HARPER GREY LLP
3200 – 650 West Georgia Street
Vancouver, British Columbia, V6B 4P7
Canada

Tel: 604 687 0411
Fax: 604 669 9385

CASE SUMMARY: APPEAL BY CICPO FROM ORDER OF APPLICATIONS JUDGE REFUSING TO ORDER MINISTER OF HEALTH TO MORE STRINGENTLY ENFORCE REGULATIONS IMPOSING ON SUPPLIERS OF GENERIC PHARMACEUTICALS AN OBLIGATION TO SUPPLY THE WHOLE PROVINCE DISMISSED

The *Pharmaceutical Services Act* ("Act") tries to ensure that patients receive generic drugs rather than more costly brand name equivalents. The Minister of Health ("Minister") maintains a formulary of equivalent drugs. If a drug is equivalent, pharmacists must, in most cases, prescribe the less expensive of the two.

Decisions reviewed; Appeals; Judicial review; Standard of review; Correctness; Remedies; Mandamus

Council of Independent Community Pharmacy Owners Inc. v. Newfoundland and Labrador, [2017] N.J. No. 283, 2017 NLCA 45, Newfoundland and Labrador Supreme Court – Court of Appeal, July 25, 2017, B.G. Welsh, C.W. White and M.F. Harrington JJ.A.

For a generic drug to be listed on the formulary, a drug manufacturer applies and provides evidence about equivalency. The price of drugs is a relevant factor for consideration because adding generic drugs can impact drug prices and supply.

In 2012, the legislative requirement that only a drug manufacturer could have a drug listed in the formulary was removed. Since then, "private label" drugs, supplied by companies other than the manufacturer, could also be added.

The Council argued that private label generics were creating drug shortages, citing increased shortages since the legislative change. The Council contended because a private label company purchases but does not make more of the drug, when it sources drugs, that must impact the supply to other patients in the province.

The Council sought an order requiring the Minister to remove any pharmaceuticals from the formulary where the supplier cannot fulfill an ongoing obligation to supply the whole province. The Council interpreted the regulations as requiring any supplier of generic drugs to be able to provide an ongoing supply for the province.

The Court held that the Act and its regulations do not give the Minister a public legal duty to remove drugs from the formulary if there are shortages of that drug.

The regulations specify that, as a precondition for admission to the formulary, an applicant must confirm that it can supply that drug to "…meet the needs of the market for that drug throughout the entire province." The Minister does not have discretion to waive this requirement. While supplying the province is a requirement on an application to be included on the formulary, there is no requirement to continue to meet the supply requirement once the drug is listed on the formulary.

The Council argued that because the formulary is renewed every six months, the regulatory supply requirement must be met at each six month interval. The Court rejected this argument, finding that labeling the formulary as valid only at every six month interval is merely "…a matter of administrative convenience" and does not indicate a requirement to meet the supply requirement anew each time.

1. 19(4) of the Act sets out the process for removing drugs from the formulary. The Minister has discretion (not a duty) to remove a drug from the formulary where the manufacturer is not adhering to the price quoted for the drug on approval or does not comply with pricing requirements set out in the regulations. The Minister may also remove a drug from the formulary where it is "advisable in the public interest" or where the "minister considers it necessary to do so."

The process for removing a drug from the formulary is "flexible and contextual", unlike the application process where "every requirement must be met." If a supplier cannot supply the whole province with a drug once it is on the formulary, that is one factor that could support removal, but it would be weighed against other factors.

While the Court accepted that the Minister has a public legal duty to enforce the legislative scheme, the record did not support a finding that the Minister refused to enforce the Act or regulations. The decisions not to remove drugs were not "so irrational as to constitute evidence of bad faith."

An affidavit from the Acting Director of the Pharmaceutical Services Division indicated that the primary cause of the recent shortages had been a disruption in supply chains outside the province, rather than an in-province supply issue.

The issue of whether the Minister had a public legal duty to act was reviewed on correctness standard; there was no error in the application judge's analysis. Enforcing an ongoing supply of drugs is a political matter. The appeal was dismissed with each party bearing its own costs, given that the matter had some general public importance.

This case was digested by Julie K. Gibson of Harper Grey LLP. If you would like to discuss this case further, please feel free to contact her directly at jgibson@harpergrey.com or review her biography at http://www.harpergrey.com.