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VIA E-MAIL
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Re: Novartis Response Regarding Proposed Amendments to the Patented Medicines Regulations

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), we thank you for the opportunity to participate in the consultation around the Proposed Amendments to the Patented Medicines Regulations – Protecting Canadians from Excessive Drug Prices ("Discussion Paper") of Health Canada ("HC") issued in May 2017.

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 generic medicines and biosimilars (Sandoz). Currently, the Canadian Novartis group of companies employs over 1800 Canadians from coast-to-coast.

Novartis is committed to science-based innovation through the discovery and development of innovative medicines to improve the well-being of all Canadians. Continual long-term research and development ("R&D") lies at the heart of our value to patients and the health care system. Revenues from today's successful innovative medicines are reinvested in R&D to discover, develop, gain regulatory approval and bring to patients the next generation of innovative medicines that bring incremental benefits to patients and society[1] (i.e. improved longevity and health status and decreased use of non-pharmaceutical health services).

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.

Novartis would like to specifically highlight the following six priority points.

1. **"Willingness-to-pay" is an issue that payers already manage. It is not an appropriate basis for price regulation.**

Discussion around the pricing of patented medicine should recognize the uniqueness and complexity of the Canadian health care system. PMPRB is an independent quasi-judicial body mandated to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The PMPRB's national price regulation role is unique and does not exist in the other developed countries. The pricing and reimbursement of innovative patented pharmaceuticals in Canada is controlled at several levels 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 federal, provincial and territorial public and private drug plans, hospitals and group purchasing organizations ("GPO").

Unlike many drug systems in Europe, Canada does not have a single drug payer but rather has a mixed system of public and private payers across 10 provinces, 3 territories together with the federal government. Novartis welcomes the assessment of best practices from the other developed countries, however, it must be acknowledged and recognized that these best practices involve negotiations with payers. Given the lack of centralized authority, Canada's market is not conducive to considering the payer issue of affordability and "willingness-to-pay" at the federal level. 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. As a non-payer, the PMPRB is not in position to assess these factors which are arguably not consistent with the legislative standard of "excessive price."

Furthermore, Canada already has similar mechanisms in place through pCPA and many private drug plans. The "willingness and ability-to-pay of payers", assessed via cost-utility thresholds and budget impact analyses, are revisited on several occasions during the life-cycle of the medicine by the HTA bodies, the pCPA, and the different public and private payers.

The government has not provided a clear justification for duplicating these efforts, or alternatively, enshrining Canadian Agency for Drugs and Technologies in Health ("CADTH") analysis into price regulation.

Health Canada should reconsider the proposed additional price determination factors and focus on measures more directly relevant to the PMPRB's non-excessive pricing mandate.

2. **Pharmacoeconomics has value in payer decision-making processes but is not an appropriate tool for price regulation.**

Pharmacoeconomics provides a rough assessment of the cost and value trade-off of any medicines that impact health for the purposes of payer decision-making and helps inform price negotiations. Pharmacoeconomic analyses have several limitations, often relying on numerous assumptions, which are

explored in detail in the submissions of our associations. These tools have particular limitations when it comes to drugs for rare diseases with very small patient populations. It should be noted that pharmacoeconomics is only one of many factors that goes into pharmaceutical decision-making process that rightly includes other important elements such as patient input. Given its inherent limitations and lack of connection to patient and societal preference, pharmacoeconomics is not useful to regulate price ceilings.

Pharmacoeconomic analysis thresholds are not used anywhere in the world to regulate ex-factory prices. Application of such thresholds could have significant unintended impacts on products that are actually marketed and available to Canadian patients. The proposed policy regarding pharmacoeconomic analysis thresholds should not be pursued.

3. **Health Canada should reconsider the criteria used to arrive at the proposed international basket and provide a more robust analysis of options.**

While there is an opportunity to review the appropriateness of the current basket of countries, the important step of identifying and aligning on the specific 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 specific criteria are 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.

4. **The impact of filing confidential rebates with the PMPRB is highly uncertain and 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.

The Health Canada discussion paper notes that rebates "would be taken into consideration by PMPRB when determining whether a patentee is compliant with ceilings set to determine price excessively." The use of confidential rebates in price regulation could have unintended impacts on pricing and rebating practices in the provinces.

We recommend this policy proposal not be pursued.

5. **Efforts to decrease regulatory burden for patented generic products must be equally applied to patented brand products that do not benefit from real-world market exclusivity.**

The current regulatory burden and periodic reporting associated with patented medicines is substantial to both industry and PMPRB. Since PMPRB's role is to ensure that patentees do not abuse their patents 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 brand medicine has exclusivity and ends when there is loss of exclusivity; removing the regulatory burden and periodic reporting for branded medicines competing in a multi-source environment and treating them in an equivalent manner to patented generic drugs (i.e. complaints-based only).

This could be very practical to implement. Once an Abbreviated New Drug Submission (generic drug submission) is approved by Health Canada, the PMPRB could cease to require filings for any of these multi-source products (i.e. INCLUDING the original brand product that may still have associated patents that do not confer any real-world market exclusivity). We would be pleased to further discuss opportunities for reducing regulatory burden with Health Canada.

6. **If implemented, the proposals would have unintended consequences and potentially detrimental impacts on the predictability of the Canadian pharmaceutical market, innovation, and ultimately patient access. For these reasons, the government should engage in a multi-stakeholder dialogue before proceeding with any regulatory reforms.**

Novartis recognizes that affordability, accessibility, and appropriate use of pharmaceuticals are an important concern for all Canadians. Our view is that achieving sustainability of the health care system requires a comprehensive approach involving all key stakeholders. Novartis is concerned that pursuing PMPRB 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.

Radical price controls have shown to produce undesired effects on access to medicines; translating in greater morbidity and mortality.[2] The Proposed Amendments would contradict the government's Innovative Agenda by creating additional short and long-term undesired consequences on the Canadian economy (i.e. negatively impacting employment, discouraging investments, etc.). Given these risks, the potential impacts of the proposed changes in this PMPRB pricing reform should be clearly identified, assessed and debated in the public domain. As such, we recommend that the government convene a joint public forum with all interested stakeholders in advance of any draft regulations to explore these policy proposals and their potential impacts further. Discussions around sustainability of the healthcare system should aim to ensure that current and future generations of Canadians continue to have timely access to the best available medicines.

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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 medicine and sustainability of the healthcare system. Additionally, we trust that any changes to the Patented Medicines Regulations will be appropriately transitioned and only be applied prospectively to new molecules, not yet made commercially available in Canada.

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.

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

[2] 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.