Bill C-17 Enacted by Parliament: A New Chapter in Regulatory Enforcement?

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Overview

- Introduction to Bill C-17
- History of legislative reform
- Content of Bill C-17
- What does this mean for stakeholders
- Next steps

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Introduction

- Bill C-17: *An Act to amend the Food and Drugs Act,* aka *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*
- Passed into law on November 6, 2014
- First substantial amendment to the *Food and Drugs Act* in 50 years - grants new powers to Health Canada
- Applies to drugs and medical devices ("therapeutic products") but not NHPs
- Unanimous support in the House of Commons and Senate

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The Lead-up

Timeline	
1998	Legislative renewal initiative
2004	Consultations on new *Canada Health Protection Act*
2006	Health Canada "*Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food*"
2008	Bill C-51 – *An Act to Amend the Food and Drugs Act*
2008-2014	• Senate investigation on prescription drugs • Increased publicity and media scrutiny • Increased international regulatory cooperation • Spike in FDA enforcement in the United States • Spike in Health Canada enforcement
2014	Bill C-17 passed into law

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Amendments to the *Food and Drugs Act* - Health Canada's New Powers

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Section 21.1
Power to Require Information

- If Health Canada believes that a product may present a serious risk of injury to human health, it can order any person to provide information in their control that Health Canada believes is necessary to determine if the product presents such a risk.

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Section 21.31
Power to Require Assessment

- Subject to new regulations, Health Canada can order a manufacturer to conduct an assessment and provide Health Canada with the results.

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Section 21.32
Power to Require Further Tests

- Subject to new regulations, for the purpose of obtaining additional information about a product's effects on health or safety, Health Canada can order a manufacturer to compile information, conduct tests or studies or monitor experience in relation to the product and provide Health Canada with the information or the results.

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Section 21.2
Power to Require Label Modification

- If Health Canada believes that doing so is necessary to prevent injury to health, it can order a manufacturer to modify a product's labeling or modify or replace its packaging.

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Section 21.3
Power to Order Recall

- If Health Canada believes that a product presents a serious or imminent risk of injury to health, it may order a person who sells the product to recall it.
- No person shall sell a product that the Minister has ordered another person to recall.

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Section 21.1(2)(3)
Confidential Business Information

- Health Canada's powers to compel information will include confidential business information.
- Health Canada can disclose confidential business information, without notice or permission:
  - To any person, if Health Canada believes that the product presents a serious risk of injury to human health; or
  - To a government, a person from whom Health Canada seeks advice, or a person who carries out functions relating to the protection or promotion of human health, if the disclosure is related to the protection or promotion of human health or the safety of the public.

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Section 21.4(2) Transparency

- Health Canada must ensure that all orders made under these new powers are publically available.
- Public disclosure is mandatory.

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Sections 30(1.2) & 21.71 Clinical Trial Disclosure

- The Minister may make regulations requiring holders of CTAs and ITAs to disclose safety information about a product to Health Canada when the study is completed or discontinued.
- Holders of CTA's and ITA's shall ensure that information concerning the clinical trial is made public within the prescribed time and in the prescribed manner.

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Section 30.12
Disclosure of Safety Information

- The Minister may make regulations requiring manufacturers provide Health Canada with information they become aware of regarding:
  - Serious risks related to a product that have been communicated outside of Canada;
  - Changes to a product's labelling that have taken place outside of Canada; and
  - Reassessments, suspensions or revocations of a product's marketing authorization outside of Canada

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Misc.

- Prescribed healthcare institutions must report information regarding serious adverse drug reactions and medical device incidents to Health Canada (Section 21.8).
- Knowingly making a false or misleading statement to Health Canada or knowingly providing false or misleading information to Health Canada is an offence (Section 21.6).
- The definition of “device” excludes combination products where the medical purpose is achieved solely by pharmacological, immunological or metabolic means or by chemical means in or on the body (Section 2).

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Section 31
Offences and Punishment

- Maximum fine upon conviction for a contravention of the *Food and Drugs Act* or its regulations increases from $5,000 to $5,000,000 per day.
- Unlimited fine at the discretion of the court where the violation knowingly or recklessly caused a serious risk of injury to human health.
- Officers, directors, agents or mandataries who direct, authorize, assent or acquiesce to the offence is a party and subject to punishment even if not individually prosecuted.

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Section 31.3
Due Diligence Defence

- Due diligence is a defence in a prosecution under the *Food and Drugs Act*, except where the violation was made knowingly or recklessly.
- Although the offence is committed, due diligence may excuse liability.
- Ontario Court of Appeal has defined due diligence as taking all of the care that a reasonable person might have been expected to take in the circumstances.

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Compliance – What Does This Mean for Stakeholders

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Compliance

- Health Canada's published approach to compliance and enforcement is based on risk to health.
- Corrective action to bring a company into compliance is pursued before formal enforcement steps are taken.
- Health Canada's *Compliance and Enforcement Policy* (POL-0001) is almost 10 years old.
- Does Bill C-17 signal a new approach? (punishment as deterrence?)

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Compliance & Due Diligence Defence

- Due diligence defence revolves around a company's compliance program.
- Involves policies and procedures intended to ensure compliance with applicable health product laws, regulations and recognized industry standards.

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Compliance Program

An effective compliance program should be:

- Comprehensive: Address all areas/activities that expose the company to a compliance risk.
- Properly documented: For effective dissemination/ training and to create an evidentiary record.
- Mandatory: A condition of employment and grounds for dismissal with cause.
- Monitored: Audit, enforcement and corrective action.

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Compliance Program

Regulatory Compliance Checklist:

- Quality Systems & GMP
- Clinical Trials
- Labeling
- AE Reporting
- Recalls
- Advertising

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Compliance Program

Field Compliance Checklist:

- AE surveillance
- HCP interactions
  - Pre-market and off-label promotion
  - HCP consultants and ad boards
  - Learning programs
  - Medical meetings and conventions
- Sample distribution

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Compliance Program

Other Legal/Ethical Issues Checklist:

- Patient Privacy
- Confidential information
- Anti-Spam

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