First Do No Harm: Responding to Canada’s Prescription Drug Crisis

Annual Report

2013–2014

On behalf of the First Do No Harm National Advisory Council
First Do No Harm: Responding to Canada’s Prescription Drug Crisis: Annual Report

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Executive Summary

The Strategy

First Do No Harm: Responding to Canada's Prescription Drug Crisis (the Strategy) is a 10-year roadmap to reduce the harms associated with prescription drugs while giving important consideration to their therapeutic uses. Under the leadership of the Canadian Centre on Substance Abuse (CCSA), the Coalition on Prescription Drug Misuse (Alberta) and the Nova Scotia Department of Health and Wellness, in partnership with Health Canada’s First Nations and Inuit Health Branch’s Prescription Drug Abuse Coordinating Committee, the Strategy was developed by the National Advisory Council on Prescription Drug Misuse—a diverse group of individuals representing governments, health professionals (including coroners, dentists, nurses, pharmacists and physicians), patients and families, First Nations, enforcement officials, regulators, industry leaders and researchers.

The Strategy presents 58 achievable short- and longer-term recommendations around five streams of action: Prevention, Education, Treatment, Monitoring and Surveillance, and Enforcement, and three areas of focus that cut across all streams: Legislation and Regulation, Research and Evaluation and Performance Measurement.

The Strategy was released in March 2013 and during the first year, six implementation teams were formed, one for each stream of action, and one for Legislation and Regulation, to breathe life into the recommendations. Over 50 individuals were recruited, many of them leaders in their field, representing a similar number of organizations and broader networks from across the country, to commit to one or more of the implementation teams and to the First Do No Harm National Advisory Council (NAC) that now guides the implementation of the Strategy. The result of this commitment is reflected in the substantial progress that has been made in the first year since the Strategy was launched.

National Initiatives

Members of NAC and the implementation teams were engaged on the national and provincial stage in activities that align with the recommendations of the Strategy such as:

- Participation on the Federal, Provincial and Territorial Working Group on Prescription Drug Abuse;
- Presentations to House of Commons Standing Committee on Health’s study of the role of the federal government in addressing prescription drug abuse;
- Leadership of, and participation in, the Symposium on Prescription Drug Abuse co-hosted by CCSA’s CEO, Michel Perron, and the Honourable Rona Ambrose, Minister of Health;
- Presentations to the Senate Committee examining prescription pharmaceuticals in Canada;
- Participation in a number of initiatives at the provincial and territorial level that align with the recommendations contained within the Strategy, including research on British Columbia’s Take-Home Naloxone pilot program, changes to Alberta’s buprenorphine/naloxone prescribing regulations and Ontario’s creation of a real-time surveillance system to track overdose deaths and injuries in hospital emergency rooms; and
- Advocating for the support of prescription drug-related initiatives announced during the 2013 Speech from the Throne.
Activities of the Implementation Teams

The First Do No Harm Executive Council (representing co-leads from each of the implementation teams and the co-chairs of the First Do No Harm National Advisory Council) met through the year to guide the implementation of the Strategy and share their activities within their organizations to leverage the efforts of each member organization. In addition, the majority of the implementation teams committed to monthly teleconference meetings to plan and execute projects in alignment with the recommendations. Highlights of these projects included:

- Supporting the Institute for Safe Medication Practices in developing patient education materials on the safe use of opioid medications;
- Completing an environmental scan of existing social marketing campaigns related to prescription drugs, including evidence of their effectiveness to inform future social marketing initiatives;
- Conducting a review of professional and federal guidelines on the safe disposal of prescription medication;
- Participating, as co-investigators and knowledge user partners in the Second Chances study of the effectiveness of British Columbia’s Take-Home Naloxone program;
- Developing competencies required to address harms of prescription drug use for a range of healthcare practitioners who work with patients facing addictions, mental health, co-morbidities, concurrent disorders and pain issues;
- Completing an environmental scan of existing continuing education offerings for both prescribing and dispensing healthcare professionals to identify gaps and opportunities for improvement;
- Conducting a survey of physicians, pharmacists, dentists and nurses practicing within the province of Alberta to better understand healthcare professionals’ perceptions of illicit drug use and local strategies for action with a view to informing educational curricula;
- Contributing to a Canadian Institutes of Health Research (CIHR) grant application to conduct a systematic review of existing strategies, frameworks, collaborative networks and materials to promote the appropriate use and reduce abuse of prescription opioids, and identify gaps, inconsistencies and duplication among strategies to guide future research and practices;
- Securing funding for meetings of stakeholders to begin standardizing the elements of a national prescription drug surveillance system and a prescription monitoring program (PMP) community of practice;
- Completing a literature review on the core components of effective PMPs;
- Completing a study to determine the cost-impact of prescription drugs on the Canadian criminal justice system, including law enforcement, prosecution services and correctional services;
- Hosting the first annual National Prescription Drug Drop-off Day, which resulted in the return of over 900 kilograms of drugs that are now no longer available for diversion, and planning for the next event in 2014;
- Writing letters to Health Canada to address areas for improvement in labelling and product monographs and to provide recommendations for changes to the Controlled Drugs and Substances Act and the re-scoping of the National Anti-Drug Strategy (NADS) to include prescription drugs;
Reviewing federal regulatory requirements with a view to identifying areas where regulations could be strengthened;

**The Way Forward**

With so many activities underway across the country, the momentum behind the First Do No Harm Strategy is building; however, funding for the Strategy’s implementation has been very limited. Despite the shortage in resources, the teams have managed to move forward and have prioritized activities to be address in the coming year; however, to do so requires contingent engagement of all members and member organizations and on funding to support the significant work that lies ahead. Through the availability of appropriate resources, CCSA can effectively continue in its leadership role, as requested by NAC, to see the Strategy through to its full implementation. This work includes providing the backbone support and guidance required to implement the needed action, share information, build upon the initiatives that are underway, and leverage the momentum that has been created to achieve a greater collective impact.

To get involved, contact pharma@ccsa.ca.
Introduction

First Do No Harm: Responding to Canada’s Prescription Drug Crisis (the Strategy) is a 10-year roadmap to reduce the harms associated with prescription drugs while giving important consideration to their therapeutic uses. The Canadian Centre on Substance Abuse (CCSA), the Coalition on Prescription Drug Misuse (Alberta) and the Nova Scotia Department of Health and Wellness led the development of the Strategy, in partnership with Health Canada’s First Nations and Inuit Health Branch’s Prescription Drug Abuse Coordinating Committee. The Strategy, initiated in response to a growing nation-wide concern about harms associated with prescription drug use in Canada, was developed by the National Advisory Council on Prescription Drug Misuse — a diverse group of individuals representing governments, health professionals (including coroners, dentists, nurses, pharmacists and physicians), patients and families, First Nations, enforcement officials, regulators, industry leaders, and researchers.

Focus of the Strategy

The Strategy addresses prescription drugs that have legal status and therapeutic uses, together with a high potential for harm. These medications include:

- Opioid pain relievers such as those containing oxycodone, hydromorphone, fentanyl, morphine and codeine;
- Stimulants such as those containing dextroamphetamine, methylphenidate and amphetamines;
- Sedative-hypnotics such as those containing benzodiazepines such as diazepam and alprazolam; and
- Those medications used to treat addiction and pain, but that can also result in harm, such as methadone and buprenorphine.

The Strategy focuses on the harms associated with these prescription drugs and recognizes that the harms need to be considered along with the benefits the drugs can deliver. The harms include addiction, illness requiring hospitalization, overdose and death associated with problematic use, over-consumption, poly-drug use and non-medical use, as well as with therapeutic use, when medications are not taken as prescribed. The associated impacts and costs—physical, emotional, psychological and public safety—are borne by individuals, families, communities and society at large.

Effective treatment and prevention approaches need to attend to the diversity of populations, including their geographical and cultural contexts, and many other factors that contribute to risk and the impacts of these prescription drugs across the system.

To reduce these harms, the Strategy also addresses:

- Diversion away from the authorized supply chain from manufacturer to patient;
- Inappropriate prescribing and dispensing behaviour; and
- Addiction, mental health, co-morbidities, concurrent disorders and pain, all of which are affected by these prescription drugs.
The Recommendations

Through a commitment to coordinated action across its multi-sectorial membership, the National Advisory Council worked intensively for 14 months to develop the Strategy. The final product outlines 58 consensus recommendations in five streams of action: Prevention, Education, Treatment, Monitoring and Surveillance, and Enforcement; and three areas of focus that cut across all streams: Legislation and Regulation, Research, and Evaluation and Performance Measurement. A full description of these recommendations is available in the Strategy document, First Do No Harm: Responding to Canada’s Prescription Drug Crisis released in March 2013.

The present report summarizes the progress that has been made in the first year since the landmark First Do No Harm Strategy was released.
Breathing Life into the Recommendations

Building on the momentum created through the development of the Strategy, many of the members of the National Advisory Council on Prescription Drug Misuse agreed to co-lead implementation teams to breathe life into the recommendations laid out by the Strategy.

Six implementation teams (hereafter referred to as Teams) were assembled, one for each stream of action, as well as one for the Legislation and Regulations area of focus. CCSA identified additional co-leads, as required, to provide direction to the work of each Team. The first step for the co-leads was to recruit subject matter experts, some of whom were already involved in the Strategy’s development, as well as new members who joined the Strategy since its launch in March 2013, to commit to taking action on the recommendations. To date, over 50 individuals, many of them leaders in their field, representing a similar number of organizations and broader networks from across the country have made a commitment to one or more of the Teams and to the First Do No Harm National Advisory Council (NAC) that now guides the implementation of the Strategy (see Appendix A for the NAC governance structure).

The Teams are responsible for the implementation of the Strategy’s 58 recommendations. Team activities involve meeting regularly, monitoring progress, assessing resource needs, setting annual priorities, developing plans of action with concrete deliverables and recruiting new members as needed to achieve milestones towards fulfillment of the recommendations.

The Executive Council, composed of the team co-leads and NAC co-chairs, also met by teleconference to share information, identify areas for potential collaboration, coordinate Strategy implementation and communicate on behalf of the Strategy.

In March 2014, the NAC met face-to-face to celebrate the year’s accomplishments, identify opportunities for cross-team collaboration and solidify each Team’s work plans for the year ahead. The meeting included representatives from Health Canada who reported on federal activities related to prescription drug abuse and listened to updates from each of the Teams on the work completed over the previous year and the opportunities and challenges facing them as they look ahead. The meeting was a reminder of the value of face-to-face time in creating momentum and inspiring the voluntary group working to implement the Strategy.

Despite working with limited resources, the Teams have remained committed to the Strategy’s implementation and have been able to prioritize and take action toward the fulfillment of many of the Strategy’s recommendations. All the while, CCSA has continued to provide backbone secretariat and other support, helping teams with recruitment, identifying priorities and timelines for taking action, exploring funding options, and supporting research initiatives.

Many of the activities of the first year involved conducting the foundational preliminary work required for the full realization of the recommendations. These activities represent early days in what is a 10-year initiative. The following sections of this report summarize national activities in which NAC members have been involved, as well as the priority recommendations and corresponding accomplishments of each of the implementation teams.
The First Do No Harm Strategy on the National Stage

A number of activities of a national scope have taken place over the past year that complement the Strategy and are helping to move the recommendations forward. CCSA and many members of NAC have participated directly in the majority of the following national initiatives.

The 2013 Speech from the Throne

The 2013 Speech from the Throne included several commitments related to the First Do No Harm Strategy: a) to expand Canada’s National Anti-Drug Strategy to address the growing problem of prescription drug abuse; b) to ensure that drug labels are written in plain language and that the potential side effects of medication are accurately indicated; and c) to introduce new patient safety legislation to help identify potentially dangerous drugs and ensure the quick recall of unsafe drugs.

The expansion of the National Anti-Drug Strategy to include prescription drug abuse was welcome news to CCSA and the First Do No Harm NAC and implementation teams. The announcement was received as Health Canada’s recognition of the importance of taking action to address the issue at a national level, as articulated in the First Do No Harm Strategy for Canada.

Funding to Support Expanded National Anti-Drug Strategy

The 2014 federal budget included $44.9 billion dollars over five years to support expanding the focus of the National Anti-Drug Strategy to include prescription drugs. The money will be directed towards initiatives such as educating Canadian consumers on the safe use, storage and disposal of prescription drugs and enhancing the treatment and prevention of prescription drug abuse in First Nations communities.

Proposals submitted to the Health Canada’s Drug Treatment Fund Program can now include prescription drug abuse within their scope. Those involved in the First Do No Harm Strategy hope to secure some of this funding to support the implementation of the Strategy.

Federal/Provincial/Territorial Working Group on Prescription Drug Abuse

The Federal/Provincial/Territorial (FPT) Working Group on Prescription Drug Abuse is made up of representatives from provincial and territorial health ministries and Health Canada. The group, co-chaired by Carolyn Davison, from the Nova Scotia Department of Health and Wellness, and Michelle Kovacevick, from Health Canada, was formed to address concerns about harms associated with prescription drug use. In addition to Carolyn Davison, other members of NAC are also part of the working group, which has helped to ensure a coordinated effort by the working group and the First Do No Harm implementation teams. During their most recent meeting, the group agreed to target a number of short-term activities that include initiating the development of a national surveillance plan, establishing a prescription monitoring program (PMP) network, and coordinating activities to educate health practitioner, including dentists, nurses, pharmacists and physicians.
Dr. Beth Sproule, Lead of the Monitoring and Surveillance Team, has been invited to work with the FPT Working Group toward establishing a national surveillance system and network of PMPs. In addition, Nova Scotia has provided funding to host a meeting in May 2014 of the Monitoring and Surveillance Team, the FPT representatives of prescription monitoring programs and other key stakeholders to discuss and initiate a consensus process to standardize the key elements of a national surveillance system, specifically data streams, definitions and common terminology, and core indicators. The meeting will also serve to initiate the development of a Canadian prescription monitoring program community of practice, including the framework, objectives, core components and priorities.

**House of Commons Standing Committee on Health**

In November 2013, the House of Commons Standing Committee on Health began a study of the federal government’s role in addressing prescription drug abuse in Canada. The committee was chaired by Ben Lobb, M.P. for the Ontario riding of Huron-Bruce. The study focused on the following three areas:

- The current scope of the problem, including what populations are most at-risk;
- Best practices for prevention and raising awareness of the problem; and
- Promising strategies to address this issue at the community level.

A series of meetings were held through to February 2014 during which 17 members of First Do No Harm implementation teams plus additional member organizations, as well as CCSA CEO, Michel Perron, presented witness statements to the committee. Many referenced the First Do No Harm Strategy in their testimony.

The final report on the federal government’s role in addressing prescription drug abuse in Canada was released on April 10, 2014, and listed 20 recommendations, most of which align closely with those found in the reference to the First Do No Harm Strategy. These recommendations include:

- **Recommendation 5**: Health Canada review, in cooperation with stakeholders, inappropriate marketing practices that have an effect on prescribing practices;
- **Recommendation 8**: The federal government continue to implement its National Anti-Drug Strategy with consideration to the CCSA’s pan-Canadian strategy entitled *First Do No Harm: Responding to Canada’s Prescription Drug Crisis*;
- **Recommendation 10**: The federal government endeavour to share best practices across jurisdictions on the prescribing of drugs with addiction potential;
- **Recommendation 18**: Health Canada work with territorial governments and Inuit Tapiriit Kanatami and the CCSA to collect Inuit-specific data to inform an Inuit-specific approach to the issues surrounding prescription drug abuse; and
- **Recommendation 20**: The federal government target funds through the National Anti-Drug Strategy to establish an awareness campaign focusing on the risks associated with prescription drug abuse and how to properly and security store, monitor and dispose of prescription drugs.

**Ministers Symposium on Prescription Drug Misuse**

On January 24, 2014, the Honourable Rona Ambrose, Minister of Health, and Michel Perron, CEO, CCSA co-hosted the Symposium on Prescription Drug Abuse in Toronto, Ontario. The invited attendees represented a range of disciplines and organizations, many of which were members of NAC. Attendees included experts in the field of addiction and pain treatment, and representatives of health professional...
regulatory authorities and professional associations (including dentists, nurses, pharmacists and physicians), law enforcement, academic institutions, patient safety organizations, First Nations, government, and the pharmaceutical industry. Also in attendance were George Da Pont, Deputy Minister of Health, and Ben Lobb, M.P., Chair for the House of Commons Standing Committee on Health.

The event addressed prescription drug abuse in the context of the three major themes of the National Anti-drug Strategy, Prevention, Treatment and Enforcement, along with a breakout session on Prescriber Practices and Education led by Dr. Louis Francescutti, President, Canadian Medical Association, and Dr. Kathy Lawrence, President, College of Family Physicians.

Over the course of the day, five common themes or suggestions were emphasized across the four sessions:

- PMPs in every province and territory that allow information sharing across prescribers, dispensers and enforcement agencies to support the monitoring of prescription and disbursement of prescription drugs to identify high-risk patients and high-risk prescribing behaviour.
- A national surveillance system to track patterns of prescription drug misuse and harms at national, provincial and territorial levels to evaluate the impact of interventions and provide evidence to inform ongoing policy and practice. The system would include data from provincial/territorial and national (Non-Insured Health Benefits) PMPs, as well as hospital admissions, emergency room visits, coroner’s data, poison control centres, veterinarians and enforcement.
- Improved prescriber education to ensure appropriate use of prescription medications and non-punitive approaches to continuing education.
- Improved access to a range of addiction and pain treatment services, including the physical and economic availability of non-pharmacological and traditional treatment options.
- Recognition of the collective effort that will continue to be required to address the highly complex issue of prescription drug abuse and to leverage the work that has already been initiated, including the National Anti-Drug Strategy and the First Do No Harm Strategy.

These themes are consistent with recommendations of the First Do No Harm Strategy and reinforce that the Strategy continues to reflect the concerns of the nation’s leaders and experts dealing with the issue of the harms associated with the use of prescription drugs.

The event provided CCSA and NAC members with the opportunity to develop new relationships with partners interested in becoming involved in the Strategy. CCSA and NAC have welcomed the involvement of the Canadian Medical Association in the implementation of the Strategy and look forward to collaborating with this organization.

**Senate Committee Examining Prescription Pharmaceuticals in Canada**

In November 2013, the Standing Senate Committee on Social Affairs, Science and Technology was authorized by the Senate to examine and report on four main aspects of prescription pharmaceuticals in Canada including:

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

A number of members of NAC have presented evidence to the committee under one or more of the above themes. In January 2014, the committee released its first report, *Prescription Pharmaceuticals in Canada: Off-Label*, including 18 recommendations. The recommendations include suggestions to improve drug labelling and prescriber education, as well elements of monitoring and surveillance, which are all consistent with the recommendations of the First Do No Harm Strategy.

**Other National Initiatives**

In March 2013, CCSA and several NAC members participated in a roundtable meeting of the Surviving Opioid Overdose with Naloxone (SOON) project funded by Canadian Institutes of Health Research (CIHR). SOON is a national interdisciplinary collaboration of community stakeholders, patient leaders and knowledge users, along with content experts from diverse clinical fields, methodologists and industry. At this meeting, participants reviewed the state of the art in overdose rescue. The initiative will see the development of standardized protocols, optimization of implementation strategies and the identification of the best means to evaluate outcomes.

CCSA and other members of the NAC continue to participate on the National Opioid Use Guideline Group (NOUGG) of the National Faculty of the Michael G. DeGroote National Pain Centre in knowledge mobilization activities related to the *Canadian Guideline for Safe and Effective Use of Opioids in Chronic Non-Cancer Pain*. This Guideline and related resources, such as the *Opioid Manager and Practice Toolkit*, are now available on the National Pain Centre website (nationalpaincentre.mcmaster.ca/guidelines.html).

In response to a request for suggestions about gaps in the regulations or improvements to them, the First Do No Harm Executive Council submitted recommendations to Health Canada on the *Controlled Drugs and Substances Act* (CDSA) and the expanded scope of the National Anti-Drug Strategy. The group also drafted a related letter to Health Canada to address identified areas for improvement in labelling and product monographs. See copies of the submissions in appendices B and C.

**Provincial/Territorial Initiatives**

In addition to activities at the national level, provincial initiatives are underway from coast to coast to address harms associated with prescription drug use.

The British Columbia Centre for Disease Control is closely following the results of their newly implemented Take-Home Naloxone pilot program. In the first nine months since the program launched in August of 2012, 14 overdose reversals were reported. A largely positive response to the program has been reported among stakeholders supporting its expansion beyond the three health authorities in which it was piloted. In addition, CCSA and other NAC members are part of the research team for the Second Chances study that will perform a more thorough evaluation of the program. The implementation of the program is consistent with the Strategy’s recommendations to review the evidence on community-based initiatives to reduce overdose and related deaths, and increase the implementation of effective initiatives.

Alberta has been a strong supporter of the First Do No Harm Strategy, providing funding for a number of the projects on which CCSA and the implementation teams were actively involved. Details of these initiatives are provided in the next section of this report. In addition, the College of Physicians and Surgeons in Alberta approved prescribing changes for buprenorphine/naloxone to help remove barriers to patient care as set out in the Strategy’s recommendations. In some cases, particularly for patients in hospitals or other care settings with controlled medication dispensing...
processes or for incarcerated patients, physicians no longer require a methadone exemption to prescribe these medications.

A number of activities have been underway in Ontario to address prescription drug harms. One of the most significant is an initiative announced by the Ontario Ministry of Health and Long-Term Care to create a real-time surveillance system to track overdose deaths and injuries from approximately 90 hospital emergency rooms. The new system, expected to launch later this year, will allow public health units to know in real-time if there is a rise in opioid overdoses in their community and plan their response accordingly. The development of a national prescription drug surveillance system is a critical component of the First Do No Harm Strategy.

In early 2013, the government of Prince Edward Island released a new strategy to address mental health. Under this initiative, the government has agreed to invest $1.2 million in immediate actions to address the rise in prescription drug addiction within the province. The funds supported the creation of a Chief Mental Health and Addictions Officer, new prescribing guidelines to reduce misuse of prescription drugs, a new inspector to investigate irregularities in prescribing, expanded methadone treatment and access to buprenorphine/naloxone, and a 10-bed transition unit to support patients after detox.

The government of Nova Scotia has also taken significant steps to address prescription drug harms in the province. Through its mental health and addictions strategy, it is directing funds to monitoring and surveillance efforts as well as prescriber education through the Atlantic Mentoring Network for Pain and Addiction. Enhancements to the Drug Information System (DIS) within the province permit pharmacies to connect directly with the system, allowing the PMP to receive information directly from the DIS. The province has used information gathered through its PMP to conduct a review of its Drug Utilization Review process to adjust the criteria for identifying cases for inquiry. A quality improvement initiative directed toward physicians who prescribe a large proportion of the provinces’ opioids was also initiated in the past year.

British Columbia’s Ministry of Health launched a provincial academic detailing module, Opioids in Chronic Non-Cancer Pain (CNCP). This 30-minute continuing medical education session involves pharmacists meeting with physicians one-on-one to discuss the benefits and harms of opioids in CNCP, the importance of an initial short-term, structured opioid trial, the characteristics of specific opioids and opioid formulations, and the role of opioid stewardship in improving patient and public safety.

Multi-pronged initiatives like those of Prince Edward Island, British Columbia and Nova Scotia, consistent with recommendations from the Prevention, Education, Treatment, Monitoring and Surveillance, and Enforcement streams of the Strategy, reflect the intractable nature of the prescription drug problem and the need for a strategic and coordinated approach to have an effective impact.
Priority Recommendations and Team Activities

To focus their efforts, the implementation teams selected priority recommendations from the Strategy that they could action with the resources available to them. The following subsections summarize the selected recommendations and the actions taken in the first year.

Prevention

Recommendation 3: Identify, develop, promote and evaluate evidence-informed, culturally safe practices, resources and policies to build community and individual capacity to address conditions that increase or protect against harms associated with prescription drugs for municipalities and communities, particularly rural, isolated and remote communities; and individuals and families, including patient decision aids related to the treatment of chronic pain, the risk for addiction and the impact of misuse.

The Institute for Safe Medication Practices (ISMP) Canada has produced a resource to educate patients and families about opioid pain medications and promote safe use, particularly during the transition from hospital to home. The Prevention Team is reviewing the resource and providing ISMP with feedback on the content. The review will also evaluate the applicability of the resource for use in other settings such as pharmacies to support patient education during the dispensing process. The Prevention Team will identify opportunities to develop tailored versions of the resource for this and other purposes.

In Hamilton, Ontario, CCSA and other team members were involved in a series of three meetings to develop a local strategy, A Practical Approach to Prescription Drug Misuse and Diversion, led by the Michael G. DeGroote National Pain Centre and funded by through a CIHR dissemination grant. This initiative is developing a template for communities interested in taking collective action on this important health and safety issue.

To address prescription drug concerns at the municipal and community level, the Prevention Team identified partners working in this area with whom they hope to engage in the coming year. The team has approached the Canadian Federation of Municipalities to discuss their interest in becoming involved in taking action on this recommendation, particularly to address by-laws in some municipalities that prohibit needle exchange programs, supervised injection and consumption sites, and methadone clinics. The Prevention Team has also identified the National Native Addictions Partnership Foundation as a critical partner in exchanging information with First Nation communities.

Recommendation 4: Develop, implement and evaluate evidence-informed prescription drug-related social marketing campaigns and related resources directed to specific populations or communities, including information about the benefits, harms and limitations of use as prescribed and of non-medical use; appropriate use; signs and symptoms of misuse, addiction and overdose (and actions to be taken); safe storage and disposal; other strategies to prevent harms (e.g., related to drug-impaired driving); and wellness promotion and alternatives to pain medications (e.g., self-care strategies).

Social marketing campaigns are resource-intensive endeavours. To ensure that future campaigns related to prescription drug misuse are evidence-informed and fill an identified need, CCSA was funded by Health Canada to conduct an environmental scan of existing social marketing campaigns related to prescription drugs. The review considered the evidence used in developing the campaigns, as well as the results of any evaluations completed on their effectiveness. The review also identified the target audiences and provided a gap analysis outlining the areas or audiences that current
campaigns are not addressing. The results of this review can inform the development of targeted, evidence-informed, effective campaigns to address prescription drug harms in Canada.

**Recommendation 6:** Develop and promote guidelines for individuals and families related to the use, safe storage and disposal of prescription medications. Guidelines should include family assessment, community medication disposal resources and strategies to address barriers to safe storage (e.g., locked boxes) and disposal.

The Prevention Team examined existing guidelines regarding the safe storage and disposal of medications by pharmacies to identify gaps and best practices. A search by CCSA for existing guidelines for pharmacies has now been completed and found a lack of consistency across jurisdictions. The team is also reviewing federal guidelines on medication disposal as well as examining available research related to supply chain security. These reviews of existing professional and federal guidelines in conjunction with existing research, will help identify gaps where guidelines need to be developed or improved, and establish best practices for storage and disposal that should be promoted.

**Recommendation 8:** Review existing evidence and/or conduct objective and independent research and make recommendations on the effectiveness, including cost-effectiveness, of community-based prevention initiatives designed to reduce overdose and related deaths (e.g., take-home naloxone programs).

To expand the body of knowledge related to the effectiveness of community-based prevention initiatives, an application was submitted for a CIHR Partnerships for Health Systems Improvement grant for *The Second Chances Study: A Mixed Methods Investigation into the Effectiveness of Take-Home Naloxone Training for People at Risk of Opioid Overdose*. Dr. Jane Buxton, from the University of British Columbia, is the study’s principle investigator. Two CCSA staff are involved as co-investigators or knowledge user co-applicants, as well as several NAC members. The study will be focused on British Columbia’s Take-Home Naloxone program that was launched in August 2012. Part of the Strategy’s role is to share learnings with other jurisdictions and assist in local implementation. Sharing the results of this study will provide an opportunity for other provinces interested in establishing similar programs to learn from British Columbia’s experience.

**Recommendation 10:** Develop and evaluate accessible evidence-informed resources for practitioners and educators working with youth to help incorporate prescription drug-related harm prevention into programs and policies, while ensuring that unintended consequences are avoided. This should include population health promotion initiatives that focus on asset building and the promotion of resilience; and building prescription drug-related content into existing prevention initiatives by leveraging what already exists in communities.

In the interest of leveraging existing work, the Prevention Team has reviewed results of an environmental scan of evidence-informed resources that incorporate the prevention of prescription drug-related harm into education programs. The team is reviewing the scan, conducted by Nova Scotia, to identify practices to implement in other jurisdictions. These results, in conjunction with the results of the Health Canada-funded scan of social marketing campaigns and related resources focused on youth, will help to build an inventory of resources for practitioners and educators to incorporate prevention messaging into their work with youth.
Education

Recommendation 1: Establish and implement core competencies for all types of healthcare practitioners in the assessment and management of addictions, mental health, co-morbidities, concurrent disorders and pain. Identify existing competencies and standards of care to determine the extent to which they address the harms associated with prescription drugs; develop competencies with involvement from practitioners, individuals, families, industry and the community; work with educators to embed these competencies into the core curricula for each healthcare practitioner; ensure that cultural considerations are reflected in these competencies; include competencies related to the provision of trauma-informed services; and include competencies regarding understanding and influencing the determinants of health and their impact on patients’ prescription drug harms.

The Education Team developed an inventory of existing competencies and standards of care for a range of healthcare practitioners involved in addictions, mental health, co-morbidities, concurrent disorders and pain. A review of this inventory enabled the team to determine the extent to which these existing competencies address the harms associated with prescription drugs. While various disciplines have developed relevant competencies, no one set of competencies comprehensively addressed the full range of skills required for appropriately prescribing the medications of concern to the Strategy.

An initial set of competencies was drafted and reviewed by the members of the multi-disciplinary Education Team to address this gap. Following a number of revisions, the competencies are now ready for broader consultation, review and input by relevant professional associations, academic institutions and accrediting organizations. In addition, further outreach to a cross-section of cultural groups is planned to ensure cultural considerations are adequately reflected in the competencies the team has developed.

Recommendation 2: Develop accredited healthcare practitioner continuing education programming specific to the appropriate use of these prescription drugs. Encourage regulatory and educational authorities for prescribing and dispensing healthcare practitioners to adopt core competencies that affect the prevalence and severity of addiction and overdose, which includes patient selection, dose titration, monitoring and tapering.

To address gaps in healthcare practitioner continuing education programming, the Education Team undertook an inventory of the relevant educational offerings for prescribing and dispensing practitioners. With funding provided by Health Canada, an environmental scan of existing continuing education offerings for both groups was conducted. The completed scans will be used to identify where the most significant gaps exist. The team will take steps to address the gaps, either through the development of new programs or through efforts to increase the availability and uptake of existing quality course offerings.

To recruit support and expertise for the team’s education-related initiatives, the team will share the Strategy with undergraduate education institutions, accreditation bodies, licensing and regulatory bodies for healthcare professionals and professional organizations (including dentists, nurses, pharmacists and physicians), commercial providers and educational institutions responsible for continuing education programs. These groups will be asked to identify representatives who can provide input on the Education Team’s suggestions to improve healthcare practitioner continuing education, as well as other team initiatives.
NAC members are part of a CIHR-funded knowledge synthesis project led by Dr. Andrea Furlan of the University of Toronto. CCSA’s Dr. Amy Porath-Waller and Education Team co-lead Dr. Norm Buckley are involved as knowledge users on the Research and Knowledge Exchange Team. The project will conduct a systematic review of existing strategies, frameworks, collaborative networks and materials to promote the appropriate use of prescription opioids and reduce the abuse of these drugs; create an open-access database of all materials found in the review; and identify gaps, inconsistences and duplication among strategies to guide future research and practices.

**Recommendation 3: Implement accessible academic-detailing programs (e.g., RxFiles Program in Saskatchewan) that provide evidence-informed education on prescribing and dispensing practices in all provinces and territories and evaluate the effectiveness and impact of these programs. Link these programs to prescription monitoring programs, where possible, to determine change in practice.**

Similar to addressing gaps in continuing education, to improve access to quality academic-detailing programs in all provinces and territories, the Education Team identified the need to first establish what programs were already in place and whether any evaluation work had been completed to establish their effectiveness. The team developed a list of existing provincial academic detailing programs, including information on what services they offer and how effective they have been in influencing prescriber practice. The next steps will be to review the information gathered to identify where academic detailing programs are absent and, based on the experience of existing programs, determine what services new programs should consider adopting and how existing programs could be modified to improve their efficiency and effectiveness.

**Recommendation 8: Train and equip multidisciplinary practitioners (e.g., healthcare practitioners, emergency medical services, law enforcement, corrections and addiction counsellors) to recognize and manage prescription drug overdoses**

With the support of Alberta Health, CCSA embarked on a survey to better understand health professionals’ perceptions of prescription drug misuse (PDM) and local strategies for action. The survey, issued to physicians, pharmacists, dentists and nurses practicing within the province of Alberta, assessed their perceptions of the extent and distribution of PDM among their patients, clinical manifestations and risk factors for PDM, barriers to identifying patients engaging in PDM and strategies for preventing and addressing PDM. The results of this study will help inform the development of education and prevention initiatives aimed at addressing and reducing the harms associated with PDM, such as addiction, overdose and death. An expert panel from Alberta is currently analyzing survey results, with the final report expected to be released by summer 2014. Further discussions are planned with decision makers in Alberta to determine the required steps for moving forward.

**Treatment**

**Recommendation 3: Identify, develop, as needed, promote and evaluate funding mechanisms and incentives that improve and promote access to withdrawal management programs, including in rural and remote areas and for those on opioid treatment or other medications.**

Alberta Health provided funding to pilot and evaluate an on-line Methadone Maintenance Treatment (MMT) workshop for service providers in its province. The course, being developed and hosted by the College of Physicians and Surgeons of Alberta, is intended to help improve access to effective methadone maintenance treatment services in underserved and remote jurisdictions across southern Alberta with a view to applying this approach in other parts of Canada that have similar challenges. As part of the workshop, an evaluation will be conducted to compare the effectiveness of the on-line workshop with a similar face-to-face offering. The Treatment Team is also compiling
guidelines for the delivery of MMT workshops, which will prove valuable to organizations across Canada who deliver similar training.

Recommendation 4: Promote the use of evidence-informed guidelines for treatment of addiction, mental illness, co-morbidities, concurrent disorders, and acute and chronic pain (including effective non-pharmacological approaches). Develop new or update existing guidelines as needed with input from specialty societies (e.g., emergency physicians, nurse practitioners, family practitioners) representing various healthcare settings; search for and appraise existing guidelines; assess the adaptability of existing guidelines to various settings and/or the need for new guidelines; adapt guidelines as indicated; develop new guidelines as indicated; and update existing guidelines as needed.

Treatment guidelines vary considerably by type of treatment they address, patient population, level of evidence and jurisdiction. Simply identifying the guidelines in use across Canada at both a provincial and national levels has been a significant task the Treatment Team has undertaken. While inventories for a number of provinces are complete, the team is working to ensure that guidelines from all provinces and territories are included. The next steps will be to appraise the guidelines and identify mechanisms to share best practices across the country and determine where effort should be directed to develop or update existing guidelines.

Recommendation 6: Identify, develop, evaluate and implement effective, evidence-informed screening, brief intervention and referral to treatment for prescription drug harms that can be used with or adapted for a variety of patient groups (e.g., those with addiction, dependence, mental health, co-morbidities, concurrent disorders, chronic pain, etc.).

In addition to guidelines for treatment, the Treatment Team is also gathering screening, brief intervention and referral to treatment (SBIRT) approaches that are being used across the country and could be adapted for use in other locations and with other populations. CCSA and NAC members recently co-authored a review that evaluated the effectiveness of existing SBIRT approaches. The review will be a valuable foundation for the future work of the team and guide the next steps in adapting SBIRT approaches for use with a variety of patient groups.

**Monitoring and Surveillance**

Recommendation 1: Standardize the key elements of a Canadian prescription drug surveillance system, such as: data holders; data streams (e.g., coroner reports, poison centre records, IMS Health data, losses and thefts data, post-market surveillance related to adverse events data, medication incidents); definitions and common terminology; indicators (explore potential linkages with other projects such as the National Treatment Indicators, Drug and Alcohol Network of Surveillance Experts, Canadian Tobacco, Alcohol and Drugs Survey and existing provincial surveillance systems); collection methods; reporting; and links with data systems for alcohol and other drugs, as well as risk factors and sentinel surveillance for local planning.

The Monitoring and Surveillance Team has primarily been focused on securing funding to support the implementation of the recommendations that fall within their stream of action. To develop national standards for a drug surveillance system, a consensus exercise is required to ensure that those interested in adopting the standards are involved in the process and supportive of the final result. The team has secured funding from the Nova Scotia Department of Health and Wellness to host a meeting of stakeholders from across the country, including those from the FPT Working Group on Prescription Drug Abuse, and representatives of prescription monitoring programs to initiate this work.
Meanwhile, members of the team have met with the U.S.-based RADARS (Researched Abuse, Diversion and Addiction-Related Surveillance) group. The group has significant experience in the surveillance area and is receptive to working with the team to develop a national surveillance system for Canada.

**Recommendation 3: Create a Canadian community of practice for PMPs:** Identify and share effective and evidence-informed practices; establish standardized components of Canadian PMPs; leverage resources; benefit from and share with international programs; collaborate on research; engage in knowledge exchange; provide knowledge and expertise to jurisdictions interested in developing PMPs; and determine the effectiveness of specific promising practices, such as real-time access by prescribers and dispensers.

Similar to Recommendation 1, the Monitoring and Surveillance Team is prepared to host a meeting of interested parties to kick-off a Canadian community of practice for PMPs. This practice group will likely meet initially in conjunction with the meetings required to standardize elements for the national prescription drug surveillance system outlined in Recommendation 1, with some potential overlap in the stakeholders involved in each.

Using funding made available by Alberta Health, a literature review on the core components of effective PMPs is being completed. The review updates a systematic review assessing the evidence base for PMP best practices and then assesses Alberta’s PMP as to how well it incorporates these best practices to assist with continuous improvement and evolution. The review will provide a strong foundation for all provinces to establish new, or improve existing, PMPs and create consistency in approaches to monitoring, data analyses and related responses.

The FPT Working Group on Prescription Drug Abuse has also prioritized the establishment of PMPs. The group has agreed to work collaboratively with the Monitoring and Surveillance Team, combining both the resources and expertise required to progress in establishing effective PMPs in all jurisdictions.

**Recommendation 7: Establish an ongoing formal program of research on the effectiveness of PMPs, core components and impact, including unintended consequences.**

Monitoring and Surveillance Team Lead, Dr. Beth Sproule, has secured funding through Phase 1 of the CIHR Canadian Research Initiative in Substance Misuse (CRISM) program to develop a PMP Research Network. Phase 1 funding is designed to build teams of academic researchers and service providers around common projects in substance misuse. The funding will be used to develop a team that can support an ongoing formal program of research on PMPs that can feed a continuous cycle of improvement for Canadian programs.

The fulfillment of these Monitoring and Surveillance recommendations will serve as the foundation for all future team implementation activities.

**Enforcement**

**Recommendation 1:** Determine the impact of addressing illicit use, including the diversion and trafficking of prescription drugs, on law enforcement resources for policing and related activities, such as prosecution and corrections, and identify specific recommendations for action to prevent diversion for criminal purposes. Conduct a cost-impact assessment related to prescription drugs on law enforcement resources and public safety.

Public Safety Canada funded a study to determine the cost impact of prescription drugs on the Canadian criminal justice system, including law enforcement, prosecution services and correctional services. The study, launched in early 2013, was completed at the end of March 2014 and is a first step in furthering our understanding of the full impact of illicit prescription drug use on Canada’s
criminal justice system. The results are currently under review and are planned for release by the summer of 2014. These findings will inform future decisions and contribute to a greater understanding of the societal costs of prescription drugs in Canada.

Recommendation 3: Promote the safe storage and disposal of prescription drugs. Review or develop protocols for police, regional public health organizations, local pharmacies and others to implement and evaluate take-back initiatives that aim to encourage the safe storage, distribution, and disposal of narcotics and other controlled drugs, including the risks of sharing or lending prescription drugs. Review the evidence related to and evaluate the impact of take-back initiatives (e.g., awareness, amount of drugs no longer available for diversion, public security outcomes, reduced harms and unintended consequences, if any) Identify, review or develop regulations related to the measurement and disposal of medications returned to pharmacies or other locations.

The Canadian Association of Chiefs of Police (CACP) in partnership with the Canadian Centre on Substance Abuse, Public Safety Canada, various provincial/territorial police associations and local police forces (e.g., Ontario Association of Chiefs of Police, Nova Scotia Chiefs of Police Association, Winnipeg Police Service, Toronto Police Service, Hamilton Police, Rothesay Regional Police) hosted the first Annual National Prescription Drug Drop-Off Day, on Saturday, May 11, 2013 during Police Week 2013. This drug prevention strategy, modeled after the US Drug Enforcement Administration’s National Prescription Drug Take-Back Day, is intended to get unused and expired prescription medication out of people’s homes by providing a safe and convenient means of disposal. Event organizers reported the collection of over two tons of prescription medication during the event.

CACP and Public Safety have agreed to continue this strategy to address the safe disposal of prescription drugs through a renewed commitment to holding annual prescription drug drop off days for the next three to five years. The next date was set for May 10, 2014. The CACP is pursuing funding from Health Canada to establish a part-time program coordinator position to help expand the number of police associations that participate in the event across Canada, with a particular focus on engaging municipal police departments, some of which held their own prescription drug drop off events in 2013. Improvements to the dissemination of promotional materials and reporting of drugs collected are also planned for the next event.

Through funding provided by Alberta Health, CCSA developed a toolkit to evaluate the effectiveness of prescription drug drop-off initiatives. The Enforcement Team provided input on the final product. Use of the evaluation toolkit during future drop-off days will provide evidence of the effectiveness of drug take-back initiatives in preventing illicit use of the prescription drugs and increasing public awareness of the risks that unused prescription drugs can pose.

Recommendation 5: Ensure that death investigations across Canada are conducted in an evidence-informed and consistent manner. Develop and promote the implementation of a death investigation guideline for coroners and medical examiners that includes information on prescription drugs, as well as the impact of these drugs on cause of death or factors associated with cause of death, and that clarifies morphine equivalents.

The Chief Medical Examiner for Nova Scotia has agreed to join the Enforcement Team to lead the development of best practice guidelines for the investigation of prescription drug-related deaths. Provincial/territorial coroners and medical examiners must conduct death investigations according to specific provincial or territorial policies. The development and promotion of best practice guidelines at the national level will be a first step toward achieving investigative and reporting consistency of prescription drug-related deaths across the country. The Enforcement Team plans to engage the Chief Coroners and Medical Examiners of Canada to help develop, review, approve and implement the guidelines.
Legislation and Regulation

Recommendation 1: Review Health Canada’s regulatory and related information requirements throughout the supply chain, from manufacturers and distributors to the healthcare practitioners who prescribe and dispense, including the drug approval process, to examine vulnerabilities in the supply chain, identify information required to exercise levers, work with provinces and territories to access necessary information and strengthen regulations as indicated.

The Legislation and Regulation Team has drafted a letter to Health Canada to address identified areas for improvement in labelling and product monographs (Appendix C). Suggestions include labelling on high potency opioids indicating the potential risk for dependence or addiction when a medication is used as prescribed.

Another letter has been submitted to Health Canada about the department’s review of the Controlled Drugs and Substances Act and the re-scoping of the National Anti-Drug Strategy (NADS) to include prescription drugs (Appendix B). Recommendations in the letter include de-listing high-dose opioid formulations; pre-approval for opioid prescriptions exceeding 200 mg/day; changes to the drug approval process, both generic and branded; and increasing the transparency of clinical trial data. The Legislation and Regulations Team is also reviewing federal regulatory requirements with a view to identifying areas where regulations could be strengthened.

Recommendation 4: Consider implementation of complete lifecycle surveillance as a condition of approval of new and existing branded or unbranded opioids, sedatives and hypnotics, and stimulants to enhance understanding of their potential risks and therapeutic effectiveness.

The Legislation and Regulation Team is developing proposed changes to product surveillance requirements for high-risk medications. Once the proposed list of changes is complete and discussed with the Executive Council, these will also be submitted to Health Canada for consideration.
A National Priority

Evidence from across the country confirms that the harms associated with prescription drugs, including diversion, addiction, overdose and death, remain a significant issue in Canada.

Reports of problematic use show rates increasing in provinces like British Columbia, where 2008 rates of trying prescription pills without a prescription doubled among aboriginal youth grades 7 to 12 since 2004 (11 % to 22%) (Tsuruda, Hoogeveen, Smith, Poon, Saewyc, & the McCreary Centre Society, 2012). The Alberta Youth Experience Survey produced an estimate that 17.2% of middle and high school students reported using prescription drugs without a prescription in the 12 months prior to the survey (Alberta Health Services, 2009). In Ontario, 72% of students who use prescription drugs obtained them from home (Brands, Paglia-Boak, Sproule, Leslie & Adlaf, 2010). Similar rises in rates of individuals seeking help have also been reported. Also in Ontario, admission rates for treatment programs to address prescription opioid addiction have doubled (Fischer, Nakamura, Rush, Rhem, & Urbanoski, 2010). Nova Scotia has experienced a similar influx in demand for treatment. Since 2006, the province has seen a 112% increase in the number of people in withdrawal management for opioid addiction with a noted disproportionate increase among women (161%) compared with men (91%) (C. Davison, personal communication, 2013).

Even more tragic are the opioid-related deaths reported across the country. A 2013 study of the characteristics of opioid-users whose death was related to opioid-toxicity reported that of the 2,330 drug-related deaths in Ontario between 2006 and 2008, over half were attributed in whole or in part to opioids (Madadi, Hildebrandt, Lauwers, & Koren, 2013). In British Columbia, the opioid death rate (2.7/100,000) is similar to motor vehicle crash deaths related to alcohol (2–3/100,000) (Corneil, Elefante, May-Hadford, Goodison, & Harris, 2012).

The full extent of the impact of harms associated with prescription drug use in Canada has not been quantified, but estimates for the United States are in the order of $50 billion, with crime and lost productivity accounting for 94% of these costs.

Over the past year, a significant number of activities to address these harms have been initiated by all levels of government, industry, not-for-profit and community organizations, and care providers. As the second largest consumer of prescription opioids in the world, Canada has good reason to make reducing harms associated with prescription drug use a national priority and to continue to support the work of the First Do No Harm implementation teams.
The Way Forward

With so many activities underway across the country, the momentum behind the First Do No Harm Strategy is building. However, the coordinated work and good will of the members of NAC and the implementation teams must be leveraged as much as possible. Despite limited resources, the teams have managed to move forward and have plans for significant work in the future, as they address the challenges that present themselves and take advantage of opportunities.

Challenges

Resources to support the implementation of the Strategy’s recommendations are limited and progress on the recommendations is affected by this shortage. Initiatives such as conducting or evaluating research to resolve unanswered questions, social marketing campaigns, developing a surveillance system, expanding the availability of existing treatment services, developing prescriber education offerings or expanding prescription drug take-back initiatives are all costly activities that require human as well as financial resources to move forward.

With so many initiatives underway, it is important that these efforts remain coordinated, ensuring that resources are used efficiently, that best practices are shared with all those involved and that existing work occurring in different jurisdictions is leveraged. Mechanisms are required to create the infrastructure to coordinate efforts and exchange information across all stakeholders.

Opportunities

Perhaps the biggest opportunity for the First Do No Harm Strategy is to take advantage of the good will and commitment of the implementation team members and their organizations that continue to take action on the recommendations set out in the Strategy. This group of over 50 volunteers from across the country has remained united in their common goal to address the harms associated with prescription drug use and implement the Strategy’s recommendations.

At the same time governments (federal, provincial, territorial and local) and the media are increasing their attention to the issue and reaching out for the direction and expertise that the Strategy and the implementation teams have provided and continue to provide.

Excellent work is underway across the country as proven by initiatives outlined in this report. By sharing and building upon these initiatives and the momentum they create, a greater collective impact can be made. With the appropriate resources in place, CCSA can effectively continue in its leadership role, as mandated by NAC, to guide and support the implementation of the First Do No Harm Strategy and reach the shared vision of reducing the harms associated with prescription drugs through the recommendations in the First Do No Harm Strategy.

Get Involved

Would you like to be involved in the implementation of the First Do No Harm Strategy? Have you or your organization implemented any changes in your practice or organization that reflect the First Do No Harm Strategy recommendations? Let us know and we can share your experience with others.

For more information, contact pharma@ccsa.ca. A copy of the Strategy document, First Do No Harm: Responding to Canada’s Prescription Drug Crisis, is available from the CCSA www.ccsa.ca.
References


Appendix A: Governance Structure for the First Do No Harm Implementation and Evaluation Phases

Each implementation team has a member who contributes to the evaluation of the strategy by also being a member of Evaluation Team. The two co-leads of each implementation team in addition to the three Strategy co-chairs make up the Executive Council that reports to the National Advisory Council. The Council provides guidance and additional expertise to the implementation of strategy.
Appendix B: Controlled Drugs and Substances Act and National Anti-Drug Strategy Letter

April 7, 2014

Mr. Greg Loyst
Director, Health Policy and Strategic Planning, Health Canada
Room 1605
1st Floor Main Statistics Canada Building
150 Tunney's Pasture Drive
Ottawa ON K1A 0K9

Reference: Controlled Drugs and Substances Act (CDSA) and Re-Scooping of the National Anti-Drug Strategy (NADS) to Include Prescription Drugs

Dear Mr. Loyst,

This letter follows receipt of correspondence dated January 31, 2014 from Mr. Robert Janiro, Director General, Controlled Substances and Tobacco Directorate at Health Canada, in which he requested suggestions regarding gaps or improvements to regulations as part of the Controlled Drugs and Substances Act (CDSA), and the expansion of the scope of the National Anti-Drug Strategy (NADS). We are pleased to provide our comments as the three co-chairs of the First Do No Harm National Advisory Council (NAC) on behalf of the Executive Council. While we will begin by addressing the CDSA and NADS broadly, the main point we wish to make is that we would like to establish an ongoing dialogue with Health Canada's Policy and Strategic Planning Division to discuss the suggested changes to the CDSA in greater detail and based on the principles outlined in the First Do No Harm strategy.

Regarding the CDSA, we recommend that any legislative and regulatory revisions be reviewed to ensure they do not restrict the ability to gain access to controlled substances for the purpose of conducting research. Research helps us better understand the physical and social effects of controlled substances, including both potential harms and therapeutic benefits. It also helps us develop evidence-informed responses to the harms associated with prescription drugs, in order to reduce health, social, and economic impacts on Canadians. As well, to make informed decisions health care practitioners and patients require the best available research evidence.

To that end, researchers, including those working for industry, should be required to provide to Health Canada all data from clinical trials on all pharmaceuticals. Health Canada, in turn, should make this information publicly available.

We would also like to recommend that the NADS consider approaches to substance use as a comprehensive continuum spanning a broad range of interventions. Funding mechanisms that reflect this continuum will support a more integrated, collaborative approach between recipients, rather than promoting divisions between components such as prevention and treatment.

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We would now like to specifically address the CDSA and NADS in the light of First Do No Harm: Responding to Canada’s Prescription Drug Crisis – hereafter referred to as the Strategy – which we were pleased to release in March of 2013. In accordance with Strategy recommendations, below you will find our suggestions in the following key areas: Supply chain security, Monitoring and Surveillance, Education of the public and health providers, and Access to effective treatment.

By way of background, the Strategy is a 10-year plan resulting from comprehensive consultations involving over 30 partners representing the healthcare community, governments, First Nations, the pharmaceutical industry, law enforcement, and people with lived experience and their families. All worked together for almost a year to reach agreement on 58 recommendations, covering prevention, education, treatment, monitoring and surveillance, enforcement, legislation and regulation, evaluation and performance measurement, as well as research. We have attached a copy of the Strategy for your reference and guidance.

Underlying the Strategy is a recognition that prescription medicines, when used appropriately, are an integral part of the toolkit available to the healthcare professional community in particular, and society generally, to treat various ailments. However, certain prescription drugs, such as opioids, sedatives, hypnotics and stimulants, are also associated with the potential for serious harm including addiction, overdose and death.

Given the devastating impact these drugs can have on individuals, families and communities, immediate and sustained collective action to prevent or reduce these harms is essential. We were therefore pleased to see the intent included in the Speech from the Throne to expand the NADS to address prescription drug abuse, followed by a financial commitment of $44.9 million over the next five years in the 2014 Economic Action Plan.

Supply chain security. In terms of legislation and/or regulatory amendments, the Strategy calls for a review of Health Canada’s regulatory and related information requirements throughout the lifecycle of a prescription drug. This review would involve a close examination of the entire supply chain, including: the approval processes; the roles of manufacturers and distributors; healthcare practitioners that prescribe these drugs; as well as those who dispense prescription drugs, and the disposal of unused products. This review would identify vulnerabilities in the supply chain and ascertain information gaps regarding controlled substances.

More specifically, we have identified two potential gaps in the current supply chain that require specific attention. The first involves the ability of home care providers to remove and safely dispose of controlled medications when a patient dies at home. The second relates to the safe and secure disposal of controlled drugs returned to pharmacies. It may be possible for Health Canada to use the existing regulations (e.g., Narcotic Control Regulations Article 43, in the case of the latter gap) to issue policy guidelines that reduce the risk of diversion.
Further, certain codeine pharmaceutical products are exempted from the Regulations to the CDSA making them available for purchase in pharmacies without a prescription. These products can result in harms similar to other opioid products, with no clear rationale for their exemption status. The exempted status should be removed for these products to ensure that the same controls and monitoring are in place as for all other codeine products.

**Monitoring and Surveillance.** In the same vein, consideration should be given to the implementation of a complete lifecycle surveillance system as a condition of approval for new and existing branded or unbranded opioids, sedatives and hypnotics, and stimulants. This would enhance our understanding of their potential risks and therapeutic effectiveness, including the review and development of regulations related to the handling, documenting, and disposal of medications returned to pharmacies or other locations. The review should consider how to allow better information access and sharing between the federal, provincial and territorial jurisdictions. This includes the implementation of prescription monitoring programs in each province and territory and standardizing national surveillance data collection so pan-Canadian comparisons are possible.

Surveillance is also required to identify potential unintended consequences or changes in the regulatory system. Such unintended impacts may include limited access to effective treatments for pain, mental health and addiction.

Furthermore, compliance inspection from federal, provincial and territorial governments should be better coordinated. Priority should be given to measures that would reduce barriers impeding immediate access to, and sharing of, relevant information related to arrests and convictions of possible diverters between law enforcement and regulatory colleges, prescribers and dispensers.

**Patient Education.** To provide accurate and more easily accessible information on prescription drugs and the associated adverse events or harms, the Strategy calls for a review of existing patient brochures, product labels and inserts (including prescriber indication) regarding these medications. It also suggests that auxiliary labels and recommendations for specialist consultation and patient education should be considered. Such revisions should be standardized as needed, and use plain language to ensure comprehension, and thereby prevent or reduce harms associated with using these prescription drugs. Information should also include warnings related to the risks associated with operating a motor vehicle while using these medications.

In this regard, the proposed regulatory changes published in Canada Gazette Part I of June 22, 2013 related to the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Consumption) were a step in the right direction, and should be implemented without further delay.

Product monographs, which form the basis for these brochures, labels and inserts and which have considerable influence over prescribing practices, should be reviewed by a panel of independent experts on a regular basis (i.e., annually or bi-annually). More frequent reviews should occur and relevant...
revisions made in a timely manner if post-market surveillance identifies that safety concerns have arisen that are not reflected in the product monograph. This would ensure that the monographs are accurate, complete and safe. It would also improve the safety of pharmaceutical marketing campaigns, as companies are not allowed to make claims that are inconsistent with the product monograph. As well, these monographs can also inform social marketing campaigns and other public education and health promotion initiatives and resources.

Additionally, patients require accurate information regarding effective non-pharmacological and alternative pharmacological treatments for pain, mental illness, concurrent disorders, and addiction.

**Healthcare provider education.** Healthcare provider education in the fields of pain management, addiction and mental health is currently lacking. This gap contributes to inappropriate prescribing, both excessive prescribing and inappropriate under-prescribing. The lack of access to optimal care contributes to inappropriate use of restricted prescription medications (‘self medication’) by members of the public for their underlying conditions including both pain and mental health disorders. Prescriber and dispenser education as well as pre-certification training, academic detailing, and best practice guidelines should be based on the content of product monographs and updated as required when post-market surveillance or other new evidence indicates the need for revisions. Healthcare provider education at all levels should also include the assessment and treatment of pain, mental health conditions and addiction. Such training is currently very limited and a much of the non-medical use of opioids has been associated with untreated or undertreated pain or mental illness.

**Access to effective treatment.** Avoiding inappropriate use of prescription drugs can be promoted by supporting ready access to optimal care for those experiencing pain and mental illness. When addiction to prescription drugs is identified, ready access to optimal care should be available. Another key strategy recommendation involves a review of the federal regulatory requirements for medication-assisted treatment of substance use disorders (e.g., opioid substitution with methadone or buprenorphine/naloxone) to determine whether and how they impact a patient’s access to treatment should also be part of the CDSA review process. For example, opioid substitution programs are the most effective treatments for prescription opioid addiction, yet barriers exist to these effective approaches. Related to Section 56 of the CDSA, in most provinces, buprenorphine can only be prescribed by physicians with a methadone exemption, and/or for patients in whom methadone is contraindicated. However, many communities lack physicians who are licensed to prescribe methadone, thus limiting patient access to both methadone and buprenorphine. Further, access to appropriate non-pharmacological and culturally-specific treatments for pain, mental illness, and addiction should also be improved and promoted. We recommend that Health Canada review the Section 56 requirement for the use of methadone, and consider whether methadone could be appropriately regulated at the provincial level.

Another aspect of access to treatment relates to people who are involved in the criminal justice system. Patients who are addicted to prescription opioids often get involved in trafficking (usually at a low level) to finance their addiction.
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Effective programs, for example through drug courts, offer treatment as an alternative to a criminal record or jail under specific circumstances (e.g., non-violent offences, no association with a criminal organization, first offense, as well as acceptance of opioid substitution therapy and monitoring). In addition, we have significant concerns that the amendments to the CDSA that came in as part of the Safe Streets and Communities Act will particularly adversely affect aboriginal and other marginalized populations who are addicted to prescription opioids and become involved in trafficking, as is described in the recent report by the BC Provincial Health Officer.  

In summary, our submission should be taken in the context of many months of work and consultation done by the NAC in the development of the First Do No Harm strategy. As mentioned at the beginning of this submission, these proposals are part of 58 recommendations that impact many stakeholders—including, but not limited to, the federal government. It is important to recognize that the solutions necessary to address Canada’s prescription drug crisis do not reside solely with the federal government, but with a vast array of stakeholders, including provincial and territorial jurisdictions, and regulatory bodies like the professional colleges of various healthcare providers. Coordination and collaboration at all levels will be required to ensure healthier and safer individuals, families and communities across Canada.  

We cannot agree with the premise that health care practitioners, such as physicians and nurse practitioners, should assume the responsibility to determine the acceptability, dose and use of marijuana for medical purposes when that obligation clearly rests with others, such as manufacturers and regulators, as stipulated by the CDSA, for any drug legally available for prescribed use in Canada. We recommend that marijuana used for medical purposes require the same evidence and safety standards that apply to pharmaceutical products under the CDSA. We also recommend that alternate methods of authorization to possess, other than requiring physician or nurse practitioner documentation (e.g., a prescription), be explored. Further, there are a number of pharmaceutical cannabinoid medications that are reasonable alternatives to crude marijuana.  

In accordance with the First Do No Harm strategy and to ensure the safety and security of patients, while undertaking a review of the CDSA, Health Canada should examine the evidence regarding the effectiveness of tamper-resistant or abuse-deterrent technologies in reducing the harms associated with drugs with high abuse potential. If such technologies are found to be effective, Health Canada should require the use of them in product formulations, particularly for new products, while still ensuring efficacy for their target indication.

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1 Provincial Health Officer’s Special Report: Health, Crime, and Doing Time  
(http://www.health.gov.bc.ca/pho/pdf/health-crime-2013.pdf)
In conclusion, CCSA has the mandated load in the strategy’s development and implementation, and is therefore committed to improving health outcomes for all Canadians. In order to meet this common objective, we are interested in working with you to establish an ongoing dialogue with Health Canada’s Policy and Strategic Planning Division to discuss the suggested changes to the CDSA in greater detail and based on the principles outlined in the First Do No Harm strategy, in the spirit of cooperation and open discussion and with a view to improving client outcome. In addition, we remain at your disposal should you require additional explanation or context with respect to this submission.

Sincerely,

Michel Perron
Chief Executive Officer
Canadian Centre on Substance Abuse and NAC Co-chair

CC: Dr. Susan Uhan,
College of Physicians and Surgeons of Alberta and NAC Co-chair
Carolyn Davison
Nova Scotia Department of Health and Wellness and NAC Co-chair

Attachment: First Do No Harm: Responding to Canada’s Prescription Drug Crisis
Appendix A: First Do No Harm Executive Council Membership (In Alphabetical Order)

Cameron Bishop, Reckitt Benckiser Pharmaceuticals
Anne Bowby, Ontario Ministry of Health and Long-Term Care
Dr. Norman Buckley, McMaster University
Carolyn Davison, Nova Scotia Department of Health and Wellness
Dr. Brian Emerson, BC Ministry of Health
Dr. Ramm Hering, Direction 180 Clinic
Dr. Maldon Kahan, Women’s College Hospital
Micheline Lavoie, Public Safety Canada
Chief Mark Mander, Kentville Police Services
Dr. David Mock, University of Toronto
Michel Perron, Canadian Centre on Substance Abuse
Dr. Peter Selby, Centre for Addiction and Mental Health
Dr. Beth Spraul, Centre for Addiction and Mental Health
Dr. Susan Ulan, College of Physicians and Surgeons of Alberta
Appendix C: Labelling and Product Monograph Letter

First Do No Harm: Responding to Canada’s Prescription Drug Crisis

March 18, 2014

The Honourable Rona Ambrose, P.C., M.P.
Minister of Health
Brooke Claxton Building, 16th Floor
Turnney’s Pasture
Health Canada
Ottawa, Ontario K1A 0K9

Dear Minister Ambrose,

On behalf of the members of the Legislation and Regulations Implementation Team of the First Do No Harm Strategy to address prescription drug abuse, which was established as an outcome of the recommended national strategy “First Do No Harm: Responding to Canada’s Prescription Drug Crisis”, we are writing to request a change in the process by which Health Canada approves Product Monographs.

Enclosed for your review, please find a critique of the 2009 OxyContin product monograph written by Dr. Mel Kahan, and a letter in response from Kimby Barton, who at the time was interim director of the Bureau of Cardiology, Allergy, and Neurosciences. Ms. Barton stated that Health Canada’s process for approving product monographs is based on the information provided by the manufacturer. Therefore, Health Canada cannot request changes to the monograph based on information supplied by external experts or stakeholders, because the ministry’s purview is regulation rather than clinical practice. However, it is the view of this Committee, that product monographs are, in fact, guides for clinical practice, providing detailed advice for clinicians on drug indications, dosing, and contraindications – subsequently, there should be a requirement by Health Canada for outside input from experts before a product monograph is approved.

The 2009 response from Health Canada also suggests that inaccurate or incomplete product information will not cause harm, because physicians rely on multiple sources for product information. As you know, Minister, product monographs have a significant effect on physician prescribing and clinical decision making. Physicians consider product monographs to be the definitive source of prescribing information, and pharmaceutical marketing and education is based on the information contained in a drug’s product monograph. There is abundant evidence that the OxyContin® product monograph, and Purdue’s OxyContin® marketing and educational campaigns, had a sustained and pernicious influence on physicians’ prescribing practices. In keeping with the national strategy on prescription drugs, “First Do No Harm: Responding to Canada’s Prescription Drug Crisis”, we urge Health Canada to take immediate steps to ensure that this does not happen again with other medications by re-examining the policies & regulations that form the basis for approvals of product monographs in Canada to ensure that information gained post-approval, or for similar newly approved drugs, can be incorporated into the product monograph at the direction of Health Canada. We further note with concern that the product monograph for Hydromorphone Contin® and other opioids contain some of the very same inaccuracies that were in the OxyContin® monograph.
On behalf of the Committee, we suggest that product monographs be reviewed by a panel of independent experts on a regular basis (i.e. annually or bi-annually), especially if the medications are new or if safety concerns have arisen that are not reflected in the product monograph, and that Health Canada be given the authority to require changes to the product monograph based on input from the expert panel. This would ensure that the monographs are accurate, up-to-date, and complete and that they guide safe practice. We believe that it would also improve the safety of pharmaceutical marketing campaigns, as companies are not allowed to make claims that are inconsistent with the monograph. It is our contention that this external review process could be done at little extra expense and without needlessly delaying approvals.

We would appreciate the opportunity to meet with you to discuss this further. Thank you for attention to this matter.

Sincerely,

Dr. Mel Kahan  
Co-Lead, Legislation & Regulation Committee  
First Do No Harm National Advisory Council  
Head of Addiction Medicine,  
Women’s College Hospital

Cameron Bishop  
Co-Lead, Legislation & Regulation Committee  
First Do No Harm National Advisory Council  
Reckitt Benckiser Pharmaceuticals (Canada)

C.C.:

The Honourable Rona Ambrose, P.C., M.P., Minister of Health  
Mr. George De Pont, Deputy Minister of Health  
Ms. Julie Vaux, Chief of Staff, Office of the Minister of Health  
Mr. Barbara Sabourin, Director General, Therapeutic Products Directorate, Health Canada  
Ms. Kimy Barton, Director, Bureau of Cardiology, Allergy & Neurological Sciences, Health Canada  
Mr. Michel Perron, President & CEO, Canadian Centre on Substance Abuse  
Ms. Eve Adams, Parliamentary Secretary to the Minister of Health  
Mr. Ben Lobb, Chair, Standing Committee on Health  
Dr. Fred Fry, Vice-Chair, Standing Committee on Health  
Ms. Libby Davies, Vice-Chair, Standing Committee on Health  
The Honourable Senator Kenneth Ogilvie, Chair, Senate Standing Committee on Social Affairs, Science and Technology  
The Honourable Senator Art Eggleton, Deputy Chair, Senate Standing Committee on Social Affairs, Science and Technology  
Members of the Legislation & Regulation Committee, First Do No Harm National Advisory Council