August 4, 2020

Dr. Mitchell Levine
Chair, Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Dr. Levine,

Subject: Consultations on the June 2020 Draft PMPRB Guidelines

On behalf of Astellas Pharma Canada, Inc. I am writing to provide our feedback on the June 2020 draft PMPRB guidelines that would operationalize the major changes to how the government of Canada regulates the prices of patented medicines.

As General Manager of Astellas Canada and as a Canadian, I draw on nearly twenty years of experience in the innovative pharmaceutical industry and over a decade leading our patient access and commercialization efforts in Canada. I have overseen how the Canadian policy environment affects access to therapies that are critical to helping patients survive transplant surgeries, address chronic conditions facing older Canadians and treat cancer and other life-threatening diseases.

Canadians with both public and private insurance plans have generally benefited from relatively timely access to innovative therapies compared to other jurisdictions, as well as research investments in hospitals and institutes that allow patients and healthcare leaders to benefit from access to life-saving therapies in development.

Astellas has contributed to and supports the submission of our industry association, Innovative Medicines Canada, and we hope that the following additional comments help highlight some of the concerns, issues and recommendations that are of importance to Astellas.

These specific issues relate to:

1. Ensuring that existing medicines, which have been historically compliant with PMPRB guidelines, are not unduly penalized by the new pricing regime
2. Avoiding the use of market size factors and pharmacoeconomic evaluations
3. Addressing and limiting the extensive discretion that the revised guidelines provide to the PMPRB staff

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4. Outstanding operational issues and inconsistencies in the guidelines (presentations vs. written) that require further clarification, and unfairly ask industry to contribute to consultations without the full picture being available from the PMPRB

1. Existing medicines

With respect to existing medicines, we recognize that the June 2020 revisions would reduce the impact of previously proposed price decreases for many patented drugs that are currently on the market. For example, removing the application of the economic factors to the "gap" medicines that have both a DIN issued and a sale before January 1, 2021 provides a greater degree of clarity for these products. As well, ensuring that line extensions continue to benefit from relatively clear price ceilings provides – with no or limited application of the economic factor adjustments – an additional degree of commercialization certainty for our on-market patented medicines.

However, the PMPRB should go further, and consider allowing the MLP to be set based on the highest international price (HIP) within the new basket of countries, and not the lower of the non-excessive average price (NEAP) and the HIP.

With respect to reassessments, we recommend that future price adjustments to the MLP – especially for grandfathered and gap medicines – be implemented on a consistent and fair basis. For example, if the MLP is greater than the maximum international price (MIP) +10%, then compliance with the revised MIP price needs to occur within two reporting periods. However, if the MIP increases over time and is now higher than MLP, the current guidelines do not allow the MLP to be increased. In other words, if Canadian prices are to be referenced to PMPRB11 countries, then the guidelines should be fair in that prices should be allowed to increase as well. Adjustments like this will ensure the PMPRB facilitates and supports compliance and the continued deployment of medicines that Canadians need.

In sum, we recommend that the PMPRB adhere to its original commitment to provide patentees with "bright lines" regarding allowable prices in Canada.

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2. Pharmacoeconomic value and market size adjustments

It is APCA's position that the central concept of maximum rebated price (MRP) is unviable as a result of the June 2020 federal court decision referenced and as further discussed in the IMC response to the 2020 draft guidelines.

In addition to the above, we disagree with the use of pharmacoeconomics to set price ceilings due to the subjectivity and lack of consistency of the assumptions used in economic models. It is impossible for a manufacturer to predict how CADTH (or INESSS) will manipulate model assumptions to determine a reanalysis of the base case cost-utility analysis. These evaluations could have significant impact on PMPRB determinations on therapeutic criteria level and the Maximum Rebated Price (MRP) calculations.

The exclusive use of cost-utility analyses to determine a MRP is particularly problematic in many therapeutic areas, and especially for rare diseases and oncology. Past reviews by CADTH with recalculated base case analyses have resulted in pharmacoecomonic pricing that did not align with the value recognized during the clinical review. There is also very limited transparency regarding CADTH's reanalysis, as models are not shared with sponsors, and are not subject to external reviews and audits. Perhaps, the quality of CDR re-analysis should be expected to be similar to what is expected of industry. Perhaps using an ICER range would be more reasonable than just presumably using the CDR based case re-analysis at face value.

Market size should not be a tool used to regulate MLP prices. There are already a number of tools used by payers, including provincial governments and private insurers, to manage affordability.

3. Extensive discretion provided to PMPRB

The revised guidelines would provide excessive discretion to staff regarding evaluations of therapeutic criteria level and price tests.

Regarding therapeutic criteria levels, PMPRB staff are often poorly placed to evaluate comparative clinical value. Previously, the PMPRB relied on the Human Drug Advisory Panel (HDAP) to establish levels of therapeutic improvement and therefore determine which tests will apply to new-patented medicines. The new therapeutic criteria level

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(TCL) determinations will be made by staff, who generally do not have clinical experience. These evaluations will be made with no oversight, appeal opportunity or deliberative framework, adding to the uncertainty facing patentees who seek clarity on acceptable prices before launch.

We are also concerned that many advanced therapeutics will be classified as TCL IV (no or slight improvement relative to other medicines sold in Canada) due to evidence limitations. This may be driven by perceived clinical uncertainty based on early data or alternative clinical trial designs, leading to excessive regulated price ceilings that do not allow for subsequent price increases nor reflect any pending data. At the same time, HTA systems in Canada, most notably INESSS, are moving towards a "promise of value" concept. Other systems – including Health Canada – are considering clinical value beyond traditional RCT studies. We strongly recommend, therefore, that any determinations of TCL be conducted by an independent evaluation body and that allowances be made for precision therapeutics, rare diseases and cancer, which may not have traditional and head-to-head data available.

Finally, we are concerned about the broad power for the PMPRB to adjust or implement novel or unpredictable price tests in the context of an investigation under section 94 of the revised guidelines. Both of the examples used in the draft suggest that this power will be used to adjust regulated maximum prices downwards, which only adds to the uncertainty of patentees in terms of prices that will be allowed in under the proposed system.

4. Outstanding operational issues

Many outstanding operational issues are not clear in the guidelines.

These include, but are not limited to:

- Clarity on the reporting requirements for upcoming reporting periods and timing for coming into compliance across different categories of products (grandfathered, gap and medicines sold with a DIN after January 1, 2021)
- Clarity on the Non-Excessive Average Price (NEAP) and which NEAP will apply going forward for currently-marketed medicines

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The online help tool that is being developed to answer some of these questions should have been available at the time of publication of draft guidelines to allow for consultation on these issues with patentees as key elements of the proposed regulatory changes. It is reasonable to allow further consultation once the online help tool becomes available so industry can better understand how PMPRB intends to calculate and operationalize the guidelines.

Thank you in advance for considering our submission.

Sincerely,

Frank Stramaglia
General Manager
Astellas Pharma Canada, Inc.