Environmental Scan and Performance Evaluation for the Patented Medicine Prices Review Board

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Executive Summary

In 2001 the Patented Medicine Prices Review Board (PMPRB) decided to update its Environmental Scan and to evaluate the Consultation and Communications policies. Therefore, through the results of a tendering process, BDO Dunwoody & Associates Ltd. (BDO) was requested to conduct an Environmental Scan and a Performance Evaluation of the Consultation and Communications Policies through direct consultation with various stakeholder groups.

With input and assistance from the PMPRB management team, BDO developed an interview guide that was used to facilitate the interviews. There were two distinct sections to the interview guide. The first section contained questions specifically geared to the environmental scan and the second section contained questions specifically related to determining the effectiveness of the PMPRB’s consultation and communications policies and activities.

The PMPRB ensured that interviewees were selected from the following stakeholder groups:

- Federal Government
- Pharmaceutical Industry
- Health Professional Associations
- Consumers/Seniors Associations
- Patient Advocacy Groups
- Provinces (Health Ministries)
- Private Insurers
- Academics
- Human Drug Advisory Panel

With the list of confirmed interviewees provided by the PMPRB, BDO scheduled and conducted the interviews during the months of August and September. The interviews were conducted via telephone or in person depending on the individual’s location and availability.

The following is an overview of the results of the environmental scan and the evaluation of the consultation and communications policies.

Environmental Scan

The objective of the environmental scan was to identify the major issues facing the pharmaceutical sector over the next three to five years. The overall results of the environmental scan focused on four main areas. The issues raised focus on issues in the patented medicines pharmaceutical industry that may have a direct impact on the PMPRB. Some of the responses generated from the questionnaire were specific to each individual stakeholder’s group. There were a number of issues and concerns identified, however the following four were the most prevalent and are listed in the order of importance based on the frequency of responses.

1. Increasing prices of drugs in Canada

   The majority of stakeholders, other than the pharmaceutical industry, feel that the issue of increasing prices of drugs will be a continuous concern. Although the stakeholders were aware that the PMPRB’s mandate only covers the prices being charged by the manufacturer for patented drugs they felt that the issue of the price of drugs in general was of major concern. The stakeholders indicated that the rising price of drugs is increasing the overall cost of health care for Canadians. This increased health care cost impacts the availability of medications and treatments to those who really require it, especially with our aging population.

   There were various suggestions as to what actions the PMPRB could pursue. A common suggestion for improvement was that the PMPRB should consider the economic value of drugs in relationship to the
increased benefit, (effectiveness) especially at the beginning of the price review process. The pharmaceutical industry suggested price review methods should consider a greater array of elements such as the Human Development Index (HDI)\(^1\).

2. **Balancing drug prices and research and development spending**
   A major issue that the stakeholders felt existed is the need to balance price regulation of drugs and the need for research and development of new drugs and treatments in Canada.

   It was recommended that:
   - The PMPRB consider the impact on the extent of research and development when reviewing prices.
   - The pharmaceutical industry be more involved in the review process.
   - The PMPRB stay current on the trends in research and development both nationally and internationally.

3. **New technology associated with medication (genetics, biotechnology etc.)**
   The emergence of new gene therapy and biotechnological drugs will have an impact on the price review process. The concern is that the new costs for the research and development of these drugs and treatments will not be adequately considered when using the current price review structure.

   The PMPRB needs to develop methods to evaluate new drugs and gene therapy medications that recognize the value of the new treatments and the impact that further research and development of these drugs will have on the overall health care available to Canadians.

4. **Transparency of the PMPRB pricing review process**
   Several of the stakeholder groups indicated that they felt the PMPRB needs to be more transparent during and after the price review process in order to increase consumers’ confidence in the process.

   The interviewees recommended that the PMPRB hold more open meetings to communicate and clarify the price review process. It was also recommended that the PMPRB publish all information and statistics, upon completion of the review process for a given drug.

**Review of Consultation and Communications Policies**
The second component of the questionnaire was focused on obtaining feedback and recommendations on the PMPRB’s efforts to consult and communicate with the various stakeholders. The series of seven questions resulted in the emergence of some common themes among the stakeholders.

The brand name industry representatives felt that they have not been well consulted and are not adequately consulted or represented on the Working Group on Price Review Issues. Conversely, most of the other stakeholders felt that the consultations are appropriate and that there is a good diversity of members on the Working Group. The majority of the stakeholders suggested that the PMPRB hold more public meetings and increase its face-to-face meetings with the various individual stakeholders. It was also suggested that the PMPRB involve more, and smaller, organizations in its consultations.

\(^1\)The HDI is an annual report prepared by the United Nations Development Programme that studies the quality of life in many countries. The index uses factors such as life expectancy, adult literacy rate and per capita income to determine the rankings.
In general, communication from the PMPRB seems to have improved over the past few years, although stakeholders feel that there is still room for some improvement. The majority of the interviewees indicated that they used the PMPRB’s website, NEWSletter and annual report frequently. Although they feel these media are very useful, they provided some comments and suggestions for improvement. These suggestions included:

- The website contain more links to other related sites;
- Both the website and the NEWSletter should provide for the solicitation of feedback from the stakeholders; and
- Both the NEWSletter and website should provide more statistical information regarding the price review process and results.
Section One  Introduction

1.1  Background

The Patented Medicine Prices Review Board (PMPRB) is an independent quasi-judicial body created by Parliament in 1987 under the Patent Act. The PMPRB protects consumer interests and contributes to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive.

The PMPRB is responsible for regulating the prices that patentees charge for prescription and non-prescription patented drugs sold in Canada for human and veterinary use. If, after a public hearing, the Board finds that a price is excessive it may order the patentee to reduce the price and take measures to offset any excess revenues it may have received. The PMPRB reviews the “factory-gate” price at which the manufacturer sells the product to wholesalers, hospitals or pharmacies. The PMPRB’s jurisdiction covers patented medicines marketed or distributed under voluntary licences. The PMPRB has no authority to regulate the prices of non-patented drugs, including generic drugs sold under compulsory licences, and does not have jurisdiction over prices charged by wholesalers or retailers nor pharmacists’ professional fees.

In 1995, the PMPRB launched a strategic planning process. As the first step in the process, an environmental scan of the health care sector was performed. The purpose of the scan was to identify the major issues that may affect the PMPRB over the next few years. In addition, feedback was obtained from the PMPRB stakeholders on its perceived performance.

As a result of the environmental scan in 1995, the PMPRB has developed a Strategic Plan. In 1998, the PMPRB released the “Road Map for the Next Decade”, which outlines the results of a year long nation-wide discussion with stakeholders. The stakeholders’ comments, although varied on some of the topics, were all taken seriously and have provided the foundation for the PMPRB’s future course of action with respect to their mandate, jurisdiction and pricing mechanisms. The Road Map contained, along with many other things, a newly developed Consultation Policy.

The Consultation Policy was designed to:

- Facilitate input and feedback from stakeholders and the public on the PMPRB’s activities;
- Ensure that the PMPRB is able to consider the views of all stakeholders when making policy decisions; and;
- Facilitate an on-going exchange of information and feedback among the PMPRB, its stakeholders and the public.

In 1999, the PMPRB approved a revised Communications Policy. The Communications Policy was designed to reflect the concept of transparency and accountability espoused by the PMPRB and the overall objective was to identify issues of interest to stakeholders and to communicate information between the PMPRB and its stakeholders.

Through the results of a tendering process, BDO Dunwoody & Associates Ltd. (BDO) was requested to conduct an Environmental Scan and a Performance Evaluation of the Consultation and Communications Policies for the PMPRB through direct consultation with various stakeholder groups.
With input and assistance from the PMPRB Management team, BDO developed an interview guide (see Appendix 1) that was used to facilitate the interviews. There were two distinct sections to the interview guide. The first section contained questions specifically geared to the environmental scan and the second section contained questions specifically related to determining the effectiveness of the PMPRB’s consultation and communications policies and activities. This interview guide was sent to the selected interviewees, in advance of the interviews, by the PMPRB along with a request that they participate in the project. The PMPRB followed up with phone calls to each potential interviewee to confirm their willingness to participate.

The PMPRB management team selected the interviewees based on the following criteria:

- The starting point was the list of stakeholders/organizations consulted during the 1995 external environmental scan. This criterion was established to facilitate the monitoring of any changes in that particular group’s perception of the PMPRB and the issues relating to the industry.
- The stakeholder/organization had knowledge of the pharmaceutical environment.
- The stakeholder/organization has had interaction with the PMPRB consultation and communications policies.
- The stakeholder/organization has a breadth of experience in the field.

The PMPRB also ensured that each major stakeholder group identified in Appendix 1 was consulted.

With the list of confirmed interviewees provided by the PMPRB, BDO scheduled and conducted the interviews during the months of August and September. The interviews were conducted via telephone or in person depending on the individual’s location and availability.

The level of participation from each interviewee varied from very enthusiastic commentary to very short and quick responses. Some interviewees felt that they were not knowledgeable in certain areas and felt that they would not be able to add anything of value and therefore chose not to answer some of the questions. Other respondents perceived that their stakeholder group was not significantly affected by the PMPRB and therefore were hesitant to answer some of the questions.

1.2 Objectives

The objectives of this project were three-fold:

- To conduct an environmental scan, through the analysis of the PMPRB’s working environment and consultation with the PMPRB’s stakeholders, to identify and analyze the issues that may impact the PMPRB over the next three to five years.
- To evaluate the effectiveness of the Consultation Policy, included as an attachment to the Road Map, released in 1998, and consultation activities undertaken by the PMPRB since the parliamentary review of the pharmaceutical provisions of the patent legislation in 1997.
- To evaluate the effectiveness of the PMPRB’s Communications Policy to ensure that stakeholders understand the organization’s role and responsibilities.
1.3 Scope

As outlined in the Request For Proposal’s Statement of Work, BDO:

- Conducted a review of the PMPRB literature;
- Developed an interview guide which was discussed and approved by the PMPRB management;
- Conducted interviews with stakeholders in the official language of their choice. The list of stakeholders to be interviewed was compiled with the input of the PMPRB management; and
- Presented draft and final reports to the PMPRB’s Management Committee and the Board.

Scope Limitation

The environmental scan consisted of twenty-six planned interviews with twenty-three participants who actually participated. The individuals in the various stakeholder groups to be interviewed was determined by the PMPRB and provided to BDO.

The results reported are based on the compilation of the responses provided by the participants.
2 Environment Scan

2.1 Environmental Scan

Environmental scanning involves understanding the changing external environment that may impact an organization. Conducting the scan of the PMPRB’s environment identified issues, forecasted the future direction of them and assessed their impact on the PMPRB.

The goal of the environmental scan was to alert decision-makers to potentially significant external changes before they occur in order to allow sufficient lead-time to react. Consequently, the scope of the environmental scan was quite broad.

There are a number of different environments to be considered when conducting the scan. These environments include:

- Clients or recipients of the product or service (in this case the product is the review of the price of patented medicines and the remedial action);
- Political (legislative and regulatory);
- Social (demographics);
- Technological (science and research); and
- Economic.

In the case of the PMPRB, the consortium of stakeholders represents each of the aforementioned environments and was the target audience for our project. The stakeholder groups for the PMPRB are listed in Appendix 1.

Continuous scanning is necessary if decision-makers are to understand, anticipate and respond to the threats and opportunities posed by changes in the external environment. It was important that the PMPRB’s decision-makers participate in this process. Through participation, they develop a shared understanding of high priority issues and a view of the dynamics of the changing environment.

The objectives of the environmental scan were to:

- Ensure the PMPRB’s understanding of stakeholder issues and concerns.
- Identify major issues in the pharmaceutical and health-care sectors.
- Provide feedback to the PMPRB from its stakeholders.

With a view to the future of the PMPRB over the next three to five years, the stakeholder groups were asked to identify what they perceived would be the major challenges or issues, nationally and internationally, facing the PMPRB. The stakeholder groups were then asked to rank the issues and challenges identified according to their importance to their organization. In addition, interviewees were asked to provide suggestions as to how the PMPRB might address each of the identified challenges.

The responses generated from the questionnaire that have an impact on the PMPRB were specific to each individual stakeholder’s group.
In summarizing the results, four main issues emerged from the environmental scan:

1. **Increasing prices/costs of drugs in Canada**
   The majority of stakeholders, other than the pharmaceutical industry, feel that the issue of increasing prices of drugs will be a continuous concern. Although the stakeholders were aware that the PMPRB’s mandate only covers the prices being charged by the manufacturer for patented drugs, they felt that the issue of the price of drugs in general was of major concern. The stakeholders indicated that the rising price of drugs is increasing the overall cost of health care for Canadians. This increased health care cost impacts the availability of medications and treatments to those who really require it, especially with our aging population. They felt that there will be increasing pressures on the PMPRB to keep prices down even though there is some understanding that the industry needs to make a profit in order to have the financial ability, and incentive, to continue to perform research and development in Canada.

   There were various suggestions as to what actions the PMPRB could pursue. A common suggestion for improvement was that the PMPRB should consider the economic value “what is the real value of the drug entering the market” in relationship to the increased benefit, (effectiveness) especially at the beginning of the price review process. It was also suggested that the PMPRB develop new pricing methodologies, and that various stakeholders should be directly involved in the price review of drugs. The pharmaceutical industry felt that the PMPRB’s price review methods should include a greater array of elements than it currently does, such as the Human Development Index (HDI).^2^

2. **Balancing drug prices and research and development spending**
   A major issue that the stakeholders felt existed is the need to balance price regulation of drugs and the need for research and development of new drugs and treatments in Canada. As the pharmaceutical industry indicated, “promoting research and development is difficult when product prices are regulated... Too much emphasis is placed on price regulation and not enough on research and development.” It was felt by some stakeholders that Canada must be able to compete on a global scale and this can only be accomplished when a balance is achieved.

   It was recommended that the PMPRB consider the impact of forfeiting research and development expenditures in Canada when reviewing prices. The PMPRB must ensure that regulations are in place to enable a constant balance between drug prices and research and development. The pharmaceutical industry suggested that the PMPRB should involve them more in the review process. The PMPRB should remain current on the trends in research and development initiatives both nationally and internationally. As one interviewee indicated, there is an underlying plan in Europe to draw all the research and development away from other countries—this would be detrimental to the Canadian pharmaceutical industry. Some stakeholders stated that the PMPRB must always consider the impact of the loss of research and development activities in Canada when regulating prices.

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^2^ (The HDI is an annual report prepared by the United Nations Development Programme that studies the quality of life in many countries. The index uses factors such as life expectancy, adult literacy rate and per capita income to determine the rankings.)
3. **New technology associated with medication (genetics, biotechnology etc.)**
The emergence of new gene therapy and biotechnological drugs will have an impact on the price review process. The concern is that the new costs for research and development of these drugs and treatments will not be adequately considered when using the current price review structure. This could result in a lower price, which will cause a decrease in research and development.

The PMPRB needs to develop methods to evaluate new drugs and gene therapy medications that recognize the value of the new treatments and the impact that further research and development of these drugs will have on the overall health care available to Canadians. A new price review process should consider the following:

- A new category of drugs (i.e. prevention vs. treatment drugs)
- New standards of comparison
- The benefits emanating from the new drugs
- The category established for preventative drugs
- Extended cost considerations relating to this new category of drugs

4. **Transparency of the PMPRB pricing review process**
Several of the stakeholder groups indicated that they felt the PMPRB needs to be more transparent during and after the price review process in order to increase consumers’ confidence in the process.

The stakeholders stated that the PMPRB should be able to answer the question “Why is this drug worth this price?” It was suggested that there needed to be a more analytical and more consistent approach to pricing, as this would lend support to the PMPRB’s decisions. It was strongly recommended that the PMPRB hold more open meetings to communicate and clarify the price review process with stakeholders. It was also recommended that the PMPRB publish all information and statistics used in the price review process for a given drug once the review is complete.

Presented below is a summary of responses to the three questions that formed the basis of the Environmental Scan that were frequently identified by the interviewees:

**Post-Market Surveillance**: Several interviewees suggested that the PMPRB’s mandate be amended to include post-market surveillance of new drugs. Currently, there is no review conducted once patents have been granted and the prices have been established. It was suggested that after a period of time, say 5 years, that a review of the drug should be conducted to see if it has lived up to the claims made at the time the patent was granted and the price was “set” by the PMPRB. The PMPRB should have a method of requiring manufacturers to compensate for failed results. Conditional pricing, for example, would be a possible means of following a drug while it is utilized in the market place.

**Economic Value**: Demonstrating the “cost effectiveness” (the rising cost of drugs to consumers (i.e. the actual value of new drugs)) of a new drug was identified as a major challenge facing the PMPRB. It was suggested that the PMPRB review the economic value of a new drug when regulating the price. The economic value should be considered at the commencement of the process. Determining the economic value would involve extensive analysis. It was suggested that by working closely with Health Canada and maintaining clear roles and responsibilities between the PMPRB and the Department, the price review process could better account for a drug’s economic value.
Other issues identified include:

- Approval time for new drugs - by harmonizing the approval of medications (nationally and internationally), the return on investment will be recovered sooner, thus promoting additional research and development activity.

- Market globalization - the disparity between the Canadian and the US pricing systems will put tremendous pressure on the Canadian government. This challenge may be addressed by monitoring the American prices and cross-border purchasing trends.

- Globalization and two-tiered economies (developed vs. under-developed countries) will impact drug prices by allowing the undeveloped countries to obtain the drugs at a lower price compared to that of the developed countries. This will possibly reduce revenues and as a consequence reduce research and development levels. To counteract this potential challenge, the PMPRB should gather more international information to update their pricing methods. By placing more emphasis on international pricing and promoting investment in Canadian research and development, the negative impacts of globalization will be reduced.

- Constantly changing government policies have an influence on drug prices, which, in turn, affect insurance coverage.

- Consideration of the effectiveness of the drugs (i.e. the health benefit) and not solely the price is required.
3.1 Consultation and Communications Policies

The Consultation Policy is designed to reflect the values of transparency and public accountability and to encourage and facilitate input from all stakeholders. The objectives of the Consultation Policy are to:

- Facilitate input and feedback from stakeholders and the public on the PMPRB’s activities;
- Ensure that the PMPRB is able to consider the views of all stakeholders when making policy decisions; and
- Facilitate an on-going exchange of information and feedback among the PMPRB, its stakeholders and the public.

The report of the Standing Committee on Industry, released in 1997 following its review of the pharmaceutical provisions of the Patent Act, underscored the concern of Canadians about the cost of drugs and its impact on the healthcare system. The report also touched on a number of key areas directly affecting the role and mandate of the PMPRB. One of the recommendations made by the Standing Committee was that the PMPRB should consult with stakeholders to assess its current statistical reporting, and to determine what other information might be gathered and shared with the public.

The brand name industry representatives felt that they have not been well consulted and are not adequately represented on the Working Group on Price Review Issues. Conversely, most of the other non-industry stakeholders felt that the consultations were appropriate and that there is a good diversity of members on the Working Group. The majority of the stakeholders suggested that the PMPRB hold more public meetings and increase the face-to-face meetings with the various individual stakeholders. It was also suggested that the PMPRB involve more, and smaller, organizations in their consultations.

Communications Policy

The objective of this section was to evaluate the effectiveness of the PMPRB’s external Communications Policy to ensure that stakeholders understand the PMPRB’s role and responsibilities. The Communications Policy was designed to reflect the concept of transparency and public accountability espoused by the PMPRB. Effective communications are fundamental to the PMPRB’s success in explaining its mandate.

The objectives of the Communications Policy are to:

- Communicate information on patented drug prices and R&D expenditures by patentees;
- Inform stakeholders about the PMPRB’s role within the healthcare environment;
- Identify and address issues of interest to stakeholders that are relevant to the mandate and operations of the PMPRB; and
- Identify and respond to the information needs of interested parties and the media.
In general, communication from the PMPRB seems to have improved over the past few years, although stakeholders felt that there is still room for some improvement. The majority of the interviewees indicated that they used the PMPRB’s website, NEWSletter and annual report frequently. Although they felt these media are very useful, they provided some comments and suggestions for improvement. These suggestions included:

- The website contain more links to other related sites;
- Both the website and the NEWSletter should provide for the solicitation of feedback from the stakeholders; and
- Both the NEWSletter and website should provide more statistical information regarding the price review process and results.

Presented below is a summary of responses to the seven questions that formed the basis of the Evaluation of the Consultation and Communications Policies that were frequently identified by the stakeholders:

In response to how the stakeholders felt they had been consulted by the PMPRB in general, the non-industry stakeholders indicated that they had been consulted adequately to extremely well. Some suggested that the process could be improved by including smaller organizations. Some indicated that when they had been consulted it was at the appropriate frequency and level while others felt that they could be involved in the process to a greater extent.

Conversely, the brand name industry representatives’ felt that the industry had been consulted regularly however it was perceived as not always necessarily at the right level or fairly. Their perception was that they were involved in a limited role and/or were excluded from participating more actively in the PMPRB’s activities. They felt the focus has always been on driving the prices of drugs down. The pharmaceutical industry wants a better balance between price control and research and development expenditures.

In reference to the Research Agenda and Notices of Comments, there was a wide range of responses. Some of the non-industry stakeholders were aware of them and of those who were aware of them some responded to them while others did not. Of those who did not respond some were in agreement with the recommendations, some felt that the issues did not have an impact on their stakeholder group, and others were under very tight time constraints and were unable to respond. There were also some of the non-industry stakeholders who indicated that they were not aware of the Research Agenda and Notices of Comments.

The majority of the industry stakeholders interviewed indicated that they had reviewed the Research Agenda and Notices of Comments and that they had participated. However, they also added that they felt that this was not an effective way to consult and communicate with stakeholders. Too much effort has been put into satisfying all other stakeholders’ interests and this has become too political (too democratic – i.e. consensus building) and cumbersome.

When asked if the stakeholder had any suggestions that might enhance the PMPRB’s consultations with the stakeholder one main theme arose. Many stakeholders suggested that more formal, face-to-face meeting with the stakeholders be held. It was suggested that all stakeholders be notified of upcoming meetings and conferences to enable them to attend. A few stakeholders mentioned the issue of including smaller organizations in the consultation process. There is an underlying perception by some of the interviewees that the PMPRB tends to pay more attention to those that speak the loudest.
Other suggestions that were mentioned are as follows:

- The PMPRB could increase and improve the information dissemination and communication through published monthly reports.
- The PMPRB should strive to involve more and smaller organizations by providing them with resources - not just dollars but by providing the PMPRB personnel to help them understand the issues.
- The PMPRB should request specific stakeholders for input. It was felt that the environmental scan approach was not focused enough.
- The PMPRB give presentations on who they are and what they do.
- The PMPRB should be consulting different stakeholders from the industry each time, ensuring that all stakeholders affected by a decision are given a chance to be involved.

The objective of the fourth question was to determine whether the stakeholders felt that they were being heard by the PMPRB in the consultations and communications and to gather input from the stakeholders on how the PMPRB could improve solicitation of their input and feedback with regards to the PMPRB’s policy decisions.

All non-industry stakeholders felt that they were being heard by the PMPRB. Many of the non-industry stakeholders gave suggestions for improvement such as:

- The PMPRB should increase their consultations and communications with smaller organizations and allow those organizations a more participatory role in the PMPRB’s processes.
- There should be more face-to-face meetings and discussions with stakeholders regarding their concerns.
- The PMPRB should advise people that their comments are welcomed. The PMPRB should be more open to suggestions and make it clear to stakeholders that they are receptive to their input.

Conversely, the majority of the pharmaceutical industry respondents felt they were not being heard by the PMPRB. There was an underlying perception that the PMPRB does not completely understand the pharmaceutical industry. It was suggested that the PMPRB should stop expanding their mandate and instead, focus on maintaining the balance between research and development and price regulation.

The objectives of the fifth question were to determine which communication tools are most commonly used, how effective the stakeholders found the communications tools and what suggestions the stakeholders had for improving them.

The majority of stakeholders were aware of, and had used, the PMPRB’s website, NEWSletter and Annual Report. In general, it was felt that these three means of communication were effective and insightful. However, several of the pharmaceutical industry representatives felt that some of the communications did not accurately reflect the industry’s concerns or accomplishments (i.e. the increase in research and development in Canada was downplayed while being compared to that of the US).
There were suggestions provided for improving the communication tools, such as:

- The website could be improved by providing links to other pertinent organizations and sites of interest to the various stakeholders.
- The website and NEWSletter could indicate more openness to receiving input from stakeholders.
- The NEWSletter could contain more statistical information in order to assist stakeholders in the monitoring of trends in the industry.

The sixth question solicited suggestions for additional information or ways of communication that could be provided by the PMPRB. The following are the various suggestions provided by the stakeholders:

- A survey of the general public could be conducted.
- Communications should be kept in easy to understand terms instead of technical and/or scientific language.
- A list of contacts’ names and numbers could be published in order for the PMPRB to be more approachable.
- Better communication can come from face-to-face meetings.
- The PMPRB could send out more information electronically (emails) which could include related website links.
- More of the PMPRB’s publications should be put on the website, as well.
- Publications should be more specific and less generic.
- Research studies and project updates should be published on the website.
- There could be more communications with the stakeholders during price reviews and the information published during the process, not just after decisions have been made.

The objective of the seventh question was to determine the overall effectiveness of the PMPRB’s consultations and communications, over the past three years, in communicating their roles and responsibilities to the stakeholders.

Many stakeholders indicated that they are more familiar about the PMPRB’s roles and responsibilities today than they were three years ago. Some indicated that this was a result of their own research or direct involvement with the PMPRB rather than improved consultations and communications by the PMPRB. Others responded that they were already completely aware of the PMPRB’s roles and responsibilities previously and that has not “improved” in the last three years.

Several of the stakeholders indicated that they felt that the PMPRB’s consultations and communications have improved in the last three years. However, most felt that there was still room for improvement. The following are the various suggestions provided by the stakeholders:

- More work is needed on keeping stakeholders informed of drug price reviews currently in progress and of any emerging issues.
- More transparency is needed for the drug price review process.
- There could be more of a human aspect to the PMPRB, such as the ability to deal directly with Board Members.
4.1 General Comments

The final question of the project was to solicit general comments and feedback about the environmental scan, consultation and communications activities of the PMPRB.

There were a variety of further comments or suggestions that were provided. Some of the interviewees felt that:

- More transparency is needed in the price review process.
- There is a good diversity of membership on the Working Group on Price Review Issues.
- The PMPRB should expand its focus to include global issues and also be able to balance the price and costs of new drugs with research and development concerns.
- More effort needs to be done on consulting with the general public and less with stakeholders.
- The price regulation process should be improved.
- The PMPRB’s mandate should be expanded and they should include the general public and smaller organizations more in their consultations.
- Improvements to the website are needed such as having more on-line access to reports.
Appendix 1

Environmental Scan and Performance Evaluation for the Patented Medicine Prices Review Board

Interview Guide

July 27, 2001
IDENTIFICATION

Interviewee

Name: ____________________________________________

Organization: ______________________________________

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<td>Private Insurers</td>
</tr>
<tr>
<td>Academics</td>
</tr>
<tr>
<td>Human Drug Advisory Panel</td>
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</tbody>
</table>

Interviewer

Name: ____________________________________________

Date of interview: ________________ 2001
Notes:

This questionnaire was built with the intention of addressing the three following objectives:
to identify and analyse the major trends and issues that may impact the Board over the next three to five years;
to evaluate the effectiveness of the Board’s Consultation Policy and Consultation Activities; and
to evaluate the effectiveness of the Board’s external Communication Policy.

The questions were built to take into consideration the stakeholder’s different needs. The interviews are expected to last between 30 and 45 minutes.
SECTION 1 - ENVIRONMENTAL SCAN

The objectives of this section are to identify and analyse major trends and issues in the pharmaceutical sector that may impact the PMPRB (Board) over the next 5 years.

Questions:

1. From the perspective of your stakeholder group, what do you think will be the major challenges in the pharmaceutical sector over the next five years? This includes either domestic or international issues.

1.1 (1st Challenge)

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

(2nd Challenge)

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

1.2 (3rd Challenge)

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____________________________________________________________________________________________________

2. Please rank these challenges according to their importance to your organization. (RANK 1st, 2nd AND 3rd IN LEFT HAND MARGIN OF QUESTION 1)
3. (FOR EACH CHALLENGE MENTIONED IN QUESTION 1 ASK)

What specific actions, if any, do you think the Board should take on each challenge?

3.1 (For the 1st challenge)  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________

3.2 (For the 2nd challenge)  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________

3.3 (For the 3rd challenge)  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________  
____________________________________________________________________________________________________
Section 2 - Effectiveness of Consultation and Communication

Context:
The PMPRB’s Road Map for the Next Decade was released in September 1998. It summarized what the PMPRB heard during its consultations on its role, function and methods. It also included an Action Plan that described how the PMPRB was to address the issues and concerns raised.

In November 1998, the PMPRB held a stakeholders’ meeting to obtain feedback on the Road Map for the Next Decade. It was followed in January 1999 with the creation of the Working Group on Price Review Issues. Composed of representatives of the PMPRB’s main stakeholder group, the Group was tasked with analyzing and reporting on three issues: the use of the U.S. Department of Veterans Affairs (DVA) formulary prices in the international price comparison; the price review process for new patented drug products; and category 3 drug prices.

The PMPRB now wishes to evaluate how well (or not) it has done on implementing its Action Plan under the Road Map for the Next Decade in the areas of consultation and communications.

The objectives of this section are to:

- evaluate the effectiveness of the Consultation Policy, included as an attachment to the Road Map for the Next Decade released in September 1998, and consultation activities undertaken by the PMPRB since the released of the Road Map; and

- evaluate the effectiveness of the PMPRB’s Communication Policy to ensure that stakeholders understand the organization’s role and responsibilities.
Appendix 1

Questions:

1. The Board is committed to consult with its stakeholders to obtain their input on how the Board should address the manner in which it fulfills its mandate. Prior to today’s consultation interview, how well do you feel that you have been consulted by the Board, in general?

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2. Since the implementation of the Consultation policy, the Board has published its Research Agenda and a series of Notices and Comments on several issues.

Have you had the opportunity to review the Research Agenda and the Notices and Comments? (If yes, go to ii)

i) If not, would you say that:
   A) You were not aware
   B) It was not related to your stakeholders’ interest
   C) Other – specify

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ii) If yes, did you participate? (If yes, no further questions)
If not, would you say that:
   A) You agreed with the recommendations
   B) It was not related to your stakeholders’ interest
   C) You were not given a chance to participate
   D) Other - specify

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__________________________________________________________________________________________________________________________________________________________

__________________________________________________________________________________________________________________________________________________________
Appendix 1

3. Do you have any suggestions that might enhance the Board’s consultations with stakeholders such as yours?

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

4. Are you confident that you are being heard by the Board?
   Is there anything you would recommend to facilitate input and feedback between the Board and
   stakeholders, such as yourself, with a view to ensuring your participation in the Board’s policy decisions?

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____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

5. In the last year, have you seen or referred to any of the following communication tools:
   Toll-free line:   Website:  NEWSletter:
   Brochure:    Other: ______________________

If you used these communication tools, how effective did you find them and do you have any suggestions for
enhancing them?

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

6. What additional information or ways of communication would you like to see the Board provide to
effectively communicate with you and your stakeholder group?

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________

____________________________________________________________________________________________________
Appendix 1

7. Compared to three years ago, would you say that you are now more familiar with the Board's role and responsibilities? If not, what additional information would you require?

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______________________________________________________________________________________________

8. Do you have any other comments or suggestions that you would like to make regarding the Board’s Environmental Scan, Consultation activities, and its Communications?

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