Patented Medicine Prices Review Board (PMPRB)

Stakeholders Consultations on Excessive Price Guidelines

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Welcome and Opening Remarks

Dr. Brien Benoit, PMPRB Chairperson, said that "it is our hope that these consultations will contribute to the Board's understanding of stakeholder issues." He said the Board wanted to identify areas in the guidelines that need to change to make them more relevant. "We have not made up our minds."

Providing some history for the consultations, Benoit related that in 2005 stakeholders raised many relevant matters that fell within the purview of the Board. These were further analyzed in the 2006 *Discussion Guide on the Board's Excessive Price Guidelines*. Thoughtful comments from more than 40 stakeholders reflected the need to carry the discussion forward. These consultations will further explore the issues, and a spring 2007 meeting with key stakeholders will collate what has been said and identify desirable changes to the guidelines.

Benoit reminded participants of the key factors that must be considered in deeming a drug excessively priced: its price in the relevant market, the price of other drugs in the same therapeutic class in the relevant market, and the drug's international price. If the Board is still unable to determine excessive price, it is empowered under the *Patent Act* to consider other factors such as production and marketing costs of the drug.

While the *Patent Act* does give the Board considerable latitude in interpretation, the goal of the Excessive Price Guidelines is to provide transparent and predictable guidance. The guidelines are not binding on the Board or the patentees but serve to guide the patentee towards an appropriate drug price.

Benoit dispersed fears that each consultation is "a finger-pointing exercise," adding that they are intended to be an open and collegial forum. "We are all striving for a fair price and to best serve the Canadian public."

Presentation 1: What We Heard Report

Barbara Ouellet, the PMPRB's Executive Director, explained that the major issue triggering the review of the guidelines was not the perceived increase in drug prices but high introductory drug prices. Of the subsequent concerns raised by stakeholders, the Board chose to consult on three issues: how medicines are categorized, whether the introductory price tests are appropriate, and what the relevant market is at which to regulate prices.

Category 1 is limited to new strength or comparable new dosages of existing drugs (e.g., line extensions) and Category 2 to a new drug product that provides a breakthrough or substantial improvement over existing drugs. Category 3 includes "everything else": all other new medicines with moderate, little, or no therapeutic improvement over existing comparable ones.

The Human Drug Advisory Panel (HDAP) determines the category and which comparators and comparative dosages to use, based on publicly available literature. The panel's job is to focus on the science only, therefore, it receives no price information. Normally only new drugs are reviewed by the HDAP although the Board can refer line extensions, if necessary.

Stakeholders were divided in their opinion about the categories. Some said categories should be abandoned altogether, since the current system does not recognize incremental innovation, and suggested replacing categories with a clear definition of excessive price.

Others said the categories need a greater evidence base but should be refined and even further subdivided. Everyone had problems with Category 3; some suggested it rewards drugs with little or no improvements, while others found it did not reward innovation adequately.

The Act references "a market in Canada, any market and the relevant market" in terms of which market to look at for comparative pricing. Ouellet explained that companies must file information for each of four customer classes, for each province and territory, and for the Canadian market as a whole—52 markets for each drug.

The average Canadian transaction price that is currently used may mask price differences in different customer classes and regions. The *Discussion Guide* indicates that most prices fall close to the average with some extremes as much as 25% either way. Ouellet noted that some stakeholders were concerned that if there is negotiation below the maximum non-excessive (MNE) price, "someone else is negotiating above it."

Some stakeholders wanted to stay with the current approach, since the majority of the prices are within the guidelines and since some variation among customer class and jurisdiction is normal and acceptable. Changing the current approach would only complicate the review and may reduce company incentive to offer lower prices to some customer classes.

The need to clarify the use of rebates and discounts was identified. Currently the Board looks at net price and identifies a number of benefits to be deducted from the price. Should the Board look more closely at cases where the selling price exceeds the MNE price?

Ouellet related that other stakeholders confirmed the importance, in terms of equity, of reviewing drug prices by customer class and jurisdiction. Should some be paying different prices as a function of where they live? Should there be a separate review for each customer class? Despite these suggestions, stakeholders did not identify when or how often reviews should happen, nor what the trigger should be. Most stakeholders agreed that reviews should be done on a case-by-case basis.

One participant wondered what the actual users - the HDAP - said about the application of the system. Ouellet stated that the panel made a submission that explained its struggle

with categorization and the lack of evidence. A true breakthrough was obvious to the panel, but the difficulty lies with categories 1 and 3. A line extension (i.e., Category 1), for example, actually may offer a moderate improvement over comparable drugs because of a novel delivery mode.

Among the panel's recommendations was that line extensions offering moderate improvement be part of Category 3. The definition of "category thresholds" remains problematic.

Another delegate asked if Canada could look internationally for guidance or best practices. Ouellet agreed that all countries struggle with the drug pricing issue. She commented that European countries look at bottom line government reimbursement and negotiate for a whole set of drugs. In Canada, "we look at each drug in isolation as opposed to its value to the whole class."

Presentation 2: Principles Underlying Patented Medicine Price Regulation

Sylvie Dupont, Secretary of the Board, noted that the Board was created as an independent, quasi-judicial agency through an amendment of the *Patent Act*. The Board ensures that drug prices are not excessive. It also reports regularly to Parliament on drug prices, trends of all medicines, and research and development (R&D) expenditures as reported by industry. Dupont outlined what the Board does not do—for example, "We don't set prices."

In 1987, consumer protection was incorporated into the Act as one of five pillars. This led to the establishment of the Board with the remedial powers to influence the price of patented medicine. But how should the Board interpret "consumer protection"?

The source of the Board's authority is set out in Sections 79–103 of the Act. However, there is no explicit mention of consumer protection in the Act. How can the pricing factors set out in Section 85 be applied in practice while reflecting the government's consumer protection principle?

Although Section 85(2) allows the Board to consider production and marketing costs, it has never done so. The pricing factors can neither be given equal consideration nor be applied simultaneously; each would give a different non-excessive price outcome. Are there key principles that reflect the conservation protection mandate?

Stakeholders have put forth many principles including lowest reasonable price, value-based pricing, and international parity/consistency. Are those the right principles? No principle is likely to be paramount for all drugs all the time, stated Dupont, and she provided a series of frameworks to illustrate.

In one framework, the underlying principles may be value-based pricing, price stability/predictability, access and affordability, and Canada should pay its fair share. The objective would be that Canadian prices are primarily driven by domestic markets but should never exceed international parity. The dominant price factors applied here would be the price at which other medicines in the same therapeutic class have been sold in the relevant market and the price at which the medicines have been sold in countries other than Canada.

Dupont asked stakeholders to consider two main questions:

- Are the principles reflective of the Board's mandate, or are there others to be invoked?
- What priority groupings should be emphasized in carrying out price regulation?

Breakout Session 1: Guiding Principles

Group 1— Red

Facilitator Ron Desroches asked participants which principles are or are not relevant to the PMPRB's mandate and, among them, which are the most important.

A participant suggested that, in the absence of entirely objective technical standards, the question of whether principles should exist is rhetorical. The nature of the PMPRB's work is to make judgements in a legislative environment with the guidance of the Minister of the day, and it requires guiding principles to narrow and elaborate that intent. "I don't see how they could do what they do without principles." A participant agreed, but asked whether the principles would be necessary if the factors in the Act were more explicit.

Another participant observed that the consultations articulated how stakeholders see the Board, but not how the Board sees itself.

Several participants agreed that the term "excessive" should be further defined. The judgement of what is excessive should be informed by the costs of both making and marketing a given medicine, such as, if a drug that costs $5 million costs only $10 million to develop. It was noted that the *Patent Act* is not a *Consumer Protection Act*. While this suggests a link to the abuse of patent monopolies, "how do you get from that to consumer protection?" Lowest reasonable price may be defined as the price that allows a reasonable return on investment, as opposed to an upper limit on price.

Discussion revolved around the need for perspective-neutral principles, since individual perceptions of a medicine may depend on role or need. For example, a time-pressed lawyer might be willing to pay more for an ulcer drug that requires two weeks less than existing drugs, but another might not. Reasonable price is perspective-dependent, whereas international parity is perspective-neutral.

The policy intent of the then-Minister is understood to have focused on affordability for the consumer and for the health care system. If this is the case, the PMPRB must interpret "reasonableness" from the perspective of government, not industry or health care providers. This role should be clarified, as "the role of a regulator is very different from that of a consumer watchdog."

The PMPRB was created as but one of five pillars within the overall pharmaceutical environment. It is important that the PMPRB not affect the other elements of that environment such as by making it economically unviable to introduce certain types of products in Canada and thus deterring overall R&D goals. Consumer protection should be "nuanced." Value for money is a better principle; balance is required between promoting industry and protecting the consumer.

The Canadian courts, said one participant, have ruled that some policy instruments exist exclusively for one or two of the five pillars. That speaker specifically saw the PMPRB's role as being consumer protection. Another argued that "hard cases make bad law" and that the unique circumstances of the cases ruled upon should not be applied to the overall principles.

Group members then discussed different principles and their underlying rationale. International parity and comparisons are important principles. Value-based pricing is also important; it is the rationale for the category system and the basis on which innovation is rewarded. Value may be defined at the macro (value to the health care system) or micro (value to the individual) levels, and each may be radically different.

Participants discussed whether incremental improvements offered by a drug with low development costs would justify a high price.

If a drug plan does not see value in a particular innovation, such as a new delivery system, but an individual patient does and is willing to pay, should the Board stand in the way of that perceived value? The Board should not bother regulating prices in cases where no monopoly exists and consumers have choices. This might create an oligopoly and a drift in overall prices. Logically, then, price regulations should be extended to include generic drugs.

The group discussed the linked principles of accessibility and affordability. Weight should be placed on accessibility; a breakthrough delivery system of an existing drug should be priced at something reasonable from both the buyers' and sellers' perspectives. A participant suggested that accessibility is overemphasized, since an unknown number of patients receive drugs that are not approved for sale in Canada through the SAP or overseas.

Meanwhile, inconsistent, provincial reimbursement for SAP medicines constitutes another barrier to access. Canada's price regulations are also a key factor in many companies' "go/no go" decisions.

Group members agreed that the PMPRB should not promote accessibility, as it is not within the Board's mandate. But the PMPRB should avoid being a barrier to it. Affordability is the main concern, as dictated by contemporary fears of undue price increases. A price can be non-excessive but still unaffordable.

Participants then discussed the principle of international parity. International prices can change due to shifting exchange rates, dosing, costs of therapies, etc. From a regulatory perspective, a price with international parity one day may be the highest in the world the next. Mathematical guidelines should be flexible and take such factors into account. International parity offers a simple test for whether a price review should be initiated or not.

Simple principles for what constitutes an excessive price are needed, based on international comparisons with simple, easy to understand criteria. These criteria may include a fair individual share based on purchasing power parity.

Transparency and simplicity should be split, and simplicity should be changed to "avoid excessive or unnecessary complications," the French category system being a counter example. Meanwhile, decision making is easier in the French system due to its lack of transparency.

Transparency is highly socially desirable, and the manufacturers and consumers affected by the price review process are entitled to know the basis upon which decisions are made. However, "24/7" scrutiny can create inefficiency, prevent decisions, and result in sub-optimal outcomes. Participants agreed that processes, not data, should be transparent. It was noted that transparency is often confused with accountability.

Staff also should have flexibility regarding the application of the guidelines within defined limits. In many cases, expensive hearing processes may be avoided with a mutually acceptable compromise, which staff currently lack the authority to propose.

Participants noted that sample Framework 3, which was balanced between the national and international, best matched their consensus.

Group 2—Green

Facilitator Suzanne Laplante asked everyone to consider whether or not the PMPRB needs guiding principles at all. If so, are any missing? What degree of importance should be attached to each one?

One participant said that principles are needed. "The alternative would be a *caveat emptor* marketplace, and they don't work."

Another said that accessibility refers to affordability and not necessarily the lowest reasonable price, which may lead some companies to pull back from producing drugs.

"Accessibility means that the consumer has access to a wide variety of drugs and can afford them."

Canada is not a major market, said one group member, but the PMPRB needs to look at the global context. That participant did not want accessibility linked to affordability. Another stated that accessibility should be the overarching public objective at the macro-level policy basis.

One member of the group declared that the PMPRB's mandate was non-excessive pricing, not accessibility. Value-based pricing, using relative values, should be the main objective. "Value-based pricing is a unifying interest. From industry's perspective, you want your product to be appreciated for its value."

It is not in the PMPRB's mandate to look out for industry. However, the PMPRB serves as a surrogate for the market, and its raison d'être is to take into account the interests of both industry and the consumer. The PMPRB came into existence to protect consumers, so that should be the underlying principle. The Board should protect consumers' ability to afford and access drugs. There needs to be a balance where value-based pricing meets affordability and accessibility.

A member agreed with that underlying principle but said that for patients with cancer, affordability and accessibility are huge issues, and these have to be the main principles.

Vendors now have an extension on the life of patents. This monopoly is where they can recoup their investment.

Accessibility can be viewed from the perspective of economic welfare—the value of patents for creating manufacturing in Canada, demand curves, etc. The lowest price should be sought, but it conditions arguments about relevant markets.

There are two definitions of affordability: to society and to the point of service. The PMPRB does not control the whole puzzle.

"Simplicity and transparency are important. Otherwise, the system becomes an administrative burden, and the price increases."

A question was posed regarding the principle of Canada paying its fair share: fair share of what and on what basis?

If Canada is 2% of the world market's drug consumption, Canadians should pay 2% of the IP and R&D costs. "There are two aspects of fair share: fair share of the Canadian market and fair share of the Canadian market in the world market." If fair share is at the same level as macro-level policy, it can stay. Otherwise, it is not important.

Consistency over time, though, is important so that decision makers can act without having the ground shift under them. “It’s either a free market or it’s not,” said one participant.

“Consistency is applying the same pricing principles throughout the life of a drug,” said another.

One participant said this was the first time the guidelines had been reviewed since 1994, and that is too long. He suggested finding a balance in terms of predictability and consistency for both patients and industry.

Another member said generics had been outside the purview of the Board, and that was an aberration that needed to be addressed as soon as possible.

Another participant replied that there is no price competition. It is more a concept of fairness and a level playing field. If brand names are regulated, generics “cannot pick up the creep and charge accordingly.” There is a need to strive for something that is in keeping with the cost of production, because the fixed costs have been borne by somebody else.

The group agreed that this included all non-patented, single-source, generic medication. “If we’re going to regulate, we should regulate the whole market.”

International parity should be one of the PMPRB’s principles. One member wondered if the Board had the option not to. Another did not see it as an important goal.

It is time to look at alternative ways of determining fair price. Perhaps it is possible to use relative value scales such as those used to evaluate physicians versus other medical practitioners (e.g., radiologists).

A participant said that Canada is keeping “down” with the Jones’, because pricing in this country is based on prices already being controlled in other countries.

“I don’t see parity as an instrument; it’s a principle.”

Canada has not kept up with leading or best practices in this field.

A member noted that a principle of accountability is missing. It is important in the business world, and it goes to transparency. “If you want confidence in any system, you need transparency, or you lose confidence on the industry and consumer side.”

Price stability and predictability were good for the payer and for the industry, so they should be principles.

To the comment that markets change and, even in perfect market conditions, there should be periodic adjustments, a participant replied that such a situation was part of predictability—if X happens, then Y automatically follows. It would be akin to a volume-based discount.

If a company were going for orphan drug status, it would get the status. However, as doctors find off-label uses, there would be real danger that the strategy would backfire.

There is a down side to any policy. The orphan drug market and what it represents is open for abuse, because people on the other side are paying artificially elevated prices.

Orphan drugs, said one group member, are outside the Board's mandate and are a separate policy issue.

"Lowest reasonable price is not asking for bargain basement pricing, but it's important for consumer budgets. What can the end-user bear?"

The group allocated a priority to the principles using three points for top priority, two for second, and one for third. The totals were:

- Accessibility and accountability=5
- Value-based pricing=12
- Economic welfare=11
- Simplicity=2
- Fair share=0
- Consistency over time=2
- International parity=0
- Stability and predictability=0
- Accountability for the PMPRB=3
- Lowest reasonable price=5

Group 3—Blue

Facilitator Ron Andrews asked participants which principles are/are not relevant to the PMPRB's regulatory mandate.

One participant questioned to what degree differentiation between products and category of products is possible or even warranted. The Board bases its decisions on the three price factors but has never clearly defined "excessive price." How those price factors are assessed is unclear however.

Another group member said the Board works in the context of a marketplace that regulates drug prices through competition and the Board's only "job is to determine if the price is excessive." Others agreed that the market should allow for price setting within a certain therapeutic class and that such price setting is not part of the Board's mandate.

The distinction between founding and operating principles should be made, observed a participant. The Board's founding principle is consumer protection, while operating principles could, for example, include proportionality of a drug's price to its value.

One delegate indicated that the marketplace does not always work well with respect to pricing. Consumers cannot use their purchasing power to signal whether or not a drug actually represents an improvement, because they simply lack the information to do so. Organizations and private/public drug plans, the biggest purchasers in the Canadian marketplace, however, are able to make that choice. It is the Board's job to help them do so—at least, in principle.

Does this also mean that physicians and other health care professionals cannot make decisions relating to drug improvement? The previous participant noted that "they have no incentive to do so." Health care professionals do not use price as a determining factor, since they do not pay for the drugs.

Certain principles were proposed:

- The determination of excessive pricing should take into account drug efficacy. The latter could be framed as a principle, as it is related to the value that different consumers place on specific drugs.
- Transparency "speaks to objectivity and accountability." It also deals with the consideration of expertise in decision making.
- Guidelines have to be clear and concise for government, consumers, and industry parties to understand them.
- Consumer involvement should be an overarching principle.
- Reliability and consistency are required over time, with changes in panel and Board members. No extraneous matters (e.g., prevailing politics) should influence decisions. Industry and consumers need to have certainty and confidence in the review process.
- Principles should be flexible over time as evidence for drugs accumulates. At the time when the Board examines a drug price, there may not be a lot of evidence available. A cancer vaccine, for example, would require a flexible approach to pricing.
- Access in terms of availability on the Canadian marketplace but also in terms of equitable access to all Canadians could encapsulate another principle. Some participants stated, however, that access was not under the purview of the Board, while others saw a direct link between the notions of fairness, affordability, and access. The customer, after all, is the primary stakeholder, and, "We can't forget that R&D is financed by consumers." But who is the consumer? Should the term be "all consumers"? Is it the Canadian individual or organizations? This has to be clear, because it relates to the issue of drug access and availability on the market in all provinces to all consumers.
- Lowest reasonable price and proportionality to the drug's value should stand as principles. The latter would send signals as to what type of drugs should be rewarded, although this requires determination of value.

- The fairness (to the consumer) principle is important, but companies also should be rewarded for innovation, since without their work, products would not be on the market. The financial health of the pharmaceutical industry is in the best interest of the public, said one participant, adding that the patent signifies one reward.
- In light of the HDAP's comments about the lack of evidence for categories, one delegate suggested the principle of exclusivity—the Board makes no decisions about excessive pricing if there is no evidence. The concept of an evidence base also flows directly from the fairness and objectivity principle.

One stakeholder queried whether the Board risks the "non-introduction of new drugs" into Canada. More reasons exist than ever before to prevent companies from introducing a drug in this market.

Another participant commented that many bodies are involved in the drug review process (e.g., HC, CDR) at various stages. It seems as though they "work in silos." Can they work together to expedite the process?

One delegate affirmed that in the pharmaceutical sector, "you have no perfect marketplace; the idea of price competition is not supported by evidence." The health care system does not allow driving down the price either. In the end, the consumer is paying more than necessary.

Returning to the issue of who the consumer is, one stakeholder referred to the relative competitive or negotiated power between buyers and sellers. The Canadian marketplace is dominated by hospitals, employee-based insurance plans, and the ultimate pricing powers of provinces. What is the relevance of the individual consumer in the Board's protection mandate?

The initial mandate was to protect consumers in the traditional sense. That traditional consumer has been replaced by large groups (e.g., hospitals, provinces, etc.). Does the Board still feel the need to protect the real consumers? Is it the Board's mandate to protect the provincial budget? Who needs to be protected and to what degree?

This led to a discussion about how provinces decide to list a drug, which could not only be a function of affordability but also of the perceived value of a drug. Provinces have sufficient bargaining power and information to negotiate with companies, stated one delegate. The Board should consider those who really need protection: the stakeholders who lack the most information.

Group 4—Yellow

Facilitator Roger Nopper asked the group whether the PMPRB should have guiding principles or not. One participant suggested, given that the principles are related to values, that they might be set more appropriately through legislation. She suggested that a political discussion that engaged the public, rather than stakeholders, perhaps would be more appropriate.

Other participants said that some of the principles do not flow from the Act, that they are not within the mandate of the PMPRB and that they need to be consistent with the Act to be more effective. It would be useful to have more explicit guidelines. It was suggested, for example, that the principles need to illuminate what "excessive pricing" means.

A PMPRB representative pointed out that the eight principles being discussed represented stakeholders' views on the activities of the Board. For example, some stakeholders perceive that lowest reasonable price, rather than the MNE, is a principle that underpins the Board's mandate. Another participant said principles should not be taken beyond what the law says: "Follow the law." Another perspective was given that it was necessary, however, to also achieve the "spirit of the law."

There was agreement that the overall, most important principle centred on determining "excessiveness," and the Act spells out the factors related to excessiveness. However, there needs to be further interpretation and analysis of the principle of excessiveness. Additionally, there are overall factors that guide the determination of what constitutes excessiveness, and other criteria also need to be considered.

One participant said excessiveness is not something that can be nailed down. While consistency over time is important, he did not see how consistency over time can be achieved regarding excessiveness.

Several participants agreed that a principle of efficiency should be included.

Value-based pricing was seen, on the one hand, as a key principle, because it measures how valuable a drug is for the user. On the other hand, value-based pricing was seen as being subjective.

There are certain cases—such as, for example, the reduction of side effects with the drug Prozac—where such outcomes are not viewed as value added. So a drug that makes a seemingly dramatic difference in the reduction of side affects still is not seen as belonging in the breakthrough category. Payers are the ones who assess the end-use value of a drug. The PMPRB does not have a mandate to assess the value of a drug.

A lengthy discussion ensued regarding international parity/consistency. It was suggested that as international comparison is part of the Act, the principle should read "international comparisons," not "international parity."

Participants commented, however, that comparison with other countries is difficult, because it is complex and subjective, and the outcomes are not always clear. The drug development process is largely international, so there is also a need to have some regard for international parity to gain access to those drugs. For example, vaccines are at a premium in terms of supply; it is simply a supply-and-demand issue.

One participant made the point that Canada has an issue with the need for innovative pharmaceutical capacity development—again, for example, with vaccines. Another participant said there are significant complexities involved in comparing with other countries when analyzing price structures and currency fluctuations.

There was agreement that simplicity, efficiency, and transparency are key principles. It was suggested, however, that price stability should actually read "price test stability," as it is price *testing* that needs to be predictable. The principle of consistency is related to consistency in the way things are measured.

Regarding accessibility and affordability, the PMPRB has a role to play. Accessibility is a key principle both from the manufacturers' perspective and the consumers' perspective. One participant said the Board also has a role to play in ensuring that certain drugs are accessible in Canada. The way the PMPRB fulfills its mandate impacts accessibility. For example, some of the older drugs for diabetes were rather inexpensive; however, the new drugs are quite expensive. The PMPRB needs to examine whether there is a disincentive to having them on the market because of their cost.

Other participants said that one could not say "maximum non-excessive" and also call it fair or affordable. If affordability is a principle, it might need to be offset with accessibility.

However, a participant pointed out that accessibility is not a factor in determining excessiveness. Affordability is handled through subsequent systems of determining payments to the users.

The term "lowest reasonable price" seems to contradict the term "MNE price." One participant stated that if there is an overall principle to drive prices too low, this could affect access. On the other hand, a drug may be accessible, but whether Canadians can afford it is another question. Some participants did not see lowest reasonable price as a viable principle, but MNE was.

Regarding the term "fair share" as it relates to the amount of innovation dollars that Canada spends, this has no relevancy as to whether a price is excessive or not. If the principle of international parity were accepted, then the concept of Canadian fair share would be redundant. In determining an MNE price, the Board does consider the cost of R&D as it is spelled out in Section 85(2) of the Act.

If international parity is clear, then the term "Canadian fair share" does not have to be used, as that would be a duplication. Canada is a very small portion of the market. The addition of that principle does not illuminate the Act and therefore is not helpful. However, if R&D is deemed important, then it was suggested that policies be created to support its development.

Plenary Session: Report Back

The facilitators presented a summary of the discussions on guiding principles in the breakout meetings.

Participants in Group 1 agreed that guiding principles are important, because they counter a lack of clarity in the Act.

Guiding principles should be used to protect the consumer, and all principles should allow for flexibility and equitable pricing across Canada.

Prices should adapt to changing environments. There should be a balance between macro (the health system) and individual considerations (the willingness of patients to pay for new technology).

Group members said that accessibility is overblown—consumers may have access to drugs outside the normal channels—and that affordability should be the principal business of the PMPRB.

The lowest fair price should allow reasonable return for investment to industry. When does a price become excessive?

The process for determining MNEs should be simple, said participants, and every process should be transparent (except for access to the IP).

The group decided the third framework best reflected the Board's use of guiding principles.

Group 2 concluded that all principles that refer to transparency, predictability, consistency, and simplicity are key, but it added efficiency, because some stakeholders viewed the Board's process as becoming lengthy and complicated. Principles should be clear, consistent, and as close as possible to the Act. The overall principle is excessiveness.

Opinion about the principle of value-based pricing was divided. Pricing is important, because it measures the value of a drug to the user and helps determine excessiveness. There was concern about subjectivity. The board's mandate is not to assess the value of a drug.

Some participants suggested revising the language: one said the wording should be "price test stability," not "stability/predictability" and another, that the wording for "international parity" should be "international comparison." There were concerns about whether Canada is comparing the same price structures in comparator countries.

If international parity is applied and clear, then "Canada's fair share" is a duplication, said one participant. It should not be a principle, because Canada is a small market.

Regarding accessibility/affordability, the Board should ensure access to drugs. Access is not a factor in determining excessiveness.

Group 3 questioned which consumer the Board is protecting—the patient who takes the pill, or the provinces?

The group developed a list of principles for the Board to consider: evidence-based, transparency as it supports objectivity and accountability, clarity and conciseness, and consistency and coherence.

Regarding accessibility/approval, Group 3 recommended focusing on the introduction and sale of drugs in Canada. Accessibility means "on the market." Drugs should be available to all consumers.

In terms of fairness and affordability, participants recommended focusing on the customer as the primary stakeholder. R&D companies should be rewarded for innovation.

When participants discussed exclusion, they concluded that where there is no evidence, there is no decision.

Group 4 said there should be a principled approach to regulation that drives accountability.

Affordability should not be linked to access. Protection of the consumer should be the primary point, although without simplicity, the system is unworkable.

Value-based pricing is a common goal of consumers and producers. The suggestion was made that "economic welfare" might be a new, underlying principle for the whole system. Another new principle might be one that relates to transparency. The same principles should be applied over the life of a patent.

The Board should consider a new approach for pricing based on a relative value scale. This is an opportunity to rethink the system. Regarding reasonable price, participants asked, what can the market and the end-user bear? The group gave value-based pricing the highest level of support.

Both stability and predictability are good for industry and the consumer.

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

Group 1—Red

The group began by discussing the *Patent Act*. While the purpose of the meeting was not to change the legislation, participants felt that the discussion should be situated in a collective understanding of the PMPRB's business.

A PMPRB representative explained that the PMPRB's responsibility is to limit the prices of patented medicines to ensure that they are not excessive. With the Act awarding greater monopolies to industry, the Board was created to prevent "mischief" regarding those monopolies. The Board's raison d'être is more explicitly stated in the regulatory impact document.

Participants noted that the Board's mandate is subject to interpretation, according to the objectives of the interpreter. It is clear, however, that the PMPRB was not intended to be a consumer advocate, but rather to prevent the abuse of patent monopolies. The PMPRB protects Canadians from excessive prices not because it is a moral issue, but to ensure continued access to affordable medicine.

Desroches asked participants whether categories should exist.

Reasons that categories should not exist include the fact that there is no requirement for categories in the Act, and the categories may not reflect the true therapeutic value of medicines. It is possible to review prices without categories by applying the factors in the Act and making a subjective judgement call. Meanwhile, no other industry conducts price comparisons without using categories.

International parity could provide a simple, category-free benchmark of excessive price. For entry-level drugs, assessors could use information from multiple tests and make a conclusion. In both cases, categories would not be necessary. "It's clear, make the decision, and if it's not, then go to the Board," a participant proposed, noting that this would fit the principle of simplicity. Rather than making the price review process more efficient, categories may actually waste time by sparking arguments over categorization. Price is the real issue.

"How much of the concern about the value of categories is based on the fact that we have lousy categories?" a participant asked. While better categories that reflect "the reality on the ground" would be preferable, categories make common sense and make regulators' jobs easier.

It is very inefficient for the PMPRB to have its own unique category system, since "a small platoon" of staff is required to categorize each submission. Furthermore, the fact that the true therapeutic value of a drug may not be known until a decade after its release detracts from the logic of categories. A participant agreed that drugs should be categorized after their true benefits are known and described an existing system that rates drugs (with one to four dollar signs) according to their known economic value. This scale is most useful for consumers and contributes to the overall affordability of the system by helping prescribers make decisions. Rating medicines requires accurate information about their real benefits however.

Overall, categories should make the price review process more efficient, should not add complications, and should contribute to the overall affordability of the system. The PMPRB should not have its own categories.

A participant said she had hoped to hear more about how the categories are actually employed in the price review system and what issues exist.
A drug's category has become the determining factor in its price test, rather than vice versa. If the price of a drug is not excessive, why worry about determining its category? This might lead to a two-category system, split between products that are easily assessed and those that are not, such as moderate improvements or purely technological advances.

"The categories as they exist are all evidence-based, and, as it stands, there is not enough evidence," a participant said. Others agreed that this is "the big issue"; for example, many drugs are tested against a gold standard that no longer exists when they arrive on the market. It is crucial to know how the current categories are actually used.

A PMPRB representative explained that the categories do indeed determine which price test will be employed. For example, Category 1 drugs are only compared to other strengths of the same drug, while Category 3 drugs are compared to the top of their therapeutic class. The question of what a drug should be therapeutically compared to is the source of contentious debate. In practice, a drug is only placed in Category 2 if it is so different that there is nothing to compare it to. As a result, very few drugs are placed in this category.

The creation and acquisition of relevant evidence is crucial, a participant stated.

A PMPRB representative said that the guidelines direct the Board to consider factors such as improvement in outcomes, significant reductions in adverse events, and reduced hospitalization. Factors the Board is not allowed to consider include compliance. While a drug with sustained release might produce better outcomes because patients do not forget to take it, the Board cannot take this into account. A participant stated that none of this information would be available beyond a speculative basis at the time of review.

Participants then discussed changes to the existing categories. Category 3 should be split, separating "moderate improvement" into its own category. Category 1 is as objective as possible and the least open to debate, participants agreed—it is only when new technology is introduced that the issue becomes problematic. The value of the categories, how they are used, and their implications are the real issues at hand.

In response to a question, a PMPRB representative agreed that the Act does not direct the Board to use categories. Rather, it lays out the five factors and directs the Board to go to broader principles if they prove insufficient. She added that although the price of international comparator drugs is mentioned in the Act, it has never been applied in a test. A participant countered that it had, in the case of Humalog and for an HIV drug, but in both cases public consultations were conducted.

Participants reiterated that price should be of primary concern.

Desroches asked participants whether prices should be reviewed in sub-markets of the Canadian market.

No, participants said, unless there is a need. With ten provinces, three territories, and various alternate markets such as vaccine tenders, it would be too unwieldy. Regarding access and affordability, the real problem is prices in comparator countries. "I want to know what large Canadian payers are paying relative to large HMOs in the States!" she said. A participant noted that negotiations related to Ontario's *Bill 102* will not be transparent, meaning that it will not be clear what Ontarians will pay relative to out-of-pocket consumers or payers in Saskatchewan.

As the proportion of costs being paid out of pocket increases, the rising cost of drugs will become a significant accessibility issue, and it will have to be someone's responsibility. Participants agreed that ensuring accessibility and regulating prices in a complex market are not part of the PMPRB's mandate. "I don't think there's a jurisdictional impediment—it doesn't matter where the point of sale is," a participant said. "It's just that it would be an administrative nightmare."

Participants discussed the differences between the MNE price, or a ceiling, and the PMPRB's current practice of establishing an average price. Several participants suggested that setting a ceiling and letting market forces work beyond that was the best option. A PMPRB representative noted that it is difficult to reconcile averaging with the idea of true non-excessive price since, with an average, some classes or jurisdictions will still pay above that benchmark. It was noted that if most buyers are individuals with no influence, "there's an awful lot of purchasers out there paying more."

Examining sub-markets might be appropriate when seeking more information if a price seems excessive, but it should be done on a case-by-cases basis rather than across the board to avoid overload. Meanwhile, it was noted that, due to transparency, manufacturers would know in which cases this would occur.

Dividing by sub-markets contributes to a "patchwork quilt" of reimbursement or "postal code prescribing." Participants suggested that this is an excellent argument to reduce the number of payers in Canada, since smaller jurisdictions like Atlantic Canada have no clout in negotiations.

Group 2—Green

Laplante asked the group to consider whether or not there should be categories, and if not, what would replace them.

A participant said she was not particularly in favour of categories but had yet to hear of anything that might replace them. Another declared that there should be no categories,

because they do not make sense and they are subjective. There are, for instance, no categories on milk or gas.

The first participant replied that cancer professionals disagree on cancer drugs, so it is impossible to ask patients or consumers to sort this out. They do not have the facts or the information. Another was ambivalent as well about the categories. She said the Act did not make them mandatory.

Three participants did not feel knowledgeable enough to discuss the issue.

Price should be based on value. If the categories can help judge the value, they are a good idea.

Categories should be removed, but the tests should still apply. The process would be less transparent than the current one.

Categories are selected when a product is launched. Once a drug gets into the community, there may be additional benefits or problems. “The artificial system of categories isn’t working, because real-world efficacy isn’t involved at this stage.”

There was a difference of opinion among group members as to whether or not the categories were clear.

One person said that “value-based” was an ongoing battle. The Board’s mandate is to regulate prices, not value.

Another replied that, as spelled out in the Act, tests are based on not allowing an excessive price. If the discussion was not about changing the Act, then it was about how to make a test to find what is excessive. The categories do not help with that or make the process easier. Already, he said, there are minor inconsistencies. The Average Transaction Price (ATP) is a mean price. The international test is a median price. What would happen if it were the other way around?

The member who was ambivalent asked how abolishing the categories would improve the system. “If we’re going to throw them out, we have to be clear about why. If a good argument can be made that the system will be more transparent or more efficient without them, then go ahead. I haven’t heard a strong argument for getting rid of them, but I do understand the problems and we do need systemic reform.”

A participant suggested eliminating Category 3 but said that deciding what constitutes a breakthrough in Category 2 would still be “messy.”

If a line extension is absorbed differently, it may be a totally different drug. The categories do not acknowledge that.

In reply to a question about the public's point of view, a participant said that most consumer organizations do not have the capacity to understand the system nor, therefore, to critique it.

In the absence of categories, would all three forms of tests be applied to every drug? Or would the PMPRB determine which test to apply? A member suggested reviewing the Act and creating another system. Questions arose amongst participants as to whether tests would be eliminated if categories were abolished and what would replace them. In the case of a breakthrough, for example, it would be impossible to do a TCC for lack of comparators.

"Categorizing drugs isn't the problem; it's the way we categorize them. They are a starting point. Companies can appeal a category, so they aren't locked in. We don't have a reasonable alternative here."

Someone asked if the categories or the tests were the problem. "The factors that give rise to the tests are in the Act and can't be changed. The categories are not in the Act."

Should prices be reviewed in sub-markets of the Canadian market? A participant replied that the economic welfare test should apply. "I'm not talking about categories of drugs, but about categories of buyers. Can they be defined as markets? What are the implications of regulating down to these areas? Businesses will always have an incentive to discriminate prices, and it's not always a good thing."

That would only work if Population A knew what Population B was getting. "Why would any Canadian put up with different prices around the country?"

There is a relationship between price and bulk purchases. That is why inventors file patents—not to give discounts. Nobody should be held to ransom because they live in a less populated province.

In terms of any monopoly, a patent holder has a better return by segmenting the market. Price discrimination is more efficient.

The underlying goal is to ensure that Canadians are not paying excessive prices. "We have to recognize that what is not excessive in Ontario or BC *is* excessive in the Maritimes. In a perfect world, we'd all pay the same price. The reality is that by segmenting, Canadians do not have access to drugs based on where they live. We should take into account the realities that give Canadians fair, equal, and equitable access to drugs. The definition of 'excessive' depends on where you live."

Further dividing the 52 markets would not create any advantage. Purchasing power varies across the provinces and over time. The PMPRB is not the only mechanism.

A member said that whether companies sell to a province or to a hospital, perhaps the hospital will pay less, but one will balance out the other. Another replied that subsidizing is required in certain cases.

"The final price will be the same, no matter how we address the issue. So we don't need sub-markets."

Group 3—Blue

In response to a question about how the drug categories relate to drug value, a PMPRB representative explained that the guidelines were created when value assessment was being widely discussed. "They were not considered perfect or right."

Are Category 2 drugs subjected to a "lower bar" than Category 3 drugs? Category 3 drugs are assessed on therapeutic value comparison and then on the maximum international price, while Category 2 drugs are subject to the median international price. A PMPRB representative commented that in 20%–25% of cases, the MNE price would be lower if the category were different.

One stakeholder questioned whether the categories actually help the Board do its work. Are there other methodologies that would work better? There exists no definition of MNE price other than the price factors listed in the *Patent Act*. Having categories can lead into a debate about the distinction between moderate and little improvement and add another level of uncertainty and lack of transparency.

The real background for the Act was operational, commented another participant. At the time of category creation, there were to be as few as possible to reduce debate. This fit with industry views and was practical.

What is the difference between categories in terms of market price? There was some debate about whether Category 2 drugs could be sold at a better price given that the "hurdle is greater." A Category 2 drug "is better than anything else. There is no therapeutic class comparison test, and it is automatically subjected to the international median."

Is there a time difference in reviewing the categories? That depends on the agreement between the Board and the patentee. When there is disagreement, it can be a lengthy review.

A long review process, however, does not preclude access to the drug. Private and public insurers will not wait for a Board decision to reimburse a drug. A PMPRB representative reiterated that for the Board's jurisdiction "to become real," the drug needs to be patented

and sold. The Board has no jurisdiction, for example, in cases where companies test the waters with payers but are not yet selling a drug.

Participants discussed priority reviews within Health Canada and how they may affect the Board's process. If a drug is considered a priority in the approval system but a Category 3 drug by the Board, it becomes an issue for disagreement between agencies and industry as well.

One participant suggested the non-excessive price for all drugs should be no higher than a therapeutic class comparator or the median international price. Such a simplified process could accelerate the Board's decision making by eliminating the need for categories—perhaps going with Category 3 tests only. Another delegate agreed that the categories are too subjective, and, from a fairness perspective, it would be best to "get rid of them."

Countering, another stakeholder stated that categories are extremely important. It is a matter of explicitly stating why they exist. She recommended a category-linked price structure for different levels of improvement.

How do the categories apply over the evolution of a drug? Evidence for any given drug accumulates over time, leading to category changes. It was agreed that this is a re-benching rather than a category issue, although the number of categories would determine how many "revisits" could take place for a single drug.

Currently there are four active Board hearings dealing with introductory prices, which underline the difficulty the Board is facing on this issue.

One participant wondered if categories were designed as a prioritization tool. The response was that Category 1 drugs are "a no-brainer," Category 3 drugs are also relatively straightforward, but Category 2 "is a nightmare."

The categories serve as administrative and operational tools with no basis in law. It is up to the Board to operationalize the Act. The essential question is do the categories add or detract from the guiding principles?

Various issues arose from the subsequent discussion:

- If categories have to exist, they should be very few and very clearly defined.
- Category 1 is important; two of the current Board hearings are about drugs in that category.
- It is "unreasonably difficult for a drug to obtain Category 2 status."
- Categories do not always allow for therapeutic innovation.
- Patient compliance is totally ignored in the equation (some drugs have large benefits if only consumers administer them properly).
- Categorization supports incremental drug value.
- The principle that the MNE price not exceed the average therapy cost on the market remains regardless of categories.
- The pricing that exists between categories should reflect the value of a drug.

Another participant said the Category 3 test should use the maximum international price with a retrospective assessment of the value of the drug on the market. If there has been substantial improvement, then there would be room for a price increase. This would allow for the incorporation of efficacy data. Therefore, she suggested using Category 3 to set the initial MNE price.

Participants discussed having only two categories. The bulk of drugs are in Category 3 anyway. "We don't need Category 2." Simply test the lower of the therapeutic class comparison or the median international price with the possibility of review down the road.
It was countered that this would not be accepted by companies. What happens to drugs with substantial improvement? One could, suggested a delegate, compare them with drugs of 50 years ago. Another stakeholder suggested the MNE price be the higher of the therapeutic class comparison or the international maximum price. The definition of "therapeutic class" remains a problem.

Should prices be reviewed in sub-markets of the Canadian market?

Within the Canadian market, drug prices differ among provinces, commented one stakeholder. Québec, in contrast to other provinces, has stipulated no price increases. Québec has a policy whereby patented medicine is listed for 15 years without mandatory substitution, thus regulating price increases.

The Board's mandate is to manage and control the prices of drugs under patent. What happens when those patents expire and there is no generic competition? It was clarified that the Board no longer has jurisdiction after patent expiry.

One participant suggested, "It is natural to have variability in the marketplace." Therefore, the Board's average measure is appropriate, provided all transactions are within the MNE price.

Another stakeholder stated that the data from the May 2006 *Discussion Guide* did not indicate that the "any market" issue was a significant problem. She added that going to an any market system would be complicated. The next delegate agreed, adding that a move to any market may also discourage discounts to some customer classes such as hospitals.

Once the Board determines the non-excessive price for a given drug, no Canadian should pay above that price, declared one participant. The following stakeholder countered that there is variability in this, and it would require a therapeutic class comparison in all markets—that level of regional analysis is rarely done.

The session ended with a discussion about the impact of discounts on selling prices. If there is a discount, the average selling price drops, and the benchmark is reset.

Group 4—Yellow

Nopper summarized the issue of "any market" pointing out that currently the PMPRB uses the ATP provided by patentees for four classes of customer: pharmacy, hospital, wholesaler, and other. Prices are filed in each province and territory or for Canada as a whole.

Using the ATP may mask different prices for different customer classes or in different federal, provincial, or territorial jurisdictions. The question is should another approach be taken? Stakeholders in the past have had mixed responses to this question.

Some participants expressed their concern about parity on all levels. All citizens need to benefit from the PMPRB regulations, and there needs to be a mechanism to identify variations in prices. The PMPRB must investigate any excessive prices and provide transparency of information to stakeholders as well as consumer groups. All groups need to know if they are paying more than another group and may thereby ask the PMPRB to investigate. "Flagging and investigating are two different things."

One participant pointed out that the ATP may not be so variable now. However, stakeholders rely on the PMPRB to be prudent and watchful and to investigate any major discrepancy with the MNE price or trends with the ATP.

On the other hand, industry does not support analysis by subdivisions, because there is a focus on market-based pricing in certain districts, and price negotiation is the nature of that reality. Therefore, industry's position is to keep the current guidelines that relate to the Canada-wide level, starting from the ATP.

A participant expressed concern about one market subsidizing another. One participant pointed out that provinces and territories, hospitals, and private insurers all have the power to negotiate; however, the uninsured public is without that same power. Price variations by sector contradict the notion of consumer protection. While agencies may be reluctant to share the discounts they are getting, it is important that reporting processes are transparent and different groups have opportunities to negotiate.

Another participant mentioned the administrative burdens inherent within negotiations and the subsequent impact of costs on health plans. It was suggested that the PMPRB might want to ask customers and users about this. Also, if a thorough market analysis resulted in no variation and no need for negotiations, then perhaps more resources would be invested in patient care, for example.

Hospitals achieve significant discounts through negotiations. A participant offered his opinion that those who are getting discounts are not concerned about the administrative costs of negotiations. Another participant spoke about the difficulty of making price comparisons: it is hard to get at the reality of a price when list prices, discounts, and rebates are considered. Also, in the cancer sector, for example, the whole landscape is changing dramatically with drugs that are very expensive. One patient's treatment can be equivalent to a nurse's entire salary for a year.

A participant questioned what the PMPRB's existing power and authority is regarding examining price variations, investigating rebates and taking action. It was suggested that graphs disclosing net income should reflect rebate amounts.

A PMPRB representative responded that most ATPs are reviewed, and there have been no investigations to date.

Nopper asked whether there should be categories of drugs to determine the MNE.

A participant stated that there was a need for categories as a yardstick to determine how valuable a drug is—even if they function as a blunt instrument. Another participant said they were not convinced either way, because if the therapeutic value of a drug were somehow incorporated, categories would be less necessary. The categories are somewhat artificial, because there are many different categories of drugs amongst different organizations. If there were clarity on what constitutes non-excessive price, there might not be a need for categories.

Several participants expressed the view that it is difficult to assess the real value of a drug in the early stages of its categorization, because scientific evidence can be limited or initially immature.

The categories could be more sophisticated. It would be particularly helpful to capture progressions between Category 2 and Category 3.

A participant said that forces in the marketplace remove the need for categories. Many participants did not agree with this statement. One pointed out that certain companies benefit excessively, because they are the only brands being sold in doctors' offices, and generic brand drugs do not market themselves. Thus, market forces are something to be concerned with. In the cancer sector, market forces are not working.

Another participant voiced his opinion that breakthrough drugs should have prices that reflect their value. They are in a class of their own. Industry's position is that it is very difficult to have different tests for different categories, and it is not worth the effort.

A participant supported the notion of transparency for all reviews. Another group member pointed out that categories are going to become less relevant as things get more complicated, especially in biotechnology. There is a need for greater sophistication. France, for example, has five categories and the lowest cost, so manufacturers are keen to launch new products in France first.

Plenary Session: Report Back

The facilitators presented a summary of the discussions on categories and "any market" in the breakout meetings.

Group 1 saw the PMPRB's mandate, as stated in the Act, as subject to interpretation. The PMPRB must ensure that manufacturers are not abusing their patent monopolies with MNEs and that consumers have access to affordable drugs. It is impossible to judge the value of a drug down the line.

Although opinions differed, many group members leaned towards abolishing categories. In the absence of categories, tests could be applied.

If there must be categories, however, they might be "cost-effectiveness" and "value tests." Categories should make the decision process more efficient. They should reflect reality, contribute to the affordability of the system and be applied only in exceptional cases.

Category 3 needs to be broken down into "moderate" and "little or no" improvement.

In Category 1, if a drug simply has a new strength, there should be no change. However, the category could be broken down if the drug includes a new technology for absorption. In view of the above two points, would there be too many categories?

Group 1 said there should not be sub-markets except in cases where prices are excessive.

Group 2 said the status quo is acceptable, because the system seems to be working and is not too cumbersome.

The PMPRB must be prudent and watch for major discrepancies in MNEs or trends in ATPs. Stakeholders also must be watchful and investigate discrepancies. Stakeholders want the Board to provide transparent information so that the public knows if it is paying excessively in certain areas.

Some group members said that categories are needed—even though they are a blunt instrument—because a yardstick is needed to determine the value of drugs. Market forces influence prices and also make categories necessary. However, market forces do not work when it comes to cancer drugs.

The categories, stated others, are artificial, because other means of categorizing drugs exist. If there were clear principles to determine what an MNE is, categories might not be necessary.

Some said that greater sophistication is needed in determining the categories, especially Category 3. Currently, when categories are attributed to drugs, the scientific information is limited or immature.

Categories 1 and 2 seem to be working and are probably efficient. Category 2 has a value, but there needs to be a process to mark progression in both categories 2 and 3.

What would replace categories, and what would be the measure if they were abolished? Most advocacy groups do not have the resources or expertise to comment on categories. One group member said that nothing in the Act says categories are mandatory. Another said that categories are needed to distinguish between drugs.

The transparency of the categories was an issue for some. Categories should not address value; they should address the MNE.

What is the problem, asked participants—the categories or the factors in assessing the categories?

Regarding markets, participants in Group 3 expressed the idea that there should be single, fixed, fair, and equitable pricing across the country. Price discrimination allows for better efficiency

Patients should be considered when dealing with subsidies.

The final price will balance out when various discounts are taken into consideration. There is a price difference depending on where a person is in the supply chain.

Group 4 participants had two views on categories:

- The PMPRB should return to the basic principles in the Act, so there is a strong argument to abolish categories—period.
- Categories support assessment and are very important. Price structure should reflect the value of a drug.

Categories are too subjective, and they do not allow for innovation. If there must be categories, they should be fewer and better defined.

Category 2 is extremely difficult to attain. Category 3 could be a starting point for all drugs based on the absence of evidence at the beginning of the process. Category 2 should be abolished. The initial test for Category 3 could be the TCC or the international test. There would be a possibility to re-bench later on in the process.

Variability regarding markets is normal, so the national average is a good measure.

There was a concern in Group 4 that examining sub-markets may discourage discounts. A review should take place at a lower level than being considered. No Canadian should pay more than the MNE. There needs to be a definition for “market.”

Presentation 3: Re-benching of an Introductory Price

Ginette Tognet presented a summary on re-benching, which she explained can be thought of as a “second review” or “re-assessment” of the original maximum non-excessive price.

Currently, re-benching is possible under only two circumstances: if a drug was previously sold only under the Special Access Program (SAP) prior to its first Notice of Compliance (NOC), or if the drug was sold in less than five comparator countries when the price was reviewed.

Other potential reasons for re-benching have been suggested, including instances when a drug is granted a second indication, if there is a change from treatment of a rare to a common disease, or if there is any change in the primary indication for a drug.

Health Canada is developing a regulatory approach that recognizes the life-cycle of drugs from development to use. It might be possible for PMPRB to adopt a progressive or renewable maximum non-excessive price. Potential "pros" of this approach include reducing market disruption and encouraging compassionate pricing, while potential "cons" include price unpredictability or de-listing of drugs on public formularies.

In response to a question about whether prices would be driven up if re-benching became more and more accepted, Tognet replied that if the scientific evidence does not exist for comparator drugs, the price would not go up.

A participant asked whether all new drugs should be assessed instead of industry selecting drugs on which it thinks it can raise the price. Tognet replied that such a question should be discussed in the breakout groups.

Breakout Session 3: Discussion of Re-benching

Group 1—Red

Desroches asked whether an introductory price should ever be re-benched, and why or why not.

Re-benching might be reasonable:

- At the NOC, if a product was first sold under the SAP;
- If new indications or clinical data regarding efficacy are discovered;
- If there is a change in international comparator countries.

A participant asked whether originators would bother to re-bench a product if generic drugs exist and theorized that it could go either way. Originator companies should have the right to initiate re-benching.

Participants discussed automatic timetables for re-benching such as whether Category 2 drugs should be re-benched automatically once real-world data is available regarding their projected benefits. Participants agreed this would be possible, though not necessarily desirable. Meanwhile, it would be unfair to include similar drugs that have

entered the market since re-benching, as this would penalize the initial innovator. Lipitor is an example of a successful challenger to a Category 2 drug.

The PMPRB's existing structure could not support thousands of additional review requests per year.

A drug with revised indications should be re-benched, a participant said, suggesting Vioxx as a "classic" example. If a significant new side effect is discovered for a Category 2 product two years after its release, should the indications be revised or the product re-benched? Would manufacturers bother, or would they simply pull the drug off the market? "I see a ton of unintended consequences," a participant said.

Another participant predicted an unanticipated "domino effect" onto other drugs in the same class. Others noted that new indications are added to biologics all the time, which would require re-benching each time. There is also the possibility of penalizing innovators if their breakthrough product is found to be not as effective as expected, and newer drugs have found less expensive production processes in the meantime. Furthermore, re-benching will carry a significant cost to the manufacturer. Formularies would not allow higher prices anyway.

A participant asked about the difference between the post-market surveillance information manufacturers must provide regulators and the information the PMPRB requires for progressive licensing.

"A lot of this is conceptually attractive, but what is the economic impact of driving up the cost of doing business?" a participant asked. Manufacturers dislike uncertainty, and periodic reviews will "drive the industry crazy." It is also uncertain what kind of structures the PMPRB would need to handle such a volume of files coming back. A participant noted that focusing on Category 2 drugs would reduce the size of the "bureaucratic enterprise."

The idea of re-benching is exclusive to Canada, although France and the UK review prices on a yearly cycle; most countries leave prices up to market forces.

Anyone should be able to initiate re-benching at any time, participants agreed. This would obligate the manufacturer to provide the evidence.

Coordinated research and analysis is required to inform these policy decisions. A significant amount of information is available regarding changes in the market over time, so the value of these policy options should lend it to analysis. "We need to work on the evidence that informs the policy," a participant said.

Re-benching should not be cyclical, as it would be too costly for all involved. The CDR's cost-effectiveness review will still influence the price negotiations between payers, purchasers, and manufacturers. Companies already lose their market share when their

patent ends and generics appear; prices will not drop, because companies must make their money before that occurs.

It was suggested that some companies use the SAP to artificially create a market. If so, re-benching should not be allowed at the NOC. Others argued that SAP requests go to manufacturers' medical departments; "the guys in marketing don't even know about it." Many "one-offs" are thus not reported to the PMPRB and are not included in calculations.

Regarding progressive licensing, changes to an NOC could constitute a trigger for re-benching. These could include changes that would impact health and safety or that could significantly affect sales or market share such as a warning to limit the use of Vioxx to rheumatoid arthritis patients. A participant noted that the PMPRB might be duplicating the CDR's work, thereby making different outcomes from the two bodies a confusing possibility. The CDR should report on its findings and share its information.

New information that might make re-benching necessary would thus include safety and efficacy information, evidence from clinical trials, and anything that would change the clinical practice for a drug. A participant suggested that the process "seems more trouble than it's worth," as manufacturers would simply reintroduce such a product as a new drug and have its price reviewed thus. Another suggested that there would be no incentive to re-release a drug if the indication were for a smaller patient population or to re-release an old drug like thalidomide with a completely different set of indicators.

Different organizations react differently to new information about progressive licensing, and it may not be appropriate for the PMPRB to act. Overall, there would have to be very compelling evidence that a price had become excessive.

Participants agreed that originator companies; the PMPRB; federal, provincial, and territorial governments; and any individual with credible information should all be allowed to initiate re-benching.

Participants asked whether any evidence exists that the lack of a mechanism for re-evaluating prices has caused a problem. Payers want prices to be re-evaluated when new indications are discovered. In the absence of an existing federal, territorial or provincial government mechanism for re-benching, the PMPRB is being asked to fill the role.

The group discussed provincial price regulation processes such as Ontario's new *Bill 102*, which will keep prices low by threatening manufacturers with de-listing. One participant suggested that if one province could be convinced to include generic drugs, the rest would follow suit. "Get PEI on board!" he said.

Group 2—Green

Laplante asked the group to consider whether or not the PMPRB should re-bench drugs and, if so, under what conditions.

One participant replied that she did not agree with re-benching. “It’s a Pandora’s box.”

Another said that re-benching is inexcusable. The only situation in which it would be acceptable was if the price always dropped.

A group member stated that it is not the job of the PMPRB or of re-benching to subsidize R&D.

“I like that it introduces evidence-based decisions in the process, so it takes care of weakness at the beginning of the process. It’s not always going to be to the benefit of patients, but it would lead to a fair price.”

A participant declared that the price will rise if Canada compares against other countries, to which another participant replied that it would depend on when a drug was re-benched and why.

If industry were confident that the price would always go up, it would ask that every product be re-benched. This fits in with the PMPRB’s mandate to protect consumers.

A member said that if a drug focuses on a small group of patients, there are few comparator products and there is, therefore, little influence in the marketplace to drive down the price. Re-benching is one of the tools available to control price points.

An example was given of a drug that had not changed price in 12 years. The fluctuation in the Canadian dollar changed the relative price, and the company had to bring the price down in keeping with comparator drugs elsewhere.

A member stated that a form of re-benching exists already if the price of a drug is higher than in comparator countries. Companies have to submit data on pricing every six months and make reimbursements if prices are deemed too high.

Another member replied that the background materials in the participants’ kit specified two rules under which re-benching takes place already. He said those rules should continue.

Cancer affects two of every five Canadians, said a respondent, so cancer drugs are not a small issue. She asked if drugs could be re-benched after a specified period of time. Are the companies afraid of real-world evidence, she wondered. She cited Herceptin as an example: evidence has shown that it is not as effective as originally thought.

A member noted that prices abroad are negotiated with companies after five years, so that is a form of re-benching. Countries with budget constraints reduce the price across the board. Canada is unique in that, unlike other countries that have a price regulator and a reimbursor, it does not.

One member stated that there should be re-benching for second indications.

On the subject of when re-benching should take place, a participant said that two examples are codified (as in the participants' kit), and one is automatic based on international data. If the Canadian price for a drug is above the median price and the ATP, a price review for that indication is automatically triggered.

When asked if re-benching should take place under other circumstances, a member said that it should not matter how many indications a drug is used for—the initial price is for the initial indication. If re-benching looks at a second indication, the drug would be assessed against different comparators, so there may well be a different price.

Another member said that re-benching is done when a drug gets a new NOC, when it is an SAP drug or when it is sold in at least five countries or within three years, whichever comes first.

One group member pointed out that some companies perform studies and say there is no new indication, but the drug continues to be used off-label. Under those circumstances, the end user continues to pay a high price for the original indication, and there will be no ability to re-bench for the second indication.

Another member agreed that this is a risk. Companies will move more into off-label use, especially in experimental therapies. A third member agreed and said it could also lead to a decline in innovation.

Re-benching should be an ongoing process based on clinical evidence from other jurisdictions and price.

An automatic trigger based on a specific time period or a certain amount of evidence was suggested.

Would it be too onerous for the patent holder to provide that information? It was replied that clinical trials are not on websites, and anybody can look at them—how onerous that would be.

In response to a question about what evidence should be submitted to support re-benching, clinical evidence and price comparisons from abroad were suggested.

Vioxx was mentioned as an example of a well marketed drug that provinces were accused of not making accessible to patients. Although it proved to have dangerous side effects, there were no big reimbursements from the vendors. Patients are still uninformed about the dangers and still ask for it.

The point was made that a company was overpaid for a product that does not work. When a drug is first priced by the PMPRB, it is based on insufficient evidence. "Patients

deserve the relevant evidence, and professionals have to make that decision. Patients cannot identify when re-benching should be done."

A participant asked, "At what point between being pulled from the market because it makes your foot fall off and not meeting two out of five criteria do you need to re-bench?"

In response, a PMPRB representative said that the Board approves pricing. Yes, drugs should be re-benched for effectiveness, but that is beyond the mandate of the Board.

Another member disagreed. "The PMPRB exists to protect consumers," and price and efficacy are related.

A participant supported that statement, saying that re-benching goes to consumer protection. Although she understood the constraints of legislation and that consumer protection was not worded in the Act, it does not relieve the PMPRB of that mandate.

The group wanted to make it clear to Laplante that their views on re-benching apply only to Category 2.

Group 3—Blue

Andrews asked participants two questions:

- Should the introductory price ever be re-benched? Why/why not?
- When should re-benching occur?

One participant endorsed the idea of re-benching in cases where evidence is limited at introduction and to better reflect incremental innovation. If, for example, there is evidence that a Category 3 drug is actually a Category 2, then a price increase may be in order. Another delegate suggested that re-benching could be complaint driven. Off-label use is a concern. How prevalent is it? Could it be considered in re-benching?

"If you assume that the current MNE price is generous and you give the manufacturer the benefit of the doubt, there will be greater pricing freedom," proposed one stakeholder. At the same time, the evidence would have to be applied uniformly. Leaving it to industry would create a disincentive for R&D in one area and not in another. A re-benching system must be accompanied by a system that supplies the evidence for it.

Can re-benching cause price increases? In theory it can, but in practice there have been few examples of this. A PMPRB representative indicated that a compassionate SAP price could increase with an NOC. Under the SAP, companies used to sell drugs for very low prices that were used as a benchmark price by the Board. Now "companies give them away or sell them at market price," commented one stakeholder. It was suggested that if the SAP price were truly a compassionate price (versus the market price), it would be a good re-benching opportunity.

One participant guessed that, once on the market, a drug's price invariably would be re-benched downwards given that the initial price had various factors calculated into it (e.g., R&D, marketing). Re-benching downward will have an impact on accessibility, since companies may revisit their marketing strategy if their prices are pushed too far down. The participant reminded everyone of the impact that German and French government reimbursement policies have had on price reduction and drug availability. "Do we want to go there?"

Others noted that company production costs (e.g., economies of scale, improved efficiency) may well decline over time, offsetting any downward push of prices due to re-benching. Prices may not necessarily go down. If, for example, the Canadian marketplace is significantly supplied by imports and transportation costs rise, drug costs could increase.

A PMPRB representative reiterated that the Consumer Price Index (CPI) is a factor in the Act that the Board must take into account. The CPI is a good surrogate for manufacturing and marketing costs, but it does not automatically increase every year.

The fundamental issue is whether re-benching is actually merited, especially if the evidence is difficult to assess. Maybe the current three-year review process (or achieving sales in five comparator countries) is the best solution. Some felt that the question of re-benching should be revisited at a later date given the current changing circumstances (e.g., progressive licensing).

Asked under which conditions re-benching should occur, one participant responded that new indications (off-label or NOC driven) should be a trigger with the SAP drugs to be included at their initial NOC.

If the Board wanted to differentiate between smaller increments of drug value, it could mandate a subsequent review, said one delegate who added that this type of differentiation cannot be made at introduction. The review could act as a complement to categories.

A discussion ensued about category changes, how that assessment is made, and its price implications. The CDR does not review new indications, but if the review is not positive, the company can go back with another submission.

A PMPRB representative explained that manufacturers can choose the SAP or an NOC price for a drug. "Just because the SAP price was below the NOC, doesn't mean it was compassionate." Is a cost analysis needed? Do manufacturers have to provide a rationale in support of a drug price (i.e., their marketing, distribution costs)?

Some review of the costs involved in developing price is warranted, but it would depend on the category of the drug. For example, a Category 3 drug might require less stringency than a Category 2 drug. "That would push the SAP price up as high as possible,"

countered another stakeholder, noting that if companies were held to that price it would be a disincentive.

The next delegate suggested that re-benching may not be in the best interest of some patients (e.g., life-threatening diseases, rare genetic diseases). There the "SAP will be dammed." The current tendency for product approval is to monitor the safety of a drug if it makes a big difference in survival.

A PMPRB representative reminded participants that re-benching goes beyond the SAP. She asked the group to consider scenarios that could impact drug cost. If there is no re-benching, "there is no second kick at the can."

The group debated whether drug prices should change quickly for a one-time event. It can be done in the context of a public hearing. Consider a catastrophic manufacturing failure, and the drug price cannot increase. Does that mean that Canadians have no access to that drug?

A PMPRB representative stated that the kind of information needed to demonstrate a catastrophic event (e.g., a rare, raw material) might not be available (i.e., a change in acquisition cost for the main ingredient of a drug). Given that there will always be unexpected situations, the Board has the right to make exceptions to the guidelines without taking them to a public hearing.

One participant proposed that there be exceptional re-benching for the public good; this could address numerous issues in rare circumstances. A PMPRB representative agreed that giving staff the ability to re-bench in exceptional cases would be more in the public's best interest than hearings.

There have been at least two cases where prices have gone up and manufacturers sold the drugs elsewhere. Another participant said one consequence of the current system is short supply. It is availability and the true health needs of Canadians that should factor into pricing.

One piece of evidence might be the shortage of a drug that has no therapeutic alternative and its impact is significant (e.g., the Chiron plant closure for flu season). Is that another caveat for re-benching? There is no one answer for different situations, and the Board already deals with such occasions on a case-by-case basis.

One participant indicated that she would be "loathe to define situations other than matters significant to public health where the Board can do what it wants including re-benching."

Would the exceptions be extremely rare (e.g., a national emergency) or relatively common (e.g., more evidence)? Do the current guidelines allow for upward re-benching when the average selling price changes? What happens if this change persists over time in different customer classes? In such a case, the Board would look at what is going on in the particular market.

The fact that companies can "play with indications" is becoming an important issue. Drug development stops after the first NOC even though a greater number of indications for one drug could mean increased profits. The rarest indication "gets through the system first." Secondary indications are discovered later and marketed to a larger population. If the therapeutic market, which lacks precise definition, is taken into consideration, then it also changes the incentives for companies.

Group 4—Yellow

Regarding the question of whether there should be re-benching, participants pointed out that it is a challenge to be consistent, and there is the question of how to have different prices reflect different indications.

While the theory of re-benching is attractive, the reality from the patentee side is that it is difficult to get a payee to accept a price increase based on re-benching. In response to a comment made in plenary about patentees only doing research for the purpose of increasing prices, a participant reminded the group that there is mandatory disclosure of clinical trials.

Another participant pointed out that *The New England Journal of Medicine*, for example, had not signed on to re-benching and that this was an example of the difficulty in achieving consistency through compliance. A participant raised the issue of whether re-benching actually had "any real teeth" in terms of applying consistency.

Several participants agreed that if the PMPRB allowed re-benching based on new indications, it would be logical to allow requests for investigations to come from multiple sources—from a variety of stakeholders, not just from industry. Another participant disagreed, saying that a price should stick even with new indications and that if a new indication emerges where the current price is higher, then that is an opportunity for an increase in market share. Other participants disagreed with this. They did not know how one could have two different prices for a drug that has two different indications. "One drug, one price, regardless of the uses."

One group member gave the example of a drug that is patented for cancer but that can be used effectively, in very tiny amounts, for a non-cancer situation. In this instance, it has been difficult to obtain smaller amounts of the drug, because the manufacturer does not want the drug market to increase for that indication, as it is not in their best interest to sell the drug in micro amounts.

Another example is the drug thalidomide. Many years ago, the cost of this drug was measured in cents. Currently thalidomide has remarkable indications in the treatment of certain cancers—and yet, it is not being offered in Canada, and consumers are purchasing it in the US in the price range of $6000.

A participant indicated that the two existing examples of re-benching under the guidelines are not contentious. However, another pointed out that re-benching for Category 3 medicines could affect the issue of the introduction of new drugs to the market in Canada, because manufacturers try to list with countries that have the highest pricing.

A suggestion was made that the PMPRB negotiate with manufacturers to establish a five-year price, for example. Manufacturers as well as the PMPRB would benefit, as both parties are motivated to minimize the uncertainties of re-benching.

What does the PMPRB do when a "first-of-its-kind" drug, used in an uncommon situation and classified as a breakthrough drug, emerges in two years as being a drug that is used commonly and is no longer considered a breakthrough drug? Currently the drug stays in its class, and competitors help set the price through market forces. So to be effective, one has to compete in that price range.

The drug Botox was given as an example of a drug that has two different prices for two different uses. Botox is used for cosmetic purposes as well as to treat cerebral palsy and rheumatoid arthritis.

Some participants felt that the benefits of re-benching lay primarily on the side of industry and that re-benching is, therefore, a tool that enables manufacturers to charge higher prices. This is the case, for example, when a drug is initially inexpensive and then is found to be more valuable than was originally thought for treating certain illnesses. It is incumbent upon a manufacturer, then, to submit new evidence. The manufacturer also must pull the drug and then re-introduce it. A participant pointed out that it is unproductive to have a beneficial drug pulled because of a lack of ability to re-bench. Thalidomide is an example of that.

A participant asked a PMPRB representative if there were examples of re-benching where the prices went up *or* down. The representative responded that there had never been an example of real re-benching, that the existing two examples in the guidelines are very rare and that re-benching should be up *or* down. However, there is an increase in situations where drugs are being found to have multiple uses. It is necessary to be fair to industry as well as to consumers.

A participant suggested that the PMPRB needs to consult with everyone who influences prices, including drug plan deliverers, because there are different systems doing different things, and they are not always aligned.

Participants agreed that if re-benching is used, it must allow for the price going up or down. It is important that all stakeholders have an opportunity to apply for re-benching.

In terms of significant changes in pricing associated with biotechnology, a participant pointed out that prices can vary significantly depending on manufacturing capacity, technical challenges, and access to biological materials and their extraction.

Another point was made that there is powerful evidence to suggest that drug plans must adjust to the realities of increased costs for certain drugs.

Regarding progressive licensing, there was agreement that progressive licensing procedures add yet another layer of complexity to the issue of re-benching and that its introduction came at a bad time. In that regard, there was a lack of coordination and a yearning for cohesiveness. “What happens at one phase can contradict and impact another phase.”

Plenary Session: Report Back

Ron Desroches, the facilitator for Group 1 (Red), reported the results of his group’s discussion. Re-benching should occur when a new or revised indication is added or if there is a change in international comparator countries. Re-benching should not be cyclical, as it would be too expensive. Category 2 drugs should be re-benched when a review of the evidence confirms their categorization.

Re-benching should be able to be initiated by originator companies, by the PMPRB, or by federal, provincial, and territorial governments—the latter because they run drug plans. Generally, anyone should be allowed to initiate re-benching based on evidence.

Arguments against re-benching included the risk of unintended consequences such as a domino effect on other drugs in the same class and the risk of penalizing innovators and increasing manufacturing costs. Other arguments against re-benching included that formularies will not allow higher prices, that it would increase uncertainty, and that most other countries allow market forces to work and do not re-bench. Group members asked what structures would be allowed to handle the process.

In general, the question of re-benching lends itself to policy analysis and research. The group speculated as to whether companies are creating markets through the SAP. It noted that there is no mechanism for governments to re-bench on their own and asked whether the PMPRB should fill that role.

Finally, re-benching might be necessary if progressive licensing raises information regarding safety, efficacy, or clinical practice, provided this information would affect the excessive price.

The facilitator for Group 2 (Green), Suzanne Laplante, explained that her group had not reached a yes or no decision. It is difficult from a market point of view, and particularly from a patentee’s perspective, to get a higher price accepted by consumers. The market can push a price down in the event of situations like a new indication, making re-benching unnecessary. Single drugs should have one price, irrespective of their indications. Finally, re-benching a price downward may cause delays on market entry, because manufacturers will delay Canadian releases until their product is available in all other countries.

A re-benched price may better reflect the value of a drug but create more uncertainty in the process, which is contrary to the values identified the morning of the consultation. If re-benching occurs, it should be in a context where prices can go up or down. Requests for re-benching should be allowed from any recognized stakeholder group and should be done on a case-by-case basis rather than automatically—especially for new indications.

Progressive licensing will add complexity to an already complex process, because there are too many layers, phases, and groups. The issue of re-benching will become even more complex if the two are overlapped. There is a need to streamline the process between the different organizations that assess drugs in Canada. If progressive licensing does occur, it will be an opportunity to examine the different systems that exist between licences.

"Re-benching yes, re-benching no, re-benching maybe," reported Ron Andrews, the facilitator for Group 3 (Blue). Arguments in favour of re-benching included using it as a means of taking new information into account, since, in many cases, when a drug is first introduced little information is available. In this scenario, prices could go up or down. Off-label use might also be a trigger for re-benching.

The group cautioned that the market would never allow re-benching and that it would serve as a disincentive for research. Participants generally agreed that the PMPRB should "be careful what you wish for" and beware of unintended consequences such as discouraging research.

A system would be required to generate the information and evidence required for re-benching. Participants noted that re-benching downward based on a compassionate NOC price would affect accessibility.

Other circumstances in which re-benching might be necessary include a new indication, off-label use or an NOC, or if the value of or indicators for a drug change. Any drug moving from the SAP to an NOC should be re-benched automatically. Suggested scenarios could include external supply forces or a catastrophic manufacturing event in which shortages occur and no other therapeutic options are available. The group speculated, however, that this might be "killing an ant with a hammer" and that the Board already has the ability to deal with exceptions. The group asked whether exceptions are rare or routine.

Roger Nopper, the facilitator for Group 4 (Yellow), reported his group's conclusions. Asked whether prices should be re-benched, some group members said no, as it would open a "Pandora's box." Others said yes, with the proviso that prices always go down. They liked the concept provided it was founded on evidence-based decisions and fairness.

Concerns were raised regarding price instability and appropriate timing. It was noted that yearly presentations of price information already constitute a form of re-benching. Participants said evidence must be tied to pricing, and re-benching should be based on

existing documentation. It was suggested that re-benching could be triggered by the introduction of a second indicator.

Suggestions as to when re-benching should occur included every five years, or at the SAP and an NOC. Automatic reviews are already triggered every six months with international pricing however.

Concerns were raised that re-benching could lead to increased off-label use. Other comments included that ongoing re-benching should be linked to evidence and that re-benching should only apply if no other drugs exist in a product's therapeutic class. Re-benching should occur within a specific timeframe or with the introduction of new evidence.

Suggested required components included clinical evidence and international pricing. It was noted that efficacy is beyond the PMPRB's mandate.

After all of the facilitators' reports, a participant said it appeared that re-benching was "coming out of left field." A much broader consultation would be required before going forward. More data is also needed regarding the potential impact of re-benching such as research as to what would have happened had re-benching existed over the past decade.

Another participant asked members of the green group to elaborate on their suggestion that linking progressive licensing and re-benching would cause complications. A member of the group explained that rolling data submissions and a life cycle approach would add more indications during a product's life, while re-benching would be designed to evaluate them. The result would be two processes effecting similar outcomes at different speeds on different sides of the equation.

Another participant said the intention would be that the same information base would be used in both licensing processes. "The idea is more synchronization, not less." One participant said it would be very wasteful for the PMPRB to conduct a review every time, as the CDR already reviews drugs with new indications for reimbursement purposes.

A participant expressed concern that re-benching blurs the lines between Health Canada's focus on safety and efficacy, and the CDR's focus on efficiency. "We don't need one system that does everything."

Evaluation of Session

Desroches thanked participants and asked them to evaluate the session.

Positives included discussion materials provided in advance, the opportunity to interact with individuals from different fields and areas of expertise, and the presentations given by Board staff and Benoit. "They were very helpful," a participant commented.

Participants also identified areas for improvement. One of them noted that, due to participants' differing levels of information and the amount of material to be covered, it was difficult "to do more than scratch the surface in these short sessions."

While the timing and balance of the sessions were good, another participant said, too much time was devoted to re-benching given the relative newness of the topic. It might have been better saved for subsequent discussions.

Finally, in the future, facilitators and note takers should be cycled through the groups to give a different flavour to each workshop.

Next Steps and Parting Message

On behalf of the other Board members, Benoit thanked the facilitators for their hard work and the staff for their efforts in putting the consultation process together. "We've found these very fruitful," he said.

"The staff think their work is done, but it's actually just beginning," Benoit said. On December 13, staff and the Board will meet to decide next steps.

The compilation of notes from each consultation will be available on the website in January. In the spring, certain stakeholders will be reconvened to discuss any potential changes to the Guidelines that the Board considers to be appropriate and necessary. Benoit noted that the PMPRB's website is updated regularly, and its newsletter is readily available upon request.

Benoit thanked participants for coming and said he appreciated the opportunity to "put faces to the names we hear all the time."