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Patented Medicine Prices Review Board (Rethinking the Guidelines) Box L40, 333 Laurier Avenue West, Suite 1400 Ottawa, Ontario K1P 1C1 Fax: 613-952-7626

Response to PMPRB Guidelines Modernization – Discussion Paper

On behalf of Life Sciences Ontario, our board of directors, and members, I am writing to express our deep concern with regards to the potential negative impact of the proposed PMPRB modernization on Canada's innovation ecosystem.

Canada's pharmaceutical industry is an anchor for the nation's innovation economy. In Ontario, this industry represents a third of the total employment in life sciences and more than half the total revenues of the entire life sciences sector.¹ It is also the highest-paying sub-sector, with average annual wages 30 per cent higher than the Provincial average.¹

More importantly, the pharmaceutical industry plays an active role in supporting the development of made-in-Canada innovation. While other sectors showed recent declines in R&D expenditures from 2014-2015, the pharmaceutical industry's R&D expenditures grew by 23.4% (22 companies in Canada's top 100 R&D spenders), raising its share of the top 100 spend from 9.1% to 11.5%.²

One of the world's largest pharmaceutical companies, Johnson & Johnson, chose Toronto for its first JLABS innovation centre outside of the United States. Clearly, Canada currently has the scientific and entrepreneurial prowess to attract this calibre of investment. This partnership also demonstrates pharma's commitment to work with Canadian innovation centres to fill gaps in funding and commercialization expertise. However, we cannot expect this support by multinational pharmaceutical companies to continue indefinitely without reciprocating it. We must demonstrate, as a nation, that we are committed to innovation by aligning our public policies to match with our values.

PMPRB continues to use an antiquated approach to assessing the R&D investments of pharmaceutical firms by limiting metrics to SR&ED eligible expenditures. As such, it fails to recognize a significant portion of commonly occurring R&D expenditures. The lack of recognition of these expenditures serves as an additional disincentive to further R&D investments.

The discussion paper also focuses much time and effort on determining what constitutes "excessive" pricing of pharmaceutical products. LSO recognizes the immense challenges associated with managing public healthcare costs and ensuring patients and taxpayers receive innovative interventions at a fair price. However, PMPRB must recognize that pharmaceutical development is a complex process that varies widely from product to product. Biologics versus small molecule, disease pathways and mechanisms of action, personalized medicine and market size (ie. rare diseases): These are just a few factors that can raise the development cost of pharmaceutical products, and in turn, the price for the end user.

¹ Life Sciences Ontario Sector Report 2015

² RE\$EARCH Infosource Inc.; Canada's Top 100 Corporate R&D Spenders

PMPRB has a duty to acknowledge, understand, and factor in these complexities when determining what constitutes fair pricing. This is especially important with new medications that treat an unmet need. To ignore these complexities by comparing new medicines to other therapeutic classes devalues scientific discovery and undermines innovation. It directly contradicts the very kind of policy approach needed to build a viable innovation agenda for Canada.

The best way PMPRB can recognize these complex factors is through fair market comparison with treatments for the same disease or condition. PMPRB has a well-established system for international market comparison, including the highest international price comparison (HIPC) test, which is demonstrated to be effective and fair. Arbitrarily changing this system to a lowest international price comparison (LIPC) to artificially lower prices (by preferentially excluding certain markets such as the US) is likely to create negative consequences: namely, divestments in R&D, a stalling of innovation, and the unavailability of new medicines in Canada.

In conclusion, Canada's significant investments in research and education have resulted in world-class scientific discoveries. Governments at all levels are developing policies to nurture and further develop these assets, in order to grow Canada's knowledge economy and ensure our future prosperity. In reviewing pricing policies, PMPRB must look through this innovation lens to align with these values. Failing to do so will be contrary – and ultimately detrimental – to Canadian innovation.

Sincerely,

Vor from

Jason Field President & CEO Life Sciences Ontario