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Doug Clark
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

July 29, 2020

Dear Mr. Clark;

On behalf of the National Myeloma Canada Advocacy Committee and Myeloma Canada I am pleased to provide you with a response to the call for public consultation on the PMPRB draft Guidelines 2020 released on June 19, 2020. Myeloma Canada is fortunate that it is supported by a strong patient community who is very much engaged in public health discussions affecting drug access policies which have a direct impact on them. The advocacy committee members have participated extensively in the various update sessions offered by the PMPRB, stakeholder education sessions and webinars in the last two years to inform themselves and to shape their views on the proposed modernisation of the PMPRB guidelines. Their comments and the input they offer is guided by their unique experience as patients with multiple myeloma. Although Myeloma Canada is participating and supporting the CONECted submission it is important that I share with you the views directly expressed by our patient community which parallel the CONECted submission. They are as follows:

1. GENERAL

In the current circumstances, we acknowledge the progress that PMPRB has made and we want to reiterate myeloma patients' objective to have access to effective drugs in a timely manner at fair and sustainable prices. What is 'sustainable" is a broader public policy issue. Something that is critical but has not been really dealt with nor is it directly within PMPRB's mandate. This is an issue that must become part of a broader discussion and must be included in the evaluation process of changes to the PMPRB regulations and guidelines.

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While as patients we remain concerned about the impact of the PMPRB proposed changes on our ability to access new drugs and clinical trials. in good faith we support the modernisation of the PMPRB Guidelines provided that an effective evaluation process is immediately developed and implemented to ensure that the goals of the PMPRB's new Regulations and Guidelines are being met and that patients are meaningful participants in the design and implementation of the process.

We recognize the importance of drugs to patient health and allowing them to continue to contribute to the economy; the value of drugs to reducing other costs in the health system (eg. associated with hospital stays); and ensuring broader accessibility to health care, particularly in

remote areas. Increasing the health care system's proportionality of spending on drugs, even expensive ones, may not only be in the broader health interests of Canadians but also be a wise economic decision!

2. THERAPEUTIC CLASS COMPARISONS:

The Guidelines set out how the therapeutic class of a drug will be determined. Essentially this will be done by the PMPRB staff. It will not be done by CADTH as part of the Health Technology Assessment (HTA) analysis. The Guidelines focus on new drugs. They do not appear to deal with existing drugs and potential changes in a therapeutic class. This would require a closer look.

Issues:

1. Myeloma patients require a range of drugs to respond to the cancer as it changes. While a drug may be deemed to fall within Level III or perhaps even IV as having a similar impact to other comparators in the class, with particular patients it in fact may be a Level II providing "considerable improvement in therapeutic effect, relative to other medicines sold in Canada" and in fact may work where other comparators do not.

2. With respect to existing drugs, again on a quick review, there is no reference to looking at changes to a therapeutic class and what evidence would be used. This would be an area for real world evidence.

3. Both 1 and 2 above suggest that the process of classification may better be done within the HTA process. Not a change that we are advocating for at this point but something that could be integrated into the proposed Guidelines Monitoring and Evaluations Plan and in particular in assessing the impact on access to medicines and PMPRB processes.

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3. RESEARCH:

The issue of what criteria is used to measure research investment is not clear. Is what is being measured Direct Investment, that is, research that a pharmaceutical company takes on essentially "in house" or has complete control over, most notably perhaps through clinical trials where the company either does all the work internally or contracts out portions to perhaps academia or clinical researchers? Does it include In-Direct Investment, that is, funding of research chairs, funding research directed by academics or clinical researchers or others?

The presumption that research is not related to price may be correct depending on the parameters used for measuring investment. In which case, the important issue would be to encourage investment irrespective of pricing. This is not perhaps a job for the PMPRB but it is important at a minimum that all investments be recognized and included in the statistics to encourage continued engagement of pharmaceutical companies in research in Canada. This is particularly important for Myeloma Canada where with a small patient cohort research resources are limited.

Despite the conclusion of the PMPRB that investment in research is not related to domestic drug pricing, if investment could be leveraged through pricing, perhaps in the net pricing negotiations, this should also be considered and encouraged.

Further, identifying and measuring the impact of the proposed changes on direct and in-direct research should be a critical component of the evaluation process. This may include revising and perhaps expanding the current scope of what is defined as research investment and setting a benchmark to measure against based on that definition.

4. EVALUATION PROCESS:

PMPRB is committed to an evaluation process. The details are yet to be worked out. It would be critical to have patients meaningfully engaged in this process. This could perhaps be done with a patient advisory committee, although having a separate advisory committee may risk sidelining patients, depending on the scope and mandate and relationship of the committee to the PMPRB and the process. As patients, we need to be "at the table".

Another option may be to set up a joint stakeholder committee which in fact is given authority beyond simply advising to overseeing the development and implementation of the evaluation process. As the PMPRB is essentially a "consumer protection agency" the stakeholders would be the consumers, that is, public payers, private payers, and patients along with the PMPRB.

Given the potential impact of the proposed changes to the PMPRB Regulations and Guidelines, it is vitally important that the evaluation process be started immediately. We need to have clear objectives, measuring tools and processes to ensure that the

Regulations and Guidelines are meeting their goals. From a patient perspective that would be that effective drugs are accessible in a timely manner and that prices are fair and sustainable. Monitoring and reporting need to be done at least on a quarterly basis so that any problems can be addressed and, if necessary, the Guidelines can be adjusted. Essentially the process would be iterative. In that regard, indicators for what will evidence "problems" will need to be set out along with mitigation strategies.

5. IMPLEMENTATION

We suggest that the PMPRB consider the implementation of the Guidelines be rolled out in stages. The first stage could be modifying the comparator countries, which in itself is projected to reduce drug prices by an average of 20% and the second stage would progress to the therapeutic class development. If separated into two stages, with Stage 1 being perhaps a full year, the evaluation process could initially determine the effectiveness of only the revised comparator countries. This would also allow more time for the evaluation process to be fully developed for Stage 2,

We are grateful to the PMPRB for reaching out to Stakeholders to solicit our input to the 2020 guidelines and we appreciate the work undertaken by you to try and ensure Canadians pay a fair price for medications. Ultimately what is important is that the proposed changes support and advance the health of Canadians by ensuring that they have access to effective treatments in a timely manner. We look forward to working with the PMPRB to monitor and evaluate the implementation of the proposed changes to ensure that their goals are met.

Regards,

Martine Elias
Executive Director Myeloma Canada
On behalf of the National Myeloma Canada Advocacy Committee

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