August 4, 2020

Douglas Clark
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Sent via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

**RE: PMPRB June 2020 Revised Draft Guidelines consultation**

Dear Mr. Clark,

On behalf of the Canadian Psoriasis Network (CPN), thank you for the opportunity to provide feedback on the PMPRB's June 2020 Revised Draft Guidelines.

CPN is a national non-profit organization focused on enhancing the quality of life of people with psoriatic diseases (psoriasis and psoriatic arthritis). Psoriasis is a non-contagious, chronic, inflammatory condition that affects the regeneration of skin cells and that touches an estimated half a million Canadians and their families. About one third of psoriasis patients will develop psoriatic arthritis. Psoriatic diseases increase one's risks of other serious health conditions including depression, metabolic syndrome, diabetes, cardiovascular disease and irritable bowel diseases. Particularly for people with severe symptoms, psoriatic diseases can negatively affect all aspects of one's life including self-image, social and intimate relationships, school and work. Living well with these conditions takes a holistic approach to physical and mental health, which for many includes prescription medicines. There is no cure, though new innovations bring us closer to closing this gap.

**Basis of our submission**

CPN works closely with the broader patient community on issues related to drug and health policy, including as a member of the Best Medicines Coalition and as a co-organizer of the Patient's Redefining Healthcare Summit.  CPN is also an affiliate of the Canadian Skin Patient Alliance (CSPA) and endorses their submission to this consultation as a member of the skin patient community in Canada.

In this submission, we aim to highlight key considerations for the Revised Draft Guidelines in light of the perspectives we most often hear from the psoriasis patient community when it comes to accessing medicines. Specifically:

- **Psoriatic disease patients often cannot afford medicines that are available in Canada, particularly new treatments**. Access to innovative medicines in particular, which can put people into full remission of symptoms in many cases, are out of reach for most people who are not enrolled in a private drug plan,

a public drug plan or a Patient Support Program. For those who do have public or private drug insurance, the copayments and deductibles can be significant.

- **Treatment options matter to psoriatic disease patients.** In Canada, treating psoriasis can be an onerous process and usually involves failing on several different medications before finding one that is effective for the individual. Several factors may contribute to this, including the individual's unique response to different treatments as well as the nature of psoriatic diseases and the tendency for people to build a tolerance to treatments over time. This is compounded by drug plan policies that often take a step-therapy approach that requires patients to fail on certain treatments in order to possibly access others that may be more appropriate for them. Waiting to find a treatment that works, or hoping that they will be able to access other options if and when their current treatment fails, results in many people with psoriasis feeling like their lives are passing them by as they worry that options may run out and that symptoms may return and/or worsen.

In light of these perspectives, we offer the following for your consideration.

**1. Improve the affordability of medicines for all patients in Canada**

In our analysis of the Revised Draft Guidelines, one of the main questions that we used as a guiding principle is how will the cost savings inferred from these reforms have a direct benefit to patients? We want to see speedy entry of safe and efficacious innovative treatments into Canada to help address unmet need and we want to ensure that new medicines reach the people who may need them. As such we support the federal government's original mandate to improve access and affordability of prescription drugs and the PMRPB's objective to reduce drug prices, inasmuch as these goals improve access for patients, including to new medicines.

What is unclear is just how this reform fits into the bigger picture for patients and how these savings will be translated into actually helping people manage their out-of-pocket drug costs, included coinsurance costs. We recognize that making health policy is not the role of PMPRB, except as it relates to its specific mandate around drug pricing. That said, it is worth revisiting the original mandate letter to the Minister of Health in 2015 which stated in part, "Improve access to necessary prescription medications. This will include joining with provincial and territorial governments to buy drugs in bulk, reducing the cost Canadian governments pay for these drugs, making them more affordable for Canadians, and exploring the need for a national formulary".

**Using the savings from PMPRB for the health system is consistent with the broader goal of the government to improve access to necessary prescription (patented) medicines. As such, we encourage the PMPRB to make a recommendation to federal-level policy makers to commit to work with their**

**provincial and territorial counterparts to reinvest any savings from PMPRB reforms to helping people in Canada access and afford the medicines that they need.**

**2. Address potential unintended consequences of reform**

Important aspects of the Revised Draft Guidelines continue to raise questions about the potential unintended consequences of reform for patients. As such, CPN encourages PMPRB to consider calls for a phased approach to implementing changes if required to address significant outstanding concerns.

To help understand the potential implications of the Revised Draft Guidelines on the psoriatic community, CPN commissioned case studies of two newer patented medicines to treat psoriasis (see Appendix). Early analysis indicates that a level of uncertainty is inherent in the current approach. Specifically, it is not straightforward to apply the definitions of each Therapeutic Criteria Level (TCL) because their definitions are open to significant variation in interpretation. For instance, each include "high QALY gains" as a criterion, but it is unclear how the PMPRB will determine how high these gains have to be in each of the first two TCLs. Though we are relieved to see that this would not have a significant impact on the two drugs analyzed, each drug will need to be looked at on a case-to-case basis. While we cannot make assumptions about how potential price reductions and even minor uncertainties may affect the multi-faceted deliberations of drug manufacturers, we still have questions about how reforms may have unintentional consequences for patient access. For instance, how might the introduction of this new process fit in with (or impede) the existing process in place for negotiations with pCPA, that must make pricing decisions in the medium term that match (or better) prices that will be established following PMPRB review?

**To help address this issue, we support the call from Save Your Skin Foundation and members of the oncology community to create and publish an algorithm, or more clearly defined criteria, for how drugs get categorized in the different TCL levels, that can be used to create greater certainty within the existing price negotiation processes.**

A further issue that remains unclear to us is raised by the CSPA. As set out in the revised draft guidelines, it appears that the focus is on regulating the rebate system that underlies how drug plans negotiate prices. Though drug plans apparently stand to benefit from the proposed approach, patients who pay coinsurance or who pay out-of-pocket for their prescriptions, will only stand to benefit from the reduction in list prices of patented medicines. Unfortunately, many in this population probably cannot afford to pay for drugs even at a reduced price.

**CPN supports CSPA's calls for PMPRB to review its approach through an equity lens that takes into consideration these patients as well, an approach that CPN would support as a principle for all drug policy analysis.**

### 3. Engage patients in comprehensive evaluation and monitoring

CPN supports calls for engaging the patient community in developing and overseeing a comprehensive post-implementation monitoring and evaluation plan. We encourage PMPRB to engage patients, caregivers and their representatives from across disease and disabilities, including dermatology and immunology, in all aspects of this process including developing metrics that are important to patients. These may include monitoring and evaluating cost savings and how these are being redirected back to patients; as well as how the proposed changes effect access to new medicines and whether patients are losing access to medicines to manage their health; as well as the impacts on clinical trial research in Canada.

**CPN calls for PMPRB to establish mechanisms for engaging the patient community meaningfully in establishing and implementing a robust post-implementation plan for monitoring and evaluating the regulatory reform.**

### 4. Patient engagement in PMPRB

CPN further supports calls for increasing the engagement of patients, caregivers and their representatives across PMPRB structures. This includes representation on the Board, and across its processes, including representation on the Human Drug Advisory Panel and as active participants in the *Guidelines Modernization and Evaluation Process*. PMPRB can develop a formal patient engagement program following the ICER model, co-created with patient groups (see pages 49-50).

We further recommend that patient engagement includes diverse representation from across diseases and disabilities, including dermatology and immunology, and across diverse social demographics. This includes meaningful engagement and representation from populations who experience inequities in the Canadian healthcare system such as Indigenous populations, racialized communities and people affected by poverty.

**CPN encourages PMPRB to use this opportunity to imbed diverse patient engagement in its structure and processes based on best practice.**

In closing, we appreciate the opportunity to provide feedback on the Revised Draft Guidelines and thank you for your consideration. We look forward to future opportunities to work together.

Antonella Scali
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Appendix: PMPRB ceiling price proposed draft guidelines – June 2020
Psoriasis Case Studies (2020-07-30 ver0.1)

## Introduction

In June 2020, the PMPRB issued its updated draft Guidelines for determining the ceiling prices of patented pharmaceuticals.

Canadian Psoriasis Network (CPN) wishes to estimate the effect these latest draft Guidelines may have on the ceiling prices for two psoriasis (assumed category I) pharmaceuticals and, subsequently, make a judgement about how this may affect access in Canada. This is the subject of this analysis and report.

## Method

The PMPRB 2020 draft Guidelines are used in this analysis to estimate plausible Maximum Rebated Prices (MRPs) or the market size adjusted Maximum Rebated Price (MRP[A]s) of drugs for the treatment of psoriasis that have recently been reviewed by CADTH and are now being funded in Canada. These estimates of the MRP/MRP[A] that these drugs may have gained under the proposed draft guidelines are compared with the publicly submitted price to CADTH. This comparison results in an estimate of the price reduction that would be required for each drug to be considered compliant with the PMPRBs proposed pricing regulations. Depending on the size of these price reductions, a judgement is made as to whether or not the drug is very likely, likely, unlikely or very unlikely to have been launched in Canada had these guidelines been in place when these drugs were considering entering the Canadian market. This judgement has as an underlying assumption that the PEP, and subsequently the MRP, will be, in effect, transparent to the world under the proposed guidelines.

The analysis uses key data available in CADTH reports together with the pricing algorithm for category I pharmaceuticals described in the 2020 draft Guidelines to estimate the price reduction from the submitted price required to meet the regulations.

The two drugs reviewed in this report are as follows:

- Skyrisi (risankisumab) for the treatment of moderate to severe plaque psoriasis in adults; and
- Tremfya (guselkumab) for adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

For Category I pharmaceuticals, the 2020 draft Guidelines (in contrast to the 2019 draft Guidelines) now simply note that the Pharmacoeconomic Price (PEP) will be determined from the re-analysis of the base case provided by Canada's HTABs (being information to be supplied by the patentee). Thus although the equation presented in the 2019 draft Guidelines has been removed from the document, it remains a reasonable means by which to estimate the PEP from information that is largely available in CADTH's published reports and, therefore, is used in this analysis. In addition, the 2020 draft Guidelines have amended the ICER thresholds to be used in calculating the PEP which are now dependent on the newly introduced Therapeutic Class Level (TCL) into which the drug falls. Further, to calculate the Maximum Rebated Price (MRP), a second test – the Reduction Floor, its level also dependent on the TCL – is used

and the higher of the two prices calculated from the PEP or Reduction Floor becomes the default MRP. Finally, the MRP may be adjusted depending on the market sales with the adjustments also being dependent on the TCL (referred to as the MRP[A]).

The analysis estimates the MRP/MRP[A] for the full range of TCLs described in the draft Guidelines and at three assumed levels of revenue. A range is calculated rather than point estimates to eliminate the need for additional assumptions and, thus, reduce the risk of the judgements subsequently made being assumption driven.

## Results

### Skyrisi (risankisumab)

### Estimation of MRP/MRP[A]

Indication (coverage requested): for the treatment of moderate to severe plaque psoriasis in adults.

*Compared with brodalumab*

| Item | CADTH Base Case |
|---|---|
| ICER threshold - TCL 1 (a1) | 200,000 |
| ICER threshold - TCL 2, 3 and 4 (a2) | 150,000 |
| Incremental QALYs (b) | 0.01 |
| Incremental costs (c) | 15,264 |
| Treatment costs (d) | 57,500 |
| Submitted public price (e) - $/syringe | 2,467.50 |
| | |
| PharmacoEconomic Price - PEP if TCL 1 (e*(a1*b+d-c/d) - $/syringe | 1,863.97 |
| PharmacoEconomic Price - PEP if TCL 2, 3, or 4 (e*(a2*b+d-c/d) - $/syringe | 1,851.10 |
| | |
| MRP as percent reduction of submitted price with floor test | |
| If TCL 1 | 20% |
| If TCL 2 | 25% |
| If TCL 3 | 25% |
| If TCL 4 | 25% |
| | |
| MRP as percent reduction of submitted price with market size adjustment | |
| Where revenue < $12M and TCL 1, 2, 3 or 4 | 0% |
| | |
| Where revenue $25M and TCL 1 | 10% |
| Where revenue $25M and TCL 2 | 13% |
| Where revenue $25M and TCL 3 | 13% |
| Where revenue $25M and TCL 4 | 13% |
| | |
| Where revenue $125M and TCL 1 | 27% |
| Where revenue $125M and TCL 2 | 30% |
| Where revenue $125M and TCL 3 | 30% |
| Where revenue $125M and TCL 4 | 30% |

Assumptions:
- Treatment cost is not reported in the CADTH reports. It was estimated by solving for treatment cost given CADTH statements of the percentage price reduction required to meet an ICUR of $50,000.
- Submitted public price is the Maximum List Price (MLP) as price adjustments from the above calculations are applied to the MLP.

### Interpretation of results

- TCL does not result in significant variance in the estimates of the PEP – thus, in this case, price is not very sensitive to the ICER thresholds used. The reason for this is that QALY gain is so small, small changes in price have very large effects on the resulting ICERs.
- Similarly, TCL creates little variance in price either through the floor test or the adjustors of MRP
- What influences potential price reductions the most is the adjustment of MRP given revenue.

Overall, given anecdotal evidence of the price reductions sought by the pCPA, these potential price reductions appear manageable and, thus it appears the MRP calculation algorithms themselves would have been unlikely to affect a launch decision had the 2020 draft Guidelines been in place at the time of the launch of risankisumab.

## Tremfya (guselkumab)

### Estimation of MRP/MRP[A]

Indication (coverage requested): for adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

*Compared with infliximab*

| Item | CADTH Base Case |
|---|---|
| ICER threshold - TCL 1 (a1) | 200,000 |
| ICER threshold - TCL 2, 3 and 4 (a2) | 150,000 |
| Incremental QALYs (b) | 0 |
| Incremental costs (c) | 5,625 |
| Treatment costs (d) | 101,000 |
| Submitted public price (e) - $/syringe | 3,059.74 |
| | |
| PharmacoEconomic Price - PEP if TCL 1 (e*(a1*b+d-c/d) - $/syringe | 2,910.54 |
| PharmacoEconomic Price - PEP if TCL 2, 3, or 4 (e*(a2*b+d-c/d) - $/syringe | 2,905.24 |
| | |
| MRP as percent reduction of submitted price with floor test | |
| If TCL 1 | 5% |
| If TCL 2 | 5% |
| If TCL 3 | 5% |
| If TCL 4 | 5% |
| | |
| MRP as percent reduction of submitted price with market size adjustment | |
| Where revenue < $12M and TCL 1, 2, 3 or 4 | 0% |
| | |
| Where revenue $25M and TCL 1 | 3% |
| Where revenue $25M and TCL 2 | 3% |
| Where revenue $25M and TCL 3 | 3% |
| Where revenue $25M and TCL 4 | 3% |
| | |
| Where revenue $125M and TCL 1 | 19% |
| Where revenue $125M and TCL 2 | 19% |
| Where revenue $125M and TCL 3 | 19% |
| Where revenue $125M and TCL 4 | 19% |

Assumptions:
- Treatment cost is not reported in the CADTH reports. It was estimated by solving for treatment cost given CADTH statements of the percentage price reduction required to meet an ICUR of $50,000.
- Submitted public price is the Maximum List Price (MLP) as price adjustments from the above calculations are applied to the MLP.

### Interpretation of results

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- What influences potential price reductions the most is the adjustment of MRP given revenue.

Overall, given anecdotal evidence of the price reductions sought by the pCPA, these potential price reductions appear manageable and, thus it appears the MRP calculation algorithms themselves would have been unlikely to affect a launch decision had the 2020 draft Guidelines been in place at the time of the launch of risankisumab.

## Other observations

- The 2020 draft Guidelines use ICER thresholds that bear no relationship with those implicitly used by CADTH. It is widely accepted anecdotally that CADTH uses a threshold of $100,000 for oncology drugs and $50,000 for other technologies when proclaiming the price of a technology is not at a level considered cost effective. It is odd, therefore, that in the process of proposing new draft Guidelines that the proposed ICER thresholds used across the Canadian health system have not been made congruent with one another.

- This analysis did not try to determine into which TCL the drug under analysis would fall. The reason for this is that the definitions of the TCL are open to significant variation in interpretation. For example:

  TCL 1 includes ". . . is the first medicine . . . that effectively treats a particular illness or effectively addresses a particular indication in a clinically impactful manner . . . " and, therefore, leaves a question mark over impactful treatments that are used in an indication for a sub-group of patients (defined, potentially, by a genetic marker) that gain no benefit from treatments already available for the indication.

  TCL 1 notes that "A high QALY gain is normally associated with medicines at this level." TCL 2 also notes "A high QALY gain is normally associated with medicines at this level." But how high in each case?

  The difference in ICER threshold between TCL 1 and 2 is significant and can result in non-trivial differences in PEP estimates. However, in these case studies, TCL has a very limited effect on the resulting estimates of MRP because in these examples, price is not very sensitive to ICER threshold.l

- The creation of different TCLs will create a level of uncertainty over how the PMPRB will classify drugs as, for the short term at least, there will be no history on which stakeholders may base their judgements. Key stakeholders needing to understand this judgement include both manufacturers making decisions to bring products to market and the pCPA (or payer negotiators) who must attempt to make pricing decisions that in the medium term are not higher than those established on PMPRB review. The pCPA may address this uncertainty through two means: either delaying its negotiations where it has the greatest uncertainty or by negotiating higher price reductions than it might have otherwise. Either way, the uncertainty introduced in the short term may manifest itself as private decisions by manufacturers to not launch in the Canadian market.

  Again, however, in the case studies considered here, little additional uncertainty is created by TCL classification as the price is not very sensitive to TCL.