BILL C-17: AN ACT TO AMEND THE FOOD AND DRUGS ACT

Protecting Canadians from Unsafe Drugs

What's the issue?

- Bill C-17 amends the Food and Drugs Act, which hasn't been substantially updated in over 50 years.
- It was introduced to the House of Commons by the Minister of Health in December 2013.
- The Bill has *two main goals*:
  - Strengthen safety oversight of therapeutic products throughout their lifecycle
  - Improve reporting of serious adverse reactions and incidents.
- The Bill applies to: prescription and OTC drugs, vaccines, gene therapies, cells, tissues and organs, and medical devices. The Bill *does not* apply to natural health products.

Important definitions

- ***Therapeutic product:*** **any drug or device or combination of drugs and devices, but does not include natural health products.**
- ***Therapeutic product authorization:*** **an authorization that permits the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product.**

What has changed?

Bill C-17 introduces a number of updates to the Food and Drugs Act. These include:

The power to require information, tests or studies

- If the Minister believes a therapeutic product poses a "serious risk of injury to human health," they may order a person to provide them with information regarding this risk.
- The Minister may order the holder of a therapeutic product authorization to compile information and conduct tests, studies or assessments of the product and provide the results to the Minister.
- The Governor in Council may make regulations requiring information to be provided on any identified risks, label modifications, recalls, and revocations of licenses that have occurred outside of Canada.

The ability to require a label change

- The Minister may order that a label be revised to include new harm information or that packaging be changed, if they feel it is necessary to "prevent injury to health".

The power to recall therapeutic products

- If the Minister believes that a therapeutic product presents "a serious or imminent risk of injury to health," they may order a product recall.

Tougher penalties for those that commit violations

- Increases existing penalties up to a maximum penalty of $5,000,000 and/or 2 years in prison.
- Introduces new penalties specifically for violating provisions relating to therapeutic products.

Mandatory reporting by healthcare institutions

- Enacts mandatory reporting for health care institutions of a "serious adverse drug reaction" that involves a therapeutic product.
- Specifics regarding the affected institutions, the type of information and manner of reporting, will be included in the regulations.

What does it mean?

Bill C-17 provides the opportunity for more information to be collected on the potential or observed risks of therapeutic products and allows for mandatory reporting of adverse reactions, both within and outside of Canada.

Bill C-17 gives the Minister of Health increased authority to take quick action when a serious health risk is identified. The provisions of the Bill give the Minister a greater ability to order tests, assessments, label changes and product recalls, should they feel it necessary to protect the health of patients.

The Bill also enacts more significant penalties for violating the Bill, in an effort to deter therapeutic product authorization holders from committing serious offences.

How are patients affected?

Bill C-17 aims to increase patient safety through enhanced reporting of safety information.

- Mandatory reporting of health care institutions provides a potential opportunity for patients to communicate their experiences and concerns regarding adverse reactions or incidents.
- The Bill allows regulations to be made that require safety information to be provided to the Minister for clinical trials of a therapeutic product that involve human subjects.

Bill C-17 aims to ensure that potentially unsafe products are removed from the market quickly.

- The Bill gives the Minister the power to take direct and timely action when potential risks are identified, in order to minimize the harm to patients.

Bill C-17 aims to consider the harm caused to patients when violations of the Bill occur.

- The Bill stipulates that sentences for any offence must take into account the harm or risk of harm caused by the offence and the vulnerability of the consumers of the therapeutic product.

What's New? Amendments from the Standing Committee on Health

Specifications regarding "confidential business information"

- The Minister may disclose confidential business information about a therapeutic product without notification or consent, in cases of serious risk of injury to health
- The Minister may disclose this information to: a government, a person from whom the Minister seeks advice, or a person involved in the protection or promotion of health

Increased public disclosure

- The Minister must ensure that orders to provide information, modify labelling or packaging, and recall a product are publicly available
- Any decisions and reasons regarding the issuance, amendment, suspension and revocation of therapeutic product authorizations must also be made publicly available
- Information regarding clinical trials or investigational tests must also be publicly disclosed

For more information:

http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6375723&File=4
http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-eng.php
http://www.hc-sc.gc.ca/dhp-mps/legislation/unsafedrugs-droguesdangereuses-faq-eng.php

Legislative Process

The legislative process can take anywhere from 6 to 12 months to complete, depending on the length of debates and the priority of the Bill on the Parliamentary agenda.

Bill C-17 has already passed through the *First* and *Second Reading* stages in the House of Commons. Members of Parliament have had the opportunity to debate the Bill and it was supported by all three parties.

Bill C-17 has also passed through the *Committee* stage in the House of Commons. The Bill was examined and debated by the **Standing Committee on Health**. The Committee heard testimonies by witnesses, debated the Bill clause by clause and voted on amendments. A report was submitted to the House of Commons detailing the Committee's recommendations.

This report was presented in the House of Commons for Members of Parliament to evaluate and debate. All amendments of the Health Committee were deemed passed. Bill C-17 entered the *Third Reading* stage, as a final version of the Bill was presented to the House of Commons. Members of Parliament voted to send the Bill on to the Senate.

Bill C-17 will follow the same process in the Senate. The *First Reading* of Bill C-17 occurred before the Senate entered summer recess. When the Senate returns in the fall, there will be a *Second Reading*, followed by a referral to the Senate **Standing Committee on Social Affairs, Science and Technology.** After the *Third Reading*, a final vote will determine whether the Bill is passed.

If Bill C-17 successfully makes its way through Parliament, it will be published in Part I of the **Canada Gazette**. A time window of 30 to 75 days will be established for public consultation.

The Bill will then be passed on to the Governor General for approval during the *Royal Assent* stage. Once approval is received, Bill C-17 will officially come into force as legislation.

Legislative Timeline

Opportunities for Input

The Government set an aggressive agenda to get Bill C-17 through the necessary stages before the summer recess. The Bill was successfully passed through the House of Commons, however it did not proceed further than the *First Reading* in the Senate before summer recess began. Progress on Bill C-17 is expected to resume in the fall. Although the Bill moved quickly through the House of Commons, there are still opportunities for input. The summer break provides organizations and individuals with the chance to become informed about Bill C-17 and the existing opportunities to influence the legislative process.

Talk to your MP

You can reach out to your Member of Parliament (MP) at any stage during the legislative process to discuss Bill C-17.

Although Bill C-17 has already passed through the House of Commons, elected officials can still influence the Bill's progress.

Your MP can represent your opinions and concerns to other elected officials in the House of Commons.

Give a testimony

Individuals and organizations can apply to give a testimony to the Senate Standing Committee that will evaluate Bill C-17.

A testimony consists of an opening statement presented to the committee. Following this, committee members can ask the presenter questions.

In addition, any individual or organization may submit a brief, even if they do not appear before the committee. Briefs can include opinions, comments and recommendations.

Submit to the Gazette

The Canada Gazette is the official newspaper of the Government of Canada. Part I of the Gazette contains proposed regulations in the final stage of the legislative process.

Individuals and groups have the opportunity to review and submit comments on these proposed regulations before they are enacted.

Comments must be submitted within the 30-75 day consultation period to the designated contact on the Gazette website.