

VIA E-MAIL

July 31, 2020

Dr. Mitchell Levine
Chairperson
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1

Subject: Novartis Pharmaceuticals Canada Inc. Response to the PMPRB Revised 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 our comments and concerns as part of the Federal Government's public consultation regarding the Patented Medicine Prices Review Board ("PMPRB") Draft Guidelines (second version) issued on June 19, 2020 ("Draft Guidelines").

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 employs approximately 1,600 Canadians from coast to coast, of which more than 863 people are employed by Novartis with the remaining employed by Sandoz. We are one of the largest pharmaceutical companies in Canada, both in terms of existing medicines and future product portfolio and are at the forefront of bringing innovative medicines to Canadians. In 2019, we launched the first CAR-T therapy in Canada. In 2020, we plan on delivering to Canadians the first gene therapies for the treatment of both spinal muscular atrophy and vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations.

Novartis remains deeply concerned that crucial stakeholder feedback, which was previously communicated, has yet to be addressed or factored in the most recent Draft Guidelines. As we and many other stakeholders have stated on several occasions, the pricing reforms will have unintended consequences and detrimental impacts on the predictability of the Canadian pharmaceutical market, innovation, and ultimately, patient access to medicines.

Novartis, as a member of both Innovative Medicines Canada ("IMC") and BIOTECanada, continues to be in full agreement with, and fully supports, the two responses submitted by our industry associations. We believe a better path forward can be achieved to address both affordability and accessibility of medicines.

From a Novartis perspective, we believe that, the lack of 1), clarity and predictability, 2) fairness, 3) confidentiality and 4) practicability associated with the Draft Guidelines will jeopardize the ability of patentees, such as Novartis, to launch new medicines in Canada. As an innovator of new medicines we believe that any approach to address affordability, as is being done in other countries, should remain under the responsibility of the payers in order not to impede new product launches and stifle future innovation. We continue to seek an open dialogue with the PMPRB and the Federal government towards better reforms that meet the needs of all stakeholders. Fundamentally, we believe that sound principles should be adhered to with these reforms and at a minimum, the following areas require further attention and modifications through the PMPRB consultation process:

1. The Guidelines need to be clear and predictable

The revised Draft Guidelines are unclear and provide no predictability to patentees. For example, the backbone of the proposed Maximum Rebated Price (“MRP”) formula would be based on 1) the use of a pharmacoeconomic (“PE”) value which would be determined by a Health Technology Assessment (“HTA”) body or 2) the use of the median domestic therapeutic class comparator (“dTCC”) value which would be determined by the PMPRB Staff. Unfortunately, these values will be provided to the patentees a few months after the product is launched in some cases, or several months or years after the product is launched in most cases. This lack of clarity and predictability during the planning phase, more specifically when Global Launch Sequence decisions are made (Go / No-go decisions), could bring patentees to take unwanted and undesired decisions of either delaying or not introducing medicines in Canada due to the uncertainty. The introduction of these new elements in the Guidelines, which rely on a highly arbitrary and subjective process, will create unnecessary uncertainties. Because of the lack of clarity and predictability and untenable business impacts, the MRP component is a threat to future product launches in Canada and should be removed.

2. The Guidelines need to be fair

PE analyses, which often rely on numerous assumptions, are only one of many important factors and elements used in the pharmaceutical decision-making process that rightly includes other important elements. In fact, PE analyses only provide a rough assessment of the range of cost and value trade-offs of a medicine for the purposes of payer decision-making and to help inform price negotiations with payers. Additionally, given their inherent limitations and lack of connection to patient and societal preference, to our knowledge, PE analyses are never used to regulate price ceilings in any country. PE analyses do not provide one single value, they provide a range of possible outcomes. As such, we will continue to question the fairness of relying on one PE value in the context of pricing regulations. Can the PMPRB guarantee that the single value selected by the HTA body is the right value when estimates differ widely?

Furthermore, while the proposed market size adjustment to the MRP (i.e. MRP[a]) is positioned by the PMPRB as a way to address affordability, the proposed formula only relies on the gross revenues of the medicine. This proposed market size adjustment is applied irrespectively of the savings the medicine might be bringing to Canadians as it does not include the very important fundamental concept of “incremental” cost or value. While budget impact analyses are also part of the decision-making process of payers, these analyses rely on the “incremental cost” assessments, which could be associated with actual savings from the new medicines. The PMPRB appears to have opted for the easy and simple, yet unfair option, of regulating price on the basis of gross revenues of a medicine (i.e. profitability) without taking into account important factors such as real savings. Therefore, we will continue to question the fairness of this approach, especially in the context of pricing regulations. Because of the lack of fairness, the MRP component is again a threat to future product launches in Canada and should be removed.

3. The Guidelines need to protect the Confidentiality of Business Information

The protection of intellectual property and confidential business information is a fundamental element for all patentees who research, develop and commercialize new medicines. For example, the introduction of the different MRP ceilings undermine confidential business information and is inconsistent with the recent Federal Court decision¹ because it significantly overvalues PE value and/or market size and all but ignores the other section 85 factors under the *Patent Act*. Because of the lack of confidentiality, the MRP component is a threat to future product launches in Canada and should be removed.

4. The Guidelines need to be practical

The PMPRB, as a national price ceiling regulator, is an independent quasi-judicial body mandated to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive. The “raison d’être” of the Guidelines should be to provide guidance to patentees on how to be compliant. Unfortunately, there are still several unrealistic expectations in the Draft Guidelines. In fact, the Draft Guidelines remain excessively complex, unclear and are not in a sufficiently advanced state of development to be effectively implemented by January 1, 2021, the effective date of the regulations.

An example, which also supports the ongoing theme that the MRP component should be removed from the Guidelines, is the unrealistic expectation that the patentees are to be compliant with the new MRP within only two reporting periods of the MRP being known. This suggests that the PMPRB does not appreciate nor recognize the uniqueness and complexity of the Canadian health care system. In order to be compliant with the new MRP, the patentee would have to make numerous and sometimes complex changes to ensure the annual national average transaction price (“NATP”) remains below the MRP. Because of the lack of practicability, the MRP component is again a threat to future product launches in Canada and should be removed.

Simple Case Study – For illustration only

Medicine XYZ is a new preventive treatment required annually and it is expected that all Canadians would be treated. For the purposes of this case study, let’s assume this new medicine is a treatment for COVID-19². A medicine all Canadians, and the world are waiting for. The List Price of the medicine (\$10), which is also the annual cost per patient, is at the Median of the PMPRB11. Given that all Canadians would require this annual treatment, the expected annual revenues for this medicine would be approximately \$376M. A cost that our society certainly can afford, and one that would provide tremendous value to society at large. As a reminder, the Federal Government estimated the overall cost associated with COVID-19 to be around \$929.7B³.

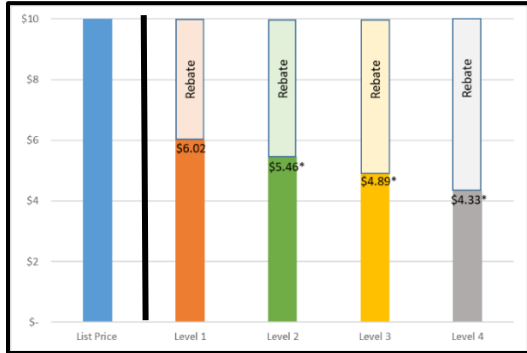
This new medicine would be classified as Category 1 as it would trigger the \$50M annual revenues threshold for market size. As a result, the patentee would be assigned a MRP. At annual gross revenues of \$376M, the potential MRP[a] would range between \$7.15 (corresponding to a rebate of 28.5%) and \$4.33 (corresponding to a rebate of 56.7%). See Figure 1 for the potential scenarios based on the Therapeutic Criteria Level.

¹ *Innovative Medicines Canada v Canada (Attorney General)*, 2020 FC 725 (Federal Court Decision, The Hon. Justice Mason, Docket T-1465-19 June 29, 2020)

² For illustrative Purpose only. Medicine XYZ would probably be exempted from investigations as per section 90 of the Draft Guidelines unless a complaint is received. In which case, it is unclear what the outcome would be.

³ <https://www.cbc.ca/news/politics/covid-19-economic-programs-1.5543092> - visited on July 28th 2020.

Figure 1. List Price and potential MRP[a] ceilings for annual revenues of \$376M



Lack of Clarity and Predictability: There are several potential outcomes for the MRP[a] that will not be known to the patentee until the \$50M is triggered; hence the potential ceilings ranging from \$7.15 to \$4.33

Lack of Fairness: What are the direct and indirect costs associated with COVID since March? Is the \$10 annual treatment cost or the annual expenditures of \$370M excessive from a Canadian perspective? Interesting when the medicine is placed in context of "incremental cost".

Lack of Confidentiality: The MRP[a] ceilings can be determined as presented above. At best the MRP[a] ceiling would be \$7.15 for Level 2, 3 and 4 but as low as \$4.33 (Floor for Level 4). If Level 1, the MRP[a] ceiling would be \$6.02.

* MRP[a] could be \$7.15 if the median dTCC > MLP (Level 2 - 4)

Questions for Canadians: Is the patentee abusing its monopoly power in this example? At List Price of \$10, is the medicine excessively priced? Can Canadians afford this medicine which corresponds to 0.04% of the overall cost of COVID-19 estimated by the Federal Government?

Summary and Final Recommendations

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 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" for the multiple Canadian payers. The focus and the responsibility of the PMPRB should remain with ensuring that the Maximum List Price (MLP) of new medicines in Canada is not excessive.

Discussions 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 conclusion, we trust that the PMPRB will make all the appropriate changes to the Guidelines to help with its defined mandate which is to ensure that drug prices are not excessive. Novartis requests that in light of the recent Federal Court Judicial Review decision as well as the many stakeholder comments, the concept of the MRP will be removed. Furthermore, we ask that the PMPRB and Federal Government engage with the pharmaceutical industry to embark on an alternative path towards a more fair approach for all parties in addressing drug affordability.

Again, on behalf of Novartis, I thank you for the opportunity to participate in this consultation and welcome an opportunity to discuss with you these reforms in greater detail.

Sincerely yours,



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