Canada Moves to Update Drug and Device Legislation

Jeffrey Graham, Borden Ladner Gervais LLP

In 2008, the Government of Canada introduced legislation to overhaul the Food and Drugs Act (Canada). However the proposed legislation died before passage in that Parliament and was not re-introduced.

Since that time officials at Health Canada have been working on what has been termed the Progressive Licensing Project to assess areas for improvement and consult with relevant stakeholders including industry, end users and the public.

Most recently, on December 6, 2013, the Government of Canada introduced legislation that will provide the greatest impact on improving patient safety. Bill C-17 entitled the "Protecting of Canadians from Unsafe Drugs Act" proposed changes to the Food and Drugs Act that will improve Health Canada's ability to collect post-market safety information, and take appropriate action when a serious risk to health is identified.

The intention of the Government is that the proposed amendments to the Act will provide better protection of patient health and safety, and greater consumer confidence in therapeutic products on the market. In addition, the Bill proposes to amend the Act regarding therapeutic products (i.e., a drug or a

device or a combination of drugs and devices but not a natural health product) in order to improve safety by introducing measures to, among other things,

(a) Strengthen safety oversight of therapeutic products throughout their life cycle; and

(b) Improve reporting by certain health care institutions of serious adverse drug reactions and medical device incidents that involve therapeutic products.

The proposed amendments to the Act include:

- Power to compel drug companies to do further testing on a product, including when issues are identified with certain at-risk populations such as children,
- Power to compel drug companies to revise labels to clearly reflect health risk information, including updates for health warnings for children,
- Power to recall unsafe therapeutic products,
- Increased fines and penalties to better reflect the serious nature of the offence, up to a maximum penalty of $5,000,000 and/or 2 years in prison.
- New authority to reference documents (such as lists or technical standards) in regulations without requiring a regulatory amendment each time a change to the document is made.
- Mandatory reporting by healthcare institutions of serious Adverse Drug Reactions (ADRs) and medical device incidents.

Next Steps

In a majority Parliament, government legislation normally is enacted into law with minimal changes. This is most likely to be the fate of Bill C-17. Enactment of the Bill into law and accompanying regulations should be on the agenda for 2014.

About the Author

Jeffrey Graham is a partner in the Toronto office of Borden Ladner Gervais LLP and is the National Leader of the Life Sciences team. Jeffrey acts for healthcare corporations and investors in financing and licensing transactions and in respect of regulatory compliance and corporate law matters. He provides strategic public policy advice to financial and health sector participants, federally and provincially. Jeffrey is Past President of the Toronto Biotechnology Initiative, now known as Life Sciences Ontario. He can be reached at 416.367.6174 and at jgraham@blg.com.

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