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Department: Market Access

December 18, 2023

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Re: Patented Medicine Prices Review Board (PMPRB) Scoping Paper Consultation

Submitted via email

Dear recipients:

Boehringer Ingelheim (Canada) Ltd. is pleased to provide feedback on the "*Scoping Paper for the Consultations on the Board's Guidelines"* as published by the PMPRB on November 10, 2023, on the website.

List price guidelines have a significant impact on the pharmaceutical innovation landscape in Canada and on the timing of availability of innovative medicines for Canadian patients. It is our experience the uncertainty associated with the guideline development process in recent years has created a negative impression of Canada and reduced its attractiveness for new product launches.

With the new round of consultation, Boehringer Ingelheim urges the PMPRB to take a forward-looking approach inclusive and supportive of innovation within the Canadian business environment.

Prior to providing feedback on the six themes identified in the November 2023 Scoping Paper, we would like to take this opportunity to comment on the following:

Section A. Effective Patent Duration in Canada versus the PMPRB11 Countries

When considering the appropriateness of comparing list prices in Canada to the basket of PMPRB-11 countries, we believe that such comparisons should represent an "*apples-to-apples*" approach and that significant differences in the period of market exclusivity (i.e., the *effective patent protection period)* allowed by Canada relative to each of the PMPRB-11 basket countries must be considered.

In addition to local market dynamics, the list price of medicines in a country is impacted by the time frame in which that medicine can be sold prior to the introduction of generic versions. When assessing this extremely important factor, significant differences exist between Canada and all the PMPRB-11 comparator countries. Whereas medicines in all PMPRB-11 comparator countries are eligible for a patent term extension of up to 5 years via the issuance of a Certificate of Supplementary Protection (CSP),[1] prior to the

[1] Supplementary Protection Certificates (SPCs) & Patent Term Extensions (PTEs) (mewburn.com)

signing of the Comprehensive Economic and Trade Agreement (CETA) there were no such allowances in Canada. The signing of the CETA agreement in September 2017 allowed for new chemical entities (drugs) that met specific criteria[2] and received first regulatory approval in Canada after September 2017 to potentially be eligible for up to a 2-year CSP patent term restoration period (Figure 1).

The CSP term begins the day after the expiration of the underlying patent, and then it ends on the date according to the calculation below, including both the "CSP Term Begins" date and the "CSP Term Ends" date. If the calculation below is greater than 2 years, the CSP Term is capped at 2 years. For example, if the NOC issued on December 31, 2017 and the patent was filed on January 1, 2012, the calculation would be as follows:

CSP Term = [NOC date – patent filing date] – 5 years
CSP Term = [December 31, 2017 – January 1, 2012] – 5 years = 6 years - 5 years = 1 year
The patent will expire 20 years from the patent filing date, which is January 1, 2032. Therefore, the CSP term would begin on January 2, 2032, and if it expired exactly one year later, the CSP would expire on January 1, 2033.

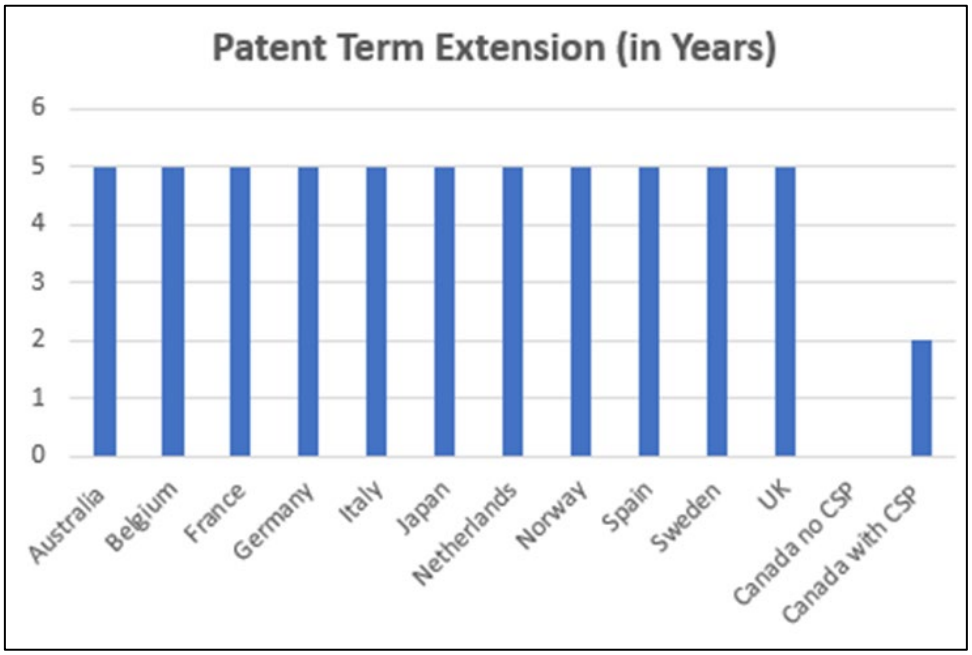

Figure 1. Patent term extension (in years) for the PMPRB 11 countries versus Canada

[2] **(1)**When it filed its application for the authorization for sale in Canada (i.e. an NDS), no application for a marketing approval equivalent to an authorization for sale, with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, had been submitted in a country prescribed by paragraph 6(1)(a) of the CSP Regulations (the European Union and any country that is a member of the European Union, the United States of America, Australia, Switzerland, Japan, and the United Kingdom); or **(2)** if one or more of those applications for a marketing approval had been submitted in one or more of those countries, the NDS was filed before the end of the i) 24-month period, if the application for a CSP was filed no later than the first anniversary of the day on which section 59 of the CETA Implementation Act comes into force, or ii) 12-month period, in any other case, prescribed in paragraph 6(1)(b) of the CSP Regulations that begins on the date of submission of the first of those marketing approval applications.

Operationally, this means that drugs in Canada issued a NOC prior to September 2017 may face generic competition 5 years earlier than the same drug in another PMPRB-11 country.[3,4] Even when one considers the potential for the granting of a 2-year CSP (post CETA) in Canada, the market and generic competition dynamics remain different between Canada and the PMPRB-11 countries. The importance of this additional 3 to 5 years of market exclusivity (from generics) in the PMPRB-11 countries versus Canada cannot be overstated as it has a significant impact on the pricing of a medicine, allowing PMPRB-11 countries to lower list prices over time while maintaining the ability to generate revenue required to fund future research and development of innovative new medicines. These differences are highly relevant when considering some of the topics included in the Scoping Paper, including (but not limited to): The approach that the Board should take with respect to existing medicines with prices above the HIP of the PMPRB11; Distinguishing between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines), and; the frequency and type of price reviews that occur during a product life cycle.

As an example, in the case of Pradaxa (dabigatran), the first generic dabigatran was approved by Health Canada on **February 19, 2018**. This is in contrast with the first generic dabigatran that was approved by the European Medicines Agency on **May 31, 2023**, over 5 years later.

[3] Can I request an extension of the patent term in Japan? | Epo.org
[4] Patent Term Extension In Different Countries | IIPRD

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Notice of Compliance Search Results

From Health Canada

Click on the link to get more details of an individual Notice of Compliance.

New search

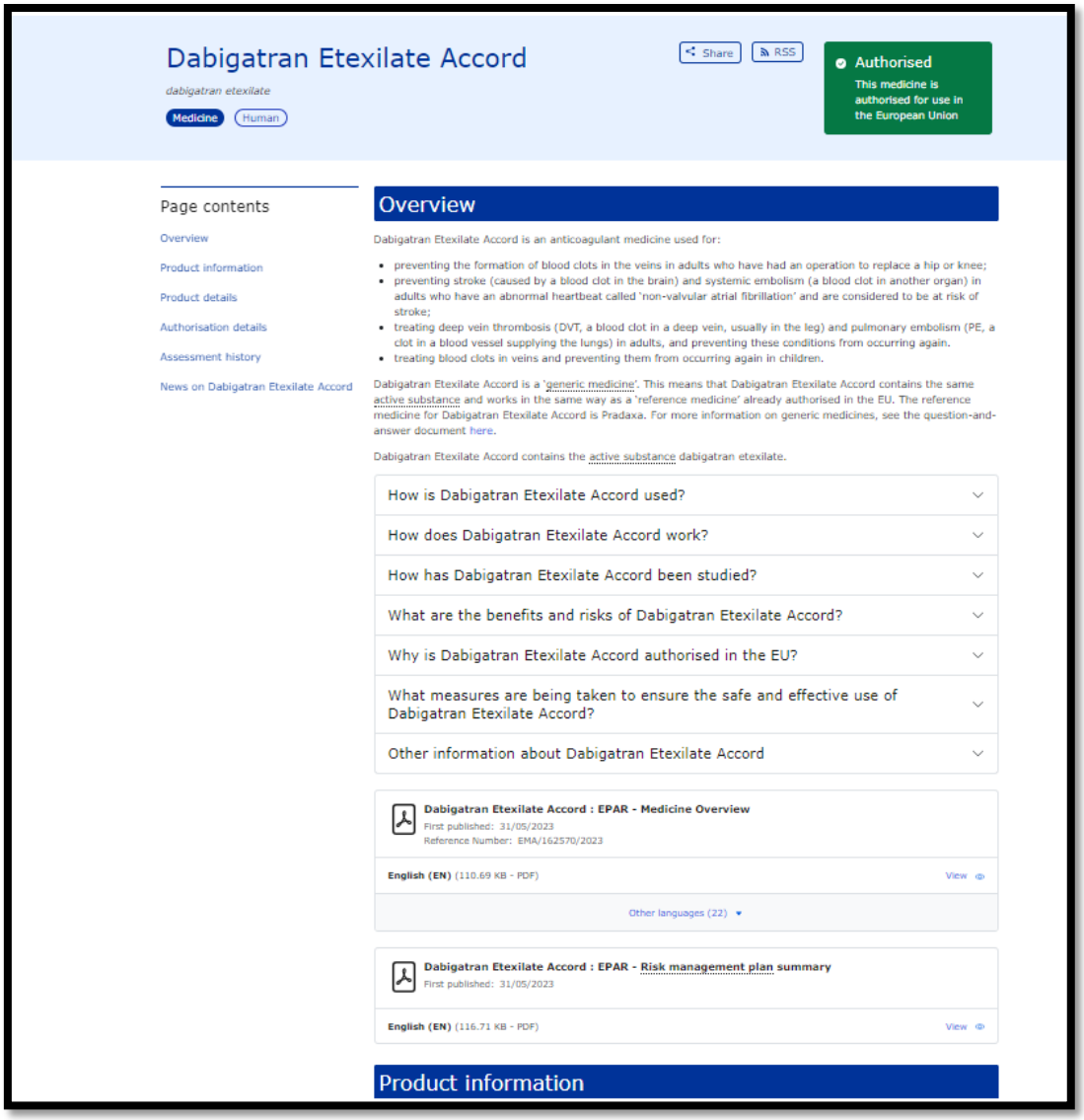
Filter items | Showing 1 to 10 of 12 entries | Show 10 entries

List of searched Notices of Compliance (NOC)

Product(s)	Manufacturer	Published Notes	Notice of Compliance date	Medicinal ingredient(s)	DIN(s)
APO-DABIGATRAN	APOTEX INC		2022-07-20	DABIGATRAN ETEXILATE MESILATE	00000N/A
APO-DABIGATRAN	APOTEX INC		2020-08-27	DABIGATRAN ETEXILATE MESILATE	00000N/A
APO-DABIGATRAN	APOTEX INC		2019-09-04	DABIGATRAN ETEXILATE MESILATE	00000N/A
PRADAXA	BOEHRINGER INGELHEIM (CANADA) LTD LTEE		2019-02-07	DABIGATRAN ETEXILATE MESILATE	00000N/A
APO-DABIGATRAN	APOTEX INC		2018-02-19	DABIGATRAN ETEXILATE MESILATE	02468913, 02468905, 02468891
TEVA-DABIGATRAN	TEVA CANADA LIMITED		2018-02-19	DABIGATRAN ETEXILATE	02463458, 02463466
PRADAXA	BOEHRINGER INGELHEIM (CANADA) LTD LTEE		2015-06-09	DABIGATRAN ETEXILATE MESILATE	00000N/A
PRADAXA	BOEHRINGER INGELHEIM (CANADA) LTD LTEE		2014-08-12	DABIGATRAN ETEXILATE	00000N/A
PRADAXA	BOEHRINGER INGELHEIM (CANADA) LTD LTEE		2014-06-26	DABIGATRAN ETEXILATE MESILATE	00000N/A
PRADAXA	BOEHRINGER INGELHEIM CANADA LTD LTEE		2012-09-07	DABIGATRAN ETEXILATE	02312433, 02358808, 02312441

1 2 Next →

Notice of Compliance Search Results (canada.ca)



Dabigatran Etexilate Accord

dabigatran etexilate

Medicine | Human

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Authorised
This medicine is authorised for use in the European Union

Page contents

- Overview
- Product information
- Product details
- Authorisation details
- Assessment history
- News on Dabigatran Etexilate Accord

Overview

Dabigatran Etexilate Accord is an anticoagulant medicine used for:

- preventing the formation of blood clots in the veins in adults who have had an operation to replace a hip or knee;
- preventing stroke (caused by a blood clot in the brain) and systemic embolism (a blood clot in another organ) in adults who have an abnormal heartbeat called 'non-valvular atrial fibrillation' and are considered to be at risk of stroke;
- treating deep vein thrombosis (DVT, a blood clot in a deep vein, usually in the leg) and pulmonary embolism (PE, a clot in a blood vessel supplying the lungs) in adults, and preventing these conditions from occurring again.
- treating blood clots in veins and preventing them from occurring again in children.

Dabigatran Etexilate Accord is a 'generic medicine'. This means that Dabigatran Etexilate Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Dabigatran Etexilate Accord is Pradaxa. For more information on generic medicines, see the question-and-answer document here.

Dabigatran Etexilate Accord contains the active substance dabigatran etexilate.

How is Dabigatran Etexilate Accord used?

How does Dabigatran Etexilate Accord work?

How has Dabigatran Etexilate Accord been studied?

What are the benefits and risks of Dabigatran Etexilate Accord?

Why is Dabigatran Etexilate Accord authorised in the EU?

What measures are being taken to ensure the safe and effective use of Dabigatran Etexilate Accord?

Other information about Dabigatran Etexilate Accord

Dabigatran Etexilate Accord : EPAR - Medicine Overview
First published: 31/05/2023
Reference Number: EMA/162570/2023

English (EN) (110.69 KB - PDF) View

Other languages (22)

Dabigatran Etexilate Accord : EPAR - Risk management plan summary
First published: 31/05/2023

English (EN) (116.71 KB - PDF) View

Product information

[Dabigatran Etexilate Accord | European Medicines Agency (europa.eu)]

B. International Price Referencing (IPR)

When launching new drugs and/or new indications, it is common for corporate head offices of pharmaceutical companies to use IPR tools such as the NAVLIN Database by Eversana (NAVLIN | Global Pricing & Market Access Database) to determine launch sequencing.

Below are the countries that NAVLIN cites that directly (primary) or indirectly (secondary) use Canada as a price reference country. The list is inclusive of price referencing at launch and during the life cycle of the drug. It is our experience that international companies set pricing with mandatory minimums, reflecting these IPR considerations, and countries which cannot address corporate requirements are de-prioritized.

COUNTRY	REFERS TO	PRIMARY/SECONDARY
AUSTRALIA	CANADA	P
BAHRAIN	CANADA	S
BRAZIL	CANADA	P
CHINA	CANADA	P
COLOMBIA	CANADA	P
CHILE	CANADA	P
EGYPT	CANADA	P
INDIA	CANADA	P
KUWAIT	CANADA	P
LEBANON	CANADA	S
MALAYSIA	CANADA	P
MEXICO	CANADA	P
NEW ZEALAND	CANADA	P
OMAN	CANADA	P
PHILIPPINES	CANADA	P
QATAR	CANADA	S
SAUDI ARABIA	CANADA	P
SOUTH AFRICA	CANADA	P
SOUTH KOREA	CANADA	P
TAIWAN	CANADA	P
THAILAND	CANADA	P
UNITED ARAB EMIRATES	CANADA	P
VIETNAM	CANADA	P

Source: NAVLIN 2023, P = primary referencing, S = secondary referencing

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C. Boehringer Ingelheim's Response to themes in Scoping Paper

In response to the six themes proposed by the PMPRB, Boehringer has provided input to select questions:

Theme 1. Efficient Monitoring of Prices without Price Setting

a. What elements of the 2010 Guidelines should be retained? Which ones and why?

None of the elements of the 2010 Guidelines should be retained. The 2010 guidelines were developed based on an entirely different group of comparator countries, the PMPRB-7, and notably a pricing threshold based on the median international price (MIP), which are no longer relevant.

b. Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement?

The categorization of medicines by therapeutical class comparator characteristics are outside the mandate of the PMPRB as this is a factor not listed in section 85 of the *Patent Act,* hence the PMPRB should refrain from using any categorizations that is not as per its mandate.

c. Should the Board accord more weight to one or more of the factors set out in s. 85 of the Act in designing the Guidelines?

As stated in the Industry Coalition submission, it has repeatedly been confirmed by the courts that during an investigation, the PMPRB must consider all section 85 factors. No single factor may dominate the others, and in all cases, the PMPRB may not use any of the section 85 factors to drive prices below a threshold that would otherwise be considered non-excessive.

d. If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure? (e.g., HIP or MIP?)

The basket of PMPRB-11 countries already have mechanisms of price containment in place, hence it is only appropriate that the guidelines recognize the Highest International Price (HIP) for Canadian price assessments.

e. How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have few or no international prices?

A review should be conducted if and only when 5 or more countries within the PMPRB11 basket have launched. Since launch sequencing are integral to new and innovative products coming to Canada, the guidelines should consider not having mechanisms which could hinder new and innovative products from being launched first in Canada.

i. How soon after an expedited review should a full price review take place?

The price should only be assessed once – either at launch or at a later time when the product is launched in at least five countries within the PMPRB11 basket, and not be reassessed during the Canadian patent life unless there is evidence of conduct that meet a standard of patent abuse. As outlined in the introduction section, due to the significant differences in CSP, the effective patent term in Canada for most drugs is shorter than the PMPRB-11 countries, hence a secondary price review is not a true "*apples-to-apples"* comparison.

Theme 2. Transition to PMPRB11 – New versus Existing Medicines

a. Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?

Yes, products launched before July 1st 2022 should be "grandfathered" and considered reviewed and not be assessed again. These medicines were assessed as per the PMPRB-7 and the change to the basket of countries should not be applied to medicines which were compliant as per the previous guidelines. In addition, whereas the majority of drugs that were launched in Canada prior to July 1, 2022 would not be eligible for any additional CSP (the potential eligibility for up to 2 year CSP for select drugs came into effect in 2017), those drugs launched in PMPRB-11 countries are eligible for 5 year CSP.

b. What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?

As per our response to Theme 2.a, existing medicines launched before July 1st 2022, should not be reassessed under any circumstance, unless there is evidence of conduct that amounts to patent abuse. Existing medicines that are compliant with their non-excessive average price (NEAP) must be grandfathered under the new regime. The NEAP compliant price may follow the allowable consumer price index (CPI) increase.

International references may vary over time as a drug is launched in different countries, or if there is a reduction in price or a drug becomes generic in different countries. A non-excessive price in Canada cannot become excessive (in the sense of patent abuse) simply because the drug is launched in one or more countries or a PMPRB-11 reference price has changed. This would result in an arbitrary variation in the maximum non-excessive price over time. As stated by the Quebec Court of Appeal's decision in *Merck Canada c Canada*, 2022 QCCA 240 ("QCCA Decision"), arbitrary pricing thresholds are not constitutionally justified.

The initial NEAP, plus the allowable CPI increase, should be considered the maximum non-excessive price for existing medicines, irrespective of new pricing data in the PMPRB-11. The PMPRB-11 cannot be used to lower the price of existing medicines. Any other distinction between "existing" and "new medicines" reflects a pursuit of "optimal" or "reasonable" prices, which is a form of price control.

Theme 3. Price Reviews during Product Life Cycle

a. How often should price reviews be conducted? (1-5 years).

As mentioned in question 2.a and 2.b, only upon launch or at a later time when the product is launched in at least five countries within the PMPRB11 basket, and not beyond that, unless there is evidence of conduct of patent abuse.

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b. What criteria besides time should be used to trigger a price review?

The only trigger to consider for a price review should be substantial evidence of patent abuse. Any factors outside the sections of the *Patent Act* cannot be considered for a price review.

i. Approval of a significant new indication?
ii. Significant change to the therapeutic class comparators? Availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators?
iii. Departure from identified pricing thresholds?

As mentioned above, the PMPRB should not knowingly and unknowingly violate its mandate. No criteria, including time, should be relied upon to re-assess or re-bench medicines for which the price was already reviewed at launch. As stated above, there should only be an initial price review at launch (or shortly thereafter), following which the PMPRB may only monitor against the allowable CPI increase. A fluctuation in exchange rates or a decrease in price in a comparator country cannot result in creating an excessive price in Canada where the Canadian price did not change at a rate greater than CPI.

c. How should the PMPRB treat the allowable Consumer Price Index increase in the context where international list prices are decreasing?

CPI increase is a provision in section 85 of the *Patent Act,* patentees are well within their rights to take CPI increases. As mentioned in Section A. of this response, due to significant differences in allowable CSP, the comparator countries within the PMPRB 11 have a longer effective patent term which allows for pricing decisions to be made which allows for patentees in these countries to decrease prices.

The factors enumerated at section 85 of the *Patent Act* must not be used to achieve “optimal” or “reasonable” or “fair” pricing, or be used as a price control tool generally. They cannot be used to drive prices below non-excessive thresholds at any point in the life cycle of a medicine.

Theme 5. Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

a. What efficiencies could be gained by co-ordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?
b. How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical ecosystem to support a whole of government approach to issues relating to patented medicines?

As per the Industry Coalition submissions, the PMPRB does not exercise a “health” mandate. It derives its power exclusively from the *Patent Act*, that is to ensure drug prices are not sold at “objectively excessive” levels as a function of patent abuse. Any measures that aim to align, complement, integrate or coordinate with these bodies would be well outside the scope of the PMPRB’s constitutional limits. The final guidelines must not have the effect of substituting the PMPRB for the provincial health ministers and agencies.

Theme 6. Engaging with Patients, Health Practitioners, Pharmacy, and other Stakeholders

a. What role do the PMPRB Guidelines play in your decision-making process in Canada and globally (if applicable)?

"Launch sequencing" of new and innovative products is a very rigorous and integral process in the planning of launch of new and innovative medicines globally. Canada cannot think of itself in isolation and is part of this global pharmaceutical ecosystem. As mentioned above, international companies set pricing with mandatory minimums, reflecting IPR considerations, and countries which cannot address corporate requirements are de-prioritized thereby impacting patients and their access to new and innovative medicines.

b. How can the PMPRB better engage with you?

Boehringer strongly recommends that the PMPRB continue the new era of openness and transparency to ensure market certainty for patentees while following up on the outputs from the suggested establishment of the multi-stakeholder working group.

Conclusions

While the healthcare systems in PMPRB-11 countries may have similarities to Canada, there are significant differences such as effective patent life of new drugs which can have a significant and dramatic effect on prices over time. This must be considered while developing the new guidelines.

We thank you for the opportunity to provide feedback on the Scoping Paper. We urge the PMPRB to establish new guidelines to demonstrate that Canada is a reasonable, predictable, and stable market for pharmaceutical innovation. Boehringer Ingelheim would be pleased to continue discussions during the development of future guidelines.

Sincerely,

Carole Bradley-Kennedy
Director, Health Economics, Pricing and Outcomes Research