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Re: BMS Response to PMPRB Draft Guidelines Consultation

On behalf of Bristol-Myers Squibb Canada Co. (BMS), I wish to thank you for the opportunity to provide input into the Draft Guidelines as proposed by the PMPRB last November 21st 2019.

Introduction

At BMS, our mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. With the recently proposed Draft Guidelines, we are concerned that they will severely limit our ability to live out our mission to help patients in Canada. As a member of Innovative Medicines Canada (IMC), we fully agree with and support the position submitted by IMC and believe the Draft Guidelines will create additional uncertainty and complexity for patients and industry alike.

In addition, we would like to emphasize the need for a delay to the implementation timeline that has been proposed to assure that there is a framework that offers operational feasibility and sufficient time to transition to a new way of working, which the current process and proposed framework cannot do.

A recent impact analysis, published by PDCI, estimates the impact of the PMPRB Draft Guideline changes at \$41.8 billion. This represents a significant difference from Health Canada's original CBA estimate of \$8.8 billion, which dates back to a December 2017 evaluation that was prepared before the PMPRB's Draft Guidelines were released (November 2019). This significant difference in impact suggests that the PMPRB Draft Guidelines are not aligned from an impact perspective with the original intent and extent of the regulation.

As currently structured, the Draft Guidelines are overly complex, include significant operational barriers to implementation and are not sufficiently advanced nor aligned with Regulations to provide guidance to industry on how to work. We do not see how they can be effectively implemented by July 1, 2020 and therefore strongly recommend a delay.

We would also reinforce the need for the PMPRB to engage with industry through technical working groups to develop more predictable regulatory tools which support core principles of predictability, operational feasibility, efficiency, fairness and transparency. The working groups should be aimed to develop a framework that truly reflects a risk-based approach and that can be used to guide reimbursement decisions and ensure Canadian patients can access new medicines in a timeframe comparable to the present day.

1. Predictability and the proposed pricing model

At the onset of this reform, the new Guidelines were expected to provide patentees with clear “bright lines” on anticipated maximum list prices for our drugs in Canada, both pre- and post-launch. Pricing predictability is a key component in estimating market attractiveness and launch feasibility. It is this predictability which guides our investment decisions regarding key elements of programs that benefit Canadian patients. Programs such as:

- Investment in local-market clinical trials - which provide the medical community with a Canadian experience that is deemed essential in provincial listing decisions, while providing a select group of Canadian patients access to drugs well ahead of market authorization
- Patient access programs (PAPs) - which give Canadian patients access to drugs ahead of the listing/funding in their province
- Patient financial assistance – which is key for patients who cannot afford their deductibles or copay. This assistance benefits thousands of Canadians each year by giving them access to the new treatments they need when they would otherwise not be able to afford them
- And, the types of promotions we can put behind each brand

Reassessment criteria should promote predictability

Although the Draft Guidelines provide clear thresholds for Category 1 triggers, they also spell out several opportunities for the PMPRB to reassess both list and net prices over the life of the drug. As a patentee, all such conditions for reassessment reinforces that there is a lack of predictability, which is a key required component to decision-making around launch and which allows us to make investment decisions in clinical trials and support patient programs. Reassessments would mean that patentees would have no reasonable expectation of stable pricing over the planning horizon.

Grandfathering – new framework should be prospective only

In the current Draft Guidelines, the new MLP calculation (PMPRB 11) would establish the median international price as the upper limit for every patented medicine and would be replacing the current (PMPRB 7), which sets the upper limit at the highest international price. Grandfathering that allows for existing rules to apply to all existing medicines would, in our view, respect the business and investment decisions that were made in the past that aligned to the PMPRB pricing model of the time.

- We agree with the IMC position that new regulations should only apply to new drugs launched after the new regulations take effect.
- This would respect the significant investments by patentees into research and clinical trials to bring these innovations into Canada.
- In return for investments that have been made in the past, it is reasonable to expect a stable regulatory environment that would provide future revenue streams that may not otherwise have happened.

2. Insufficient protection for confidentiality

While the Patent Act and Section 29 of the Draft Guidelines assure us the confidentiality of information submitted to the PMPRB will be protected; we are concerned that the new maximum rebate price formula (MRP) together with components found in publicly available HTA final recommendations, would make it possible for third parties to estimate the Pharmacoeconomic Price (PEP) and/or net price of a drug. This would be unique internationally and is a cause for significant concern. Other jurisdictions use pharmacoeconomic information as an input to price negotiation, rather than to establish a regulated price.

Confidentiality is meant to maximize the positive effect of the negotiated agreements that have so far granted access to innovative drugs for Canadian patients and affordable prices for the public payers. Approach to pricing and information sharing should therefore preserve the confidentiality of these agreements with the manufacturers.

We agree with IMC that the MRP policy will impact the PMPRB's ability and responsibility to protect confidential pricing information that must be submitted by patentees under the new system. Given the significant international sensitivity associated with this information, it is reasonable to suggest that the current proposals will negatively impact product launch decisions in Canada.

3. Pharmacoeconomic Value Threshold (PVT) is too subjective

We believe the proposed PVT of \$60,000 is too restrictive for oncology and niche drugs. ICERs are subjective in nature and were never intended for use as an absolute price setting mechanism.

While ICERs are used by payers in Canada and other countries around the world to assess the relative value of a new treatment over existing therapies, pharmacoeconomics (PE) measure the allocative efficiency of a drug and are useful to inform and support provincial funding decisions. Currently no jurisdiction in any country attempts to set excessive price levels in this way. CADTH recommendation are issued with a public drug plan perspective rather than a broader societal perspective and make no attempt to single out a specific price level for the country; pCPA negotiations use ICERs as a starting point in a reimbursement discussion; but they acknowledge the inherent subjectivity of this metric and do not use it as an end point to set prices.

We agree with IMC that a single ICER threshold for all Canadians (public, private and cash paying) is unattainable given the many different subjective variables (ie. therapeutic comparators allowed, time horizon considered) and different perspectives that would need to be blended together to accurately capture an effective "excessive price" threshold.

4. Fairness and Operational Feasibility

In addition to what IMC outlines in terms of operational feasibility, readiness and fairness in the application of the Guidelines, we would like to underline the following areas of concern.

Market size adjustments

Market size price reductions adjust pricing downward in-line with higher sales volumes. As volumes increase, matching MRP reductions are required. (ie. volume rebate). Making price adjustments purely based on market size becomes an attempt to control the revenues of patentees, which is incompatible with the Patent Act and the PMPRB's mandate.

Lowest price sources

In the Draft Guidelines, the dTCC test requires the use of the lowest price source in the country. However, there is no obligation for the PMPRB to only use the lowest prices they can find; rather, the Regulations require the PMPRB to consider all prices: "*the prices at which the medicine has been sold in the relevant market*" and "*the prices at which other medicines in the same therapeutic class have been sold in the relevant market*". We suggest that the PMPRB should instead use a better representative of the Canadian prices such as a weighted average or the median of published price sources (all provinces).

MRP Concept and operational issues

At the time that PMPRB is assessing ceiling price, most manufacturers would not have any product listing agreements in place with payers and therefore would have no rebated price to assess against an MRP. It can take upwards of two years to achieve formulary listings on government-sponsored plans and, in some instances, a listing is never achieved.

- Once listing agreements are in place, invoices for gross-to-net price differences can also often take up to two years post-listings before they can be issued, especially when they include capitation and other non-standard discounts. In addition, listing agreements have an effective start date that can occur at any time in the calendar year and end 12 months later. This is very different from the PMPRB's calendar year perspective which will create additional distortion of the true ATP numbers for any given year.
- The challenges of using "confidential" MRP thresholds for all payer types, including all private payers, are significant. For example, not all private payers have the ability to execute listing agreements given the complexity of the adjudication process at the pharmacy level, also making it almost impossible to ensure confidentiality.
- In our opinion, this clearly illustrates why the MRP concept is not operationally feasible.

5. Jurisdiction

The PMPRB's present mandate is to ensure that patentees do not charge prices that are deemed excessive over the patent life of a drug. Current provisions of the Draft Guidelines, however, go

further to give PMPRB price-setting privileges. For example, annual list price increases or flat pricing strategies are now disallowed. Moreover, in-line with IMC comments, we believe that the move to the median therapeutic class comparison is inconsistent with an excessive price standard, as is the market-size approach.

We also disagree with the Board's expansive view of its jurisdiction as reflected in the section on legal framework. There is no reference to consumer protection in the form of monitoring excessive pricing as a form of patent abuse, as set out in recent case law.

Conclusion

In summary, the framework as defined in the Draft Guidelines, proposes fundamental changes to the current framework that do not appear to add simplicity or "bright lines" regarding how they work. We strongly recommend that more time is needed to refine the guidelines that are being proposed and we would welcome the opportunity to participate in any technical working groups that had this objective as mandate.

Furthermore, changes to the PMPRB Guidelines should not act as a deterrent of foreign investments into Canada's innovative drug industry. Canadians benefit greatly from new drug discoveries developed, studied and/or imported into our country. Access to new therapies and treatments are therefore vital to both extending/enhancing the lives of Canadians while strengthening our economy.

Our market currently enjoys the benefits of being a tier 1 country, launching our drugs in the same sequence as major markets in Europe. As it stands, the new Guidelines will likely change our status, relegating Canada to a 2nd or 3rd tier country resulting in significant delays in the launch of new compounds and increased no-launch scenarios. At BMS we are already having discussions about the viability of bringing several new innovative products to Canada, and based on our interpretation of the Guidelines, we are really concerned that some these may never be available for Canadian patients.

We appreciate the opportunity to provide input into the proposed changes for the Draft Guidelines. We hope these will help the Federal Government to reframe the timeline and process needed to craft more meaningful policy changes that will help address sustainability issues and improve timely access to life-saving drugs in Canada.

Best regards,

Al Reba
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Bristol-Myers Squibb Canada Co.