patented Medicine Prices Review Board approves a Voluntary Compliance Undertaking for the medicine Neulasta**

The Board issued a Notice of Hearing on March 16, 2009, pertaining to allegations of Board Staff that Neulasta had been, and was being, sold by Amgen Canada Inc. at prices exceeding those indicated by the Board's Excessive Price Guidelines. On October 13, 2009, the Hearing Panel received a Joint Submission by Amgen and Board Staff along with a Voluntary Compliance Undertaking ("VCU") which proposed to resolve the issues raised in the Neulasta proceedings.

Amgen will reduce the price at which it sells Neulasta to the 2009 maximum price, and will make a payment to the Government of Canada in the amount of \$6,730,120.32 to offset any revenues above the maximum prices from the date of introduction of Neulasta to June 30, 2009. Amgen will also offset revenues greater than the 2009 maximum price it received from July 1, 2009 to December 31, 2009.

Amgen will ensure that the price of Neulasta remains within the Board's Guidelines for the period it remains under the Board's jurisdiction.

By Order of the Board, the proceeding into the price of Neulasta is concluded.

The Board Order is a public document and is available on the PMPRB Web site, along with the parties' Joint Submission and the VCU (under Regulatory; Hearings; Neulasta, and under Voluntary Compliance Undertakings).

*Neulasta (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive antineoplastic drugs.*

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Reference: Sylvie Dupont, Secretary of the Board  
Tel: (613) 954-8299; Toll-Free: 1 877 861-2350  
E-mail: [sylvie.dupont@pmprb-cepmb.gc.ca](mailto:sylvie.dupont@pmprb-cepmb.gc.ca)

The mandate of the Patented Medicine Prices Review Board is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive; and, to report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees.

Canada