Minister of Health · Ministre de la Santé

Ottawa, Canada K1A 0K9

MAR 2 6 2015

Dr. Kelvin K. Ogilvie
Chair, Standing Senate Committee on Social Affairs,
Science and Technology
The Senate of Canada
Ottawa, Ontario
K1A 0A4

Dear Dr. Ogilvie:

Pursuant to Rules 12-24(1) and 12-24(3) of the Senate of Canada, I am pleased to respond on behalf of the Government of Canada to the Report of the Standing Senate Committee on Social Affairs, Science and Technology, entitled: *Prescription Pharmaceuticals in Canada: Unintended Consequences*, tabled in the Senate of Canada on October 21, 2014.

I would like to thank the Committee once again for its ongoing work in studying prescription drugs in Canada and, in this case, unintended consequences in the use of these products. I would also like to take this opportunity to thank the Committee for its diligent work, and key role, in moving the *Protecting Canadians from Unsafe Drugs Act* (*Vanessa's Law*) through the legislative process. *Vanessa's Law*, which received Royal Assent in November 2014, will significantly enhance patient safety in Canada.

The Government of Canada agrees in principle with the Committee's recommendations and recognizes the importance of preventing and reducing unintended consequences in the use of prescription drugs. The Committee's efforts are consistent with the Government of Canada's objective of protecting the health and safety of Canadians. This commitment is demonstrated by the increasing number of health-related initiatives such as the expansion of the *National Anti-Drug Strategy* (NADS) to include prescription drug abuse; the launch of Health Canada's Regulatory Transparency and Openness Framework; the implementation of *Vanessa's Law* and the *Plain Language Labelling Initiative;* and, the launch of *Antimicrobial Resistance and Use in*

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Canada: a Federal Framework for Action, all of which will have significant and positive impacts on patient safety in Canada and will contribute to reducing unintended consequences in the use of prescription drugs.

Our response is grouped according to the themes developed by the Committee in its report, namely: 1) Optimize Electronic Health and Prescription Drug Databases; 2) Resolve Cross-jurisdictional Data-Sharing Agreements; 3) Address Prescription Drug Abuse, Misuse and Addiction; 4) Improve Efforts to Address Antibiotic Resistance; 5) Reduce the Exposure of Canadians to Counterfeit and Substandard Drugs; 6) Reduce the Impact of Drug Shortages; 7) Implement Policies Specific to Environmental Concerns Related to Prescription Drugs; and, 8) Reduce the Risks Associated with Consumption of Multiple Prescription Drugs.

Optimize Electronic Health and Prescription Drug Databases

To date, the Government of Canada has invested $2.1 billion in *Canada Health Infoway* (Infoway) to support the implementation across all jurisdictions of Electronic Health Records (EHRs) and related technologies, which includes drug information systems (i.e., prescription drug databases). The focus of this pan-Canadian collaboration has been to develop EHRs first. Infoway reports regularly on their full implementation, including prescription drug dispensing profiles. Progress to date illustrates that, on average, the information from EHR repositories is available for 90% of Canadians; and continued efforts by Infoway and jurisdictions, including on drug dispensing profiles (currently in place for 57% of Canadians), will contribute to achieving full availability of EHR systems. With inroads made on EHRs, the scope of Infoway's funding was expanded in 2010 to include support for jurisdictions to accelerate the implementation of Electronic Medical Records (EMRs) in community-based settings, so that the clinical data they contain can be incorporated in a patient's health history. As a result, the rate of adoption of EMRs in community-based settings, which was 24% in 2007, has increased significantly in recent years up to 77% in 2014. Moreover, part of the federal funding provided to P/Ts for EMR deployment is intended to support the implementation and use of electronic prescribing, as part of efforts to improve clinical value, or meaningful use of the tools. In order to further support uptake, Infoway has also implemented a comprehensive, multi-faceted clinical engagement strategy to promote awareness and encourage use of electronic health tools by healthcare practitioners. This strategy involves a Clinician Education Campaign that has reached about 34,000 clinicians and ten

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networks where clinician leaders have mentored over 10,000 of their peers for technology adoption.

The Canadian Institute for Health Information (CIHI) has made concerted efforts over the past decade that have led to significant improvements in the availability of high-quality, comparable information about prescription drug costs and use, particularly for individuals covered by public drug programs, as documented in the National Prescription Drug Utilization Information System (NPDUIS). By partnering with stakeholders, CIHI has created databases, measurement tools and standards that enable reporting on key aspects of prescription drugs in Canada, such as: drug expenditures, trends in use of drugs, safety and medication errors, potentially inappropriate drug use, polypharmacy and hospitalizations related to adverse drug reactions. While CIHI's current data holdings provide some information on the unintended consequences in the use of prescription drugs, the deployment of electronic records will provide a more complete picture of drug use amongst Canadians.

One of the key remaining gaps stems from the lack of information about health services provided in primary healthcare, where 80% of all healthcare encounters take place. To address this gap, jurisdictions are exploring, with CIHI and Infoway, the need for a minimum set of data standards for EMRs in primary care. Structured data in those systems will facilitate the use of clinical decision-support algorithms such as reminders and alerts (e.g., for contraindications), and the sharing of information across settings for better coordination of care and improved surveillance.

Finally, non-comparable data cannot enable reporting on health system performance goals, support system-level decision-making, nor support research. CIHI will continue to produce analyses on prescription drug use, and will continue to work with Infoway to support the adoption of common data standards.

Resolve Cross-Jurisdictional Data-Sharing Agreements

Health Canada facilitates cross-jurisdictional data sharing and addresses privacy and confidentiality concerns through financial support of CIHI and through the work of its First Nation and Inuit Health Branch FNIHB.

CIHI develops and maintains comprehensive, integrated health information, and works with F/P/T partners and health facilities to improve the breadth and

depth of Canada's health data. CIHI has built and maintains 27 critical pan-Canadian databases that enable jurisdictions to use and compare data. As well, it has produced analyses on health and healthcare in Canada that are relevant, timely and actionable; increased the understanding and use of data through education, reporting tools and strategies; and, developed information standards that allow jurisdictions to understand, compare and use the data effectively.

CIHI utilizes its P/T relationships to access, store, analyze and disseminate key information to partners and stakeholders through NPDUIS. Currently, prescription drug data, specifically for individuals covered by public drug programs, is accessible to P/T officials and healthcare system managers via CIHI's secure data portal. As work continues amongst jurisdictions to accelerate the implementation of EMRs, these electronic health systems provide potential sources of information that could be integrated to enhance data holdings that can be leveraged by clinicians, health systems managers and governments, to improve patient safety.

CIHI also works closely with data partners to ensure access to anonymized health data. For example, it works with the Public Health Agency of Canada (PHAC) on a number of surveillance activities that support health promotion and prevention research and programing. CIHI also partners with Statistics Canada to avoid duplication and ensure value-for-money for Canadians, enhancing the quality and availability of data that informs decisions on health and healthcare. Specifically, CIHI and Statistics Canada are working together to provide researchers outside government access to anonymized data through Statistics Canada's Research Data Centres and through CIHI's data request service. CIHI also works collaboratively with other organizations that are funded in full or in part by the Government of Canada to leverage these organizations' capacities in the collection and analysis of P/T health data, such as the Canadian Patient Safety Institute (CPSI), the Canadian Foundation for Healthcare Improvement (CFHI), the Canadian Agency for Drugs and Technology in Health (CADTH), and the Canadian Institutes of Health Research (CIHR).

For its part, FNIHB works with P/T governments and First Nations and Inuit partners to facilitate greater access to and sharing of anonymized and non-anonymized health data to support better decisions from planning to point of care. Examples include creation of data linkages with Provincial administrative databases, creation of client registries and participation in public health information systems and the development of electronic medical records.

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Address Prescription Drug Abuse, Misuse and Addiction

The Government of Canada recognizes that prescription drug abuse (PDA) is a critical public health and safety issue that is having devastating impacts on individuals, families and communities across Canada. As announced in the 2013 *Speech from the Throne* and *Economic Action Plan 2014*, the Government of Canada has committed to expanding the scope of its NADS to address PDA. Over the next five years, the Government of Canada will invest over $44M to advance work in a number of priority areas that have been highlighted in the Committee's report, including: educating Canadian consumers on the safe use, storage and disposal of prescription drugs; enhancing PDA research, and community and stakeholder PDA prevention and treatment initiatives; enhancing prevention and treatment services in First Nation Communities; increasing inspections to minimize the diversion of prescription drugs; and, building surveillance data to track and monitor PDA in Canada. Health Canada will continue to report annually to Canadians on the expansion of the NADS, including efforts to tackle PDA as part of the department's Report on Plans and Priorities and Departmental Performance Reports.

As highlighted in the Committee's report, the Government of Canada plays an important role in helping to combat PDA through its regulatory oversight of the drug supply chain. In Canada, the oversight of prescription drugs with abuse, misuse and addiction potential, such as opioids, involves the *Food and Drugs Act* (FDA) and the *Controlled Drugs and Substances Act* (CDSA). This legislative framework balances access to controlled substances for legitimate medical, scientific or industrial purposes with minimizing the risk of diversion to illicit markets or uses.

The Government of Canada provides Canadians and their healthcare providers with the information they require to make informed decisions about the use of drugs with high addiction potential. Specifically, prescription drugs approved for sale in Canada have a Product Monograph (PM) that outlines information regarding the safe and effective use of the drug and that includes information such as contraindications, warnings, precautions, adverse reactions, drug interactions, and symptoms and treatment of an overdose. As well, the potential for dependence, tolerance, misuse, and abuse are all currently included in all PMs for opioid drug products.

The PM also has information targeted to the consumer, which includes warnings regarding the potential risks associated with a drug under the

recommended conditions of use. As an enhanced safeguard, the PMs of the more recently approved opioid analgesics have also been updated to include a section called "Patient Counselling Information". This section identifies for the physician the most serious safety issues that Health Canada feels should be communicated to the patient. Warnings regarding the potential for dependence, tolerance, overdose and abuse are highlighted in this section.

In August 2014, Health Canada completed class-wide label changes for all controlled release opioid drugs, to enhance their safe prescribing and use. The PM changes included a restriction in the indication for use as well as standardized wording, which more clearly outlines the risks and safety concerns associated with high dose controlled-release opioids, and encourages more appropriate patient selection and monitoring. Changes implemented to the indications for controlled-release opioid drugs removed opioid use for "moderate" pain. The new label clarifies that these drugs should be used for the management of pain severe enough to require daily, continuous, long-term opioid treatment that is opioid-responsive, and for which alternative treatment options are inadequate. In addition, Health Canada is implementing the *Plain Language Labelling Initiative* so that health product labels are clear, accurate and easier to understand.

Health Canada is committed to being transparent and open in its work and in the information that it provides to Canadians. As such, in April 2014, I was pleased to launch the Regulatory Transparency and Openness Framework which lays out concrete deliverables to improve access to timely, useful and relevant health and safety information. Recent achievements under the Framework include; the posting on Health Canada's website of Good Manufacturing Practices inspection summary reports for drug establishments with non-compliant ratings, the launch of the Drugs and Health Products Register- a new web tool designed to provide easy access to information on medicines and vaccines, and the posting of summaries of drug safety reviews.

As part of our ongoing commitment to being a modern and effective regulator, Health Canada is regularly examining its legislative and regulatory frameworks with a view to identifying areas for improvement, and to take advantage of new and emerging innovations in the pharmaceutical sector. A recent and significant example is the passage/Royal Assent of *Vanessa's Law*, which will improve Health Canada's ability to collect post-market safety information, and take appropriate action when a serious risk to health is identified, including the power to require label changes/package modifications or recalls.

As highlighted by the Committee's report, several drug manufacturers are in the process of developing new formulations of opioids, designed to resist a number of common tampering methods and potentially provide barriers to abuse. While the science around tamper-resistance continues to evolve, the Government of Canada is encouraged by these efforts, and agrees that tamper-resistant technologies have a role to play in a comprehensive approach to tackling PDA. This is why, in June 2014, Health Canada published a Notice to Interested Parties in the *Canada Gazette* inviting stakeholders to provide feedback on a regulatory proposal under the CDSA to require that drugs at high risk for abuse, like controlled-release oxycodone, have tamper-resistant qualities before they are authorized for distribution in Canada. Health Canada has also released a draft guidance document, entitled: Tamper-Resistant Formulations of Opioid Drug Product Submissions, aimed at providing direction to companies interested in advancing tamper-resistant formulations of prescription drugs. The Department will continue to consult with industry and P/Ts as the Government of Canada moves forward with the development of the proposed tamper-resistant regulations.

The Committee has also recognized that prevention, prescriber education, and collaboration among levels of government and stakeholders are essential elements in addressing PDA. The Government of Canada agrees and will continue to work with its partners to increase awareness about the risks associated with PDA, and increase knowledge about how to properly and securely store, monitor and dispose of prescription drugs.

A segment of the current NADS television campaign focuses on PDA; targeting youth 13 to 15 years of age and their parents. Following this, Health Canada will launch a $6.9M/five-year national campaign to increase awareness about the harms and risks associated with PDA. The campaign will feature traditional (i.e., radio, print) and digital advertising, as well as public outreach to educate people on the harms of PDA and on the importance of safely storing, monitoring and discarding prescription drugs, in order to prevent diversion and misuse. At the same time, the Government of Canada is working with the Canadian Association of Chiefs of Police and the Partnership for a Drug Free Canada to encourage people to bring back their unused drugs to pharmacies or local drop off programs. An annual National Drop-Off Day event was held in hundreds communities across the country on May 10, 2013 and 2014. Last year, over 1.5 tons of unused drugs were returned.

Health Canada's Anti-Drug Strategy Initiatives Fund also provides funding to support a variety of recipients in delivering health promotion and prevention projects that facilitate the development of national, provincial, territorial and local/community-based solutions to drug use, and promote public awareness of substance abuse issues. To date, 35 projects have already been expanded to include a focus on the dangers associated with the abuse of prescription drugs.

Health Canada is also working with P/T partners to facilitate the development and sharing of best practices in prescribing prescription drugs. F/P/T Ministers of Health met in October, 2014, and agreed on a number of actions to address PDA. These included a commitment to working with all regulatory colleges across the country to improve prescribing practices through, for example, enhancements to standards of practice as well as strengthening monitoring and enforcements measures. F/P/T officials are also engaging with health professional colleges to determine potential gaps in prescriber education and training and the best ways to address them. Recognizing the important role of pharmacists, F/P/T officials will also consult with the pharmacy community to strengthen knowledge and practices to address PDA. In support of these efforts, the Government of Canada has issued a targeted call for proposals to support the development of prescriber education tools and mechanisms.

The Government of Canada will continue to play an important leadership role in supporting pan-Canadian data collection and reporting efforts with respect to PDA. In September, 2014, F/P/T Health Ministers committed to collaborating on reporting, surveillance and data in order to strengthen the national response to PDA. Ministers agreed to establish a Prescription Monitoring Program (PMP) network and to build the foundation for a national surveillance plan through the development of a national surveillance framework. PMPs operate in some, but not all, P/Ts; they monitor trends in prescribing and help to identify patients receiving prescriptions from more than one physician. Health Canada's Non-Insured Health Benefits Program (NIHB) Program also has a PMP that closely monitors utilization profiles of clients at high risk of misusing certain drugs such as opioids, stimulants and sedatives. The national PMP network, which is supported by Health Canada, has representatives from all jurisdictions and will engage with key national regulatory authorities and other experts. With appropriate privacy safeguards in place, the PMP network will facilitate the sharing of information and best practices across jurisdictions and help to inform the development of PMPs in

P/Ts that do not already have them. A longer term goal will be to look at opportunities to standardize data collection and areas for interoperability/data-sharing.

Furthermore, the Government of Canada will continue to invest in research related to emerging substance abuse issues through the Canadian Research Initiative in Substance Misuse (CRISM). Launched in 2014, CRISM, is jointly funded by CIHR and NADS, and is comprised of four multi-disciplinary teams of academic researchers and health care service providers from across the country. CRISM seeks to support research on existing and emerging substance misuse issues in Canada, including prescription drug abuse.

As highlighted by the Committee, CIHI is also well positioned to undertake data collection and public reporting activities related to PDA. With an additional $4.28M funding support from the Government of Canada over the next five years, CIHI will engage with P/Ts and stakeholders to create data standards and indicators to improve the availability of comprehensive, comparable pan-Canadian data and information on PDA. More specifically, CIHI will improve the quality and quantity of comparable PDA data; and support all jurisdictions' ability to reliably detect and swiftly report on trends and issues of concern. This work will entail leveraging current capacity and continuing to develop the capacity of EMRs and EHRs.

As noted in the Committee's report, while the abuse of prescription drugs impacts all segments of our society, it has had a particularly heavy burden on some First Nations communities across Canada. The expansion of NADS to include PDA also involves enhanced prevention and treatment services in First Nations communities. These resources are being used to build and enhance existing services and community capacity to address PDA consistent with *Honouring Our Strengths: A Renewed Framework to Address Substance Use Issues among First Nations People in Canada.*

The Committee's report also recommended that Health Canada's NIHB for First Nations and Inuit review the program's drug formulary, with a view to encouraging the use of non-opioid alternatives, wherever appropriate. Health Canada regularly reviews its Drug Benefit List (DBL) for drugs that may lead to increased abuse or diversion. This review evaluates the risk to the patient compared with the potential benefits of using the drug and may result in a listing status change. For instance, in February 2012, NIHB removed CR oxycodone (OxyContin) from its DBL. Subsequently OxyNeo (tamper resistant

oxycodone CR) was introduced to the Canadian market and is covered by the NIHB Program in some circumstances. Since this measure was implemented the number of First Nation and Inuit clients receiving long acting opioids has declined by 10%. NIHB will continue to implement listing changes to increase access to non-opioid pain treatment options.

Consistent with the Committee's report, the NIHB has also completed an analysis of the current "limited use" status of Suboxone. In February 2014, the NIHB Drug and Therapeutics Advisory Committee (DTAC), comprised of qualified health professionals who bring impartial and practical expert medical and pharmaceutical advice to the NIHB Program to promote effective and safe use of drugs, recommended that Suboxone remain as a limited use benefit; however, the committee also recommended that coverage criteria be extended to include coverage for patients with a lack of access to methadone. The new criteria came into effect September 15, 2014, and allow access to Suboxone for a larger number of patients across all jurisdictions. The new criteria also align coverage for Suboxone with methadone/Methadose under the NIHB Program. The Program will continue to provide physicians with the choice of treating opioid addiction with the drug that best suits the needs of their patients.

Improve Efforts to Address Antibiotic Resistance

The Government of Canada recognizes that antimicrobial resistance (AMR) is a growing public health concern and that addressing this issue is a shared responsibility in Canada. As such, in October 2014, the Government of Canada published a document, entitled: *Antimicrobial Resistance and Use in Canada: a Federal Framework for Action*, which represents the actions of five key federal departments and agencies in the area of AMR: the Public Health Agency of Canada (PHAC), Health Canada, the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC), and CIHR. The Federal Framework, which maps out a coordinated, collaborative federal approach to responding to the threat of AMR, focuses on three pillars, namely: Surveillance (detecting and monitoring trends and threats in order to inform strategies to reduce the risks and impacts of AMR), Stewardship (conserving the effectiveness of existing treatments through infection prevention and control guidelines, education and awareness, regulations, and oversight) and Innovation (creating new solutions to counteract loss in antimicrobial effectiveness through research and development). As part of these efforts, the Government of Canada has laid a foundation for action from all sectors and will bring together P/Ts, and human and animal health stakeholders, to

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determine opportunities to better reduce the threat of AMR in Canada and to develop a pan-Canadian approach.

Specifically, to implement the Federal Framework, PHAC is leading the development of the *Federal Framework Action Plan*. The Action Plan has been developed in concert with Health Portfolio partners and AAFC, and is expected to be published in Spring 2015. The Government of Canada is committed to leading on activities to prevent, limit, and control the emergence and spread of AMR, and this Action Plan builds on the strategic areas of focus and priority action items outlined in the Federal Framework by identifying concrete steps that will be undertaken by PHAC, Health Canada, CFIA, AAFC and CIHR. That being said, the Action Plan is only the first of a series of actions. It is intended to outline initial efforts to address AMR, which focus on ensuring that all partners and stakeholders are informed and engaged so that they can move forward together with a united objective. The Action Plan will be updated regularly both to demonstrate the progress being made, and to continue to identify new initiatives being undertaken as they move forward. Building on the Action Plan, the Government of Canada is also engaging P/Ts via the Public Health Network Council (PHN) and other P/T tables to develop a national approach to AMR across sectors. Recognizing the important role in health delivery, regulations and education that P/Ts play, and in response to calls for cross-sectorial engagement of all stakeholders in human health and agri-food sectors, a series of consultations will be undertaken to take stock of existing practices relating to antimicrobial use, identify best practices for responsible antimicrobial use, and explore how to best leverage existing education opportunities.

Also in October 2014, PHAC established the External Advisory Group on AMR (EAGAR) to discuss comprehensive strategies to minimize risks in Canada. The EAGAR is comprised of representative expert stakeholders from industry and academia. The Advisory Group provides scientific and medical advice to PHAC while also providing a unique opportunity to leverage existing expertise to strengthen current networks on AMR, develop new opportunities for engagement and more directly impact outcomes of these activities in a comprehensive manner. Furthermore, in November 2014, PHAC launched a pilot AMR awareness campaign featuring messages related to responsible antimicrobial use, as well as infection prevention and control, for healthcare professionals and parents. PHAC will evaluate the effectiveness of the messaging used during the 2014 awareness campaign to inform a 2015 campaign and future public awareness and education activities for the general public, and health professionals working in community, hospital and long-term

care settings. In Spring 2015, PHAC will also lead, with support from HC, CFIA, and AAFC, the convening of a Ministerial Roundtable on AMR, with the focus of discussion to be Stewardship. This will serve as a launch pad for further work for the Government of Canada on AMR and antimicrobial use stewardship.

Furthermore, to enable a more complete national picture of AMR and antimicrobial use in human, animal and food systems in Canada, the Canadian Antimicrobial Resistance Surveillance System (CARSS) will be created. CARSS will build on existing PHAC surveillance systems and integrate available antimicrobial resistance data, clearly articulate and track antimicrobial resistance at a national level, and expand surveillance activities at the hospital and community level. The expansion of community-based surveillance will address a gap in the understanding of antimicrobial resistance and use where Canadians live. Coordination of surveillance information through CARSS will support timely decision-making and intervention at the national level to further protect the health of Canadians. CARSS will also inform the global response to antimicrobial resistance through the World Health Organization. As well, CFIA, AAFC, Health Canada, and PHAC continue to collaborate in providing surveillance information on antimicrobial resistance in animal agriculture. Moving forward this work will be strengthened and linked to CARSS.

Canada also co-sponsored the resolution on AMR at the 67th World Health Assembly in May 2014, and PHAC is participating in the development of the World Health Organization Global Action Plan to be presented to the World Health Assembly in May 2015. For example, PHAC is working with its federal government colleagues at the World Organisation for Animal Health (OIE) to provide expertise to the OIE on the development of data standards on animal antimicrobial use to support international data gathering and analysis. Canada is a leading country on the Global Health Security Agenda (GHSA)'s AMR Action Package.

For its part, as per the April 2014, Notice to Stakeholders, Health Canada is working closely with the CFIA and other stakeholders on approaches to increasing veterinary oversight for medically-important antimicrobial drugs used in medicated feeds and those that are administered through drinking water, while maintaining appropriate access for needed therapeutic uses. As well, drug companies with medically-important antimicrobial veterinary drugs with growth promotion claims have been notified of the upcoming removal of these claims, and meetings on how and when to proceed are underway.

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New diagnostic tools are in development to provide doctors and veterinarians with the point-of-care information they need to accurately diagnose an infection and to promote appropriate prescription of antimicrobials. Innovative vaccines under development are being prioritized to address some of the most significant threats posed by antimicrobial resistance through a Canadian Action Plan on Vaccine Research, Innovation and Development. As well, PHAC and CIHR are building upon previous collaborative efforts in the establishment of the Canadian Immunization Research Network (CIRN). The national network is composed of key vaccine researchers who develop and test methodologies related to the evaluation of vaccines as they pertain to safety, immunogenicity and effectiveness, and program implementation and evaluation.

In addition, under the *Growing Forward 2* policy framework, money is made available to support industry-led and/or internal research aimed at identifying alternatives to antibiotics or their prudent use in livestock production.

The Government of Canada continues to support, through CIHR, domestic health research and innovation while collaborating with international partners to contribute to global research efforts on AMR, antimicrobial use, novel therapies and alternatives. CIHR has identified antibiotic resistance and alternatives to antibiotics as research priorities since its inception in 2000. As well, in its 2013-2018 Strategic Plan, CIHR's Institute of Infection and Immunity highlights promoting the development and commercialization of new products and strategies in the field of AMR. This includes not only antibiotic development, but also diagnostic and alternative treatments to counteract resistance.

Research is underway to better understand the nature of AMR, investigate novel therapies, identify alternatives to antimicrobials, develop diagnostic tools, and discover new ways of using existing antimicrobials. Specifically, the Government of Canada is supporting the Canada/United Kingdom (UK) Partnership on Antibiotic Resistance; a collaboration between CIHR and the UK's Medical Research Council (MRC). Through a joint Canada-UK investment of over $7 million over four years, research teams are working to find new targets for antibacterial drugs and new ways to block resistance.

Canada co-leads the first transnational call of the European Union's Joint Programming Initiative on Antimicrobial Resistance, which supports research on novel strategies for overcoming AMR. Funding for this initiative will be expanded for research clusters that bring industry and government

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researchers together. In particular, with vaccine development, rapid diagnostics, and the discovery of alternatives to antimicrobials, the usefulness of the treatments we already have can be sustained and conserved to protect those Canadians at most risk. There is also ongoing research on the prevention of AMR, how to limit its spread and transmission, and how to educate patients on the proper use of antibiotics.

In addition to promoting research into developing new antibiotics, the Government of Canada is also supporting research in other areas targeting AMR such as blocking resistance, optimizing drug dosage and delivery, and discovering new therapies to overcome AMR and restore susceptibility to conventional antibiotics. These alternatives are critical as resistance is rapidly acquired when new antibacterial products do make it to the market.

Reduce the Exposure of Canadians to Counterfeit and Substandard Drugs

The Canadian drug supply chain is complex and globalized. It is made up of a broad network of regulated parties that distribute, fabricate, import, process, package/label, or wholesale drugs. These parties are responsible for complying with the FDA and its Regulations which require that their products are safe, efficacious and of high quality.

Health Canada uses a collection of regulatory compliance and enforcement tools to monitor and verify that regulated parties comply with these legislative and regulatory requirements, which reinforces the integrity of the drug supply chain. Specifically, the Department identifies potential non-compliance through various channels, including consumer or industry complaints; referrals from other federal or provincial regulatory agencies; international regulatory partners; or, through Health Canada's compliance monitoring activities, which include inspections, market surveys and a product sampling program. The primary objective of Health Canada's compliance and enforcement approach is to protect the health and safety of Canadians. Incidents of non-compliance are prioritised and action is taken based on the risk they may pose to health and safety of Canadians.

Health Canada works closely with the Canada Border Services Agency (CBSA) to verify that imported drugs comply with Canadian import requirements. Specifically, the CBSA may refer suspected non-compliant drugs to Health Canada to undergo an admissibility determination for entry into Canada. Drugs that are deemed by Health Canada to be non-compliant

are recommended for refusal of entry into Canada to the CBSA. Alternatively, the CBSA can refuse entry of a drug, without Health Canada consultation, on the basis of non-compliance with the applicable regulations.

All foreign sites manufacturing drugs destined to the Canadian market undergo an on-site, physical examination by Health Canada or a trusted partner authority. Health Canada leverages its relationships with trusted regulatory partners to assure the quality of the manufacture of drug products imported for sale in Canada from foreign sites. The assessment of Good Manufacturing Practices (GMP) evidence can be either through the onsite inspections of the foreign sites, when deemed necessary, or through the review of information from inspections conducted by mutually recognized regulatory agencies or from Pharmaceutical Inspection Convention/Cooperation Scheme (PIC/S) partners.

Over the last decade, the size and complexity of the global supply chain has significantly increased. As a result, and similar to other trusted partner authorities, Health Canada is currently moving its Foreign Site Good Manufacturing Practices (GMP) Compliance Assessment program to a more risk-based approach where a site risk profile will be assigned to each foreign site. The latter will take into consideration the location of foreign sites, product risk, type and origin of GMP evidence, and compliance history. This approach will enable Health Canada to identify foreign sites that represent a higher risk to health for Canadians and take appropriate compliance and enforcement actions. This is expected to result in an increased number of foreign on-site inspections in comparison to previous years.

Health Canada is actively monitoring the integrity of the supply chain by identifying substandard drugs in the supply chain or preventing their entry into it, whether they are manufactured domestically or imported. In November 2013, new regulatory amendments extending licensing and GMP requirements to the manufacture of active pharmaceutical ingredients (API) came into force. The phased implementation of these amendments will lead to an increased quality and safety of drugs for Canadian consumers by further strengthening the drug supply chain in Canada. This is achieved by extending quality controls further upstream in the supply chain as well as enabling Health Canada to verify that products are sourced from or through licensed establishments producing APIs. Canadian regulations for finished product testing state that each batch (also called lot) of a finished dosage form of a drug shall be tested against the approved specifications for that drug prior to its release on the Canadian market whether it is produced domestically or at a

foreign site. Foreign sites performing those tests are assessed for GMP compliance based on the results of inspections conducted by our trusted partner authorities or on-site inspections conducted by Canadian Inspectors.

The Committee raised concerns relating to the sale of unapproved medicines by Internet pharmacies. Health Canada shares these concerns. Internet pharmacies conducting licensable activities, such as fabricating, packaging/labelling, distributing or wholesaling of drugs in Canada, must hold a valid Establishment Licence for those activities and are subject to regular inspections. When Health Canada identifies potential incidents of non-compliance, such as the lack of market authorization for a drug, it performs compliance verification and takes appropriate and proportional actions to mitigate risks to health.

Compliance is normally achieved through a cooperative approach between Health Canada and the regulated party. However, a number of compliance and enforcement options are available if necessary, when the regulated party is unable or unwilling to correct non-compliance, including, for example, on-site visits, product seizures or public advisories. In addition, powers available under the Criminal Code may be used by Health Canada to investigate, which could potentially lead to prosecution by the Public Prosecution Service of Canada (PPSC), under the offence sections of the FDA.

The passage of *Vanessa's Law* strengthens the Government of Canada's enforcement tools including recall powers to remove unsafe drugs; penalties for unsafe drugs, including new fines of up to $5 million per day instead of the previous $5,000; and, discretion for the courts to impose stronger fines if violations were caused intentionally.

Health Canada works collaboratively with provincial Colleges of Pharmacy, the Royal Canadian Mounted Police (RCMP), the CBSA and international counterparts to address risks relating to the sale of unapproved drugs by Internet pharmacies operating in Canada. In these cases, Health Canada plays a key role, specific to its regulatory function of compliance and enforcement.

To promote public awareness of the issue of purchasing drugs online, Health Canada has an educational document posted on its website entitled "*It's Your Health – Buying Drugs over the Internet*" explaining the risks of purchasing drugs online. In addition, over the past four years, Health Canada has proactively issued numerous public communications to Canadians regarding

the risks of buying drugs online and has worked in cooperation with the RCMP to raise awareness and take action on counterfeit drugs.

As part of strengthening the supply chain, Health Canada recognizes the importance of enabling consumers, health-care professionals, and retailers to make more informed decisions about the drugs they buy, prescribe, and sell. As part of *Health Canada's Regulatory Transparency and Openness Framework*, a number of initiatives are underway to empower Canadians by making more data and information available than ever before. Information has been made available to Canadians regarding GMP inspections of Canadian facilities and Health Canada is looking at ways to make even more information available regarding Health Canada's compliance and enforcement activities.

Health Canada continues to collaborate with various other federal departments and regulatory agencies, such as the U.S. Food and Drug Administration, to prevent, detect and deter non-compliant drugs from entering the country. This is achieved by developing intelligence capacity related to specific incidents, detection methods, lessons learned, and laboratory techniques both domestically and globally to supply program areas with information to enable strategic monitoring, investigations, and laboratory analysis. Specifically, Health Canada works with the CBSA and RCMP to build and reinforce a secure supply chain. The import and sale of counterfeit drugs is addressed by enforcing the *Criminal Code* and prohibitions under the FDA and its Regulations, and through the new *Combating Counterfeit Products Act,* which came into force on January 1, 2015. This new legislation amended the *Copyright Act*, *Trade-marks Act* and the *Customs Act* to provide for the implementation of new border measures that enables the CBSA to detain commercial shipments of suspected counterfeit or pirated goods and share certain information about those shipments with registered rights holders (RH) to allow them to seek remedy in civil court. The CBSA, the RCMP and Health Canada will continue to apply sound investigative and enforcement practices when applying the measures in this Act to protect the safety, security and prosperity of Canadians. When incidents of suspected counterfeit drugs are referred to the RCMP for investigation, Health Canada plays a supporting role in providing scientific and regulatory expertise and laboratory analysis to facilitate an investigation.

Health Canada also recognizes the importance of collaborating with international regulatory partners to address counterfeit drugs. The Department participates in several international fora with the goal of coordinating a global response to counterfeit drugs. In 2013, Canada

presented at the United Nations Office on Drugs and Crimes' Commission of Narcotic Drugs session, Resolution 56/8 entitled "Promoting initiatives for the safe, secure and appropriate return for disposal of prescription drugs, in particular those containing narcotic drugs and psychotropic substances under international control." Additionally, Mutual Legal Assistance Treaties and Memoranda of Understanding with foreign law enforcement agencies assist with cross-border criminal investigations into counterfeit drugs.

Health Canada looks for new and innovative ways to help conduct its regulatory activities, such as the use of the CD-3 Counterfeit Detection device at the border. Health Canada is currently in the process of evaluating, via a Proof of Concept study, whether the CD-3 Counterfeit Detection device can cost-effectively support compliance and enforcement efforts at the border. While the field evaluation has recently been completed, the results of the Proof of Concept are not yet finalized. The findings and recommendations of the Proof of Concept will be finalized in 2015.

Reduce the Impact of Drug Shortages

The Government of Canada recognizes that drug shortages are a complex, global problem, which requires that key stakeholders be involved, and that they each fulfill their distinct roles and responsibilities in order to advance the communication, mitigation and prevention of shortages. To this end, the Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) enables all levels of government and key stakeholders from across the drug supply and healthcare systems to work towards a rigorous and coordinated approach to drug shortages.

As reflected in the *MSSC Protocol for the Notification and Communication of Drug Shortages*, the timely, comprehensive, reliable sharing of pertinent information is essential for all stakeholders; especially for healthcare practitioners and their patients, to enable them to make informed decisions for their health and well-being. With this in mind, guidance developed by the MSSC, including the Protocol and the *MSSC Multi-Stakeholder Toolkit*, require that manufacturers provide information on therapeutic alternatives, when posting information on actual shortages. As well, Health Canada will continue to encourage P/Ts and the providers of federal drug plans to consider the availability and need of therapeutic alternatives.

As noted, the Government of Canada understands the importance of providing patients, and those that care for them, with the information they need to make informed decisions about their health. On February 10, 2015, I announced

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that the Government of Canada is advancing regulations that will require manufacturers to publicly report drug shortages, which will provide increased information to Canadians in a more timely, comprehensive and reliable manner.

As an additional measure to promote advance drug shortage reporting from industry, the Government of Canada has implemented a Public Notification Register for Drug Shortages that lists all of the companies that have committed to providing voluntary public notification on www.drugshortages.ca, and includes public letters to companies that fail to do so. Health Canada has publically issued two of these letters to date.

In addition to moving forward with mandatory drug shortage notification, the Government of Canada will work collaboratively with members of the MSSC to advance best practices in contracting and procurement, address the underlying causes of drug shortages and advance prevention strategies to reduce their occurrence.

Implement Policies Specific to Environmental Concerns Related to Prescription Drugs

The Government of Canada shares the Committee's concerns regarding potential environmental impacts related to the use of prescription drugs. In 2006, the Government of Canada launched the Chemicals Management Plan (CMP) to further enhance its role in protecting Canadians and their environment from exposure to harmful chemicals. Under the CMP, Environment Canada and Health Canada jointly assess environmental and human health risks posed by chemical substances, including prescription drugs, and develop and implement measures to prevent or manage those risks. Specifically, Health Canada has developed a regulatory framework proposal for new medicinal ingredients in human and veterinary drugs, which takes into account the special characteristics and use patterns of drugs and which, along with more robust data requirements, will result in a better assessment of the potential risk to the Canadian environment. The proposed framework is consistent with the approach taken in Europe for the assessment of the environmental effects of prescription drugs.

As mandated under the CMP, Health Canada has also been carrying out research on existing legislation and non-regulatory initiatives (NRI) that could mitigate the release into the environment of substances contained in products regulated under the FDA, such as prescription drugs. NRI are important tools

that contribute to minimizing environmental risks posed by improperly stored and discarded products without having to rely on regulatory tools. To date, the research has revealed four main themes as potential areas for improvement using NRI, namely: education and guidance; take-back programs; logos and labelling; and, uniform definitions.

Health Canada has implemented the First Nations Food, Nutrition and Environment Study (FNFNES), which is a cross-Canada sampling program for prescription drugs in the surface waters of First Nations communities south of the 60th parallel. To date, the FNFNES has identified 42 prescription drugs to be monitored in First Nations communities and its results on prescription drugs in water are publicly released through regional reports.

For its part, Environment Canada conducts environmental surveillance for substances and classes of substances that it has determined to be a priority. This includes monitoring and surveillance activities to support the evaluation of prescription drugs. On an annual basis Health Canada reviews and updates its priorities for the environmental monitoring and surveillance of prescription drugs and shares them with Environment Canada. Over the years a broad range of prescription drugs has been monitored in surface water and wastewater. Based on the results from initial surveys, subsequent studies on the occurrence and fate of prescription drugs may focus on selected compounds that are present at higher levels and/or may pose a greater risk in the environment. The scientific data produced by Environment Canada is shared within the CMP program, and is made publicly available through scientific articles and risk assessments. Environment Canada and Health Canada will continue to work within the CMP framework to ensure that monitoring activities for prescription drugs are targeted and meet program needs.

Reduce the Risks Associated with Consumption of Multiple Prescription Drugs

The Government of Canada recognizes that overmedication is a pressing patient safety concern and that additional training and continuing education of healthcare professionals could reduce the incidence of consumption of multiple prescription drugs. That being said, the delivery of healthcare services, including the training and education of healthcare professionals, rest with P/Ts and health professional colleges.

In specific situations, Health Canada works with P/Ts on issues surrounding the training and continuing education of healthcare professionals. For

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example, as noted in the section on PDA, Health Canada is working with P/T partners to facilitate the development and sharing of best practices in prescribing prescription drugs. In support of these efforts, the Government of Canada has issued a targeted call for proposals to develop new evidence-based guidelines for drugs at high risk of abuse, where guidelines do not exist. The Government of Canada will also support the development of prescriber education tools and mechanisms to improve the uptake, monitoring and evaluation of existing guidelines. F/P/T officials are also engaging with health professional colleges to determine potential gaps in prescriber education and training and the best ways to address them.

Health Canada has been working on specific initiatives, such as the *Plain Language Labelling Initiative* and *Vanessa's Law,* which could reduce overmedication and will improve overall patient safety. These initiatives are intended to contribute to reducing the risks associated with the consumption of multiple prescription drugs by increasing the information available to healthcare professionals and Canadian patients, to allow them to make informed decisions.

I trust this response demonstrates the Government of Canada's commitment to improving drug safety, including reducing the risks to Canadians of unintended consequences in the use of prescription drugs. We will continue to work closely with other government departments, stakeholders and jurisdictions involved in addressing the issues raised by the Committee.

Yours sincerely,

Rona Ambrose

Hon. Rona Ambrose, P.C., M.P.

Attachments – Appendix – List of Recommendations

Appendix to the Letter

List of Recommendations
Senate Standing Committee Report entitled:
Prescription Pharmaceuticals in Canada: Unintended Consequences

Theme 1: Optimize Electronic Health and Prescription Drug Databases

1. The committee therefore recommends that the Minister of Health —in conjunction with recommendations 9, 10 and 11 of the committee's *Post-Approval Monitoring Report* regarding electronic medical records, electronic health records and provincial drug information systems, and with recommendation 1 of the committee's *Off-label Report* regarding electronic prescribing—take an active role in working with the provincial and territorial governments to:
   - Establish targets for the implementation of each electronic health and prescription drug system;
   - Promote the use and accelerate uptake of these databases by health professionals through an aggressive targeted awareness campaign; and,
   - Report publicly on the progress of implementing electronic health and prescription drug systems.

Theme 2: Resolve Cross-jurisdictional Data-Sharing Agreements

2. The committee therefore recommends that the Minister of Health urge provincial and territorial Ministers of Health to ensure access to anonymized health data by those agencies, institutes and researchers whose responsibilities require such access.

Theme 3: Address Prescription Drug Abuse, Misuse and Addiction

3. The committee therefore recommends that Health Canada post regular updates on its website regarding its progress towards expanding the National Anti-Drug Strategy to include prescription drug abuse.

4. The committee further recommends that the prevention component of the expanded National Anti-Drug Strategy require that;
   - Health Canada develop and implement Canada-wide public awareness campaigns on the risks and harms of prescription drug abuse; and,
   - The Minister of Health work with provincial and territorial Ministers of Health and stakeholders including the College of Family Physicians of Canada, the Royal College of Physicians and Surgeons of Canada, the Federation of Medical Regulatory authorities of Canada and the Association of Faculties of Medicine of Canada, to optimize physician

education and training regarding prescription drug abuse and addiction; and,

- The Minister of Health work with interested stakeholder groups to identify opportunities for pharmacist involvement.

5. The committee further recommends that ongoing discussions related to the expansion of the National Anti-Drug Strategy include negotiations with all jurisdictions to ensure access to data on prescription opioid use for those stakeholders involved in assessing the problem of prescription drug abuse.

6. The committee further recommends that Health Canada, through its representation on the Board of Directors at the Canadian Institute for Health Information (CIHI), urge that CIHI be mandated to track, and regularly report on, prescription drug use, particularly use of those drugs that have been identified as having a high potential for misuse, abuse and addiction based on information from provincial/territorial drug information systems.

7. The committee therefore recommends that Health Canada include a prescription drug's potential for addiction as part of the department's assessment of a drug's safety and effectiveness such that addictiveness is noted as one of the risks associated with using the drug.

8. The committee further recommends that Health Canada reassess the safety and efficacy profile of any approved drug that has a high potential for addiction.

9. The committee therefore recommends that, as a condition of market approval, all prescription opioids that have a potential for abuse be required to incorporate tamper-resistant technology in their design.

10. The committee further recommends that Health Canada extend the requirement for "Black Box" labelling noted in recommendation 17 of the committee's *Post-Approval Monitoring Report* to those drugs of high addictive potential.

11. The committee further recommends Health Canada implement requirements under the *Narcotic Control Regulations*:
    - specifying the comprehensive information, including cautions regarding addiction and abuse potential, that must be provided to consumers by practitioners and pharmacists; and,
    - restricting opioid prescriptions to the 200mg "watchful dose" identified in the *Canadian Guideline for Safe and Effective Use of Opioids for Non-cancer Pain*.

12. The committee therefore recommends that the expansion of the National

Anti-Drug Strategy;

- Provide adequate and sustained funding for prescription drug addiction services for First Nations; and,
- Provide physicians serving First Nations' communities with culturally-sensitive pain management training, including the use of non-opioid options.

13. The committee further recommends that Health Canada's review of the Non-Insured Health Benefits program:
    - include in its review of the drug formulary, a thorough assessment of all pain relievers, both prescription and non-prescription, with a view to encouraging the use of non-opioid alternatives wherever appropriate;
    - include a requirement that tamper-resistant opioids be listed in preference to products without tamper-resistance;
    - include an analysis of the current "limited use" status of Suboxone®; and,
    - be completed and reported publicly on an urgent basis.

Theme 4: Improve Efforts to Address Antibiotic Resistance

14. The committee therefore recommends that the Public Health Agency of Canada establish a multi-disciplinary, inter-agency group tasked with implementing a national action plan to address antibiotic resistance, as outlined by the Canadian Committee on Antibiotic Resistance in 2004. The action plan must include:
    - a national public awareness campaign on the causes and consequences antibiotic resistance;
    - renewed surveillance efforts, including a requirement that the Public Health Agency of Canada work with the provinces and territories to require that hospitals collect data and report on antibiotic use and the emergence of antibiotic- resistant bacteria; and,
    - a mandate for the Public Health Agency of Canada to assemble, analyse and report publicly on these data, much like the model of the European Union.

15. The committee further recommends that the federal government:
    - develop and implement a policy, in collaboration with and acknowledgment of the numerous parties involved, to ban or substantially reduce the use of antibiotics as growth promoters in food-producing animals; and,
    - post regular updates on all relevant federal government websites on the progress of implementing its new policy which aims to reduce the use of antibiotics as growth promoters in food-producing animals.

16. The committee further recommends that the federal government encourage research into the development of new antibiotics in a variety of

ways, including but not limited to:

- exploring incentives for the pharmaceutical industry such as extended market exclusivity, priority review and guidance on clinical trial design, to acknowledge the limited market for new antibiotics that would likely not be a first line therapy; and,
- creating a funding program specifically for antibiotic development at the Canadian Institutes of Health Research.

Theme 5: Reduce the Exposure of Canadians to Counterfeit and Substandard Drugs

17. The committee therefore recommends that the Minister of Health consult with stakeholders and review the issue of Internet pharmacies operating in Canada that are selling unapproved medicines with a view to implementing the necessary changes, whether they be legislative, regulatory or other, so as to facilitate the successful prosecutions of these enterprises.

18. The committee further recommends that the Minister of Health, along with law enforcement and border security organizations, engage international counterparts in discussions to develop and enter into an international treaty to facilitate prosecutions for the counterfeiting of prescription drugs globally.

19. The committee further recommends that Health Canada implement a public awareness campaign warning of the risks of purchasing prescription drugs from online pharmacies.

20. The committee therefore recommends that the Minister of Health direct Health Canada to immediately develop and implement a new inspection policy for drug manufacturing sites which:
    - mandates increased inspection activity by Health Canada, either alone or in collaboration with MRA partners, as well as the United States, of sites in countries whose regulatory system is not recognized by Health Canada as equivalent;
    - prohibits the use of records as the only information used for inspections but rather requires that inspections involve on-site, physical examinations;
    - requires public reporting on the results within one year of these site inspections; and,
    - commits to reporting publicly any noncompliance issues detected by the inspection activities of drug regulators of other jurisdictions for sites for which a Canadian Drug Establishment Licence has been issued.

21. The committee therefore recommends that the Minister of Health:
    - establish an inter-agency task force which includes relevant representation from federal and provincial health and law enforcement

agencies and the Canada Border Services Agency, to assess imported drugs, determine which types of drugs are most often counterfeited or not meeting GMP standards and determine the countries in which those drugs are being manufactured;
- provide the task force with the authority to create advisory bodies composed of experts from the pharmaceutical industry, academia, etc.;
- report publicly on the findings of the task force; and,
- determine the regulatory, inspection and enforcement actions necessary to address the issue of counterfeit and substandard medicines.

22. The committee further recommends that Health Canada:
    - report publicly on its pilot program that randomly samples and tests medicines at the border using Raman Spectroscopy, including Health Canada's intentions as to whether to implement the use of the technology on a permanent basis; and,
    - Ensure, in collaboration with its European Union and United States partners, that all batches of imported prescription pharmaceuticals are tested.

Theme 6: Reduce the Impact of Drug Shortages

23. The committee therefore recommends that Health Canada, as a member of the Multi-Stakeholder Steering Committee on Drug Shortages, propose that non-primary care providers, such as dentists, be included as one of the stakeholders on the Multi-Stakeholder Steering Committee on Drug Shortages.

24. The committee further recommends that Health Canada amend the requirement in the *Food and Drug Regulations* regarding notification of drug discontinuance so as to provide longer notice when drugs are to be discontinued.

25. The committee further recommends that Health Canada request that the Multi-Stakeholder Steering Committee on Drug Shortages undertake a review of the drug shortages website to determine what modifications are necessary to address the concerns raised by stakeholders, related to timeliness of the information, usability, searchability, and the addition of other categories of information.

26. The committee further recommends that Health Canada urge the Multi-Stakeholder Steering Committee on Drug Shortages, through its Multi-Stakeholder Working Group, to fulfil its commitment to include clinical information about therapeutic alternatives on the drug shortages website within a year.

Theme 7: Implement Policies Specific to Environmental Concerns Related to Prescription Drugs

27. The committee further recommends that the managers of public drug programs take action to include alternative therapeutics on their drug formularies that can be accessed in the event of a drug shortage. This includes,
    - the federal government's drug programs for First Nations and Inuit, Veterans, Refugees, Armed Forces and federal inmates; and
    - Health Canada, as a member of the Multi- Stakeholder Steering Committee on Drug Shortages, urging its provincial and territorial counterparts to incorporate therapeutic alternatives on their respective drug formularies.

28. The committee therefore recommends that the Minister of Health and the Minister of the Environment clarify the roles of their respective departments with respect to pharmaceutical contaminants in the environment, including but not limited to:
    - determining the list of pharmaceutical substances to be monitored in the environment;
    - environmental sampling and testing of freshwater, groundwater, bio-solids, etc.;
    - public reporting on the levels of pharmaceutical contaminants detected by surveillance; and,
    - describing Health Canada's environmental assessment of approved drugs and how the information is used.

29. The committee therefore recommends that Health Canada, in consultation with stakeholders, develop and implement an aggressive public awareness campaign to encourage Canadians to take advantage of local Take Back programs and drop-off locations.

Theme 8: Reduce the Risks Associated with Consumption of Multiple Prescription Drugs

30. The committee therefore recommends that the Minister of Health encourage provincial and territorial Ministers of Health to ensure that medical students and health professionals receive sufficient training and continuing education on the issue of overmedication and the associated increased risk of adverse drug reactions. Programs should include the role of regularly updated optimal prescribing guidelines and patient medication reviews and should consider prescribing services that have been implemented in other countries.