

VIA E-MAIL

November 30, 2022

Mélanie Bourassa Forcier
Vice-Chairperson
Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1

Subject: Sandoz Canada Inc. Response to the PMPRB Draft Guidelines

Dear Mrs. Bourassa Forcier,

On behalf of Sandoz Canada Inc. ("Sandoz"), a generic and biosimilar company, I would like to share with you the significant concerns we have regarding the Patented Medicine Prices Review Board ("PMPRB") Draft Guidelines issued on October 6, 2022.

Sandoz's purpose, as global leader in generic pharmaceuticals and biosimilars, is to discover new ways to improve and extend people's lives. In addition to holding the global number one ranking in biosimilar and generic antibiotics, dermatology and transplantation medicines, Sandoz portfolio includes six biosimilars and over 700 generic products covering 280 molecules and medicinal ingredients spanning over multiple therapeutic areas including, but not limited to, anti-infectives, cardiovascular, central nervous system, oncology, ophthalmology, transplantation, and women's health. Sandoz' broad offering translates into substantial and ongoing savings for patients and payors, which help to ensure the sustainability of healthcare systems in the face of significant budgetary pressures, while also freeing up funding for innovative medicines.

Sandoz recognizes that affordability, accessibility, and appropriate use of pharmaceuticals are important concerns for all Canadians. As an important leader in the medicines' ecosystem, Sandoz strongly believes in a well-balanced access to all medicines; including the innovator, the generics and the biosimilars, where the substantial and ongoing savings obtained with the early introductions and swift transitions to generics and biosimilars will be reinvested to support new innovative medicines to benefit all Canadians, current and future generations. On this note more specifically, Sandoz encourages all payors to take full advantage of their generic and biosimilar policies by strongly encouraging their members to transition to these more affordable options once available.

While Sandoz, as a member of Canadian Generic Pharmaceutical Association (“CGPA”), is in full agreement with, and fully supports, the response submitted by this industry association, we would like to emphasize our concern with the proposed PMPRB Draft Guidelines as we believe that, if implemented as is, the proposed changes will have unintended and unwarranted consequences on all Canadians, including current and future generations. More specifically, we are strongly concerned that these proposed PMPRB Draft Guidelines will block the most innovative medicines from entering the Canadian market and will certainly reduce Canada’s ability to attract new investments.

“All pharmaceuticals should be recognized based on the incremental therapeutic benefits they bring”

Sandoz believes that all new medicines should be recognized based on the incremental therapeutic benefits each of these medicines bring. Determining the Maximum List Price (“MLP”) of a new innovative medicine using the lowest of the Median International Price (“MIP”) and the domestic Therapeutic Class Comparison (“dTCC”), *without taking into consideration the incremental benefits this new medicine brings versus the comparator*, raises both fundamental and practical concerns. For example, a new innovative medicine bringing *substantial* therapeutic benefit, such as decreasing mortality, would be assigned, under the proposed Draft Guidelines, a MLP not only lower than the MIP *but potentially lower* than the price of a less efficacious comparator.

Furthermore, in addition for not acknowledging any “qualitative” appreciation of the value the new medicine brings, the PMPRB is proposing to use the lowest price of the medicine identified as the comparator. In other words, the price of the medicine identified in the dTCC could be a generic medicine launched more than 30 years ago and priced at 10% of the originator (ie 90% lower than the reference Brand medicine). This unjustified and unfair “race to the bottom”, should the new innovative medicine be capped at the price of much older medicine, will only block innovative medicines from entering the Canadian market; depriving us, all Canadians, of the medicines we really need.

“Radical price controls have shown to produce undesired effects on access to medicines; translating in greater morbidity and mortality.”ⁱ

Similarly, to many other industries in Canada, the pharmaceutical industry has been facing increasing pressure on their costs due to the high rate of inflation. Any initiatives and/or policies resulting in the decrease of prices, specifically given the unprecedented high inflation and the ongoing disruption at the global supply chain, will only threaten the already fragile viability of existing medicines and the introduction of new cost-saving generics and biosimilars to the Canadian market. Furthermore, such initiatives and/or policies would further contradict the government’s Innovation Agenda by creating additional short and long-term undesired consequences on the Canadian economy and would jeopardize the various life Science strategies already implemented in Canada by the different governments.

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. We also trust that these changes will continue to acknowledge the incremental therapeutic benefits of new medicines. It is of the responsibility of the PMPRB to 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.

Sincerely yours,



Michel Robidoux
President and General Manager

ⁱ 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.