

Torys on Food and Drug Regulatory

F&DR 2010-4
April 13, 2010

Court Affirms Health Canada's Broad Discretion in Review of Drug Submissions

By [Eileen McMahon](#), [Andrew Shaughnessy](#) and [Teresa Reguly](#)

In a recent decision of the Federal Court in *Hospira Healthcare Corporation v. Canada (Attorney General)*¹ the Court affirmed that Health Canada has broad discretion in interpreting the *Food and Drug Regulations* to determine the content of an application for the marketing approval of a drug.

Before a drug can be sold in Canada, a manufacturer must apply for marketing approval – known as a “notice of compliance” or NOC. To obtain an NOC for a new drug product, a manufacturer must submit a new drug submission (NDS) (comparable to a new drug application or NDA in the United States) to Health Canada for review. Hospira filed its NDS without any pre-clinical or clinical data, but relying on the widespread use of its drug to establish safety and efficacy. Its drug had been widely used in western countries, but had only been available in Canada on a limited basis.² Health Canada rejected Hospira's NDS at the screening stage for failure to comply with the requirements of section C.08.002 of the Regulations. Hospira applied to judicially review and set aside this decision.

The case turned on the specific interpretation of subsections C.08.002(2)(g) and (h) of the Regulations, which provide that an NDS shall include (i) detailed reports of the tests made to establish the safety of the new drug and (ii) substantial evidence of clinical effectiveness. Hospira's position was that the safety and effectiveness of its drug could be demonstrated on the basis of published literature references and reports of post-marketing experience, which were included in the NDS. In Hospira's view, this information was sufficient to demonstrate safety and effectiveness; there was no need for Hospira to perform any testing of its own. Health Canada asserted that subsections C.08.002(2)(g) and (h) impose a requirement for independent clinical data. Even if this requirement is not explicit, the Minister of Health has the discretion to insist that such data be included in an NDS.

The Court agreed with the Minister, observing that the plain wording of the Regulations allows for considerable flexibility in what is acceptable evidence of a drug's safety and efficacy. The decision of the Minister was determined to be, in the legal sense, reasonable. (Hospira has appealed this decision.)

The significance of this decision is that the Minister is entitled insist upon the inclusion of independent clinical and pre-clinical data in an NDS, even though the

¹ For the full decision, please see <http://decisions.fct-cf.gc.ca/en/2010/2010fc213/2010fc213.html>.

² The product had been available through the restrictive Special Access Programme, which authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada.

To discuss these issues, please contact the authors.

For permission to copy or distribute our publications, contact [Robyn Packard](#), Manager, Publishing.

To contact us, please email info@torys.com.

Torys' bulletins can be accessed under Publications on our website at www.torys.com or through the Torys iPhone app.

This bulletin is a general discussion of certain legal and related developments and should not be relied upon as legal advice. If you require legal advice, we would be pleased to discuss the issues in this bulletin with you, in the context of your particular circumstances.

© 2010 by Torys LLP.
All rights reserved.

Regulations do not specifically include the words “clinical trial data” or “pre-clinical data”; the Minister must be afforded a discretion to determine what information is compliant with the Regulations. The decision highlights the broad discretion afforded to Health Canada in its review and approval of drug submissions. Further, although the policies of Health Canada do not technically have the force of law, this case underscores the difficulty manufacturers face when they try to deviate from the policies of Health Canada. Given that courts are reluctant to interfere with the exercise of the Minister’s discretion, those asserting special circumstances will want to consult their regulatory and legal advisors to maximize positive outcomes. 