



THE HILLTIMES --- RESEARCH



February 23, 2022



Table of Contents

Research

New PMPRB rules on third-party rebates, economic factors are unconstitutional, says Quebec Court of Appeal

Upcoming Events

Minister Duclos to make an announcement

Minister Fraser to make an announcement

Minister Sajjan to speak at “Galvanizing Momentum for Universal Vaccination debate”

Press Releases

Public Services and Procurement Canada

Canadian Medical Association

New PMPRB rules on third-party rebates, economic factors are unconstitutional, says Quebec Court of Appeal

RESEARCH EXCLUSIVE | FEBRUARY 23, 2022

The federal Liberals' plan to reduce pharmaceutical drug prices through changes to Patented Medicine Prices Review Board regulations (PMPRB) hit a significant snag on Feb. 18 when the Quebec Court of Appeal found that two of three key elements of that plan are unconstitutional.

“The Quebec Court of Appeal decision is now law. It is law in the province of Quebec and it is a constitutional ruling. And as a result, we can say that the basket of countries ... is within [the PMPRB's] jurisdiction and that's it,” said Eileen McMahon, a partner and co-founder of the intellectual property and food and drug regulatory practices at Torys LLP. McMahon, who spoke by phone to Hill Times Research on Feb 23, is not involved in the court action.

Before the Quebec Court of Appeal was a series of changes to how the PMPRB would regulate the prices of new approved medicines in Canada. The regulations were finalized in August 2019 and they are meant to be in force in July 2022 after multiple delays.

RELATED: [NOT ALL NEW PMPRB RULES IN PLAY AS DRUG PRICING REGULATOR WAITS FOR APPEAL COURT DECISION ON THIRD-PARTY REBATES](#)

The Quebec Court of Appeal's Justices Robert Mainville, Benoit Moore and Guy Cournoyer presented a unanimous decision. They found the following unconstitutional: a change that would allow the PMPRB to judge a pharmaceutical manufacturer's proposed price for a new medicine by three newly-created regulatory factors (pharmacoeconomic value; the market size for the drug; and the gross domestic product in Canada and gross domestic product per capita in Canada); and a new requirement that manufacturers share the details of third-party rebate agreements with the PMPRB.

The appeal court upheld the federal government's decision to add new countries and eliminate others from an already-existing “basket” or list of comparator countries the PMPRB uses to understand what other countries pay for medicines.

Seven pharmaceutical companies, including Merck Canada, Janssen Canada and Bayer Inc. participated in the legal action against the Attorney General of Canada.

PMPRB's price regulating powers limited to Patent Act, says Quebec Court of Appeal

The issue was whether the PMPRB can regulate drug prices overall for the purpose of making drugs more affordable or whether the powers allowed to it under the new regulations would infringe on provincial and territorial jurisdiction.

The judges' reasoning is based on the role of the PMPRB, as defined by the 1987 Patent Act, which established the board and outlines its responsibilities.

"So, the federal Parliament has the constitutional power to regulate patents and patents of invention. And that allows them, in the [appeal] court's reasoning, to regulate excessive or abusive prices that would result from a monopoly that's created by a patent," said Miriam Clouthier, an associate at the law firm, IMK Advocates, who represented the Cystic Fibrosis Treatment Society as an intervenor in the court action (and spoke to Hill Times Research on Feb. 22 with her client's knowledge).

"But what the federal Parliament can't do is directly regulate the prices within a whole market. That falls within provincial power over civil rights in the province. Provinces have constitutional jurisdiction over contracts and regulation of markets, generally," she said in summarizing the appeal court's reasoning for its decision.

As for an updated basket of countries, the appeal court concluded that the change to the list was allowed because it is the federal government's prerogative to establish a list of countries that would allow Canada to analyze the competitiveness of prices in Canada as compared to prices in the international market, according to Clouthier

Hill Times Research was unable to independently review the French-language decision. McMahon and Clouthier have read the decision and provided their understanding and analysis.

The appeal followed a decision by Justice Sophie Picard of Quebec's Superior Court on Dec. 18, 2020. Picard said the PMPRB did not have the authority to enforce the rule requiring pharmaceutical manufacturers to share the details of their third-party rebate agreements with public and private insurers. However, the introduction of new regulatory factors and the updated basket of comparator countries was constitutionally sound, as per her decision.

The pharmaceutical companies then appealed Picard's decision on the regulatory factors and the basket of countries. The Attorney General of Canada, the defendant, appealed Picard's finding that the PMPRB could not enforce the disclosure of third-party rebate agreements.

Case proves politicians not always right, patient advocate says

Chris MacLeod, a lawyer and founder of the Cystic Fibrosis Treatment Society, said his view is that the elements that were struck down by the Quebec Court of Appeal are “dead.” As for whether the federal government could appeal this decision to the Supreme Court, MacLeod said in a Feb. 22 phone interview that only six per cent of the cases presented to Canada’s highest court are actually heard.

MacLeod was quoting a figure from the Supreme Court’s 2020 “year in review” report. Reports for recent years back up the fact the court actually hears very few cases as compared to the number of applications for leave to appeal that it receives. In 2019, it allowed seven per cent to reach the Supreme Court level; and in 2018, it granted leave to appeal to eight per cent of the cases brought before it.

In a Feb. 23 emailed statement to Hill Times Research, a spokesperson for Health Canada said, “The Government of Canada remains firmly committed to improving the access to and affordability of quality medicines for Canadians. The Government of Canada will review the court’s findings in order to make a decision about next steps.”

A spokesperson for the PMPRB said on Feb 23 that they are reviewing the decision and have no further comment at this time.

MacLeod said he is “thrilled” with the Quebec Court of Appeal’s decision and that it serves as a “reminder” for patient groups that litigation is an option when they don’t agree with a policy.

“A lot of patients tend to be shy ... to challenge government because people are nervous [about] government generally. This shows that you can do it, you can succeed at trial, you can succeed at the court of appeal,” he said. “We appealed actively, trying to engage public officials to revisit this policy. Clearly, we weren’t successful in doing that. And we’re now seeing the courts step in ... It really is a reminder that we shouldn’t be shy to raise our concerns, and just because the politicians don’t agree with us, [it] doesn’t mean they’re right.”

The changes to the PMPRB regulations have been heavily debated since the federal Liberals first announced in May 2017 that they were going to consult on the issue. While the government has said the result would be lower drug prices, the pharmaceutical industry and many patient groups have opposed the changes, saying they would discourage manufacturers from bringing new innovative medicines to Canada.

Federal Court of Appeal to hear similar case on Feb. 28

The Quebec court case is just one of two. An appeal that is focusing on whether the Patent Act gives the PMPRB the administrative power to enforce the changes is taking place at the Federal Court level. (The Quebec case focused on whether the PMPRB was infringing on provincial and territorial areas of jurisdiction.)

The federal court appeal is led by Innovative Medicines Canada, which is challenging a Federal Court decision from June 29, 2020, written by Justice

Michael Manson. Like the Quebec Superior Court's Justice Picard, Manson struck down the component of the regulation related to third-party rebate agreements, and maintained the PMPRB could enforce the new regulatory factors and the updated list of comparator countries.

RELATED: [Innovative Medicines Canada sees a partial win in Federal Court challenge against updated PMPRB regulations](#)

A hearing for the federal appeal will be held on Feb. 28.

When asked whether the Quebec appeal decision could impact the case before the Federal Court of Appeal, McMahon noted that the issues being studied by the two courts are different, but she expects that the Quebec appeal will be addressed by the parties.

Minister Duclos to make an announcement

Location: Quebec City, QC - Date: February 24, 2022

Health Minister Jean-Yves Duclos (Québec, Que.) will announce new funding for health research training in a hybrid event co-hosted by the Canadian Institutes of Health Research and Université Laval. This event will take place in Salle Hydro-Québec, Pavillon Alphonse-Desjardins, 2325 rue de l'Université, Université Laval. Call 613-957-0200.

Minister Fraser to make an announcement

Location: Chester, N.S. - Date: February 24, 2022

On behalf of Health Minister Jean-Yves Duclos (Québec, Que.), Immigration, Refugees and Citizenship Minister Sean Fraser (Central Nova, N.S.) and Barbara Adams, Nova Scotia's Minister of Seniors and Long-term Care, will announce support for safe long-term care in Nova Scotia. This event will take place at 50 Shoreham Village Cres. Call 613-957-0200.

Minister Sajjan to speak at “Galvanizing Momentum for Universal Vaccination debate”

Location: New York, USA - Date: February 25, 2022

International Development Minister Harjit S. Sajjan (Vancouver South, B.C.) will participate in the Galvanizing Momentum for Universal Vaccination debate, convened by His Excellency Abdulla Shahid, President of the UN General Assembly. Sajjan will deliver a statement on behalf of Canada concerning immediate COVID-19 vaccine availability for everyone everywhere. Contact Yentl.Beliard-Joseph@international.gc.ca.

Public Services and Procurement Canada

FEBRUARY 23, 2022

Minister of Public Services and Procurement Filomena Tassi (Hamilton West-Ancaster-Dundas, Ont.) announced that the government has signed a new conditional agreement with AstraZeneca for 100,000 doses of its antibody therapy, Evusheld, for the prevention (pre-exposure prophylaxis) of COVID-19. The antibody therapy is under review by Health Canada for use in specific high-risk patient populations, such as people who are immunocompromised. Health Canada is currently prioritizing the review of all COVID-19 vaccines and drugs. The full release is available [online](#). Call 613-323-6621.

Canadian Medical Association

FEBRUARY 23, 2022

Canadian Medical Association President Dr. Katharine Smart issued a statement: "As federal, provincial and territorial justice and public safety ministers meet this week, the Canadian Medical Association reminds governments and the public about Bill C-3, legislation passed in December 2021 that aims to protect health care workers from threats, violence and harassment, and patients from being denied care," she said. "However, legislation alone will not protect health care workers or patients. We encourage public safety ministers and law enforcement agencies to ensure the new bill is enforced across Canada." The full release is available [online](#).