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Standing Committee on Health (HESA)
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Subject: HESA Committee study on the PMPRB changes

Dear Honourable Members,

Thank you for the opportunity to provide input into the HESA committee's study on the PMPRB changes. Over the past several years, AstraZeneca Canada (AstraZeneca) has actively participated in all relevant consultations regarding this reform.[1]

AstraZeneca employs more than 875 Canadians who work to research, develop and commercialize innovative medicines across our main therapeutic areas of cardiovascular, renal and metabolic diseases; oncology; and respiratory & immunology illnesses. In 2019, AstraZeneca invested more than $145 million in Canadian health sciences research in our core therapy areas.

Our company is now entering an exciting new period of research, innovation and unprecedented scientific advances. At the moment, more than 80 percent of our existing pipeline is focussed on precision medicines – innovative therapies that target an individual's unique genetic makeup. As we enter this era of precision medicines, there will be more certainty involved in treatment as we are better able to predict which patients will respond to a given therapy. This will lead to improved health outcomes for patients and significant long-term savings for payers and health systems.

AstraZeneca is also very involved in the fight against COVID-19. We recently announced an agreement with the Government of Canada to supply 20 million doses of our COVID-19 vaccine candidate AZD1222 at no profit during the pandemic period, should clinical trials prove to be successful and authorization be granted by Health Canada. Following this supply agreement, Health Canada announced the initiation of a rolling review for AZD1222 – marking the first authorization review of a COVID-19 vaccine submission in Canada. Globally, AstraZeneca has announced several partnerships to enable supply of roughly 3 billion doses of the vaccine in order to support broad and equitable access at no profit during the pandemic period. Moreover, we are

[1] Please see our most recent submission to the PMPRB's 2020 Guidelines consultation: https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/june2020/June%202020%20submission_AstraZeneca%20Canada_EN.pdf

currently investigating two of our existing medicines for their potential use as treatments for COVID-19.[2]

In order for AstraZeneca to bring these life-prolonging and life-saving scientific innovations to Canadians, we need a future-focused, thriving life sciences ecosystem. Much of this ground-breaking innovation, which we are hoping to bring to Canada, is being threatened by the federal drug pricing controls. It is now undeniable that the reforms have already reduced Canadians' access to medicines, even before the new pricing system has become fully operational. Over the past two years Canada has seen a dramatic drop in the number of new medicines marketed in this country, whereas medicine launches in other jurisdictions have been rising.[3]

Similar to many other companies in Canada, AstraZeneca has also been faced with the dilemma about whether to delay product launches as a result of the new pricing system. The new rules are impacting dozens of our pipeline medicines and vaccines, as well as new indications under development for our existing products, some of which are combinations with other developers.

Many of our experimental medicines are highly innovative first in class treatments that have been or are expected to be granted priority review by Health Canada. In fact, several of our medicines have gone through Project ORBIS, a new international health authority collaboration which provides a framework for simultaneous submission and review of oncology products among international partners to bring needed treatments to patients sooner. There is a significant disconnect between this progressive policy and the PMPRB changes which are adding a potentially insurmountable barrier on top of an already complicated, costly and uncertain commercialization pathway, that will prevent access to many Canadians who need these medications.

This is a particularly troubling development in the context of the ongoing COVID-19 pandemic. The PMPRB continues to experiment with novel and uncertain approaches to price regulation, at a time when new research, innovation, medicines and vaccines are extremely important. The latest PMPRB Annual Report also confirms that prices of patented medicines in Canada are on the decline and have remained consistently lower than the median in the seven comparator countries.[4] This calls into question the need for the reforms in the first place.

During this unprecedented pandemic, we should all be striving to build a healthcare system for the future – one that rewards innovation and encourages commercialization of medicines and vaccines that will keep Canadians in the workforce, out of hospital, raising families, and contributing to our nation's post-COVID economic recovery. But as other countries transition to data-driven, outcomes-based health care, the federal government's approach continues to put short-term cost savings above all other considerations. This short-sighted approach will ultimately

[2] https://www.astrazeneca.com/media-centre/articles/2020/investigating-an-existing-medicine-as-a-potential-treatment-for-covid-19.html

[3] https://lifesciencesontario.ca/news/canada-may-be-losing-its-status-as-a-top-global-destination-for-new-medicine-launches/

[4] 2018 PMPRB Annual Report: https://www.canada.ca/en/patented-medicine-prices-review/services/reports-studies/annual-report-2018.html

cost Canadians dearly in terms of lives lost, poorer quality of life, lost medical research and investments, and increased provincial health system spending.

During this public health crisis we have seen unprecedented levels of cooperation between the innovative pharmaceutical industry and all levels of government as we've helped co-create solutions, contributed to policy development, made donations of PPE to front line health care professionals, and invested heavily in the development of diagnostics, vaccines and therapeutics. We must ensure these advancements continue and we must also safe-guard against future health care and economic crises.

In this context, the following are several of Astra Zeneca's key concerns with respect to the amendments to the *Patented Medicines Regulations* and the PMPRB's Final Guidelines:

1) **There is continued uncertainty about how the new pricing system will work in practice, particularly with respect to the proposed economic factors**: Unfortunately, many of the next generation of cutting-edge therapies – medicines and vaccines that can save lives, cure previously untreatable diseases, and keep Canadians healthy and productive – will continue to face barriers to entry into Canada as a result of the uncertainty created by the proposed use of economic factors. Businesses need clear rules of engagement to guide their medicine launches and investment decisions, and the proposed system for applying these factors remains unclear and extremely complicated. While the wide-scale application of these factors has been delayed, our sector continues to live in a perpetual state of limbo, which adds to the uncertainty in the Canadian market.
2) **Innovation continues to be penalized**: The federal government has set the ambitious goal of doubling the size of the life sciences sector by 2025 and is now looking to our sector to develop solutions to address COVID-19. It is therefore regrettable that the PMPRB continues to penalize and target innovation by mandating the highest price reductions for some of the most innovative and widely beneficial medicines. Creating disincentives for companies to develop and commercialize medicines in Canada goes directly against our country's innovation priorities and is not in the best interest of Canadians or our economy.
3) **Excessive discretion is provided to PMRPB staff regarding evaluations and decisions that may be beyond the scope of their expertise**: The PMPRB's Final Guidelines provide confusing discretion for PMPRB staff to use whatever price tests they feel they need during an investigation: *"Staff may utilize any of the tests described in the Guidelines and modifications or variations of those tests (e.g., MIP instead of HIP or median as opposed to the top of the dTCC) depending what it believes most appropriate to the factual circumstances surrounding the price of the patented medicine under investigation."* It is difficult for companies to set their prices when an investigation of the price, if any, would use completely different rules than prescribed by the Guidelines. It is worth noting that with these Guidelines, the PMPRB appears to be drifting further and further away from its mandate. This is a very concerning development and will further complicate companies' commercialization efforts.

Final thoughts

AstraZeneca is an innovative biopharmaceutical company with a long track record of pushing the boundaries of science to create life-changing medicines. We want to continue to be able to bring these cutting-edge therapeutics to Canadians who need them. However, the federal government's price controls, and the PMPRB's approach to operationalizing the regulations, continue to perpetuate uncertainty, penalize innovation, and create barriers to commercializing medicines that will improve and save the lives of Canadian patients.

Considering the inoperability and unreasonableness of the PMPRB changes and the global pandemic that we are all working tirelessly to address, we urge your committee to recommend that the government make an immediate regulatory change, specifically, to remove the economic factors from the Patented Medicines Regulations, as these mandated criteria are the most uncertain aspect of the reforms.

All of the changes, including the revised basket of countries, should be considered more carefully – using case studies and drawing on global experts with pharmaceutical sector experience – to ensure that Canada regains its status as a priority G7 jurisdiction for the research, development and deployment of medicines and vaccines.

We want to thank the HESA Committee for undertaking this important study and for considering our submission. We hope that this committee can call on the Government of Canada and the PMPRB to revisit its current flawed approach to medicine price regulation and consider a more balanced pricing framework – one that supports an innovation-driven healthcare system, enables the biopharmaceutical sector to contribute to a healthy economy, and ensures that Canadians can continue to have access to the latest life-changing health innovations.

Yours Sincerely,

Jane Chung

Country President, AstraZeneca Canada