Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

RE-BENCHING

As part of its November 2006 meetings with stakeholders, the Patented Medicine Prices Review Board (PMPRB) is interested in discussing the issue of a possible re-benching of the price of a patented medicine after it has been on the market.

This is an issue that was raised in some of the submissions the Board received to its call for stakeholder views on the questions raised in the May 2006 Discussion Guide on the Board's Excessive Price Guidelines (Guidelines).

The subject was also included in the Progress Report of the federal-provincial-territorial National Pharmaceuticals Strategy, which stated: "Introductory price assessments for patented drugs by the PMPRB (i.e., the maximum non-excessive introductory price) are based on the approved indications, or uses, of the drug at the time of its initial review. Although a drug might later be approved for additional indications characterized by lower prices, the PMPRB lacks a mechanism in its Excessive Price Guidelines to re-evaluate the price of the product."

PATENTED DRUG PRICE REVIEW PROCESS

The price of a patented medicine is reviewed when it is first sold in Canada to determine the benchmark price. The review is based on the evidence available and the approved indication of the medicine at that time.

If the price at which the patentee sells the medicine does not exceed the Guidelines, that price establishes the benchmark price. If the price at which the patentee sells the medicine is excessive, the maximum non-excessive price determined through the application of price tests set out in its Guidelines establishes the benchmark price.

Once the benchmark price is established during the period of first sale in Canada, price increases in the future are generally limited to increases in the Consumer Price Index (CPI).

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

RE-BENCHING

CURRENT CIRCUMSTANCES WHICH MAY GIVE RISE TO POSSIBLE RE-BENCHING

The Guidelines currently provide for two limited exceptions for the re-benching of a price, as described below.

- The Guidelines provide that an interim benchmark price is established when the introductory price test is the median of the international prices (MIP) but the drug product is sold in fewer than five of the seven comparator countries identified in the *Patented Medicines Regulations*.
    - The MIP is recalculated when the drug product is sold in five countries or after three years, whichever comes first.

- The Guidelines also provide that it may be appropriate to review the price of a drug product at the time of the issuance of the first Notice of Compliance (NOC), which is Health Canada's market authorization, when the drug product was previously sold as an un-approved drug, based on a specific case-by-case request from a physician (through Health Canada's Special Access Program (SAP).
    - The Guidelines do not provide any guidance on the criteria or acceptable evidence for such a re-review.

BACKGROUND

- Under the Guidelines, the benchmark price is established based on the evidence available at the time of a patented medicine's first sale in Canada. As a drug is prescribed over time, it may become apparent that the drug is useful in treating other conditions. It is also possible that, over time, new evidence shows that the drug product is not as effective, or is more effective, in treating the original indication than was suggested by the evidence available when it was first sold.
- A new treatment use for a drug product might not be as a result of a subsequent NOC for that new use, but rather developments in clinical opinion and practice (sometimes referred to as "off-label" use).

Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

RE-BENCHING

PURPOSE OF THE DISCUSSION

Given the interest shown on the issue of re-benching, the Board would like to hear the views of its stakeholders regarding the general concept of re-benching. In particular, specific feedback will be sought on:

- Should the price ever be re-benched?
- When should re-benching occur?
- What evidence would be needed to support re-benching?

CONSULTATIONS
EXCESSIVE PRICE GUIDELINES

November 2006