The Canadian Government Proposes Amendments to the Regulation of Drug Pricing

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Due to concerns about the growing percentage of the health care budget allotted to drug spending in Canada and the relative drug prices in Canada compared to other developed countries, the Canadian government is proposing changes to the way in which prices for patented drugs are regulated, as set out in the Protecting Canadians from Excessive Drug Prices consultation document published by Health Canada on May 16, 2017 (the "Proposal"). The Proposal notes that despite significant changes in the pharmaceutical market (e.g., introduction of higher cost drugs such as biologics as well as greater differences between public list prices and lower actual market prices due to confidential discounts and rebates), the *Patented Medicines Regulations* (which govern patented drug price regulation along with the *Patent Act*) have not been substantively changed in over two decades. Thus, the intention of the amendments is to significantly lower the cost of prescription drugs by modernizing the pricing framework under the Patented Medicine Prices Review Board (PMPRB) and the *Regulations*.

According to the Proposal, the main limitations of the current regulatory framework are that it: (a) does not provide tools beyond price comparisons and CPI for the PMPRB to assess whether a price is excessive; (b) links prices for new medicines to countries with high drug prices; and (c) does not require patentees to report on rebates provided to customers in Canada beyond the first point-of-sale (i.e., the actual market prices paid).

To address these issues, a risk-based approach has been presented to guide amendments to the drug pricing regime by focusing more on the assessment of the economic value of new drugs to the Canadian health system and less on international drug price comparisons. In particular, drugs that are considered to have a higher potential to exert market power (and therefore charge "excessive" prices) would face a higher degree of regulatory scrutiny, while drugs with a lower perceived market power would face a relatively lower degree of oversight.

Briefly, the main amendments in the Proposal include:

* the use of economics-based price regulation factors (e.g., pharmacoeconomic evaluation for the drug, the size of the market for the drug in Canada and other countries, and the gross domestic product in Canada) to arrive at prices that reflect Canada's willingness and ability-to-pay for drugs that provide demonstrably better health outcomes;

* an update of the list of countries used for price comparison, including an increase in the number of comparator countries from seven to twelve (while removing Switzerland and the United States from consideration), so that it is more aligned with the PMPRB's consumer protection mandate and median OECD prices;
* implementing a complaints-based system of oversight for patented generic drugs that are considered a lower risk for excessive pricing, whereby patentees only report the identity and pricing information following a complaint or at the PMPRB's request;
* updating the reporting requirements of patentees to allow the PMPRB to operationalize the new pricing factors; and
* requiring patentees to provide the PMPRB with third party information related to rebates and discounts on domestic prices, including reporting all *indirect* price reductions given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit in Canada (e.g., discounts and rebates to third party payers such as provincial drug plans).

The proposed amendments to the drug pricing framework have the potential to significantly impact the business of patentees in Canada. Given the potential wide-reaching impact of the proposed changes (and the fact that this will be the first time in more than twenty years that the government will be substantially updating the *Regulations*), innovative drug companies may be highly motivated to participate in Health Canada's consultation on these proposed amendments to the drug pricing regime in Canada. The Fasken Life Sciences team has extensive experience in this area and is available to consult with stakeholders interested in responding to the Proposal.

The consultation period closes on **June 28, 2017**.