Overview of Bill C-51: Food and Drugs Act Amendments

CAPRA Symposium, October 6, 2008

Adrienne M. Blanchard
Tel: (613) 786-0223
Fax: (613) 788-3510
adrienne.blanchard@gowlings.com

2600-160 Elgin Street
Ottawa, Ontario
K1P 1C3

Overview of Presentation

- Background to Bill C-51
- Progressive Licensing Framework
- Bill C-51 Provisions

Background: Canada's Food and Consumer Safety Action Plan

- 2006-2007 – Blueprint for Modernization I & II
- January 5, 2008 – Health Canada Discussion Paper "Strengthening and Modernizing Canada's Safety System for Food, Health and Consumer Products"
- April 8, 2008 – Bill C-51 tabled in the House
- April 30 & May 1, 2008 – Bill C-51 debated at Second Reading
- Died on the Order Paper when federal election called

Bill C-51: *An Act to amend the Food and Drugs Act*

- First modernization of the *Food and Drugs Act* in 50 years
- Provides the legislative framework for progressive licensing
- Much of the scheme will be shaped in regulations
- Consultations at a stand-still during election

Progressive Licensing Framework (PLF)

- PLF criticized as Health Canada's attempt to "fast track" drug approvals
- Oversight over product through its life cycle – risk/benefit analysis
- No NOC – a "market authorization" instead, subject to terms and conditions

Provisions of the Bill

- Definitions
- Prohibitions
- Authorizations and Licenses
- Powers of the Minister
- Consultation
- Information
- Administration and Enforcement
- Other Measures
- Regulations

Preamble

- Preamble – Not part of the Act
  - Objectives: protect, promote and improve human health
  - Ongoing assessment of a therapeutic product over its life-cycle
  - Benefits and risk assessments are to be made on scientific and objective evidence
  - A lack of full scientific certainty is not to be used as a reason to postpone measures that prevent adverse effects on human health if those effects could be serious or irreversible – This is the "precautionary principle"
  - Recognizes the importance of "meaningful involvement of the public in seeking the input of those impacted by regulatory decisions"

Definitions

- Drugs and medical devices are all part of broad definition of “therapeutic product”
- An umbrella definition of “practitioner” is provided
- Confidential Business Information

Prohibitions

- Providing misleading information to the Minister
- Anti-tamper provisions
- Falsely, knowingly, recklessly, communicating fear that a food, therapeutic product or cosmetic is adulterated, tampered with, and injurious to human health
- Anti-counterfeiting

Powers of the Minister

- Minister can require
  - Information and tests from authorization holders
    - Including after a clinical trial is discontinued
  - Label revision
  - Product Reassessment
  - Product recall

Authorizations and Licenses

- The grant of market authorization is based on the Minister being of the opinion that the “benefits that are associated with the therapeutic product outweigh the risks”

- Powers on licensing
  - suspension (immediate if impending risk)
  - revocation (manufacturer will have opportunity to input)

- Conditions in regulation; others may be applied

Consultation

- May establish committees for the purpose of seeking advice
- Would cover expert committees that assist the Minister in making decisions on market authorization
- Regulations permit rules to be made

Confidential Business Information

- Minister can disclose personal information and confidential business information in certain circumstances

- Minister can disclose confidential information to bodies for the protection/promotion of health/safety of the public; eg. CADTH / provincial drug plans, etc. (information can be shared to those with *functions* relating to the “effectiveness, cost effectiveness or appropriate use of a therapeutic product.”)

- Information on licenses / authorizations / information about therapeutic products will be available to the public. Risk/benefit information may be disclosed.

Regulations

- Regulations
  - Extensive empowering provisions to allow the Governor in Council to make regulations
  - Notable authorities include:
    - Tracing systems re: sale or import of products – re: place of origin or destination
    - Establishing pre-clearance or in transit requirements for imported goods
    - Exempting activities from the Act

Administration & Enforcement

- Administration and Enforcement
  - Increased powers for inspectors re: inspection, seizure, forfeiture, etc.

- Offences
  - Offences for contravening the Act have been increased significantly, up to, in some cases $5 million per incident and/or five years in jail
  - unlimited liability for willful or reckless contravention

- Transitional issues

THANK YOU

Adrienne Blanchard
613-786-0223
adrienne.blanchard@gowlings.com