



March 2015



PRESCRIPTION PHARMACEUTICALS IN CANADA

Final Report

Standing Senate Committee on
Social Affairs, Science and Technology

The Honourable Kelvin K. Ogilvie, *Chair*

The Honourable Art Eggleton, P.C., *Deputy Chair*





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ORDER OF REFERENCE

Extract from the *Journals of the Senate* of Tuesday, November 19, 2013:

The Honourable Senator Ogilvie moved, seconded by the Honourable Senator Runciman:

That the Standing Senate Committee on Social Affairs, Science and Technology be authorized to examine and report on prescription pharmaceuticals in Canada, including but not limited to:

- (a) the process to approve prescription pharmaceuticals with a particular focus on clinical trials;*
- (b) the post-approval monitoring of prescription pharmaceuticals;*
- (c) the off-label use of prescription pharmaceuticals; and*
- (d) the nature of unintended consequences in the use of prescription pharmaceuticals.*

That the papers and evidence received and taken and work accomplished by the committee on this subject during the First Session of the Forty-first Parliament be referred to the committee; and

That the committee submit its final report no later than December 31, 2014 and that the committee retain until March 31, 2015, all powers necessary to publicize its findings.

After debate,

The question being put on the motion, it was adopted.

Extract from the *Journals of the Senate* of Tuesday, December 9, 2014:

The Honourable Senator Ogilvie moved, seconded by the Honourable Senator MacDonald:

That notwithstanding the Order of the Senate adopted on Tuesday, November 19, 2013, the date for the final report of the Standing Senate Committee on Social Affairs, Science and Technology on prescription pharmaceuticals in Canada, be extended from December 30, 2014 to April 30, 2015 and that the date until which the committee retains powers to allow it to publicize its findings be extended from March 31, 2015 to July 31, 2015.

The question being put on the motion, it was adopted.

Gary W. O'Brien
Clerk of the Senate



MEMBERS

The Honourable Kelvin Kenneth Ogilvie, *Chair*
The Honourable Art Eggleton, P.C., *Deputy Chair*

The Honourable Senators:

Maria Chaput, Jane Cordy, Tobias Enverga,
Nancy Ruth, Judith Seidman, Asha Seth,
Carolyn Stewart Olsen, John Wallace.

Ex Officio Members:

The Honourable Senators Claude Carignan,
P.C. (or Yonah Martin) and James Cowan
(or Joan Fraser).

Other Senators who have participated from time to time in the study:

The Honourable Senators Ataulhjan, Bellemare,
Beyak, Callbeck, Campbell, Chaput, Demers,
Doyle, Hubley, Housakos, Lang, Maltais,
McInnis, Mercer, Moore, Munson, Neufeld, Oh,
Peterson, Plett, Raine, Rivard, Tannas and Verner P.C..

Parliamentary Information and Research Services, Library of Parliament:

Sonya Norris, Analyst.

Clerk of the Committee:

Jessica Richardson.

Senate Committees Directorate:

Diane McMartin, Administrative Assistant.

INTRODUCTION

In fall 2014, the Standing Senate Committee on Social Affairs, Science and Technology (“the committee”) completed a four-phase study on prescription pharmaceuticals, as described in the Order of Reference adopted on 22 November 2011.¹ The committee tabled reports on each of the four phases of this study:

- *Canada’s Clinical Trial Infrastructure: A Prescription for Improved Access to New Medicines* (the “Clinical Trials Report”) in November 2012;
- *Prescription Pharmaceuticals in Canada: Post-Approval Monitoring of Safety and Effectiveness* (the “Post-Approval Monitoring Report”) in March 2013;

- *Prescription Pharmaceuticals in Canada: Off-Label Use* (the “Off-Label Use Report”) in January 2014; and,
- *Prescription Pharmaceuticals in Canada: Unintended Consequences* (the “Unintended Consequences Report”) in September 2014.²

In addition, a roundtable discussion with 16 expert witnesses was held on 6 June 2014 to get an update on Canada’s clinical trial infrastructure and to explore certain issues that either spanned several phases of the study or that required further inquiry. This document provides a brief overview of the committee’s findings over the course of the pharmaceutical study and includes insights provided during the roundtable discussion as well as additional relevant updates.



¹ The study was re-established at the beginning of the second session of the 41st Parliament with a new order of reference on 19 November 2013.

² All four pharmaceutical reports of the pharmaceuticals study can be accessed on the [committee’s website](#).



DRUG REGULATION IN CANADA

In Canada, drugs are regulated under the *Food and Drugs Act* (the Act), which essentially defines drugs as including any substance for which a health claim has been made and includes both non-prescription drugs (over-the-counter medications as well as natural health products) and prescription drugs. The committee's study focussed exclusively on prescription drugs.

Pursuant to the Act, the *Food and Drug Regulations* set out the requirements for obtaining approval from Health Canada to market a drug in this country. The regulatory oversight begins in the early stages of drug development when human trials are carried out to determine whether a new drug is safe and effective. This refers to the clinical trial phase of drug development, which was the focus of the first phase of the committee's study. Once clinical trials have shown a drug to be effective with an acceptable safety profile, its manufacturer may submit for market approval from Health Canada. If the department is satisfied that the new drug submission provides sufficient information about the new drug's quality and efficacy, and that the benefits associated with taking the medicine outweigh the risks (the safety profile), the department may approve the drug for sale in Canada.

Once a drug is on the market there are regulatory requirements for the manufacturer to report on the drug's safety and effectiveness when used by the general population, also referred to as the drug's "real-world safety and effectiveness" and the department collects and analyses reports of adverse drug reactions, sometimes called side effects, that have been voluntarily submitted by patients and health professionals. This process refers to the post-approval monitoring of drug safety and effectiveness, which was the focus of the second phase of the pharmaceutical study.

Health Canada's drug approval is based only on the information that was provided in the drug

submission, and therefore is limited to those conditions, dosages or sub-groups of the population for which there is clinical trial data. However, "real-world" use of an approved drug frequently includes its use outside of the conditions, dosages or sub-groups of the population provided in the drug's departmental approval. This practice is known as "off-label use," which was the focus of the third phase of the committee's study and is discussed in section 4 below.

In the last phase of the pharmaceutical study, the committee explored the unintended consequences linked to the use of approved prescription drugs. These issues include abuse, misuse and addiction; antibiotic resistance; counterfeit and substandard drugs; drug shortages; environmental concerns; and, overmedication.

CLINICAL TRIAL INFRASTRUCTURE

In November 2012, the committee tabled *Canada's Clinical Trial Infrastructure: A Prescription for Improved Access to New Medicines* ("the Clinical Trials Report") reflecting the testimony of witnesses who appeared over the course of 11 meetings. The Clinical Trials Report emphasized the importance of encouraging clinical trial activity in Canada as it allows patients access to new drugs, and provides physicians with the opportunity to become familiar with treatments that may become available. However, the committee also cautioned that patient safety must not be compromised as a consequence of attracting research dollars.

The committee found that Canada's approach to clinical trials has been passive and fragmented which has led to a steady decline over the last decade in the number of trials that are being conducted across the country. As such, there has been a reduction in research investment in Canada as well as a decline in patient access to new medicines. The Clinical Trials Report contained 12 recommendations aimed at increasing and streamlining clinical trial activity in Canada while



optimizing patient safety. Specifically, the recommendations addressed the need for a more coordinated approach to clinical trials, including standardization of ethics review and the creation of research networks; urged implementation of mandatory registration of clinical trials including all results; asked that drug approval be granted only when participants in clinical trials reflect the population that is expected to consume the drug; requested that Health Canada address the unique elements necessary for the development of drugs for rare diseases (also called orphan drugs); and, highlighted that inspection practices by Health Canada of clinical trial sites must be improved, and that inspection results must be made public. Finally, the committee called on the Minister of Health to amend the Act so as to require increased departmental transparency and allow for increased penalties for contravening the Act.

During the June 2014 roundtable discussion, the committee was told of the Canadian Clinical Trials Coordinating Centre (CCTCC), created in spring 2014 and housed within the Health Charities Coalition of Canada. The CCTCC is a collaborative effort of the Canadian Institutes of Health Research (CIHR), Canada's Research-based Pharmaceutical Companies (Rx&D) and HealthCareCAN.³ The committee is encouraged by this progress and CCTCC's stated goal of increasing clinical trial activity in Canada by attracting research investment through improved coordination of clinical trial activities and streamlined approach for companies and researchers. The committee hopes that the CCTCC is able to begin to reverse the trend of declining clinical trial activity in Canada.

As well, concerns were raised at the roundtable that the new CCTCC may not acknowledge and



³ HealthCareCAN is a new organization created by the merger of the Association of Canadian Academic Healthcare Organizations and the Canadian Healthcare Association.



accommodate the unique needs of the rare diseases community and that some stakeholders, particularly the private clinical research sector, may be excluded from the process. These were concerns specifically raised by the committee in its Clinical Trials Report. Finally, the committee again heard strong support for mandatory registration of clinical trials and for public disclosure of clinical trial results, whether positive or negative, as recommended in the Clinical Trials Report. In this regard, the committee notes that Bill C-17, an act to amend the Food and Drugs Act (Vanessa's Law), was tabled in December 2013 and is now law, having received Royal Assent in November 2014. The new provisions include a requirement that certain information about clinical trials be made public in a manner to be defined in regulations. The committee trusts that regulations related to this provision will reflect the spirit of transparency and openness that underlies Vanessa's Law.

POST-APPROVAL MONITORING OF SAFETY AND EFFECTIVENESS

In March 2013, the committee tabled *Prescription Pharmaceuticals in Canada: Post-Approval Monitoring of Safety and Effectiveness* ("the Post-Approval Monitoring Report") reflecting the testimony of witnesses who appeared over the course of eight meetings. The Post-Approval Monitoring Report made 19 recommendations intended to improve Health Canada's oversight of the safety and effectiveness of approved drugs.

The committee heard that once a drug is approved for sale in Canada, its real world safety and effectiveness reflects the drug's use among the general population, rather than in the small, controlled groups of individuals who participated in the clinical trials. For example, sub-groups of the population including children, the elderly and pregnant and nursing women, are often excluded from clinical trials. However, once a drug is approved it can be, and is, prescribed to

individuals within these sub-groups of the population despite the lack of safety and effectiveness information. This is one type of "off-label" use and is further discussed below. As such, effective monitoring of pharmaceuticals once they are on the market is essential in order to properly assess their real world safety and effectiveness. While Health Canada has implemented changes in recent years in order to improve its post-approval monitoring activities, the committee noted that Canada lags behind most other industrialized countries in this regard.

The committee recommended changes to drug legislation and regulation, as it had in the Clinical Trials Report, to bring Canada more closely in line with other jurisdictions, such as the European Union and the United States. In this regard, the report recommended that the Minister of Health be granted the authority to order drug companies to; provide certain types of information, make label changes, conduct additional tests and, issue recalls. The committee also recommended that





making certain types of information public must be mandatory and that modernized drug regulations must be adopted as soon as possible. In support of the modernized framework which applies a “life-cycle” approach to drug regulation, the committee recommended that adverse drug reaction (ADR) reporting and the department’s handling of those reports must be improved, including full implementation of electronic databases and placing greater emphasis on long-term drug safety studies. In order to accomplish the necessary improvements, the committee recommended that the department apply equal resources to both pre- and post-approval drug regulatory activities.

The report acknowledged and commended the newly created Drug Safety and Effectiveness Network (DSEN) within the Canadian Institutes of Health Research. DSEN was created to carry out additional research on approved drugs where ADR reports submitted to Health Canada suggest potential safety issues. The committee is supportive of DSEN and the work it conducts. Recommendations made in the report aimed to strengthen DSEN’s independence, introduce transparency, expand its mandate, and ensure its long-term stability. In addition, the committee noted that DSEN, or in some cases the drug manufacturers, should conduct drug safety and effectiveness studies in specific sub-groups of the population, namely children, the elderly and pregnant and nursing women.

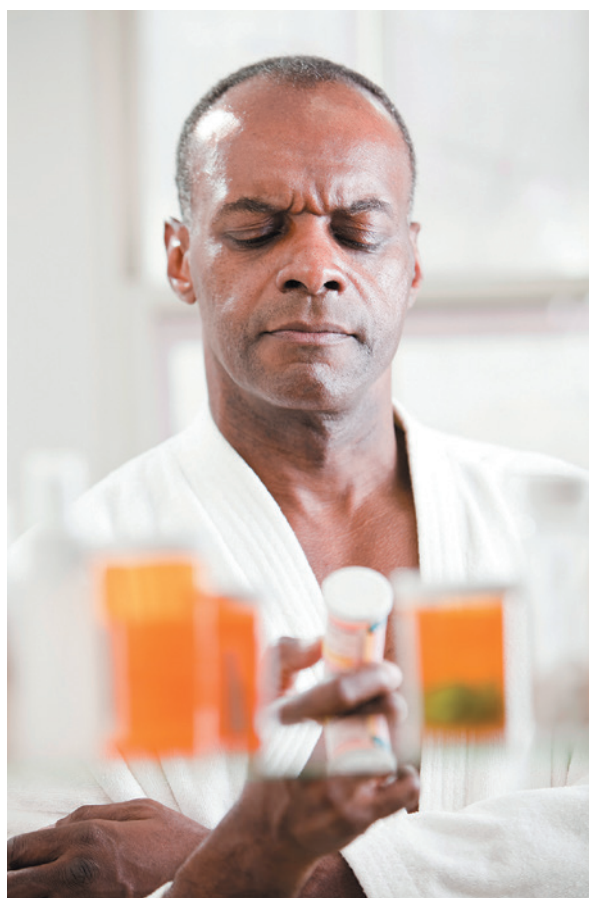
The Post-Approval Monitoring Report emphasized the need for, and recommended, full implementation and uptake of electronic systems for dispensed prescription drugs, electronic health records and electronic medical records. In terms of improving the provision of safety information to patients, the report recommended mandatory inclusion of a Patient Information Leaflet with all prescription drugs which should include contact information to facilitate the reporting of ADRs to Health Canada. Finally, the committee urged improvements to

drug labelling requirements in order to highlight new and higher risk medicines, strategies that are already in place in other jurisdictions.

OFF-LABEL USE

In January 2014, the committee tabled *Prescription Pharmaceuticals in Canada: Off-Label Use* (“the Off-Label Use Report”), reflecting the testimony of witnesses over the course of seven meetings. The Off-Label Use Report made 18 recommendations addressing the issues of data collection; research and information sharing; specific sub-groups of the population; assessments of off-label use; electronic formats; and, the Orphan Drug Framework.

Health Canada approves drugs for sale in this country based on the safety and efficacy data generated during clinical trials. As such, the approval granted is specifically for the conditions,





dosages and population sub-groups studied in the clinical trials. However, once a drug is on the market, physicians may choose to prescribe it beyond the approved criteria. This is referred to as “off-label” prescribing and is the prerogative of a prescriber. Of particular concern is the fact that children, the elderly and pregnant and nursing women are seldom included in clinical trials sometimes due to ethical considerations or to multiple medical conditions. As a result, many of the approved drugs that they are prescribed are done so without the benefit of any safety and effectiveness data for their population sub-group. Thus, out of necessity, off-label drug use is common among these sub-groups of the population as there may be no alternative.

The report noted that the extent of off-label prescribing is not known and that, in fact, physicians are frequently unaware that they are prescribing off-label. Consequently, little is known about the most common types of off-label use. As such the committee recommended that the department’s ADR form be modified in order to improve data collection in this area. This would allow the department to separate side effects associated with off-label use to be analysed separately.

While the committee acknowledged the benefits of some off-label prescription drug use, it cautioned that in other instances a lack of evidence of effectiveness can mean that patients are consuming drugs that are not helping or are causing harm, or both. To address these potential problems, the committee recommended that DSEN take an active role in assessing the effectiveness of off-label drug uses. Further, it recommended an expanded role for the Canadian Agency for Drugs and Technologies in Health to conduct and share its findings wherever possible

on the safety and effectiveness of off-label prescription drug use.

The Off-Label Use Report also emphasized the need to implement many of the committee’s previous recommendations from the two earlier reports. Those recommendations addressed: the need for more drug research that evaluates safety and effectiveness in certain sub-groups of the population; electronic medical records, electronic health records and electronic systems of dispensed prescription drugs; patient-access to the ADR form; and, additional legislative authorities. In addition, recommendations in this report pertained to: expanding Health Canada’s recently announced Orphan Drug Framework to include older drugs; making public the department’s rationale for drug approval decisions, both positive and negative, including those for new uses for older drugs; monitoring off-label drug use among certain sub-groups of the population, and addressing enforcement of the prohibition on off-label drug promotion by drug manufacturers.

As indicated above, the pharmaceutical reports have emphasized the exclusion of some sub-groups of the population when it comes to drug development as well as safety and effectiveness. Specifically, the Off-Label Use report urged improved monitoring of off-label drug use in long-term care homes for the elderly and enhanced pediatric surveillance through existing programs. Further, the committee applauds the report entitled *Improving Medicines for Children in Canada* issued by the Council of Canadian Academies in September 2014.⁴ The committee trusts that this report will serve to inform important policy and regulatory decisions by Health Canada as it looks ahead to implementing the new clinical trial and post-market authorities granted in the recently amended *Food and Drugs Act*.

⁴ Council of Canadian Academies, “[Improving Medicines for Children in Canada](#),” September 2014.



UNINTENDED CONSEQUENCES

In October 2014, the committee tabled its report on the final phase of the four-phase study on pharmaceuticals entitled *Prescription Pharmaceuticals in Canada: Unintended Consequences* (“the Unintended Consequences Report”), which made 30 recommendations. The Unintended Consequences Report highlighted six issues, or unintended consequences, related to the use of prescription drugs: abuse, misuse and addiction; antibiotic resistance; counterfeit and substandard drugs; drug shortages; environmental concerns; and, the prescribing to, and use by, patients of multiple drugs.

Throughout this final phase of the study, electronic databases remained a prominent theme, as they had been throughout the entire pharmaceuticals study. Members were told that implementation of those databases, accompanied by controlled access to the data they contain, would help to address many of the unintended consequences listed above. In this regard, the committee reiterated in this fourth report that the implementation of electronic health and prescription drug databases must be accelerated by establishing targets and regularly reporting on progress. Further, the uptake of these databases

should be encouraged with a pan-Canadian awareness campaign.

Access to health data, with appropriate privacy considerations, across jurisdictions by all relevant stakeholders was also recommended. In this respect, the committee was told during the June 2014 roundtable that the Canadian Institutes of Health Research are in discussions with provincial deputy ministers to improve access to data. As well, provincial privacy commissioners together with privacy authorities within provincial health ministries are attempting to address privacy concerns. The committee was also told about a study underway at the Council of Canadian Academies called “Timely Access to Health and Social Data for Health Research and Health System Innovation.” This report is expected in spring 2015 and the committee trusts that it will be considered as policymakers strive to optimize data access as it relates to drug safety and effectiveness.

Abuse, Misuse and Addiction

The Unintended Consequences Report described the growing problem of prescription drug misuse, abuse and addiction, and the poor response by all relevant sectors to date. While the committee is





pleased that Health Canada has announced that prescription drugs are to be included within the National Anti-Drug Strategy, the report also included a number of recommendations specific to the unique issues associated with prescription drugs. Recommendations included: introducing public awareness campaigns as well as enhancing professional education and training as needed elements of the expanded strategy; improving access to data about the level prescription opioid consumption in Canada; require the tracking of and reporting on the use of high-risk prescription drugs by the Canadian Institute for Health Information; adding addiction potential as a risk factor within a drug's assessment by Health Canada; re-assessing approved drugs to include their addiction or abuse potential; requiring tamper-resistant formulations as a condition of market approval; requiring special labelling for addictive drugs; introducing additional requirements for physicians and pharmacists under the *Narcotic Control Regulations*; ensuring sufficient resources to address prescription drug abuse, misuse and addiction in First Nations communities; and finally, expanding the Health Canada review of the First Nations and Inuit Non-Insured Health Benefits program to include the drugs available for pain management.

Antibiotic Resistance

The number of bacterial infections that have proven to be resistant to one or more antibiotics has been increasing for many years. This resistance has emerged for a number of reasons including the overuse and misuse of antibiotics, by prescribing them to people who do not have a bacterial infection. However, the misuse of antibiotics as a growth promoter in the feed of food-producing animals is another significant contributor to antibiotic resistance. To address this increasing public health threat, the Unintended Consequences Report included recommendations for the implementation of a renewed national action plan with a focus on public awareness campaigns, coordinated surveillance efforts and

improved public reporting. The committee also called for a ban of, or meaningful reduction in, the use of antibiotics in food-producing animals and urged the federal government to increase its efforts to encourage research and development of new antibiotics. Contributors to the June 2014 roundtable discussion agreed with these recommendations but emphasized that these actions cannot be applied by Canada in isolation but rather that Canada must collaborate with other countries to address antibiotic resistance on a global scale.

Counterfeit and Substandard Drugs

With respect to counterfeit prescription drugs, the committee was told that significant quantities of fraudulently produced medicines are coming into, or through, Canada each year by post, courier streams and illegitimate online pharmacies. Members heard that effective enforcement activities must involve global cooperation among multiple agencies. As such, the committee called for improved regulation of Internet pharmacies and enhanced enforcement of counterfeit practices involving multi-jurisdictional collaboration. Further, the committee recommended that the production and sale of substandard drugs, those that fail to meet the requirements set out by Health Canada, can be addressed by the creation of an inter-agency task force. Its role would be to identify those products most likely to be affected. The report also indicated that inspection activities by Health Canada need strengthening and that batch testing of imported prescription drugs similar to the approach taken in the European Union should be implemented.

The report emphasized the need for transparency and that Health Canada must publicly disclose relevant information about substandard and counterfeit drugs. In support of these recommendations, the committee points to recent events involving the drug manufacturer Apotex. The Minister of Health acknowledged that Health Canada was not able to persuade the company to



voluntarily recall one of its products, even though the department indicated that it was aware that the company was importing substandard ingredients to a Canadian plant for the manufacture of a blood pressure medication.⁵ The committee notes that the department has options other than a product recall in order to address importation of substandard ingredients. For example, the Minister of Health has the authority to suspend or cancel a manufacturer's establishment licence as well as suspend the products market authorization under current drug regulations. Never-the-less, the committee notes and is pleased that the Minister of Health has since been granted the authority to order drug recalls under the recently passed amendments to the *Food and Drugs Act*. Another approach that is available to the department is to be more transparent with inspection results and advise the public whenever a drug manufacturer has violated the requirements of their product authorization or establishment licence.

Drug Shortages

Drug shortages are not a new phenomenon, but they have been shown to be increasing in frequency and duration over the last ten or fifteen years. The committee found that, in regards to drug shortages, there is more that can be done by the Minister of Health and Health Canada to minimize the impact on the health of Canadians. The Unintended Consequences Report recommended that: non-primary care providers such as dentists be included on the Multi-Stakeholder Steering Committee on Drug Shortages; the *Food and Drug Regulations* be amended to require more notification of drug discontinuances; the drug shortages website be reviewed and that changes to improve its usefulness be implemented; the provision of therapeutic alternative information be improved; and finally, drug formularies, both federal and

provincial, include therapeutic alternatives to facilitate quick response to drug shortages.

Environmental Concerns

The environmental concerns associated with prescription drug use include excretion of consumed drugs into the sewage system as well as the improper disposal of unused medicine into landfill or sewers. With respect to these environmental concerns, the committee called on the Minister of Health and the Minister of the Environment to clarify their respective roles in monitoring the level of pharmaceuticals in groundwater. It also recommended that Health Canada implement a public awareness campaign



⁵ Toronto Star, Jesse McLean and David Bruser, "[Feeble Health Canada can't block dodgy drug imports](#)," 19 September 2014.



encouraging proper disposal of unused prescription medication, such as the “Take Back” programs managed by pharmacies.

Consumption of Multiple Drugs

Finally, the consumption of multiple drugs, often referred to as polypharmacy, by some Canadians, particularly the elderly who may be afflicted with multiple chronic conditions, is an issue that was raised earlier in this study in the context of certain sub-groups of the population. As mentioned above, recent amendments to the *Food and Drugs Act* now permit Health Canada to order drug safety and effectiveness studies in this sub-group of the population. In addition to earlier recommendations

on this issue, the committee recommended that the Minister of Health encourage the provinces and territories to implement appropriate training for medical students and continuing education for health care providers about opioid use, update prescribing guidelines regularly, and require patient medication reviews.

UPDATED DRUG LEGISLATION

Over the course of this four-phase study, the committee made a number of recommendations for updated legislation and regulations. At the time of the roundtable discussion, Bill C-17, an Act to amend the Food and Drugs Act, had been tabled and referred to the House of Commons





Standing Committee on Health for study. The bill proposed several amendments that addressed some of the recommended changes this committee suggested, including several new authorities for the Minister of Health, some additional prohibitions and a harsher penalty provision. The bill was amended at committee stage in the House of Commons to introduce some transparency provisions, including the introduction of a requirement for the public disclosure of clinical trial information and drug safety information.

Participants in the roundtable discussion indicated that the proposed new transparency provisions are commendable but would not be successful until there is similar change in the institutional culture at Health Canada. Additionally, while all panellists who spoke to this issue were supportive of the proposals, several of them indicated that the bill does not include as many proposals as an earlier initiative that would have amended the *Food and*

Drugs Act. Bill C-51, which included many similar provisions to those in Bill C-17, was tabled in spring 2008, but it also included provisions respecting clinical trials, market authorizations and additional prohibited activities, such as tampering, hoaxes and counterfeiting that are not included in Bill C-17. Members heard that one way to assess whether or not Health Canada translates the enabling legislation into regulations that accomplish the goals of effective oversight with sufficient transparency and openness is to seek parliamentary review of regulatory proposals. Overall, however, there was a sense that the proposed amendments contained in Bill C-17 are a positive step towards updating Canada's *Food and Drugs Act* and a significant advance that will put Canada more in line with international trends in terms of pharmaceutical drug regulation. Bill C-17, an Act to amend the Food and Drugs Act, became law in November 2014.



CONCLUSION

Over the course of nearly three years, the Standing Committee on Social Affairs, Science and Technology has studied prescription pharmaceuticals in Canada including the development, approval, regulation and unintended consequences associated with their use. The committee is encouraged by the new amendments to the *Food and Drugs Act* including several authorities that have been recommended in these reports. However, this bill can only be considered a first step. The committee heard overwhelming support during the roundtable discussion for the recommendations it made throughout these reports and it urges the federal government to implement them with a view to elevating Health Canada's performance to that of a model pharmaceutical regulator on the world stage.

Although the committee was discouraged by frequent testimony regarding Health Canada's passive role in drug regulation, its lack of transparency in relaying safety information to the public, its inability to conduct adequate inspections at all phases of a drug's life-cycle and in some cases, the department's failure to provide this committee with reliable testimony, it hopes that the department shares its belief that Canada's drug regulatory regime should be second to none.

The committee considers it essential that the regulations that will be implemented pursuant to the new provisions in the *Food and Drugs Act* reflect the spirit of transparency and openness that resonates in Bill C-17, Vanessa's Law.





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