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RE: Otsuka Canada Pharmaceutical Inc (OCPI): Comments on Canada Gazette, Part I December 2, 2017

Thank you for the opportunity to provide commentary on the proposed changes to the Patented Medicines Regulations. As a relatively new entrant to the Canadian Pharmaceutical market, we believe that Otsuka Canada Pharmaceutical Inc. (OCPI) has a unique perspective on why a Global Japanese pharmaceutical company decided to invest in Canada. In large part, this was driven by Canada's well established pharmaceutical environment, with its clear rules of engagement providing a fair and secure market place. In addition, Canada is home to many centers of excellence and higher learning which provide a fertile space for innovation.

In the last few years, OCPI has brought Canadians a first in disease treatment for Autosomal Dominant Polycystic Kidney Disease (ADPKD), which Canadians were the second in the world to access, and the first ever once-monthly dopamine D2 partial agonist to help treat Canadians suffering from schizophrenia. In addition to providing life-altering medications, OCPI has also created and funded an ADPKD registry to gather real world Canadian evidence, positioning Canadian researchers and clinicians at the forefront of this new and evolving field. In the area of Mental Health (a key area of focus for both Federal and Provincial governments), OCPI has supported critical Canadian research into the impact of psychotic relapses on brain function.

With the publication of the proposed amendments to the Patented Medicines Regulations in the Canada Gazette part 1 on December 2, 2017, significant uncertainty has been introduced with regards to the pricing evaluative framework. Furthermore, a number of the proposed changes appear to duplicate processes that are already in place to address concerns regarding medication affordability, equitable drug access, and optimal use of drugs. This would add unnecessary complexity and uncertainty to the existing process.

Canada was one of the first countries globally to systematically incorporate Health Technology Assessment (HTA) into policy in the early 1990's and has significant experience in the form of two HTA bodies: the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS). CADTH has a stated mission to enhance the health of Canadians by promoting the optimal use of health technologies, and Provincial insurers systematically refer to CADTH reviews to help guide their funding decisions.

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INESSS's mission is to promote clinical excellence and the efficient use of resources in the health and social services sector and they assess "...in particular, the clinical advantages and the costs of the technologies, medications and interventions used in health care and personal social services."[1] Although the report recognizes the "...significant expertise that can be necessary to prepare and validate cost-utility analyses..." the proposed regulatory changes would enable the PMPRB to "...consider the introduction of the concept of a maximum cost per QALY." This concept is not further defined and the methods of its application to the drug pricing and reimbursement process, unclear. Despite the many years of experience at CADTH and INESSS, a maximum cost per QALY has not been endorsed by either of these organizations, likely in part owing to the limitations inherent to QALY. QALYs have been shown not to capture all dimensions of health benefits, or appropriately measure interventions that reduce short term-disabilities, or many undesirable health states and difficult conditions for patients.[2] The principal focus of the Canadian HTA processes is the evaluation of the cost-effectiveness/cost-utility of treatments for the specific populations of interest for Provincial insurers. The population covered by public drug benefit plans differs from the population covered by private insurance, and their value assessments also differ. As such, a single QALY cannot offer a representative assessment of value for all Canadians.

Cost-effectiveness and affordability, however, are not interchangeable. The question of affordability is nuanced. The confidential pricing that is commonplace among Public Drug Plans (Product Listing Agreements (PLAs) reflects that reality, a reality which integrates not only the clinical value of a medicine, but also considers regional budgets, treatment patterns, and health system sustainability. The Canadian market place has evolved and modernized. With the advent of the pan Canadian Pharmaceutical Alliance (pCPA), the coordinated efforts of the participating Public drug plans have resulted in a significant reduction in the cost of pharmaceuticals. In fact, as of March 31, 2017, the pCPA's efforts have led to a $1.28 billion a year in estimated combined jurisdictional savings.[3] In the proposed amendments to the *Patented Medicines Regulations*, it is stated that "Provincial insurers are some of the biggest payers of patented medicines in Canada." As such, the pCPA is best positioned to address medicines that are likely to "pose affordability challenges". In fact, the proposal calls for the PMPRB to develop market impact tests would duplicate the budget impact analysis already provided by manufacturers to Provincial payers as part of the drug reimbursement process.

Such duplication will add complexity to the already lengthy and challenging process of making innovative medicines available to Canadian patients. Once Marketing Authorization has been granted by Health Canada, a number of sequential processes including HTA, pCPA negotiations and, ultimately Provincial discussions to finalize agreements, equitable availability (i.e. both privately insured and publicly insured patients) of a drug routinely takes more than one year, limiting access to branded pharmaceuticals during market exclusivity.

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[1] https://www.inesss.qc.ca/en/about-us/about-the-institut.html

[2] Knapp M. "Economic outcomes and levers: impacts for individuals and society" Int Psychogeriatr. 2007 Jun;19(3):483-95, https://www.ncbi.nlm.nih.gov/pubmed/17391570

[3] http://www.canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/

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Private insurers utilize several options to manage the affordability of medication coverage: a number of Private plans are "Public Drug Plan mimicking", leveraging Health Technology Assessment (HTA) bodies' and Provincial reimbursement decisions. Analogous to the Provincial insurers, numerous large Private Insurers have entered into product listing agreements with manufacturers. These developments are not unexpected as private insurers are typically large, for-profit entities that are planning for and responding to changing market realities. With the advent of PLAs, special authorization criteria, managed plans, step therapy, public mimicking plans, and programs such as Great-West Life SMART drug plan (Sustainable, Managed and Reasonable Treatment) and Drug Watch from Manulife which aim to provide a comprehensive analysis of new drugs "...to help ensure those eligible for coverage have the potential to deliver the highest level of health outcome at the most prudent price."[4], it is clear that insurance companies have the resources they need to mitigate the potential for excessive pricing without changing the current PMPRB guidelines.

Health System Reform and Questions of Value

OCPI supports inclusive health system reform such that Canadians continue to have access to leading healthcare they expect while helping ensure the sustainability of the system. It is our view that the proposed changes at the PMPRB will not accomplish this task and instead will limit or delay investment and the launch of medicines in Canada because of the significantly increased uncertainty in the process. Limiting Canadians' access to innovative treatments may reduce drug expenditures in the short term, but recent evidence demonstrates that such an approach can have deleterious consequences on health outcomes.[5] It is our position that the current PMPRB regulations, coupled with initiatives lead by both private and public insurers to increase spending efficiency offers Canadians the best hope for a health system that meets society's needs from both a clinical and economic perspective. The current PMPRB guidance and oversight is tasked with regulating publicly available patented drug prices such that Canada is not an outlier. However, questions of value and affordability are best addressed by payors themselves as they are the most familiar with the constraints they face regarding this issue.

Concluding Remarks

In reviewing the materials provided and presented by the PMPRB, it appears that much of the context for changing the guidelines is based on a few recent outliers. Furthermore, the proposed regulatory changes in the Canada Gazette part 1, Dec 2, 2017 lack clarity and the necessary information required to properly assess their impact, as well as duplicating processes that are already managed by CADTH/INESSS and the pCPA. The proposed changes will lead to greater uncertainty in the Canadian pharmaceutical market place and will make investing in Canada more challenging. OCPI believes that the current PMPRB guidelines are effective, well understood, and provide a degree of certainty with regards to the pharmaceutical pricing environment in Canada. This is important as it helps the pharmaceutical industry plan investment. In the global pharmaceutical industry, Canadian affiliates work to secure global funds for investment in local markets which helps drive local innovation.

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[4] http://www.manulife.ca Accessed October 14, 2016

[5] Rawson NS., Canadian Health Policy, September 26, 2016

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Aside from patent length differences with that of other jurisdictions, a number of processes including HTA reviews and negotiations with pCPA and payors, delays widespread availability of drugs to Canadian Patients and decreases the effective length exclusivity of the Marketing Authorization granted by Health Canada to Innovative drug developers. We believe patients would experience better health outcomes by decreasing this period to allow patients to benefit from these innovations earlier.

OCPI supports reform that improves health system sustainability and medication affordability; however, we do not believe that the proposed changes to the scope of the PMPRB guidelines will result in this outcome. Canadian data demonstrates that changes to improve medication affordability have occurred and are ongoing both at CADTH/INESSS and at the payor level, which is the appropriate venue for such reform.

Sincerely,

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