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VIA E-MAIL

February 14, 2020

Dr. Mitchell Levine
Chairperson
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
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Subject: Novartis Pharmaceutical Canada Inc. Response to the PMPRB Draft Guidelines

Dear Dr. Levine:

On behalf of Novartis Pharmaceuticals Canada Inc. ("Novartis"), an affiliate of Novartis AG, I would like to share with you significant concerns we have regarding the Patented Medicine Prices Review Board ("PMPRB") Draft Guidelines issued on November 21st, 2019. These comments are limited to the Draft Guidelines and are made without prejudice to any positions taken by Novartis in ongoing litigation on the *Patented Medicines Regulations*.

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 two businesses; innovative medicines (Novartis Pharmaceuticals) and cost-saving generic medicines (Sandoz). Currently, the Canadian Novartis group of companies who operate as independent entities (Novartis Pharmaceuticals Canada and Sandoz Canada) employ over 1000 Canadians from coast to coast, of which more than 856 people are employed by Novartis with the remaining employed by Sandoz. Novartis, one of the largest pharmaceutical companies in Canada both from an existing and upcoming portfolio, requests that the PMPRB and the Federal Government address and consider all the comments and recommendations received from the stakeholders directly impacted by this ongoing Pricing Reform.

As mentioned by many stakeholders, on several occasions, the Pricing Reform will have unintended consequences and detrimental impacts on the predictability of the Canadian pharmaceutical market, innovation, and ultimately, patient access to medicine. More specifically, from a Novartis perspective, based on our review of the PMPRB Draft Guidelines, the impact of the proposed changes to our business is estimated in the hundreds of millions of dollars, and will subsequently have consequences on our ability to provide medicines (new and existing) to Canadians. In addition, the changes will directly impact our future level of investments, as well as have a detrimental impact on our current workforce in Canada and limit our future growth in the country. It should be noted that Novartis has not yet been able to identify another industry in Canada that would have been imposed such drastic and important changes without any proper meaningful consultation and without proper assessment of the consequences. Sadly enough, the

unintended and unwarranted consequences of the Draft Guidelines, if implemented as is, will have a direct impact on all Canadians, including current and future generations.

While Novartis, as a member of both Innovative Medicines Canada ("IMC") and BIOTECanada, is in full agreement with, and fully supports, the two responses submitted by these industry associations, we would like to specifically reiterate the following three priority points:

1. **MAINTAIN THE INCREMENTAL THERAPEUTIC BENEFITS ASSESSMENT** - ***"pharmaceuticals should be recognized based on the incremental therapeutic benefits they bring"***

Novartis strongly believes that all new medicines should be recognized based on the incremental therapeutic benefits each of these medicines bring. As such, Novartis is very concerned with the PMPRB's proposal to use the *median* domestic Therapeutic Class Comparison ("dTCC") as part of the calculation of the Maximum List Price ("MLP") of a new medicine. Determining the MLP of a new innovative medicine using the lowest of Median International Price ("MIP") and the median dTCC of all potential comparators, without taking into consideration the incremental benefits this new medicine brings, is not only inappropriate and wrong, but raises both fundamental and practical concerns.

For example, a new innovative medicine bringing *substantial* therapeutic benefit (ex: decreasing mortality) could be assigned, under the proposed Draft Guidelines, a MLP not only lower than the MIP *but also lower than the price of less efficacious comparators,* which could include several older, less efficacious generic medicines. This approach, as proposed by the PMPRB, does not provide any "qualitative" appreciation of the value the new medicine brings, and from Novartis point of view, clearly falls outside the legislative mandate of the PMPRB to protect Canadians from excessive prices.

In addition, Novartis would like to provide additional concerns with another proposed change that could have a detrimental effect on Canadians: the Reasonable Relationship Test. The proposal of not allowing patentees to price multiple strengths of the same medicine at parity, will inevitably force patentees to make difficult decisions such as delaying the launch of some medicines in Canada due to the potential impact the Canadian price may have on other countries based on International Pricing Reference ("IRP"). More importantly, in some instances, the patentees may also have to make the difficult decision to not launch at all some specific strengths and/or some formulations.

From a Novartis' perspective, it is clear that the appropriate stakeholders were not involved nor consulted when the Draft Guidelines were constructed. PMPRB, *as the Pricing Regulator for Canadians,* should ensure that the changes to the Guidelines won't have the unwarranted and undesired effect of depriving current and future generations of Canadians from having access to the medicines they really need.

Recommendation: Novartis strongly believes that a more comprehensive approach that continues to consider incremental therapeutic benefits, and thus innovation, is warranted. Discussion regarding potential alternatives should be a mandate of future expert technical working groups; until then, the existing PMPRB process to assess new medicine, which includes therapeutic benefit assessment, should be maintained.

2. **REMOVE THE MAXIMUM REBATED PRICE - "Willingness-to-pay" and "Ability-to-pay" for all medicines need to remain with those managing and setting priorities of their budgets, namely the payers.**

While Novartis recognizes that the sustainability of the healthcare system is an important and real concern for all Canadians, Novartis believes that the discussions around "Willingness-to-pay" and "Ability-to-pay" for medicines, especially in the context of ensuring healthcare sustainability for current and future generations,

goes beyond the current mandate of the PMPRB. The PMPRB, as a price regulator, and more importantly *as a non-payer*, is not in a position to arbitrarily assess and determine the "Willingness-to-pay" and "Ability-to-pay" of the multiple Canadian payers.

The role of the PMPRB in Canada, as a pricing regulator, is unique and does not exist in any other developed countries. While Novartis appreciates that the PMPRB often compares itself to agencies in other developed countries, it must be acknowledged and recognized that these comparisons are inappropriate and lead to important misconception.

In fact, within its uniqueness and complexity, the Canadian healthcare system already involves many other key stakeholders/agencies that have the responsibility to ensure the ongoing assessment of the "Willingness-to-pay" and the "Ability-to-pay" for all medicines, new and existing, on several occasions during their life-cycle:

- Canadian Agency for Drugs and Technologies in Health ("CADTH") including the Common Drug Review ("CDR") and the pan-Canadian Oncology Drug Review ("pCODR"),
- Institut national d'excellence en santé et en services sociaux ("INESSS"),
- Pan-Canadian Pharmaceutical Alliance ("pCPA"),
- Hospitals and group purchasing organizations ("GPO"),
- Federal, provincial and territorial public drug plans, and
- Private drug plans.

As such, Novartis can only challenge the notion that additional pricing controls, such as the proposed notion of a Maximum Rebate Price ("MRP"), are required to address the sustainability of the healthcare system. Not only does the proposed inclusion of a MRP undermine the uniqueness and complexity of the Canadian health care system, it is not consistent with the legislative standard of "excessive price". The focus and the responsibility of the PMPRB should remain with ensuring that the MLP of new medicines in Canada are not excessive.

Recommendation: Novartis strongly believes that the "Willingness-to-pay" and the "Ability-to-pay" for all medicines need to remain with those managing and setting priorities of their budgets, namely the payers. Discussion regarding potential alternatives to address the sustainability of the healthcare system, including any changes to our unique and complex Canadian healthcare system, should not be done in silo, and most importantly should be led by the Federal, Provincial and Territorial governments – not the PMPRB. In the meantime, Novartis requests that the notion of MRP be removed from the proposed Guidelines.

3. <u>POSTPONE THE IMPLEMENTATION OF THE GUIDELINES</u> - Implementation of the Guidelines should be prospective only and should provide appropriate time for patentees to prepare.

Novartis is very concerned by how the PMPRB is rushing through the consultation in order to implement the Revised Guidelines by July 2020, while dismissing all the potential direct and indirect consequences these changes will generate. It is Novartis' understanding that the potential implementation of the Guidelines on July 2020 was arbitrarily chosen and could easily be postponed to a later date when all changes have been well thought out and addressed, and more importantly, that all stakeholders directly impacted are provided appropriate time to prepare.

Furthermore, Novartis challenges the notion that the introductory price of new medicines that received a Drug Identifier Number ("DIN") on or after August 21st, 2019 would be assessed under the Revised Guidelines irrespective of when these would be finalized and implemented. Not only is this inappropriate and procedurally unfair, but the lack of predictability and high uncertainty resulting from the magnitude of

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the proposed changes is already creating undesired consequences, such as delays in launch and/or decrease in investments and support for these medicines. Again, it is the responsibility of the PMPRB to ensure that the changes to the Revised Guidelines won't have the unwarranted effects of depriving Canadians from the medicines they really need. As a result, the PMPRB should address the situation and provide more clarity and certainty to patentees by making an official statement that the Revised Guidelines, once finalized, will only apply to new medicines with DINs granted afterwards.

Finally, with close to 100 DINs reported to the PMPRB and many upcoming launches, Novartis is concerned by the fact that July 1st 2020 is just around the corner and provides less than 4 ½ months to appropriately prepare. These timelines are not reasonable for any industry to adjust to without significant negative implications to one's business model. Moreover, Novartis would like to stress again that the much warranted technical working groups mentioned by the PMPRB have not yet been initiated. As such, Novartis is again reiterating the importance for the PMPRB to postpone the implementation and take the appropriate time required to conduct a "meaningful consultation" with knowledgeable and impacted stakeholders to ensure that a thorough analysis of all the unintended consequences of the proposed changes are made and all questions/concerns have been addressed.

Recommendation: Novartis strongly encourages the PMPRB to postpone the implementation of any changes to the Guidelines and to quickly engage all stakeholders, mainly those directly impacted by these changes, into a meaningful dialogue. Our common goal is to ensure that current and future generations of Canadians have timely access to the best available medicines they need; we welcome the opportunity to work together toward that goal.

In conclusion, we trust that the PMPRB will only make the appropriate changes to the Guidelines to help with its current mandate which is to ensure that drug prices are not excessive. Novartis trusts that these changes will continue to acknowledge the incremental therapeutic benefits of new medicines and that the proposed scrutiny on MRP will be removed. Furthermore, we ask that the PMPRB postpone the implementation of the Revised Guidelines, engage stakeholders in meaningful discussions to ensure that concerns are adequately addressed and, as importantly, provide patentees with the appropriate time to prepare for these significant, complex and burdensome changes to our business model.

Again, on behalf of Novartis, I thank you for the opportunity to participate in this consultation and look forward to meeting with you at the upcoming Policy Forum.

Sincerely yours,

Christian Macher
Country President and Oncology General Manager Canada
Novartis Pharmaceuticals Canada Inc.