Bristol-Myers Squibb Canada

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Karen Reynolds
Executive Director
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch
Health Canada
Brooke Claxton Building, 10th Floor
70 Colombine Driveway, Tunney's Pasture
Ottawa, Ontario, K1A 0K9

Re: **Canada Gazette, part 1 – Regulations Amending the Patented Medicines Regulations**

Dear Mrs. Reynolds,

On behalf of Bristol-Myers Squibb Canada Co.(BMS), I wish to thank you for the opportunity to provide input into the changes to the Patented Medicines Regulations as proposed in the Canada Gazette, part 1 consultation published on December 2, 2017.

## Introduction

At BMS, our mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. We are concerned that the proposed changes in the Canada Gazette – part 1 (CG-1) will limit our ability to live out our mission in Canada. As a member of Innovative Medicines Canada (IMC), we agree and support the position submitted by IMC. In particular, we would like to emphasize the following:

### *Mandate*

The PMPRB's mandate is to regulate excessive prices of patented medicines. The Board should not strive to become a price-setting agency unless they can also provide access to the market. However the PMPRB neither provide access to drugs nor do they guarantee reimbursement following a successful negotiation as that role is held by the pCPA and the provinces through a separate process.

*Flawed Policy Rationale*

We also believe that the policy rationale for changes of this magnitude is flawed and not justified. According to the PMPRB's latest annual report Canadian drug prices for patented medicines:

- were in the mid-range of the PMPRB 7 [1] for 2016
- price increases have remained below the CPI and even declined in some years[2]
- At 61%, Canada's access to new drugs ranked in the middle of the PMPRB 7. It remained above the OECD median (45%), and above all the new counties proposed (33% - 56%).[3]

*Proposed changes will mean reduced access to future drug technologies.*

Any change to PMPRB regulations should not act as a deterrent to foreign investments into Canada's innovative drug industry. Canadians benefit greatly from new drug discoveries developed 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.

The excessive force of the proposed regulations will certainly result in crippling access of Canadian patients to new medicines from our company. Significant delays in the launch of new compounds and increased no-launch scenarios, are likely to result.

Our market currently enjoys the benefits of tier 1 countries, launching our drugs in the same sequence as major markets in Europe. As it stands, the suite of new rules will likely change our status, relegating Canada to a 2nd or 3rd tier country resulting in significant delays in access to medicines.

*International Schedule*

The CG1 document clearly articulated a desire to align to the median of OECD prices. Except for lower prices, no rationale was given as to why the OECD median is a more appropriate target than the median of the PMPRB7 or G10 countries, nor how this new basket will now make it possible for the PMPRB to "fulfill its mandate to protect Canadian consumers from excessive prices for patented medicines"[4].

To the contrary, we believe the proposed basket will cripple access of Canadians to future advancements in drug technologies. Replacing countries which reward innovation with countries that do not aptly reward the value of patented medicines will lead to an erosion of access to drug innovations in Canada. This is clearly not in the best interest of Canadians.

[1] Table 12, PMPRB Annual Report 2016
[2] Figures 6 and 7, PMPRB Annual Report 2016
[3] Share of NASs launched by OECD country, Q4-2015, PMPRB Annual Report 2016
[4] As stated in the 'Objectives' section of the Canada Gazette Part 1 on Regulations Amending the Patented Medicines Regulations

*Inappropriate use of Pharmacoeconomics*

Used by payers in Canada and other countries to assess the relative value of a new treatment over existing therapies, pharmacoeconomics (PE) measure the allocative efficiency and are useful to inform and support funding decisions. Currently no jurisdiction in any country attempt 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.

We agree with IMC that a single equitable ICER threshold for all Canadians (public, private and cash paying) is unattainable given the many different 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.

*Confidential Information Reporting is inappropriate*

We agree with IMC and are fundamentally opposed to the requirement for patentees to report confidential net prices. Obligation to report such rebates in the future undermine the basic rationale for confidentiality which paved the way for the introduction of PLAs in Canada. Reporting confidential discounts will jeopardize their allowance in future drug reimbursement negotiations and critically impact future launch decisions. In addition, it opens the door to complex legal issues.

*Prospective application*

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

*Trade Impacts*

We also agree with the IMC position that the current consultation may undermine Canada's trade commitments with the World Trade Organization (TRIPS), US (NAFTA) and EU (CETA).

## Conclusion

We appreciate the opportunity to provide input into the proposed changes in CG-1. We thank you for providing an official forum where key and informed stakeholders can comment on the proposed regulations and help the Federal Government to craft more meaningful policy changes that will help address sustainability issues and improve timely access to life-saving drugs. But our work is not done as Canadians have yet to benefit from future medicines that will help patients prevail over serious diseases. We look forward to an open and transparent dialogue with the PMPRB, Health Canada and/or the Minister's cabinet, in anticipation of our continued successful collaboration to bring these new drugs to Canadian patients in need of them.

Best regards,

**Al Reba**
General Manager
Bristol-Myers Squibb Canada Co.