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VIA E-MAIL

October 24th, 2016

Mr. Douglas Clark
Executive Director
Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1

Subject: Novartis Pharmaceutical Canada Inc. Response to the PMPRB Guidelines Modernization Discussion Paper

Dear Mr. Clark:

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), an affiliate of Novartis AG, we thank you for the opportunity to participate in the dialogue around the Guidelines Modernization Discussion Paper ("Discussion Paper") of the Patented Medicine Prices Review Board ("PMPRB") issued in June 2016.

Novartis AG is a leading international healthcare company focused on providing solutions to address the evolving needs of patients and societies. Novartis AG is a leader in meeting patient needs and offers a diversified portfolio through its three businesses; innovative medicines (Novartis Pharmaceuticals), eye care (Alcon) and cost-saving generic medicines (Sandoz). Currently, the Canadian Novartis group of companies who operate as independent entities (Novartis Pharmaceuticals Canada, Sandoz Canada and Alcon Canada) employ over 1900 Canadians from coast to coast, of which more than 700 people are employed by Novartis with the remaining employed by Sandoz Canada and Alcon Canada.

Novartis, as a member of both Innovative Medicines Canada ("IMC") and BIOTECanada, is in agreement with, and fully supports, the two responses submitted by these industry associations.

As members of these two industry associations, Novartis is committed to science based innovation through the discovery, development and marketing of innovative medicines to improve the well-being of all Canadians.

Continual long-term research and development ("R&D") lies at the heart of the value of these pharmaceutical companies. Revenues from their successful medicines have been reinvested in R&D to discover, develop, gain regulatory approval and bring to patients the next innovative medicines that bring incremental benefits[1] (i.e. improved longevity and health status and decreased use of non-pharmaceutical health services) not only to the patients but to the society overall. In this context, it is important to keep in mind that revenues from today's innovative medicines are reinvested in the R&D that will bring us the next generation of medicines and potential cures to diseases.

Novartis recognizes that sustainability of the healthcare system is an important concern for all Canadians. Discussions about the sustainability of healthcare system must take a comprehensive approach, which includes ensuring that current and future generations of Canadians continue to have access to the best available medicines. Novartis is concerned that pursuing PMPRB reform in isolation, without putting pricing in the context of broader health policy frameworks and regulations that appropriately recognize innovation, could translate into less R&D investment, slow down innovation and, eventually, negatively impact patient access to effective therapies and new breakthrough treatments.

Novartis encourages the PMPRB, provincial and federal governments and others involved in conversations about healthcare sustainability to recognize patented medicines for the benefits they bring to society and the savings they produce in other areas of the healthcare system. As outlined in the Canadian Centre for Health Economics report, Changing the Way We Think About Drug Prices: Insights from Economics[2], "Pharmaceutical R&D is a capital asset that incurs costs and yields benefits over time."

Discussion around affordability of medicine, in the context of access to medicine and healthcare sustainability, goes beyond the current mandate of the PMPRB. Affordability must be examined from a holistic and societal perspective, looking at all aspects of healthcare expenditures. These discussions are most appropriately led by federal, provincial and territorial governments and must involve input from all health system stakeholders.

More specific to this current PMPRB Discussion Paper, Novartis wishes to provide additional observations on the following topics: 1) Therapeutic Benefits, 2) Price Differential, and 3) Regulation limited to single-source patented drugs.

1-Therapeutic Benefits

Novartis supports the notion that pharmaceuticals should be recognized based on the incremental therapeutic benefits each innovative medicine brings. The PMPRB's notional idea to categorize drugs based on potential for abuse of statutory monopoly using economic-based thresholds, without any recognition of the incremental therapeutic benefits, raises both fundamental and practical concerns. Novartis believes that a more comprehensive approach that continues to consider incremental therapeutic benefits and thus innovation is warranted.

Additionally, in its Discussion Paper, page 14, the PMPRB seems to have interpreted the Celgene Supreme Court decision as supporting the PMPRB's position to dismiss the appropriateness of categorizing new patented drugs based on perceived therapeutic benefit to align price ceiling with innovation. Novartis

respectfully disagrees with PMPRB's interpretation. It is Novartis' understanding that the appeal before the Supreme Court was limited to a jurisdictional question. Further, the Supreme Court acknowledged the existing approach whereby the price of new patented medicines is compared to the price of comparable medicines to determine whether the price is excessive. The Supreme Court did not provide any negative comment on the existing approach and thus the Supreme Court decision does not provide any support for the position that the PMPRB appears to be now taking that new patented dugs should not be categorized based on therapeutic benefit.

2- Price Differential

In the section "Any Market Review", page 19 of the Discussion Paper, PMPRB questions whether price variation between provinces and payer types should be considered a form of excessive pricing.

On this topic, it is worth noting that price variation that may arise after the introduction of a drug is often a function of difference in provincial price policies or different market dynamics (i.e. formulary listing dates, benefits provided to certain customers, etc.).

The PMPRB currently reviews the prices of drugs by provinces/territories and by classes of customer (hospital, wholesaler and pharmacy) at introduction or during investigations to ensure the prices are not excessive. The current guidelines allow for some price flexibility between provinces/territories and classes of customers as long as the price in each respective market is below or equal to the ceiling price. Moving to one single price by potentially establishing the ceiling based on the lowest priced market is not aligned with current market realities. Furthermore, this would be in contradiction with the 2010 PMPRB Guidelines changes related to the DIP methodology which was introduced to recognize that the offering of benefits to certain customers can be beneficial.

Novartis also believes that price differential offers the ability to improve the overall well-being of society by bringing the notion of equity in the equation. By definition "equity" means "giving everyone what they need to succeed" as opposed to giving everyone the same thing regardless of where they started (i.e. equality). The publicly-funded programs, which are developed to provide insurance coverage for those most in need, based on age, income, and medical condition, are advantaged by a price differential. From a societal perspective, removing this opportunity could have undesirable implications for populations with the greatest need.

3- Regulation Limited to Single-Source Patented Drugs

Novartis welcomes the opportunity to provide comments on additional aspects of the guidelines that would warrant reform. One area for potential reform is the current regulatory burden and periodic reporting associated with patented medicines competing in a multi-source environment. Since PMPRB's role is to ensure that patentees do not abuse their rights by charging consumers excessive prices during the statutory monopoly period, we feel the PMPRB's focus should be limited to the period of time the patented medicines has market exclusivity (i.e. monopoly). As such, Novartis recommends that the role of PMPRB be limited to the time period where the patented medicine has exclusivity and end when there is loss of exclusivity.

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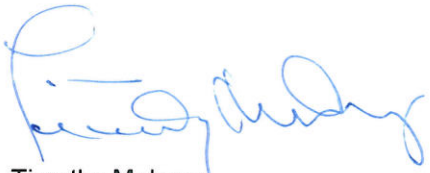
In conclusion, we trust that any changes to the Guidelines brought forward by the PMPRB will only be applied prospectively and that appropriate transition time will be provided to all stakeholders. Novartis trusts that these potential changes to the Guidelines will help PMPRB in its current mandate which is to ensure that drug prices are not excessive. In parallel, Novartis, as a leading healthcare company and member of both IMC and BIOTECanada, encourages all stakeholders to continue the discussions around affordability of medicine, access to medicine and the sustainability of the healthcare system.

Again, on behalf of Novartis, I thank you for the opportunity to participate in the discussion around the modernization of the guidelines and look forward to being an active partner in any future discussion.

Sincerely yours,



Timothy Maloney
President
Novartis Pharmaceuticals Canada Inc.

[1] Lichtenberg, F.R. The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings. Montreal Economic Institute. 2016

[2] http://www.canadiancentreforhealtheconomics.ca/papers/changing-the-way-we-think-about-drug-prices-insights-from-economics/. Visited on October 14, 2016