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LEGISLATIVE SUMMARY

Bill C-17:
An Act to amend the Food and Drugs Act

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Any substantive changes in this Legislative Summary that have been made since the preceding issue are indicated in **bold print**.

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(Legislative Summary)

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Ce document est également publié en français.

CONTENTS

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1 BACKGROUND

Bill C-17, an Act to amend the Food and Drugs Act (alternative title: Protecting Canadians from Unsafe Drugs Act [Vanessa's Law][1]), was introduced in the House of Commons by the Minister of Health on 6 December 2013. According to its summary, the bill amends the *Food and Drugs Act*[2] in order to strengthen oversight of pharmaceuticals and medical devices as well as improve reporting of adverse reactions associated with these products.[3] The bill addresses patient safety issues that were referred to in the Speech from the Throne at the opening of the 2nd Session of the 41st Parliament in October 2013, including the need to ensure that (1) drug side effects are clearly indicated and (2) unsafe drugs are recalled quickly.[4]

In 2007, the federal government announced the Food and Consumer Safety Action Plan.[5] The Plan proposed a "life-cycle approach" to regulating health products, which involved shifting from pre-market safety and effectiveness assessments to the continual assessment of risks and benefits both before and after a product reaches the market.[6] Part of that plan was to be implemented through Bill C-51: An Act to Amend the Food and Drugs Act, which was introduced in April 2008.[7] Among other things, Bill C-51 would have granted additional authorities to the Minister of Health to:

- place more obligations on the manufacturers;
- require post-approval studies;
- require health care institutions to report adverse drug reactions;
- order product recalls; and
- expand inspection powers.

Bill C-51 died on the *Order Paper* at the dissolution of the 39th Parliament. Bill C-17 proposes some of the same amendments to the *Food and Drugs Act* with respect to drugs and medical devices as had been brought forward in Bill C-51.

In March 2013, the Standing Senate Committee on Social Affairs, Science and Technology tabled its report, *Prescription Pharmaceuticals in Canada: Post-Approval Monitoring of Safety and Effectiveness*, which reiterated the call for a modernized legislative framework for drugs.[8]

2 DESCRIPTION AND ANALYSIS

Bill C-17 consists of 15 clauses: Clause 1 addresses the alternative title of the bill and clauses 2 to 12 contain amendments to the *Food and Drugs Act*. Clauses 13 and 14 include transitional and coordinating amendments, and clause 15 contains information with respect to the bill's coming into force. The following description provides an overview of clauses 2 through 15.

2.1 Definitions (Clause 2)

2.1.1 Amended Definition of the Term "Device"

The amended definition of "device" introduces changes that provide grammatical consistency. The changes also clarify that the modifications produced by a device can be to parts of the body, and not only to the body as a whole. The amended definition replaces the statement that a device "does not include a drug" with text stating that a device does not include an item that produces the diagnostic or therapeutic effect solely by delivering a drug or other substance into or on the body.

2.1.2 Introduction of the Terms "Therapeutic Product," "Therapeutic Product Authorization" **and "Confidential Business Information"**

Clause 2 establishes new definitions for products regulated under the Act. Namely, definitions for "therapeutic product" and "therapeutic product authorization" are added. A therapeutic product is a drug or a device, or a combination of the two, but does not include "natural health products" as defined in the *Natural Health Products Regulations*.[9] A therapeutic product authorization is the authorization that permits the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storing and testing of a therapeutic product**. Finally, the term "confidential business information" is introduced as it relates to the public disclosure provisions described below.**

2.2 Therapeutic Products (Clauses 3 to 5)

Clauses 3 to 5 of Bill C-17 contain the majority of the provisions required to implement the intent of the bill, which is increased monitoring of the safety of approved drugs. These clauses amend the Act by adding a new section on therapeutic products after the existing provisions pertaining to devices. They establish new authorities for the Minister, new requirements for authorization holders and health care institutions, and a new prohibition.

2.2.1 Powers of the Minister

New section 21.1**(1)** authorizes the Minister to order a person to provide the Minister with any information in the person's control regarding a therapeutic product that the Minister believes "may present a serious risk of injury to human health" and that "the Minister believes is necessary to determine whether the product presents such a risk." **Further, new section 21.1(2) authorizes the Minister to disclose any confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates if the Minister believes the product presents a "serious risk of injury to human health." Finally, new section 21.1(3) authorizes the Minister to disclose confidential business information to a government, ministerial advisors, or persons responsible for functions related to human health or safety "if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public."**

New section 21.2 authorizes the Minister to order label or packaging changes for therapeutic products if the Minister "believes that doing so is necessary to prevent injury to health."

A recall authority is included in new section 21.3. The Minister may order the recall of a product, or have the product sent to a specified place, if the Minister believes that a therapeutic product "presents a serious or imminent risk of injury to health." The new authority includes a provision to order corrective action (new section 21.3(2)), and it prohibits the sale of recalled therapeutic products unless the Minister specifically authorizes such a sale (new section 21.3(3); new section 21.3(5)). Finally, the recall provision states that a person can be convicted of contravening the prohibition against selling recalled products only if it is proven that the person had been notified of the recall notice or that reasonable steps had been taken to notify the person.

New sections 21.31 and 21.32 replace section 21.4. The sections establish that, subject to the regulations, the Minister may order therapeutic product authorization holders to:

- conduct assessments and provide the results to the Minister (new section 21.31); and
- in order to improve understanding about a product's effects on health and safety:
  - compile information, conduct studies and tests, or monitor experience regarding a therapeutic product (new section 21.32(*a*)); and
  - submit the requested material to the Minister (new section 21.32(*b*)).

New section 21.4 specifies that the orders issued under these new authorities are not statutory instruments as defined under the *Statutory Instruments Act*. **Further, this section authorizes the Minister to make any orders made under sections 21.1 to 21.3 publicly available.** Under new section 21.5 the Minister can apply to a court of competent jurisdiction for an injunction in certain circumstances.

2.2.2 Prohibition, Compliance and Public Disclosure

New section 21.6 prohibits a person from knowingly making false or misleading statements or providing false or misleading information to the Minister about a therapeutic product. New section 21.7 requires that therapeutic product authorization holders comply with the terms and conditions set out in authorizations. **New section 21.71 requires that prescribed information about clinical trials and investigational tests be made public in the time frame and manner prescribed in regulations.**

2.2.3 Mandatory Reporting for Health Care Institutions

Under new section 21.8, prescribed health care institutions will be required to report to the Minister serious adverse drug reactions and medical device incidents that involve therapeutic products. Specifics, such as the type of information, the manner of reporting and the affected health care institutions, will be included in the regulations.

2.3 Regulations (Clauses 6 and 7)

2.3.1 Regulation-Making Authorities for Therapeutic Products

Clauses 6(1) to 6(3) contain new section 30(1.2) of the Act, which sets out the regulation-making authorities of the Governor in Council with respect to therapeutic products.

Clause 6(1) of the bill pertains to authorizations, label and package changes, product recalls and the provision of information by authorization holders.

Clauses 6(2) and 6(3) set out additional regulation-making authorities that are subject to separate coming-into-force provisions. These include regulations respecting assessments, tests and studies, the monitoring of experience, information compilation, the definition of "serious adverse drug reaction" and "medical device incident," and reporting by health care institutions.

New section 30(1.3) requires that the Minister take existing information management systems into account before making any regulations regarding reporting by a health care institution with a view to minimizing its administrative burden.

Clauses 6(5), 6(6) and 6(7) contain editorial amendments to existing sections 30(2), 30(3) and 30(5).

2.3.2 Incorporation by Reference

Section 30.5(1) of the Act permits regulations to incorporate any documents by reference. Clause 7 amends that section to include regulations pertaining to therapeutic products.

2.4 Offences and Punishment (Clauses 8 to 12)

Clause 8 of the bill adds to the Act penalties specifically for contravening provisions pertaining to therapeutic products. These penalties are more severe than those already contained in sections 31 (for offences under the Act, including those pertaining to natural health products and cosmetics) and 31.1 (for offences under the Act relating specifically to food).

Clause 9 sets out the penalties for contravening provisions of the Act pertaining to therapeutic products. New section 31.2 increases or modifies the penalties as follows:

- for a first summary conviction, from the maximum $500 fine and/or three months' imprisonment to a maximum $250,000 fine and/or six months' imprisonment; and
- for conviction by indictment, from a maximum $5,000 fine and/or three years' imprisonment to a maximum $5,000,000 fine and/or two years' imprisonment.

Subsequent offences could be subject to increased punishment. New section 31.3 permits the defence of due diligence.

The bill also establishes penalties for wilfully or recklessly contravening the provisions of the Act as they relate to therapeutic products. New section 31.4 provides that:

- for a summary conviction, the penalty for a first offence is a maximum $500,000 fine and/or a maximum of 18 months' imprisonment; and
- for an indictable offence, the penalty is a fine whose amount is at the court's discretion and/or a maximum of five years' imprisonment.

Subsequent offences could be subject to increased punishment. Due diligence cannot be used as a defence for offences under this section.

New section 31.5 requires that, when imposing a sentence, the court consider the harm or risk of harm posed by the offence and the vulnerability of the affected consumers.

New section 31.6 states that if an offence is committed by a legal person other than an individual (i.e., by a corporation), certain directors, officers, agents or mandataries of the corporation may be liable.

Finally, new section 31.7 states that an offence under new sections 31.2 or 31.4 that continues for more than one day is considered as a separate offence for each day that the offence is committed or continues to be committed.

Clause 12 amends section 35(1) of the Act to incorporate new sections 31.2 and 31.4 created in this bill.

2.5 Transitional and Coordinating Amendments (Clauses 13 and 14)

Clause 13 stipulates that the definition of "therapeutic product authorization" applies to all authorizations for the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of therapeutic products that were issued before this section comes into force. Clause 14 allows for the adjustment of the numbering of regulation-making authorities under new section 30(1.2), depending on which provision comes into force first.

2.6 Coming into Force (Clause 15)

Clause 15 allows for two coming-into-force dates to be fixed by Order in Council: one for clauses 4, 6(2), 10 and 11 (clause 15(1)), and the other for clauses 5, 6(3) and 6(4) (clause 15(2)).

3 COMMENTARY

The bill was referred to the House of Commons Standing Committee on Health following its second reading on 30 May 2014. During the Committee's study, some witnesses suggested that natural health products should fall within the scope of the bill. As stated in section 2.1.2 of this Legislative Summary, natural health products are specifically excluded from the proposed definition of

"therapeutic product." However, other witnesses supported the proposed definition and suggested that introducing such a change would have significant implications and would slow down, if not halt, some much-needed updates to the *Food and Drugs Act*. As such, the definition of "therapeutic product" was not amended, and natural health products remain outside the scope of Bill C-17.

NOTES

1. The alternative title "Vanessa's Law" recognizes the late daughter of Terence Young, Member of Parliament for Oakville, Ontario, who died from complications attributed to a prescription medicine.
2. *Food and Drugs Act*, R.S.C., 1985, c. F-27.
3. Bill C-17: An Act to amend the Food and Drugs Act, 2nd Session, 41st Parliament.
4. Government of Canada, *Speech from the Throne*, 2nd Session, 41st Parliament, 16 October 2013.
5. Health Canada, "Health Canada: The Food and Consumer Safety Action Plan."
6. Ibid.
7. Bill C-51: An Act to amend the Food and Drugs Act, 2nd Session, 39th Parliament.
8. Senate, Standing Committee on Social Affairs, Science and Technology, Prescription Pharmaceuticals in Canada: Post-Approval Monitoring of Safety and Effectiveness, 1st Session, 41st Parliament, March 2013.
9. *Natural Health Products Regulations*, SOR/2003-196.