



June 28, 2017

Health Canada
Patented Medicines Regulations Consultations
70 Colombine Driveway, Tunney's Pasture
Mail Stop 0910 Floor 10
Brooke Claxton Building
Ottawa, Ontario
K1A 0K9

To Whom It May Concern:

The Canadian Medical Association (CMA) is pleased to provide its comments with respect to Health Canada's Patented Medicines Regulations Consultations. The CMA is the national voice of Canadian physicians. Founded in 1867, the CMA's mission is helping physicians care for patients. The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and over 60 national medical organizations.

As the second-largest share of total health expenditures in Canada, forecast to be 16% in 2016, the cost of drugs is of significant concern to physicians.¹ In 2014, 42.6% of prescribed drug spending (\$12.5 billion) came from the public sector.² Pharmaceuticals play an important role in overcoming disease and maintaining health but access to these drugs can be problematic outside of hospital care due to their cost. This is why the CMA has called for a pan-Canadian system of catastrophic coverage for prescription drugs.³ We viewed this as a step toward the development of comprehensive, universal coverage for prescription medicines in Canada.⁴

¹ CIHI. National Health Expenditure Trends 1975-2016, December 15, 2016

² *Ibid*

³ Canadian Medical Association (CMA). *A New Vision for Health Care in Canada: Addressing the Needs of an Aging Population. 2016 Pre-budget Submission to the Minister of Finance.* Ottawa: The Association; 2016 Feb 12

⁴ *Ibid*





In its brief to the Commission of Inquiry on the Pharmaceutical Industry in August, 1984, the CMA stated that we “fully support the objective of providing prescription drugs to patients at the lowest possible cost that is consistent with wise health care delivery.”⁵ This remains our objective. This submission will address the proposed improvements to the regulations raised in the consultation document from a broad perspective.

Economic Considerations

The ability of the PMPRB to monitor drug prices has long been the subject of review and concern.^{6,7} The CMA is pleased that the Government of Canada is undertaking this review to provide the Patented Medicines Prices review Board (PMPRB) with a new regulatory framework to protect Canadians from excessive prices and improving the regulatory process. The board needs to use every economic measure and tool at its disposal to ensure Canadians pay fair and equitable prescription drug prices.

As the Eastman Commission pointed out in its 1985 report, “Canadian consumption is a small proportion of world consumption so that Canadian patent policy has little effect on the world-wide profitability of the pharmaceutical industry.”⁸ Indeed, Canadian pharmaceutical sales represent 2% of the global market which makes us the tenth largest world market.⁹ Yet our small size with respect to the global market has not shielded us from high prices. For example, a recent study found that although the volume of therapies purchased in Canada across six classes of “primary care medicines” was similar, we paid an estimated \$2.3 billion more for them in 2015 than if these treatments had the “same average cost per day in Canada as in the nine comparator countries combined.”¹⁰

Prescription medication spending is an issue for many Canadians, especially when it has an impact on compliance with prescription regimes, an unintended consequence of the manner in which the board’s regulatory framework has been applied. On the

⁵ Canadian Medical Association (CMA). *Brief to the Commission of Inquiry on the Pharmaceutical Industry* August 15, 1984

⁶ Gray C. Patented drugs: Is the price right? *CMAJ* 1998 158:1645

⁷ Silversides A. Monitoring the price of new drugs *CMAJ* 2006 174(11):1548-1549

⁸ The Commission of Inquiry on the Pharmaceutical Industry. *The Report of the Commission of Inquiry on the Pharmaceutical Industry* H.C. Eastman, Commissioner. Ottawa Minister of Supply and Services 1985 p. 347

⁹ Industry Canada. Pharmaceutical industry profile. https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html (Accessed 2017 June 20)

¹⁰ Morgan SG, Leopold C, Wagner AK. Drivers of expenditures on primary care prescription drugs in 10 high-income countries with universal health coverage. *CMAJ* 2017;189:E794-9



Commonwealth Fund's 2013 International Health Policy Survey, 8% of the Canadian respondents said that they had either not filled a prescription or skipped doses because of cost issues.¹¹ Himmelstein et al. reported on a survey of Canadians who experienced bankruptcy between 2008 and 2010. They found that 74.5% of the respondents who had had a medical bill within the last two years reported that prescription drugs was their biggest medical expense.¹²

The CMA is especially worried about the impact high drug costs have on seniors in the absence of universal drug coverage. They have access to some level of drug coverage in all provinces and territories but it is not even.¹³ Eight provinces have an income-test that determines the deductibles they will pay while in two they pay a small portion of the cost with the province or a third-party insurer covering the rest.¹⁴ All three territories have plans for those who qualify but the provisions may be limited.¹⁵ A recent study found that older Canadian adults (55 and older) had the second-highest prevalence (8.3%) of cost-related non-adherence (CRNA) for prescribed medications.¹⁶ CRNA was higher among those with lower incomes and lower among those over 65.

Finally, the CMA remains very concerned about ongoing shortages of prescription drugs. We would caution that whatever measures the government undertakes to strengthen and improve the PMPRB do not exacerbate drug shortages.

International Comparisons

The PMPRB's current benchmark "that Canadian prices for patented drugs should be less than the median of prices in selected comparison countries" places us at a distinct disadvantage.¹⁷ As the authors note, "it puts Canada well above the OECD average by

¹¹ Schoen C, Osborn R, Squires D, Doty M. Access, affordability, and insurance complexity are often worse in the United States compared to ten other countries. *Health Affairs* 2013;32(12):2205-15.

¹² Himmelstein D, Woolhandler S, Sarra J, Guyatt G. Health issues and health care expenses in Canadian bankruptcies and insolvencies. *International Journal of Health Services* 2014;44(1):7-23.

¹³ Vebeeten D, Astiles P, Prada, G. *Understanding Health and Social Services for seniors in Canada*. Ottawa: The Conference Board of Canada, 2015.

¹⁴ *Ibid*

¹⁵ *Ibid*

¹⁶ Morgan SG, Lee A. Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries *BMJ Open* 2017;7: e014287. doi:10.1136/bmjopen-2016-014287 (access 2017 Jun 16)

¹⁷ Zhang R, Martin D., Naylor CD., Regulator or regulatory shield? The case for reforming Canada's Patented Medicines Prices review Board. *CMAJ* 2017 April 10;189:E515-6. doi: 10.1503/cmaj.161355



aligning Canada with countries that spend more from the outset.”¹⁸ The PMBRB should expand its range of comparator countries beyond those identified originally (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States) to include those OECD countries with middle to low patent drug pricing.¹⁹

Furthermore, to ensure that the process is clear and transparent for Canadians, the PMPRB should “set prices closer to what comparator countries actually pay for their drugs as opposed to the “sticker” prices that most commonly represent the starting point for confidential negotiations.”²⁰ Canadians deserve that much after years of paying such high prices for their patented medicines.

The CMA is very concerned about the cost of medications. In the absence of universal drug coverage and, at a minimum, a pan-Canadian system of catastrophic coverage of prescription drug costs, a strengthened and robust regulatory framework for the pricing of patented medicines in Canada is crucial. The CMA calls on the federal government to revise the PMPRB regulations such that it provides Canadians with transparency and clarity around the setting of patented medicines prices while achieving the lowest costs possible and ensuring we continue to have access to a wide array of pharmaceutical products.

Sincerely,

Granger R. Avery, MB BS, FRRMS
President

¹⁸ *Ibid*

¹⁹ *Ibid*

²⁰ *Ibid*