Canada Drops its Most Controversial Patented Drug Pricing Amendments

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After almost two years of suspense for pharma industry stakeholders, the Government of Canada will proceed with the implementation of some, but not all of the amendments to the Patented Medicines Regulations. Partial implementation became the only realistic path forward for the regulations after key sections were found unconstitutional by Federal and Quebec courts. This marks a substantial retreat from the government's attempt to use the regulations to expand PMPRB jurisdiction.

Health Canada will be moving forward with implementation of the new basket of comparator countries for pricing comparisons. There will also be reduced reporting requirements for those medicines at the lowest risk of excessive pricing.

The government will not proceed with the new price regulatory factors. The government is also dropping the requirements to file information net of all price adjustments. This regulatory revision will be published in late Spring 2022.

The amended regulations have been highly contentious. A combination of fierce opposition from the brand name pharma industry and patient interest groups, as well as the COVID-19 pandemic, have factored into a series of delays. As noted above, the Federal Court and the Quebec Court of Appeal have both held invalid (ultra vires) the amendments that required patentees to use a new price calculation that included discounts, rebates or other benefits provided to third parties (e.g. public and private insurers) when reporting medicine prices and revenue information to the Board. The Quebec Appeal Court went a step further than the Federal Court, finding that the Regulation’s new pharmacoeconomic price regulatory factors were also invalid. See our recent article on the court decisions for more information.

The PMPRB itself was also cautioned against expanding its own jurisdiction in a recent, different court case. In that case, involving the Alexion drug Soliris (see our article here), the Supreme Court of Canada recently denied the PMPRB’s request for leave to appeal.

The resolution of all this litigation should provide more certainty for innovator drug companies. The PMPRB’s jurisdiction will remain clearly limited to the control of excessive prices resulting from patent monopoly and may not encroach on general price regulation.

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