

Pharma in brief - Canada

Ontario Divisional Court dismisses judicial review application of a rebate order made under the Ontario Drug Benefit Program

Case:	<i>1671183 Ontario Inc. o/a Pharma Stop v. Ontario (Ministry of Health and Long-Term Care)</i> , 2015 ONSC 6779 (Divisional Court File No. 503/12)
Nature of case:	Application for Judicial Review of a Rebate Order made under the <i>Ontario Drug Benefit Act</i> , RSO 1990, c. O.10
Successful parties:	Ontario Ministry of Health and Long-Term Care
Date of decision:	November 20, 2015

Summary

1671183 Ontario Inc. (operating as **Pharma Stop**) is a wholesaler of pharmaceutical products. Pharma Stop sought judicial review of a rebate order made by the Executive Officer of the Ontario Public Drug Programs. The Executive Officer found that Pharma Stop was in receipt of prohibited rebates from generic drug manufacturers, and imposed a \$2.9 million financial penalty. Pharma Stop's application was dismissed.

Background

The *Ontario Drug Benefit Act (ODBA)* creates a mechanism by which the Ministry of Health and Long-Term Care (**Ministry**) covers most costs of select prescription drugs for eligible persons, as set out under the *ODBA* and related regulations (i.e., the Ontario Public Drug Programs). The *Drug Interchangeability and Dispensing Fee Act (DIDFA)* creates a mechanism by which a generic drug may be listed as "interchangeable" with an equivalent brand drug.

The *Transparent Drug System for Patients Act (TDSPA)*, creates anti-rebate provisions under the *ODBA* and *DIDFA*, which prohibit drug manufacturers from paying rebates in return for pharmacies dispensing the manufacturers' generic drug products. The Executive Officer is responsible for enforcing the anti-rebate provisions under the *TDSPA*.

In 2008, the Ministry ordered an inspection under the *ODBA* and discovered that certain drug manufacturers were paying rebates to pharmacies, contrary to the anti-rebate provisions on the *TDSPA*.

Following the inspection, the Executive Officer issued a Rebate Order that required Pharma Stop to pay a significant financial penalty for accepting prohibited rebates. Pharma Stop sought reconsideration of the Rebate Order, which resulted in a Varied Rebate Order and a reduction in the amount owed by approximately \$5.8 million to about \$2.9 million. Pharma Stop then applied to the Federal Court for judicial review of the Varied Rebate Order.

An investigator's report was created to summarize the results of the inspection (**Report**).

Powers of the Executive Officer

Pharma Stop argued that the Executive Officer did not have authority to regulate wholesalers (e.g., Pharma Stop), and did not have jurisdiction to use the Report for the purposes of enforcement under the *DIDFA*. Justice Swinton rejected both arguments.

Regarding Pharma Stop's first argument, Justice Swinton held that the Executive Officer was clearly authorized to regulate wholesalers under the *DIDFA* (s. 12.1) and *ODBA* (s. 11.5), and had jurisdiction to impose the rebate order at issue on the basis that Pharma Stop had received prohibited rebates.

Regarding Pharma Stop's second argument, Justice Swinton held that Executive Officer is responsible for enforcing the anti-rebate provisions under the *DIDFA* and *ODBA* and that she may appoint inspectors under the *ODBA* (s. 14) for the purpose of enforcement. The Court found that Executive Officer was not precluded from using the information gathered during an inspection to enforce the anti-rebate provisions.

Procedural fairness

Pharma Stop argued that it had been denied procedural fairness because a reasonable apprehension of bias results from the overlapping roles of the Executive Officer in the investigation process, in determining compliance, and in imposing a penalty. Pharma Stop also argued a lack of procedural fairness on the basis that it took twenty-seven months to issue the Varied Rebate Order, and that it was only ever provided a redacted copy of the Report.

Justice Swinton rejected these arguments, and held that there had been no denial of procedural fairness in the circumstances.

Link to decision:

[1671183 Ontario Inc. o/a Pharma Stop v. Ontario \(Ministry of Health and Long-Term Care\), 2015 ONSC 6779](#)

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