Patented Medicine Prices Review Board (PMPRB)

Stakeholders Consultations on Excessive Price Guidelines

Toronto, Ontario
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Welcome and Opening Remarks

Board Member Tim Armstrong welcomed participants to the Toronto session of the stakeholder consultation.

The purpose of the consultation process was to engage stakeholders in a number of key issues relating to the introductory prices of patented medicines, Armstrong explained. The consultations were not about changing the *Patent Act*. Rather, the goal was to discuss potential changes to the Board's Excessive Price Guidelines that might improve them from the perspective of all stakeholders.

The Board's objective is to ensure that the guidelines provide predictability and transparency in the drug pricing process and maintain the credibility of the process for all those affected by how it works.

In March 2005, the Board made a request for stakeholder input into the way drug prices were reviewed. Having received a substantial number of suggestions, many of which fell within the purview of the Board's price review process, the Board initiated the 2006 consultations. A *Discussion Guide* was released in May, to which over 40 stakeholders submitted thoughtful comments on important issues.

Following these consultations, a further stakeholder meeting will be held in 2007 to discuss any specific changes the Board deems appropriate.

Parliament has identified several key factors that the Board must take into account including the price of other medicines in the same therapeutic class, the price of medicines of the same class sold internationally, and changes to the Consumer Price Index (CPI). If the Board is not able to determine whether a drug has been sold at an excessive price, it is empowered to consider additional factors such as cost of manufacture.

The *Patent Act* allows the Board considerable leeway in applying these factors. However, the need for transparent guidelines led the Board to issue the Excessive Price Guidelines under sections 96(4) and 96(5) of the Act, changes to which must involve consultation with stakeholder groups. The guidelines are not binding on the Board or patentees but have, over the years, proven to be a useful resource and have facilitated voluntary compliance under the regulatory price regime.

Presentation 1: What We Heard Report

Barbara Ouellet, the PMPRB's Executive Director, provided historical context and discussed the response the PMPRB received to the *Discussion Guide on the Board's Excessive Price Guidelines.*.

The focus of the face-to-face meetings was to discuss the issues that are within the Board's authority: how drugs are categorized, whether introductory price tests are appropriate, and what the "relevant market" is at which to regulate. A total of 43 submissions were received from various stakeholder groups regarding the *Discussion Guide*.

Stakeholders' feedback included fundamental concerns about the categories of drugs under the Excessive Price Guidelines, as follow:

- Category 1: new strength or a comparable new dosage of an existing medicine (line extensions);
- Category 2: breakthrough medicines or substantial improvement over existing medicines;
- Category 3: moderate, little or no therapeutic advantage over existing comparable medicines ("me too" drugs).

Opinion on the drug categories was divided between the extremes of eliminating and altering the categories. Some said the current system does not recognize innovation, particularly incremental innovation, and suggested replacing the categories with a clear definition of excessive price. Others suggested new categories or improvements such as refining the evidence base to include real-world applications.

The majority saw Category 3 as problematic—either too generous or too restrictive—though all agreed that it does not adequately acknowledge the relative value of new medicine. It was suggested that the category be divided into "moderate" and "little or no" improvement.

Ouellet turned to the subject of "any market," noting that the Act refers to markets in several different ways. For example, "any market" implies multiple markets, while "the relevant market" implies a single one. Patentees are required to file for four classes in multiple markets, so as many as 52 prices may exist for one drug. The use of an average transaction price in the guidelines may mask significant price variation between different regions and jurisdictions, and some stakeholders expressed concern that companies raise prices for some to offset discounts for others.

Some stakeholders supported the current approach of reviewing prices at the national average and said changes would complicate the system and could unfairly push prices down. Others disagreed, however, and called for the clarification of issues such as the inclusion of discounts and rebates in average price calculations. Additional review in cases of potential excessive pricing was recommended.

Stakeholders also raised substantial concerns regarding equity. There was general agreement that price reviews should be conducted on a case-by-case basis where warranted such as reviews by region or class of customer.

Presentation 2: Principles Underlying Patented Medicine Price Regulation

Sylvie Dupont, Secretary of the Board, discussed the guiding principles. She asked how the PMPRB should interpret its consumer protection mandate.

The PMPRB was established in 1987 by an amendment of the *Patent Act*, which outlines the scope of the Board's authority, powers, and reporting and consultation requirements in sections 79 to 103. Although consumer protection is mentioned nowhere in the Act, it was nevertheless cited by the then-Minister of Consumer and Corporate Affairs as the "principle" under which the PMPRB was created.

The statutory mandate of the PMPRB is to apply the pricing factors outlined in sections 85(1) and 85(2) of the Act. Therefore, it also must reflect the government's intent of protecting consumers' interests.

Dupont listed the five excessive price factors and two sub-factors outlined in the act, noting that each factor cannot be applied at the same time, nor be given the same consideration. The question posed was which factors should be given more emphasis, and when. Furthermore, which key principles reflect the PMPRB's mandate, and how should they be weighted?

Stakeholders suggested numerous principles, including

- 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.

The question remained how to apply these principles and whether they were the correct ones. Dupont commented that no one principle is likely to be paramount for all drugs at all times and used three frameworks to illustrate how the underlying principles might be linked to price factors.

A participant asked whether the PMPRB considers the price of other medicines in the same class sold in other countries. Ouellet explained that Board Staff does not consider this at present. The guidelines were last changed in 1994 and do not provide guidance for Staff on that matter. However, any issue coming before the Board in a public hearing would address anything in the Act, so that factor would be discussed.

Armstrong noted that Section 85(1) addresses factors that are considered mandatory in a contested review.

Breakout Session 1: Guiding Principles

Group 1—Green

Facilitator Ron Desroches asked participants to consider which of the draft principles reflect the PMPRB's core mandate.

One participant questioned the meaning of "fair share," which was defined by another group member as the "fair share of R&D costs" at the international level. For example, if a biological drug costs $25,000 per patient in Canada, it will be accessible to Canadians only if Canada pays its fair share of R&D costs in the world market. "If we are only 3% of the world's population, how much should we have to pay to have access to a catastrophic drug?" another participant asked.

"I don't think we pay our fair share," one participant commented. "And that's why some drugs won't be marketed in Canada." Another group member agreed that certain products are considered too costly to launch in the Canadian market, thus depriving Canadian consumers of potential benefits.

The concept of fair share is linked to international parity and consistency as well as to affordability and accessibility to medications. "It doesn't matter if you have a thousand pills: if the patient can't afford it, the drug might as well not be there," one participant noted. For example, since many prescriptions are paid for through third-party agreements, some drugs may not be included in the provincial formulary lists, and their availability may be seriously curtailed.

Access to medication was flagged as a key issue, since even at the lowest reasonable price, some drugs could still remain unaffordable and, therefore, inaccessible to patients. A participant took issue with the phrase "lowest reasonable price," noting that it is "not possible to call a price both 'lowest' and 'reasonable.'" Others agreed that "just reasonable" made more sense.

"My observation of 'lowest price' was in the Ontario government's formulary," one group member said. "It has nothing to do with reality, but more with what government agencies will pay for. 'Reasonable' and 'affordable' are better criteria." However, it was pointed out that market forces can dictate the price of a medication.

While factors such as international pricing should be considered in determining the definition of lowest reasonable price, it can be difficult to determine the international price of any given medication.

The group discussed the link between lowest reasonable price and value-based pricing. One participant suggested that the new "biologic response modifiers," which can arrest the symptoms of rheumatoid arthritis, could be examples of medications with significant value to those who use them. These drugs should be priced to reflect not only their innovation but also their high value to the patient.

One group member recalled the days when the high price of a recently released antibiotic was justified: the patient would be cured more quickly and would therefore return to work in days rather than months, thus earning the money to pay the higher price for the medication. "A medication may save a life, and that is its human value. But it always comes back to accessibility and affordability."

While the Human Drug Advisory Panel (HDAP) reviews the scientific literature around the drugs it considers, patient outcomes are not factored into its deliberations. "The disconnect is that it's all about money, not health outcomes," one participant said.

The group was asked to consider how factors such as value in innovation, the relative impact of side effects, and relative therapeutic effects could refer to the value question. "Are these some aspects of the value principle?" Desroches asked. "And what are some other principles that might be considered?"

Although Canada should not have the lowest price among its comparator markets, neither should it have the highest price for any given drug, group members replied. "Drugs should not be treated as a commodity," said one. However, others disagreed, noting that a drug is a product with a market. "Anything that is sold is a commodity," another said. It was suggested that if a medication is truly innovative, it should not be treated as a commodity, but if the medication has several viable competitors, then it should be considered a commodity.

Several group members raised the issue of equity in Canada's drug pricing relative to other countries. "When we're marketing drugs in other countries like Mexico, for example, I don't get the justification for making Canada pay for the innovation behind that drug, but not Mexico," one participant said. In his experience, when medications were available behind the former Iron Curtain, pricing there was based on the drug's cost in Canada. "The question is how you come to a fair price," he said.

Desroches asked the group to consider which of the guiding principles are most important. Participants agreed that simplicity and transparency are vital. "We need to understand the rationale behind the decisions," one said. Others agreed that it would be helpful to know all the factors leading to a given decision: "We need to know how much weight these factors are being given."

The group did not hold that the PMPRB currently provides enough clarity. "We're always reading, 'we discussed, we consulted, now here's our conclusion,'" said one group member.

Price stability and predictability were also cited as important guiding principles. Participants noted that for some drug purchasers, such as hospitals or other institutions, budgetary constraints can create enormous roadblocks. While these larger scale purchasers can sometimes take advantage of bulk discounts, they often must fight with the manufacturer to keep prices low enough to accommodate tight budgets.

A participant said, "We're here today because many pharmaceutical companies chose to raise their prices dramatically in 2004. What should have been predicted became something non-predictable, because someone fell asleep at the switch. You just can't expect prices to stay the same forever." This participant pointed out that, while this kind of sudden price hike should have been expected and planned for, people were lulled into a false sense of security and were taken by surprise when prices suddenly rose.

"A flaw in this argument is that there is no proper prediction of next year's prescription product needs," said one group member. Budgeting models that account for the evolving health needs of Canadians should be put into place. "If we knew what the price increases would be, we could factor them in," said another. Discussion ensued around predictability, as participants considered whether it is possible to reliably predict drug prices over time.

"You never see price decreases," a participant said. "The price may go up, but you never see it come down. Instead, they might give you an extra piece of the chocolate bar, but there's huge resistance to lowering prices."

Desroches asked the group whether there were any principles that do not reflect the PMPRB's mandate. "So far, I'm hearing that all the principles have some usefulness," he said. "Are there some that should be off the table?" There was agreement that none of the existing principles seemed out of place.

Accessibility and affordability should be at the top of the list, participants agreed. In addition, Canada's social obligation to developing nations was highlighted. "Each country has a different demographic mix," a participant said. "Not every country has baby boomers, and baby boomers are a tidal wave of future drug users. Demographics are linked to affordability, which is linked to accessibility, and we are unable to separate them. They will always be linked."

Group 2—Yellow

Facilitator Suzanne Laplante directed her group's attention to Page 8 of the guiding principles handout. She asked whether these principles reflected the mandate of the Board and if not, why not.

One participant asked if "mandate" meant consumer protection or what is set out in the *Patent Act*. After a brief discussion, the attendees agreed that this should be taken to mean "protecting against excessive pricing."

Someone else asked for clarification of what is meant by "the prices of other medicines in the market." Did this mean all medicine or just patented medicine? The distinction matters when it comes to a definition of reasonable price. A consensus formed around the idea that it refers to all medicines, since the Board is concerned with the highest reasonable price, not the lowest.

A participant asked whether the PMPRB is a federal body—do their principles include jurisdiction over provincial governments? One must clarify where and how deeply the principles apply. Provinces may have different ideas of what value a medicine has, so that would affect things such as value-based pricing. Another participant responded that this was all about the ceiling price, that is, what a manufacturer can reasonably charge any province.

One participant said that the last point was an important one. "This is the ceiling we're talking about. We have to remind people about that. If the target is to establish a ceiling, you have to think about the principles in that context."

Echoing this, another person said that the guiding principles basically come down to finding the balance between accessibility and affordability. Also, if the goal is to establish a maximum non-excessive price (MNE), it should not be defined by what a small payer pays, but by what large entities pay.

Discussion ensued about how to correctly conceive of the highest reasonable price. An attendee put it this way: "The question should be, what is the lowest ceiling you can come down to?" Another suggested using "acceptable ceiling," because, he said, the problem with using "lowest" is that people think it is a low price—but that is not how the Board thinks about it.

This analysis about the MNE led to a discussion about the onus these regulations place on manufacturers, whose ability to raise the prices of their products is affected in the long-term by what the PMPRB sets as the introductory price. One member concluded that, in the absence of a national pharmaceutical plan, there is a mixed system, so an additional guiding principle should be that whatever system is established should align with the provincial systems.

One participant expressed a concern about the last principle on Page 8 regarding consistency of price. If Canada has a unique product, this guiding principle says that the product should be reduced in price if a given country in the basket of comparator countries discontinues a given Drug Identification Number (DIN) or Stock Keeping Unit (SKU). This can lead to confusion about principles when one thinks in terms of the highest reasonable price: which takes precedence, price increases or consistency?

Another said it depends on whether one wants stability, a sense of fairness, or predictability. He added, "What is more important, that the rules stay the same or that the consequences of the rules are the same over time?"

The previous speaker replied that she would opt for predictability and transparency over consistency, because the market can change so quickly.

This exchange prompted someone to ask a PMPRB representative whether the Board's priority is that the prices do not change or that they respond to changes in the market. He responded, "I would think the latter."

A participant concluded that principle No. 8 should read "responsiveness over time" rather than "consistency over time." Another participant punctuated this by saying that, as a businessman, he most valued "knowing the rules and knowing they're consistently applied. I want to be able to plan my business strategy."

Laplante, in summarizing the group's discussion, uncovered some confusion and discomfort with the term "fair share" in the second principle. Someone suggested that she take the phrase to mean, "The price Canadians pay for medicines should reflect the benefits they get from them." The price has to be high enough to ensure that other countries are not being forced to subsidize the prices Canadians pay.

The conversation moved to the discomfort some felt with this principle—if the price is reasonable, perforce, Canada is paying its fair share. One member commented that if the other principles actually worked, this principle would not be necessary.

Someone asked about value-based pricing. He wondered if "value" is understood as being what somebody is willing to pay for a drug. Is it really within the Board's jurisdiction to determine that? Another participant replied that this refers to the clinical value of the drug and has nothing to do with the price. Someone else said that the HDAP gives the Board information about a drug, and they make value-based decisions about the price of that drug.

Laplante said the group seemed to be comfortable with principles 3–6. They had discussed principles 1 and 2 already, so what about principles 7 and 8? After a short discussion, a consensus was reached that, because of the Board's commitment to price stability and predictability, instances where a drug is not universally unaffordable would pose a problem.

Laplante asked which principles were most important: "Are some critical and some just nice?" An attendee answered that the PMPRB had changed the market considerably. One need only refer back to the large, regular price increases of the mid-1980s to understand the shift, but it seems things have swung too far in the other direction. It is important to find a balance between the two. In other words, pricing predictability is of particular value.

Another member answered Laplante's question by saying that rewarding innovation while serving the public interest is of critical importance. Several participants concurred that where one draws the line in this equation is paramount.

Another participant added that the participants seemed to be overlooking the reportorial function of the PMPRB, in that its consumer protection function is related to an informational role. In terms of excessive pricing, the Board is essentially informing the provinces about what other provinces are paying.

This provoked a response from someone else, who said that "public interest" means everyone. "It doesn't matter who's paying for it. If it's excessive, eventually it's going to hurt me." He said that price gouging is never in the public interest, nor is an excessively low price for a drug.

Group 3—Blue

Lloyd Livingstone, facilitator of the session, introduced himself and reminded the group of its objective, which was to discuss which, if any, of the principles reflected the PMPRB's mandate of consumer protection.

One participant said she felt the principle of accessibility/affordability was important for protecting consumers, who should be able to get the medicines they need at prices they can afford.

Another participant said he felt the concept of international parity was important, because without it there would be no incentive for innovation in Canada, and the country would continue to rank behind the rest of the world in research and innovative treatments.

A stakeholder said she supported the principle of price stability/predictability, because countries where it does not exist have fluctuating drug prices. This has caused problems for drug manufacturers and consumers, especially those who depend on medicines for chronic conditions.

Another participant stated that the difficulty with the principle of lowest reasonable price was in defining the term "reasonable," which would have to be determined in some objective fashion. She also said she did not support international parity, because the comparator countries differ so much in pricing criteria, population size, health care systems, and economics.

A participant said he felt that something in the system is hampering innovation such as the CDR, which has a 60% rejection rate.

Another stakeholder said he agreed with the principles of lowest reasonable price and accessibility/affordability, especially if public drug coverage is going to be expanded in the future. He also said he supported value-based pricing as long as head-to-head trials, not placebo-to-drug trials, were used to determine value. In response to an earlier comment on international parity, he said there is no real evidence to show that Canada is suffering from not having the same drugs as other countries.

Debate followed on the issue of innovation in Canada. One participant said low pricing levels send a message to drug manufacturers that Canada is not open for business and it should launch new drugs somewhere else. Another stakeholder said he had heard the same arguments about how Canada needs to get companies to invest, but he would like to hear some new arguments to make a more credible case.

Another stakeholder suggested that innovation could be encouraged through a mix of different policies, not just with pricing. She also said that she attributed to value-based pricing those arguments that had been presented for lowest reasonable price.

This comment prompted some discussion about how value was being defined differently by the participants and by various patient groups.

The majority of the participants agreed that value-based pricing was a key principle, because it captured other interests and concerns. The group said there were flaws in the other principles, such as lowest reasonable price, which focuses on the monetary factor and makes no mention of value.

With respect to the principle that Canada should pay its fair share, the majority of stakeholders said they did not know what it meant. Livingstone said most of the stakeholders from previous meetings also did not understand what this principle meant and, therefore, did not support it.

The group then discussed possible meanings of "fair share" as a guiding principle. Some said it might refer to companies recouping research costs, while others said they interpreted it as Canada's social responsibility to help Third World countries gain access to drugs. The participants agreed that fair share was not defined well enough to be supported as a guiding principle.

A stakeholder said that, as a consumer, if she were going to pay for an innovative drug, she would want to see proof that the drug was in fact innovative. She called for head-to-head trials, not placebo trials, as well as transparency to see how the manufacturer came up with the classification of being innovative.

Another participant said he thought value-based pricing would not be appropriate for new drugs coming onto the market, because they have little supporting research. A new drug should be priced lower at launch, and if it turns out to be safer, the price could go up. If the drug turns out to be less safe, the price could go down.

In response to this suggestion, another stakeholder said it takes time to gather data, so new drugs should be priced based on reasonable pricing, and the drug companies should be given a specific period of time to prove the drug's value. If the company fails to do so, the price is lowered and the company must pay back the excess or offer discounts and rebates to consumers.

A participant said the pricing process should be efficient but not necessarily driven by simplicity. It also should be as complex as it needs to be to achieve the right results. She also said that if circumstances change in the comparator countries, those changes should be taken into account by the Canadian process.

Livingstone then reviewed the three examples of frameworks found in the discussion guide and asked the participants to consider which principles they would incorporate within their own framework.

The group agreed that its discussion seemed to indicate a consensus around the principles, with a domestic focus such as accessibility/affordability and value-based pricing. There was some disagreement on international parity as a principle.

Drug manufacturers place more importance on the price that is set by the PMPRB (also known as the list price), one participant said, adding that the list price should be based on some reasonable comparators and should take the Canadian reality into account. In response, another participant said that, to his knowledge, manufacturers are more interested in the price that will get them through the CDR.

A third participant said he understood why international parity is used, but he questioned why another country should dictate the value of health in Canada. A stakeholder suggested that, rather than looking at price, they should consider what other countries are getting for their money. As an example, he said that Americans might have to pay more for a drug, but if they can avoid going to the hospital, then they save in the end. The stakeholders expressed consensus on that point.

Group 4—Red

Facilitator Larry Arpaia welcomed participants to the session and reminded them that the questions under discussion would be

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

Participants began by discussing the principles of value-based pricing and reasonable price. A participant said that while the principle of lowest possible price may appear to protect consumers, it could, in fact, reduce the accessibility of drugs and restrict practitioners' choices. The principles of access combined with affordability, or the lowest reasonable price, are more appropriate.

Another participant noted that drug plans may decide whether a certain drug is affordable or not, creating another barrier to access.

One participant recalled that prices are established in the context of awarded patents; their purpose is to reward research, with the rationale that drugs become more affordable once the patents expire. This benefit should not be negated.

Consumers' questions about drug prices often arise at the dispensary level, where patients pay in cash, one participant noted. Canadians need reassurance that pricing "may be high, but it is reasonable and not excessive." Affordability therefore falls within the PMPRB's mandate. Another participant agreed that the lowest reasonable price principle does not mean the lowest price and enables patent and value factors to be taken into account.

A participant reminded the group that the *Patent Act* was written in anticipation of price increases following the removal of compulsory licensing and was designed to balance consumer assurance with patent protection.

One participant said the phrase "reasonable price" is similar to "in the public interest," in that it allows considerable legislative leeway but is a good starting point. Another suggested that too much clarity reduces flexibility. It was also noted that the current principles are static and do not reflect the fact that, with innovation, the value propositions of drugs change over time.

"We're dealing with an imperfect market in the pharmaceutical sector," a participant observed, since what the market will bear does not necessarily reflect the value the consumer places on a product. The principles should include consideration of the public interest and society's values.

The principle of setting prices at the international median might be an easy way to reassure the "patients in the pharmacy asking why drugs are so expensive," a participant said, as prices will never be the highest in the world. Another warned that the movement towards single international prices could result in drugs being priced at international parity while still being too expensive for their marginal benefits.

Participants agreed, however, that the PMPRB's mandate does include considering the international price, as indicated in the *Patent Act*. Some speculated on whether international parity should be applied differently for different drug types. For example, the Board might place less emphasis on comparative pricing for drugs that do not have a good precedent in Canada.

The group discussed whether including generic drug prices in international parity calculations would provide consumer protection. "This would require eliminating the 'P' in 'PMPRB,'" one participant observed. Another noted that the likelihood of every provincial and federal government altering their legislation to allow the regulation of generics is "less than zero."

Participants then sought to define value-based pricing. "Value-based" means a price that is not excessive considering the value the product brings, one suggested, "so if you're the 16th beta blocker, your value is equivalent to the others." Another suggested that rather than pricing the "16th beta blocker" equivalently, the first drugs on the market should be rewarded with a higher price. A third argued that "me too" drugs do not actually exist, since what works for one patient may not work for another.

Participants agreed that "value" and "reasonable price" are analogous terms. Value based on savings to the health care system also should be considered.

A participant said that while accessibility is an important principle, pairing it with affordability is redundant. Another observed that the pairing represents a "bureaucratic qualifier" based on limited public budgets—to which the participant responded that the issue at hand was the PMPRB's mandate, not fixing the problems of the health care system.

Other suggestions included efficiency—or prices that create an incentive for efficient research rather than "just throwing money at research and development (R&D) and charging for whatever's successful"—and transparency, particularly regarding the costs of R&D. "Are we looking at recouping marketing costs?" a participant asked. Transparency regarding the Board's decision-making process is also crucial. A third suggested principle was alignment or prices that are aligned with public policy goals, which is within the PMPRB's mandate.

The PMPRB's principles should be coupled with the dynamics of the marketplace and product life cycle; pricing and innovation are dynamic, and value changes over time. Several participants agreed that the PMPRB's role is to set a ceiling price, not to establish the suggested retail price of a drug.

Discussion turned to the principle of Canada paying its fair share. Some Americans resent "Canadian socialists taking advantage of us poor Americans to fund their system," as one participant described. While comparisons between Canada and the USA, its "elephant" neighbour, are inevitable, their systems are very different. "Fair share" can also imply an obligation to a company; Canada should pay for the value of medicine, not its "share" of R&D. It was suggested that the compromise between patent and consumer protection that was negotiated in the 1980s is now beginning to erode, as some companies refuse to introduce drugs at the PMPRB's price while still enjoying the protection of the *Patent Act*. "You can't have only one side of the coin," a participant said.

Participants discussed the principle of price stability and predictability, agreeing that it was somewhat unclear. Consistency of approach and the term "reality" were suggested as alternatives.

Arpaia asked participants to identify which principles were most important. They agreed that the basic principle should be a reasonable ceiling price based on the value of a drug. The test for reasonableness would be the value of a drug to society, which would in turn ensure price stability. "Value-based price and reasonable price are a Venn diagram," a participant said, to general agreement. Accessibility was also identified as important.

Some issues regarding reasonable price remain, however. Small, incremental increases in benefit should not command a dramatic price ceiling increase, for example. The PMPRB should also remain aware that other groups may not share its view of reasonable, a

participant said. “If the PMPRB gets too far removed and says okay, and the CDR says no, and it keeps happening, then everyone’s chasing their tails.”

Regarding value, the group noted that a drug’s value is different to the individual whose life it saves than to the government funding its purchase. Value can also depend on whether a drug cures or controls a condition.

Some participants suggested that reasonable price and value-based pricing are one and the same. However, one stated that value is subjective and described the CEO of an American pharmaceutical company who said, regarding a drug, “This is the value, too bad. Take it or leave it.” Another suggested that government agencies should value drugs according to the value Canadian society sees in that medication including factors such as affordability, quality-adjusted years, and the value of a life. A third participant said it is not the PMPRB’s mandate to “get into the value of a month of pain or of a life.”

Playing “devil’s advocate,” a participant suggested separating value from the principle of reasonable price. “Here’s a CEO saying, ‘this is the value of the drug,’ but another would say it’s different,” he observed. Reasonable price should be defined simply as the middle range of what other societies pay. However, “the word ‘value’ is being brought into the discussion—and not by us,” another participant countered. “It’s by industry. Let’s deal with it, because we’re going to have to.”

Group 5—All Colours

Facilitator Ron Andrews asked participants to examine the principles, which various stakeholders linked to the Board’s mandate, and to discuss which of them are truly reflective of the mandate and which are not.

Participants asked for and received clarification of several issues from PMPRB representatives and other attendees.

One participant stressed the importance of defining the value-base that underlies all of the assumptions and principles relating to the mandate.

Another noted the importance of ensuring that the principles clearly and explicitly capture the Board’s responsibility to ensure non-excessive prices across different jurisdictions, markets, and classes of customer. Accessibility and affordability must be captured clearly in the mandate, particularly in regard to distinct markets and customer classes.

Generally, prices in Canada are not excessive, according to one participant. However, it was noted that a price may be below the MNE and still be beyond consumers’ access, which requires the Board’s consumer protection mandate to deal with the complex balance around issues related to access.

There is a difference between the concept of access as "available for sale at a non-excessive price" and the willingness of payers to reimburse for a particular drug, another group member said. The Board's mandate is not to ensure that there is public access, only that the price is not excessive within the limited confines of its jurisdiction. Payers and the market will establish accessibility.

The mandate is explicit, a participant said: the patentee who has the patent may not charge an excessive price in relation to the principles of the *Patent Act*. The price review determines whether the product is positioned rationally compared to other G7 nations and if there is an abuse of the patent.

Several participants disagreed, insisting that it is not possible to exercise any test for price excessiveness without some analysis of access and consumer ability to pay. One of the major problems with the current system is fragmentation. There must be room in the mandate to consider context.

Participants engaged in a lengthy discussion about whether the concept of access should be interpreted narrowly or broadly. Two said accessibility should be defined simply as whether or not a drug is available on the market, whether or not payers choose to reimburse, or whether average, private consumers would find it affordable.

Several others stressed that a drug could be under its MNE and still be inaccessible to those who need it. Therefore, they argued, the PMPRB's mandate should employ broader definitions. "Availability without access is meaningless to Canadians and does not fit the Board's consumer protection mandate."

Those issues would be better dealt with by the Common Drug Review (CDR) and market forces, the two countered.

A participant said there are two important considerations regarding accessibility: a drug must be available at a reasonable price at the same time that it is not priced so low as to discourage its manufacture. Drugs must not be so expensive that they are beyond the reach of most consumers, nor should prices be so restrictive that they keep important medicines from being available to Canadians.

This is really a systems issue, another participant said. In Canada, one body determines prices and another determines value. The PMPRB should focus solely on determining the price point of excessiveness; other agencies determine value.

Accessibility is also an important issue, because the long-term market base for drugs is uncertain, a participant said. Drugs with similar applications may be withdrawn from the market, changing the importance of particular products.

Another participant stressed that timeliness is also an important issue. The front-end process for price and product approvals takes too long. A lot of evidence comes out early but matures over time. There must be some process for determining "what those shifting

sands are and ensuring that pricing reflects the actual benefits of the drug as it plays out over time."

The biggest challenge, said one group member, is defining the width and breadth of the Board's mandate within the context of a complex system. The system is challenged by the FPT, regional issues, and a health care system, which is primarily publicly funded but lacks universal drug coverage. Then there is a whole added level of complexity when considering how all these issues affect the sick person in need of the drug.

The Board's mandate also must recognize and encourage innovation, a participant said. That recognition should be stated more directly than committing to "paying its fair share."

The fundamental element driving the whole system is the ability to pay, one participant said. The PMPRB's job should be to find a balance that clears most of the clutter out of the system and arrives at a reasonable price that considers the cost of innovation, reasonable costs for drug production, and sick people's ability to pay.

Because the Board has limited time and resources, it should not extend its mandate too far—particularly over drugs that may be patented but that are not really protected from generics due to particular market situations.

Another participant stressed that the Board's mandate should include principles that allow it to consider how therapies change over time, the changing prevalence of diseases, and new applications for existing drugs. The dominant principles must relate to consumer need. Although there was disagreement about whether those principles are currently within the Board's mandate, there was general agreement that the mandate should include a principle of comprehensiveness, context, or integration of existing content expertise.

Asked to priorize which principles were most important to the Board's mandate, participants identified

- Value-based pricing that defines value as the cost of a drug in relation to its clinical outputs;
- Cost-effectiveness and healthy outcomes;
- Affordability;
- Accessibility;
- Availability.

Plenary Session: Report Back

Laplante went through the principles that Group 2 (Yellow) agreed with including value-based pricing, price stability/predictability, and international parity/consistency.

For the lowest reasonable price principle, the group agreed that a more appropriate term would be "lowest reasonable ceiling" if the intent was not necessarily to find the lowest

price. The participants also said the principle "Canada should pay its fair share" needed clarification. Accessibility/affordability should not be a principle, because it changes across different markets and regions, and the principle of consistency over time should be changed to "responsive over time" if pricing is linked to other countries.

Livingstone then presented a summary of the discussion from Group 3 (Blue), which included the importance of value-based pricing, simplicity/transparency, and accessibility/affordability.

Some participants argued that Canada is and will continue to be behind in innovation and new treatments, while other stakeholders said there is no evidence to support that claim. There was some discussion around how innovation can be encouraged through other means besides pricing.

The participants said that proper clinical research, such as head-to-head trials, need to be used when setting prices, and this research should be made available to consumers. Some said the system is stifling innovation, citing the CDR's 60% rejection rate as an example.

The group decided that a framework with a domestic focus would be most effective, because pricing should take into account what makes sense to Canadians.

Arpaia then gave a summary for Group 4 (Red), which discussed lowest reasonable price, international parity, value-based pricing, and accessibility/affordability. It added efficiency as a key component to transparency, and there was some discussion around alignment for all those principles.

Accessibility was identified as an essential piece of value-based pricing, and the group wondered if it was redundant. The participants suggested changing "lowest reasonable price" to "ceiling price." The group also said the language of the principles needs to change to update them.

Andrews said Group 5 (All Colours) focused on the principles of accessibility/affordability and Canada should pay its fair share. Some members agreed that accessibility/affordability was reflective of the mandate, because if a drug is not accessible, then consumers are not being protected, and if the price does not make the drug affordable, then it is a meaningless definition.

Discussion about systemic issues occurred. Some suggested establishing criteria or principles that could make up for deficiencies in the system such as one body to review price and another to review access.

The principles should also reflect relevance, timeliness, comprehensiveness, and integration. The group also said the wording of Section 85.1 should be changed from the past tense, and the Board needs to consider how drugs change in value and how needs change over time.

Desroches said Group 1 (Green) agreed that all of the guiding principles were reflective of the Board's mandate, but not all of them had the same importance and so weighting was a key issue.

The group put accessibility/affordability at the front end and agreed that Canada paying its fair share, international parity, and value-based pricing were strongly linked.

Some members of the group said they interpreted fair share to mean Canada's social obligations as a "rich" country. In regards to the principle of lowest reasonable price, there were concerns that "lowest" did not necessarily relate to "reasonable." The group said the decision-making process and the weighting of factors should be accessible to the public.

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

Group 1—Green

This group considered the issue of categories for new patented drug products under the PMPRB's Excessive Price Guidelines. "Should these categories exist? And if so, why?" asked Desroches.

The current system of categories makes no distinction between life-saving drugs and those that enhance lifestyle. "That's because the categories are based on the most likely payer," a participant said.

"The patient is not really the one with the mandate to decide," said another. "It is up to the payer. In that regard, we need the categories, because how else do you decide where a drug fits?" Another participant said that if there is no distinction between drugs used to improve health and those used for cosmetic or lifestyle purposes, and if the market will determine prices, the PMPRB's role will be called into question.

Some system of guidelines is needed to help decide how a new drug fits into the cascade of medications on the market as well as to ensure that new medications are categorized fairly. "If it's just another antibiotic, then it might be a Category 3," a participant said. "But if it's a new and innovative medicine, then that will raise the price." Participants asked whether factors such as R&D or the cost of bringing a new drug to the market are reflected in the current categories.

While some group members felt that the categories should be expanded, others suggested that Category 3 might not be necessary.

"Category 1 keeps prices from artificially rising," said one participant. "It applies to new and only slightly different versions of drugs that are already out there, and it helps ensure

stability." Participants asked whether such line extensions encourage greater competition among drug manufacturers, who might flood the market with competing products.

Category 2 drugs are considered breakthrough medicines, filling previously unmet needs. Participants agreed that manufacturers of this type of drug should be rewarded for their innovation as well as for the higher R&D costs that go into bringing these drugs to market.

However, some problems with this category were identified: "Things can get lumped into Category 2 when they really belong in Category 1, and vice versa. New medications, especially the new biologics, belong in Category 2 but should be in Category 1." Participants agreed that this category can be too restrictive in some cases and too loose in others. "The categories need to offer consistent value to both consumers and payers," a participant said.

There was discussion about whether determining the degree of innovation in a new medication is within the purview of the PMPRB. "The Board must take into consideration the money spent on research," a participant said. "Every province has its own system of approvals, and it can be discouraging for the manufacturer to go through so many boards …. Sometimes it's no longer worth bringing a new medication out."

A PMPRB representative confirmed that the Board currently does not take into account R&D costs, as to do so would require an amendment to the *Patent Act*.

The group discussed the role of Category 3, which covers drug products that provide "moderate, little or no improvement" over existing medicines. Some participants felt that this category is unnecessary. "We could push some products into Category 2 and others into Category 1, and let market forces decide," one of them suggested. "Category 1 appreciates pricing stability and predictability, and we have Category 2 to appreciate innovation."

The criteria for Category 1 potentially could be expanded, participants said. For example, an inhalable insulin, which improves patient compliance and leads to better health outcomes, might be considered within this category. If this product were placed in Category 2, its price would limit access, since payers would be less inclined to pay for it.

One participant emphasized that each province has an equivalent to Ontario's Trillium Fund, which pays the costs of prohibitively expensive drugs in certain circumstances. "The Board needs to understand this impact," she said. "There should be a treasury in each province. This kind of thing should be made more available."

Categorization of drugs for "orphan diseases" was discussed, with some suggestion that these medications should have their own category. "These could go into Category 2, as 'very limited use' or 'limited application' drugs," a participant suggested.

Desroches asked whether drug prices should be reviewed based on sub-markets in Canada.

"My views on that changed when *Bill 102* came out," one member of the group said. "In a closed economic system, one man's discount is another man's surcharge." Citing potential job loss and the release of larger numbers of generic drugs, the participant noted that shifting to a local market basis would distort the PMPRB's comparator mix downward, through forces other than market pressure. "I want the national price decided nationally, not locally," he said.

The group felt that sub-markets referred to both payers, such as hospitals and industry, and geographic regions. "The principle of local sub-markets applies, no matter what the market is," said a participant. "The person with the biggest amount of money at stake should get the biggest discount," another said. One group member said the Board has the right to set the price, but once it has been set, manufacturers are free to charge less than the set price.

Some participants pointed out that in any marketplace, there will be competition. For example, Shoppers Drug Mart has the highest dispensing fee in the country, while Wal-Mart and many grocery chain pharmacies have the lowest. However, this price spread is not hurting Shoppers Drug Mart, since employers and other payers still must pay the higher rate. "The marketplace used to determine what you could charge," a participant said. "But that's not the case now."

Group 2—Yellow

Laplante invited discussion, first, of "any markets" to save more time for discussion of the PMPRB's use of categories in their price reviews.

A participant said the Board's mandate is being subverted if anyone is paying more than the MNE. It should get involved if *any* of the prices are excessive. He asked, "Are they simply determining what's excessive in comparison to other things, or is there an objective price, without looking at what's charged in other markets?"

Another participant believed that the PMPRB should not look at sub-markets, since its mandate is to establish and enforce a ceiling price for drugs, and that is the same across all categories of payers. If the drug companies do not like the PMPRB's decision, they may not take the drug to market.

This drew agreement from another participant, who pointed out that the PMPRB has to be careful about how it defines a market, because some companies could get caught "offside" (by charging too much) in a particular market because of averaging. "The more you segment markets, the likelier it becomes that companies will be found 'offside.'"

Someone else asked, "Why look at the average in the first place? Why has it become an average price, when all they should really look at is if somebody's paying more than the

maximum non-excessive (MNE) price?" Another attendee summed up the various responses to this point by saying, "It comes down to this: do you want regulatory prices or market prices?" The person who asked the earlier question replied, saying, "If you tell me that the ceiling can be raised, then you're saying the ceiling is unfair," and, "If you raise the ceiling, those who are paying less will not pay more; they'll keep paying the lower price."

Laplante summarized this part of the discussion by saying that there was agreement that using the average transaction price (ATP) may not be the best methodology, to which the previous speaker added, "A ceiling is a ceiling." When someone else ventured that the use of the ATP is meant to ensure that no province subsidizes another, a participant responded, "The [PMPRB's] mandate is not for equality, it's for excessive pricing." Someone else added that unequal bargaining power on the part of different payers skews what is defined as a reasonable price, which is why averaging is not appropriate.

Another participant raised the fact that pricing involves two different elements: the introductory price and price increases. In his experience, the latter is the area of greater concern, as there seems to be more congruity among and between introductory prices than in the way different companies handle the price hikes of various medicines.

The group returned to its difficulty with the use of the ATP and concluded that if the PMPRB is going to use this approach, then the language in its guiding principles needs to be changed to reflect this. For example, it would mean changing the current definition of the MNE as a price that "is excessive in any market in Canada."

Laplante suggested that the group move on to a discussion of categories. A participant proposed that Category 3 should be changed, since there is a big difference between "moderate" and "no" improvement. The group eventually arrived at the idea of making "moderate" Category 4. In addition to line extensions, Category 1 would serve as a kind of catch-all for drugs that do not fit into any other description such as drugs that are typically used in combination when combating HIV/AIDS. An added benefit of this is that, in terms of pricing, there would be a difference between drugs that offer "no" and "moderate" improvement.

Reacting to this proposal, a participant said it makes sense to differentiate these two, but there have to be stricter controls on the pricing of drugs with little or no improvement, that is, a mechanism to provide a modest price increase for a modest improvement. Another participant, agreeing with this observation, asked why a drug seen as offering little or moderate improvement is assigned the highest possible price, the MNE, instead of an average. Laplante said the moderate category should have a higher price than its comparator, but not the highest.

A discussion ensued about the quality of evidence the PMPRB looks at when assigning a Category 2 designation compared to those of the CDR and Health Canada. There was some disagreement as to whether the Board's review process should emulate more

closely either of these models. One person said there should be consistency, at least, between the HDAP, the provinces, and the CDR.

Someone asked another participant about the new categories: specifically, if you carve up the present Category 3 into two different categories, how does this help? You now have to differentiate between moderate and breakthrough drugs. The participant replied that, whenever possible, the introductory price would reflect the severity of the condition that the medicine is meant to treat and its relative advantages. This would improve upon the current system in which a drug that is considered a moderate improvement is given the same price as the drugs it is supposedly superior to, which makes no sense.

Another participant asked about instances when the therapeutic scenario is complicated by the use of a multitude of agents such as in combination therapies. She asked how a determination about categories would be made in such a situation. The HDAP examines these cases by comparing them to the best treatment previously available. If there is an incremental benefit, the HDAP looks at whether it is moderate, substantial, etc. It looks to see if there is a substantial life improvement.

Suppose two companies simultaneously develop two potentially breakthrough drugs for the same condition, someone said, would the manufacturer of the last drug to make its way through the reviews of the concerned agencies not be unduly penalized for what could be simply bad luck?

A PMPRB representative said yes. This is possible if the drugs came out in two consecutive reporting periods. The first drug would have its price set using the International Price Comparison (IPC) test, whereas the second drug's price could be set using the Therapeutic Class Comparison (TCC) test, resulting in a lower price.

Group 3—Blue

Livingstone posed the question of whether there should be categories.

A stakeholder said he wondered why categories were needed if pricing was based on international parity. He also said he did not see the need for categories when 98% of all drugs fall into one category.

In response to this comment, another participant said the percentage quoted did not include the category of line extensions. He also said that if value-based pricing were to be used, categories would be required.

A participant asked if anyone would create sub-categories for Category 3. A participant said it would depend on the timeline of the process. If it happened early on, there would be limited data, so gross categorizations would have to be made. If the drug were to be evaluated again in two or three years, perhaps more could be given.

A participant said he was not clear on the additional value that a category would bring and perhaps that review could be put off until more information emerged.

When one drug is considered to be no better than an existing drug, it effectively has been categorized, a stakeholder said. When value-based pricing is done, the drugs are categorized as either worse, the same or better than existing medicines.

Another stakeholder said that maybe the key issue with categories is that they determine what tests could be used. He also questioned what the difference was between Category 1 and Category 3.

Within the current category system, there is no recognition of incremental improvements, a participant said. Benefits such as an improved delivery system, patients' compliance, and ease of use should be considered.

Another stakeholder said he agreed that those improvements should be recognized, but they first have to be proven with clinical data before being given a higher price.

A participant said it may not be possible to clinically prove certain benefits such as convenience, but it is something the public is willing to pay for. The lack of recognition of incremental improvements makes it difficult to justify achieving such improvements for drug manufacturers, he added.

In response, a participant said drug companies do not innovate for the Canadian market, because it's too small, but, rather, they innovate for markets in the United States, Europe, and Japan.

Referring back to the issue of categories, a participant said a fourth category could be created to separate the drugs with moderate, little or no improvements, but, at the end of the day, these categories are just being used to decide what tests to apply.

Category 2 is there to allow the manufacturers to charge a high amount for something that is innovative, and it has to be there, another participant said. However, some control is required to protect against the high cost of innovation. The rest of the categories were not as relevant, because other mechanisms could be put in place to prevent higher pricing, he added.

Another participant said he questioned whether tinkering with the categories would make a meaningful difference to the way drugs are utilized and reimbursed.

Categories 1 and 3 are there because there is a lack of faith in the health care system and a lack of faith that people will get cost-effective prescriptions from their doctors, one participant said.

A debate followed about whether or not the drug industry should be considered a free market. One stakeholder said there are things that distinguish it from a free market, and

he did not consider drugs to be a commodity. In the United States, access can be bought, which goes to show that a free market system results in the ability to negotiate, a participant said.
Livingstone then asked the group if markets should be reviewed in sub-markets. A stakeholder said that at the hospital level it should not, but when dealing with smaller groups who have little or no bargaining power, it should. The system has to help ensure that prices are not out of line for people who do not have insurance and for pharmacies that are not well established, he added.

A participant suggested setting a maximum allowable price in any market but having a system that does not penalize companies if they lower the price. At the moment, there are disincentives to lower prices.

Another stakeholder said he did not think it was fair that people with the least bargaining power pay the most for drugs. If drugs are considered to be like other products, that would be fine, but he said he did not consider drugs to be a commodity.

In response, another participant said that is the way the market works and questioned why the onus is on the drug companies. He suggested that a reasonable price be set and the provinces then decide which patients get access.

A participant said there are conditions of the market such as not charging the most to the least powerful people. He suggested establishing sub-markets that include individual pharmacies or chains of fewer than five stores and giving them a price that is within two standard deviations of the non-excessive price.

Another stakeholder wondered if that could be done more effectively at the coverage level rather than at the market level and added that he did not see why it was the Board's responsibility.

The group then discussed the pros and cons of applying Quebec's system and *Bill 130* to other provinces and the federal level.

A participant said the PMPRB is there to provide limits so that prices are not excessive, and people should not try to bend its mandate because of political will.

Group 4—Red

Arpaia welcomed participants back and asked whether prices should be reviewed in sub-markets of the Canadian market.

They should, a participant stated, because different markets have different dynamics. He suggested that the market be defined according to the categories reported to the Board: pharmacies, hospitals, wholesale, and other.

Another participant proposed a separate market for medications priced over $5000 per year, which would be reviewed based on different criteria including ethical considerations. “I think it’s needed, and I think the time is right, in 2006, for PMPRB to look at this,” she said. It was noted that drugs over $5000 per year would include expensive drugs for rare disorders and catastrophic coverage, which the provinces are currently struggling with.

One participant suggested assessing a market by examining alternative substitutes, in cases where a company may be abusing its dominant market power. Alternatives to a product might include other drugs, hands-on care, or surgery. Another participant questioned whether this actually constituted a market.

Another participant suggested that markets are geographic, organized by province. Atlantic Canada in particular does not have the same buying power as larger provinces due to volume buying.

Regarding the first definition of dividing the market into pharmacies, hospitals, wholesale, and other, a participant noted that the PMPRB issued guidance in 2005. The guidance stated that the Board does not have the intention of preventing consumers from getting better deals through hospital discounts. In practice, however, hospital discounts bring down the average transaction price (ATP) for a drug, which, in turn, brings down the PMPRB-established MNE. Although hospital buying groups are vast and can thus demand low prices, “there’s a real disincentive to offer discounts to customers” and a disincentive to innovate. Hospitals should not be included in the average market.

A participant said the issue around a separate market for drugs over $5000 per year is, “How do we pay for it, how do we sustain paying for it, and how do we make it equitable across Canada?” Incremental price increases for drugs that cost $0.35 per pill are less of a concern than those that cost $50,000 per year. For those more expensive drugs, the PMPRB should scrutinize the value of incremental change more closely. The participant expressed some concern at breaking down the market into too many sub-categories, as it would dramatically increase the Board’s workload.

Another participant noted that $5000 is an arbitrary number, since in many working neighbourhoods even $500 per year is unaffordable.

Regarding geographic markets, one participant observed that catastrophic drug needs in one jurisdiction are completely different from in another. It is crucial to consider jurisdiction when considering price, especially for biologics. Ontario’s *Bill 102* makes things “very scary,” another participant agreed, since, as the biggest purchaser in Canada, Ontario’s buying power is disproportionate to the other provinces. If the PMPRB examines the Canadian market with Ontario as its benchmark, regions like the Atlantic provinces will suffer the results.

“Why should the actions of the Ontario government decrease my consumer protection in the Atlantic provinces?” a participant asked. Another explained that the MNE is not a

ceiling, but an average: "The reason you pay $5 in Atlantic Canada is because it's $3 elsewhere." Several participants agreed that the PMPRB should establish a ceiling price across the country, above which no Canadian consumer should pay. "It's a matter of equity," a participant declared.
Support was expressed for eliminating hospitals from calculations of the ATP.

One participant asked why the PMPRB cannot simply establish a single price across the country, saying that it is "ludicrous" to have different prices in different provinces. "We have this lovely motherhood system of health care running in collision with a big corporate monster," he said.

Others observed that drug discovery is a business and that a free market for drugs is simply how Canada's health care system has evolved. Establishing a universal price would be possible, but very difficult, and would increase hospital budgets dramatically, since the free market makes bundling and volume discounts possible.

Arpaia asked participants to discuss which market would work best in Canada.

They suggested simplifying the system by establishing a ceiling cost across Canada. Rather than regulating markets, the PMPRB simply could ensure that any given transaction cost is below the excessive price. This would reduce geographic inequities. It would ensure that "no one becomes the offsetter" whereby low prices in one region are made affordable by high prices in another, since individuals even in remote areas would not pay above the ceiling price. Furthermore, the ceiling would provide predictability, as prices would never be above the MNE. It was noted that a distinction still should be made between hospitals and pharmacies due to their different market dynamics and that price adjustments should be allowed for hospitals.

Arpaia then directed participants to discuss whether categories should exist and, if so, what they should be.

Several participants agreed that the categories exist for the simple and pragmatic reason that it would be impossible to determine a non-excessive price without them. Benchmarks and clear rules are critical for determining value. Without the categories, "every new drug would be a new negotiation," a participant observed.

Participants recommended that Category 3 (moderate or little to no improvement) be separated into two categories, as moderate improvement is an important step forward. Furthermore, drugs over $5000 per year should be established as an overall sub-category; any drug from any of the four categories costing over $5000 per year would therefore be subject to a separate discussion.

In closing, a participant observed that the subject of euthanasia had been "skirted around" and that public discussion on the subject eventually would be needed.

Group 5—All Colours

Andrews asked participants to discuss suggestions from stakeholders regarding the three categories of drugs defined within the Board's mandate. He invited them to comment on whether the categories were helpful, why or why not, and what changes or omissions they would recommend. He also asked them to consider whether there should be a review based on national averages or if there should be market segmenting.

A participant said the Board's *Discussion Guide* research on market category, customer class, and geographic areas was new and very helpful. Some outliers may be very significant, so they should not be omitted. They might become more important in the future, because certain customer classes may be related to geographic areas, especially in light of Ontario's *Bill 102*, which puts new pressures on manufacturers.

Another participant said she would like to see submitted data expressed in terms of hard numbers, so it would be possible to determine if outliers are a real issue or if there are only a few drugs skewing the data. The Board already collects all the necessary data, so review should be on a case-by-case basis.

Another participant supported maintaining or lightening current triggers for review, noting that the Board has the ability to review based on complaints from stakeholders, provinces, and payers. This allows them to ask for additional insight into the regularly submitted semi-annual reports.

All participants supported continuing regular reporting for each DIN every six months.

Data is not always reflective of actual consumer price, because it reflects the price to wholesalers and their markup is not reported, it was noted.

In light of *Bill 102*, which will "change the landscape," several participants stressed the importance of differentiating between consumer class and individual/ private/ provincial payer distinctions and closely monitoring the necessity for market segmenting.

Group members noted that the actual MNE for each DIN is considered strictly confidential, so it is not available to any segment of consumers unless something has already triggered a review. This raised concerns among most participants that many consumers may be unaware they are paying excessive prices. A PMPRB representative noted that pricing information is protected under the confidentiality provisions of the *Patent Act* unless the patentee approves the release of the information. Changing that would require an amendment to the *Patent Act*.

Participants also noted a gap in the system, because there is no mechanism to review drugs that are no longer protected under patent.

Continued monitoring at the current levels is not sufficient, a participant said. Increased vigilance is necessary, particularly in light of changes wrought by *Bill 102*. It is also

important to review prices in sub-markets, to effect fairness—particularly for those consumers in vulnerable situations. It is insufficient to determine that national averages fall below the MNE. Analysis needs to go deeper than that to ensure the important principles of accessibility and affordability.

Some participants said that current monitoring of the semi-annual reports is close enough that it tends to catch sub-market anomalies, even if the national average is still within the MNE. Given this, other participants said, there should be no resistance to formalizing those closer examinations so that they continue to take place.

It is unclear whether the Board has the authority to require provinces and other payers to reveal rebates and discounts, so the ATP could be accurate. A legal opinion has been sought by the Board on this issue.

There is already real price differentiation in Canada, a participant said, because Quebec has not approved drug price increases for several years.

Discussion turned to the subject of the current category distinctions. All but one participant supported the maintenance of a category system, although there were calls for better definitions. Categories are useful, because they provide benchmarks and comparators.

The sole dissenter argued that categories are unnecessary, particularly within the Board's price-setting purview. Murkiness and difficulties in defining drugs within categories make the price approval process time-consuming and expensive. The process should be further streamlined, not additionally burdened with more complex category definitions.

Participants agreed that all three categories would benefit from clearer definitions. These would help deal with practical questions such as how to deal with new delivery mechanisms that significantly decrease side effects or changes that reduce clinical sequelae.

A participant explained how the price approval process works in practicality. A manufacturer approaches the Board with a suggested price, relevant comparators, and clinical data. Sometimes the product already has been launched before its manufacturer comes to the Board. However, once a patent is issued, the manufacturer must present clinical and sales data to the Board within 60 days. At that point a PMPRB representative said the introductory price is reviewed. If an investigation is launched, the company may either submit a voluntary compliance undertaking, or the Board may hold a formal hearing.

Some participants pointed out that, in practice, this allows companies to sell new drugs above the MNE for fairly protracted periods of time, prior to, then during the review process. During this time, consumers are not protected.

A participant said the term "innovative products" is not useful, because a product can be innovative without good clinical outcomes. It is important that the system be capable of dealing with those subtleties.

The market will determine those important issues, another group member said. "If a drug doesn't work, people will vote with their feet."

Others disagreed. They noted that drug "marketing machinery" often convinces physicians that a drug is useful before it has been clinically proven or despite clinical evidence to the contrary.

The participant supporting the removal of all categories clarified that she still supported benchmarks, but she said there should be only one test, or benchmark, applied to all drugs.

Participants discussed recommended changes to the existing categories, as follows:

- Categories 1 and 3 should contain provisions to recognize improvement or changes that may come to light over time, so they can be rewarded in the price tests.
- Category 3 should be more clearly defined. Right now, it is essentially everything that does not fall into categories 1 or 2.
- Category 3 is too broad to accommodate incremental benefits and to acknowledge the significant distinction between drugs with little and no effect. Therefore, an additional category or sub-category should be added that distinguishes between drugs with no effect and those with moderate effect.
- A clear definition of "moderate" is required.
- More sophisticated tools, many of which are already available through work being done by other stakeholders, should be used to assess drugs. For example, in oncology, it is possible to measure clinical outcomes, but it is more complex to assign acceptable price values to those outcomes.
- All the definitions need to be more outcome-oriented.

The biggest challenge, all agreed, is in dealing with subtleties and complexities that arise as the result of changing clinical data, legislative requirements, and market conditions. The whole process should be viewed as a continuum, and efforts should be made to take advantage of a wealth of already available data, rather than "reinventing the wheel."

Plenary Session: Report Back

Livingstone presented Group 3's (Blue) discussion regarding the PMPRB's three categories. "There was grudging admission that there could be arguments on both sides," he said. However, since so many other comparators are being used, the group wondered whether categories bring extra value to drug pricing.

Discussion took place about whether the current categories contain sufficient recognition of incremental gains or improved drug delivery systems. "The group felt a drug was

either a breakthrough drug or not," Livingstone said. Participants suggested that if categories are to be used, there must be some scientifically proven benefit to new medicines before they may be assigned to a category. "Then you can add more categories if necessary."

Some participants felt that categories were tainted or biased but admitted that more categories would help the pharmaceutical industry. It was felt that the Board tends to focus on Category 2 medicines. However, value-based pricing does rely on the existence of categories.

The group suggested that Category 3 be divided into two more but expressed concerns that tinkering with the system would adversely affect drug prices. It was suggested that third-party payers have their own categories as well.

Some participants expressed support for sub-markets, saying that "hospitals and other large groups can fend for themselves." Others, however, advocated setting the maximum allowable price and leaving the rest to market forces, so long as prices were kept below the ceiling price. There was concern that with a fragmented market, staying fair to each market would be a challenge.

Arpaia, who facilitated the discussion for Group 4 (Red), reported that his group had had a "wonderful discussion of markets and sub-markets." Sub-markets are necessary, but it was felt that the needs of pharmacies, hospitals, and wholesalers could unduly drive decision making. Challenges arise around keeping equitable accessibility to medications across the country, participants said. As a result of *Bill 102*, large geographic discrepancies could occur, which raise the issue of consumer protection. It is important to create drug prices that are fair and equitable for everyone, the group said.

"Some Group 4 participants raised the idea that Canada's health system is in competition with the corporate drug business," said Arpaia. This led to a discussion of what health care really is and the need for drugs as part of the health care continuum. "We came up with a typically Canadian compromise," he said. The group proposed a national price ceiling for hospitals, pharmacies, retailers, and other markets, eliminating sub-markets and moving in a slightly different direction. There should be rebate-based, volume-based discounts for hospitals, which should be de-linked from the current market.

The discussion of the PMPRB's drug categories spilled over from the group's discussion of markets, said Arpaia. There was concern that the policy's rationale is not stated. "All drugs are not created equal," participants said. The group suggested there should be four categories: line extensions, breakthrough drugs, drugs that offer moderate improvement, and drugs that offer little to no improvement to existing medicines. Under each category, there should be some recognition of drugs costing more than $5000 per year, since a need for these drugs does exist.

Andrews presented a summary of Group 5's (All Colours) discussion about markets, which was informed by the knowledge that part of the *Patent Act* requires that

manufacturers report data. The Board can look at this data and should act on a case-by-case basis, participants said. "Although things are working nicely now, with Ontario's *Bill 102* coming up, there must be more focus on this as the market changes," Andrews said. "To date, there have been no indications of abuse of the process, but this could become an issue, and the Board needs to be vigilant."

Some participants stated that categories provide benchmarks but should be better defined. Category 1 should recognize improvements in medications, and "moderate" should not be lumped in with "little or no improvement" in Category 3. In addition, more sophisticated outcome determination was called for.

One solution could be a continuum of outcomes, such as an algorithm, which would provide another perspective on the categories. Other participants suggested there should be no categories, or only one: "The price is either excessive or not. With one test, one benchmark, and one definition, there would be better timeliness, and less complexity."

Laplante summarized Group 2's (Yellow) discussion and the general consensus that there should be no sub-markets. "All Canadians are equal, and a ceiling is a ceiling," she said. The Board should look at a maximum price with no regional distinctions. "The averaging process is not the most appropriate to determine excessive pricing," some participants said. The group also discussed whether the countries currently used as comparators are really the most appropriate.

Group 2 said categories are needed, and a fourth category should be added to reflect moderate improvement over existing drugs. However, there should be stricter price controls on drugs that offer little or no improvement. "Moderate" and "little to no improvement" drugs should not have the same ceiling price.

Within Category 2, there should be harmonization and consistency in the definition of breakthrough drugs. However, the group felt that integrating and differentiating breakthrough drugs from those that offer moderate improvement will create another grey area. Category 1 medications should have a condition or exception differentiating them from Category 3 drugs. "It should be clear that a drug can't go anywhere else," group members felt.

Desroches reported that Group 1 (Green) had raised a number of general concerns and observations about categories. Participants noted that health outcomes are not considered and that the Board makes no distinction between health-related and lifestyle drugs. Some participants wondered whether these concerns are part of the PMPRB's mandate.

Group consensus was that categories are necessary to determine how a drug fits into the cascade of available drugs. Prices should reflect the R&D that goes into producing medications. There should be different strategies for different types of drugs, but overall, the process should be flexible.

Category 1 protects against artificial price increases and maintains market stability, while Category 2 encourages innovation and meets unmet health needs. However, these categories can be too restrictive in some cases and too easy in others. Defining and pricing breakthrough drugs can be a challenge. Category 3 is not needed or contains elements that should be in Category 1 or Category 2. The question of a separate category for drugs that treat orphan diseases was also raised.

Ontario's *Bill 102* likely will distort the market, leading to increased dispensing fees and other markups. While in the past, the market would correct this over time, this may no longer be the case.

Presentation 3: Re-benching of an Introductory Price

In response to Desroches' request for comments from the plenary group, a participant asked for a definition of the term "benchmark price." This is the price established by Board staff for the period in which a given drug is first sold in Canada. If the price is less than the MNE price, this is known as the benchmark price; if the price is higher than the MNE price, then it must come down to that level. After this, the Board applies CPI methodology to determine future price changes.

Barb Ouellet presented a summary on re-benching. This breakout session considered the following 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?

There are two circumstances in which an introductory price may be re-benched. Sometimes a drug is sold in Canada but has not yet been authorized for sale. This can occur on a case-by-case basis as requested by a physician, and the compassionate price originally applied may no longer be appropriate. In this case, it may make sense to look at the market price.

The second instance occurs when a drug is only sold in a few comparator countries. The Canadian price cannot be the highest in the world, and the median world price can shift according to the number of countries in which the drug is sold. In this case, a drug can be given a benchmark price, which will be re-calculated after three years.

There are other reasons why the Board, as part of the continuum of entities in the pharmaceutical environment, should think about re-benching. The introductory price assessment for patented drugs is based on approval for use at time of review but could acquire other uses. For example, a drug may be given market approval for treatment of a rare disease, and, as science develops, the same drug can be found to treat other, more common diseases. It is not necessary that the drug initially be used for something rare, however. If clinical practice determines that a drug does receive subsequent Notices of

Compliance (NOCs), it may make sense to assign different comparator drugs with different price levels.

Health Canada recently released its Blueprint for Renewal. One objective is to develop a regulatory approach that recognizes a drug's life cycle. Within that context, there may be consideration for progressive licensing for drugs.

Re-benching could have a number of impacts. For instance, if a drug is first sold at a compassionate price and then re-benched, the price will probably rise. If the drug is only sold in a few countries but that then changes, the price could go either way. If the first indication for a drug that treats a rare disease, a higher price might be assigned to reflect the R&D involved, so re-benching might ultimately reduce the price. Changes in a drug's predominant use may cause the price to rise or fall. If prices are not adjusted based on changing real-world use, they can become artificial and unduly disruptive of market dynamics.

Re-benching would not hold prices to a small sub-set of comparators. It could also encourage compassionate pre-market pricing, since there would be an opportunity to reset the price once the drug was released. On the other hand, re-benching could introduce greater unpredictability to the market. If prices drift upward, certain drugs could be de-listed on provincial formularies. It is uncertain how re-benching prices might affect patentees.

Breakout Session 3: Discussion of Re-benching

Group 1—Green

Desroches asked the group to address both sides of re-benching the price of a patented medicine after it already has been on the market.

On the negative side, participants noted that re-benching would add further layers of complexity to the already complex pricing regulatory regime.

Several participants agreed with the current allowance for re-benching, although they were uncertain about how to expand on that process. "Expanding past what's currently allowed is redundant," one of them said. "Market forces will take care of that." For example, if a drug was released initially to treat a rare condition but then found to be effective for a more common disease (thus expanding its market-share), market forces would serve to keep prices in check.

"We should avoid benchmarking so that there's only one indication per DIN," a participant suggested. "Third-party payers might pay for one DIN but not another." For example, a drug that might be used initially to treat obesity would not be approved for that purpose by third-party payers; however, the same drug would more likely be approved to treat diabetes.

"Re-benching might discourage manufacturers from filing applications for new indications on an NOC for new innovations," a participant said. Others agreed that this could translate into payers not reimbursing consumers for new and innovative medicines. "How does this work with the idea of having two or more DINs?" a participant asked. "This leaves the system open to huge abuse."

A group member noted that, several years ago, one pharmaceutical company marketed a medication as a laxative under one DIN. At the same time, the company marketed the same medicine for another purpose, under another name and a different DIN.

The group asked for clarification of the NOC. "When a pharmaceutical releases a new generic product, it must prove that the new product is comparable to the equivalent name brand," a participant said.

A benefit of re-benching is that it opens more options and offers a chance to review the Board's original decision through a new lens. "Unbendable rules are wrong," one participant said. "I am in favour of anything that provides flexibility."

Another participant raised the issue of generic drug pricing, strongly emphasizing that generic drugs should be priced significantly lower than brand name medicines, to facilitate access by all patients. While this was not part of the mandate of the meeting, the participant said it should fall under the PMPRB's consumer protection role.

It was generally agreed that a re-benching process is important to accommodate for changing circumstances. "Nothing is static," a participant said. "Re-benching allows for the application of reason."

Re-benching is appropriate in a variety of circumstances and could be initiated by manufacturers when changes are justified by new conditions. Consumer groups could also initiate re-benching if they feel drug prices are too high. "I would like to think the process is accessible to interested parties, and anyone can make a case for re-benching," a participant said. Initiation of re-benching would depend upon building a compelling argument and need not necessarily be time-limited.

Some participants agreed with the current allowance for re-benching, but one suggested that not all cases require a full PMPRB review.

Compelling evidence for re-benching could include factors such as lack of access, a participant said. In this case, consumer advocacy groups could act in response to higher-than-expected prices. "Everyone is entitled to a profit, but if a commodity is priced too high, would the Board look at this?" she asked. Other group members suggested that it would depend upon the definition of "too high."

A participant pointed out that this approach might lead to unacceptable instability for pharmaceutical manufacturers. “You think you’ve got a price, but you can’t predict where it would go,” he said.

If a medication currently in use for one purpose were discovered to have a second use as a breakthrough medication, the manufacturer might be able to make a compelling argument for re-benching. However, the definition of “breakthrough” would need to be established. An application on these grounds would require clinical evidence with supporting documentation.

“Re-benching would enable drugs to better align with their value to consumers,” a participant said. However, it was agreed that “value” is open to interpretation, and value may vary along a drug’s life cycle.

Group 2—Yellow

Laplante referred to the four questions regarding re-benching:

- Should an introductory price ever be re-benched? If so, when?
- What evidence would be needed to support re-benching?
- Should the PMPRB adopt a progressive/renewable MNE?

A participant mentioned that sometimes the HDAP gives a provisional category ranking, and if that happens to change and it becomes a breakthrough later, it should be re-benched. Currently there is no process for that.

Another concurred, saying that the MNE should be conditional, because the value of a given drug is not always known at the outset. Over several years, there may be long-term toxicities associated with the drug, which might provoke a re-evaluation of its value. One may upgrade or downgrade its designation based on use.

Someone else added that, from a consumer advocacy perspective, what really matters is what happens post-market. HIV/AIDS drugs come to the market so fast that follow-up is crucial for determining their clinical and market value.

A discussion ensued about the pricing and categorizing ramifications of off-label use, that is, a drug being used for an indication not anticipated by the HDAP and the PMPRB. The comment was made that the situation could arise where a drug manufacturer is being told to set a price that corresponds to post-market, off-label use, but Ontario’s Drug System Secretariat requires that same manufacturer not to endorse off-label uses for that same drug. It would seem contradictory for the company to have to pay that higher price.

A related comment was made that if a drug is used for an indication for which the comparators are much lower priced, the price of the off-label drug would skew the ATP upwards. However, if the price is adjusted downwards, the question becomes whether the manufacturer would continue to make it available in the same quantity.

This comment drew an objection from another participant that this should not be a consideration in price reviews. This is another issue that reflects how the facility for compulsory licensing has been gutted. Our price system should be driven by the principles laid out in the Act. If it gets to the point where the patentees are not providing an adequate quantity, that is a separate issue.

Laplante summarized by saying "yes to re-benching, but it has to be carefully considered."

A participant wanted to go back to challenge the concept of re-benching. She questioned whether this is not something that should be left to the market. She could not think of a single comparator country that re-benches based on a new indication. She said, "A product has seven years on the market, and now it's being re-benched? It should be left to the market to redefine the value."

More questions arose around pricing structures for products with multiple uses and whether or not a manufacturer might be penalized if the PMPRB guessed wrong as to how the drug would be used post-market. Laplante said these were the kinds of scenarios well served by re-benching, as the cost of a drug will "either go up or down." This prompted the response, "We all know which way it's going"—the implication being that it is always up.

To resolve these issues, another participant proposed an appeal format for re-benching; unless a manufacturer or a customer appeals the price, it stays put. There seems to be a preference for this model.

A couple of participants were concerned that adopting an appeals format would unduly favour manufacturers, but the response came that, unless the environment has changed in some demonstrable way, the price would stay the same. It was pointed out that this resembles the current provision for a CPI price increase: it is there for the companies to take, but they have to apply for it. In instances where the post-market use seems to differ from what the PMPRB supposed it would be, the HDAP could be asked to weigh in on whether the dominant use is still the same. In summing up, the participant who suggested the appeal structure said this model would allow the Board to take a less proactive stance, to "ignore all the noise and focus on the signal."

Laplante wondered if the group would be in favour of progressive licensing or life cycle reviews. The reply was that, based on the foregoing discussion, the answer was no, since the group had been contemplating an ad hoc, rather than a systematic, review process. Some said it would seem to add an unnecessary level of regulation.

The discussion moved to the issue of conditional licensing in cases where drugs may be urgently needed—as is the case with HIV/AIDS—but are later found to have toxicities that warrant a review. Some believed this is an instance where the market would take care of itself, because if a drug is that detrimental to one's health it will be squeezed off the shelves.

A participant commented on how much the *Patent Act* has changed the environment and that perhaps market forces have overtaken the PMPRB's role. Another suggested that its role needs to be updated. For instance, if there are many more NOCs, maybe the PMPRB comes into play earlier in the process as the product moves to market. One participant asked why one would want to move to a system where there is a two-year wait for a price review.

Another participant added that more time should be spent looking at efficiency and alignment—how to get products to patients quickly. There has not been enough discussion about how re-benching aligns with the new procedures now in place. This was echoed by another speaker, who pointed out that this is a real concern for consumers already facing unacceptably long delays between the CDR and the NOC.

Finally, a participant referred to the question about what criteria should be used for re-benching. To him, it was obvious that it would be the same as the original review. There was general agreement on this point, since the idea was that an appeal would be made only on the basis of a change in the environment. Introducing a new set of questions for a review would only complicate the picture.

Group 3—Blue

Livingstone asked the group if re-benching should be used.

A stakeholder said re-benching should occur in situations where an indication has been significantly broadened or changed. An example would be when a niche drug breaks through to the mainstream, such as prostate drugs that are also effective for male baldness.

Another participant questioned how the price would be determined if a drug has another indication but for a much narrower group than the original indication. A stakeholder responded that if the drug gets another indication for a narrower group, the company should not get more money, because it would not cost as much to produce. The companies have to accept that.

One participant said that in cases where a drug has more than one indication, the prescription would have to distinguish what the drug is being prescribed for.

If it's a matter of a different dosage or there is some other way to delineate the two indications, then it effectively becomes a new drug, and the company makes a new submission, another participant said.

The company could resubmit the drug if it finds the product has more benefits than originally thought, but the payers could ask for re-benching if the drug actually has less value, a stakeholder said.

Another participant added that the payer has the ultimate power and could de-list the company or the drug. But that scenario would depend on how many patients were on that drug, another stakeholder added.

If a company cannot justify the price of a drug any longer, that would warrant re-benching, a participant said, adding that there should be a mechanism so that the re-benching price is lowered but the maximum price can still be maintained.

Another participant suggested that the companies give free products to hospitals and other payers to effectively lower the price instead of writing a cheque to pay back the excess amount. He added that this would solve the problem of unpredictability for the drug manufacturers. If a company is told it can launch a drug at a certain price but there is a chance it will change in a few years, the company will not want to launch in Canada, he said.

Another participant questioned how this could be done across the country, because different provinces have different markets in terms of how many people are insured publicly.

For re-benching to result in a price increase is rare, a stakeholder said. He added that a company could launch a drug at a higher price, but in a few years, it would have to prove that it is worth it, and if it cannot, it would have to pay back the excess.

The onus should be on the company to produce data within a certain amount of time, and if the data shows moderate improvements, the price should go up, a participant said. The group expressed agreement on that point.

A participant suggested re-benching a Special Access Program (SAP) drug when it goes to the NOC stage.

A participant asked the group how often a brand product goes up in the United States.

In response, another participant said price increases are usually kept to single digits but increased more than once such as two increases of 8%.

The group discussed what other countries have done in terms of re-benching. A participant said that Germany went through a major shift of re-benching and de-listing and sent patients back to older medicines, which caused some political problems. Australia does not re-bench, while New Zealand and Japan do, the participants added.

The international price should continue to be a comparator during the time the drug is on patent, a participant said. In response, another participant pointed out that re-benching would occur far too often if that were the case.

Livingstone said that in a previous meeting a participant suggested that a company stick with the first price for the life of a drug. He asked the group for its opinions on that comment.

A participant said that is more or less the existing system.

Another participant said that price changes in other countries do not necessarily change the value of the drug in Canada.

Companies do not price drugs at the cost of development; they price at what they think the market will pay, a participant said, adding that drug companies want to maximize their profits over the limited time they have in the market.

A participant said two cons for re-benching include unpredictability and complications within the price regime. She added that re-benching should not become part and parcel of the entire process but should be used only as a last resort.

A discussion followed around the circumstances in which re-benching would be used. A participant said re-benching only makes sense for broadening indications and pre-NOC.

Another participant said if that were the case, then Category 3 would have to be broad, because when a drug is first launched, it is difficult to determine if it has moderate, little or no improvements.

A participant wondered if it was possible to reduce the manufacturer's price without lowering the list price. Another stakeholder suggested that be done on an exceptional basis only. There are not many niche market drugs that also can benefit wider markets later on, added another participant.

In closing, Livingstone thanked the stakeholders for their time and feedback. He said that although the participants represented many different interests they were able to have positive and constructive discussions with one another.

Group 4—Red

Arpaia asked participants whether an introductory price should ever be re-benched. If yes, why, and what evidence would be needed?

A participant suggested that a company might discover several different indications for a product through clinical trials and might select the indication that brings the highest ceiling price. The ceiling price would thus be artificially high and excessive for the other indications. Another argued that if said product were re-benched, the company simply would re-launch it under a different name (since off-label use cannot legally be marketed).

A participant stated that re-benching should occur, since price regulation that does not account for market realities is causing market disruption. Product rules are 17 years old, and market conditions, dynamics, and technology have changed significantly since the guidelines were established. Currently there are only two instances in which re-benching is allowed. Greater flexibility would give the Board the ability to accommodate change, such as shifting government policy, or changes in drug development due to climate change.

Asked whether re-benching would ever raise the price of a drug, one participant postulated that it could occur if the first benchmark and price were for a common condition, and new trials revealed a new, much more rare indication. The trials and process required to obtain approval for the new indication would represent significant additional costs. However, one participant expressed remaining conflict regarding the idea of an increased price, since "you're still talking about the same pill."

Several participants agreed that the process of obtaining approvals is quite expensive. Meanwhile, issues would arise regarding reimbursement and the fact that the drug was listed based on the original price. Pills could be offered at a more expensive rate and under a different trade name to those using them for the newly established indication. However, most places would simply use the cheaper product, and some would abuse the rules by listing at one price and selling at another.

Discussions of excessive price often strayed onto the subject of affordability and access, a participant said, when the focus ought to be on the ceiling price. Once a ceiling price has been established, fluctuations below that line do not matter. Participants suggested that it is unnecessary to re-bench products that never reach their ceiling price, as only 18% of products are actually sold at their MNE. It was noted that companies go out of their way to establish prices below the ceiling to allow future flexibility.

Prolonged discussion ensued as to whether de facto re-benching occurs when hospital discounts reduce the average transaction price of a drug. If the ATP of a drug is lower than the MNE over several years, based on national sales including hospital pricing, the PMPRB will hold the company to the new, lower price, a participant explained. The CPI is applied to the ATP; otherwise, the price cannot be raised and effectively has been re-benched down.

Products must be re-benched if their original benchmark included an SAP price, a participant asserted. "Hardly anyone charges for that, and if so, it's nominal—it's not fair," she said.

Another participant suggested Celebrex as an example of a product that sold far beyond the company's expectations. "It's an indication of how poorly people with arthritis were being served," he observed—but is the unanticipated mandate a rebalancing of the original price?

A participant asked why 82% of products are not sold at their ceiling price. Suggestions included the pressure of competition, a desire for flexibility, and reducing price to gain access to the formulary. Products also are never launched at the hospital price, meaning that any purchasing group will lower the ATP.

Another participant asked whether prices should be re-benched if, after several years of an artificially lowered ATP, a company loses a hospital contract and wants to raise its prices. Participants agreed that there is no current rule to allow this, though the Board may take such circumstances into account. A PMPRB representative observed that several stakeholders have suggested that hospitals be removed from calculations of the ATP for this reason. One participant said that companies are not forced into entering contracts with hospitals and should foresee the impact of bidding so low.

It was noted that companies often practically give their products away to hospitals in the hopes that patients will stay on the drug after discharge or, in the case of drugs that go to hospitals before retail, as a means of generating patient pressure. Hospitals also can agree to use a single product such as one specific beta blocker—although when British Colombia tried, they "got slaughtered; everyone and their dog came out against it."

Participants expressed additional confusion as to whether products are effectively re-benched down after every reporting period if the ATP is lower than the ceiling price—and if so, whether benchmarks are necessary. Such de facto re-benching creates a "real disincentive" for hospital discounts, said one of them.

Another participant noted that while he had assumed that the Board establishes a price, prices can in fact be set up to 30 days after a product is sold. If a drug's price on the market is found to have been excessive, the extra money is redistributed to the provinces and health funds under Section 103 of the *Patent Act*.

One participant noted that collective global prices rarely, if ever, decrease in practice. Another argued that while the prices on public formularies may not decrease, average transaction prices are nevertheless forced down.

Most participants agreed that re-benching should occur, both up and down. Appropriate circumstances might include when the ATP is consistently below the MNE or when a drug has gained an expanded indication that significantly expands its market size. Re-benching also is appropriate if hospitals are removed from calculations and are given their own separate market and review process. One participant warned that de-linking hospitals would result in higher prices for consumers.

Other circumstances that warrant re-benching might include new delivery mechanisms or policy-mandated changes such as dose counters for inhalers, which are very useful and soon to be mandatory but are expensive to install.

Participants also suggested re-benching in the event that a breakthrough drug is offered at a reduced price before all evidence is available and, in effect, "put your money where

your mouth is." Such agreements could be particularly useful in the case of biologics. Unless companies can re-bench once the full evidence is available, however, there is little incentive to enter such agreements.

Arpaia asked participants what information or rationale would be needed to trigger a re-benching. One participant asked who would be required to supply the evidence.

A PMPRB representative explained that the question at hand was whether re-benching should be automatic, upon request or whether evidence would be needed. For example, would every drug sold under the SAP have the option of having its price reviewed, or would there have to be rationale that the SAP price is inappropriate?

A participant suggested that the SAP is a risk-free means of introducing a drug to a market. Another disagreed, noting the extreme difficulty of obtaining SAP approval. As reported by numerous *Globe and Mail* cover stories, many good products are not released through the SAP due to the stringency of Health Canada policies.

The PMPRB representative confirmed that the MNE of drugs is indeed revisited when average transaction prices drop such as due to hospital discounts. If a company does not accept the CPI, the new ATP is the new benchmark price. Prices are reviewed in a three-year cycle, and the CPI can be accepted retroactively within that time. The first year is therefore the only year in which the ceiling price applies. That having been said, Board staff understand circumstances such as losing hospital contracts or the strong Canadian dollar and take them into account when applying the tests.

Group 5—All Colours

Andrews invited participants to discuss the pros and cons of re-benching, whether it should occur at all and, if so, when and according to what criteria.

Most participants supported re-benching in particular circumstances. Two, however, said there should be no re-benching save for the two existing criteria.

One group member asserted that concerns that re-benching might drive prices higher were unfounded. Once a payer has approved a price, particularly the provinces, they would not tolerate a price increase.

Other participants said that was not necessarily the case and that changing circumstances, such as the elimination of competition, could result in re-benching up. It was also noted that companies could raise drug prices, regardless of whether provincial payers were willing to pay the increases. Government payers' reluctance to approve increased prices has been due to the abuse of pricing conventions, particularly by pharmacies whose markup and dispensing fees have been high. Once the system "gets cleaned out," government players may not continue to refuse to pay justified price increases.

A participant said that re-benching was "absolutely necessary to reflect the realities of clinical experience and market realities."

Another, however, cautioned against the Board expanding its roles any further. "At some point, there needs to be acknowledgement that market forces by themselves will force that price down if the drug is going to be used."

Three other participants disagreed that that had ever, or would ever, happen. "Even when large, regional players have tried to negotiate lower prices, the reality is that it doesn't happen, because it's so hard for them to resist all the patients lined up saying they want the particular drug." The market cannot be depended on to regulate itself, so re-benching is necessary.

Rituxan was cited as an example. It was introduced for certain limited oncology indications a few years ago, but the number of indications has since expanded wildly. It has gone from serving a very small population to huge numbers, yet it remains a $26,000 drug.

A participant noted that every new drug indication has to be reviewed by the CDR. However, the price is not currently reviewed.

There was a brief discussion about the practicality of offering a drug at different prices for different indications. In general, this was dismissed as impractical, unlikely to be supported by payers, and virtually impossible to enforce at the prescribing level.

A participant said that companies often offer drugs at a high price for first indications with the intention of lowering them once additional or larger indications have come online.

Most participants supported re-benching when drug indications change over time. Two participants questioned whether the Board possessed the necessary expertise to conduct this ongoing process. Others suggested that the expert knowledge already exists in academic institutions and other bodies and stressed the importance of creating an integrated approach to re-benching.

Progressive, non-renewable price reviews were suggested at regular intervals (every five years was one suggestion). This regular process might actually help relieve some of the reluctance to raise provincial formulary prices, because both upward and downward re-benching would be seen as part of a regular process.

A participant stressed the importance of the predictability of pricing. Another countered that re-benching still would be predictable but would allow for a change in response to clinical realities.

Concerns were expressed about the Board's ability to handle re-benching with its current resource level, given the slow pace of the existing approval process. As indications get more complicated, it will become more difficult to find suitable expertise.

Another participant agreed but suggested that the solution was collaboration and integration to allow effective and efficient re-benching.

A new NOC issued to a drug already on the market should be another trigger for re-benching, said one of the group members. Most agreed that there need to be clearly defined triggers for re-benching. Some suggested that each new indication should trigger a review, while others recommended a regular, cyclical review.

A participant said that oncology examples skew the argument, because the drugs tend to be so expensive but make up only .5% of all prescribed medications. Another pointed out that they account for 10 times the amount of drug costs (5%).

New indications do not give a company extended patent protection, a participant said. Therefore, there could be situations where the Board is re-benching and the drug is coming close to the end of its chemical patent protection.

Participants suggested that criteria for re-benching could include information from private or public reimbursers, new indications approved by Health Canada, or major new clinical data. Many organizations already possess the data that could be used including disease-oriented groups, payers, and Health Canada itself. There also could be a threshold that considers the burden in terms of cost to the health system. The importance of considering factors from a systemic point of view was underscored.

One participant warned that re-benching would affect accessibility and timeliness, but several others disagreed.

Another noted that the National Pharmaceutical Strategy asked for re-benching. As various provincial and private payers are brought into the strategy, the push for re-benching will increase.

A participant said that drug companies would be less likely to provide timely and accurate information if they knew it was likely to trigger a process that would drive the price of their drug down.

Participants offered two distinct perspectives. On the one hand, some argued that re-benching might create an administrative burden that the PMPRB cannot handle. Cyclical review might affect efficiency and is not really necessary, because market forces will prevent prices from increasing and will drive prices down, when appropriate, without outside interference.

The majority of participants, on the other hand, made a case for re-benching drugs whose indications had changed on a cyclical basis. This would ensure that pricing is appropriate, given that the checks and balances of a normal marketplace do not exist in this case.

Plenary Session: Report Back

All five facilitators presented synthesized reports of the final afternoon discussions on benchmarking. Each one presented only those points that had not been raised already by other groups.

Andrews said discussion in Group 5 (All Colours) gelled into two clear perspectives.

First, once a price is established, the reality of the marketplace is that payers will not allow it to increase, so it is not helpful to increase the administrative burden already on the Board:

- The Board lacks the capacity to re-bench beyond the two existing criteria.
- There is no advantage to re-benching a drug that is nearing the end of its patent.
- Re-benching could have a negative impact on predictability.

Second, it is necessary to be able to re-bench drugs on either a cyclical or a case-by-case basis:

- Because of expanded indications extending to common disorders;
- When there is new or unexpected clinical data regarding a drug's effectiveness or other matters;
- If drugs have been released with an NOC/c.

Those who supported re-benching stressed the importance of setting criteria for which drugs should be reviewed. They recommended collecting data from existing sources such as health plans, Health Canada, or other agencies. Even though re-benching is not taking place through the PMPRB, decisions are being made at other levels, so this represents an opportunity to eliminate the duplication of reviews and tap into existing expertise.

Although manufacturers would be unlikely to support re-benching if it only ever resulted in lowered prices, cyclical review could also result in higher prices, which would encourage industry support.

Laplante reported that Group 2 (Yellow) supported re-benching in certain circumstances, most of which had already been discussed. They stressed that re-benching should not be an automatic, integrated process within the Board but should be part of an appeal or reconsideration process triggered by new environment, new data, and a change in the drug situation or the market. Re-benching must be the result of new or changed information—not just because there was dissatisfaction with the first result.

Laplante also cited a suggestion regarding the progressive licensing mechanism. This would see the pricing mechanism moved to a different place in the process with regard to

the other agency involved in overseeing various aspects of drug approval, release, and review.

Desroches said Group 1 (Green) identified the pros and cons for re-benching. Those against it cited the unnecessary burden and complexity of the process, and argued that market forces naturally move prices appropriately. They also expressed concern that re-benching could discourage industry innovation.

There was a suggestion that re-benching might help to allow only one indication per DIN so that third-party players could pay for one DIN but not necessarily another, although some were concerned about possible abuses.

Those supporting re-benching said it provides options and ensures flexibility, allowing for adaptation to changing circumstances. All agreed that any interested party should be able to present a case for re-benching provided there are compelling grounds to do so. However, there was disagreement about how to define "compelling case."

Arpaia reported that Group 4 (Red) generally agreed that evidence of new drug benefits could trigger re-benching and that government policy determining drug delivery also could be a trigger.

The importance of re-benching the actual ceiling price was discussed, noting claims that ceilings are met only 18% of the time.

Concerns were raised over the administrative complexities creating disincentives for manufacturers.

Questions were raised about

- Drugs that are released through the SAP;
- Drugs that go above the MNE;
- What happens when a drug is actually below the ceiling;
- What happens when hospitals are taken out of the mix, when significant reformulations or delivery mechanisms occur and when government policies force change.

Livingstone said supporters in Group 3 (Blue) suggested re-benching when indications significantly broaden and sustaining the price is no longer fair. Even when drugs are approved for very narrow indications, it is difficult to know how they are being prescribed.

Participants recommended developing a "compassionate" mechanism that allows less expensive access to drugs in special cases, while maintaining the list price.

There was general consensus that most re-benching would result in lower pricing. However, if a review found that higher prices were merited, there was doubt about whether payers would agree to the new prices.

It was also suggested that the international price could remain a triggering criterion for re-benching across the life of the patent in Canada.

Evaluation of Session

In a group evaluation process, participants identified two positives: many opportunities exist for the exchange of ideas, and mixed stakeholder groups allow for interesting dialogue.

They also offered suggestions for improvement:

- Provide more opportunities for wide plenary discussions.
- Include discussions on the approach to introductory prices and price tests.
- Use less jargon and fewer acronyms to make the discussions more accessible.
- Provide better access to staff and Board members who provide information.

Next Steps and Parting Message

Tim Armstrong thanked participants, staff, and facilitators for creating a vibrant and informative exchange of ideas. He invited participants to provide the Board with any additional insights or comments after the meeting.

He noted that materials from all five sessions will be available on the PMPRB Web site early in 2007. Participants would receive the record of that session within several weeks, prior to publication.

The Board is scheduled to meet on December 13 and is committed to a further stakeholder meeting in 2007 to discuss concrete suggestions arising from the 2006 deliberations.