Patented Medicine Prices Review Board (PMPRB)

Stakeholders Consultations on Excessive Price Guidelines

Halifax, Nova Scotia
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Welcome and Opening Remarks

Mary Catherine Lindberg, Vice-Chair of the Board, welcomed participants and had them introduce themselves.

The Halifax session was one in a series across Canada, engaging stakeholders on key issues around the introductory prices of patented medicines.

Lindberg noted that the issue of drug pricing in Canada is a very important one. For all stakeholders, transparency and predictability of the review process are crucial, but of equal importance is its credibility and reliability.

Lindberg said the Board hopes to gain a better understanding of its stakeholders' opinions on the Excessive Price Guidelines. She emphasized that the consultations were not about changing the *Patent Act* itself. Rather, the Board wishes to ensure that the guidelines remain relevant in the current context. No changes have yet been decided upon; whether any are appropriate must come from the participants, she added.

This session is the latest chapter in an ongoing dialogue between the Board and stakeholders. The Board has undertaken numerous consultations over the past several years. In March of 2005, the Board requested input regarding how its reviews of patented drug prices should proceed, and released the *Discussion Paper on Price Increases*. The Board cannot act independently on some of these suggestions it received, as they would require legislative amendments under the purview of the Minister of Health.

The Board can, however, consider acting on some recommendations for improvements to guidelines that are directly under its control. The Board approved further analysis of these issues through the current consultation process, which includes meetings across the country.

The Board has the latitude to develop or change its guidelines. These must advance transparency and predictability, and the development process must use open and inclusive consultations. Participants' input is not binding on the Board, Lindberg cautioned, but it is necessary and useful, and the involvement of stakeholders will help achieve voluntary compliance.

Presentation 1: What We Heard Report

Barbara Ouellet, the Board's Executive Director, presented a summary of what the Board heard from stakeholders in response to the *Discussion Guide on the Board's Excessive Price Guidelines*, which was released in May 2006.. She said that all participants had received a summary as part of their advance material, but she wanted to point out the highlights.

Over half of the written submissions received in response to the discussion guide were from patentees; the rest were from a wide range of other stakeholders.

As the addition of other Section 85 factors to the price review process would require changes to the *Patent Act* and/or its regulations, there are only three main issues within the purview of the PMPRB:

- How medicines are categorized, which is the first step in determining what type a new drug is—the process flows from that decision;
- Whether introductory price tests are appropriate;
- What the "relevant market" is at which to regulate and whether or not regulation at a national scale, as opposed to at a regional scale, is appropriate. Currently prices are averaged across the country.

The Halifax small groups would focus on three themes that emerged from the feedback:

- Potential changes to the guiding principles;
- Fundamental concerns about how drugs are categorized and whether categories are even needed. Should all drugs be processed by the Board in the same way?
- The possible need for a re-benching system after a drug has entered the market.

Ouellet confined her remarks to the issue of categorizing medicines and the possibility of regulating at any market below the Canadian average.

The Board uses three categories when reviewing the price of a drug under the Excessive Price Guidelines:

- Category 1: "line extension," when an existing medicine is distributed in a new strength or dosage;
- Category 2: breakthroughs or a substantial improvement over existing drugs, as demonstrated in clinical trials that show a significant improvement in outcomes or a significant decrease in adverse effects;
- Category 3: new drugs that do not have substantially new effects compared to existing ones and that offer only moderate, little, or no therapeutic advantage.

The Human Drug Advisory Panel (HDAP) provides scientific advice to the Board on three questions:

- What category should a new drug fall into?
- What comparable medicines are there?
- In what doses are the comparable medicines provided?

Normally, the HDAP only reviews new drugs, but staff may refer any drug in categories 2 and 3 to them if the HDAP needs advice.

Most stakeholders identified problems with the current categorization system, and Ouellet reviewed the options they had suggested for rectifying these. She noted that "everyone, pretty well, had a problem with Category 3" and that this lack of support aligned with overall concerns about the category system. In general, stakeholder opinion

was divided between "forget the categories; we don't need them" and, at the other end of the spectrum, improving and expanding the number of categories.

However, all stakeholders supported the need to acknowledge the relative values of new medications and agreed that Category 3 failed at this.

Concerns around the market average focused on the masking of important price differences for different customers or regional jurisdictions. The point was made that if some larger markets negotiated deals lower than the maximum cost, then others could be paying more than the maximum price. This would be masked by the national average, particularly if that average were close to the ceiling price.

Ouellet clarified, in response to a question, that because some prices were higher than others in different market classes, this did not mean they were excessive; all prices were supposed to be below the maximum ceiling. Some stakeholders felt that the Board was not paying attention to these issues. Others maintained that variations were small, and the vast majority of prices clustered around the average.

Some stakeholders were concerned about how the Board uses rebates and discounts in calculating the Average Transaction Price (ATP). However, said Ouellet, the regulations require the Board to deduct these before calculating the average so that the actual net price is taken into account.

A common concern was equity of pricing and whether it was acceptable for Canadians to pay different prices for drugs, depending on where they lived or whether they had insurance. Of particular interest was whether hospitals could negotiate deals to buy drugs much more cheaply than other customers. Some recommended that prices be reviewed by customer class or region, but there was no input as to when or how frequently such reviews should proceed or what would prompt them.

Although overall there was disagreement about reviewing prices as a national average or for sub-markets, there was general agreement on the desirability of conducting price reviews on a case-by-case basis. A key issue for the day's discussion was whether and how this should happen.

Presentation 2: Principles Underlying Patented Medicine Price Regulation

Ron Corvari reviewed the Board's guiding principles. The question for participants was how the PMPRB should interpret its consumer protection mandate.

The PMPRB was created in 1987 as an independent, quasi-judicial administrative agency, under one of a number of amendments to the *Patent Act* based on five main principles. One principle was consumer protection, to ensure prices charged for patented drugs were not excessive.

The PMPRB does not set market prices as such but, rather, regulates ex-factory prices to retailers, wholesalers, and hospitals. Neither does it oversee selection or utilization. The notion of "consumer protection," as such, does not appear in the Act: instead, it ties the PMPRB's powers to findings of excessive prices. It is thus important to understand the meaning and implications of the excessive price factors in the *Patent Act* and how to apply them.

Parliament identified, in Section 85, key factors that the Board shall take into consideration in deciding whether a medicine is sold at an excessive price:

- The prices at which the medicine has been sold in the relevant market;
- The prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- Changes in the Consumer Price Index (CPI);
- Other factors, which can be specified by regulation.

Also, the Board may take into account the costs of making and marketing the drug, or other relevant factors, if it still cannot determine whether prices are excessive after the first have been considered. The problem is that each factor can result in a different maximum price outcome. Which should be given more emphasis, and when, is not yet determined.

Corvari asked stakeholders to think about what are the key principles that reflect the PMPRB's consumer protection mandate and how could they be used to guide the relative weighting of the price factors. He reviewed a variety that stakeholders had suggested previously and asked if they were the right ones to be on the table.

Corvari presented three sample frameworks. One centred on international comparisons, one focused on the domestic market but assumed the Canadian price would never exceed international parity, and one was equally balanced between domestic and international prices and trends. He asked stakeholders to take into account the intent and language of the Act and which principles do or do not reflect the PMPRB's mandate. What would be the right groupings of principles to emphasize in carrying out price regulation? Are some more important than others in guiding the Board's decision making?

In response to a question from a participant, Corvari explained that besides consumer protection, the other four principles underlying the 1987 changes to the *Patent Act* were

- Protection of intellectual property;
- Harmonious international relations;
- Promotion of industrial development and research;
- Promotion of Canadian health care.

Breakout Session 1: Guiding Principles

Group 1

Facilitator Ron Andrews explained that the focus of the first breakout session was on the guiding principles for the Board, as they relate to the concept of consumer protection. Which principles are reflective of consumer protection, and why? Which are non-reflective, and why? How can the principles be logically grouped? Which are more or less important to help the Board fulfill its mandate? Are there other principles that have not arisen through the previous consultations? Andrews emphasized that he was not seeking consensus and that areas of disagreement are important information for the Board.

A participant said that value-based pricing has to be an overarching principle, because it would link back to a clear role for the Board in consumer protection. As with any commodity one chooses to purchase, she continued, price should relate to what one wants and expects for an outcome—the better the outcome, the higher the price. Value-based pricing links price and outcome.

This view was immediately challenged by another participant, who said, "This assumes the consumer *gets* to choose. When patients go to a doctor, they're not making a choice; the patient is told what they need for their condition, and the patient agrees. It's not a choice! Buying a drug to keep you from dying is not the same as buying a sweater or a car."

Andrews said that value-based pricing might be a principle, although it misses the element of consumer choice. It might work in policy-making, but not at the individual decision-making level.

A participant said that the assessment of the actual value of drugs rested with regional levels, with the provinces or regional health authorities, and with local health care professions. The Board is at a national level and does not have ready access to the information it would need to base decisions on values, although it was an important principle. The Board does not have the mandate to look at the selection or use of medication, and without that it cannot truly assess value.

The *Patent Act* was introduced by Parliament to facilitate the entry of new drugs into Canada, as they had stopped coming in due to the compulsory licensing of generics, said a participant. The Board cannot lose sight of that original goal, and she feared that too tight restrictions in the system would discourage new introductions into the Canadian market. Drugs are not developed deliberately for Canada, because the market is too small. International parity and consistency has to be a principle, as it is a way to ensure the Board achieves Parliament's original intent.

This insistence on international parity was questioned, however, as several participants were concerned that Canadian drug prices would inflate to match those of the United States. They agreed that the Board could take international parity into account, but it was critical to balance it with accessibility and affordability.

Another participant expanded on the concerns about affordability. He was worried that industry could do end-runs around the Board system by using, for example, the Special Access Program (SAP) to avoid restrictions on high prices. Even if the company has gone through the Board process and the Board has exercised due diligence, the Board has no power to block this.

Most participants agreed that using affordability and accessibility as a principle balances others, particularly that of international parity and consistency. It was agreed that companies have to make a reasonable profit, but the needs of those on the health care side facing extraordinary and increasing costs must be considered. One participant noted that "we can control almost all other costs besides the drugs, but they are truly beyond our control, particularly with oncology in general and paediatric oncology in particular. The question is whether health care organizations can even afford to buy the drugs they need."

Some participants again urged the group to consider the effects of the choice of principles to guide the Board on the introduction of new drugs. One participant said that one of industry's major concerns was the impact on profitability. It affects their willingness to invest and their desire to bring drugs into Canada.

Changes to the Board and its operations cannot be taken out of the context of Parliament's original five pillars of the *Patent Act*, another noted, even though its mandate is restricted to just one of these: consumer protection. The Board can impact the others too. And the Board has to work with other agencies in the health care system. In terms of value-based pricing, for example, the PMPRB is responsible for setting the price of a drug to be used in any way. Then the others in the system decide whether that drug provides value to patients in particular contexts.

The facilitator noted that it sounded as if it were essential that the PMPRB involve other stakeholders in assessing value for money.

A participant said that if the Board's role were consumer protection, "There's a problem, because I suspect the majority of consumers have no idea this Board exists. It needs to bridge the gap with the public. I had no idea it existed." She said that the PMPRB needs to ascertain how to engage consumers in a much broader way and relate this concept to the principle of transparency to consumers and others. All stakeholders should understand what happens and be able to capture all aspects of pricing that need to be addressed.

One participant noted the need for predictability, saying he had been involved in two processes for two drugs that were handled very differently. It is difficult when rules change every year, he said. Stability in the market is needed.

The lowest reasonable price principle is vital to consumers, especially in the cancer realm. For example, Nova Scotia is facing a fourfold increase in costs. Drugs there are $5,000–$6,000 per patient and not $40,000, often with less clinical benefit, the participant emphasized. "We're being forced to decline to pay for treatments as increases continue. The growth numbers for drug costs are not sustainable. They're increasing by 20% a year." He continued that these cost increases cannot be justified while research and development (R&D) are declining and concluded, "The best we can figure is we're paying shareholders."

Another participant identified a different principle: evidence-informed policy-making. The Board needs to do more comprehensive research and expand its information base to guide decision-making.

National parity and consistency was strongly urged. There was a sense among some participants that larger provinces are able to negotiate discounts, but the smaller jurisdictions are paying much steeper prices. One participant noted that the region has far fewer people with drug coverage than any other part of the country, with 24% with no coverage at all.

Andrews summarized the discussion this way:

- Simplicity and transparency needs more focus and has a connection with evidence-informed policy-making.
- Canada pays its fair share/international parity has little or no priority for consumers.
- Most, though not all, agreed on balance with the other four pillars.
- Predictability was important for everyone.
- Value-based pricing supports consumer protection.
- Making the balance between affordability and accessibility is critical. This is the number one principle and is what the Board and its mandate is really all about. Still, price is an important parameter and the industry is evolving toward relying on the availability of reimbursement when deciding whether to introduce new drugs to the market, not just the absolute price.

Group 2

Affordability and transparency of process are among the most important of the PMPRB's guiding principles, group members felt. However, regulatory burdens upon the industry and complexities caused by intersecting jurisdictions are also of concern.

The group was asked to consider which principles do and do not reflect the Board's mandate.

Concern was expressed about the principle of consistency over time. One group member said that this principle presupposes a single definition of excessive pricing—a notion which may be unrealistic in practice.

Another participant said that, while people expect the Board to foster price stability and predictability, these goals are not always achieved in the real world. It was noted, in response, that drugs are sometimes marketed prior to being patented. Drugs only come under the Board's jurisdiction once they are patented. Therefore, drugs could enter the market at one price and subsequently be sold at another once a patent has been granted.

A participant disagreed with this, pointing out that, in fact, most drugs are patented while still in the laboratory stage. As a result, drugs may reach the market with only 8–10 years of life left on the patent. The prices of new drugs entering the market are usually set at the maximum non-excessive (MNE) price, he said.

The speaker noted, further, that the prices of patented drugs have "barely moved" in Canada over the past 20 years, and price stability is already a fact. A significant price increase where competing products are available would likely result in drugs being de-listed from provincial formularies, making price stability easy to achieve.

He said having a patent on a drug does not automatically confer a monopoly, as alternatives often exist within the same therapeutic classes of drugs. The same speaker felt the principle of price predictability to be problematic.

"I would not want my prices to be predictable for my competitors," the participant said, indicating that he would like to have the meaning of the term "predictability" clarified.

It was mentioned that patented drug price increases are tied to the CPI, which has changed relatively little in the past 12 years. As a result, drug prices have increased little in that period. One participant disagreed with this contention.

Another participant said that price stability should be a secondary factor and that "prices could be high and still stable."

Moving to the principle of lowest reasonable price, concern was expressed by a participant about the Board becoming involved in price setting. This proved to be a minority view, however, with most participants agreeing that the Board should work to ensure the prices of drugs are reasonable. Still, clarification of "reasonable" is required.

Participants wondered if "reasonable" automatically equals "lowest" price. A participant said that striving for the lowest price "is a problem to me."

Another speaker pointed out the lack of a "streamlined process" to ensure that Canadians have access to medicine and, in particular, to affordably priced drugs. This is especially important in Atlantic Canada, where a significant number of citizens do not have drug insurance plans.

Considerable concern was expressed about conflicting jurisdictional issues between different regulatory bodies operating in isolation. Among the key issues in this respect is the fact that while the regulation of drug prices is a federal responsibility, the overall

delivery of health care is a provincial one. These issues "do not help patients and do not achieve the desired end result," one speaker commented.

A participant said there must be "some degree of sanity" in drug pricing and that it is within the Board's mandate to keep pricing reasonable.

Most group participants agreed that the Board should, on principle, ensure that prices are reasonable but that clarification of the meaning of "reasonable" is called for.

Discussion of the principle that Canada should contribute its fair share to R&D was characterised by disagreement over methods of measuring and reporting actual R&D expenditures. Participants also could not agree on questions about which countries Canada should be compared with when evaluating R&D activity. One participant pointed out that they had not seen the anticipated level of R&D investment in Canada.

Another speaker questioned whether Canada is grouped with the right nations when comparing R&D spending. He doubted that the country has the same level of R&D investment as the nations it is grouped with for comparative purposes and suggested that Canada's R&D expenditures are on par with Australia's and New Zealand's.

This contention was challenged by another participant, who pointed out that Canada invests about 100 times more on a per-capita basis than either of those countries. The same speaker noted that R&D statistics in Canada show only what drug companies choose to report, whereas other countries use a statistical definition of R&D. This makes direct comparisons difficult.

Participants agreed about the need to invest in R&D but felt that measuring this activity in a consistent and comparable manner relative to other countries is presently a problem.

The principle of value-based pricing was felt by some to be both contradictory to the principle of consistency over time and potentially too broad in interpretation to be used as a guiding principle.

One participant said the definition of "reasonable," when applied to value-based pricing, must take into account the place of the drug in the total therapeutic context. A drug might derive its value by enabling treatment with fewer hospital visits, for example, even if other drugs are available to treat the same condition.

Another offered the notion of two categories of value-based pricing. In the first case, a drug might treat a condition for which no other therapies exist. The second case relates to whether a new drug adds something to existing therapies already on the market. The participant said these two categories of evaluation are, in some sense, conflicting.

Concern was expressed over shifting costs when the use of a drug moves from a hospital to a private-care setting. Participants agreed that the central concept of value-based pricing should be value to the patient.

Another problem with value-based pricing is that the evaluation used to establish the value of a drug usually occurs early in its use when relatively little may be known about its therapeutic value. The actual value of the drug may therefore change over time. One speaker suggested re-evaluating drugs after five years of use, noting that some drugs are known to have considerably greater therapeutic value now than was thought when they were originally introduced.

The principle of simplicity and transparency of process was seen as critical by several participants.

"As soon as you go into closed-door meetings, the Board does not have credibility any more," one speaker commented.

Another pointed out that the concept of transparency is somewhat overused and not always seen in actual practice.

International parity and consistency, while viewed as a legitimate guiding principle, was seen as problematic by one participant because of a very limited number of models available for comparison between Canada and other countries.

"We need to ensure we're comparing apples to apples," said another participant.

For consumers, the principle of accessibility combined with affordability is key, another speaker said. The Board's mandate is to protect consumer interests. It was observed that questions of accessibility concern only price and that the Board controls access to drugs by controlling excessive pricing. The suggestion was made that only the concept of affordability is meaningful.

Concern was expressed over the lack of regulation of prices of generic drugs, which was described as a "free-for-all." One participant agreed "absolutely" with the idea of a sister Board to regulate generic drug prices.

Participants were asked to consider whether there are any guiding principles missing from the Board's mandate.

Some were concerned about the size of the administrative burden placed on industry to comply with the Board's reporting requirements. Drug companies presently must report four different sets of prices for every patented drug they market.

A participant pointed to problems with the process used to calculate the transaction price of drugs. Competitive bidding for hospital business may result in a lower effective transaction price for a drug in the year of the bid. If the company loses the business, he said, the effective transaction price automatically increases and subsequently may be deemed excessive by the Board even though the actual price of the drug has not changed.

Several participants felt the entire process is complicated by overlapping jurisdictions and duplication of responsibility and called for the process to be streamlined.

Group 3

Facilitator Ron Desroches asked participants to consider two questions:

- What principles are/are not relevant to the PMPRB's regulatory mandate?
- Are certain principles more important?

"There was no mention of R&D," said one participant. "How does that factor into the price-setting equation?" Someone else commented that this indicated there could be some confusion, because the mandate of the PMPRB does not include price-setting.

Because of the connection to the *Patent Act*, there is recognition of innovation on the one hand and consumer protection on the other. R&D means that companies are investing in Canada.

Another participant asked whether R&D has to be in Canada. A large portion of R&D takes place outside Canada, and it is patented here. The principles have to be fair to both the patent holders and the consumer. It is important to see what the promise and outcome really are. There is no point in copying what has been done elsewhere.

There was discussion regarding the meaning of innovation and whether there must be a new outcome or if it also can apply to a new mode of drug delivery.
Regarding the PMPRB's mandate and principles, some felt that the PMPRB's mandate is unclear and, therefore, open to various interpretations. This needs to be clarified before consideration can be given to the guiding principles.

There were changes to the *Patent Act* at the same time as the creation of the PMPRB, which points to the need for a balance between the recognition of innovation and consumer protection.

The meaning of each of the principles needs to be clarified.

Discussion turned to the lowest reasonable price principle. One has to take into consideration the investment that has gone into the development of a drug. It should be combined with accessibility and affordability. The PMPRB is supposed to protect against excessive pricing, not ensure the lowest reasonable price.

It is beyond the PMPRB's mandate to say that any price above the international median is excessive as well as to require the lowest price among international comparators.

By providing a conditional Notice of Compliance (NOC), progressive licensing (as discussed by Health Canada) would have a major impact on pricing.

On the principle of value-based pricing, there needs to be recognition of innovation as well as the value it brings to the consumer (e.g., development of a molecule that cures end-stage colorectal cancer).

Regarding adding value, cost-effectiveness is an issue for funding agencies. One participant said this is not in the PMPRB's mandate. Is it possible to separate cost-effectiveness from value?

Simplicity/transparency is an important key principle. It is important that all stakeholders know the PMPRB's role, how it goes about fulfilling its role, the PMPRB's mandate and guiding principles, and how they are applied.

While simplicity is a virtue, a number of aspects of the PMPRB's work seem complicated (e.g., how affordability is defined, who is regarded as the consumer/payer, etc.).

Discussion shifted to the principle of accessibility combined with affordability. If a drug is not affordable in Canada, it should be available for purchase outside the country. The definition of "consumer" should be "payer," which, in most cases, is not an individual—it is the government or a private insurer (a third party). If a drug is not affordable in one jurisdiction, it may not be accessible. (They are closely linked.) If a manufacturer cannot obtain the price it needs to realize a reasonable rate of return, it may not market the product in Canada—thus creating zero accessibility.

One participant said that Canadians should be able to purchase the drug elsewhere. Another said this contravenes international patent law and, in any case, is beyond the PMPRB's mandate.
"Affordability" begs the question: affordable to whom—the consumer or the third party? Affordability also changes with the magnitude of the need. Some participants said accessibility and affordability should be de-linked in terms of the PMPRB's mandate; others saw them as intertwined.

Establishing the MNE price ensures sustainability of the system. Determining affordability in different jurisdictions is up to the provinces, not the PMPRB. The determination of whether or not a drug is cost-effective can affect affordability and, therefore, accessibility (e.g., catastrophic drugs).

Affordability and accessibility become confusing in the context of the *Canada Health Act*, which creates a two-tier system whereby certain drugs are provided only in the hospital setting.

The consistency over time principle may prove to be problematic. Will the same test apply over the life of the patent, regardless of new discoveries?

As the greatest users of pharmaceuticals, seniors need to be protected, because there is a user-pay system for drugs (the *Canada Health Act* does not apply).

Plenary Session: Report Back

Responding to the presentation of key points from the breakout group discussions, one participant noted that increasing manufacturing costs are not necessarily related to price increases. What this means in practice, he said, is that the introduction of new medications, which tend to be costly, does not mean the price of all drugs increases. He said this issue should be clarified.

A participant commented on the lack of clarity in the Board's mandate. Senior citizens are the greatest users of pharmaceutical products, and many are paying for their own medications.

"The average senior citizen in Canada believes that when one person gets sick, 30 million people split the cost," the participant said. "This is not so with drugs. There, only one person pays." He called for the Board to protect consumer interests as well as to be fair to manufacturers and noted that the Board's mandate should be clarified along the lines of the *Canada Health Act*.

Responding to this, another participant said that other agencies are doing some of this consumer protection work already. There is a need to understand the function of the PMPRB in the context of this broader environment, she said.

A PMPRB representative pointed out that it is important to understand that the Common Drug Review (CDR), which makes recommendations on reimbursement to government health agencies, and the PMPRB do not always look at the same products. The PMPRB considers only patented drugs, while the CDR makes recommendations on formulary listings affecting a broader range of medications.

Further discussion in the plenary session focused on the role of the CDR relative to that of the PMPRB.

One speaker wanted to know why the CDR does not make recommendations about drugs used only in hospitals. A PMPRB representative replied that, since hospital drugs are fully paid for as part of hospital care and not billed to the patient, such involvement on the part of the CDR would not be appropriate. She said the CDR exists to advise provincial health plans about what drugs they should be paying for and to make recommendations based on cost-effectiveness.

Another participant said, in view of that, it would appear to be in the interests of the provinces to have the CDR process apply to hospital drugs as well.

This point was supported by another participant who noted that her organization purchases over 30 products that are not listed in the CDR. It would be desirable to have consistency among all provinces with respect to listing these products, she said.

Concern was expressed over whether or not the right basis is being used for international comparison in price determination, particularly with respect to public versus private (out-of-pocket) payers.

A PMPRB representative said it is the government, not the PMPRB, that chooses which countries are used for comparison. This is somewhat problematic, she said, in that because of the *Canada Health Act*, no other country has exactly the same system as Canada.

Breakout Session 2: Discussion of Categories and "Any Market"

Group 1

Andrews asked participants whether drug categories are needed.

Industry agreed to work with the category system, said a participant, but having only one would be better. She expressed her belief that Parliament's original intention of consumer protection would be better served by having only one category. Ending up with nine or thirteen categories would not help the Board's analysis. The focus should be on the words "not excessive," and a range of categories is not needed to determine that.

Another participant, though, stated that categorization is the first step in assigning value, and she would like to see five categories. In her view, that would assist the Board to help assess advances and fair increases. Another participant also agreed with the category system. She acknowledged, however, that it is sometimes difficult to classify the drugs into categories, as data may be lacking, particularly in terms of real-world usage results versus lab tests.

When Andrews said that the difficulty, then, is in applying the categories, not in their existence, a participant replied that, no, the difficulty is in how drugs are slotted into categories. A less subjective process than the HDAP, or better alignment with Health Canada, is needed.

The value of categories diminishes after the initial assessment, said another participant, as drug uses change over time. A great deal of energy and resources are spent around categorization at the launch of a new product, which seems a waste. An individual pointed out that many drugs prove to be less, not more, valuable over time.

A participant commented that the category issue might be easier if everyone knew they could recalculate and re-bench at a later date.

Another participant emphasized that there should be at least a fourth category, split from Category 3, that separates "moderate" effects from "minimal or none."

"We need the categories," he said. "A change in tablet strength is not the same as a change in how one fundamentally deals with a disease." Another participant said that breakthrough drugs for previously untreatable conditions, or those with far fewer side effects, should be separated into a new category.

In general, the group concurred that too many subdivisions into a plethora of categories would not be useful and would make the process impossible to manage and overly complicated.

A concern was voiced that "sticker shock" was now driving the system, that prices have to reflect value, and that there are drugs on the market that are low in cost but not cost-effective. Other drugs cost $100,000 but are very cost-effective.

The group canvassed the issue of the costs of niche development, orphan drugs, and how expensive it is to develop for small populations. A participant challenged the orphan drug concept, saying that it applied in the United States but not Canada. One hears this with regard to cancer drugs all the time, he said, but cancer is not a rare condition, and most oncology drugs should not be marketed as orphans. "You can't call something a niche drug when they're used all over the place."

Availability can affect demand, too, said another group member. After Ontario increased the number of dialysis centres, the number of end-stage renal patients also increased.

Another participant said there should be a category for highly priced drugs but with clear benchmarks defining the concept.

A participant stated that part of the concern is the difference in reimbursement numbers between the United States and Canada. The Australian system tries to look at the overall hit to the pocketbook, taking insurance coverage into account.

Another participant suggested that there could be one category for cost and another based on uptake and overall economic impact on the system.

Andrews summed up the essential elements:

- If you want to keep the process simple, do not add complexity to the categories.
- One category is a possibility.
- If the Board continues to use more than one category, add one, or maybe two, more.
- Make the new category different in concept from the others, with less focus on the drug itself and more on the economic impact and effect on the payers.
- Avoid complexity and administrative burdens.

Andrews then asked the group whether price should be reviewed from market to market, rather than by looking at the national average.

Some participants were opposed to this, stating that the PMPRB does not have a national mandate to provide equitable pharmaceutical services, unlike, for example, Canadian

Blood Services. Drugs fall under provincial mandates. Research into health care costs and issues shows that they are all highly variable among the provinces—why should drug costs be any different?

Other participants disagreed: Canadians need information on the sub-markets, whether through Health Canada, the PMPRB or a combination of the two. There are six provincial programs, and the federal government can also share its information. This data speaks to best practices and responsible information collection, which fall under the PMPRB's consumer protection mandate.

A participant said, "We don't deliver health care homogeneously. There's no single insurer. We have public payers making one sort of deal. Then drugstores and private payers, many with no coverage, are striking others." Two different price systems are in place—hospitals and out of hospitals, where drugs cost more. There is no transparency, no explanation for the discrepancies.

Specialists are data poor, the participant said, and without a good basis for making arguments for the national system. There are many different players carrying different sizes of sticks, for example, OHIP versus Nova Scotia Heath Services, which has far less clout. "We need to see those differences," he insisted. "The country needs to know the Atlantic perspective: those with the least are paying the most. That is not right."

Inequitable pricing means inequitable coverage, said another. Monitoring the issue is in the PMPRB's jurisdiction. The whole idea of the Board is to ensure that no one buys a product at an inequitable price. But another disagreed, saying that as long as no one is buying at prices above the maximum allowed ceiling, by definition there is no need to look further down the system.

Another participant commented that factory gate pricing was only one element of what the consumer paid and asked what the PMPRB's role is regarding the whole pricing issue.

In closing, Andrews said the group agreed on the need for better data and more transparent pricing processes.

Group 2

A participant argued against the need for categories, noting that present procedure allows Board staff to apply different tests to determine if pricing is excessive based on the class. For example, price tests for Category 3 drugs are based on a therapeutic class comparison.

The participant said that only two or three drugs have been approved under Category 2—drugs that offer breakthrough or substantial improvement over existing medicines—in the past few years. He added that approval under this category is very difficult to achieve.

Companies often do not want to go to hearings and settle for Category 3 approval instead. He cautioned that with the present obstacles to obtaining Category 2 approval, "you will never see another Category 2 drug in oncology."

Categories are "unworkable and unnecessary to us," the speaker said. "In the context of sustainability and affordability, we should work on one definition of excessiveness."

The speaker noted that 25% of Category 3 drugs are sold at prices above the international median, suggesting that 75% of such drugs are sold below it.

He expressed frustration with the category system, saying it forces new drugs to be compared with older generic ones, making fair pricing impossible—a notion other speakers disagreed with.

The suggestion was made that if categories were eliminated, a price test could be devised that allows for all principles.

One speaker took issue with the notion of eliminating categories, saying this would place control over pricing in the hands of the industry.

Speakers pointed to the difficulty of categorizing drugs, noting the huge spectrum between "moderate" and "little" advantage in Category 3. Dealing with Category 1 drugs is also increasingly difficult. It is very hard, for example, to quantify the convenience of administration of a substance. Category definitions are not clear, and the process of categorizing drugs is lengthy with frequent requests for clarification.

The degree of improvement offered by a new drug is not always immediately apparent. Noting that clinical trials do not provide complete information, one speaker pointed to a need to trap data through actual use.

Concern with the present system of categories stems mainly from frustration, but this reflected only one perspective, it was observed. One speaker cautioned against abandoning categories as a "knee-jerk reaction" to this, which would be a step backward. She urged participants to consider the original intent of the category system.

The category system generally aids the work of the Board, but more clarity is needed to distinguish Category 1 from Category 2. The participant acknowledged, as well, that Category 3 classifications are occasionally "not totally fair, but it's what fits in regulations."

Concern was expressed that there are almost no studies where one drug is compared with a comparable drug. Usually a new drug is compared with a placebo. "Frankly, the drug would not be on the Canadian market if it didn't work better than a placebo," a participant noted.

Participants acknowledged the need to recognize real breakthrough drugs with a Category 2 classification, but concern was expressed over the lack of consistency between PMPRB and CDR evaluations. A participant noted that the CDR "has never approved Category 2 drugs. This makes me question if we even want breakthrough drugs."

Participants considered whether the Board should use markets as a mechanism for determining reasonable prices and were asked to consider whether a price review should take place on an averaged national basis or whether it should discriminate by region. Some speakers felt that the present system already has a workable mechanism for resolving regional differences on a case-by-case basis, but there is a need to better inform the public about pricing issues.

In practical terms, consumers have no way of knowing if they are paying more for drugs than residents of other provinces, one speaker noted. This is of particular concern in Atlantic Canada, where about 35% of patients pay for drugs out of their own pocket.

The ability of buyers in large markets to negotiate better prices was also noted with concern. The suggestion was made that rebates offered by the industry to large buyers be given back proportionally to create level pricing for all Canadians.

Some discussion centred around how to inform consumers about drug pricing. One participant playfully suggested that the Board establish a "shame list" of companies who charge higher prices to Atlantic Canadians. Some participants said there is actually very little difference in drug prices across Canada, citing this as an example of the system working properly.

Concern was expressed, however, that the most vulnerable consumers—patients paying for their own drugs—have little protection from high prices. Large-volume buyers are better able to protect their interests in this respect.

Group 3

Participants were asked to consider the three drug categories and several questions pertaining to them.

Opinions were divided as to whether there should be drug categories at all. Those who supported them said drug categories help to establish the price test. However, some said there should be only one category—for drugs that provide therapeutic improvements. Having categories for "me too" drugs dilutes everything, and having more than one category opens up loopholes.

Others said that more categories are needed to indicate greater or lesser benefit. There is a need to distinguish between "moderate" and "little to no" benefit. There should be different price tests for different categories. With more than one category, it is easier to break things down and make decisions.

For categories 1 and 3, the market does a good job regulating price. International comparisons could be used for Category 2, which recognizes innovation.

Currently "breakthrough" is in the same category as "substantial improvement" (Category 2). They should be in different categories, because different tests apply.

There should be a separate category for drugs for rare diseases (e.g., enzyme-replacement therapy), because when those drugs are introduced, there is no evidence to indicate whether they are breakthrough.

Further categorization would aid the classification process for drugs coming to the market.

Those who did not support the categorizing of drugs said that defining excessive pricing would be simpler without categories. Also, there would be more transparency for people who do not deal with this on a day-to-day basis.

Moving on to other questions regarding drug categories, the comment was made that the market is defined by the practitioner, not the consumer, because the physician prescribes the drugs.

It is very difficult to get a Category 2 designation. There have been fewer than 20 since 1987.

There needs to be more consistency in Category 2 with other definitions of innovation (Health Canada and the Food and Drug Administration (FDA) can disagree).

As well in Category 2, "breakthrough" can mean different things to different people. "Uniqueness" may be a better term for drugs that meet an unmet need.

There was a question about how to classify changes in the mode of administration (moving from intravenous to tablet, making it easier for the patient to use a drug on his/her own). Is this innovation or Category 3? It could be considered a breakthrough or a significant improvement but would not be under the current regime.

Patient-centred values should be included among the guidelines. (Currently patient-centred improvements are included in Category 3.)

No one wants a system where small changes to a molecule result in dramatically higher prices. (This is the downside to a bias towards innovation.)

A separate category for rare drugs may set the stage for inappropriately prejudging drugs.

Pointing out the weakness of a two-tiered system, one participant said it encourages those who cannot afford end-stage pharmaceuticals to go to the hospital and receive free palliative care.

Plenary Session: Report Back

Several participants offered comments on the discussion in the breakout sessions about categories and the "any market" concept.

One participant said the discussion illustrated the need for the category system in view of the fact that the majority of Category 3 drugs are selling at less than the MNE price. The strength of market forces in this area makes it desirable to review how active the Board itself needs to be, she suggested.

The same speaker offered the view that, over time, there may be a need to review the Board's role as market dynamics change.

Another participant raised a caution about American advertising practices spreading to Canada. Manufacturers of prescription drugs are now permitted to advertise directly to the public in the United States, and the speaker said the same practice eventually will be permitted in Canada. The Board will have to be "more vigilant" in response to this, he warned.

Outside market forces, in light of the recent elections in the US, were a concern for another participant. The new Congress has been vocal in its desire to allow Canadian drug imports, she said. The speaker said this may cause Canadian prices to rise to American levels because of increased market demand.

Presentation 3: Re-benching of an Introductory Price

The issue of re-benching was not included in the *Discussion Guide* circulated in the spring of 2006 for the current consultations. However, re-benching was added in light of responses from participants in earlier meetings, Board staff review, and other factors arising from the National Pharmaceuticals Strategy and Health Canada.

There is a need to "de-jargon" the concept of re-benching, participants were told.

The re-benching process involves a second complete review or reassessment of drug pricing at a later point in time. Once a non-excessive benchmark price is established, subsequent price increases are usually tied to the CPI. Re-benching the price offers the opportunity to "start all over again."

There are presently two circumstances when re-benching might be undertaken. First, a medication that has not yet appeared on the Canadian market but that is available as an unapproved drug through the SAP may be reviewed on a case-by-case basis upon request from a physician.

There are no specific guidelines on when this may be appropriate or on what constitutes acceptable evidence. This type of re-benching happens very rarely.

Second, re-benching may occur if a drug sold in fewer than five of the seven countries used for international comparison begins to be used in five of those countries or has been on the market in Canada for three years, whichever occurs first.

Other possible reasons for price re-benching include a change in the use of a drug from a rare to a common disease and a change in the primary application of a drug.

A participant expressed concern about the fairness of tying price increases to the CPI. He said that many senior citizens have Old Age Security (OAS) as their only source of income. It seems unfair to guarantee the profits of multinational drug companies by linking their prices to the CPI when the OAS is not so linked, he said.

The speaker suggested greater fairness would be had by linking drug prices to increases in the OAS rather than the CPI.

In response, a PMPRB representative said the PMPRB's responsibility is derived from factors outlined in the *Patent Act*, which include the CPI. This issue would perhaps best be considered by the Minister of Health.

Other speakers wondered about how price control is affected by the SAP. It was noted that all patented drugs fall under the Board's jurisdiction, whether or not they are actually sold in Canada. Drugs available only under the SAP are not treated any differently than drugs with market approval.

Price monitoring is carried out by requiring drug patent holders to file information on pricing for four classes of customers in each provincial jurisdiction. The evaluation system compares this data to changes in the CPI for the year in question. A price increase that exceeds the CPI for the year automatically raises a flag in the system, participants were told.

Breakout Session 3: Discussion of Re-benching

Group 1

Andrews framed questions for participants:

- Why would you be in favour of re-benching over and above the two current situations?
- Are you in favour of maintaining those or adding more?
- Can you give examples of when re-benching should occur?

Several participants agreed with the suggestion that, if there is any significant change, the Board should re-bench. Changes could include:

- A new clinical indication;
- A new primary use;
- Off-label use becoming primary (e.g., OxyContin);
- Availability of new information, positive or negative, that could change the value of a drug, for example, as the result of head-to-head trials;
- Usage in a new population, for example, paediatric use when the drug was formerly for adults;
- Usage or an orphan or rare drug when new uses expand the population. Although somewhat captured in the other examples, participants said this needed to be separately articulated.

Andrews asked what evidence participants required for re-benching. Responses included

- Utilization by the payer. The real-world cost issue must be taken into account, said one participant: "When something that's expensive for 10 individual patients becomes expensive for 110, your perspective changes";
- New published literature or safety information or results of trials;
- A new indication, such as an NOC, approved by Health Canada;
- Reports from other countries—not only those in the basket of seven used by the Board—and other jurisdictions within Canada, for example, reports from the Canadian Association of Provincial Cancer Agencies (CAPCA);
- Reports from the CDR, the Canadian Agency for Drugs and Technology in Health (CADTH);
- Health Canada marketing information surveys, if reports become more frequently issued.

Strong opposition to re-benching was voiced by some participants, who said that:

- Re-benching moves away from the original intent of Parliament vis-à-vis the *Patent Act* and is an inappropriate, unilateral expansion of the PMPRB's mandate that should be a government decision.
- The system is not prepared to deal with potentially higher prices from re-benching. For example, a higher price could be justified for a cheap anti-cholesterol drug that further research shows reduces the risks of myocardial infarctions.
- If prices are ratcheted down too low, the introduction of new drugs into the country may become difficult.
- Canadian prices are already below international norms by 10%, as shown by the cross-border traffic into the US. If re-benching forces prices further down, the Canadian health system could be jeopardized and the delicate trade balances upset.
- Unless every province agrees that prices may fluctuate up or down, re-benching will not work. It may not be the Board's intention to drive prices down, but that would be the result, one participant said.

A participant countered that "industry is responsive to market and regulatory conditions. When the ground rules change, business changes. If re-benching became the norm, industry would adjust."

Participants generally agreed that possible rising prices for newer, justifiable uses as a result of re-benching were a new question. Several noted that further field research is just as likely to show that drugs are not as potent as had been thought when first marketed. One asked, "Are vendors *and* payers willing to take the good with the bad?"

A participant interpreted industry as essentially saying that drugs would remain at inflated prices without re-benching, noting that industry seemed concerned that more drugs will go down rather than up in price; to him, re-benching at least offers the possibility of identifying the true value of a drug.

Another participant said that older people are often long-term, chronic users of one or more drugs. They need to know up front that the drug they take could either go up or down in price. The PMPRB needs excellent and structured communication with consumers, not just about re-benching, but about many other issues too.

A participant said that deciding on utilization and education levers versus price levers for a particular situation is very complex. Little is known in a structured way about how effective the PMPRB has been, and it is necessary to be able to assess the impacts if re-benching is more widely used. She noted that there are over 22,000 drugs in the system and wondered what technical and human resources the Board would need to re-evaluate them.

It was suggested that a mechanism exists for provinces and private insurers to make a request for and evaluation of cost-effectiveness to CADTH. Another participant agreed but noted that no price cap could be imposed as a result; either the manufacturer chooses to do it, or the PMPRB will have to force the price lower. The CDR might be another relevant agency to identify particular drugs where changes might need to be made.

Andrews asked under what future circumstances it would be appropriate to adopt a progressive/renewable MNE price. Would this keep putting a company back at the starting block over and over again, he asked, triggering constant reviews of the product even if it held the same patent over time?

Is re-benching simply an opportunity to change the price, a participant responded. Or could it possibly lead to a more integrated system and better real-world feedback for changes in drug uses?

Health Canada is implementing a system of progressive licensing to introduce promising drugs to the market, without full conditions from the legislation, if there is an immediate, important need or very promising small trials. Post-market, real-world studies are then required, and, based on their results, the client base for the drug may narrow, widen or change client altogether.

Some concerns were expressed that this could mean monumental changes for payers and funders, "if they're letting drugs on the market without adequate research."

"I'm not feeling very warm and fuzzy about this," said one participant.

Another participant insisted that payers, makers, sharers, and users had to share the risk. If a drug proves more effective than forecasted, then, in terms of value for money, buyers are paying less; if not, more.

A participant pointed out that industry's hands are tied by Health Canada and FDA requirements for studies and research, and enough data to support safety and effectiveness. Another participant noted that post-marketing surveillance centres of excellence were slated for funding across the country.

Several participants agreed that, before the Board institutes re-benching or other major changes to price structures, it would be wise to watch how the Health Canada changes in drug approval work out.

The session ended with comments on the need for better communications and transparency on the part of the Board. One participant said she had no idea of its existence before being invited to the consultation.

Although the website is comprehensive and includes summary reports on the drugs the Board evaluates, if people do not know the information is there to begin with, they are not going to search for it.

Group 2

A participant opened the discussion with the observation that, while he was not against re-benching on principle, he was concerned about it being used solely to reduce prices.

"If we have faith in the value of our products, why not accept re-benching?" he asked.

Other speakers noted that re-benching could result in drug prices moving in either direction.

One of the forces driving re-benching is the "off-label" use of drugs, one participant pointed out. Capturing data on off-label use, which is seen as a great benefit to many patients, is critical, she added.

Presently re-benching usually results from drug companies coming forward with requests for the re-evaluation of a drug based on additional uses, another speaker noted.

There was support for the idea that the Board's purpose is not to control prices, but to determine the maximum acceptable price. If the market changes significantly, the price of a drug possibly should be looked at, it was suggested.

Participants were asked to consider whether re-benching is going to take place and when and why it should be done. One speaker suggested that re-benching a drug would be appropriate when the medicine has either an additional approved or indicated primary use or increased utilization. It may take years to establish the primary use of a drug.

Re-benching also may be appropriate when the drug has been in use for a while and more information is available than was obtained through the original clinical studies on its effectiveness and safety.

Collecting data about a drug's additional uses is critical, noted one speaker, suggesting that the PMPRB align itself more closely with Health Canada to gather information on additional uses.

There may be good sources of this information already available, suggested another participant. He commented that the CDR is "obsessed" with off-label use.

Re-benching might be in order if a new drug appears on the market at a lower price than an existing medicine, another speaker suggested. That probably would not be necessary because of market forces, replied another participant.

He went on to say that competitive market forces work well in many, but not all, cases. For example, the market seems less effective in regulating oncology drug prices. When the market does regulate prices well, the Board "should not be playing with it."

Nonetheless, many participants felt that re-benching is appropriate if a newer treatment enters the market at a significantly lower cost than existing ones. A participant expressed concern about having a rigid process for this.

Discussion turned to what mechanism might initiate re-benching. There was general agreement with the principle that any recognized stakeholder group could request re-benching. The same process and the same level of evidence as was used to originally establish the price of a drug would be used.

Several participants agreed that there were valid concerns about cross-border trade issues when large differences exist between drug prices in Canada and other countries, particularly the US. In particular, there was concern about American companies being reluctant to sell drugs in Canada if Canadian prices are significantly lower.

The re-benching process should, therefore, take into account the possible global impact on prices and sales, particularly with respect to the US market, to avoid potential loss of the molecule to the Canadian market.

These concerns make the guidelines under which re-benching is initiated quite important. Such guidelines should be clear, precise, and not subject to interpretation, participants agreed.

What circumstances might initiate re-benching a drug, participants were asked.

One participant was concerned about any process that would automatically trigger re-benching. Although some speakers pointed out that there are other areas in the health care field—such as licensing, where renewals and the like happen automatically— a PMPRB representative stated that automatic re-benching would never happen. “We don’t do business that way,” he said.

There was no consensus on whether re-benching should happen automatically or on a case-by-case basis, but the system needs to be very clear on exactly when re-benching goes into effect, a participant said.

Life cycle monitoring of drugs for adverse reactions and off-label uses is critical and not being adequately addressed, another speaker said. There are “huge gaps” in Health Canada’s post-market surveillance of adverse reactions and no monitoring of costs at all.

Discussion turned to the pros and cons of the cyclical review of drugs on the market.

One participant suggested that perhaps the biggest benefit of cyclical review would be job creation. The labour-intensive nature of such reviews and increased regulatory burden were cited as negatives.

On the positive side, potentially reduced prices may result from cyclical review. Cyclical review also might make pricing more reflective of scarce raw materials, such as human plasma, whose costs tend to be very volatile.

Some felt that cyclical review might alleviate concerns about invalid cost comparisons that do not take into account factors such as the cost of the administration of a substance. A self-administered drug might have a very different total cost to the system than one that has to be administered in a hospital setting. The present system does not allow for consideration of these additional costs, a participant said.

Finally, price reductions as a result of cyclical review would increase access to drugs.

Group 3

Desroches explained that re-benching is a second complete review of a drug’s price, using all factors. If the original price was less than the ceiling, then that price becomes the benchmark. If it was above the ceiling, then the MNE price becomes the benchmark. After that, the only increases are adjustments to the CPI.

There are only two circumstances where the Board would re-examine a price:

- If a drug is not approved for marketing in Canada (such as investigational drugs), but is available through the SAP. The Board may review the price before it is launched on the market.
- Seven comparator countries are listed in the regulations for international pricing: the UK, France, Germany, Sweden, Switzerland, Italy, and the US. If a drug when first introduced was sold in fewer than five countries, it will be reviewed once it is sold in at least five countries or within three years, whichever comes first.

Another reason for reassessment is when a drug initially comes to the market and the internationally based pricing may be high. Still another reason is if the drug is used for a different application. Other comparators would be relevant.

Should the introductory price ever be re-benched? Why? It is a transparency/accountability issue. Regular review would speak to fairness to consumers and manufacturers.

It helps to stay abreast of developments and take into account evidence that was not available when an item was introduced. It could strengthen the manufacturer's ability to get fair market value.

If the manufacturer sets low prices for hospitals and high prices for the community, this could be looked at during re-benching (although all prices must be below the MNE price).

The introductory price could be re-benched if there is a drastic change in the purchasing power of one province compared to another province.

Some participants said the introductory price of a drug should not be re-benched, because that would add complexity and create unpredictability regarding price changes. Unpredictability would negatively affect both the patentee and the consumer. It could become a disincentive for patentees, affect accessibility, and result in the de-listing of public formularies.

If price differentials between provinces trigger re-benching, they would be a disincentive for manufacturers to negotiate lower prices in different markets. (Some provinces are able to accommodate price increases; others are not. This is one reason for price differentials.)

There may be no good reason to re-bench on a huge scale, but the costs would be huge.

If re-benching is automatic or if it applies to too many products, the administrative burden would be too onerous. Likewise, if re-benching requires re-benching every other drug in the same category, it would be too onerous.

Re-benching should occur on an as-needed/as-requested basis by the PMPRB or the manufacturer or when there is a new indication or an indication becomes the predominant one.

Re-benching is appropriate if there are substantial changes in the marketplace and the item has been re-categorized. In any case, the item should be re-benched after three to five years.

There would need to be hard outcomes, such as mortality, rather than surrogate markers that are predictors of benefit.

What evidence would be needed to support re-benching? How would re-benching be affected by the progressive, renewable, maximum allowable price?

A change to progressive market approval licenses would necessitate a complementary change to the PMPRB's pricing process. There would be no need for re-benching, because it would be formalized within that process.

Some participants said there should not be a disincentive for manufacturers to offer price reductions to bulk purchasers.

Over the last 10 years, Canadian prices have been significantly lower than the international median, and price increases have been significantly below CPI increases.

When calculating the ATP, discounts, rebates, and free goods are deducted, along with any other benefit except for samples distributed to physicians free of charge.

It is important to note that prices may be re-benched up or down. For example, if the first indication is rare and the second is more common, re-benching may reduce the MNE price.

Currently re-benching efforts are limited to occasions where a drug was sold in fewer than five countries when it was introduced.

Plenary Session: Report Back

Participants in Group 1 who favoured re-benching said it would enable the addressing of substantive changes in the market/item.

An underlying principle would be fairness to both consumers and patentees: it would help the PMPRB to keep abreast of new developments.

It makes sense to re-bench if an item was benchmarked on a limited number of countries and if the item moves from a narrow to a broader application.

If re-benching is to take place on a claim-request basis, there need to be clear guidelines to govern the process. If there is a drastic change in the purchasing power of a province or territory with respect to a particular drug, that would trigger the re-benching process. Strict criteria would have to be established.

As a result of re-benching, the MNE price could go either up or down.

Those not in favour of re-benching said that a change in categorization may eliminate the need for the process. It would negatively impact predictability and accessibility.

If a wide variation in price between markets triggered re-benching, that would provide a disincentive for industry to give bulk discounts, etc. It would be important to understand the cost versus the benefits.

Re-benching may result in a disincentive to market the product in Canada. It is a matter of social policy interest to have many drugs and many suppliers. Re-benching would work against this.

For progressive markets, conditional NOCs would change the situation. The need for re-benching may become less important if the process is clear and formalized.

If a product were re-benched and the price lowered, and other prices depended on that product's price, what happens to the other products, asked one participant. Even if they did not ask for another indication, would their price be re-benched also?

If a drug got a new NOC for a new condition, it would be re-benched against a different basket of drugs. It would have no effect on the first basket, so there would not be a cascading effect. Regarding the other drugs in the first basket, unless there is a specific need to re-bench them, their prices would go up only by the CPI.

A participant said they hoped the PMPRB is communicating with Health Canada while the Blueprint for Renewal is being drafted so that some things are captured at a higher level.

Group 2 said that re-benching would be triggered by new evidence to include new published literature, reports from other jurisdictions (including those outside the seven countries), CDR reports, CADTH, and Health Canada information from post-marketing reports.

Participants asked what the tipping point is. New Zealand was cited as an example of disequilibrium.

It was mentioned that industry will adapt accordingly. What is required is excellent and structured communication with consumer groups to maximize the level of predictability.

Since there are finite human resources, it is important to assess the impacts on human and financial means. Getting buy-in from the other players is also important, since it would impact their resources as well.

The PMPRB's role has to be transparent. This may be facilitated through the website and effective communications. The PMPRB must provide a direct information link to consumers.

There are inherent dangers with re-benching. It could put the Canadian system at risk if prices decline further and cause disequilibrium in the current system. It was also feared that re-benching could cause the PMPRB to move away from its original mandate.

Regarding the potential for Health Canada to adopt progressive market approval licenses, the consensus was that Health Canada needs to provide more information before anyone comments on whether the PMPRB should do this or not.

Group 3's answer to the question about re-benching was a small yes. It particularly felt it is relevant if a drug has an approved or indicated additional primary use or increased utilization. Also, if there is better scientific knowledge about safe usage, it can be better evaluated.

Group 3 was also in favour of re-benching when a newer treatment enters the market at a lower price under special market conditions.

Participants felt that re-benching should not be triggered automatically but should be undertaken on a case-by-case basis, on request from an established stakeholder group, industry, or groups of interest. Participants added that the existing process should be used.
There was sensitivity to the possibility of losing access to the molecule on the Canadian market, underscoring the need to take into account the global impact on price and sales.

The guidelines need to be tight, clear, and precise with no room for interpretation.

Several reasons were given in support of re-benching:

- Re-benching provides "a nice opportunity to create new jobs."
- It provides the potential for increased access to a particular drug.
- A cyclical review would apply when rare products are used as raw materials, since a fluctuation in product cost could affect accessibility.
- Re-benching provides the potential to look at the total systemwide cost of a drug, not just the cost of individual products. For example, a drug itself may be more expensive, but if the individual can self-administer at home, hospital-related costs for a specialist would decrease.

On the down side, re-benching is a lot of work for small returns. There would be an increased regulatory burden, thereby increasing stress on support staff.

Evaluation of Session

Desroches asked participants what they liked about the day's work and whether they had any concerns.

One participant said the smaller groups worked well and suggested rotating the groups so there would be a variety of people in the breakout sessions.

Another expressed surprise that no one from the OCAPI (Health Canada's Office of Consumer and Public Involvement) had been invited. However, not everyone who was invited attended. Staff from Health Canada were scheduled to attend the Ottawa session, and a representative from Health Canada's regional office was present at the Halifax session.

The comment was made that, in the first breakout group, there should have been more definition of the eight principles and the five pillars.

Someone said that between the groups in Edmonton, Montreal, Halifax, and Ottawa, everyone should get a good idea of the important points related to the issues.

Another suggestion was to provide the names of participants at the other sessions.

A report was being produced for each session, and an annex listing the participants would be attached. This information was expected to be posted on the PMPRB's website by January.

Next Steps and Parting Message

Mary Catherine Lindberg, Vice-Chair, PMPRB, thanked everyone for their valuable participation and contributions. She informed participants that they would receive a summary report, which also would be posted on the PMPRB's website and reported in the January newsletter. Once the reports are circulated and posted on the website, the Board will start deliberating on the results.

Another stakeholder meeting will take place in the spring prior to changes in the guidelines. Lindberg advised participants: "Check out our website!"