AstraZeneca Canada Inc.
1004 Middlegate Road, Suite 5000
Mississauga, Ontario, L4Y 1M4
Phone: 1-800-565-5877
www.astrazeneca.ca

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

RE: AstraZeneca Canada Feedback on Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation

Dear PMPRB Board Members:

AstraZeneca Canada Inc. ("AstraZeneca") welcomes the opportunity to provide feedback on the PMPRB's current consultation with respect to the document "Draft Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation."

AstraZeneca is a global biopharmaceutical company focused on developing life-changing medicines. As the Canadian affiliate, our organization is committed to advancing the full cycle of life sciences innovation, from discovery and research to product launch and ultimately timely patient access. In support of this commitment, AstraZeneca has made substantial recent investments in Canada, now totalling in excess of C$1.3 billion and 1200 new jobs since 2023 alone.

Our commitment extends even further. Last year, AstraZeneca completed a separate C$3 billion agreement to acquire Fusion Pharmaceuticals in Hamilton, Ontario, which is developing next-generation radioconjugates with the promise to redefine radiotherapy for cancer patients. This is one of the largest single research investments made in a Canadian biotechnology company, ever. Collectively, these global scale investments are contributing to the growth of Canada's overall life sciences sector while directly advancing AstraZeneca's global clinical studies pipeline.

AstraZeneca has maintained a strong commitment to, and demonstrated track record of, regulatory compliance in Canada including with all PMPRB regulations and Guidelines. Ongoing, stable and predictable pricing compliance is a key enabler of our ability to ensure Canada remains globally competitive as a launch destination of choice for both investments and emerging innovative therapies. This is the fundamental point of reference for our consideration of the Board's proposed approach.

Building on our record of engagement in the PMPRB's regulatory and Guidelines reform process, we acknowledge the Board's efforts to solicit and consider stakeholder feedback, including but not limited to rights holders. We recognize that the Board is seeking to modernize its administrative approach following regulatory amendments consistent with its statutory mandate and recent jurisprudence.

As an overall proposed approach, AstraZeneca submits the following specific comments on the Draft Guidelines for Board consideration ahead of their pending implementation. We also affirm our alignment with the concurrent submissions being made by our trade associations, Innovative Medicines Canada (IMC) and BIOTECanada.

Use of Price Tests

AstraZeneca strongly supports the use of the Highest International Price (HIP) for the purposes of Initial and Annual Price Reviews as the only International Price Comparison which is appropriate, and consistent with, both the Board's statutory mandate and recent jurisprudence.

Further, AstraZeneca supports the inclusion and use of the Consumer Price Index (CPI) factor in the context of Annual Reviews. CPI remains a statutory price comparison factor for the PMPRB, and its ongoing role in the review process is fully warranted.

However, the current Guideline proposal suggests that any List Price exceeding the HIP or CPI-adjusted benchmark would immediately trigger an In-Depth Review. To optimize resourcing, AstraZeneca emphasizes the need for sensible administrative mechanisms that can distinguish between meaningful pricing concerns and minor or transient fluctuations, especially in consideration of the current uncertain economic climate.

In addition, the intended application of the CPI factor requires greater operational clarity. As one example, there is an inefficient misalignment between the availability of the annual Statistics Canada CPI factor, published each January, and the typical Provincial-Territorial administrative requirement to begin the process of submitting and reviewing prospective manufacturer price increases ahead of time in the final part of the preceding year. This will require rights holders making submissions to Provinces and Territories based on a forecasted rather than an officially published CPI rate potentially causing implementation issues for rights holders and customers.

We encourage the Board to consider available administrative practices and tools, including specifying reasonable allowances or providing a PMPRB-validated forecasted CPI rate in advance, to minimize the disruption from any differences in the availability of such a specific and important data point.

Initial Price Reviews

International prices are most variable and uncertain in the initial launch period for a given medicine, as different markets launch on different timelines. We therefore recommend that an In-Depth Review should only take place after sufficient time-on-market or the availability of sufficient international price data. Specifically, an In-Depth Review should only occur following either two (2) reporting periods or price availability in at least five (5) of the PMPRB11countries.

Annual Price Reviews

The PMPRB proposes the use of Annual Reviews that could trigger In-Depth Reviews with reference to an evolving mix of possible therapeutic comparators (e.g. that may be different from those which existed when a rights holder made its investment decision). This approach creates pricing unpredictability where rights holders may not be able to determine an allowable price at either the time of product launch nor throughout the product life cycle. Highly disruptive and arbitrary price reductions due to re-benchmarking are foreseeable under the approach to Annual Reviews.

The PMPRB should determine if a patented medicine is priced non-excessively at introduction (i.e., at or below the highest international price (HIP) of the PMPRB11 schedule) and then monitor compliance with that introductory price, plus consumer price index (CPI) increases over time. This would still allow the PMPRB to routinely monitor and validate compliance with the CPI-adjusted price benchmark established at a medicine's introduction without the need for re-benchmarking prices on an annual basis.

In addition, much greater detail is required on the Board's proposed approach to the first Annual Review post-implementation of the new Guidelines, particularly as it relates to the expected use of CPI tests. For ease of administration and reflecting the timing of information availability for all parties, we recommend that the first Annual Review post-implementation of the new Guidelines be conducted referring only to the HIP. This allows for a price assessment anchored to available information relating to the HIP while allowing for future adjustments to be made against both the HIP and an appropriate CPI figure.

Overall, to assist both Board staff and all PMPRB stakeholders, we also recommend that the Board consider developing and disclosing more detailed information related to the anticipated calculation and use of CPI in the overall review process, particularly with respect to data sources, applicable time-periods, and reasonable implementation and/or grace periods to ensure predictability and feasibility.

Existing Medicines

AstraZeneca supports an administrative approach for existing medicines that recognizes prior compliance with PMPRB regulations and Guidelines. Medicines that were deemed compliant and therefore non-excessive with the applicable legislation and Guidelines, should be exempted from further reviews other than based on verified allowable CPI adjustments. We note this has been the historical approach of PMPRB including in 2010 during the last update to the Guidelines.

Significant investments and related decisions regarding existing medicines have already been made giving consideration to existing market and operational conditions. Exempting existing medicines would promote market predictability and stability, while minimizing disruption and enabling the use of finite PMPRB resources on implementing the new approach for recent and upcoming product launches.

In addition, among the various options identified in the 2024 consultation, the PMPRB has selected the minimum transition period of one year for existing medicines. A three-year transition would be more appropriate for the Canadian pharmaceutical supply chain (e.g., pharmacists, distributors, pharmacies and generic manufacturers) which is already struggling due to a variety of cost control policies.

In-Depth Reviews

AstraZeneca recommends that prior to commencing an In-Depth Review, reasonable and proportionate operational flexibility be established to reflect external factors beyond the direct control of a rights holder (e.g. exchange rate fluctuations). This flexibility should facilitate a timely assessment and price adjustment by the rights holder before a full review is set in motion. This approach would allow for minor or incidental issues to be managed efficiently for both rights holders and Board staff, while avoiding marginal or low-value In-Depth Reviews consuming finite resources.

In addition, beyond the proposed use of the HIP and CPI as key and appropriate factors in reviews, much greater clarity and detail is required with respect to the Board's objectives and process for In-Depth Reviews.

As currently construed in the Draft Guidelines, Board staff would be afforded wide subjective discretion with respect to multiple process elements, including but not limited to:

- the weighing and use of different price factors by Board staff;
- therapeutic comparability categories, and relevance of TCC; and
- the apparent non-standardized and non-transparent potential referral to and reliance upon the Human Drug Advisory Panel (HDAP).

Each of these aspects has the potential to impact the progress and conclusions of an In-Depth Review in a consequential manner. Under the current proposals, there is no way for a rights holder to predict the outcome of an In-Depth Review, and this lack of clarity may impact decisions regarding the introduction of new medicines in Canada.

AstraZeneca recommends that all applicable review documents, and other information relevant to the review be made available in a timely fashion to the rights holder. This is necessary to enable a rights holder to address the PMPRB's actual concerns rather than inaccurate, inferred or assumed issues which may arise from a review.

Retroactive Revenue Assessments

PMPRB should provide written clarity to staff and rights holders that, in the event of a post-marketing review (e.g. due to a complaint or In-Depth Review), any possible excess revenue calculations will not be retroactive to time of product launch, but rather will only apply to the reporting period in which a complaint is received, or an In-Depth Review is initiated. This clarity is essential. Market dynamics change on a regular basis which impacts the mix of possible therapeutic comparators. Rights holders cannot be held to a different set of comparators and pricing well after date of first sale than existed at time of first sale. Under the current proposals, there is no way for a rights holder to predict the outcome of an In-Depth Review, and this absence of clarity on potential retroactive liability may impact decisions regarding the introduction of new indications in Canada.

In addition, AstraZeneca recommends that from both a practical and procedural fairness standpoint, once new Guidelines are in place, existing medicines should be fully exempted from any repayment of excess revenues based on new Guidelines, unless list price increases exceed allowable CPI adjustments.

Ultimately, the PMPRB's overall process and compliance outcomes will benefit from greater consistency, predictability, and assurances of procedural fairness at all stages, including during In-Depth Reviews.

Complaints

AstraZeneca supports the retention of Federal and Provincial/Territorial Ministers of Health as eligible parties for the purposes of submitting price complaints to PMPRB. This is consistent with established practice and the fundamental role of Canadian governments in regulating, organizing and funding our healthcare system.

We do not support expanding the categories of eligible complainers to life and health insurance companies and their trade association(s). As private businesses engaged in commercial transactions and negotiations with both rights holders and other members of the overall medicines supply chain, there is no rationale for tilting the marketplace as proposed.

Private insurers retain unimpeded access to every available resource and commercial tool, including communication with public officials within different health systems in Canada, to arrive at mutually satisfactory terms. By opening the potential for making a complaint as a named entity, there is a real risk of creating the conditions for market instability due to good faith business activities being threatened by an ongoing risk of potential recourse to PMPRB by one private party against another.

The PMPRB should design and implement an efficient complaints process that minimizes the impact on resources of examining spurious or tactical "complaints" from eligible parties and promotes overall market stability and fair and equitable commercial practices.

Conclusions

Understanding and alignment with PMPRB Guidelines is and should remain a shared interest for all stakeholders in Canada's medicines supply chain. This promotes market stability, fairness and business predictability and enables all stakeholder to focus on their contribution to realizing improved health outcomes for Canadians.

The draft Guidelines contain a number of encouraging and clearly detailed aspects, notably the defined role for the HIP and CPI as core points of reference in determining non-excessive prices for patented medicines in Canada.

Going forward, we encourage the PMPRB to further refine other aspects of its updated administrative approach as set out in the Guidelines. Perfect certainty may be elusive, but much more robust information and predictability will promote ongoing price compliance while supporting the efficient and appropriate use of PMPRB resources in support of its mandate in Canada's health system.

Please do not hesitate to contact me directly should you wish to discuss any aspects of this submission.

Yours sincerely,

Gaby Bourbara
Country President
AstraZeneca Canada