

## Pharma in brief - Canada

### Minister of Health's decision maintaining import ban on Apotex drug products declared unlawful

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**Case:** *Apotex Inc. et al v Minister of Health and Attorney General of Canada*, 2016 FC 673 (Court File No. T-1653-15)  
**Nature of case:** Application for judicial review of decision of Minister of Health  
**Successful party:** Apotex Inc.  
**Date of decision:** 15 June 2016

#### Summary

Apotex Inc., Apotex Pharmachem India Pvt Ltd. (**APIPL**) and Apotex Research Private Limited (**ARPL**) (collectively, **Apotex**) sought judicial review of a decision of the Minister of Health (**Minister**) to vary the terms and conditions of the Drug Establishment Licence (**DEL**) held by APIPL and ARPL (**August 2015 Decision**) and maintain the import ban on drugs manufactured at Apotex's APIPL and ARPL facilities.

This was the second judicial review brought by Apotex in connection with the initial import ban that Health Canada had imposed on Apotex products in September 2014. In the first judicial review (**First Judicial Review**), Apotex sought to have the Minister's decision to impose an import ban on Apotex quashed. The Court did so, holding that the Minister had not afforded Apotex adequate procedural fairness.

Apotex brought the second judicial review application in response to the Minister's August 2015 Decision and continued import ban on its products. In this instance, the Court held that there was no evidence to support maintaining the import ban and declared Health Canada's August 2015 Decision unlawful.

#### Background

##### *The First Judicial Review*

On September 30, 2014, following inspection reports initially conducted by the United States Food and Drug Administration noting data integrity issues at Apotex's APIPL and ARPL facilities and a subsequent inspection of the facilities by Health Canada, and in the face of media scrutiny and political pressure, an import ban was imposed on drug products coming into Canada from those facilities. Subsequently, the Minister made amendments to Apotex's DELs to prohibit the import of all products except those deemed medically necessary.

Apotex brought the First Judicial Review application to challenge the Minister's decision to implement the initial import ban and amend Apotex's DELs. The Court's decision in the First Judicial Review, dated October 14, 2015, quashed the Minister's decision to impose the import ban, finding that the import ban was motivated by an improper purpose and that Apotex was not afforded adequate procedural fairness. The Court further ordered Health Canada and the Minister to retract public statements connected to Apotex and the import ban made in the media.

##### *The August 2015 Decision and Second Judicial Review*

In the August 2015 Decision, Health Canada advised Apotex that it had further amended the terms and conditions of its DELs, requiring additional testing and reporting requirements for drug products made after June 10, 2015.

In March 2016, the Minister issued a decision removing all terms and conditions from Apotex's DELs affecting APIPL and ARPL (**March 2016 Decision**). However, the Minister continued to request data integrity information for Apotex's regulatory drug submissions, including for any of Apotex's Abbreviated New Drug Submissions (**ANDS**) where the ANDS included data generated at ARPL or APIPL prior to June 10, 2015, despite the removal of the DEL terms and conditions that required this information.

Apotex brought a second judicial review application seeking a judgment on the issue of whether the August 2015 Decision and resulting continuation of the import ban was unlawful on the basis of its connection to the decision quashed in the First Judicial Review and the evidence supporting the Minister's decision.

### **Application moot**

As a preliminary matter, the Minister argued that Apotex's application for review of the August 2015 decision was moot in light of the March 2016 Decision.

The Court agreed that the matter was moot, but exercised its discretion to hear the application. The Court relied, in particular, on the existence of an adversarial context between the parties, stating that an adjudication on the merits would have "collateral and practical significance on the parties' rights," including in another pending judicial review application and in an action for damages that Apotex intended to commence.

### **Minister's decision unlawful and continued import ban quashed**

Apotex argued that the August 2015 Decision should be quashed on the grounds that the Minister acted unlawfully in maintaining the import ban by varying the terms and conditions of the DEL in the August 2015 Decision, notwithstanding the judgment of the Court quashing the import ban in the First Judicial Review. Apotex also argued, among other things, that the Minister acted and rendered a decision that was contrary to the provisions of the *Food and Drug Regulations*.

The Court found that the August 2015 Decision was not independent from the 2014 import ban quashed in the First Judicial Review. The Court stated that the "two decisions are inextricably interconnected" and the facts suggest that the August 2015 Decision was not a "free-standing and uninfluenced decision, such that it was not also affected by the improper purpose that motivated the Import Ban."

On this basis, Justice Manson granted Apotex's judicial review application. He concluded that there was no evidence to justify the Minister's August 2015 Decision as a basis for maintaining the import ban, and declared the August 2015 Decision unlawful.

### **Links:**

[Apotex Inc. et al. v Minister of Health and Attorney General of Canada, 2016 FC 673](#)

First Judicial Review: [Apotex Inc. et al. v. Minister of Health, 2015 FC 1161](#)

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