Torys on Food and Drug Regulatory

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Innovative Drugs Sold Under the Special Access Programme Can Receive Data Protection in Canada

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To benefit from data protection in Canada, a drug must meet the definition of "innovative drug" under the *Food and Drug Regulations*. This definition specifically prohibits innovators from obtaining additional protection periods for drugs that have been previously approved by the Minister of Health. In a recent challenge to a drug enjoying data protection, the Federal Court ruled that the term "approved" in the definition of innovative drug under the regulations does not include authorization to sell under the Special Access Programme (SAP) because a full regulatory review of the drug (including assessment of its safety and effectiveness) would not have occurred. As a result, the fact that a drug that has been sold under the SAP does not preclude data protection being accorded when a notice of compliance (NOC) is issued for the same drug later.

Background

Innovators wishing to obtain authorization to market new drugs need to obtain approval in the form of an NOC. During this process, the innovators often file data that contain confidential or trade secret information. The data provisions of the regulations recognize that such data should be granted protection in the form of market exclusivity before a third party (such as a generic manufacturer) can directly or indirectly rely on it when filing an abbreviated new drug submission using the innovative drug as a Canadian reference product. These provisions aim to protect innovators' investments in developing new pharmaceutical products, thus giving them a competitive edge in international markets.

Under the data provisions of the regulations, the first six years are considered to be a no-filing period during which the generic manufacturer may not apply for an NOC for a new drug. That period is followed by a two-year no-marketing period during which the generic manufacturer may apply for an NOC; however, the Minister will not issue the NOC until the full eight years of data exclusivity has expired. The no-marketing period can be extended by six months if pediatric studies are conducted to learn more about the drug in pediatric age groups in which it may be used.

In *Teva Canada Limited v. Canada (Health)*,[1] Teva sought to obtain a judicial review of the Minister's decision to deny its request to delete the drug Eloxatin from the Register of Innovative Drugs maintained under the data protection provisions of the regulations. Teva had argued that Eloxatin, having been made previously available through the SAP, was not an innovative drug.

[1] 2011 FC 507.

To discuss these issues, please contact the authors.

The legal issue before the Court was the meaning of "approved" in the following definition of "innovative drug" under the regulations:

> [A] drug that contains a medicinal ingredient *not previously approved* in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph [emphasis added].

Under this definition, for Eloxatin to qualify as an innovative drug, and thus be accorded data protection, the medicinal ingredient in Eloxatin must not have been "previously approved" by the Minister. In fact, Sanofi-Aventis, the drug's sponsor, had been authorized by the Minister to sell Eloxatin for the treatment of life-threatening colorectal cancer under the SAP.

The SAP provides a means by which healthcare practitioners can request limited access to drugs that are not authorized for use in Canada but that practitioners wish to use to treat patients with life-threatening conditions. Under the SAP, drugs do not have to undergo the ordinarily formal and robust authorization process for market approval (i.e., they are exempt from the regulations' requirements to establish the safety and effectiveness of the drug).

If Teva were to successfully argue that Eloxatin had been previously approved, it would have been able to argue that Eloxatin was not subject to data protection, thus clearing the way for Teva's potential filing of a drug submission referencing Eloxatin.

Federal Court's Decision

Teva advanced two arguments before the Court. First, it argued that by authorizing the sale of Eloxatin under the SAP, the Minister had previously approved the safety and efficacy of the drug. The logic of the argument was that the Minister would not have permitted the prior authorization without being satisfied as to the safety and efficacy of the drug. But, as the Court held, drugs sold under the SAP do not undergo full regulatory review and thus do not receive market authorization (i.e., approval) by the Minister. The Court noted that the granting of market approval for a drug involves a two-part decision-making process. First, the Minister must make a factual finding (based on the evidence presented by the innovator) that a drug is safe and effective. Then, based on this finding, the Minister must give the drug market authorization (i.e., "approve" the drug for sale by the issuance of an NOC). The Court found that there was no evidence that the Minister had made a factual finding that Eloxatin was safe and effective by virtue of authorizing the SAP. The SAP sales proved only that many seriously ill people were willing to take unapproved Eloxatin in the hope of getting better.

Teva's second argument was that maintaining the listing of Eloxatin on the Register undermined the purpose and intent of the data protection provisions of the regulations since the listing of Eloxatin had resulted in two successive periods of exclusivity: one under the SAP and the other after it received its NOC. The Court dismissed this argument: the data protection provisions of the regulations were properly applied to Eloxatin because the Minister had properly considered the drug to be an innovative drug. The Court characterized Teva's argument as misplaced because it attacked the data protection regime itself and was extraneous to the issue before the Court – namely, the meaning of the term "approved." T