

Ministry of Health
and Long-Term Care

Ministère de la Santé
et des Soins de longue durée



Drug Programs Branch
Health Services Division

3rd Floor, 5700 Yonge Street
North York ON M2M 4K5

Telephone: (416) 327-8109
Toll Free: 1 866 811-9893
Facsimile: (416) 327-8123

Email Address/Courriel: drugprograms@moh.gov.on.ca
Internet: www.health.gov.on.ca

Direction des programmes de médicaments
Division des services de santé

3^e étage, 5700 rue Yonge
North York ON M2M 4K5

Téléphone: 416-327-8109
Sans frais: 1 866 811-9893
Télécopieur: 416-327-8123

PATENTED MEDICINE
PRICES REVIEW BOARD
2005 APR 14 PM 3 07
CONSEIL D'EXAMEN
DU PRIX DES
MÉDICAMENTS BREVETÉS

APR 14 2005

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Secretary of the Board
Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
14th Floor
Ottawa ON K1P 1C1

To Whom It May Concern:

This is in reference to the proposed amendments to the *Patented Medicines Regulations* as noted in the Patented Medicine Prices Review Board (PMPRB), Notice and Comment publication dated January 2005.

The PMPRB is proposing eight amendments to the Act. I am limiting my comments to amendments 3.1, 3.2 and 3.3 which relate to reporting requirements. We appreciate the opportunity to provide input to the proposed changes.

Amendment 3.1: Notification to PMPRB of new prices 60 days prior to first date of sale.

We support this amendment. The advanced notification period would allow PMPRB to more proactively identify and resolve issues related to price prior to the product being sold in the marketplace. As a result, there could potentially be a reduction in the number of Voluntary Compliance Undertakings (VCU) if the price issues are resolved sooner.

One of the challenges that we have regarding VCUs is that the financial repayments from a manufacturer are determined much later and as a result the product has been on the market for an extended period of time. As a result, if the Drug Programs Branch wanted to calculate the cost impact resulting from the higher price that is subject to the VCU, we would need to review the claims retrospectively. This was particularly challenging with the Remicade VCU since the Health Network System (HNS) adjudicated claims using a product identification number (PIN) rather than the drug identification number (DIN) since the product was dispensed as a compounded preparation and it was difficult to accurately track expenditures within the administrative databases. If issues on pricing were identified and communicated earlier, we could have implemented a process to track claims more closely regardless of when the final decision was rendered.

Amendment 3.2: Notification to PMPRB of price increases 120 days prior to the effective date.

We support this amendment. Manufacturers have communicated to the Ministry that there is increasing pressure to raise prices in the Canadian market place in response to a number of different pressures including the price differential between the Canadian and American markets. This could have a significant impact on expenditures for payers of all drug programs. The Drug Programs Branch has received a large number of price increase notices by manufacturers. It is assumed that the price increases are in compliance with the PMPRB price increase allowances.

If there are concerns identified by PMPRB with the increase of a patented product, it is important to identify this prior to the effective date. As noted in the Notice and Comment, manufacturers are not obligated to report price increases between the standard reporting periods. This amendment will ensure that reporting is done in a timely manner.

Amendment 3.3: New reporting requirements detailing the derivation of net price.

We support this amendment. Under this amendment, manufacturers would be required to provide additional details regarding how price is calculated which includes declarations on the amount of free goods and rebates for that product. In discussion with other provinces, we have noted there are a number of issues related to the pricing of patented products. For example, manufacturers have raised the possibility of introducing rebates or dual price regimens for certain products reimbursed under the provincial drug programs. The provinces look to PMPRB for guidance on some of these issues and it is important for PMPRB to have all of the information related to the pricing of a product so that more informed recommendations/advice can be provided on these issues.

Thank you for the opportunity to comment. If you require clarification on any of the points noted above, please contact myself at (416) 327-8095 or Brent Fraser at (416) 327-8118.

Sincerely,



Susan Paetkau
Director
Drug Programs Branch