Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

WHAT WE HEARD

A SUMMARY OF STAKEHOLDER SUBMISSIONS TO THE PATENTED MEDICINE PRICES REVIEW BOARD IN RESPONSE TO *THE DISCUSSION GUIDE ON THE BOARD'S EXCESSIVE PRICE GUIDELINES*

OCTOBER 2006

INTRODUCTION

This summary attempts to distill the comments sent to the Patented Medicine Prices Review Board (PMPRB) in response to a May 2006 call for submissions by then Vice-Chairperson of the Board, Dr. Brien Benoit. (Dr. Benoit has since been named as Chairperson.)

Dr. Benoit invited stakeholders to provide their views on the Board's Excessive Price Guidelines, which PMPRB staff use in the review of prices of patented medicines. His request evolved from the results of a 2005 consultation on the subject of price increases for existing patented drugs. In their comments at that time, stakeholders indicated that price increases were not their prime concern, but they did raise issues concerning, among other things, the factors specified in the *Patent Act* and the continued appropriateness and relevance of the current Guidelines.

For the 2006 submission process, a Discussion Guide on the Board's Excessive Price Guidelines assisted stakeholders in their consideration of three key issues: the categorization of new drugs; introductory price tests of new drugs; and, how the Board should address the "any market" clause of the Patent Act in the price review process. (You can access the Discussion Guide at http://www.pmprbcepmb.gc.ca/english/view.asp?x=647.)

By early September, the PMPRB had received 43 thoughtful submissions from a range of commentators, including patentees, patient and health care provider representatives, government, academics, consultants, private insurers, and health care-related organizations. A list of these respondents is attached as an annex, and their submissions are available at the web site mentioned above.

The commentary will contribute to the discussions the Board will be holding in November with invited stakeholders in Edmonton, Montreal, Toronto, Halifax, and Ottawa. A member of the Board will chair each event. The meetings, which will draw together a variety of stakeholders to further explore the issues, will complement the submission process with additional advice on how to ensure the Guidelines are as effective and relevant as possible. A final meeting is planned for the spring of 2007 to discuss potential changes.

This summary of submissions follows the three-issue structure of the Discussion Guide. Several commentators also made observations and suggestions that were not directly related to these particular issues; some of these are captured briefly in a note at the end.

ISSUE #1: Is the current approach to the categorization of new patented medicines appropriate?

Q1: Are the new patented drug categories and their definitions appropriate?

The responses to this question can be looked at according to the degree of change that commentators said the categories should undergo.

The current Excessive Price Guidelines establish three categories for new patented drug products:

- **Category 1:** a new strength, or a new dosage form of an existing medicine (some observers refer to this as a "line extension").
- **Category 2:** drug products that provide a breakthrough or substantial improvement over existing medicines.
- **Category 3:** drug products that provide moderate, little or no therapeutic advantage over comparable medicines (some observers refer to these as "me too" drugs.)

Several commentators recommended eliminating the categories and replacing them with a single definition of excessive price for all new patented drugs. These observers put forward several points as to why to end the category system, including:

- The categories do not recognize the incremental nature of innovation (such as improved drug delivery technology), or its true value to patients and the health system. If categories are to remain, the Board should find ways to recognize and reward innovators for genuine therapeutic improvements.
- In particular, the categories are unable to capture the innovative nature, and value to the health system, of biologics and vaccines. Furthermore, the prices of these products are already moderated by other forces (the PWGSC-provincial/territorial process for purchasing vaccines; and the buyer power and purchasing processes for blood products). One commentator suggested that the "categorization of new patented vaccines be determined by the comparison to prices established in the international market."
- There was a suggestion that the only drugs PMPRB should review are those in the "breakthrough" category (Category 2), negating the need for a category system. It was stated that market forces already moderate the prices of the current Category 1 and 3 drugs.
- Some commentators said the definition of breakthrough drugs (Category 2) is too restrictive, both in terms of defining therapeutic value and of the price that can be charged. If categories are to remain, the PMPRB should align its criteria for Category 2 with that used by Health Canada and the FDA to identify drugs for Priority Review Status.
- It is inappropriate for the Board to judge therapeutic value, and the current PMPRB system of categorization is "inherently subjective." This subjectivity is apparent in the disagreement between the PMPRB's system of categorization and

other systems (such as that used by France[1]). Decisions about the value of medicines should be made by the final purchasers (public and private drug plans), consumers, and health care professionals. There was a suggestion to disband the PMPRB's Human Drug Advisory Panel.

Some commentators said the categories were inappropriate, but did not suggest their elimination. These people said that the PMPRB assigns drugs to categories early in the lifecycle, when there is simply not enough information or evidence available yet on the drug's performance to make these judgments.

A few commentators said that, generally, they found the current system of categories appropriate.

A number of submissions indicated agreement with the concept of categories, but also contained specific suggestions for change. These included:

- The addition of a category or subcategory to reflect that, while "first in class" drugs are categorized as "breakthroughs" (Category 2), the drugs that follow may be significantly better and represent the real breakthrough.
- Addressing the "me-too" connotation of Category 3 drugs, which does not reflect that, for some individuals, these drugs may work better than the original. A patient-centred, real-world surveillance program is needed to determine the effect on the consumer.
- Including citizens in the categorization of medicines.
- A call for greater clarity, precision, and openness. The categories need to be better defined – suggestions were to develop explicit criteria to rate the degree of improvement, or to develop and explain the rationale for what constitutes an improvement, based on benefits and risks. Whether criteria or rationale, the reasoning should be made public, for accountability. The assessment of the degree of therapeutic improvement should engage a broad-based group of experts, and the process should be public.
- Changing the category order to 1. breakthrough; 2. moderate/little/no; 3. line extension
- Classifying patented medicines as either catastrophic drugs, or non-catastrophic drugs, for each of the three categories: "Given that by definition, catastrophic

[1] The price of reimbursable (both patented and non-patented) drugs in France has been set on the basis of negotiations between the *Comité économique des produits de santé (CEPS)* of the French government and the manufacturer within the context of a series of industry framework agreements. All products are evaluated based on their therapeutic value (*l'amélioration du service médical rendu*, or ASMR) and categorized based on their benefit. An expert group, the Transparency Commission, carries out the therapeutic evaluation and classifies drugs according to five categories, ranging from significant innovation, to no improvement, in therapeutic benefit. For more information, see http://www.minefi.gouv.fr/DGCCRF/03_publications/actualitesccrf/medicaments185.htm (in French) or http://news.investinfrance-nordic.org/2/download/how_to_be_reimbursed_2000.pdf (in English).

drugs are very costly, such classification would help provide additional focus for excessive price reviews for new patented medicines."[2]

- Several suggestions for enhancing the current system with subcategories:
    - Keep Category 2, but subdivide Categories 1 and 3 into a) "little" and b) "moderate" improvement, regardless of whether the drug is a new active substance (NAS) or a line extension.
    - Subdivide Category 2 into two sections: "breakthrough:" (no therapy exists; fills unmet need; no appropriate comparator available) and "substantial improvement:" (relative to other drugs, provides substantial therapeutic improvement and/or cost savings). Also, clarify category 3 as "a new drug that belongs to an existing class."
    - Subdivide Category 2 medicines into substantial, moderate, and/or promising improvement (based on the effect on important clinical outcomes, versus validated surrogate outcomes, versus unvalidated surrogate outcomes, respectively).
    - Use a five-level system that reflects an increasing benefit/risk ratio to patients.
    - In its response to Issue 2 questions on price reviews, one submission outlined a way to identify categories and sub-categories of therapeutic improvement ranging from highest degree of breakthrough drug to least degree of line extension.

Q2: Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?

A number of commentators cautioned against the creation of a separate category for medicines that provide "little or no therapeutic improvement." In some cases, this was related to the view expressed in responses to Question 1 that a system of categories in itself is unnecessary. "The establishment of a new fourth category…is not necessary as it has no relationship to the concept of excessive pricing."

Several respondents said determining the difference would simply be too difficult to achieve, based on the level of evidence available at the time of assessment. "The distinction between the two categories would be a fine line, and up for dispute," said one.

Others added that there would be much effort, but few benefits, involved in making such a distinction: it would "add further administrative difficulty to the Board's mandate" and "create a heavier review mechanism that could eventually complicate further the whole review process requiring more comparison tests and would not serve the purpose of the Canadian government to ensure that prices of patented medicines are not excessive." Another comment echoed this view: "Additional considerations for moderate but not substantial therapeutic improvements would complicate regulatory policy without

[2] The commentator appears to be referring to drugs whose high cost may cause undue financial hardship for Canadians. As part of the National Pharmaceuticals Strategy (NPS), federal, territorial and provincial governments are working on options for Catastrophic Drug Coverage that could address this issue.

necessarily protecting public interests….The remedy…is not to make a new category for price considerations but to better establish MNE prices among category 1 and 3 drugs."

One commentator suggested that the potential fourth category could "offer yet another mechanism for PMPRB to seek even lower prices rather than develop a system that considers a true definition of excessive in the context of abuse of patent rights as intended by Parliament."

Other respondents expressed some openness to having a separate category for "little or no" improvement, saying it would be an improvement over the current system. These commentators said the potential fourth category might better reflect incremental improvements, and change the public's negative perception of Category 3 as "me-too" drugs. There was also a suggestion to change the "little or no" title to "modest."

A number of submissions supported the addition of a fourth category. These commentators said the distinction would be most important for patients and physicians, helping them make more informed decisions about whether to stay on a drug or switch to another. "It is very important to patients particularly to have medicines that offer moderate therapeutic improvements distinguished from those that provide little or no therapeutic improvement. First of all, why would physicians prescribe or recommend drugs with very little therapeutic value or improvement for the patient? Why would these drugs even remain on the market? If a drug shows moderate therapeutic improvement, there is at least some improvement in the health of the patient compared to what the patient had been taking or doing prior to the drug."

One commentator, who supported the idea "at the conceptual level" of separating "moderate" from "little to no," said that one problem with making such a distinction was the potential for a drug that shows "moderate" improvement for only a subset of patients to be given a premium price that would be considered excessive for the majority of users for whom cheaper alternatives work as well. A suggestion was to assign the "moderate" title to drugs Health Canada identifies for Priority Review. This commentator's view was that the awarding of a patent was in itself sufficient recognition of innovation.

Q3: If the answer to Q2 is yes, on what basis would a new medicine that offers "moderate therapeutic improvement" be distinguished from a new medicine that provides "little or no therapeutic improvement?"

Several commentators reiterated the difficulty of making the distinction, saying that insufficient performance evidence is available at the time the PMPRB makes its assessment.

One submission which said it might be possible to divide Category 3 into "moderate" and "little or no" also advised that "it should be recognized that there will always be some subjectivity in the distinction between these terms and that it is impossible to create a formula that will work in all situations."

While commentators generally agreed that making the distinction would be challenging, several of them proposed approaches for doing so:

- Consider using a process similar to the French system for recognizing varying levels of therapeutic value, as determined by the French Transparency Commission.[3]
- Work from the current Guideline wording for distinguishing "substantial benefits" drugs from Category 3 drugs, using the phrase "moderate improvement."
- Base it on:
    - advanced clinical trials that measure safety, efficacy and compliance;
    - head-to-head comparisons against the drug currently thought to be most effective; and
    - extensive post-market surveillance.
- Include quality-of-life indicators from consumers.
- Require disclosure of all unpublished trials.
- Develop a framework to determine moderate vs. little or no improvement. The framework should include automatic post-marketing surveillance for drugs in the moderate category. If real-world performance of the drug is less than moderate, change its profile to "little or no," with no retroactive penalty.
- Refer to the Canadian Expert Drug Advisory Committee (CEDAC) assessments of evidence about a drug, which are based on the following criteria: the quality of clinical trial data, the comparators used, the outcome measures evaluated, the length of study and follow-up, the effect size noted, the clinical importance of the effect size and comparative harms in relation to other therapies.

[3] See footnote #1.

ISSUE #2: Is the current approach used to review the introductory prices of new patented medicines appropriate?

Q1: Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why not?

A number of submissions were of the view that the current price tests are overly restrictive and the tests do not adequately acknowledge the value of drugs that provide moderate, or incremental, improvements over existing therapies -- echoing an opinion expressed by several respondents regarding Issue 1 questions.

Some authors also repeated the call for a clear definition of an excessive price. Suggestions included "only a price that exceeds a threshold beyond which pricing would be considered truly egregious," or a price that "exceeds the prices in all the other countries and the CPI-adjusted prices of all other drugs in the therapeutic class."

Among the commentators who said there were problems with the current price tests, there was quite a wide variety of opinion as to the exact nature of those problems, and how they might best be resolved:

- A submission advised that the current tests do not assess the price of the drug in relation to improvements, if any, in health outcomes from the appropriate use of the drug. Another author said the current system is too complicated to comment on, but was concerned that the prices of new HIV/AIDS treatments are beyond the reach of many patients.
- Some respondents took issue with the use of older classes of medications as comparators in the therapeutic class comparison (TCC) test, or the need to use a Consumer Price Index (CPI)-adjusted price for comparators that have not taken price increases over the life of their product.
- Conversely, the Category 3 test (TCC) was sometimes seen as being a more advantageous test for innovators than the median international price comparison (IPC) test currently applied to breakthrough drugs (Category 2). For some commentators, this results in overly generous prices for Category 3 drugs. "While 'me too' drugs do offer choice to patients, they are alternatives and not breakthrough drugs," said one. "The introductory price should reflect generic pricing of similar products, and the production and marketing costs of generic companies. The current Category 3 test does not work and 'me too' drugs should not be allowed to price to the highest price in the class."
- "It is not clear why a higher price ceiling is permitted for Category 3 drugs than Category 2 drugs," said another commentator, who also advised that the apparent difference in defining an excessive threshold "does not seem appropriate…. Given that most drugs are priced below the maximum non-excessive price ceiling set by PMPRB's guidelines, it would seem appropriate to have a more consistent international price comparison for both Category 2 and 3 drugs."
- Options for addressing concerns about Category 3 tests included the use of median TCC; the lower of either the highest TCC or median IPC; the lower of the median or average IPC; or the median IPC as the price ceiling for all drugs.

Another submission questioned the use of the highest comparator price when performing the TCC, recommending instead the use of either the average cost of therapy or the reference price of the "gold standard" therapy.

- While several respondents saw the Category 3 test as particularly problematic, there was also a view that the Category 2 test is the main issue in that it does not properly acknowledge the benefits of breakthrough drugs.
- It was suggested that more weight be given to the IPC test, especially if other tests force the Canadian price below international prices. One submission said that "several of the foreign jurisdictions referenced by the PMPRB have rigorous price approval mechanisms in place and cases where a Canadian price is consistent with international pricing should be reflected in the Guidelines as acceptance of non-excessive pricing."
- Still other submissions advised against using international prices, because they do not fully reflect the realities of the Canadian market. In particular, nations that lack a domestic price regulation should not be used as a comparator. One commentator said the use of the "list price" in other countries in the IPC test is a problem, as it is known that many payers in those countries pay less than the list price.
- There was a recommendation to streamline the process by excluding all medication with comparators from the PMPRB's jurisdiction. There was also advice to empower Board Staff to negotiate prices with patentees using the Guidelines as a starting point.

Q2: If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement" what would the appropriate new price test be?

Those commentators who advised against the creation of a new category in response to Issue 1 chose either to reiterate their opposition, or not comment at all.

Suggestions for testing the price of a potential "little to no therapeutic improvement" category of drugs included:

- Use only the international price comparison (IPC) test for drugs in all categories.
- In the case of new formulations of existing drugs, the historical price differentials between new products entering old markets should be considered for the calculation of the applicable price ratio.
- There were proposals for two new pricing regimes (as mentioned in responses to Question 3 of Issue 1). The first called for five separate categories, beginning with those drugs that offer little or no improvement, acknowledging different levels of innovation through to the breakthrough drugs. Price tests would be based on an average of the median and highest IPC test for most drugs, with some potentially higher formula set for breakthrough drugs (e.g. the highest international price). The second regime re-orders and divides the existing categories into nine sub-categories using tests based primarily on IPCs.
- Use Category 2 price tests for all Category 3 drugs (whether that category remains as is, or is split into "moderate" and "little or no" improvement).

- The little or no improvement category should be tested against: a reconfigured reasonable relationship test (how to reconfigure was not explained); the lowest international price; the lowest therapeutic price; or the same as the moderate improvement category.
- One submission offered a series of options for both the moderate and little improvement categories: the median of the TCC for little improvement drugs, with moderate improvement drugs receiving a percentage premium; the moderate improvement category continues to receive the highest of the TCC, while the little improvement category receives a percentage penalty; or the little improvement category receives the lowest of the lesser of the highest of the TCC or the median of the IPC.

Q3: For price review purposes, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestions as to principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?

There were suggestions that the PMPRB should not include older, off-patent or generic drugs as comparators. There was also a suggestion that all medication with comparators should be excluded from the PMPRB's jurisdiction.

Some respondents advised that the Anatomical Therapeutic Chemical[4] (ATC) class should not be used in pricing tests, because the classifications are not designed for that purpose.

Others said that the current use of the ATC class is too restrictive, and that comparators should include those medicines that either have the same approved primary indication or are used in practice for the same indication as the new medicine (off-label use).

Another commentator took the opposite position, advising that a fairly restrictive definition of "comparable" medicine should be considered, because of the lack of evidence early on in the product's lifecycle. The submission went on to recommend that only those drugs that represent a significant enough market or play a substantial role in therapy be considered.

Several authors advised that the PMPRB should continue using the ATC class in the identification of comparators, but also suggested that more flexibility was needed:

- In the context of cancer treatments, use comparators that treat a variety of cancers but have similar treatment outcomes. It would also be important to make comparisons in the context of multi-drug regimes.
- Use as comparators only those drugs that are currently the most effective.

[4] The World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification system is a hierarchical system that classifies drugs according to their principal therapeutic use and chemical composition. http://www.whocc.no/atcddd/.

- Ensure that in choosing comparators, the following three sources are always reviewed: the ATC classification of a new drug; existing guidelines for treatment of the disease; and published evidence in the peer-reviewed literature. Do not assign a hierarchy to the sources; and, explain the process used.
- There were arguments for the need for head-to-head trials and patient-centred, post-market surveillance. There was a suggestion to place all new comparable or other drugs on probation until adequate evidence of effectiveness is available.
- Use a definition of equivalent that is broader than that offered by the ATC system.

Q4: Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven countries listed in the Regulations. However, Section 85(1) of the Patent Act states that the Board should take into consideration "the prices of other comparable medicines in other countries." Should the Guidelines address this factor? If so, how could this factor be incorporated into the price tests for new medicines?

Several authors answered yes to this question. One suggested that the approach be used for each and every price test. Most, however, recommended doing so only under certain circumstances; one suggested using it only as a last resort. Advice on when to employ this test included:

- When the current test places the Canadian price at a level inconsistent with comparator countries.
- When appropriate comparators are not available domestically or the same medicine is not available in reference countries.
- In cases where a price premium has been granted in comparator countries as a justification for the same premium in Canada.

Respondents who were against including the consideration of prices of other comparable medicines in other countries argued that:

- It would further complicate the existing system.
- There are different factors (i.e. the negotiation of industry agreement) that influence prices in comparator countries.
- It is not needed.

One respondent said that any changes must not occur if they disproportionately benefit one party (manufacturer, hospital, wholesaler, patient, etc).

A few respondents felt a separate consultation was needed on this issue, and only once the PMPRB clearly outlined its intentions, definitions and expected parameters.

Several respondents did not answer the question directly, choosing instead to comment on the mix of comparator countries used for doing IPCs. There was a suggestion to consider only those countries with research and development expenditures similar to Canada's, and another to base the mix on countries whose health systems are comparable to ours in terms of public financing.

ISSUE #3: Should the Board's Guidelines address the direction in the *Patent Act* to consider "any market?"

Q1: Given the price variations by provinces/territories and classes of customer illustrated in the previous figures, is it appropriate for the board to only consider an average transaction price[5] (ATP) calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?

A number of submissions stated that the Board should continue the current system of considering prices at the national level (i.e., based on total revenues from sales for all provinces/territories and all classes of customer). Some said that the data in Issue 3 of the Discussion Guide, which for illustrative purposes broke down price information by province/territory and customer class, shows that the current system is working well in terms of helping to ensure prices are not excessive: "As outlined in Figures 9 and 10, the vast majority of drug prices [are in the range of five per cent less than, or equal to,] the established MNE price, whether reviewed by province or customer class."

While prices are not uniform across markets, those who support continuing the current approach to calculating the average transaction price (ATP) said the amount of variation is acceptable. "The ATP review system looks at a national average, so it is to be expected that slight variations between regions or type of customers would exist. The figures provided by PMPRB clearly show that those variations are minimal and that they are not discriminatory."

Arguments against a review of prices at the individual market level included:

- It would increase administrative burden. "For the Board to consider each province and class of customer would introduce tremendous delays and inefficiencies into the price review process and would yield only marginal benefit."
- It could result in unfair comparisons with international prices. Maintaining the current approach of calculating a national average price based on all domestic sales is "important to avoid the situation wherein one compares the highest price of the drug in Canada to the average price of the drug in other countries."
- It could result in the end of preferential pricing to large customers. "If the Board attempts to 'control' the prices in…different markets, this will lead to a perverse incentive to raise the prices in all markets."
- It may be beyond the scope of the PMPRB. "…provincial variations are not necessarily decided by the patentee but by provincial pricing policies. Looking at the ATP on a provincial basis could be therefore seen as auditing provincial/territorial jurisdictional decisions."
- It could contribute to unfair downward pressure on the MNE. "Different markets are dictating different levels of pricing restriction on companies. The introduction

[5] Currently, the Board uses the average transaction price (ATP) for Canada as a whole to conduct the various price tests. The ATP means the price received by patentees from within the overall Canadian market.

of Bill 102 in Ontario and Bill 130 in Quebec are setting market dynamics. PMPRB must not penalize patentees for changes imposed by other entities such as the F/P/T governments. The Board should not make any attempt to ensure that all prices are forced to the lowest common denominator." [6]

- It is not an appropriate activity for the PMPRB. "PMPRB should not be involved in price control so deeply that it controls the price of medicines to different segments of the market. Other market forces or routes of price control should be used to deal with market segments that are charged higher prices."

A few commentators said that, while it appears that basing the ATP on total revenues is adequate, there are signs (including government policies) that there will be increasing deviation from the MNE by individual markets, and that therefore "modifications to the total revenues approach may be needed." It was suggested that ATP calculations should reflect concessions given to public benefit plans, and to employer plans if concessions spread to them. A related observation was that, as a result of recent government initiatives (including the direction of the federal Auditor General regarding the six federal drug plans, and Ontario's Bill 102) the PMPRB's "national uniform maximum pricing model is under challenge." This respondent expressed concern that "employer drug plan sponsors will bear increasing costs to offset the volume discounts" demanded by these initiatives.

Several submissions advised the PMPRB to consider information at the level of different customer classes and different provinces and territories. "It is what the patient pays that is a concern," said one. The current system calculates the ATP at the national level, which is too general to indicate whether individual patients in different parts of the country are paying more, less, or the same as one another. (It was recognized that the ATP is only part of the amount paid when a patient purchases a drug; other charges include retailer markup and dispensing fees.)

A number of respondents advised the PMPRB to calculate average prices at the individual provincial and territorial level. Reasons given were:

- Access to health care, where at all possible, should not be compromised based on geographic location.
- When ATP is calculated only at the national level, it "creates an inequity among provinces/territories and classes of customer. There is value in assessing how to make prices equitable."
- "It seems reasonable to ensure that no one province be left paying a price that would exceed the national MNE price."

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[6] Information concerning Ontario's Bill 102, *Transparent Drug System for Patients Act, 2006* can be found at http://www.health.gov.on.ca/english/public/legislation/drugs/hu_drugsact.html. Quebec's Bill 130, *Loi modifiant la Loi sur l'assurance médicaments et d'autres dispositions législatives* can be found at http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=2005C40F.PDF

One advised the Board to consider the four Atlantic provinces as a specific market, given the region's unique circumstances regarding catastrophic drug costs and its relatively high numbers of uninsured patients. This commentator also suggested that hospitals and retail pharmacists should be separated from one another.

Another commentator suggested that the Board be guided in this area by a broad interpretation of its mandate, which is "to ensure that patented drugs are affordable to Canadians," and added that affordability can be looked at from an individual or collective viewpoint. This commentator recommended that the Board should "leave hospital pricing alone," and said there should be different price reviews for different classes of customers.

Q2: If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-case basis, where there is significant variation in the prices charged?"

A number of commentators who recommended staying with the current national-level ATP calculation in response to Q1 also said that case-by-case reviews were unnecessary. There was a suggestion that the PMPRB could help to discourage significant price variation by raising awareness about the unfairness of such variation.

Other respondents who also wanted the PMPRB to keep the current ATP calculation said, however, that a case-by-case level of review would be warranted if there were evidence and/or a complaint that a price exceeded the CPI guideline. One of these commentators added the qualification that "the presence of simple variability between markets should not be sufficient to warrant the initiation of an investigation."

Several stakeholders said that, if there were particular issues that warrant investigation (i.e., significant variations in price or utilization), the PMPRB could investigate those specific cases further. There was a recommendation to track such reviews nationally, to prevent the risk of price creep.

It was suggested that, if deviations from MNE expand, then ATPs should be calculated by jurisdiction and by class of customer. In addition, it may be time to add "government" as a class of customer[7].

A commentator advised the PMPRB to carry out both approaches: review the prices to different classes of customers and to different provinces/territories, and also carry out reviews on a case-by-case basis, if it appears that further investigation is necessary. Doing both would "provide better clarity about what end users pay and determination of excessive pricing where it exists."

There were suggestions about defining distinct MNEs for certain customer classes: one for hospitals and one for pharmacies. Separating hospitals out from other classes "could help to avoid situations where an implicit cross-subsidy is occurring from ambulatory to

[7] The comment appears to refer to federal and provincial/territorial drug plans.

institutional players." An MNE for pharmacies "will help to ensure that individual patients in different parts of the country pay roughly similar amounts for their drugs."

A somewhat contrasting recommendation on how to ensure greater equity was to base reviews on "a national focus for each DIN, and a focus on affordability by the average or below-average Canadian across Canada. Prices do need to take into consideration the different customers and the provinces/territories but with the goal of achieving national equity of prices across them as opposed to creating different structures for each province/territory or customer."

OTHER COMMENTS

Several respondents took the opportunity to raise topics beyond the immediate scope of the Discussion Guide.

For instance, questions and concerns arose from several quarters about the PMRPB's role and interplay within the mix of bodies that have an effect on pricing and other decisions regarding prescription drugs, including, but not limited to: Health Canada; provincial drug plans; and the Canadian Expert Drug Advisory Committee (CEDAC). These comments seemed to be rooted in a desire for greater coordination and synergy among these bodies, so that the mix is effective and dynamic, rather than what some observers viewed as confusing, and even contradictory.

There were also varying opinions about the fundamental topic of Parliament's intent in creating the PMPRB. Some commentators urged the PMPRB to balance a dual role of protecting consumers and encouraging innovation, while others spoke just as strongly about ensuring that consumer protection is the dominant theme in the Board's objectives and activities.

These and other remarks not directly related to the Discussion Guide questions have been forwarded to Board members for their consideration.

ANNEX

List of respondents

Patentees

- Abbott Laboratories, Limited (Dotto, Laurie - August 25, 2006)
- Amgen Canada Inc. (Sprang, Geoff - August 23, 2006)
- AstraZeneca Canada Inc. (Cloutier, Michael S. - August 24, 2006)
- Bayer Inc (Blake, Philip - August 21, 2006)
- BIOTECanada (Schwab, Philip - August 25, 2006)
- BIOVAIL (Herman, Douglas - August 24, 2006)
- Boehringer Ingelheim (Mills, Ian R. - August 24, 2006)
- Eli Lilly Canada Inc. (McCool, Terry - August 17, 2006)
- GlaxoSmithKline (Lucas, Paul N. - August 25, 2006)
- Hoffmann-La Roche Limited (Torontali, Ilona - August 25, 2006)
- Janssen-Ortho Inc. (Albright, Penny - August 25, 2006)
- Leo Pharma (Kidson, Paul - August 24, 2006)
- Merck Frosst Canada Ltd. (Szabo, Gregg - August 17, 2006)
- Novartis Pharmaceuticals Canada Inc. (Boisvert, Alain - August 24, 2006)
- Novo Nordisk Canada Inc. (Lamanna, Vince - August 24, 2006)
- P&G (Yu, Rebecca - August 25, 2006)
- Purdue Pharma (Stewart, John H. - August 23, 2006)
- Pfizer Canada Inc. (Lallemand, Guy - August 24, 2006)
- Rx&D (Russell Williams - 25 August, 2006)
- sanofi-aventis Canada Inc (Silvestre, Jerome - August 24, 2006)
- sanofi pasteur (Lievonen, J. Mark - 25 August, 2006)
- Serono Canada Inc. (Brown, Deborah - August 25, 2006)
- Shire BioChem Inc. (Perron, Claude - August 23, 2006)
- Solvay Pharma Inc. (Webster, Sean P. - August 25, 2006)
- Wyeth Pharmaceuticals (Amstel, Amout Ploos van - August 23, 2006)

Consumers

- All Nations Hope AIDS Network (Akan, Margaret - 28 August, 2006)
- Canadian Arthritis Patient Alliance (Dooley, Anne - 24 August 2006)
- Binder, Louise - 22 August 2006

Federal/Provincial/Territorial

- BC - August 23, 2006
- Federal Health Partnership - August 25, 2006

Others

- Atlantic Canada Opportunities Agency (Collette, Monique - July 21, 2006)
- Burns, Dr. Katharina Kovacs - August 25, 2006
- Cancer Care Nova Scotia (Underhill, Theresa Marie - August 18, 2006)
- Canadian Expert Drug Advisory Committee (CEDAC) (September 27, 2006)

- Emergis Centre of Excellence (Holmes, Fred - August 24, 2006)
- ESI Canada (Aquilina, Ellen - August 24, 2006)
- Green Shield Canada (Garner, David - August 25, 2006)
- Human Drug Advisory Panel (Gray, Jean, Levine, Mitchell, McCormack, James - August 22, 2006)
- Lexchin, Dr. Joel - July 5, 2006
- Morgan, Steve - September 6, 2006
- Palmer D'Angelo Consulting Inc. (Palmer, W. Neil - August 25, 2006)
- Ruel, Pauline - August 7, 2006
- The College of Family Physicians of Canada (Maxted, John M. - July 7, 2006)
- Tomalin, Ms. Anne - August 24, 2006 (CanReg Inc.)