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February 13, 2018

Ms. 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, ON
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VIA E-MAIL
PMR-Consultations-RMB@hc-sc.gc.ca

Re: Novartis Response to Canada Gazette, Part I published December 2, 2017, Regulations Amending the Patented Medicines Regulations

Dear Ms. Reynolds:

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), I would like to share with you significant concerns we have regarding the **Regulations Amending the Patented Medicines Regulations** published in Canada Gazette, Part I on December 2, 2017.

While Novartis recognizes that affordability, accessibility, and appropriate use of pharmaceuticals are an important concern for all Canadians, we believe that achieving sustainability of the health care system requires a comprehensive approach involving the active participation of all stakeholders. Novartis is concerned that pursuing pricing reform in isolation, without putting pricing of patented medicine in the context of broader health policy frameworks and regulations that appropriately recognize innovation, could translate into less innovation and negatively impact patient access to new breakthrough treatments.

As such, we strongly encourage the government to quickly engage all stakeholders into a "meaningful dialogue" before proceeding with the proposed regulatory amendments. Our common goal is to ensure that current and future generations of Canadians have timely access to the best available medicines; we welcome the opportunity to work together toward that goal.

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Based on our review of the Regulatory Impact Analysis Statement ("RIAS") and the Cost Benefit Analysis ("CBA"), we believe that the potential impacts of the proposed regulatory amendments have not been clearly identified, assessed, presented and addressed. In fact, if implemented as is, the proposed changes would have unintended consequences and potentially have detrimental impacts on the predictability of the Canadian pharmaceutical market, innovation, and ultimately, patient access. Radical price controls have shown to produce undesired effects on access to medicines; translating in greater morbidity and mortality.[1] The Proposed Amendments would also contradict the government's Innovation Agenda by creating additional short and long-term undesired consequences on the Canadian economy (i.e. negatively impacting employment, discouraging investments, etc.). Novartis is very concerned by the fact that none of these consequences were addressed in both the RIAS and CBA and is questioning why Health Canada is expediting the implementation of these significant changes in less than one year.

As such, we are requesting Health Canada to re-assess the proposed regulatory amendments and delay the regulatory changes until a more thorough analysis of the unintended consequences are made. Furthermore, while Novartis, as a member of both Innovative Medicines Canada ("IMC") and BIOTECanada, is in agreement with, and fully supports, the two responses submitted by our associations, we would like to specifically reiterate the following three priority points:

1. **PHARMACOECONOMICS: "Willingness-to-pay and ability-to-pay", needs to remain with those managing and setting priorities of their budgets, namely the payers.**

Pharmacoeconomics ("PE") analyses provide a rough assessment of the cost and value trade-off of any medicines that impact health for the purposes of payer decision-making and help inform price negotiations. In fact, PE analyses are only one of many factors that go into pharmaceutical decision-making process that rightly includes other important elements. Given its inherent limitations and lack of connection to patient and societal preference, as described in detail in the submissions of our associations, PE analyses are NEVER used to regulate price ceilings in any country.

Discussion around the pricing of patented medicines should recognize the uniqueness and complexity of the Canadian health care system. The PMPRB's national price regulation role is unique and does not exist in the other developed countries. While Novartis welcomes the assessment of best practices from the other developed countries, it must be acknowledged and recognized that these best practices involve negotiations with payers.

The "optimal price setting of medicines", based on "willingness-to-pay and ability-to-pay" of the payers, needs to remain with those managing and setting priorities of their budgets. Therefore, the PMPRB, as a price regulator and non-payer, is not in position to assess these factors which are arguably not consistent with the legislative standard of "excessive price." Furthermore, pricing and reimbursement of innovative patented pharmaceuticals in Canada is controlled at several levels, and revisited on several occasions during the life-cycle of the medicine, by 1) the PMPRB, 2) Health Technology Assessment ("HTA")

processes (i.e. Common Drug Review ("CDR"), pan-Canadian Oncology Drug Review ("pCODR"), Institut national d'excellence en santé et en services sociaux ("INESSS"), etc.), 3) joint price negotiations via the pan-Canadian Pharmaceutical Alliance ("pCPA"), and 4) the hospitals and group purchasing organizations ("GPO"), the federal, provincial and territorial public and private drug plans.

Recommendation: The "pharmacoeconomics" factors should be removed from the list of potential new price determination factors.

2. **CONFIDENTIAL REBATES: The impact of filing confidential rebates with the PMPRB could interfere with current rebating practices that provincial governments and patients currently benefit from.**

Public payers have negotiated volume discounts for many years and these are achieved through confidential rebates. 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 these rebates. Novartis also believes that price differential, transparent or not, offers the ability to improve the overall well-being of society by bringing the notion of equity into 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). From a societal perspective, any policy that would interfere with these well-established practices could have undesirable implications for populations with the greatest need.

Recommendation: The Proposed Regulations should not require reporting of confidential third party rebates.

3. **SCHEDULE OF COUNTRIES: The selection of countries should be based on specific criteria that allow for international benchmarking against leading global economies and health systems.**

While there is an opportunity to review the appropriateness of the current basket of countries, the important step of identifying and aligning on the criteria to select these countries, prior to actually selecting the specific countries, is crucial. Novartis' recommendation is that appropriate criteria should include some consideration of those countries with similar innovation policies, same health outcomes objectives and geographic proximity. Only once the criteria have been identified, vetted and accepted, should the selection of countries be initiated. Alternatively, the pre-existing G10 nations (i.e. Belgium, Canada, France, Germany, Italy, Japan, the Netherlands, Sweden, the United Kingdom, and the United States), already representing a reasonable group of comparative nations, could be hurriedly used as an alternative to the existing PMPRB 7 basket.

Recommendation: The Proposed changes to the Schedule of Countries Regulations should be delayed until there has been further consultation.

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In conclusion, affordability and accessibility must be examined from a holistic and societal perspective, looking at all aspects of healthcare expenditures. Novartis, as a leading healthcare company and member of both IMC and BIOTECanada, encourages all stakeholders to continue the discussions around affordability and accessibility of medicines and sustainability of the healthcare system. In the meantime, we trust that the implementation of the proposed amendments to the Patented Medicines Regulations will be delayed to allow Health Canada to re-assess the proposed changes and provide a more thorough analysis of the unintended consequences of such reform.

Again, on behalf of Novartis, I thank you for the opportunity to participate in this consultation and look forward to being an active partner in future discussions.

Sincerely yours,

Janice Murray
President
Novartis Pharmaceuticals Canada Inc.

[1] Rawson, N.S.B. How might the choice of prescription drugs in provincial public insurance plans be impacted if a cost-control system like New Zealand's was adopted in Canada? Canadian Health Policy, September 26, 2016.