Patented Medicine Prices Review Board (PMPRB)

Stakeholders Consultations on Excessive Price Guidelines

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Welcome and Opening Remarks

Dr. Brien Benoit, PMPRB Chair, welcomed participants to the stakeholder consultation. He hoped the mix of stakeholders would lead to productive discussions that the Board could use in its deliberations about the Excessive Price Guidelines. The consultations were not about changing the *Patent Act* but to seek stakeholder input about the Guidelines and their relevance.

The PMPRB has had an ongoing dialogue with stakeholders, which has led to many suggestions. The PMPRB can act upon some of those suggestions, but others are beyond its authority. Some of the more complex issues raised during the Board's 2005 consultations were explored further in the 2006 *Discussion Guide on the Board's Excessive Price Guidelines.* Responses to questions raised in the guide indicated the need to carry consultations forward and led to this series of cross-country stakeholder meetings. A further consultation may take place in the spring of 2007 to discuss potential Guideline changes.

The Board must consider numerous factors (e.g., the price in comparator countries, changes in the Consumer Price Index (CPI), etc.) under Section 85 of the *Patent Act*. These factors determine whether a medicine is being, or has been, sold at an excessive price in any market in Canada. If the Board is still unable to determine excessive pricing, it can consider other factors, including the cost of making and marketing the medicine.

The *Act* gives the Board considerable latitude in terms of how it will apply the various price factors in determining whether a price is excessive. However, the need to provide transparent and predictable guidance to patentees led the Board, under subsections 96(4) and 96(5), to issue Excessive Price Guidelines. The Board's Excessive Price Guidelines are not binding on patentees, but they can facilitate voluntary compliance and act as a useful resource.

Any modifications to the Guidelines must involve a process of consultation with the federal, provincial, and territorial ministries of health and with consumer groups and the pharmaceutical industry. The Board values stakeholder input and is determined to ensure that the current process is as open and inclusive as possible.

Presentation 1: What We Heard Report

Barbara Ouellet, the PMPRB's Executive Director, provided the historical context that led to the consultations and noted that the series of meetings would focus on what the Board heard in response to its 2006 *Discussion Guide on the Board's Excessive Price Guidelines*. Specifically, she would limit her discussion to the concerns raised about drug categories and the regulation at any market.

Category 1 drugs include a new strength or a comparable new dosage of an existing medicine. Category 2 drugs include breakthrough medicines, and Category 3 drugs

represent those of moderate, little or no therapeutic advantage over existing comparable medicines.

Summarizing the comments of stakeholders, Ouellet noted that most identified problems with the current categories. Some suggested abandoning the categories altogether, while others suggested various improvements including refined category definitions and sub-categories. Many stakeholders saw Category 3 as problematic, with some finding the category too generous and others, too restrictive. It was suggested that the category could be divided into "moderate" and "little or no" therapeutic improvement.

In conclusion, stakeholder opinion on the drug categories was divided, but all supported the need to acknowledge the relative value of new medicines, which the current Category 3 is unable to do.

Ouellet gave an overview of the question of any market, indicating that regulations require patentees to file prices for the four classes of customer and also in each province/territory or for Canada as a whole. The average transaction price (ATP) that is currently used may mask variability for different classes or jurisdictions. Furthermore, the existing deviation from the Maximum Non-Excessive (MNE) price by class of customer and jurisdiction means that while some parties negotiate a price below the MNE, others pay more to compensate. The current price review process does not investigate these variations.

Reviewing the comments of stakeholders with respect to the issue of any market, Ouellet indicated that some supported staying with the current approach, others wanted clarification of rebate and discount use in the ATP, and some suggested a more focused review in excessive pricing cases. Several stakeholders were interested in price review by customer class and/or jurisdiction/region. Ouellet concluded that while there was sharp disagreement about the use of a national average (versus sub-markets) for price review, most agreed that price reviews should be conducted, where warranted, on a case-by-case basis.

A stakeholder from the meeting noted that in the initial stakeholder submissions only 3 out of 43 were consumer groups, despite the fact that it is the consumer that is fully affected by drug reviews. Why was there such disproportionate representation? Benoit indicated that although the questionnaire was sent to many diverse groups, including consumer organizations, some chose not to reply. "If you don't vote, don't criticize."

Presentation 2: Principles Underlying Patented Medicine Price Regulation

Sylvie Dupont, Secretary of the Board, reviewed the source of the Board's authority and noted that, while consumer protection is not mentioned anywhere in the *Act* itself, the Board was created under that pillar. The Board's mandate is to apply the pricing factors

in Section 85 of the *Act*, but the question remains of how consumer protection is best put into practice.

Dupont outlined the factors that the Board must consider in determining excessive pricing. How can the price factors be applied? They cannot be applied simultaneously or given equal consideration, since each factor results in a different MNE price. Should some factors be given more emphasis than others? Are there some key principles that reflect the Board's consumer protection mandate?

She briefly discussed each of the various principles that stakeholders have linked to the Board's mandate including lowest reasonable price, value-based pricing, and accessibility combined with affordability. Are any or all of these principles pertinent? Does one principle or set of principles have priority over others? Dupont suggested that it is likely a combination of principles that would best guide how the different factors for pricing would be employed.

She used three frameworks to illustrate how the guiding principles could be linked to price factors. For example, the underlying principles of value-based pricing, price stability/predictability, access and affordability, and fair share would lead to the use of comparator drug prices and international prices for the same drug.

For the subsequent breakout session, Dupont asked stakeholders to consider two questions: What principles are or are not reflective of the PMPRB's regulatory mandate? What would be the appropriate grouping of principles to be emphasized in carrying out price regulation?

One delegate was concerned about the use of the word "regulation" and suggested it was misleading. "It implies the design of a regulatory program." Dupont reiterated that the Board's mandate is to reveal cases of excessive pricing and noted that there are regulations attached. If prices are found to be excessive, the Board does have the capacity to bring the prices "back to non-excessive." She and Benoit indicated that the wording could be changed, as it might have been used in the wrong context.

Breakout Session 1: Guiding Principles

Group 1

The breakout session on guiding principles explored whether principles are reflective of the Board's mandate, the rationale behind this, the importance of various principles, and whether there is a logical grouping of principles.

The lowest reasonable price principle was considered consistent with the Board's mandate to look at consumer protection. In terms of rationale, this principle reflects consumer needs.

A participant supported value-based pricing but was unsure if the Board was mandated to consider this. “Major consumer groups and every health ministry buying medication for hospitals are concerned with value for Canadian taxpayers’ money. Value-based pricing provides a level playing field for provincial health ministries to evaluate funding and is particularly relevant for certain diseases such as cancer.”

Accessibility combined with affordability was considered reflective of the Board’s mandate to provide Canadians with the best drug possible at the most reasonable price for the problem.

One participant noted that the discussion was focusing only on the consumer protection mandate of the Board. However, the *Patent Act* was passed to address excessive pricing and to attract research and development (R&D) to Canada. The participant commented that the underlying principles of Example Framework 1 are more reflective of the wider context of the Board’s dual mandate for both consumer protection and the need for industrial policy goals, and should be integrated in the guiding principles.

It was asked what is meant by “Canada should pay its fair share.” A participant stated that the Board is not the appropriate channel to consider this principle. “While the Board’s mandate is to encourage these types of behaviours, the Board exists to ensure that effects of prices from product side as opposed to development side are not excessive.”

“The principles present a range of interpretation,” observed another participant. More definition is needed as well as a clearer understanding of the relationship between each principle and excessive price.

It was agreed that price stability/predictability falls within the Board’s mandate. One participant questioned whether, in addition to average transaction cost, opportunity cost also could be incorporated as a principle.

The simplicity/transparency principle was considered consistent with the Board’s mandate. In terms of rationale, a participant pointed to statistics: “The Consumer Price Index (CPI) has been 8% below the median over time, presenting an opportunity to look at how to simplify prices in Canada and how to maintain a stable environment with less burdensome guidelines.”

Another participant stated that application of the CPI would fall under price stability/predictability. He said the CPI could be misleading, as it encompasses too large a basket of goods. “When looking at expenditures of health and pharmaceuticals, one must factor in population growth and ageing across provinces. In oncology, expenditures on drugs have, in fact, been more than the CPI over the past five years.”

Another participant in favour of accessibility combined with affordability questioned whether this principle is fully reflective of the Board’s mandate in terms of affordability, which is not always assured. “For many reasons, including pricing and income level,

seniors do not necessarily have the accessibility they would otherwise desire." Differential pricing may be an issue for Board consideration.

According to one participant, the Board's mandate covers establishing an affordable price, but not availability.

Clarity on what constitutes "reasonable price," "consistency over time," and "excessiveness" was requested.

A PMPRB representative explained that once the base price has been established or determined not to be excessive, the issue of excessiveness is ensured through the life of the patent by the CPI. The price cannot increase by more than the CPI, one factor of the *Act* under Section 85. Patentees file pricing information twice a year, and prices are reviewed throughout the life of the patent.

A participant said that accessibility, affordability, and assessment go beyond the Board's mandate. "There are other well established processes in Canada such as the Common Drug Review (CDR) and provincial assessments. Furthermore, the Health Inflator, which is 1%–3% above the CPI, indicates the price of medication is more stable. The CPI is not reflective of a health care environment where costs are escalating," continued the participant. One must separate issues between expenditures and prices. Prices in Canada are 8% below the international median. Seven countries have higher prices. The lowest reasonable price is not commensurate with the role of the Board. "One must be careful in mandating lowest prices, because that has a consequence in terms of what is excessive," he stated.

Another participant said that lowest reasonable price implies the lowest price and a reasonable price. The mandate of what is not excessive works under the guidance of reasonable price.

In terms of a principle, it was suggested that the group of seven countries against which pricing in Canada is measured falls under international parity/consistency. A participant noted that those countries were selected given a similar industrial base to Canada.

The appropriateness of the basket of comparative countries was questioned given their high-priced profile. "The problem is, Canada does not look like them," stated a participant. "But Canada aspires to resemble them," observed another.

"If the Board is to have impact internationally, then this spills over into access to medication," commented a participant.

It was suggested that this principle be incorporated into excessive pricing. In view of the trickle-down effect, it was noted that the principle also ties in with accessibility.

In terms of a principle, it was concluded that international price comparators are not adequately reflected.

Lowest reasonable price was considered a principle of high importance with an emphasis on "reasonable." The suggestion was made to change the principle to "*most* reasonable price." A participant objected to the word "reasonable," because the mandate is excessive.

It was recommended that priorities be balanced to achieve a reflective price. According to the participant, the most important principle should balance consumer policy with R&D, followed by simplicity/transparency, international parity/consistency, and Canada should pay its fair share.

Accessibility was also considered a principle of high importance given the need to ensure that products are accessible in Canada.

Group 2

For one hour, participants were asked to discuss the principles that should or should not apply to the PMPRB's regulation mandate.

Participants agreed that the principle of price proportional to value should be a priority. It is essential that the price reflect the medicine's benefits to consumers.

One participant explained that she agrees in theory with the idea of price that reflects value but that, in practice, there is no real means of judging this, especially when the Board must rule on the aforementioned price. A number of participants agreed with this idea. Participants also agreed that value must be defined independently of market price.

In one participant's opinion, price proportional to value should be the guiding principle for everything, even though it is difficult to put into practice.

One participant mentioned the case of Lescol, in which there is a discrepancy between value and market price. According to this participant, this price war is, by and large, beneficial to consumers.

One participant began a discussion about the difference between the idea of the lowest reasonable price and of price proportional to value. In his opinion, no price is without value, the two being inseparable.

For one participant, the expression "lowest reasonable price" is erroneous. On the flip side, could we talk about the highest reasonable price? To this, one participant added that choosing the lowest reasonable price is not part of the Board's mandate; rather, its mandate is to decide whether a price is excessive or not.

One participant mentioned that consumers must be defined in a consumer context. Therefore, she rejected eliminating the "lowest" component from the principle. Some

participants discussed this idea, wondering if it is really the Board's mandate. One participant came back to the Board's mandate, namely protecting consumers' interests.

One participant wanted the term "excessive" to be more clearly defined. She felt it was important for this concept to be easier to understand, in order to avoid liberal interpretations.

According to one participant, though the Board has a mandate to protect Canadians' interests, there are other ways of protecting consumers' interests and ensuring that prices are not excessive. One participant asked whether we have necessarily protected consumers if the lowest price is not excessive.

As for international parity, one participant thought it was a principle that holds together well, despite the fact that we're lagging a bit behind what is being done elsewhere. One participant ironically added that the important thing is to "not do more than the others."

One participant mentioned that instead of the seven comparison countries, there is now a global price on innovation. He asked the group whether this pool of countries is still relevant.

In regard to the principle of "Canada's fair share," participants recognized that this refers to the fair share of innovation, which is funded through medicine purchases. One participant suggested proposing prices slightly below the highest price or slightly above the lowest price. That way, consumers are not deceived and Canada contributes fairly. In this participant's opinion, if Canada practices parity, it is doing its fair share.

One participant wondered how one could determine that Canada is doing its fair share. This participant felt it was important that the government intervene to ensure the market does not hinder innovation. He suggested reformulating this principle to reflect this last idea.

One participant mentioned that it is important to carefully choose our price range for establishing an international average. If Canada chooses to align itself with the Portuguese average, it is not doing its share. However, it is wrong to believe that the money paid for medicine funds only innovation. This participant made specific reference to pharmaceutical marketing.

One participant said he was surprised that in Canada the ability to pay varies from one province to another. This topic was of concern to several participants. However, since accessibility comes under provincial jurisdiction, the Board should not rule on this issue.

One participant suggested withdrawing accessibility since it was already reflected in the issue of reasonable price.

The subject of consistency raised many questions. Were we talking about consistency in the rules of application or a consistent price for the duration of the patent? In one

participant's opinion, there could be periodic re-assessment in a consistent methodology. Some participants felt that several stakeholders (businesses, hospitals, etc.) may find it difficult to manage mid-patent class re-assessments. One participant added that consumers and researchers could have the right to request a re-assessment, if applicable.

One participant suggested that the principles of simplicity, transparency and consistency be grouped together.

The facilitator asked participants to rank the principles according to their importance. Participants did not agree on the first principle. For some, simplicity and transparency were the most important, while most others were divided between the principle of price proportional to its value and reasonable price. In the interest of consumers, one participant wanted reasonable price to be ranked in at least second position.

Group 3

Which principles are and are not reflective of the PMPRB's mandate? One delegate suggested that the lowest reasonable price, accessibility, and value-based pricing guiding principles accurately reflect the Board's mandate. Why? These principles speak to the public interest and population health rather than individual consumer and commercial interests. He added that value-based pricing, however, could pose interpretation problems; a look at drug quality may be more appropriate.

Agreeing, another stakeholder noted that a drug is not a consumer good (like food, for instance). Public health should not be market-based, since it is much more complex than a simple commodity (e.g., the effect of vaccines). She also observed that the principle of accessibility follows and respects the Canadian philosophy of health care access. The principle also ensures that drugs are available to all segments of the population.

The group discussed some potential negative effects of the Excessive Price Guidelines. For example, a company may decide to market a drug outside of Canada if it believes the price may come under review. Such marketing strategies may leave the Canadian public without access to certain drugs simply because they are not on the Canadian market.

Does accessibility really fall under the Board's mandate? One stakeholder reminded participants that public formularies address drug accessibility and work in parallel with the Board. Access to medication is further complicated by regional disparity. Another group member stated, "I see the Board's mandate to evaluate price, not accessibility or affordability." At the same time, countered another group member, drug price most certainly affects its accessibility, and thus the Board is implicated.

Another group member noted that, under the *Patent Act*, intellectual property is protected for a given period of time, therefore providing access to a non-competitive marketplace.

A discussion about the principle of lowest reasonable price ensued.

- Is this really a guiding principle? The introduction of a drug is a commercial venture; the drug has to be commercially viable.
- In return for a non-competitive marketplace, a newly patented drug should be implicitly reasonably priced.
- A reasonable price is not necessarily the lowest: it could be above average.
- Acknowledgement of industry investment and a drug's value needs to be balanced with the public interest.
- The term "reasonable" is too vague—reasonable according to whom, the manufacturer? How is the reasonable price determined?
- Categories need to be associated with criteria that more clearly define reasonable price.
- The reasonable price, be it the lowest or the highest, is the conclusion of a process with many criteria and is therefore on firm ground.

One delegate indicated that consistency over time is a key principle, since it provides credibility to the review process. When the same tests are applied over time, the Board and its work remain credible and transparent, and people, particularly the patentees, know what is expected of them.

According to some participants, international parity is an integral part of the Board's mandate. It is essential to keep Canada's drug prices at a similar level to those in other countries. It was acknowledged that the health care systems of the seven comparator countries affect the drug price in Canada. If the United States is included in the price range, for example, the Canadian price automatically increases.

One participant suggested that international parity is more an indicator than a principle. The international price can be difficult to determine given the fluctuations in currency (e.g., the Euro). A PMPRB representative clarified that the publicly available price is verified by the government of the specific comparator country and that the average of customer class prices is used. Thus, the international price reflects all classes.

One stakeholder returned to the idea of patent protection and suggested a business case aspect in determining excessive price. Instead of an international comparison, could there not be a link to patent protection, particularly for breakthrough drugs? Such a mechanism would define excessive price in a much less subjective or necessarily international manner.

Another participant added that secondary factors, such as manufacturing cost, have never been considered by the Board. Looking at such factors, however, would increase work for the Board and the companies that would have to supply reports.

In terms of Canada paying its fair share, a PMPRB representative noted that "there is an underlying assumption of R&D. Fair share could also be in terms of pricing from the policy perspective." Canada should acknowledge investment in R&D, and most participants agreed that it should, therefore, pay its fair share, provided that the consumer

does not pay more. One delegate noted that "we must pay our fair share to have access to those drugs that we don't churn out."

Another participant indicated that while transparency is a must, the extreme complexity of some of the submitted files for price review and the factors to be considered in pricing negate simplicity as a guiding principle.

In general, the group agreed that all guiding principles are equally essential. Each principle can be important, depending on the case. As such, the Board has more flexibility to interpret. One would gain little in terms of public health by putting more emphasis on some of the principles than on others. At the same time, the group found it difficult to answer this question, since it had just decided that some of the existing principles do not belong under the Board's mandate. Some principles are more appropriate as indicators or should be dropped entirely.

Value-based pricing raises the debate of the benefits that a drug confers to the public versus the cost of production. That is a debate the public should be involved in. "You can't ignore the profits that companies are earning. Their return on their investment and the cost of manufacturing must be balanced against the value of the product to the Canadian public and its improved health."

If the principles had to be grouped, one participant would "put anything Canadian as the primary guiding principles and anything international in a secondary group." The Board is a Canadian body that came into being to fulfill a Canadian need. While the Canadian aspect is important, added another stakeholder, the international tests also must be performed according to the law. The group agreed that the principles should reflect a Canadian approach first, keeping in mind an international perspective.

Plenary Session: Report Back

The first group emphasized the importance of pricing, which was the principal discussion point of this breakout session. Participants also had many concerns over what is good in theory and what is truly applicable. A participant said that, concerning value-based pricing, variations are more a burden than an advantage.

The second group had many similarities with the first. For example, there was agreement that the lowest reasonable price was important, with the emphasis on "reasonable," which was given high importance. The authority of the provinces was also discussed. The question of accessibility and affordability was brought into a seniors' perspective.

That group also agreed that CPI is the best benchmark tool to use for assessment. As in the first group, there were some questions about the comparison of countries and their relevance. This group determined that once a price has been set, price stability should not be a mandate of the Board.

The third group perceived that accessibility was important and that it should take into account Canada's policy on accessibility and transparency. This group understood consistency in terms of maintaining transparency and credibility.

The group also had concerns about the ideas of subjectivity and reasonable pricing. They felt these terms were vague and should be better defined, with the idea in mind that the Board's mandate is non-excessive pricing, not lowest pricing. International parity shoud be an indicator, according to this group.

The third group was the first to mention returns on investment. This would help define "excessive" in a much less subjective manner, making it more of an internationally comparative approach and a business approach between countries that have different means of calculating. This group also innovated by deciding not to prioritise any criteria over the other. These are not weighted criteria and should not be given priority over one another.

One participant asked the presenter to clarify the business approach and whether this group believed that this should really be the role of the Board. The participant said she could understand that some stakeholders want a return on their investment, but it seemed that it is built into the Board's mandate.

A participant from the third group responded. She said that in 1987, this was a non-competitive marketplace, and innovative drugs were coming into this country. It seems to have changed over the years. Rewarding by returns on investment renders a marketplace too protective. This participant felt that Canada had a balance in isolation. "What does it mean to be Canadian, and is it only how we compare to other countries?" concluded this participant.

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

Group 1

A participant stated that he did not agree with categories. There should be one definition of excessive. The participant noted that categories 1 and 2 are problematic when there are no comparator drugs in the Canadian environment. Also, in terms of pain relief on a patient level, a Category 2 or a Category 3 will vary.

One definition of excessive would eliminate the need for categories altogether. Categories result in "splitting hairs" and differ by patient.

It was noted that Viagra, which is taken orally, is safer than previous methods of injecting for erectile difficulty but is in Category 3.

A participant said established tests are associated with categories. “If comparators can be established, then one can go right into tests. If the Human Drug Advisory Panel (HDAP), assigned to perform scientific reviews and determine the category, could establish comparator drugs and then apply the excessive tests, the need for categories could be eliminated and the process streamlined. We do not see the benefit of categories, which leave too much to interpretation.”

“There are too many gray zones,” stated another participant. “Categories will never be black and white. The HDAP is too small with only five members. More expert input is needed. Ad hoc committees can be formed in areas such as cardiovascular, oncology, and immunology to establish comparator drugs. With respect to Viagra, there are no drug comparisons, only treatment comparisons.”

A scientific body should look at the literature and give recommendations. This group would not be mandated to categorize drugs.

Defining “excessive” would reduce work for the HDAP. The idea is not to give the HDAP more work but to give them a more finite piece of work such as performing an extensive scientific review for CDR reimbursement purposes.

A participant stated that the process was redundant with too many players prolonging accessibility of the end product.

“Lumping no therapeutic value with breakthrough drugs is unconscionable,” noted a participant. The extent to which there is therapeutic advantage depends on the patient. The category takes patient differential into consideration. Side effects are also involved. By grouping substantial improvement, brand new drugs, and brand new medical components, the same drug is not differentiated according to strength and delivery. “Would a drug be priced the same way if it had substantial improvement or if it were in capsule or liquid form?” The participant said this was troublesome, and some differential was needed.

Categorization implies that a drug with high therapeutic value and its breakthrough should be priced differently.

A participant noted that a mechanism other than categories could achieve this objective. For example, if no comparator exists, then one would be free to price differently.

“Category 1 is reasonable for administrative efficiency,” commented a participant. In the absence of comparator treatments on the Canadian market, the basket of comparators provides a reasonable price benchmark for Category 2. This basket is based on those countries with the highest therapeutic value. Pricing for Category 3 signals the intention to support efficient innovation and provides a benchmark for industry allocation of R&D.

“Most Category 3 definitions are priced below the MNE price, which speaks to the fact that the market appears to be doing its job,” observed a participant.

The Board may want to investigate the cost of maintaining or altering current categories and the degree to which current categories are constraining.

A study to look at all products by applying CPI prices would be beneficial.

A PMPRB representative said if the average price is below or at the price ceiling, then it passes. Within that average, some prices may be above, some below. The concern is partly because of Ontario's large population versus the small population base of Atlantic Canada. Bigger provinces may be able to negotiate a better deal because of bulk purchasing. If the average passes, then the Board does not go looking.

A price review by Canadian sub-market was advocated. "Hopefully, no province would be paying above the MNE," commented a participant. "Consumer protection is part of the Board's mandate. Reviews by Canadian sub-market ensure the well-to-do are not subsidizing the not-well-to-do."

A participant noted that most aspects of the process are working. When issues arise they are dealt with case-by-case. Hospitals are paid and are able to negotiate. When the system breaks down, it is because of a heavy administrative problem. The participant voted for maintaining the status quo and for change only if the Board sees a need.

A PMPRB representative advised that the status quo means not looking at variation.

"Excessive price is a national ceiling and should be applied as such," stated a participant. The ceiling and definition should apply equally across Canada.

A participant favouring elimination of categories noted, "It appears, from charts and graphs, the vast majority of customers are receiving a price below the MNE." Excessive price does not appear to be a systemic problem in Canada. Therefore, there is no need to take on the burden of slicing and dicing. Still, there should be a mechanism for customers to request an investigation of excessive price on a case-by-case basis.

A participant in favour of categories supported case-by-case recourse as opposed to a standard procedure to simplify the process.

In presenting an argument against categories, a participant noted that the Board is involved in controlling price and not establishing price. Therefore, categories do not fit into its mandate. "At the end of the day, excessive price is not a pervasive problem in Canada. Provinces talk to each other, Quebec has the best available price approach, and most companies price nationally."

"In the long run," noted a participant, "categories may create more work for the Board. If publishing price actually reduces price, then publish price."

Group 2

One participant suggested first examining the issue of sub-markets and then that of categories. The other participants agreed. For this first participant, there should be no sub-markets. It leaves the door open to some very specific, wide-ranging cases, like a hospital or a province. In reality, neither this participant nor anyone else could give an example to illustrate this case.

One participant agreed, but suggested that it would be worthwhile for the Board to continue conducting investigations to inform the provinces or the various milieux. One participant wondered whether the Board should list the prices across the country. The response was that this was already done to find out the national price.

One participant wanted to support the principle of transparency. Through experience, he had noted that the industry signs confidential agreements related to purchasing volume. Ontario, for example, maintains a secret price, the result of a confidential agreement. That causes a problem for Quebec because it will not pay more than the province that pays the best price. If one province has secret agreements, Quebec cannot apply this principle to its own calculation. The new applications of Bill 102 in Ontario are going to change the rules of the game in a significant way: industries will have to reveal their agreements or they will not appear on the list.

As for categories, there are currently three: categories 1 and 3 permit price comparison at the national level, while only category 2 permits comparison at the international level. Categories 1 and 3 are also involved in product line extensions. In one participant's opinion, the median price is applicable only for category 2.

It seemed difficult to decipher the idea behind this classification. When she studied categories 2 and 3, one participant said she understood the basic idea, which seemed to be value added, unless one supposes that in 1 there is no value added. For this participant, a line extension is no different from a new sustained-release product. This participant specified that in Quebec and Ontario, a sustained-release product cannot be sold for more than a standard-release product.

One participant believed that categorization could reflect benefit, but that did not seem to be the case in all categories. One participant added that these categories were developed 20 years ago; what was being talked about most at that time was anti-inflammatories and their release. He gave the example of prodrugs, which are difficult to categorize. This participant concluded that only a breakthrough could move a product into category 2.

One participant suggested creating categories based on a common continuum (therapeutic advantage, for example); otherwise, only price comparison permits categorization. All participants believed that category 2 is essential, but were of differing opinions regarding categories 1 and 3. Some suggested abolition, others merger.

Since there is no national comparison scale, one participant wondered, what should be done if a Canadian company made a breakthrough and wanted its first market to be Canadian? Another participant responded that the only way to resolve the problem would be to proceed as if there were only four comparison countries: there would have to be a re-assessment when there were satisfactory comparators.

According to one participant, an existing piece of legislation requires comparison on an international level, regardless of the category for which it is recognized.

One participant mentioned the problem encountered when Health Canada gives priority to a medicine but the Board does not place it in category 2. This consistency problem within the government should be examined. One participant remarked, however, that despite Health Canada's approval, it was the Board's findings that were the most probative.

One participant said she was concerned by the fact that being part of category 2 determined whether there were comparison medicines or not. In her opinion, being able to be compared on an international level could become a repercussion and not an advantage. In many participants' opinion, it was difficult to determine what constitutes an innovation.

One participant suggested that category 3 be maintained, but that the fair price for this category be the lower price of the comparison medicines, international or domestic. One participant did not agree: she wanted the wording to mention the median instead of the lower price.

Participants agreed that a categorized medicine must absolutely have a therapeutic effect. One participant reported that a medicine that does not significantly reduce adverse effects is found in category 3.

Participants agreed that calculation of the price must be based on the lower of the following two prices: the median price of the same product on an international level or the median price of Canadian products in the same category.

In conclusion, participants wanted categories 1 and 3 to be grouped together. The discussions on innovation continued. Some examples of novelties and their respective problems were provided. One participant suggested that perhaps one day insulin administered orally would constitute a breakthrough!

Group 3

The current categories represent a methodology with which to avoid problems, and they appropriately class individual drugs, observed one stakeholder. Whether or not they are the best method may be questionable. Concurring, another delegate noted that the existing categories offer a sensible, objective, effective, and reproducible way to establish

excessive price according to specific characteristics. The categories speak to the need to relate price to the therapeutic value of a drug. Most products fall easily into the three categories.

The group discussed how drugs are priced according to their primary indication, thus falling into one of the three categories. However, it becomes "a gray zone" once secondary indications are discovered. Losec's primary indication is to treat Zollinger-Ellison syndrome while it is also now used for gastro-esophageal reflux. This therapeutic "slide" could lead to potential excessive pricing.

The example of Gleevec was given as well. This medicine is reasonably priced for its primary indication, chronic myeloid leukemia (CML), when it is prescribed at a single dose. When, however, it was approved for gastrointestinal stromal tumors (GIST) at twice the dosage, the price became excessive.

The group agreed that the categories were not the issue, but the tests applied to them and their link to the guiding principles were. For example, only Category 2 uses international comparisons. Why not apply those comparisons across categories?

When new indications are discovered for existing drugs, the Board does not re-evaluate them for excessive pricing. Re-evaluations are also not standard for drugs marketed at new concentrations.

One delegate called for greater consistency among the different players that conduct drug reviews (e.g., the CDR, Health Canada). A breakthrough drug should be defined as a breakthrough drug across the board. How can consistency be achieved with a new market entry across multiple evaluation bodies? Expedited reviews are also problematic in that industry claims of a breakthrough drug may not always materialize. However, the submission has been made.

Category 3 is not well liked by pharmaceutical companies who claim it does not sufficiently recognize the real added value of drugs. Could Category 3 be reworked in some way to take their concern into account?

One participant was concerned about the vagueness of the terms "moderate" and "little" improvement in Category 3. Could the category just be called non-breakthrough? Does Category 3, asked another delegate, consist of a range of products including very useful ones with minimal side effects? That depends on the tests applied, replied a group member; it is not simply a case of "lumping" drugs into Category 3.

The group returned to the issue of the tests that are applied to the different categories. The Board has a streamlined ability to review drugs in Category 1, but it is in Category 3 where the volume of work lies and that warrants a variety of tests. In some cases, drugs have tests applied to them that are not applicable. Here, "soft tests" might prove useful.

Most participants agreed that it was better to have the flexibility of different tests than to expand the categories. Fix Category 3 rather than add new ones. Could it be based on straight clinical tests?

The group turned to the question of whether prices should be reviewed in sub-markets of the Canadian market. Currently drug prices reflect the market in its totality. Segmenting the market could be counterproductive. Market segment information is difficult to access: in many cases it is confidential. As it stands, price review is based on published transaction prices, which are readily available. The current formula is likely to cover 95% of the actual transaction price (despite variability), observed one delegate.

It was suggested that perhaps the list price should be the only price consulted. It would set a ceiling. Considerable discussion on the potential use of the list price to determine excessive pricing followed.

- List price accounts for a company's potential return on investment and marketing costs, among other factors.
- The list price is not international; the Canadian list price is uniquely Canadian.
- Inter-provincial variability in price and the effect of Ontario's *Bill 102* could make the use of the list price unfeasible.
- The use of the list price would meet the criteria of the non-excessive price principle in all marketplaces.
- The list price is publicly available.

What happens if two different companies produce the same molecule but one has a higher list price? It was explained that this already happens, and tables that compare list prices are issued quickly. This information is already incorporated into the range of prices looked at by the Board. Companies are very sensitive to this mechanism to protect consumers and are generally compliant.

Could other parties, pharmacists for example, raise the price of a drug? One stakeholder noted that, at least in Alberta, the cost of a drug is based on acquisition costs, not the catalogue price, which takes into account dispensing costs.

Brand manufacturers sell at the Canadian list price with the exception of hospital tenders where there are gaps in list and sale prices. At the retail level, however, there is little variability.

Industry reports their sales transactions (combined for all customer classes) regularly to the Board, which uses those numbers to calculate the ATP. Although some participants raised the possibility of looking at classes or even provinces and regions separately, it was agreed that this would be too complex and the figures for those sub-markets are simply lacking.

A PMPRB representative clarified that the Board can only look at the sales figures that companies provide and has no authority to use other sources (e.g., list prices).

Plenary Session: Report Back

In the first group, there was the notion that if there was one clear definition of what is excessive, it would eliminate the need for categories. Some members of this group felt that perhaps the categories are splitting hairs.

Participants also could not understand the rationale behind the categories. The HDAP could establish the comparators for drugs, which would, according to this group, streamline the process. The participants felt that perhaps the HDAP is too small; it requires more input to expand and get more people involved. In this discussion, the idea that there are too many players in the current system was put forward. The group also felt that since most prices are below the excessive price mark, they are an indication that the market is doing its job and that there is no need for categories.

For those in favour of categories, there was the idea of breakthroughs with no therapeutic value. The categories should also include patient differences. In this group, there was some support for maintaining Category 1 as it is. Category 3 was also deemed important, because it provided a benchmark for effective R&D. However, the participants of this group asked that a cost-benefit analysis be done on categories to show their real effect.

This group also discussed markets. In favour of sub-markets, participants mentioned consumer protection, a national ceiling for excessive pricing, national support at an individual level, a complaints-driven system, and Board reporting.

Participants against sub-markets said the status quo is working, and the Board should only refer to sub-markets in exceptional cases. They also demanded that the Board's burden not be increased by a case-by-case mechanism. Among other things, participants mentioned that most companies already regulate using national prices.

The second group recognized the need for categories, if only to classify drug molecules according to fixed and reproducible criteria. However, it had concerns over gray areas regarding principal and multiple indications. Participants asked how to link with common principles and how to achieve consistency between the consulting bodies in case of fast-track reviews. They felt there was a need for harmonization between government bodies when evaluating new market entries. Some members also felt that Category 3 did not reflect any added value, which impairs the real value of those products. It seems that many drugs fall into Category 3, where the Board does most of its work. Participants asked if there is some need to work on the testing mechanisms.

There were numerous discussions about sub-markets and pricing issues in the second group. For some people, it was, "If it ain't broke, don't try to fix it." Participants suggested the use of listed and manufactured prices. People also had some concerns about the legal issues surrounding sub-markets. Finally, participants mentioned the secrecy issues impeding transparent pricing.

The last group innovated by dealing with sub-markets first. It felt it was inappropriate to revise prices according to sub-markets, except on rare occasions. However, none of the participants could give an example of what those rare occasions would be. Participants also mentioned Ontario's *Bill 102* and the need for transparency. As with other groups, this one felt it was necessary to put an end to secret agreements.

The participants of this group recommended keeping Category 2 and merging Category 1 with Category 3. They also indicated that drugs showing some improvement that have new therapeutic value but are not recognized as breakthrough should be classified as Category 3.

Presentation 3: Re-benching of an Introductory Price

Brigitte Joly 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) at first Notice of Compliance (NOC), or if the drug was sold in less than five comparator countries when the price was reviewed. Other possible reasons to re-bench could include instances when a drug is granted a second indication, or if there is any change in the primary indication for a drug.

Joly outlined potential "pros" of re-benching, including reducing market disruption and encouraging compassionate pricing, as well as potential "cons," including price unpredictability or delisting of drugs on public formularies.

Regarding this presentation, a participant asked what was meant by "compassionate" and asked for clarification about the SAP. Joly answered by saying the Board will only review prices on products that are sold. If they are given through the SAP, there is no financial transaction, and, thus, the Board will not evaluate it. A participant felt that there is no compassion in oncology drugs.

Breakout Session 3: Discussion of Re-benching

Group 1

The breakout session on re-benching considered the following questions:

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

A participant stated that marketplace dynamics prevent re-benching of Category 3.

"What if a drug initially classified as Category 2 becomes a new application?" asked a participant. "If there is no therapeutic value, then why should a drug be re-benched? Historically, the price is always higher."

"Even if a higher benchmark was allowed and a new use found for a Category 3, it is hard to see a formulary or payer at a higher price," observed another participant. "Re-benching is not worth doing. It adds to existing regulation and gets into price-setting." If a drug was launched for a rare disorder and suddenly its use widens, a company would have to decide how to sell the drug. If the objective was a wider use, then the price should be lowered. Overall, prices are stable, responsible, 8% below the median, and well controlled.

There could be circumstances where a product comes on the marketplace initially as a Category 2 and a wider use is discovered later through long-term studies, providing a breakthrough quality. It is useful to have a mechanism in place for re-categorization.

A PMPRB representative noted that the Guidelines currently allow for only two opportunities for re-benching: if the product is sold in fewer than five countries and if the product is sold under the SAP at first NOC. There is no example of a price review under any other circumstance.

Once a product's price has been established in the market, provincial governments will not increase the price even if the product may have a breakthrough property.

There is only one way to re-categorize, and that is downward. Governments will drop the price.

A participant against re-benching presented the example of Revatio, the same drug as Viagra, used for pulmonary arterial hypertension. If not priced at the same level as Viagra, no one would use Revatio. To develop a new drug in many cases may not be worth the effort.

Another participant discussed the case of Gleevec, an oncology breakthrough drug developed for a specific form of leukemia. Taken orally on an outpatient basis, it improves quality of life. Gleevec came on the market benchmarked at $30,000–$40,000 and subsequently was found effective in another malignancy where data was not previously available. For every leukemia patient, two patients will have this other condition. The drug could be categorized as Category 2, but there are fewer comparators. Dosing for the tumour is two to three times that of leukemia, costing $100. If Gleevec had come on the market for the tumour before leukemia, it would have been priced differently based on different comparators.

"If the Board had the capacity to re-bench, on what basis would re-benching occur?" asked a participant. The NOC could be used, but what if the application was not approved?

One participant considered whether the absence of re-benching would discourage innovation. “It’s up to the pharmaceutical companies, even on products where patents are already in place. Research is in their interest for business, which is the name of the game.” The marketplace ensures that pricing does not become excessive.

Canada is a very small part of the universe and will not impede innovation.

“The Board is held only to pricing factors in the *Act*,” noted a PMPRB representative. “How Guidelines are applied is within the Board’s control according to consultation with stakeholders. Anything is possible as long as it does not mean changing the *Act*.”

“Does re-benching mean changing the benchmark price up or down?” asked a participant. If the patentee can show two or more uses of a drug that are advantageous to the consumer and there is no other comparator drug for that ailment, re-benching could occur.

A participant said the drug should be re-categorized.

“It would amount to the same thing for us,” stated a PMPRB representative. “New categories are only relevant in the introductory period. The price can go up by the CPI, but if the drug has a new set of evidence and is now a Category 2, the drug is effectively reviewed from scratch. This is the notion of re-benching.”

The PMPRB representative explained that the establishment of a benchmark price following the first sale of the product in Canada. The only way for the benchmark price to be reconsidered is for the patentee to press for a hearing before the Board. The Guidelines are a way to make compliance voluntary so the Board is not in hearings all the time.

In support of re-benching, a scenario was presented whereby the patentee requests a new NOC to market a drug based on a new application. The product already has a DIN and therefore would not go back to the Board for reassessment. Criteria for re-benching include R&D and clinical trials.

Given that re-benching may cause a price reduction, it may prove a disincentive to the Board’s R&D mandate to develop new drugs and research new uses, thereby negatively impacting accessibility.

“Are we suggesting that lowering prices is a bad thing?” queried a participant. “We previously talked about consumer protection, affordability, and accessibility. Having proven a new therapeutic value, we should try to get the medication on the market.”

Another participant stated that companies evaluate the risks of going for a new NOC. If currently a Category 3 drug and the comparator for Category 2 bring the price down, the company will not seek that NOC due to the risk of a lower price to the bottom line. If the population for a new indication is small or if the population is large and there is no other

competitive agent out there, then a lower price may be attractive. “If NOC is a trigger, then the ball is left in the patentee’s court.”

“To get an NOC is an investment in trials,” commented one participant. “One needs to be conscious of the consequences and impact.” Even if the patentee has a drug for a rare disease at a high price, if not prepared to get value for a new disease at a lower price, then there is a disincentive for R&D.

Group 2

The facilitator suggested participants in this group share their points of view for or against re-benching.

One participant expressed her disagreement with the idea of a re-benching. Since the price is approved, a regulation allowing re-benchingcreates a never-ending approval system. In a price control system, if you factor in the time the Board takes to hand down a decision and add to that the time needed for reviews, the management system becomes much more cumbersome. The Board cannot even review a price request as long as the medicine is not patented. One participant felt that doing business without knowing market conditions was impossible.

Generally speaking, participants believed that the Board did not have the resources needed to do periodic reviews, except in a small number of situations or when new approved indications would change market conditions. Re-benchingopportunities must be limited. One participant concluded that taxpayer dollars must not be spent that way.

Participants in favour of re-benchingbelieved it is necessary when new indications are approved that significantly modify the use profile. Furthermore, one of the participants did not believe that two indications could have different prices.

One participant gave the example of a drug used in cases of lymphoma, now approved for cases of rheumatoid arthritis. If there are more users, the price should be reviewed. A completely different indication should allow another re-benchingto be requested. A decision could thus be quashed because the primary indication reduces symptoms. Given that this drug was a matter of survival in leukemia cases and that now it only treats the symptoms of arthritis, the user profile has changed.

One participant mentioned that companies might first put a product with certain indications on the market and withhold the request for approval for other, less innovative indications to avoid the imposition of a price that is too low. On the other hand, one participant wondered whether or not a company would be recompensed in the event an innovative use were discovered for a medicine recognized for providing lesser therapeutic effects. The participant agreed that it was a rather rare exception.

One participant cited the example of a product that recaptured a market after being abandoned by another company without first having obtained an official indication. In

such a case, there is no alternative. In fact, it is very costly to obtain a new indication without the price being adjusted. One participant cited the example of Viagra, used in the case of pulmonary hypertension.

One participant indicated that re-benchinggenerally meant a price reduction. If the Board sets off in this one direction and distances itself from its mandate of determining instances of excessive prices, how long could the Board maintain this objective? By suggesting certain changes, this participant believed that this would push the Board in a specific direction, which would distance it from its primary mandate. In reality, this was not an argument for not doing it, but a concern.

The facilitator asked the group to clarify what a significant change in use signified. For example, what is the impact of a medicine that moves from category 2 to category 1 or that is placed for a second time in the same category? The applicability of these principles left participants perplexed. What is the impact on the comparator if the value of a medicine does not allow it to gain access to category 2?

One participant wondered if a medicine has two prices, one for a certain indication and then a second for an innovative indication, how would one choose the lowest reasonable price? For one participant, this runs the risk of becoming fairly complex. The concept is interesting, though obscure, unless the categories are abolished.

If there were an ongoing price review, the fact that the Board cannot review a price before the patent is approved would confirm the cumbersome nature of the process. One principle of the federal regulation is to be as simple as possible. In this case, it seemed obvious to this participant that the proposed process was far from simple. One participant added that a new indication used by 98% of the medicine's users must be taken into consideration during a possible re-benching.

Regarding price variations, one participant indicated that hospital groups wanted to know the fixed price of a medicine over a period of three to five years. She added, however, that a clause could stipulate that the price must be reviewed when the Canadian comparator changed.

One participant added that the applications that lead to a review must be approved by Health Canada. Medicines that are not used according to directions should not be subject to a review.

One participant explained that medicine prices should better reflect the value assigned to the greatest use. However, that is known only once the medicine has been put on the market, not during the introductory period. One participant warned that before making this change, one must ensure that the number of problem cases justified the re-benching. One participant mentioned that this should be an exceptional measure.

Group 3

Some members of the group supported the idea of regular re-benching. Why? The initial price of a drug may be based on a production capacity that is no longer valid (e.g., first in the thousands, now in the millions). The price in other countries also may have fallen, and Canada should follow suit.

If 10 doses of a medication are sold at $100 one year, but three years later 10 million doses are sold at the same price, is there automatic re-benching? Currently this is not the case. Similarly, there is no re-benching when a company's cost of production rises. If economies of scale were taken into account, drug prices could increase or decrease. Re-benching would allow for price adjustment in a changing environment (i.e., changing market conditions).

Re-benching also would be appropriate to reflect changing sales volume. When a company earns greater profits than forecasted, a drug price may become excessive. In contrast, a company might have forecasted greater sales volume but is selling considerably less, and a higher price is more realistic.

Methotrexate provides an example of why re-benching is needed. Cheap for one of its indications, rheumatic arthritis, it was then packaged differently and sold much more expensively for another indication: cancer.

It was suggested that NOCs provide a natural re-benching opportunity. When a certain drug is first available, it operates under a specific NOC. Within that drug's cycle, however, another NOC can be approved and granted.

One stakeholder cautioned that, from an industry perspective, NOC submissions are business decisions. There is no requirement that stipulates filing for another NOC with new secondary drug indications. It was pointed out, however, that new indications have to be filed with the Board.

One delegate indicated that re-benching mainly applies to Category 2, a category that already needs better streamlining. Category 2 is home to the highest priced drugs that are used as benchmarks for others. Drugs in this category often have one or few indications upon market launch, but new ones are discovered with time offering an opportunity for re-benching.

Clearly, drugs are not breakthrough for the entire period of their patent. As the indications for a once-breakthrough drug accumulate, it likely will move to Category 3. Category transition could be a time to re-bench.

How does the Board evaluate submissions for two identical drugs manufactured by two different companies that are received within a short period of each other? Submissions made within six months of each other are treated as separate. Beyond that time frame they could serve as comparator drugs to each other.

Another delegate wondered who can ask for a price review. Does only the Board have that prerogative, or may consumer groups and individuals ask as well? It was suggested that there should be an automatic revision annually or every three years or upon demand from interest groups. One delegate added that a complaint commission could be established to look at re-benching when there is a significant demand for it.

Another idea was that if a medication goes through all the Board's criteria and a price variation of 20%–25% is found, then re-benching should occur (i.e., a cut-off number should be pre-determined). Should the price change in comparator countries, then automatic re-benching should also occur.

Re-benching also should be considered when there is high demand for a drug but limited supply under catastrophic conditions (e.g., a pandemic). Should the public still be paying the benchmark price under such circumstances?

Could end of patent be a point for re-benching? It was noted that at patent end, market forces (e.g., competition from generic drugs) would act to regulate the price. On the other hand, new patents on an existing patented drug could offer a re-benching opportunity. It was pointed out that with new formulation patents, drug price is re-assessed.

Currently the Board only looks at the initial patent regardless of how many are subsequently issued for that product. Subsequent patents extend the life of the patent and patent protection. A new patent, however, does not mean the price is automatically re-evaluated. It was argued that subsequent patent submissions could provide natural entry points for price re-evaluation.

What information would be needed to re-bench with subsequent patents? The company would provide the same, albeit current, information as it did for the initial patent.

The issue of patent extension as a result of court delays was raised (e.g., doxyrubicin). The pricing of the drug is protected during such legal wrangling for up to two years. Since this means that the competition has to wait to launch its product, the Canadian public is penalized by having to pay more.

It was suggested that even though the Board has no jurisdiction over the legal aspects, it could ask the company to pay back an excessive price paid during a court delay. Does this fall under the Board's mandate, or is such a situation best handled by another regulator or even a class action suit?

Another stakeholder addressed the issue of off-label use. Is the drug being used for the specified indication? For example, after a few years of commercialization of a Category 2 drug that was approved for a single type of cancer, doctors started to use it to treat other cancer types. Is this within the Board's mandate or another authority?

Re-benching does run the risk of a price increase. For example, the longer a drug is on the market, the more impact it could demonstrate and gain in value, and, therefore, it would require re-benching.

With the existing drug categories, there is the risk that companies will consider more closely which indication they will invest in (i.e., only lucrative ones) and file with the Board. Reduced investment and research into new drug indications by companies may have negative implications for public health.

Procarbazine is considered a must-have drug. Accordingly, it was allowed on the market at a 500% price increase. It became price patented and, therefore, was automatically re-benched. A PMPRB representative reiterated that the Board has no jurisdiction over non-patented drugs. In that case, the market is likely to regulate the price.

The group agreed on the need for greater clarity and transparency around re-benching. As it is, re-benching can be done on a case-by-case basis. Some delegates noted that while they could easily point to drugs on the market that need re-benching, "it needs to be fair," in an all-or-nothing approach.

Plenary Session: Report Back

In the final plenary session, groups reported back on re-benching, an evaluation was conducted, and parting comments were made by the Chair of the PMPRB.

The first group supported a re-benching mechanism due to changing market conditions and contexts. Need and precedent were already established given the lack of international comparators and volume of products.

Re-benching would involve mainly Category 2 products at end of patent when they are no longer under Board jurisdiction.

Re-benching could be an automatic process or a statutory process occurring every three years, for example. Re-benching could occur by request of a group, such as manufacturers, when a price change is obvious or when a price changes in other countries. In terms of automatic re-benching, a trigger spread should be determined.

Numerous situations justifying re-benching were identified including

- The possibility of using a certain drug for a new purpose based on high or urgent demand, such as the bird flu;
- When the same drug is sold at different prices;
- When different packages are developed for different treatments;
- When a new patent is granted to extend an existing patent;
- When there is a need to reintroduce an orphan drug as the drug is no longer available in Canada.

The same indications required for regular evaluation would apply for re-benching based on up-to-date and accurate changes to the environment.

The current mechanism is not efficient enough to study off-label use. It is not clear who should be controlling this mechanism.

It was suggested that a study group analyze complaints from consumers. When the level of complaints reaches a significant demand or there is a trend, a committee would recommend re-benching.

A reference price was not supported given the risk of creating an environment where prices would increase to industry's advantage.

Reasons against re-benching included the burden on the Board, the added work involved, and loss of clarity and transparency in the process.

An issue for further consideration concerns legal challenges that appear when there is a legal extension at end of patent. While the legal process is occurring, prices are still high.

The second group agreed that the marketplace is intolerant to any price increases. Therefore, any effort to use re-benching as a means to reduce prices after the first re-benching would be seen as price-setting.

The possibility that re-benching could cause a price reduction presents a disincentive for R&D and for offshore manufacturers to export to Canada, thereby impacting accessibility.

The group did not determine any new reasons for re-benching. However, it presented a case for re-benching when a new NOC is requested for a new application of the same drug. A request for a new NOC from the patentee or manufacturer would trigger re-benching, requiring R&D and clinical trials.

A participant responded to the assertion that the marketplace is intolerant to price increases: "This is not founded on any studies. In different cases, there may be an allocation for prices to rise."

The third group argued against re-benching at the front end due to provincial regulations, which can multiply the number of reviews, creating a heavy, time-consuming, and costly process. In any event, the Board cannot re-bench.

Market knowledge must be extensive before thinking about remarketing a product. Concrete, specific evidence about projected use must be provided. The group advocated re-benching only in rare situations such as a new application approved by Health Canada. Companies should be discouraged from marketing a drug for a specific use and then re-marketing it for another use for which there is no breakthrough.

Re-benching will push prices down. Upward re-benching would entail much resistance.

The consequences of a change in category resulting from re-benching were considered too risky and complicated. It is more important to be equitable than to prevent re-benching based on market conditions. The group turned down re-benching.

Evaluation of Session

An evaluation was conducted to learn what worked well and not so well, and to make improvements for the next three sessions. Participants' comments follow.

Small, interactive groups provided "supreme benefit," stimulating discussion, and clarification of ideas. Focusing on specific questions was helpful for discussion. A different group for each question was recommended. Mixed groups ensured that one view was not predominant.

A strong, common understanding of the purpose of the Board and the conference was lacking. Clarifying the Board's dual mandate of consumer protection and industrial development would help shape context at the beginning and may help with feedback. Participants requested a one-page reference sheet about the Board's price evaluation along with real-life examples.

Board presentations were clear and concise. Expectations of the Board were generally very clear. Board member participation during sessions was helpful.

Participants were respectful and listened carefully. There were good facilitators. Note-taking was endorsed and note-takers were commended. The conference was extremely well organized.

Benoit visited the groups throughout the day and remarked on the level of discussion. "No one was shy or uncomfortable. Ideas and opinions were expressed freely and openly, which is what we wanted."

Next Steps and Parting Message

The Board must decide on changes, Benoit told the group. A report on each of the stakeholder consultations will be circulated, and a Board meeting will be held in December to decide on the next steps in this Guideline review process.

Benoit closed by congratulating the meeting's organizers. "I have been very impressed with the way the whole consultation process came about," he said. "It was planned with

military precision. The staff worked very hard at this." He thanked participants for attending.