Otsuka

October 26, 2016

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

By email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Otsuka Canada Pharmaceutical Inc: Comments on PMPRB Guidelines Modernization Discussion Paper dated June 2016

To whom this may concern,

Thank you for the opportunity to provide input via the first phase of the PMPRB consultation process regarding the modernization of the PMPRB Guidelines. 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 marketplace. In addition, Canada is home to many centers of excellence and higher learning, which provide a fertile space for innovation.

Innovation

Over a few brief years in the Canadian market place, OCPI has brought to Canadians innovation. That innovation included a first-in-disease treatment for Autosomal Dominant Polycystic Kidney Disease (ADPKD), which Canadians were the second in the world to access, and supporting critical Canadian research into the impact of psychotic relapses on brain function. Knowledge is the foundation of innovation, and OCPI is contributing by adding to our collective understanding of the natural course of illnesses such as ADPKD by creating an ADPKD registry[1] to gather real world Canadian evidence, positioning Canadian researchers and clinicians at the forefront of this new and evolving field. In the field of mental health, OCPI has supported research, which has provided a greater understanding of the impact of consistent antipsychotic treatment on improving hospital resource utilization in the Province

[1] Otsuka Canada Pharmaceutical Inc. C-MAJOR : Canadian Medical Assessment of JINARC™ Outcomes Registry. Canadian observational cohort study of the real-life assessment of tolvaptan (JINARC™) in autosomal dominant polycystic kidney disease. https://clinicaltrials.gov/ct2/show/NCT02925221?term=156-203-00047&rank=1

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of Quebec.[2] OCPI anticipates future growth that will increase both our investment within Canada and our employment of highly skilled professionals as we seek to continue bringing innovation to Canadians.

Cost-effectiveness and Affordability

Innovation in the realm of drug discovery, however, is no longer sufficient. Questions of cost-effectiveness, value for money and affordability are increasingly being asked in assessing new therapies. Being an innovative company, OCPI is eager to partner with stakeholders to seek new and innovative ways to bring treatments to market while considering the broader implications on sustainability, on public health and on continued development and innovation.

From opening our doors in 2010 in Canada, OCPI now has more than 100 employees nationwide. A key objective of ours is to continue to grow and invest in Canada. In considering the contribution of the pharmaceutical industry to Canadians and the Canadian economy, it is important to realize that investing directly in R&D is but one benefit. There are significant investments made with Canadian suppliers, the purchase of goods and services as well as employment opportunities across the country. To meet the needs of a highly technical, innovative and continuously evolving pharmaceutical industry, the available skillset in Canada needs to advance as well. This dynamic will help Canada compete on the global stage and, in turn, secure more resources and investment.

While building a business in Canada, OCPI has contributed to innovation, research and development in this country. OCPI has supported a number of studies, scientific publications and abstracts. Over 2014 and 2015, the PMPRB has calculated OCPI's R&D to Sales ratio to average 26.25. Importantly, R&D to Sales ratios do not take into account any confidential rebates which may be agreed upon by the manufacturer and a payor (Public or Private) which serve to decrease drug expenditures and improve health system sustainability.

Canada was one of the first countries globally to systematically incorporate Health Technology Assessment (HTA) into policy in the early 1990's. Canada has 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. A strong focus of the CADTH HTA process involves the evaluation of the cost-effectiveness of novel treatments. 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) is a reflection of 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.

[2] Stip E, Larbi M, Melnyk P. et al. Impact of initiation of long-acting injectable antipsychotics on resource utilization in patients with schizophrenia. Poster presented at the Canadian College of Neuropsychopharmacology 39th Annual Meeting, June 14-17, 2016, Halifax, Nova Scotia, Canada,

The market has responded and self-regulated. With the advent of the pan Canadian Pharmaceutical Alliance (pCPA), the coordinated efforts of the participating Public drug plans have resulted in a significant downward pressure on prices paid for pharmaceuticals. The PMPRB Position Paper contends that the confidential discounts that have become "industry standard" have frustrated international efforts to contain pharmaceutical spending based on public list prices.[3] We believe that what needs to be considered is whether constraining spend by other available means is working (e.g. PLAs with Provincial Drug Plans and PLAs with Private Payors decrease drug spending), and that public list drug prices in and of themselves are not indicative of expenditures on prescription medicines.

Other key factors which are not captured by the publicly available list price metric is the term of effective patent protection and, more specifically, the duration of effective patent exclusivity during marketing of a drug once reimbursement has been obtained. The current framework assumes that any patent that pertains to a medicine may be used in order to provide exclusivity, but it is generally only those patents listed on the Patent Register that are relevant to generic competition. Furthermore, with a number of sequential processes including HTA, pCPA negotiations and, ultimately Provincial discussions, widespread availability of a drug routinely takes more than one year after Marketing Authorization has been granted by Health Canada, limiting the total sales of branded pharmaceuticals during the period of effective patent exclusivity.

In looking at market exclusive products, we see that Canadian list prices for market-exclusive patented medicines are not among the highest, rather in 2015 they were ranked 6th out of our 8 comparator countries.[4] Furthermore, Canadian market exclusive patented medicine list prices have not been increasing, but rather decreasing compared to comparator countries (Canada ranked 5th in 2010 compared to our 8 comparator countries).

The pCPA has also changed the reimbursement environment and pharmaceutical sales. The stated objectives of the pCPA are:

- *increase access to drug treatment options;*
- *improve the consistency of drug listing decisions across the country;*
- *capitalize on combined buying power of jurisdictions;*
- *achieve consistent pricing and lower drug costs; and*
- *reduce duplication of negotiations and improve utilization of resources.*

Based on the initial success of the pCPA in controlling drug expenditures, this process is now systematic, with every drug completing HTA review being considered for pCPA negotiations. The pCPA takes a number of steps towards achieving some of the desired "Whole of Government framework" outcomes of a responsible, accessible and sustainable health-system referred to in the PMPRB Guidelines Modernization Paper. According to a recent OECD report (2015), the growth rate in Health Spending in Canada has slowed down substantially in recent years and this has been driven in large part by a decline

[3] PMPRB Guidelines Modernization - Discussion Paper, June 2016.
[4] Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members.

in pharmaceutical spending. In looking at Health Spending (excluding capital expenditure), Canada averages less than the PMPRB7 countries (and is equal to the average if the US is removed from the list of comparators) – demonstrating that Canada is not an outlier.[5]

When considering the Private Payor environment, we see that the market has responded yet again: a number of Private plans are "Public Drug Plan mimicking", taking their lead from Health Technology Assessment (HTA) bodies and Provincial reimbursement decisions. Further, several large Private Insurers have begun to engage with Manufacturers to develop mutually acceptable PLAs. These developments are not unexpected as private insurers are often large, for-profit entities that are responding to market realities. With the advent of PLAs, special authorization criteria, public mimicking plans, and programs such as Drug Watch from Manulife which aim to provide "..comprehensive analysis of drugs entering the market to help ensure those eligible for coverage have the potential to deliver the highest level of health outcome at the most prudent price."[6], we believe that insurance companies have the resources they need without changing 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 while helping ensure the sustainability of the system. It is our view that a narrow focus on public list prices of medicines alone is insufficient to accomplish this task. 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.[7] It is our position that the current PMPRB approach, coupled with initiatives lead by payors 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 effective in 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. OCPI believes that the current 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.

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[5] OECD Health Statistics 2015. How does health spending in Canada compare? https://www.oecd.org/els/health-systems/Country-Note-CANADA-OECD-Health-Statistics-2015.pdf

[6] Manulife. DrugWatch™ 2015 http://pointbreakcg.com/wp-content/uploads/2015/09/DrugWatch-Brochure_GC2690-E.pdf

[7] Rawson NSB (2016). How might the choice of prescription drugs in provincial public insurance plans be impacted if a cost-control system like New Zealand's was adopted in Canada? Canadian Health Policy, September 26, 2016.Toronto: Canadian Health Policy Institute. URL: www.canadianhealthpolicy.com

In the global pharmaceutical industry, Canadian affiliates work to secure global funds for investment in local markets which helps drive local innovation.

Furthermore, looking at Canadian market exclusive (i.e. monopoly position) list prices, we see that Canadian prices are below the median for our comparator countries. In addition, instead of increasing, these prices have decreased since 2010.

Lastly, a number of processes including HTA reviews and negotiations with pCPA and payors, delays widespread availability of drugs to Canadian Patients and adversely impacts the length of effective exclusivity to Innovative drug developers who are bringing these new therapies to market. We believe patients would experience better health outcomes by decreasing this period to allow patients to benefit from these innovations earlier, and this should be a focus for the government.

OCPI supports reform that improves health system sustainability; however, we do not believe that changing the PMPRB guidelines will result in this outcome. Our view is that changes have occurred and are ongoing at the level of the payor which is more appropriate to address questions of affordability and sustainability.

Sincerely,

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