



PRICE REVIEW PROCESS FOR PATENTED MEDICINES

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Summary of Presentation

- PMPRB Overview and Mandate
- Regulatory - Price Review Process
- Scientific Review Process
- Consultations
- Board Decision and Next steps



Overview of the PMPRB

- Created in 1987 as “consumer protection” pillar of drug patent law reform
- Arms-length agency – now in health portfolio
 - ◆ No involvement in federal policy-making
- Quasi-judicial tribunal
 - ◆ Remedial orders provided for in the *Patent Act* enforceable in the Federal Court
 - ◆ *Unique structure* – both investigative and adjudicative functions
- Structure and budget
 - ◆ 5 part-time Board members
 - ◆ 62 employees
 - ◆ 2007-08: Budget \$11.6 million



Mandate of the PMPRB

- Two fold mandate
 - ◆ **Regulatory** – To ensure that prices charged by patentees (“ex-factory” prices) for patented medicines sold in Canada are not excessive, thereby protecting consumer interests and contributing to Canadian health care.
 - ◆ **Reporting** – To report on pharmaceutical trends and on R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy-making.



Regulatory

- **Price Review Process – New Patented Medicines**
 - ◆ First, a scientific review must be conducted. Purpose of scientific review is determine the primary indication/use of the new medicine, the category of the new patented medicine, the comparable drug products and the comparable dosage regimen.
 - ◆ Based on the results of the scientific review, introductory price tests are applied.
- **Price Review Process – Existing Patented Medicines**
 - ◆ Prices of existing patented medicines are reviewed based on price tests for existing patented medicines.



New Patented Medicines

- **Category 1 Drug Products**
 - Reasonable Relationship Test (RR) – compares price of new drug to prices of existing drugs with comparable dosage forms
- **Category 2 Drug Products - Higher of:**
 - ♦ Therapeutic Class Comparison (TCC) test – up to highest price of therapeutic comparators; or
 - ♦ International Price Comparison (IPC) test – up to median of prices of the new drug in the seven comparator countries**
- **Category 3 Drug products**
 - Therapeutic Class Comparison (TCC) test
- **For all drugs: Canadian price can't be the highest of 7 comparator countries****

* Clinically equivalent drug may be removed from the price tests if PMPRB has reason to believe its price is excessive

** Comparator Countries: France, Germany, Italy, Sweden, Switzerland, U.K., U.S.



Scientific Review

- Board Scientific Staff
 - With drug evaluation experience and clinical training
- Drug Information Centres (DIC)
 - Clinical expertise and knowledge of drugs
 - Responsible for searching and summarizing available information on clinical trials related to the new drug
- Human Drug Advisory Panel (HDAP)
 - Experts in drug evaluation and clinical pharmacology
- Other Experts as required



Scientific Review

- Evaluation of clinical information submitted by manufacturer
- Drug Information Research
- Category, comparators and comparable dosage regimens
- Scientific review does not consider pricing information



Consultations

- Began in March 2005 with release of Discussion Paper on Drug Price Increases for Patented Medicines.
- Feedback from stakeholders lead to a more comprehensive review of the Board's current Excessive Price Guidelines.
- Two of the issues currently the subject of review are
 - ◆ the current system of categories; and
 - ◆ the review of a maximum non-excessive (MNE) price based on a change in science (re-setting the MNE price).



Consultations: Categories

- Board heard a variety of views ranging from abandoning the current categories to adopting models used in other countries.
- Board agreed that some assessment of therapeutic value is necessary, and decided that work on options for possible revisions to the current approach was appropriate.
- Board established the Working Group on Therapeutic Improvement.



Consultations: Working Group on Therapeutic Improvement

■ Recommendations:

- ◆ Four definitions of level of therapeutic improvement (“breakthrough”, “substantial improvement”, “moderate improvement” and “slight or no improvement”).
- ◆ Definitions differ in the degree of therapeutic improvement.
- ◆ Oxford Centre for Evidence-Based Medicine Levels of Evidence
- ◆ Evaluation of therapeutic improvement to include consideration of clinical and economic/pharmacoeconomic factors.



Consultations – Re-setting the MNE price

- The price of a patented medicine is reviewed when it is first sold in Canada to determine the introductory non-excessive benchmark price. The review is based on the indication of the medicine, the clinical evidence available at that time regarding therapeutic improvement and the appropriate price test.
- After considering the comments of its stakeholders, the Board set out in its January 2008 Discussion Paper, circumstances where re-setting the MNE price may be undertaken.



Consultations: January 2008 Discussion Paper

- When the scientific information/evidence available at the time the medicine was first introduced was not sufficient to determine with confidence its category of therapeutic improvement, or when new post-market evidence suggests the initial categorization was inappropriate.
 - ◆ Three scenarios were provided when the scientific information/evidence in the introductory period might not be sufficient.



Consultations: January 2008 Discussion Paper

- ♦ A drug product is being sold as an Investigational New Drug or under the Special Access Programme and proper and sufficiently robust clinical trials have not been completed or are unavailable;
- ♦ A Notice of Compliance with conditions has been granted but Health Canada has specified further research to be undertaken post-market, to confirm health outcome improvements; and
- ♦ A drug is indicated for a rare, life-threatening disease and the scientific evidence is very limited because the patient population is too small to conduct proper and sufficiently robust clinical trials.



Consultations: January 2008 Discussion Paper

- It could be that, after being sold in Canada for say 3 to 5 years, additional clinical trials and/or post market surveillance may provide new evidence to better determine the relative category of therapeutic improvement of the medicine. Re-setting the maximum non-excessive (MNE) price would recognize the real value of the medicine. Rather than develop its own review cycle, it has been proposed that the PMPRB adopt a regulatory life-cycle approach in line with the Progressive Licensing initiative of Health Canada.



Stakeholder Feedback

- Pharmaceutical industry did not generally support the proposed circumstance for re-setting the MNE price as the proposals would limit the circumstances in which a price could be re-set and also increase price uncertainty.
- Other stakeholders were more supportive of provisions for re-setting the MNE price.
- All stakeholders felt that clear “triggers” for when prices would be re-set based on new scientific information or evidence, needed to be identified.



Board Decision and Next Steps

Working Group

- Working Group on Therapeutic Improvement submitted its Report to the Board in April 2008. Available from PMPRB Web site.

Re-setting MNE price

- Board agrees that clearly identified triggers are needed for MNE price re-setting based on new scientific information or evidence.
- Board Staff currently developing triggers for re-setting the MNE price based on new scientific information or evidence.