The Law of Data Protection in Canada

Impact on the Pharmaceutical Industry

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The Law of Data Protection in Canada: Impact on the Pharmaceutical Industry

I. Introduction to Data Protection

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IV. Data Protection in Other Countries – A Comparison

V. Current Challenges to the New Law

I. Introduction to Data Protection

- August 16, 1995
  - ➢ data protection laws are first introduced in Canada
  - ➢ applied to data contained in information filed by an innovator on or after January 1, 1994
  - ➢ minimal protection (if any) for undisclosed data

I. Introduction to Data Protection (cont'd)

Data Protection - Definition

- C.08.004.1 of Canada's *Food and Drug Regulations*
  - Applies to pharmaceutical and agricultural products
  - A period of market exclusivity
  - Distinct from patent exclusivity
  - Prohibits the use of confidential tests or data submitted as a pre-condition to obtain marketing approval, *e.g.* →

I. Introduction to Data Protection (cont'd)

- Confidential Tests or Data required to be submitted in a new drug submission: [C.08.002(2)(3)]
  - ➢ detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended
  - ➢ substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended
  - ➢ any additional information or material respecting the safety and effectiveness of the new drug

I. Introduction to Data Protection (cont'd)

- Amendments were initially proposed in December of 2004
- Re-introduced on June 17, 2006, after considerable comment from industry stakeholders
- New amendments proclaimed into force on October 5, 2006, along with changes to Canada's *Patented Medicines (Notice of Compliance) Regulations*

I. Introduction to Data Protection (cont'd)

- October 5, 2006 – significant changes are made to the law:
  - 8 years of protection for "innovative drugs"
  - 6 year no-filing period prohibits any second entrants or generic manufacturers from filing a drug submission for 6 years from the date of NOC issuance for an "innovative drug"

II. Canada's Previous Law on Data Protection

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- Canada introduced the concept of data protection in 1995 in order to implement its international treaty obligations:
  - Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement; and
  - North American Free Trade Agreement (NAFTA)

II. Canada's Previous Law on Data Protection (cont'd)

TRIPS – Article 39(3)

- Requires the protection of data from unfair commercial use
- Applies to protect data that must be submitted as a condition for obtaining marketing approval for pharmaceutical or chemical products utilizing new chemical entities

II. Canada's Previous Law on Data Protection (cont'd)

NAFTA – Article 1711

- requires a reasonable period of protection where generic manufacturers are prohibited from relying on original data to obtain marketing approval.
- a reasonable period of time =
  - "not less than five years" from the date that regulatory approval was granted to the data originator;
  - should account for the nature of the data; and
  - should account for the data originator's efforts and expenditures in producing the original data

II. Canada's Previous Law on Data Protection (cont'd)

- *Food and Drug Regulations* were amended on August 16, 1995 [C.08.004.1] to introduce data protection
  - ➢ 5 year period of market exclusivity beginning on the date of issuance of the first NOC
  - ➢ applied to new drugs containing a chemical or biological substance not previously approved for sale in Canada
  - ➢ only applied to protect original data if the Minister of Health "directly" relied on the original data to approve a generic drug submission based on a reference product for a new drug

II. Canada's Previous Law on Data Protection (cont'd)

Bayer Inc. v. Canada (Attorney General)

- 1998 decision of the Federal Court of Canada
- Pivotal decision in determining the scope of data protection in Canada
  - Issue: whether C.08.004.1 was intended to confer 5 years of market exclusivity in Canada on an innovator manufacturer in respect of a new drug for which an NOC has been issued?

II. Canada's Previous Law on Data Protection (cont'd)

Bayer Inc. v. Canada (Attorney General) cont'd

- *Food and Drug Regulations* do not require the Minister to review the original/innovator submission before approving a generic drug on the basis of bioequivalence
- In the usual course, the Minister does not rely "directly" on the confidential data contained in the original NDS to approve an ANDS
- In fact, the Minister's decision to approve an ANDS is based exclusively on information contained in the ANDS which establishes the pharmaceutical and bioequivalence of the generic drug to the Canadian reference product.

II. Canada's Previous Law on Data Protection (cont'd)

Bayer Inc. v. Canada (Attorney General) cont'd

- "data protection does not arise where bioequivalence forms the basis of the submission"
- decision upheld by the Federal Court of Appeal, leave to appeal to the Supreme Court of Canada dismissed

II. Canada's Previous Law on Data Protection (cont'd)

- Practical effect of the Bayer decision -

= the 5-year period of market exclusivity was never implemented in Canada to protect the confidential data submitted in an original new drug submission

III. 2006 Amendments to the Law of Data Protection

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WHY?

"to provide new drugs with an internationally competitive, guaranteed minimum period of market exclusivity of eight years."

"to provide an adequate incentive for innovators to invest in research, and to develop and market their products in Canada."

III. 2006 Amendments to the Law of Data Protection (cont'd)

"to clarify and effectively implement Canada's NAFTA and TRIPS obligations with respect to the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilizes a new chemical entity."

Regulatory Impact Analysis Statement (RIAS), Oct. 5, 2006

III. 2006 Amendments to the Law of Data Protection (cont'd)

Highlights of the New Law

1. Term of data protection is extended from 5 to 8 years, beginning on the date the first NOC is granted for an "innovative drug".
2. 6 year no-filing period prohibits generic manufacturers from filing an ANDS for the first 6 years of the 8 year term.
3. 6 month extension available for the submission of pediatric studies within the first 5 years of the 8 year term.

III. 2006 Amendments to the Law of Data Protection (cont'd)

4. Drugs removed from the Canadian market will no longer qualify for data protection.

5. The Minister will maintain a Register of Innovative Drugs which lists those drugs subject to data protection.

6. No retroactivity – NOC issued on or after June 17, 2006 are eligible.

1. Extended Term of Protection

- Extended from 5 to 8 years

(6 year no-filing period) + (2 year no-marketing period) = 8

  - No NOC can be issued to a generic manufacturer seeking approval on the basis of "a direct or indirect comparison" between the generic drug and innovative drug until 8 years after the day on which the NOC was issued for the innovative drug.
  - Data protection in Canada is no longer subject to the "bioequivalence exception" established in the Bayer case

1. Extended Term of Protection (cont'd)

"Innovative Drug" - Definition

In order to qualify for data protection, the product in question must qualify as an "innovative drug":

- a drug that contains a medicinal ingredient;
- not previously approved in a drug approved in Canada; and
- not a variation of a previously approved medicinal ingredient

e.g.