



**IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR
COURT OF APPEAL**

Citation: *Council of Independent Community Pharmacy Owners v.
Newfoundland and Labrador*, 2017 NLCA 45

Date: July 25, 2017

Docket: 201401H0113

BETWEEN:

COUNCIL OF INDEPENDENT COMMUNITY
PHARMACY OWNERS INC.

APPELLANT

AND:

HER MAJESTY THE QUEEN IN RIGHT
OF NEWFOUNDLAND AND LABRADOR

RESPONDENT

Coram: Welsh, White and Harrington JJ.A.

Court Appealed From: Supreme Court of Newfoundland and Labrador
Trial Division (G) 201401G2024

Appeal Heard: April 4, 2017

Judgment Rendered: July 25, 2017

Reasons for Judgment by White J.A.

Concurred in by Welsh and Harrington JJ.A.

Counsel for the Appellant: James Goodwin

Counsel for the Respondent: Rolf Pritchard Q.C. and Mark Sheppard

White J.A.:

[1] The Council of Independent Community Pharmacy Owners (“CICPO”) appeals from an oral decision and subsequent order of an applications judge refusing to order the Minister of Health, by way of *mandamus*, to more stringently enforce paragraph 4(e) of the *Interchangeable Drug Products Formulary Regulations, 2012*, NLR 23/12.

[2] For the reasons that follow, I would dismiss the appeal.

Background

[3] The *Pharmaceutical Services Act*, SNL 2006, c P-12.01 attempts to ensure that whenever possible patients receive inexpensive generic drugs instead of expensive brand-name equivalents. It requires the Minister of Health to maintain a list of equivalent drugs, the Interchangeable Drug Products Formulary (s. 19). When the formulary says two drugs are equivalent, pharmacists must prescribe the cheaper option unless the prescription forbids substitutions or unless the customer requests the more expensive drug (s. 21).

[4] Pharmaceutical equivalency is not the only consideration in deciding whether to include a generic drug in the formulary. In the pharmaceutical services market, which is heavily regulated and characterized by imperfect competition, including generic drugs in a formulary can have unexpected effects on drug prices and availability. For an illustration, see e.g. *Katz Group Canada Inc. v. Ontario (Health and Long-Term Care)*, 2013 SCC 64, [2013] 3 S.C.R. 810. The price of drugs is a relevant consideration: see s. 4(c) of the *Regulations*. And so, critically to this appeal, is the availability of a reliable supply of drugs across the province: see s. 4(e).

[5] Until 2012, only a drug manufacturer could apply to have a drug listed in the formulary. In 2012 this requirement was removed, allowing the formulary to include “private label” drugs supplied by companies that did not manufacture them. These private label drugs are often supplied by companies like Sanis Inc., a wholly owned subsidiary of Shoppers Drug Mart Inc., which runs a large pharmacy chain in this province. Shoppers is in turn owned by Loblaws Inc, which owns another large pharmacy chain.

[6] CICPO says that, in the complicated dynamics of the pharmaceutical market, private label generics are leading to drug shortages:

... Prior to changes in the legislation in this province, shortages of pharmaceuticals occurred less than 5 times per year. In 2013 there were over 30 shortages. Recently, there has been an alarming increase in the number of shortages.

Sanis Ltd., a wholly owned subsidiary of Shoppers Drug Mart Inc., is a Supplier of generic pharmaceuticals in this province but does not manufacture its own pharmaceuticals. Sanis Inc. sources their products directly from other Suppliers. In two [instances], Sanis Inc. is the only Supplier able to supply the generic pharmaceutical. Where Sanis Inc. sources their pharmaceuticals from the other Suppliers, the other Suppliers must be withholding supply of these generic pharmaceuticals to patients in this province in order to supply Sanis Inc.

[7] While CICPO appears to want the province to stop including private label generics in the formulary, it is seeking narrower relief. It says that, under the regulations, suppliers of generic pharmaceuticals have an ongoing obligation to supply the whole province. It seeks an order requiring the Minister to enforce that obligation and remove pharmaceuticals that fail to supply the whole province.

Analysis

[8] In deciding whether to order the Minister to fulfill a public legal duty, the applications judge had to apply the principles of *mandamus*, as set out in *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 at 767-768 (C.A.), *aff'd* [1994] 3 S.C.R. 1100:

1. There must be a public legal duty to act:
2. The duty must be owed to the applicant: Generally, the rule is that *mandamus* cannot issue with respect to a duty owed to the Crown. Historically, this issue has been framed as one concerning standing to bring a *mandamus* application. The Supreme Court has considerably loosened the requirements for standing over the decades...
3. There is a clear right to performance of that duty, in particular:
 - (a) the applicant has satisfied all conditions precedent giving rise to the duty; ...
 - (b) there was (i) a prior demand for performance of the duty; (ii) a reasonable time to comply with the demand unless refused outright; and (iii) a subsequent refusal which can be either expressed or implied, e.g. unreasonable delay; ...
4. Where the duty sought to be enforced is discretionary, the following rules apply:

(a) in exercising a discretion, the decision-maker must not act in a manner which can be characterized as “unfair”, “oppressive” or demonstrate “flagrant impropriety” or “bad faith”;

(b) *mandamus* is unavailable if the decision-maker’s discretion is characterized as being “unqualified”, “absolute”, “permissive” or “unfettered”;

(c) in the exercise of a “fettered” discretion, the decision-maker must act upon “relevant”, as opposed to “irrelevant”, considerations;

(d) *mandamus* is unavailable to compel the exercise of a “fettered discretion” in a particular way; and

(e) *mandamus* is only available when the decision-maker’s discretion is “spent”; i.e., the applicant has a vested right to the performance of the duty.

...

5. No other adequate remedy is available to the applicant: ...

6. The order sought will be of some practical value or effect: ...

7. The Court in the exercise of its discretion finds no equitable bar to the relief sought: ...

8. On a “balance of convenience” an order in the nature of *mandamus* should (or should not) issue.

(Underlining in original.)

[9] The first question is whether the *Act* or *Regulations* give the Minister “a public legal duty” to remove drugs from the formulary because of shortages.

[10] The applications judge clearly identified the crucial issue as a determination of whether the first principle set out in *Apotex* had been satisfied. He concluded that it had not:

This matter raises the issue of the proper boundaries between what a court can do, and what the legitimate role of government is, and the court really has the authority to interfere only when government is failing in the performance of a legal duty, and as the cases by both sides made clear, the court will only interfere – well, the first condition of interfering with the operation of government in this sense is where there is what we refer to as a clear legal duty, which would

normally be found in a statute. It is not – the court does not have the authority to interfere in the policy making of government, how government chooses to enforce its policies or conduct its operations generally.

[11] The *Regulations* contemplate that drugs should not be included in the formulary unless the supplier can supply the whole province. That is a precondition for admission under s. 4 of the *Regulations*:

An applicant shall provide the following before the advisory committee will consider its submission for a drug to be included in the formulary:

...

(e) confirmation satisfactory to the minister or the advisory committee that the applicant is able to supply the drug to meet the needs of the market for that drug throughout the entire province; ...

[12] The Minister has no discretion to waive this requirement. Nevertheless, it only applies “before the advisory committee will consider” an initial application. Once the drug is included in the formulary, the imperative language of s. 4(e) no longer binds it.

[13] CICPO asserted that the formulary is renewed every six months and that the requirements of s. 4 must be met afresh each time. Perhaps the Minister republishes the formulary every six months, or reviews the formulary every six months. The copies of the formulary in the record are labelled as being effective for a six-month period. But that is a matter of administrative convenience; neither the *Act* nor the *Regulations* requires fresh applications every six months. Once included, a drug remains in the formulary until it is removed. The requirements of s. 4 only apply once.

[14] The scheme for removing drugs is quite different. It is set out in s. 19(4) of the *Act*:

The minister may remove a drug from the formulary where

(a) the manufacturer is not adhering to the price quoted for the drug upon approval for entry into the formulary;

(a.1) the manufacturer does not comply with pricing requirements set out in the regulations;

(b) removal from the formulary is advisable in the public interest; or

(c) the minister considers it necessary to do so.

[15] This section gives the Minister a discretion, as opposed to a duty, to remove drugs if it is “necessary” or “advisable in the public interest”. Unlike the initial application process, where each requirement must be met, the removal process is flexible and contextual.

[16] If a supplier is unable to supply the whole province with a drug, that is relevant and could support removal. But it is only one factor. The Minister would have to weigh it against other relevant factors, such as the effects of delisting a drug on patients who depend on it.

[17] CICPO says the Minister has a public legal duty to enforce the legislative scheme, citing *Distribution Canada Inc. v. M.N.R.*, [1993] 2 F.C.R. 26 (C.A.). I am prepared to accept that. It is, however, only if the Minister “turned his back on his duties” or behaved with “bad faith or negligence”, as Desjardins J.A. said, that the Court could intervene.

[18] But the record does not support a conclusion that the Minister is refusing to enforce the *Act* or *Regulations*. The Minister has a broad discretionary power to remove drugs in the public interest, weighing a number of competing factors. CICPO has pointed to a number of instances where the Minister chose not to exercise that power. Taken either individually or together, the decisions not to remove drugs are not so irrational as to constitute evidence of bad faith.

[19] In addition, the Minister provided an affidavit from the Acting Director of the Pharmaceutical Services Division outlining the Minister’s approach to shortages. According to the affidavit, the primary cause of recent shortages is disruption in supply chains outside the province, and that an effective policy response must be coordinated with other provinces and territories.

[20] I would not comment on the wisdom of the Minister’s approach, except to say that it is not evidence of bad faith or a refusal to enforce the *Act*. As the applications judge said, “to enforce an ongoing supply of drugs or to take some kind of investigative steps ... are political issues as opposed to legal issues.”

[21] Whether or not there is a public legal duty on the Minister to act is a question of law to be reviewed on the standard of correctness.

[22] The applications judge did not err in his determination that there is no public legal duty on the Minister to act.

Conclusion

[23] I would dismiss the appeal. I would agree with the applications judge that each party bear its own costs as the matter does have some general public importance.

C. W. White J.A.

I Concur: _____

B. G. Welsh J.A.

I Concur: _____

M. F. Harrington J.A.