



February 13, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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By email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Subject: Lundbeck Canada Inc. submission to PMPRB Draft Guidelines Consultation

Dear Dr. Levine and colleagues on the Patented Medicine Prices Review Board (PMPRB),

Lundbeck Canada Inc. (Lundbeck) appreciates the opportunity to provide input on the Patented Medicine Prices Review Board's (PMPRB's) Draft Guidelines for the implementation of the recent changes to the *Patented Medicines Regulations*. Lundbeck supports and has had an opportunity to contribute to the input from our industry association, Innovative Medicines Canada (IMC). The purpose of our submission is to highlight some of the unique challenges that the new pricing framework will have on patient access to treatments for brain diseases. We also want to thank the PMPRB staff for meeting with Lundbeck representatives in December 2019 and in January 2020.

Lundbeck is one of Canada's leading pharmaceutical companies focused on treatments for people living with brain diseases. As a global pharmaceutical company majority-owned by the Lundbeck Foundation, we develop and commercialize innovative medicines that focus on conditions such as depression, bipolar disorder and schizophrenia and other neurological diseases, including Parkinson's disease, Alzheimer's disease and migraine. We have been helping Canadians with brain diseases for more than twenty-five years.

The federal government has placed a high priority on working with the provinces and territories to improve the mental health of Canadians, including as a priority area for renewed health agreements. The most recent Speech from the Throne¹ and the Health Minister's mandate letter² both identify the need to "make sure that Canadians are able to get mental health care when they need it."

Unfortunately, the new price control system will make it much more difficult for Canadians to get access to new treatments, which is especially important in the mental health space. We support and want to contribute to government efforts to improve health system sustainability and the affordability of medicines, however, we have major concerns that the proposed approach will counteract other investments and efforts by the Government of Canada. Below we offer a number of considerations to help support a more functional pricing regime.

¹ https://www.canada.ca/content/dam/pco-bcp/documents/pm/Speech-from-the-Throne_2019.pdf

² <https://pm.gc.ca/en/mandate-letters/minister-health-mandate-letter>

CURRENT CHALLENGES OF TREATING MENTAL ILLNESS

At the moment, over 7.5 million Canadians are struggling with a mental health problem.³ It is a struggle that 1 in 3 Canadians will experience during their lifetime.⁴ In economic terms, mental illness costs the Canadian economy over \$50 billion each year through health care costs, lost productivity, and reductions in health-related quality of life, and that number is expected to reach \$2 trillion in the next two decades.⁵

Thankfully, like many other disease areas, mental illnesses can be treated. Pharmacotherapy has been a mainstay of psychiatry and is responsible for saving and improving the lives of millions of Canadians with mental illnesses. In this regard, a wide choice of pharmacotherapies is critical in this clinical area because the majority of patients must try several treatments and sometimes combinations of therapies before finding what works for them. And a treatment regimen that works for one patient may not necessarily work for another. This is because mental illnesses such as major depressive disorder and schizophrenia do not manifest in the same way in each individual. While outcomes are improving, there is still room for improvement. This is why it is important for companies like Lundbeck to be able to continue to innovate and to continue to bring innovative treatments to the Canadians who need them.

IMPACTS OF NEW PRICING REGIME ON ACCESS TO MENTAL HEALTH TREATMENTS

Lundbeck has serious concerns about the new **economic factors**, particularly the PMPRB's intention to use Canadian Agency for Drugs and Technologies in Health (CADTH) interpretations of **pharmacoeconomic value** to set the Maximum Rebated Price (MRP). As it is, CADTH's evaluations already represent a significant obstacle to access mental health treatments.

CADTH routinely rejects medications for the treatment of mental illnesses disproportionately to drugs for other illnesses and takes longer to provide its recommendations. To illustrate, since the inception of the Common Drug Review (CDR), 76% of mental health drugs received a negative recommendation versus 48% for non-mental health drugs.⁶ As of 2019, CDR has rejected every single new drug submission for attention deficit hyperactivity disorder (ADHD) and major depressive disorder (MDD), despite these having been previously approved by Health Canada as both safe and effective (favorable risk benefit ratio).⁷

³ https://www.mentalhealthcommission.ca/sites/default/files/2017-03/case_for_investment_eng.pdf

⁴ <https://www.canada.ca/en/public-health/services/about-mental-illness.html>

⁵ https://www.mentalhealthcommission.ca/sites/default/files/2016-06/Investing_in_Mental_Health_FINAL_Version_ENG.pdf

⁶ Tran, K., et al., HTA decisions and access to mental health treatments in Canada's public drug plans. Canadian Health Policy, February 2017. (Note that the study reviewed spending for all provinces, excluding Quebec, plus the federal Non-Insured Health Benefits program.)

⁷ Canadian Health Policy Institute (CHPI). HTA and public coverage of new mental health drugs in Quebec and Canada. Canadian Health Policy, July 2019.

The problem is that CADTH applies the same evaluation criteria to all non-cancer treatments without regard to the noteworthy differences in patient populations and response to treatment. With medications for the treatment of brain disease being particularly stigmatised or when taking into consideration the aforementioned rejection rates, one could go as far as to say that they are discriminated against. Treatments for mental illnesses are typically viewed as affecting a person's temperament and quality of life and not their overall health, which is preposterous in today's day and age. Mental illnesses being viewed as "non-life-threatening," despite the fact that roughly 90% of the 4,000 suicides in Canada every year are mental illness related is not only nonsensical but is insulting to the people who struggle with these illnesses for the better part of their lives.⁸

It is important to keep in mind that health technology assessments (HTA) are not consistent with eventual use in clinical practice. Many of the new drugs rejected by CDR were eventually covered by public and private drug plans across Canada. This underlines the fact that the HTA process is not synchronized with actual clinical practice and that the health community, private drug plans and employers place a higher value on these products than Canada's HTA methods currently allow.⁹ At Lundbeck, we routinely hear from mental health opinion leaders who express their frustration with the methods used by CADTH which limit their access to potentially life saving medications. Among those methods are subjective analyses in diseases where interpretations can differ from one HTA expert to another as well as the use of arbitrary pharmacoeconomic thresholds as the basis for price regulation.

The current HTA system has many deficiencies, but it still offers pathways to reimbursement. However, taking these deficiencies and applying them to the price regulation level could effectively block access altogether to effective and safe treatments if the prices of new treatments are required to be lowered to unsustainable levels in order to meet CADTH's ICER threshold. This issue will have a dramatic impact on all therapeutic areas, but particularly in the mental health space, where access to as many different treatment options as possible is absolutely vital given the heterogeneity of the impacted patient population.

The new **market size adjustment methodology** also represents an arbitrary means of controlling company revenues with no meaningful connection to whether a medicine is priced excessively or whether the medicine has the potential to save costs to the system. This measure will not only unfairly punish many of the most successful medicines that hold the most promise to the most people, but will also create significant disincentives for the commercialization of new therapies in Canada. Moreover, under certain scenarios, the market size adjustment methodology would bring potential net prices below the lowest available international prices (LIP) in the PMPRB 11 countries, which goes beyond the original policy objectives of aligning Canadian prices with the

⁸ Weir E., Suicide: The hidden epidemic. Canadian Medical Association Journal. 2001;165(5):634; Mościcki EK. Epidemiology of completed and attempted suicide: Toward a framework for prevention. Clinical Neuroscience Research. 2001;1:310-23; cited in Health at a Glance, Statistics Canada, June 16, 2017 (<http://www.statcan.gc.ca/pub/82-624-x/2012001/article/11696-eng.htm#n1>).

⁹ Canadian Health Policy Institute (CHPI). HTA and public coverage of new mental health drugs in Quebec and Canada. Canadian Health Policy, July 2019.

international median prices (IMP) of the PMPRB 11. Another limitation to the market size criteria is that it is based on forecasts. There is currently no mechanism in the Draft Guidelines that permits patentees to move back from Category I to Category II if the forecasts are not achieved.

The Draft Guidelines are also ambiguous and unclear in many areas, which is creating significant **uncertainty** in the Canadian pharmaceutical market place. As currently drafted, it is difficult to understand and predict the allowable price ceilings for the MLP and MRP, which complicates business planning. For instance, the use of **domestic Therapeutic Class Comparisons (dTCC)** to set the MLP and in some cases the MRP lacks clarity around how the PMPRB will select the comparators. The terminology used (e.g., *typically, normally, may, and in some cases*) points to an arbitrary selection process that can be unilaterally adapted to meet the desired cost savings (e.g. through the proposed use of generics as comparator drugs). This ambiguity around the allowable ceiling prices creates problems for long-term business planning. Moving forward, there needs to be appropriate price floors for all products to ensure some degree of certainty around pricing.

Another question that needs to be considered is **what if Canada is the first launch country before any of the PMPRB 11 markets?** In this circumstance there would be no comparator among the PMPRB11. The current Draft Guidelines have not contemplated how the interim Maximum List Price (iMLP) would be set for the first three (3) years, creating extensive uncertainty and further deterring manufacturers from launching new medicines in a timely manner in Canada. One potential solution would be to allow manufacturers to set their prices more liberally in the early years (e.g. the first 3 years or until 5 countries from the PMPRB 11 have launched). This will also allow an appropriate determination of the international median price and the applicable lowest international price floor to a certain medicine.

There are also ongoing concerns about the **confidentiality provisions**, which require the disclosure of confidential commercial terms and net prices to the PMPRB to develop the MRP. The methodology used to derive the Pharmacoeconomic Price (PEP) with publicly available inputs can be used by competitors, in Canada and elsewhere, to determine the confidential ceiling price by reverse-engineering the information. This will create further disincentives for companies to enter into product listing agreements with payers in Canada.

In addition, the Draft Guidelines will have a much greater financial impact than the estimate provided by Health Canada in the cost-benefit analysis (CBA) associated with the regulatory amendments published in Canada Gazette Part II on August 21st, 2019. A yet to be released assessment prepared by a third-party expert commissioned by IMC suggests the proposals will result in up to \$41.8 billion net present value (NPV) in negative impacts over ten years. This compares to the \$8.8 billion impact estimate in Health Canada's revised CBA. This significant difference is partially explained by the fact that the CBA was not based on the Draft Guidelines, but rather, was based on a notional Guideline scenario that is materially different from the PMPRB's November 2019 policy implementation proposals.

In sum, there are too many moving parts and uncertainties regarding the application of the new pricing regime. Moving forward, Canadian affiliates will face difficulties in making a compelling business case to their global headquarters to prioritize the Canadian market for new drug launches, clinical trials and investments in health research. A recent Life Sciences Ontario survey suggests that many companies are already faced with these tough decisions.¹⁰

RECOMMENDATIONS

Given the above considerations, Lundbeck Canada encourages the PMPRB to adapt its proposed approach, as outlined in its Draft Guidelines, by considering the following high-level recommendations:

1. **Use the economic factors in exceptional circumstances only:** The proposed economic factors are causing significant uncertainty for industry and will lead to unpredictable and unsustainable price reductions for innovative medicines. The PMPRB itself has acknowledged the “inherent uncertainty in ICER values and the cost utility analyses upon which they are based.”¹¹ Given this level of uncertainty, we encourage you to take a more measured approach to the application of the economic factors, applying them only in exceptional circumstances. We believe the same should also apply to the market size adjustment methodology and only consider it on an exceptional and actual sales basis. For instance, the PMPRB can consider using them as a back-up tool to investigate potential excessive pricing as part of a hearing.
2. **Provide greater clarity about how the new pricing system will work in practice:** We encourage you to work with our industry association, Innovative Medicines Canada (IMC), to provide greater clarity around the workability of the new regulatory framework. More extensive case studies should be done to ensure that the new system does not lead to unexpected and unintended consequences. As a first step, the PMPRB should aim to establish Industry Working Groups as soon as possible to address the remaining areas of concern.
3. **Implement the Guidelines over a longer time horizon and gradually:** Lundbeck recommends taking the time to get it right, which means having extensive dialogue with industry to resolve any outstanding issues and properly assessing the impact of each of the changes, before moving forward with an approach. A longer time frame and a gradual approach will allow patentees a more reasonable time to comply with the new guidelines taking into considerations all the existing complexity of the systems and stakeholders involved.

¹⁰ <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>

¹¹ PMPRB Draft Guidelines Backgrounder, p. 7: <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/backgrounder-draft-guidelines-en.pdf>

FINAL THOUGHTS

In conclusion, the recent changes to the *Patented Medicines Regulations* and the PMPRB's Draft Guidelines will increase the uncertainty innovators already face in developing and commercializing new mental health treatments in Canada. Lundbeck fully supports reform that contributes to health system sustainability, and better and more affordable access to medicines for patients; however, we do not believe the proposed Draft Guidelines as they stand will make a positive contribution to these objectives. We are concerned that the Draft Guidelines present several potential unintended consequences that would make the situation worse, including less access to innovative medications that are aligned with patients and government priorities, coupled with significant losses in R&D investments and highly skilled jobs that are key to growth across Canada.

Given the unmet medical and psychiatric needs of a diverse patient pool, the growing disease burden of people living with diseases of the brain, the federal government's focus on mental health, and promising medical advances in this area, we strongly encourage the PMPRB to work with industry to develop a more pragmatic approach – one that improves patient access and affordability, while addressing the potential unintended consequences.

Sincerely,

A handwritten signature in blue ink, appearing to read "Sylvie Pilon".

Sylvie Pilon
Vice President & General Manager
Lundbeck Canada Inc.