

**Patented Medicine Prices
Review Board (PMPRB)**

**Stakeholders Consultations on
Excessive Price Guidelines**

**Edmonton, Alberta
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Welcome and Opening Remarks

Mary Catherine Lindberg, Vice-Chair, PMPRB, welcomed participants to the consultation on the PMPRB's Excessive Price Guidelines. She invited participants to introduce themselves, and then outlined the purpose and objectives of the consultation process.

Drug pricing in Canada is an important issue, Lindberg said. To better understand the issues and perspective of key stakeholders concerning the current Excessive Price Guidelines, the PMPRB is hosting consultations across the country. These consultations are not about changing the *Patent Act* that provides the PMPRB's mandate; rather, they are about "identifying potential areas and directions for change that would help ensure the Guidelines remain relevant."

In March 2005, the Board distributed its *Discussion Paper on Price Increases* and asked stakeholders for input on the ways that patented medicine prices are reviewed. These issues were further analyzed in the 2006 *Discussion Guide on the Board's Excessive Price Guidelines*. The Board heard back from over 40 stakeholders, many of them raising "complex matters" about the price review process. The Edmonton meeting was a follow-up to that feedback, and similar meetings were scheduled to take place across the country in the following weeks. By the spring of 2007, the Board hopes to host another round of stakeholder meetings to discuss potential changes to the Guidelines.

The Board values the input of all its stakeholders including federal, provincial, and territorial ministries of health, consumer groups, and the pharmaceutical industry. With stakeholders' input, the Board believes the consultation process will be "as open and inclusive as possible." Lindberg encouraged participation in the sessions that day.

She explained the three-step format for the discussions would include presentations by PMPRB staff followed by breakout sessions with a facilitator, and would end with summaries of each breakout session shared with the entire group. Lindberg thanked participants for attending, and invited Barbara Ouellet to make the first presentation.

Presentation 1: What We Heard Report

Barbara Ouellet, Executive Director, PMPRB, provided context for the present consultation. In 2004, she explained, the Board began to hear concerns about rising drug prices. The Board decided to investigate the issue and, in 2005, distributed the *Discussion Paper on Price Increases*. Stakeholder submissions identified a range of introductory price issues. In May 2006, the *Discussion Guide on the Board's Excessive Price Guidelines* was released, a document that sought input from a variety of stakeholder groups. The Board received input from 43 stakeholders, and their feedback is summarized in What We Heard.

The feedback identified three main issues:

- How medicines are categorized;
- Whether introductory price tests are appropriate;
- The “relevant market” at which to regulate.

Ouellet explained that there are three categories of drugs:

- Category 1: line extensions;
- Category 2: breakthrough drugs (which need to be backed up with clinical trials);
- Category 3: all other drugs (which may or may not have advantages over existing drugs).

When reviewing the feedback on the *Discussion Guide on the Board’s Excessive Price Guidelines*, the Board noticed that many respondents identified problems with these categories. Some wanted to eliminate categories altogether; others suggested improving upon or expanding existing categories. All respondents felt that the current system did not adequately acknowledge innovation—especially Category 3.

The discussion guide also outlined the way the Board “regulates at the average price of medicine regardless of customer class.” In other words, when the Board reviews a new patented medicine for excessive pricing, it first calculates the average price of comparator drugs used in all markets: pharmacies, hospitals, wholesalers, and others. This current practice does not seek out variations in class of customer or market.

Some of the feedback on this “any market” Guideline supported the current system, but other feedback requested clarification in the use of rebates and discounts in calculating price. As well, some respondents pointed out that it was unacceptable for Canadians to be paying different prices for the same drug in different parts of the country.

At the end of her presentation, Ouellet invited questions from the group. One participant asked for clarification on the ways that the three categories drive price. Ouellet explained how the system worked and referred participants to a more detailed explanation in the conference binder.

One participant commented on how valuable and thorough he found the discussion paper and thanked the PMPRB for its work.

Presentation 2: Principles Underlying Patented Medicine Price Regulation

Sylvie Dupont, Secretary, PMPRB, explained that the PMPRB was established to protect consumers by ensuring that the prices charged for patented drugs are not excessive. The question at hand was how the Board should interpret its “consumer protection” mandate.

Dupont reviewed Sections 79 to 103 of the *Patent Act*, which outline the scope of the Board’s authority, remedial powers, and reporting and consultation requirements. She

noted that nowhere in these sections do the words “consumer protection” appear. Nevertheless, this is the principle under which the PMPRB was created.

To reflect the government’s intention of consumer protection, the Board reviews drugs on the basis of the five primary and two secondary excessive price factors outlined in Section 85 of the *Patent Act*. Not all factors can be applied simultaneously or given equal consideration, Dupont noted, and asked which factors should be given more emphasis during an application, and when. Appropriate guiding principles could provide the link between the factors outlined in the *Act* and the application of these factors when assessing whether or not prices are excessive.

Dupont presented a list of possible principles based on the feedback received from stakeholders in response to the *Discussion Guide on the Board’s Excessive Price Guidelines*. Suggested principles include

- lowest reasonable price;
- Canada paying its fair share;
- value-based pricing;
- price stability/predictability;
- simplicity/transparency;
- international parity/consistency;
- accessibility combined with affordability;
- consistency over time.

Dupont presented three sample frameworks to demonstrate how various principles might apply in different situations.

Dupont invited questions from the group, but no further clarification was requested.

Breakout Session 1: Guiding Principles

Group 1

Facilitator Laura McPherson directed group members to the list of suggested principles in their binders, and asked participants to discuss which of these principles they considered relevant to the PMPRB’s regulatory mandate and which ones they did not.

Referring to the simplicity/transparency principle, one participant commented that transparency is an important principle, especially when dealing with a subject that can be so complex. However, should it be linked with simplicity? The group agreed that although both concepts were relevant, they should not be grouped together. Simplicity is more suited to a regulatory function, and the PMPRB plays more of a “safety-net” role than a regulatory role.

Then the discussion moved to the lowest reasonable price principle. One participant raised the question of how to best express this concept in a principle statement. If

government policies drive prices to be competitive, can the lowest reasonable price really be a principle? Another participant agreed the “dilemma” lies in acknowledging that the purpose of the Board is to prevent excessive pricing, but asked how one can know the lowest reasonable price.

The word “excessive” is relative, a participant said. Individuals should ask, “What is the dynamic when a regulatory government interacts with the free market?” Another participant challenged this view, suggesting that the group was not in fact discussing the free market. In a way, the Board “leaves the free market and enters the world of the quasi-regulatory market.” The original participant agreed, acknowledging, “We’re trying to be the best of both worlds, which is pretty much impossible—but totally relevant for a patent review board.”

Further discussion on this topic emphasized that the Board’s role should not be to sanction a free enterprise perspective on any of these principles. While it is true that patents create monopolies, the PMPRB mandate is outside the realm of market forces.

Discussion moved to the idea of how to determine a reasonable price. Various participants asked: A reasonable price for whom? For what? Under what circumstances?

McPherson asked if perhaps these questions were related to the principle of value-based pricing. She asked the group for some “headline statements” to help capture the discussion to that point. The group revisited the principle of transparency and added accessibility, value-based pricing, and stability/predictability to its list of relevant principles.

Transparency is critical, the group agreed, for making a complex topic understandable. Transparency will allow everyone to see exactly why a price has been determined to be excessive or not. The Board needs to ensure transparency in determining the cost of a drug and in applying factors.

Next, the group looked at the principle of accessibility combined with affordability. In general, participants did not like the wording, but all agreed that the idea of accessibility was relevant. They reworded the principle to read “accessibility and affordability for the Canadian public” to ensure that the consumer would not be negatively affected. One participant noted that a principle that focuses on accessibility may give the Board “the freedom to interpret situations in terms of consumer protection.”

The conversation then turned to the principle of value-based pricing. Here, the group emphasized that the word “value” needed to mean “value to the patient, not value to the market.” This is a “very relevant” principle, because it ensures that a new drug is compared to other drugs to guarantee its therapeutic value. There are two ways of valuing a product. The Board needs to consider a drug’s value to the patient “rather than what the market will bear.”

Price stability/predictability was also deemed a relevant principle. From the perspective of hospitals and insurers, predictability is needed to create budgets and forecast costs. From a consumer perspective, predictability ensures that an individual does not become the “victim of a huge price increase.”

At this point in the session, one of the participants asked the PMPRB representative attending the session, how the PMPRB had developed these principles. She explained that the PMPRB does not have principles, but feedback to the discussion paper suggested that principles may be a useful tool in ensuring consumer protection. This breakout session was intended to explore that idea.

One participant suggested the addition of another new principle: patient impact-based pricing. Drugs can do “a lot of nasty things,” and the Board needs to be aware of the risks involved with the drugs that it is reviewing.

A participant asked whether, if the negative impact of a drug is severe, the price should be affected. Is it right to pay a lot for a drug with severe negative side effects? The drug’s therapeutic value often comes at great cost to a patient.

Another participant agreed but raised the question, “If you have information that a drug is the only effective treatment, but you also know that it has severe side effects, how do you deal with that as a principle?” The negative impact of certain drugs is a powerful influence on the health care system, because other costs are incurred to offset these effects. As one participant stated, “At the end of the day, the family and community bear problems of long-term disability.” Are later, long-term effects considered when making cost decisions?

Before returning to the plenary, McPherson asked the group if they could sum up the discussion by pointing out the principles they considered most relevant and those that were not relevant to the PMPRB’s mandate. Everyone agreed that transparency and accessibility were the most important and should be considered overarching principles. The group felt that the fair share principle was too vague to be a principle.

Group 2

The first principle addressed states, “Canada should pay its fair share.” This group felt that the principle reflects the mandate of consumer protection, because it is desirable that Canada compete internationally; however, this principle is not well applied.

A participant stated that it is difficult to evaluate what Canada’s fair share should be, because it is impossible to assess all of the “behind-the-scenes discounts” available in other countries that cannot be available in Canada, such as the massive discounts offered to the uninsured patient market in the US. The group stated that the same points apply to the international parity/consistency principle.

The accessibility combined with affordability principle, which was identified as very important, is also reflective of the mandate, but there were concerns about its application. Under a reference-based pricing policy, for any given condition, only one drug is funded, even if other drugs would be more beneficial for some individual patients. A participant pointed out that “talking about pricing and Guidelines is irrelevant if you can’t get the drug.”

The underlying rationale behind the accessibility principle is that the inverse of excessive is accessible. “We are only concerned with excessive pricing because it impedes accessibility,” observed one participant. If “me too” drugs are set with very high prices internationally, that could drive a higher price in Canada than is necessarily fair; manufacturers may wait to introduce a product in Canada until they get a high price internationally.

Another participant observed that the lengthy approval process of the Canadian regulatory bodies delays accessibility to some drugs. One participant asked, “Which is more important in this principle, access to the market or patient access to the drug?” Other participants responded that one cannot and should not separate or choose between them.

A participant commented on the inclusion of marketing in determining value-based pricing. In the Canadian drug industry, he explained, marketing is directed at physicians and not consumers; however, the physician does not pay for the drug. Often drug marketing is in the form of discounts and samples, which are difficult to capture.

The group agreed that the lowest reasonable price principle is intuitively synonymous with the consumer protection mandate. It was also felt that the value-based pricing principle is critical, but there was some concern that it is not being applied appropriately. A new drug can carry a high price if it is comparable to other high-priced drugs, although it may have little benefit. This is especially apparent in cancer drugs. The group felt that “value” should reflect the value of having access to that drug, not only the value to the drug company and its investors to develop that drug.

For moderate to incremental improvements, value could be based on a scale. For instance, if a drug is delivering 10 per cent more benefit in therapy, then it should be given a 10 per cent premium in price. A drug’s value also will change over time and is very difficult to determine for drugs that arrive “with promise but no evidence.” Similarly, a first-in-class drug like Avastin should not be rewarded as a breakthrough drug if it does not demonstrate a high value.

The international parity/consistency principle currently only considers 20 countries, which is a fraction of the real world market. This is also an issue for the fair share principle. India, for example, is emerging as a major purchaser, but it is not counted in evaluating if Canada is paying its fair share. Some countries that clearly should be included are India, Australia, New Zealand, and South Africa.

The group agreed that the consistency over time principle is very important. A discussion about re-benching ensued, key points of which were expanded on during the later breakout session specifically centred on re-benching.

A participant stated that “simplicity” and “transparency” should not be part of the same principle. “It’s too easy to apply simplicity in a way that doesn’t support transparency or even reasonable fairness,” she explained. Transparency, on the other hand, is a “great principle, but hard to apply.” The rationale behind this principle, as stated by one participant, is openness, fairness, and coherence within the constraints of any privacy and confidentiality issues related to commercial interests.

The group agreed that the most important principles for the reflection of the PMPRB’s mandate are accessibility and affordability and the lowest reasonable price.

One participant expressed surprise that governments are not one of the four market categories the PMPRB measures, but hospitals are. He attributed this to the fact that it is a historical market, and governments were historically organized in a different manner. “Drugs are important in hospital settings, but it’s chump change in the total market for most drugs.” A participant who had done research in the area stated that hospital contract prices are always better than the consumer market. The first participant continued that the pricing should be taken from the major payer markets. The group called this concept “real market pricing.”

Ouellet explained that the four classes of customers are in the regulations and that governments are not bulk purchasers. They may pay for the drug, but the first group that purchases the drug is one of those customer groups. “We don’t know of a government that buys in bulk and becomes a distributor,” she explained.

A participant pointed out that governments enter into contracts and negotiate price. Governments do group purchasing, which is so subtly different from bulk buying that it does not warrant governments being excluded. Ouellet explained that the sales made by the governments are reported, so the data is captured. The group decided that “real market pricing” is a process for ensuring fairness and accessibility.

One participant mentioned the new Ontario *Transparency Act* that protects what the government of Ontario pays for drugs. The Ontario government thus has the opportunity to obtain the best price for itself, which could result in the rest of the market paying extra to offset that discount. The contracts between government and industry will not be transparent, so the price paid by government will not be easily accessible. This is an issue for the fairness and accessibility principles.

Group 3

Participants began by commenting on which principles from the list provided (or others) best reflected the PMPRB mandate and why.

Simplicity and transparency were cited as highly reflective of the mandate because of the number of stakeholders involved and the need for accountability. These principles help to ensure that issues are understandable and enhance predictability.

A new principle was proposed to address patients' hopes of future cures through innovation: pricing must encourage this and ensure that Canadians get access to the best medicines in the world. This concept also links to accessibility and value-based pricing.

Value-based pricing and simplicity/transparency are most important, agreed a participant. Stability and predictability are reasonable, but the meaning of value-based pricing must be clarified. (Whose values are being talked about?)

This stimulated discussion about questions raised by value-based pricing. Value to individual patients differs from value to society, it was noted. The public may have different spending priorities and may be more concerned with affordability than quality of life for a few patients. How does one determine fair pricing? The answer is not simply what governments wish to pay. What about individuals who can afford to pay privately but are currently prevented from doing so by the public system? It must be considered that the public system might change significantly in the future.

These questions go beyond the scope of the PMPRB. Still, it was argued, pricing has broad implications, such as if prices are so low that valuable products do not come to Canada. That is an industry decision not controlled by government, another participant argued. The PMPRB should examine therapeutically effective products on the international market that are not in Canada when considering pricing. The PMPRB must also consider not just value to patients, but to physicians who want a choice of the best products for their patients. Quality of life and therapeutic effectiveness are among key points to consider in determining value. It was also noted that agencies must often make decisions about value without adequate comparability data.

Encouraged to comment on the other principles, one participant said that Canada should pay its fair share if it wants to be a player and attract research and development (R&D). Simplicity and transparency are important, he agreed, and international parity is a reasonable price test. Indeed, if this were the only price test, things would be a lot easier.

Another participant proposed comparing prices to countries beyond the seven listed. This was challenged with an argument that comparing prices in countries with price controls would create "a race to the bottom."

If one is looking at consumer protection and international parity, it must be remembered that the Canadian market is smaller than most, it was noted. Attracting R&D means Canada does need to play, but it is not certain that that will lead to fair pricing. Pricing is just one factor, said another participant. Companies want to do R&D wherever the best research is being done, and in this sense Canada is seen as attractive. However, this participant agreed that unfair pricing could drive companies out.

Affordability was also discussed, with more questions about who defines affordability and how. Also, why is this test applied to pharmaceuticals but not surgeons? One participant said that discussion does happen at the macro level.

The group also considered what principles might be non-reflective of the PMPRB's mandate, with lowest reasonable price cited as problematic. This is laden with value judgments about what is reasonable, and it conflicts with other key principles like simplicity and transparency. It is unclear and may not be appropriate, several group members agreed.

Provincial governments are interested in value, noted another. Is that the role of the PMPRB? Other processes already look at the value of drugs, and a PMPRB role may conflict with those processes. If the results are different, this may also confuse the consumer. Other participants were not convinced—how could other bodies do their evaluations without an established price? Even if the price is not set at that point, the PMPRB regime provides a good indication of what it will be.

Discussion turned to other, potential, new principles. Perhaps under simplicity, there should be consideration of the efficiency and cost-effectiveness of regulations, it was proposed. Board hearings are very expensive for everyone.

The group then looked at rating the various principles. Some supported a high rating for simplicity, transparency, and value-based pricing, while acknowledging challenges in the latter's execution and definition. Canada paying its fair share and international parity were seen as priorities for one participant but were low on the list for another.

The group also explored possible agreement on low-priority principles, with discussion focused on "lowest reasonable price." This really depends on perspective, one noted. From the consumers' perspective, the matter is quite important. The participant wondered whether principles of accessibility and affordability are consistent with the PMPRB's mandate, or more a question of value-based pricing, lowest reasonable price, and the consumer protection mandate. The participant also question what is meant by accessibility, and whether it includes access to new or a choice of products.

The original intent of the PMPRB was to ensure that prices would not become excessive because of the monopoly granted through patent rights. Payers have responsibility to seek the best possible price, while the PMPRB sets the upper threshold; these are two different issues. For the PMPRB, the question is whether the price is reasonable. It is not certain that the mandate extends to getting consumers the best possible price, nor that the PMPRB has that ability.

This led to some consensus that it was someone else's responsibility to look at lowest reasonable price, accessibility, and affordability rather than the PMPRB's, and that benchmarking was primarily about determining a reasonable price. Although it was suggested that these are beyond the scope of the PMPRB, these are all still very important principles, stressed a participant.

If the intent is value-based pricing, a participant asked, how does one respond when the price is set and then the company demonstrates greater or lesser value? Re-benching would address that, another replied.

In wrapping up, a participant said the unique Canadian government structure requires a uniquely Canadian policy.

The group also briefly discussed proposed frameworks. One participant supported Framework 1 from the presentation. Another supported frameworks 2 and 3 but not Framework 1, saying he did not think international pricing always had validity for Canada: other countries may not have the same products as in Canada for comparison. Several others supported Framework 2, with suggestions to drop the access and affordability components and add simplicity and transparency.

Framework 2 offers a made-in-Canada approach and consumer protection, one noted. There was some concern that by focusing on Canada's relatively small market, Framework 2 could cause distortion, with low prices at the risk of not getting some products. Participants returned to the PMPRB's need to focus on excessive pricing instead of lowest pricing, considering value in broader terms than simply affordability and the jurisdictional question, with provinces perhaps having more leverage on pricing.

Concluding remarks acknowledged that it was complicated, that terms like "accessibility" needed definition and that overlapping PMPRB/provincial jurisdiction was an issue.

Plenary Session: Report Back

The first group identified the guiding principles that reflect the PMPRB's mandate. Simplicity and transparency were given a high grade of importance, because they create accountability, coherence, and predictability. Value-based pricing was given a similarly high importance; however, the definition of value was problematic.

"Canada should pay its fair share" is an important reflection of the mandate, as Canada wants to attract R&D. The group noted that this principle is contradictory. It does not specifically address the consumer protection mandate, and it is difficult to evaluate what Canada's fair share should be.

The principle of international parity does reflect the mandate but is not very important. Overall, the group felt the principles include many problematic abstract nouns.

The group identified two new principles: pricing to ensure that Canadians get the best medicine, and efficiency and cost-effectiveness of the regulations. The lowest reasonable price principle does not reflect the PMPRB's mandate, according to this group. It "flies in the face of transparency," and the definition of "reasonable" is hard to apply.

The group preferred the second and third frameworks because they are “made in Canada.” The group felt that “accessibility and affordability” should not have been included in the last two frameworks and that “simplicity and transparency” should have been an underlying principle for the second framework.

The second group approved of the linking of “simplicity” and “transparency” in one “key” principle, although the components are challenging to enact together. Some felt that “simplicity” should be linked with “consistency.” “Transparency” is important because the PMPRB must explain the rationale behind their decisions.

The group discussed the PMPRB’s role as a “safety net”; the Board “sets a ceiling below which prices must fall.” The lowest reasonable price principle, because it depends on the definitions of “reasonable” and “excessive,” can be seen from multiple perspectives.

The group felt that price stability is an important principle, because predictability is important for budgeting. The accessibility principle is also important. The fair share principle was less important for this group, as it is currently too vague.

The group was unsure whether “value-based pricing” reflects the mandate, as it relies on the definition of value. A new principle was proposed emphasizing value to the patient rather than market value. The group also felt that there should be a patient impact principle that explores the risk to patients.

The last group had many ideas in common with the previous two. Their area of greatest concern was accessibility and affordability and consumers’ willingness to pay. They were concerned about relating price to accessibility. The lowest reasonable price principle is intuitively related to consumer protection.

The value-based pricing principle should refer to the value of an accessible price rather than the value of profit. The consistency over time principle is related to re-benching. There was a concern that the international parity and consistency principle does not assess more countries.

Transparency must be understood within the constraints of confidentiality. The group felt that although simplicity is important, it does not support transparency.

A new principle called real market pricing was considered, but it was determined that it is part of a process for ensuring fairness and accessibility.

A member of the last group pointed out that, while they felt accessibility was a very important principle, the previous group had had concerns with the principle in application.

Breakout Session 2: Discussion of Categories and “Any Market”

Group 1

McPherson began the session by directing participants to the definitions of the three categories in their binders. She asked them to consider these questions:

- Should there be categories, and, if so, what should they be?
- Should prices be reviewed in sub-markets of the Canadian market?

The group agreed that categories were needed as a way to decide if a drug price is excessive or not. They are useful and provide criteria. Consistent outcomes and value-based pricing can only occur if categories are used.

However, are the existing categories the “right” categories? One participant said he “wasn’t convinced the three categories we have are appropriate.” The categories need to be simple and clear, but there is insufficient information at market-entry for true simplicity and clarity.

Many of the participants expressed concern over the inherent “rewards” in drug development. Development is rewarded through the patent system, through tax breaks for research, and then again through the review process if the drug shows even minimal innovation. While everyone agreed that innovation should be rewarded, they wondered if the current categories were “rewarding without innovation.” One participant noted, “I can see the need for the innovative category more than the need for the other two categories.”

Changing the direction of the discussion, one participant acknowledged, “We need categories, but there also needs to be a definition of excessive.” How can the categories be effective if they are not informed by an appropriate definition of “excessive”? Would it not make more sense, one participant asked, to start out with a definition and from that point categorize the areas of concern that drive pricing?

This question spurred several related questions:

- Does one need to consider sales volume in the categories?
- Is there a category to establish introductory prices that might be okay in one instance but not okay in another?
- What if the drug under review is applicable to more indications than initially thought? Should its price be lowered because sales are more voluminous than expected?
- Is the issue of “indication creep” captured in the existing categories?
- If one is in Category 1, it is possible to “get out” of it should the status of the drug change?

The group acknowledged that some of these questions might be more appropriate to the re-benching discussion in the afternoon, and agreed that an appropriate and workable definition of “excessive” would help better define the categories.

Several revisions to the current categories were recommended:

- Shift the current Category 3 to the first category, and combine it with the existing Category 1. The different aspects of the category can be broken down into a, b, and c components (where a equals line extension, b equals moderate improvement, and c equals little or no improvement).
- Keep the current Category 2, but indicate that market forces are considered more in this category than in the “new Category 1.”
- Consider the development of a new category: “tried and true,” to ensure that drugs that work reliably are considered in the pricing decision.

At this point, the PMPRB representative attending this session did clarify that all drugs are currently looked at as comparators including the “tried-and-true” drugs and generic drugs.

McPherson shifted the group’s focus and asked participants to consider the “any market” question.

The discussion began with a comment on the relevance of the principle of transparency. Technically, a price that is higher than the Consumer Price Index (CPI) in one market could “pass” depending on the average price involving other markets. If this is the case, that information needs to be evident.

One participant raised the concern that it would be unfair to have individuals pay more so that large institutions pay less. If the current system of “any market” means that this could happen, then the system needs to change. If the variation in price amongst classes is not monitored, companies can meet the Guidelines even though the price might negatively impact the customer class. The customer class needs to be treated differently than the other classes.

Agreeing with this concern, another participant proposed the idea of defining the “acceptable variations in price between markets.” He stated, “If the Board accepts there will be variation markets and there is such a thing as excessive variation, let’s define that. If there is a ‘magical per cent’ that constitutes an acceptable or unacceptable variation, let’s define that too.” Countering this point, one participant suggested that some variation in price is okay.

Some participants expressed concern that the Board actually “facilitates the behaviour of incentives.” Is the answer to subdivide by market by separating hospitals and consumers? Some participants thought so, but one of them raised the point that this argument only works if the drugs sold to hospitals and consumers are the same. He said that the drugs bought by hospitals are rarely the same as those used by consumers.

McPherson wrapped up the session with a review of the points she would present at plenary.

Group 2

In attempting to determine the benefits of categories in excessive pricing, a participant wondered if there are different price expectations associated with different categories. For instance, breakthrough drugs could be expensive because the only benchmark is the international price.

Another participant stated that categories should be a subset of the principles that were discussed in the previous breakout sessions. She pointed out that even if categories did not exist, information about drugs would have to be sorted in some way. Category 1 was logical to her, because “me too” drugs should be compared to similar drugs. Category 2 is problematic, however, because of the perception that it is a reward.

A participant introduced the industry term “product life cycle management.” Category 3 is problematic, because it does not measure the “life cycle” of a product. He asked if three categories are really adequate.

Another participant repeated that categories are logical formulations of rules, but they are problematic if they carry a value. Manufacturers may be reluctant to release a Category 1 or a Category 3 drug in Canada if they feel that it will receive a low price. This can restrict patient access to valuable drugs. Although a drug with a higher benefit should be accorded a higher value, the value should not be inherent in the category.

Categories are acceptable because they allow consistency, said another participant. Manufacturers know before entering the process which pricing tests will be applied to their product.

A participant stated that categories 2 and 3 are slightly blurred. Her concern with Category 2 was with rewarding a company that has invested in new research but has a drug with marginal impact. A drug like Tarceva could be the first in its class, but it may not be truly meritorious as a breakthrough drug for extending survival by 8–20 weeks. Another participant responded that the improved quality of life for the patients with extended survival *does* justify the drug as a breakthrough. She pointed out that manufacturers may increase their sales if their product is priced low.

Another participant pointed out that first-in-class drugs, such as Fabrazyme, may not have any evidence of benefit because of the disease population size and lack of robust trial data. He called these “drugs of promise.”

“Allocating the Category 2 status, which could reward a manufacturer, has a serious impact on accessibility in Canada,” said one participant. Putting drugs that only have marginal benefit into Category 2 actually impedes accessibility in Canada.

Some drugs can actually straddle two categories: a drug may offer incremental benefit for the majority of people but offer a total cure for a sub-population.

A participant observed that a drug like Paroxetine, which has eight indications with Notices of Compliance, could be in both Category 1 and Category 3. Should the price vary with each indication? Another participant agreed, stating that a drug originally in Category 3 should not be able to use a line extension mechanism to get a Category 2 price.

A participant suggested that there should be a new category for drugs of promise.

Category 3 is a concern because of benchmarking. In lipid-lowering drugs, Fibrate set the ceiling at \$2.40, although the market competes at \$1.40. Currently Lipitor is the only patented drug in that category that is promoted to physicians. It could have any price up to \$2.40. A participant called it re-benching when “categories mature.”

Another participant pointed out that in some drug categories there are long breaks between when drugs are introduced. Sometimes it makes no sense to tie the new drugs to the price of the old ones.

It is difficult to categorize a drug like Viagra, which is now being used for pulmonary hypertension as well as erectile dysfunction. Often when a drug gets a new indication its price starts to jump.

Shifting to a discussion around sub-markets, the participants felt that the simplicity afforded by not considering sub-markets when reviewing prices is an advantage. They thought that the four classes of customers are no longer relevant, especially as the lines between communities and hospitals are blurred in most provinces that have regional health authority structures. Simplicity must be balanced by accuracy, and looking at outdated customer classes increases complexity and reduces accuracy.

Another participant stated that the Board should not spend 80 per cent more effort to get only a 20 per cent return; in other words, the extra effort required to include sub-markets would not translate into a significant increase in accuracy.

A participant reminded the group that “what we really want from the Board is to bind the upper level.” Below that ceiling, business rules determine prices.

Ontario’s new legislation was mentioned as a potential problem. Because the prices they negotiate will not be transparent, they may not be taken into consideration when the Board calculates the average price.

One participant stated that her community wants the average taken on a regional basis. Another participant pointed out that if business rules are expected to determine prices below the “excessive” ceiling set by the PMPRB, then Ontario’s *Transparency Act* should not be a problem.

The majority of the group felt that an analysis that included sub-markets would not address the major concern over other provinces subsidising Ontario’s contracted prices,

because governments are not considered a class of customer. The notion of alleviating this through provincial cooperation with the PMPRB was considered.

Ouellet interjected that the PMPRB is aware of all deals made by the manufacturer. However, the problem is that the rebate is not transparent beyond the PMPRB. She explained that “we know that with the rebate you’re only paying \$5,” so the manufacturer passes the excessive price test. “But as far as anyone else knows, you’re paying \$10.”

Group 3

In answer to the question of whether there should be categories, discussion began with a vote of support for categories, though they could be defined differently. A participant disagreed, proposing that categories be eliminated because the descriptors are subjective, the HDAP does not always have the required expertise, and the required data are rarely available when the product is launched. The HDAP does get expert outside consultation, it was noted, but this has been reduced lately.

Another participant said she supported categories, though maybe for the wrong reasons. Some way is needed to rate the products, she said—if not categories, then how else?

In response to questions, a PMPRB representative confirmed that the HDAP gives closer scrutiny to Category 2 and Category 3 drugs and also assigns new products to the three categories.

A participant cited the example of two new drugs developed concurrently: a slight difference in release timing meant that only the first one out had a Category 2 rating, which implies a higher price. Apart from Category 1, it is hard to say where to draw the lines between other new products. It is becoming increasingly difficult to secure a Category 2 rating, he added, so almost everything falls into Category 3.

Another participant said she was undecided. Although categories promote transparency, people need to be sure they are valid. But eliminating categories flies against the principle of value-based pricing. If all drugs are lumped together, how does one rate them?

Participants compared the PMPRB process to other systems, asking about the French system, for example, and noting differences from the Health Canada and US Food and Drug Administration (FDA) systems for evaluating drugs.

A participant expressed opposition to categories, though for different reasons, arguing that big companies can “game” the PMPRB system to try to secure a preferred rating. Decisions are based largely on information provided by the manufacturers, so by controlling what information is released, they can influence the outcome.

Another participant agreed that there may not be enough information to make the categories work as intended, but asked, since price tests are linked to the categories, what tests would be used for different drugs in their absence.

A participant suggested four categories: new drugs, drugs with dosage changes, comparable drugs, and drugs with little or no therapeutic value. Another proposed that if categories are used, there should be a more transparent process than leaving it up to a panel of three people. A further issue arises from using a particular price test based on the assigned category—and then a Category 2 product turns out not to be a breakthrough or vice versa.

If the original intent of parliament was to prevent excessive or abusive pricing, there should be some control of that, for example, if Canada has the highest price in the world for a product. But if only one category gets used, that is not in anyone's interest.

It is hard to discuss this issue without getting into pricing and price tests, it was observed. But if the decision is to eliminate categories, this forces a discussion on prices and price tests.

The question was posed: should prices be reviewed in sub-markets of the Canadian market? After seeking clarification of why this question had arisen, one participant said it is probably not doable. There are too many confidential agreements covering rebates and complex bundling arrangements to determine actual prices being paid.

A PMPRB representative explained that rebates are reported to the Board in confidence.

Several further arguments were raised against reviewing prices in sub-markets of the Canadian market: it is too complex, it would deter industry from offering better prices to hospitals, and it might deter compassionate use programs. One participant was encouraged by the lack of price variability reflected in the tables provided, saying it was not clear why this was even seen as an issue. One concern was over the difficulty of comparing Canadian and US prices if both countries do not use the same methods.

Responding to further questions, a PMPRB representative explained that price data are collected for four classes of customers and for all provinces and territories as well as Canada, which means potentially 52 prices for each product.

One participant questioned the value of such a complex process, while another suggested simply using published prices. It was explained that, under Ontario's new legislation, the actual price will differ from the published price, which reduces transparency. This is already happening, so the question is whether it should be continued or expanded.

Asked if the Board was concerned, a PMPRB representative said concerns were brought to the Board. It is known that there are differences, so the Board wishes to know if it is enough to change practices.

Some provinces are concerned that they are paying more because of their size, a participant added. Another acknowledged that from a consumer perspective, there may be concern about the cost of drugs being artificially lowered for hospitals, with the result that patients pay even higher prices for the same drugs after they go home. However, provinces can control this, it was suggested. Provincial plans can cover roughly half the market, so they can determine prices.

A participant asked if this question related to the PMPRB's reporting or regulatory role. To clarify, it was noted that the question was about whether the PMPRB should regulate the maximum price in sub-markets.

Another participant argued that this would preclude deal-making that could benefit consumers, and suggested establishing a maximum price that cannot be exceeded, yet does not preclude discounts. Agreement was expressed for the PMPRB setting a cap while allowing others to negotiate discounts. Another participant did not see any need to regulate prices in sub-markets, based on the data, as the majority of prices were below MNE.

Wrapping up, it was acknowledged that smaller provinces might have a different perspective on this question if they do not enjoy the benefit of bulk purchasing.

Plenary Session: Report Back

The first group agreed on the use of categories, because they ensure a life cycle management of drugs and their related prices, and categories allow for consistency in the approach to pricing, which results in transparency and certainty.

There were concerns with each of the categories, however. Category 1 provides opportunities to revisit categories 2 and 3, but line extensions must be linked to new mechanisms of delivery. The concern with Category 2 centred on the way value is determined and how the impact of a drug is assessed. Drugs of promise may require a new, separate category. The concern with Category 3 was the requirement for re-benching.

Some members of the second group did not support categories, because category descriptors are subjective, and adequate data is rarely available when the product is launched to accurately place it in a category. Other members of the group felt that categories are necessary, but the evidence does not support the current category definitions.

The third group felt that categories are a useful tool to determine excessive pricing. However, biologics, new indications, and small, vulnerable populations may not be included in the current categories. Some members felt that categories are inappropriate when there is not enough information available about a drug. In addition, categories can generate rewards for products, but a product should be rewarded based on its innovation

and not on its category. It was also felt that categories 1 and 3 could be combined and that breakthrough drugs should be in a category numbered 1. The group also felt that a category should be created for “tried-and-true” drugs.

A participant observed that “there’s nothing inherently wrong with the categories.” The problem arises from the value associated with each one. Another participant pointed out that drugs with incremental increase in benefit “would be rewarded by greater volume and market share as opposed to higher prices.”

The first group felt that prices should not be reviewed by sub-market, because the current system is simple. The issue is how to balance simplicity with greater accuracy. The Board should create the price ceiling, and specific price negotiations should take place in the sub-markets.

A concern was that Ontario’s *Transparency Act* could force other consumers to pay higher prices. It was felt that the sub-market analysis would not alleviate this concern, and it would not provide higher quality data.

The second group felt that the consumer protection mandate is being met without including sub-markets in analysis.

Some members of the third group, in contrast, felt that sub-markets should be included, because they would more accurately reflect the market. Others, however, felt that the different drug usage in each customer class would make sub-market analysis too difficult. They felt that “most Canadians do not want uneven prices.”

Ouellet explained that manufacturers must file price information, including any discounts or rebates, for all four classes of customer in each jurisdiction. Currently that data is analysed by determining the total average, but the potential exists to analyse the data by sub-market.

A participant stated that the Board should maintain the same excessive price for all Canadians and not only the average of all Canadians.

Presentation 3: Re-benching of an Introductory Price

Paul De Civita discussed re-benching, a concept that has arisen within the last two years. De Civita explained the two circumstances in the PMPRB’s current Guidelines under which re-benching could occur: first, when a drug under the Special Access Program (SAP) is granted an NOC; second, when a drug that was originally sold in fewer than five countries increases that number to more than five countries.

Another possible reason to re-bench is when a drug is granted a second indication. This could be tied to Health Canada’s new initiative on progressive licensing for drugs and biologics.

De Civita outlined some advantages and disadvantages of re-benching and then asked the participants to address the following three questions during the breakout session:

- Should the introductory price of a patented drug ever be re-benched?
- When should re-benching occur?
- What evidence would be needed to support re-benching?

Ouellet added that the *Act* stipulates that the relevant market for each product should be considered. Therefore, when the market in which a drug is sold markedly changes, should the PMPRB take those new market dynamics into account?

A participant asked if a drug with a new off-list use, such as Avastin, could be considered for re-benching. Ouellet answered that the “real-world use” for a drug would be evaluated.

Breakout Session 3: Discussion of Re-benching

Group 1

McPherson asked participants to consider three questions:

- Should the introductory price of a patented drug ever be re-benched?
- When should re-benching occur?
- What evidence would be needed to support re-benching?

In response to the first question, one participant stated, “Yes, if it’s done for the right reasons. But no for the vast majority of reasons.” Picking up on this assessment, another participant added that periodic review of drug prices is a good thing, but a system that re-benches for the “right reasons” must be created. If not done properly, it could lead to a lot of time and energy being spent re-benching drugs that are never going to change.

Another participant suggested that one way to avoid bogging down the PMPRB with unnecessary paperwork and false leads would be to create an advisory panel that specifically looks at this issue and recommends that the Board review certain drugs.

Participants responded enthusiastically to the idea of an advisory panel and wanted to develop it further. One participant envisioned the panel as a type of “horizon scanning group” that would look for the drugs that need to be re-benched. The panel would not be responsible for re-benching, but it would be responsible for making recommendations to the Board for reconsidering the prices of specific drugs. Then the Board would decide how to follow up. Another voice of support suggested that such a system would “reduce overlap and redundancy and ensure that only the drugs that needed re-benching would be looked at.”

Developing the panel idea even further, one participant noted that the PMPRB would continue to take responsibility for the two re-benching scenarios that it currently assumes: when new NOCs are granted and when the drug is sold in only a few foreign countries.

However, when re-benching is required outside the current scope of the Board, the advisory panel would be used. For example, if a drug clearly becomes “the therapeutic drug of choice for an indication other than one [for which] it was initially intended, we have an obligation to look at this for the purpose of re-benching.”

The direction of the discussion shifted to consider the times when re-benching would be inappropriate. For example, it should not occur if manufacturers “complain that their competitors get higher prices” and so they want re-benching to see if they can get a higher price. It would also be unacceptable if the pricing dynamic changes but the therapeutic value does not.

One participant cautioned against taking away “the few normal, competitive market forces that may exist in the current structure.” The idea of continually re-benching a product would lead to an unpredictable, fluctuating market.

One participant disagreed with this approach and insisted that the system needs to value a product based on its therapeutic use. He proposed the idea that manufacturers should be able to raise prices as long as the product shows a marked therapeutic improvement. He argued, “If it is cheap to manufacture, that’s the spirit that will drive the market forward.”

This position was challenged by several participants who insisted that if a new treatment is effective, but it is also inexpensive to produce, then the cost to the consumer should remain low.

McPherson asked the group to consider the question of timing. When would this advisory board recommend a price review?

All agreed that the forces that “trigger” a review had to be simple. One participant noted that care needs to be taken with such a complex issue to ensure that the re-benching system does not “intervene too much on market forces.”

The discussion returned to the advisory panel idea. The panel would be made up of experts, and these experts would need to establish and apply criteria for deciding whether or not to recommend re-benching to the Board. Anyone would be able to ask the panel to consider recommending a drug for re-benching: consumers, advocacy groups, manufacturers. However, the Board would apply criteria to the request and use these criteria to decide whether or not a drug should be recommended for review. For example, if a manufacturer requests re-benching, the request will not be considered if pricing dynamics have changed but therapeutic use has not.

The process needs to be simple, but it also needs to “prevent swamping.” This is accomplished through the criteria: individuals or organizations requesting re-benching must meet the criteria. As well, the system would need to be wary of replication. Perhaps a two-page, online form would be all that is required to make the request, and the advisory panel would use that information to shape its investigation.

At this point, McPherson asked the group to review the summary notes for presentation to the plenary.

Group 2

The participants agreed that re-benching is obviously a good choice, particularly in the interest of fairness to both the patient and to industry. As one participant observed, “why would you say no?”

Health Canada’s reviews of new indications could trigger re-benching. A drug can drift into different categories that have different benchmarks than those of the category the drug was originally tied to. For example, Rituxan drifted from cancer use to arthritis use, so in the latter instance its use is chronic for life, which should be reflected in the price. Prices should be adapted when the drug’s use changes.

Another participant stated that a drug’s price *before* it is granted an NOC should not establish a benchmark, because then there is no benefit to the company to enter a drug under the SAP. A participant disagreed and cited Oxalyplatin as an example of a company that used the SAP to obtain a higher price than they would get after an NOC.

This led to a discussion of access to the market. Some manufacturers that are seeking a new indication will create a free trial of the drug to promote that new indication. Some old generic drugs may have new indications, but no manufacturer wants to explore them because the drugs cannot be protected without a patent. A participant stated that the central point is that if re-benching is conducted, “you don’t get these games going on for products with different indications.”

It was a consensus that the Board needs to re-examine whether a drug’s initial price reflects how the drug is actually used. It was also agreed that the initial price of a drug should not dictate a permanent benchmark.

A Health Canada review of a new drug indication is a clear trigger for re-benching. However, evidence for a new indication could be compelling enough to trigger re-benching without a Health Canada review. Vancomycin was cited as an example. It was introduced as a community drug, but it has been discovered to be effective against resistant “super-bugs,” and as a result, it is now held in reserve. The drug’s market has shrunk, so its price should change.

Criteria for the PMPRB to conduct re-benching and for the patentees to request re-benching were discussed. It was felt that there should be a means for large purchasing groups to request re-benching if a new, off-label use for a drug emerges. The participants agreed that drugs should be able to be recategorized as a result of a re-benching. This could provide an incentive for the manufacturer to conduct follow-up clinical work.

The group briefly discussed the recent change to the exclusivity period for clinical trials.

The legislation includes a provision for third parties to complain about a price, but not to be actively involved in its re-benching.

Re-benching could result in a radical category change. Thyroid medicines are not commonly developed, because the market competes at a very low price. At the other extreme, Rituxan is an expensive drug in an already expensive class of drugs for rheumatoid arthritis. Categories need to be rethought. A participant pointed out that short-term or long-term use of the drug is not considered when it develops a new indication.

A participant summarized that a mechanism must exist for some categories of customers—perhaps the four standard customer classes with the addition of governments—to request a formal review of a drug’s price when new indications emerge that have a major impact on the utilization of the drug.

It was observed that to address the issue of certainty and predictability, there should be a limit to how frequently a price review can be requested. Advocacy groups will require an avenue to this mechanism, and this could be achieved through cooperation with governments.

The group felt that it was not qualified and did not have the time to determine what specific evidence would be persuasive enough to trigger this re-benching process. Some ideas that were discussed included objective, blinded, clinical trials and “level one evidence.” The participants agreed that the PMPRB should conduct a series of consultations to determine what evidence should trigger re-benching.

A participant observed that Health Canada is changing its conditional licensing process: manufacturers, particularly those submitting “drugs of promise,” are now required to submit additional evidence after the Notice of Conditional Compliance has been issued. The PMPRB should follow Health Canada in becoming more interactive.

One participant proposed that a patentee should be able to request re-benching at any point in time, but there should be restrictions on how often third parties can request it. In essence, the Board can conduct re-benching after a new NOC; third parties can request re-benching subject to criteria, which have to be built; and the patentee can request re-benching at their discretion.

Another participant was uncomfortable with the absence of restrictions for patentees, and the group decided that re-benching should always be conducted only at the discretion of the Board, to “protect from trivial competitions for adjustments in price.”

Group 3

Discussion began with the facilitator asking if there was consensus on the need for some form of re-benching. In general, it should not happen, replied one participant. Raising prices will have market consequences, so manufacturers will not be rewarded when price increases are approved; they will be penalized only when prices are reduced. If special

situations arise—for example, a new indication is found for a costly drug, and it becomes commonly used—they should be dealt with in a new way.

Perhaps there is only a need for international re-benching, it was suggested, to ensure that Canadian prices still fall within reasonable bounds from an international perspective. Another participant challenged, this, however. If the a priori principle is that it should be a value-based pricing system, then logically there must be re-benching, because value may increase or decrease over time as circumstances change. This raised the question of how to determine value, and it was reiterated that all these issues are interlinked.

Drug utilization can also change over time, and this can provide more real-world evidence of value, which could in turn influence prices. This suggests the need for a cap, it was proposed, to ensure that prices do not rise beyond the reach of consumers.

To illustrate the complexity, a participant described the example of Viagra, which was originally introduced for impotence. Evidence subsequently emerged of its potential usefulness in treating pulmonary hypertension, a condition currently treated by far more expensive drugs. This prompted the manufacturers to reformulate Viagra so that it could be reintroduced as an entirely new product, thereby allowing it to be sold at a far higher price, even though the only difference from the original product was a new slow-release mechanism.

A PMPRB representative confirmed that a new formulation of an existing product would get a new DIN. If there was also a new patent due to the slow-release mechanism, then the PMPRB would review it as a new product, looking at comparator drugs for this indication. The PMPRB representative also confirmed that re-benching could result in a price change for the original patients, and it was noted that this raised issues of differential pricing.

A participant expressed concern that re-benching would threaten the Board's consumer protection mandate if new benefits are discovered over time. The reverse could also occur, it was noted. Once the price is established, that should be it, said another participant. Manufacturers should not be allowed to raise their prices because of unexpected new benefits. But, it was countered, if prices cannot be increased accordingly, would this be a disincentive? It is complicated, a participant acknowledged, but if the product is still "just plain Aspirin," companies should charge the same price regardless of new benefits.

Participants next considered the questions of why and when re-benching should occur. Why not just re-bench all drugs on a regular cycle, like in the UK, where such reviews are done every seven years? This is not fair, argued a participant. Companies can only ever revise prices downwards, because markets will not allow them to go up. Suggestions about when to re-bench included extreme situations when a common indication is found for a very expensive drug or when the price/volume changes are very significant for a new indication, as in the case of Viagra.

Participants also discussed implications and questions about off-label use. This is common for oncology products, where new indications may be found through trial and error, and utilization gradually changes (indication creep). One participant said off-label use is not significant outside of such oncology drugs. Another said this depends on the drug, with certain products having a higher rate of off-label use, particularly if they are not highly toxic. This raises questions about what evidence is needed to ensure that utilization for a new indication is valid, it was noted.

A participant said that as products reach the later stages of the marketing cycle, companies may not feel it is worth the effort to pursue re-benchmarking. The group discussed the need to look at actual utilization patterns instead of just the NOC and whether benchmarking should be done before the NOC. If companies do not consider it worth the effort to apply for the NOC, why should the PMPRB make the effort to re-benchmark?

If high-priced drugs for a rare disease are found to have new utility in treating a common disease, then market forces will bring the price down anyway, a participant said. Not re-benchmarking them will not affect this. Another added, however, that while prices may fall, they may not fall enough to be in line with median international prices for similar treatments. This is relevant to the principles underlying the PMPRB mandate, he said, and existing PMPRB processes do not provide any opportunity to assess this.

Other than the initial snapshot provided in setting the benchmark price, the PMPRB only reviews CPI increases. It is a valid concern for the companies that re-benchmarking will only result in prices going down, but there is still a need to look at prices that may become excessive over time.

A PMPRB representative confirmed that subsequent reviews are only done if prices rise more than the CPI.

The facilitator reviewed key points, noting that all but one participant saw the need for some mechanism to review prices for certain circumstances. One suggested having regular reviews. A participant added that, while the original analysis in most cases focuses on benefits for the severest forms of disease, most drugs tend to be increasingly used over time for less severe forms. So in that sense the value can also change significantly over time.

Another participant used the analogy of consumer electronic prices dropping over time, suggesting that it should be the same for drugs. He opposed re-benchmarking, arguing that price declines as a result of re-benchmarking are not relevant to the PMPRB mandate and that potential increases would only benefit industry. Another participant, however, questioned whether electronics and health care were comparable in this sense. If there is re-benchmarking, the price test should also change, a participant added.

If a new indication is found, whether off-label or not, and more people begin using it in the rest of the world, prices may come down internationally while staying the same in

Canada, a participant reiterated. Without re-benching, there is the potential to keep prices artificially high.

Participants discussed the market forces that affect prices and agreed it was a complex issue. In the wider scheme of things, one remarked, it is not drug prices that are driving health care costs, but rather utilization.

Plenary Session: Report Back

The three breakout groups reported back on key discussion points regarding re-benching.

The first group supported re-benching. Arguments included fairness to patients and industry, a mechanism to adapt the price for new uses, and the need to allow manufacturers and consumers to get a fair price. How to re-bench should be based on the change of use, and it was acknowledged that this would be a challenge. The group also proposed some means to allow third-party interveners to trigger a request for re-benching. This process also should allow for re-categorization.

When a new use is approved for a product, there should be a mechanism to review the price. The patentee should be able to apply for such a review, as should third parties, at the discretion of the Board and based on established criteria. There needs to be a transparent process to determine the evidence that will be needed in such cases, for example, through a consultative process similar to this one. Also, consider linking reviews to Health Canada's conditional licensing process. The need for longitudinal data was also noted.

A participant from this first group clarified that the group's emerging consensus differed from other proposals for a routine periodic review, which would entail a great amount of work. The idea was that a new NOC could trigger a re-benching request, so that the PMPRB would not be bombarded with requests for price increases, and that there also could be requests from other parties based on clearly established evidence criteria.

In the second group, those supporting re-benching argued that it was easy and eloquent but noted a need to know what other countries were doing. More facts are also needed, or the answers will be too naive. They also proposed the need for a simple way to trigger such a review. There were suggestions that re-benching should be done periodically, and, again, they wondered what other countries were doing. It was felt that more information was needed before they could make recommendations about what evidence should drive the process.

This group proposed creating an advisory body that could examine such issues and make recommendations on proposals to re-bench. The Board would make a decision, taking into account this advice. Suggestions about when to re-bench included when the price becomes excessive and when the use changes. The group also saw the need to provide a mechanism for ad hoc requests.

Arguments against re-benching included distinguishing between changes in pricing dynamics and therapeutic benefits. It is very complex, and it may be hard to determine what is affecting change, but, again, the proposed advisory body could help resolve such issues.

In the third group, arguments in favour included the basic principle that if one supports a value-based system, then re-benching is needed whether this is done by the province or by the PMPRB. The potential for differential pricing is another issue.

Re-benching should be done when there is a significant new indication for an existing product or when a very expensive drug for a rare disease moves to a common indication. In terms of how this occurs, key points included the need for some sort of reasonability test for international comparisons and what to do about products that move from a primary use to a Level 2 reformulation with a new patent. Proposed triggers for re-benching included utilization patterns, since there may be utilization before the NOC. Regular re-benching was also proposed for all drugs to keep an eye on excessive prices. Without re-benching, it was suggested, prices could be kept artificially high.

Arguments on the “no” side included that there should be no need for this and that it only serves industry. It was also proposed that if re-benching is done, there should be the ability to change the price test.

In summary, the third group gave a very qualified “yes,” depending on the process. Opponents of re-benching said manufacturers should live with the first price, although it was questioned whether this would be a disincentive.

Evaluation of Session

Participants were asked to comment on ways to improve this consultation process. One asked if there would be other opportunities to offer comments on the process directly, and Dupont replied that direct feedback by email would be very welcome. Other comments on the process included:

- Provide standard feedback forms.
- Provide more context about the issues. There were a few situations where more context would have helped to get informed discussion going (e.g., how price factors are assessed relative to categories and how the PMPRB gathers pricing data across jurisdictions).
- Provide a glossary of terms such as value-based pricing or else clarify what is meant by such terms in the presentations.
- Provide more understanding of what happens in other countries. It is hard to determine what excessive pricing is, for example, because people have different understandings and perspectives.
- Explain what was originally meant by consumer protection.
- Provide concrete, real-life examples that illustrate the concepts to be discussed.

Some found the presentations too short and not descriptive enough, especially on re-benching.

However, one participant said, “This was one of the most interesting discussions that I’ve had in recent years—so something worked very well.” Another stated, “I learned a lot from meeting with the small group. Did the PMPRB get what it wanted?”

This was just the start, Ouellet replied. Participants clearly grappled with the complexity, as did those who gave written submissions. Resolving it will still be a challenge for the Board, though progress was certainly made.

Next Steps and Parting Message

Lindberg thanked participants for their attendance, and said the discussion was very helpful and interesting.

Next steps include four more sessions to be held in Montreal, Toronto, Ottawa, and Halifax. A report on this session will be compiled and sent to each participant in the next few weeks for comments and corrections. A final report covering all five sessions will then be compiled and will be posted on the PMPRB website, likely in the new year. After that, the Board will review all the information and discuss where to go with it. The Board probably will return to seek further stakeholder input on any proposed changes to the Guidelines.

Lindberg closed by stressing the Board’s appreciation for participants taking time from their busy schedules to participate in this discussion