



Provincial Health Services Authority

July 30thth 2020

Dear PMPRB

Thank-you for providing the opportunity to give feedback on the June Draft Guidelines.

As a Provincial Cancer Agency, BC Cancer's priority is to ensure access to life preserving medications, support research and development to advance the science of cancer and improve treatment options as well as ensure sustainability of a comprehensive, publicly funded health care system that supports current and future generations of British Columbians. BC Cancer strongly believes that cancer treatments should be available to all British Columbians based on need rather than on their ability to pay, and BC Cancer continues to fund most oral and intravenous cancer medication throughout our province. The high and rapidly growing cost of cancer medicines is challenging our ability to meet our commitments. Annual expenditures on cancer drugs in B.C. are increasing at a rate close to 12 per cent per year and even before the recent economic impacts of COVID-19, such rates of cost growth were considered to be unsustainable.

BC Cancer therefore supports the PMPRB's efforts to update their guidelines and use their mandate to prevent pharmaceutical patentees from charging consumers and public payers excessive prices.

The expansion and revision of the basket of countries from the 'Original 7', that included the US and Switzerland to the "PMPRB11", is a positive development and we are pleased to see that this has not been revised in the updated guidelines.

We remain worried that other proposed changes to the guidelines, even with the amendments updated in June 2020, may have negative impacts on access to new oncology drugs and may not achieve the goal of controlling the ballooning expenditure on cancer drugs in Canada.

We appreciate the efforts of PMPRB to explain and walk through in detail with stakeholders the details of the guidelines and changes that have been made since the November draft. As stated in the PMPRB introduction to the updated guidelines the intent is to "provide greater transparency and predictability to patentees regarding the process...whether a patented medicine appears to be priced excessively in any market in Canada". Feedback from patentees on the November 2019 draft expressed concern that even at that time; the guidelines were complex and introduced sufficient uncertainties that it would impact their willingness to submit new drugs to regulatory approval and market in Canada. The updated guidelines are no less complex and arguably may introduce even more uncertainty. The threat of reduced access to life saving cancer medications continues to be of concern.



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Legal challenges to the draft guidelines have already begun, and impact of sustained legal battles on the ability of PMPRB to positively affect drug pricing coupled with uncertainty associated with unknown judgements, may undermine the stated intent of the PMPRB guidelines of improving transparency and predictability to patentees.

We understand the threshold for Category I drugs has been increased in the latest draft guidelines and those changes were in part in response to feedback from multiple stakeholders, including concern from Cancer Agencies. However, the revised higher threshold and the inclusion of pharmacoeconomic value criteria may have the unintended consequences of being misinterpreted as being an acceptable pricing level and could result in increasing costs particularly to the cancer system.

Furthermore, current calculations of pharmacoeconomic value need further empirical studies using Canadian data for them to be considered robust. BC Cancer understands some of this research is currently being developed, and this represents an important way forward for value based pricing in Canada. However, in the meantime it seems premature to implement current calculations of pharmacoeconomic value as a mechanism to avoid excessive pricing, because we are not yet confident the calculations are reflective of the real value of new drugs. More work needs to be done to validate current methodology and empirical evidence before using it to set prices.

The cancer drug space is very dynamic, and the spend on any one cancer drug may change dramatically and rapidly as new evidence emerges, expanding patient eligibility or indications or the converse, where a drug may suddenly become obsolete and replaced in the space of a few months. It is not clear, how PMPRB will use these guidelines to assess pricing and use the mechanism it has available, to monitor and apply some of the proposed factors in this rapidly changing space. Our experience is that it is becoming more challenging to predict the cost of new medications based on factors known at the time of introduction.

Despite some concerns as to the impact these changes will have to the drug ecosystem in Canada, BC Cancer is supportive of efforts to curtail excessive drug pricing. We have seen some incredible progress in many areas of cancer treatment over the last few years, including some truly breakthrough drug treatments that are allowing our patients to live longer and better lives. We want to continue to access these new life altering therapies and ensure we have a sustainable, publicly funded health care system that meets the needs of all Canadians now and into the future.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Kim N. Chi'.

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