Canadian Skin Patient Alliance
Alliance canadienne des patients en dermatologie

Canadian Association of Psoriasis Patients
Association canadienne des patients atteints de psoriasis

Via consultation portal

August 4, 2020

Douglas Clark
Executive Director
Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

RE: SUBMISSION ON PMPRB REVISED DRAFT GUIDELINES

Dear Mr. Clark,

On behalf of the Canadian Skin Patient Alliance (CSPA) and the Canadian Association of Psoriasis Patients (CAPP), thank you for the opportunity to provide input regarding the Patented Medicine Prices Review Board's (PMPRB's) Revised Draft Guidelines.

The Canadian Skin Patient Alliance (CSPA) is a national non-profit organization dedicated to improving the life of people in Canada living with diseases, conditions and traumas that affect the hair, skin and nails. Our patient community includes people living with skin cancers and more than 2,000 rare diseases. We advocate for best care and treatment options for all skin patients; we provide educational resources to our patient community; and we support the members of our Affiliate Member organizations who work specifically on their disease areas such as burns, scleroderma, melanoma and psoriasis.

The Canadian Association of Psoriasis Patients (CAPP) was founded as a national not-for-profit organization to better serve the needs of psoriasis patients across the country.

The CSPA and CAPP support the objective of the revised draft guidelines to reduce the prices of patented medicines in order to make more treatments accessible to patients in Canada and improve the sustainability of the health system on which we rely. We often hear from patients who struggle to access patented medicines that have been prescribed to them and support efforts to reduce drug prices where this has the effect of improving patient access to patented medicines. The CSPA appreciates several positive changes in the revised draft guidelines, including a process to recognize the therapeutic value of medicines, for which CSPA had advocated in its previous submission. However, we remain concerned about the potential impacts of this specific approach to lowering drug prices on patient access to patented medicines in Canada.

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We have closely followed the public debate on this issue and benefitted from many analyses that have been shared publicly. While we cannot speculate on the actions of patented medicine manufacturers in response to the new regulatory regime (as implemented according to these revised draft guidelines), it is our duty to seek to understand the impacts on patients and participate in public debate about these issues with a view to protecting and improving patient access to patented medicines in Canada. In this spirit, we offer our perspectives on the revised draft guidelines and their impacts on skin patients.

As members, the CSPA and CAPP support the submissions of the Best Medicines Coalition and the Medicines Access Coalition – BC. These submissions include important themes on which we offer our perspectives on behalf of the skin patient community, including those who live with psoriatic diseases.

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

Many skin patients struggle to afford the patented medicines that have been prescribed to them, especially when treatment plans take a step therapy approach that requires patients to fail on certain medications in order to access others that may be more effective.

The revised draft guidelines appear to be focused on regulating the rebate system that underpins how drug plans negotiate prices. However, we are concerned about the disproportionate benefit of this approach to regulating drug prices. As set out in the revised draft guidelines, drug plans stand to benefit from limits on rebates. However, patients who access drug plans and are responsible for paying co-insurance will still be paying this portion based on the list prices. For skin patients, this amount can be burdensome and even prevent access to patented medicines. Patients who pay out of pocket will only benefit from the reduction in list prices of patented medicines. **We encourage the PMPRB to review its approach through an equity lens that takes into consideration these patients as well.**

2. **Comprehensive access to patented medicines**

As noted in our previous submission, many new medicines are becoming available to skin patients in Canada through clinical trials and as marketed drugs to better treat a diversity of skin disorders, including psoriasis and atopic dermatitis (eczema). For some, these important innovations are bringing us closer to a cure. **It is vital to our community that new treatments will continue to be available to skin patients in Canada to improve our health outcomes and quality of life.**

It is not clear from the revised draft guidelines how the PMPRB's work will change the current process by which patented medicines reach patients in Canada. **We call on the PMPRB to work with its counterparts** at Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Institut national d'excellence en santé et en services sociaux (INESSS), the pan-Canadian Pharmaceutical Alliance, and public and private drug plan providers **to develop a clear schematic of how the existing process will change as a result of the expanded mandate of the PMPRB that includes opportunities for patient input.**

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Further, it is not clear how this new regulatory regime will impact the potential for novel funding agreements that incorporate real world evidence or amortize the cost of precision or genetic medicines over a longer time period. These approaches have the potential to mitigate the existing financial impacts of patented medicines on the health system, and we would benefit from greater clarity on how these pieces will fit together.

3. **Accountable, transparent and inclusive governance must incorporate patient perspectives**

The patient community continues to emphasize the need for meaningful patient engagement in the design, implementation, monitoring and evaluation of the new regulatory regime. We do not expect the government to take action only when it has perfect information. However, given the consequences to patients of negative impacts of the regulatory regime, **we call on the PMPRB to include patients in the development of a robust monitoring and evaluation system** that reports publicly on its findings. As well, **we call on the PMPRB to embed patients in its governance, including the Board and Human Drug Advisory Panel.**

The PMPRB's reliance on economic evaluations conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH) does not fully satisfy the need for patient input processes, despite CADTH's leadership in this area. In our view, the processes currently in place to develop economic models would benefit from improved patient engagement – for example, where the CADTH evaluation excludes consideration of the impact on caregivers of a specific disease in its economic model, which is often underappreciated in skin diseases, patients currently have no recourse to debate this. Further, it is not clear how the PMPRB will rely on CADTH's pharmaco-economic evaluation when the request is for a narrower indication than the market authorization granted by Health Canada. **We would appreciate the PMPRB clarifying whether the same assessment will apply to the broader indication and whether more patient input would be sought in this case.**

4. **Concern about potential impacts on research in Canada**

We note that there are concerns about the impacts on clinical trials being conducted in Canada in light of comments by and reports from the patented medicines industry. The CSPA is helping lead a new network of dermatology patients, clinicians and researchers to improve skin research in Canada, including clinical trials. **We would appreciate being made aware of any efforts by the PMPRB to measure impacts on clinical trials and related research going forward so that we may share our insights.**

5. **Unique concerns of specific patient populations must be addressed**

The skin patient community in Canada includes patients living with cancers and psoriatic diseases, both of which have their own unique concerns about the implications of these guidelines on whether and how they will be able to access patented medicines.

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Cancer patients. Cancer patients in Canada access patented medicines through distinct processes. The impacts of a general approach to drug pricing regulation must consider the impacts on the cancer community and ensure that this vulnerable group is not disproportionately negatively affected by the new regulatory regime. We encourage the PMPRB to review and consider input directly from cancer groups, including any case studies, and continue discussions with them.

Psoriatic diseases. We appreciate the analysis and case studies undertaken by a group of patient organizations, including CSPA Affiliate Members Save Your Skin Foundation and Canadian Psoriasis Network, which was shared in advance with CSPA. Early analysis of case studies prepared for patented medicines to treat psoriatic disease suggests that important technical aspects of the revised draft guidelines are not congruent with the approach taken by CADTH in its pharmaco-economic analyses. These also suggest that it is not straightforward to apply the definitions of each Therapeutic Criteria Level (TCL) to the treatment landscape for psoriatic disease in Canada. Specifically, each of TCL 1 and TCL 2 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 these TCLs. This is especially important where there are multiple existing treatment options but there still remains significant unmet need.

In psoriatic disease, there are several existing treatment options but new treatments offer important benefits. Further, because of how the immune system works, patients often have to switch to a different molecule in order to optimize their treatment. Approximately 40% of people living with psoriatic arthritis and receiving biologic treatments continue to have persistent disease activity.[1] This underscores the need for new treatment options becoming available to patients in Canada living with immune system diseases, such as psoriatic arthritis and psoriasis, and that these considerations must be incorporated into the PMPRB's assessment of the value of a new treatment option.

Thank you for considering our feedback. Please do not hesitate to contact me if you have any questions about our experience and perspectives.

Sincerely,

Rachael Manion
Executive Director
Canadian Skin Patient Alliance

[1] Filip Van den Bosch & Laura Coates, "Clinical management of psoriatic arthritis", *Lancet* (2018) 391:2285-94.