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Major Changes Proposed to Canada's Patented Medicines Regulations

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On May 16, 2017, the Federal Minister of Health, the Hon. Jane Philpott announced a number of proposed regulatory changes to the *Patented Medicines Regulations* (the "Regulations"). The proposed regulations are being implemented with the primary intent of "protecting Canadians from excessive drug prices"[1]. The proposed modernization framework constitutes the most significant suite of regulatory changes in twenty years. As noted in our blog post dated July 1, 2016, these proposed changes are part of ongoing reform to Canada's regulatory framework relating to patented drug prices.

Health Canada has released a Consultation Document that proposes five main amendments to the Patented Medicines Regulations. Central to the modernization of the framework is the shift to a "risk-based" approach to regulation – that is, "drugs with higher potential to exert market power would face a higher degree of regulatory scrutiny while drugs with medium or lower risk of excessive prices would face respectively lower oversight."[2]

The proposed amendments are as follows:

(1) The addition of new factors to determine whether a drug price is excessive.

Under the current regulatory regime, section 85(1) of the *Patent Act* sets out a number of indicia that the Patented Medicine Prices Review Board ("PMPRB") must consider when determining whether a medicine is being sold at an excessive price. A key paradigm shift proposed in the Consultation Document is the inclusion of willingness and ability-to-pay of payers into the section 85(1) calculus. Specifically, the Consultation Document proposes that the Regulations be amended to include an additional three factors, being,

a. a "pharmacoeconomic evaluation" for the medicine, which "identifies, measures, and compares the costs and benefits of a given drug to patients and the healthcare system"[3], and could include, for example, the concept of a fixed cost per quality-adjusted life year ("QALY") which quantifies benefits of a medicine by measuring lengthened or improved quality of life;

b. the size of the market for the medicine in Canada and in countries other than Canada, which would allow the PMPRB to develop market impact tests for drugs posing affordability challenges, and which may leave room for future downward price corrections; and

c. Canadian Gross Domestic Product, both in aggregate and *per capita*, which would provide a method to assess a drug's affordability on national and individual scales.

(2) Amending the list of countries used for international price comparisons.

The PMPRB was established in 1987 to provide a consumer protection counterweight to regulatory reforms that strengthened patent protection for drugs. The prevailing belief at the time was that price and patent protection were the key drivers of R&D investment. In determining whether a medicine was being sold at an excessive price in Canada, the PMPRB was charged with taking into consideration the price of a drug or drugs in the same therapeutic class in seven countries (the “PMPRB7 Countries”) with some of the highest levels of R&D: France, Germany, Italy, Sweden, Switzerland, the UK and the US.

However, in response to rising patented drug prices relative to the PMPRB7 Countries and record low investment in pharmaceutical R&D in Canada, Health Canada is proposing revisiting these assumptions, noting that "there is no evidence of a determinant link between domestic prices and the location of industry R&D investment."[4] The proposed amendments to the Regulations would include updating the benchmark countries to those with consumer protection measures, economic standing and pharmaceutical market characteristics closer to Canada's, specifically: Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden and the United Kingdom.

(3) Reducing regulatory burden for generic drugs with a patent.

The amendments to the Regulations would result in decreased regulatory requirements for patented generic drugs such that these drugs would only be required to provide identity and pricing information to the PMPRB in the event of a pricing complaint, rather than on a systematic basis. The rationale for this amendment is that there is a reduced risk of excessive pricing of generic drugs due to the increased competition they face.

(4) Modernizing reporting requirements for patentees.

In connection with the implementation of additional section 85(1) criteria to the Regulations, the proposed amendments would require patentees to submit a cost utility analysis and the estimated uptake of the medicine, by approved indication.

(5) Providing information related to third party rebates.

Finally, the amendments to the Regulations would require patentees to report to the PMPRB all indirect price reductions, including discounts and rebates provided to third-party payers, the rationale being that this would provide the PMPRB with a better sense of the actual prices paid for a given drug in the market.

Concurrently with the announcements regarding the proposed changes to the Regulations, Minister Philpott

also announced a number of other proposed policy changes including the expansion of Health Canada's priority review policy, continuing to work with provinces and territories to develop a common drug formulary, better alignment of Health Canada and the Canadian Agency for Drugs & Technology in Health processes, and strengthening data collection relating to public and private drug plans.[5]

Consultation on the proposed changes to the Regulations is open until June 28, 2017 with more information available here.

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[1] Government of Canada, May 16, 2017, News Release, "Government of Canada taking action to protect Canadians from high prescription drug prices".

[2] Health Canada, "Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations", pg 8 [Consultation Document].

[3] Consultation Document, pg 10.

[4] Consultation Document, pg 12.

[5] Remarks from the Honourable Jane Philpott, Minister of Health, to the Economic Club of Canada – May 16, 2017
