

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

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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
- Applies to drugs and medical devices (“therapeutic products”) but not NHPs
- Unanimous support in the House of Commons and Senate

The Lead-up

Timeline

1998	Legislative renewal initiative
2004	Consultations on new <i>Canada Health Protection Act</i>
2006	Health Canada “ <i>Blueprint for Renewal: Transforming Canada’s Approach to Regulating Health Products and Food</i> ”
2008	Bill C-51 – <i>An Act to Amend the Food and Drugs Act</i>
2008-2014	<ul style="list-style-type: none">• Senate investigation on prescription drugs• Increased publicity and media scrutiny• Increased international regulatory cooperation• Spike in FDA enforcement in the United States
2014	Bill C-17 passed into law

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

Overview

- C-17 amendments to the Food and Drugs Act:
 - Grant new investigative and enforcement powers to Health Canada
 - Substantially increase the potential punishment on conviction for non-compliance
- Several of the new powers are not yet in force and will be implemented with the release of new regulations
- In late March 2015, Health Canada published its “Guide to New Authorities”

Section 21.1

Power to Require Information

- If Health Canada believes that a therapeutic 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.

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.

Section 21.32

Power to Require Further Tests

- Subject to new regulations, for the purpose of obtaining additional information about a therapeutic 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.

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 therapeutic product's labeling or modify or replace its packaging.

Section 21.3

Power to Order Recall

- If Health Canada believes that a therapeutic 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 therapeutic product that the Minister has ordered another person to recall.

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 therapeutic 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.

Section 21.4(2)

Transparency

- Health Canada must ensure that all orders made under these new powers are publically available (public disclosure is mandatory).
- In most cases, advance notification and an opportunity to respond will be provided.
- Orders will be accompanied by “reasoned decisions”.

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.

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 therapeutic product that have been communicated outside of Canada;
 - Changes to a therapeutic product's labelling that have taken place outside of Canada; and
 - Reassessments, suspensions or revocations of a therapeutic product's marketing authorization outside of Canada

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).

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.

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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