FEDERAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE AND USE IN CANADA

BUILDING ON THE FEDERAL FRAMEWORK FOR ACTION

PROTECTING CANADIANS FROM ILLNESS

Public Health Agency of Canada
Agence de la santé publique du Canada

Canada

TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP, PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.

—Public Health Agency of Canada

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Public Health Agency of Canada

Health Canada

Canadian Food Inspection Agency

Canadian Institutes of Health Research

Agriculture and Agri-Food Canada

National Research Council Canada

Industry Canada

INTRODUCTION

A Commitment to Leadership

In October 2014, the Government of Canada released *Antimicrobial Resistance and Use in Canada: A Federal Framework for Action*. The Framework maps out a coordinated, collaborative federal approach to responding to the threat of antimicrobial resistance (AMR).

The Government of Canada is committed to taking action 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 Framework by identifying concrete steps that will be undertaken by the Public Health Agency of Canada (PHAC), Health Canada (HC), the Canadian Food Inspection Agency (CFIA), the Canadian Institutes of Health Research (CIHR), Agriculture and Agri-Food Canada (AAFC), the National Research Council (NRC), and Industry Canada (IC).

In addition to its work in the areas of surveillance, stewardship, and innovation, the Government of Canada is committed to taking a leadership role both nationally and internationally. Specific leadership activities include the following:

ACTIVITY	TARGET COMPLETION DATE
PHAC lead with support from HC, CFIA, CIHR, and AAFC: Engage with international partners to develop and implement a Global Action Plan on AMR. The first phase will be working towards endorsement of a Global Action Plan by the World Health Assembly.	May 2015
PHAC lead with support from HC, CFIA, CIHR, and AAFC: Work with federal, provincial, and territorial (F/P/T) partners and human health, animal health, agri-food and industry stakeholders to develop a pan-Canadian framework to address AMR. The first phase will be working towards identifying the incremental elements of a pan-Canadian approach for endorsement by P/Ts and stakeholders.	Fall 2015
PHAC lead with support from HC, CFIA, CIHR, and AAFC: As part of the work under the Global Health Security Agenda (GHSA), support the development of an integrated and global package of activities to combat AMR that spans human, animal, agricultural, food, and environmental sectors. This includes: that each country have a national AMR plan in place to take a comprehensive, "One Health" approach to AMR; strengthened surveillance and laboratory capacity at national and international levels; and improved conservation of existing treatments and support development of new treatments, diagnostics, preventative measures and systems.	2019

However, our work does not end here. This Action Plan is only the first of a series. 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 we can move forward together with a united objective. This Action Plan will be updated regularly both to demonstrate the progress being made, and to continue to identify new initiatives being undertaken as we move forward.

Provinces, territories, and other stakeholders also play a key role by virtue of their responsibility for the delivery of health care, approval of antimicrobials for medical coverage, and the regulation of antimicrobial use (AMU) in agriculture and veterinary medicine. The Government of Canada is committed to working with all jurisdictions and stakeholders to deliver on this Action Plan.

SURVEILLANCE

Detecting and monitoring trends and threats in order to inform strategies to reduce the risks and impacts of antimicrobial resistance.

ACTION 1: Establish and strengthen surveillance systems to identify new threats or changing patterns in antimicrobial resistance and use, in human and animal settings.

As indicated in the Federal Framework, the World Health Organization, the World Economic Forum, and numerous countries around the world consider AMR to be an increasingly serious threat to global public health. However, both within Canada and internationally, there is a lack of comprehensive information on the scope of the problem of AMR, particularly outside of hospital settings (e.g., how are antimicrobials being used, how many bacteria are resistant, to which drugs, how are they being spread). This information is needed to determine the full magnitude of the problem and is essential to monitor the effectiveness of stewardship interventions, and this information can only be gathered from effective surveillance.

In Canada, there are already robust surveillance systems in place, including the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) and the Canadian Nosocomial Infection Surveillance Program (CNISP). While these surveillance systems and others contribute important information, there is no comprehensive and integrated national picture of AMR in human health and within the agri-food system in Canada.

The Government of Canada will continue its existing surveillance activities, as well as the supporting laboratory services, in support of efforts to combat AMR. This will include regular review of these surveillance systems to make required adjustments (e.g., incorporating additional data sources and new technologies).

The Public Health Agency of Canada is establishing the Canadian Antimicrobial Resistance Surveillance System (CARSS) to strengthen coordination and integration of Agency AMR/AMU activities and information. CARSS will also provide leadership on AMR/AMU surveillance, inform and direct the expansion of surveillance activities to areas of greatest need, and provide useful and relevant information to stakeholders and the public in support of antimicrobial stewardship interventions to further protect the health of Canadians.

The Canadian Food Inspection Agency and Agriculture and Agri-Food Canada will work on the development of key components of an agri-food AMU monitoring, tracking, and reporting system. This will include identifying data collection and reporting needs across stakeholders and decision makers including needs for international, national, and P/T reporting.

Other specific activities that will be undertaken moving forward include the following:

ACTIVITY	TARGET COMPLETION DATE
PHAC lead with support from HC, CFIA, CIHR, and AAFC: Building on existing surveillance systems such as CIPARS and CNISP, the Public Health Agency of Canada will complete work to establish a blueprint for CARSS. The integrated information from CARSS will help create a better understanding of the linkages between practices for the use of antimicrobials, observed patterns of resistance, as well as the spread of AMR, and will be used to inform public health interventions and policy decisions relating to AMR and AMU. These efforts will be incremental and include:	
• The issuance of the first annual CARSS report; and	Spring 2015
• Expanding to a national approach through discussions with F/P/T and other external partners.	Fall 2016
PHAC: As part of the creation of CARSS, the Agency will:	
• Pilot the collection of antimicrobial susceptibility data from clinical laboratories to better understand community-associated AMR issues and trends.	Spring 2015
• Review existing priority AMR organisms being monitored by Agency surveillance systems and confirm the priority microbes to be included.	Winter 2015
• Identify any requirements for surveillance transformation at the Agency to align with CARSS.	Spring 2016
PHAC and HC: Analyse data on antimicrobial prescriptions collected by Health Canada's First Nations and Inuit Health Branch to provide a more comprehensive picture of AMU in Canada, and include findings in the annual Government of Canada Human Antimicrobial Use Report.	Fall-Winter 2015
CFIA and AAFC: Identify AMU surveillance data requirements for the animal agriculture sector in support of the creation of a robust monitoring, tracking, and reporting system for AMU.	Spring 2016
CFIA and AAFC: Work collaboratively with veterinary associations and P/T partners to begin to quantify antimicrobial usage in livestock in other dosage forms (e.g., water and injection) and under prescription.	Spring 2016
CFIA and AAFC: Work with stakeholders to develop options for the collection and storage of AMU data for animal feeds and livestock production linking species, production classes, purpose of administration, and dosage quantities.	December 2016

ACTIVITY	TARGET COMPLETION DATE
CFIA: Conduct baseline work on *Salmonella*, *E. coli* O157:H7 and non-O157 and indicator organisms in cattle carcasses and isolates from each positive sample preserved for molecular characterization including AMR.	March 2017
CIHR lead with support from PHAC: Support research on mode of transmission of resistance between organisms and the transmission of resistant bacteria among the different reservoirs (animal-environment-human). Support research and dissemination of results regarding the studies on intervention and surveillance of AMR.	December 2019

STEWARDSHIP

Conserving the effectiveness of existing treatments through infection prevention and control guidelines, education and awareness, regulations, and oversight.

ACTION 2: Strengthen the promotion of the appropriate use of antimicrobials in human and veterinary medicine.

As outlined in the Federal Framework, AMR occurs whenever antimicrobials are used and will therefore be a constant factor in both human and veterinary medicine. Strong stewardship practices by everyone are therefore essential to continue to combat AMR.

An important consideration in preserving the effectiveness of existing antimicrobial drugs is promoting disease prevention efforts with the aim of minimizing or eliminating the need for antimicrobials. Infectious diseases caused by resistant organisms can be prevented if appropriate measures are implemented. For example, effective hand-washing techniques and regular cleaning of surfaces can eliminate bacteria that cause disease. These measures can be equally effective against resistant bacteria. The Government of Canada has been and will continue to be involved in developing and disseminating information and professional practice guidelines for infection prevention and control in a variety of human and animal settings. By preventing the spread of infectious diseases, we can reduce the need for treatment using antimicrobials, which in turn contributes to conserving the effectiveness of available treatment options.

An example of recent work related to infection prevention is the Public Health Agency of Canada's November 2014 presentation of *National and International Infection Prevention and Control Key Activities and Initiatives: An Environmental Scan* at the 2014 Canadian Patient Safety Institute Infection Prevention and Control Canada Summit. This document outlines key infection prevention and control initiatives, their strengths, and areas for improvement in current practices. By sharing these best practices and identifying potential gaps that need to be addressed, improved measures can be put in place to help decrease the spread of infectious diseases – which will help contribute to decreased use of antimicrobials.

In addition to infection prevention and control, the Government of Canada will continue efforts to facilitate and enhance education and awareness on when and how to use antimicrobials, as well as the choice of the correct antimicrobials to use for treatment of certain conditions. For example, the Public Health Agency of Canada's work on resistant strains of gonorrhea has led to the development of specific guidance for healthcare professionals.

To underscore the critical role of education and awareness, in November 2014, the Public Health Agency of Canada launched a pilot AMR awareness campaign featuring messages related to responsible AMU, as well as infection prevention and control, for healthcare professionals and parents.

The Canadian Institutes of Health Research is funding and will continue to fund various projects that aim at evaluating or improving current practices in the prescribing of antimicrobials, or that are looking at alternatives in order to reduce consumption of antimicrobials. In 2013-2014, the Canadian Institutes of Health Research invested $1 million in stewardship projects, and that amount has been steadily increasing every year over the last five years, showing a greater interest in that type of research.

In the agri-food sector, significant progress is being made by Health Canada to promote the prudent use of antimicrobials in food animal production. Health Canada is working with federal partners, drug sponsors, food animal producers and other stakeholders to remove growth promotion claims of medically-important veterinary antimicrobial drugs by December 2016. Health Canada will work closely in aligning this initiative with the United States (US) Food and Drug Administration's approach. Working step in step with the US is critical, given the high degree of integration of the meat and livestock production markets in both countries. About 60 of these products have been identified and discussions are underway with affected drug sponsors regarding a concrete plan to implement this measure. In November 2014, Health Canada communicated with individual drug sponsors to provide guidance, procedures and timelines to support the voluntary removal of growth promotion claims of medically-important antimicrobial drugs. Continuing engagement of affected drug sponsors and other animal health stakeholders is creating the collaborative atmosphere to focus discussion on embracing antimicrobial stewardship and the need for increasing veterinary oversight of AMU in food animal production.

To promote optimal use of antimicrobials by healthcare professionals and consumers, Health Canada will continue to oversee the appropriate labelling of products. This will ensure that drug labels appropriately reflect the current knowledge related to prudent use and AMR in every submission filed by industry. If warranted, sponsors of human antimicrobials will also be requested to update their labels with new information related to bacterial susceptibility to antimicrobials.

In addition to these efforts, Health Canada will assess on an ongoing basis the feasibility of applying current and new tools to incentivise filing of new human antimicrobial drug submissions on a case-by-case basis. Current tools include the Priority Review policy, the Notice of Compliance with Conditions policy, and the potential for remission of drug submission fees for products that have low commercial profitability. New regulatory tools that will be available in the future include the orphan drug framework, which may be applicable for certain antimicrobial products.

Agriculture and Agri-Food Canada will also continue to support the development of assurance systems through the Growing Forward 2 Agri-Marketing Program. An example of a system is the Canadian Quality Assurance (CQA) program, the pork industry's on-farm food safety program, which includes best practices on the prudent use of medications (including antimicrobials), requires that a detailed accounting of all medications and specifies that procurements are through a valid client veterinarian relationship.

Moving forward, the Government of Canada will continue to promote the appropriate use of antimicrobials through:

ACTIVITY	TARGET COMPLETION DATE
PHAC: Evaluate the effectiveness of the messaging used during the November 2014 AMR awareness campaign. The lessons learned from this significant investment will be used to inform future public awareness and education activities for the general public, and health professionals working in community, hospital and long-term care settings – including expanding the reach of the 2015 awareness campaign.	Winter and Spring 2015
PHAC lead with support from HC, CFIA, CIHR, and AAFC: The Minister of Health will host a Roundtable on AMR, with a focus on stewardship.	Spring 2015
HC, CFIA and AAFC: Convene multi-lateral discussions with F/P/T partners, stakeholders and other interested parties to discuss and refine federal proposals for increasing veterinary oversight for veterinary antimicrobials for food animal production.	Spring and Summer 2015
PHAC: Undertake a scan of the current Canadian and international landscape of healthcare associated infections to help identify potential gaps in infection prevention and control practices. This information will also assist the Agency in identifying future AMR-related interventions.	Spring 2016
PHAC lead with support from HC, CFIA, and AAFC: In response to calls for cross-sectoral engagement of all stakeholders in human health and agri-food sectors (e.g., government, industry, health professionals, veterinarians, licensing bodies), a series of consultations will be undertaken to take stock of existing practices relating to AMU, identify best practices for responsible AMU, and explore how to best leverage existing education opportunities.	Spring 2016
PHAC: To promote appropriate AMU, the Agency will update the Sexually Transmitted Infections Guidelines with current treatment recommendations, and deliver two webinar sessions to promote specific AMR-GC (gonorrhea) guidance. These webinars will be used to promote online learning activities.	Spring 2016
HC and CFIA: Work with drug sponsors to facilitate their submissions for label changes to remove growth promotion claims of medically important antimicrobial drugs and associated references in the Compendium of Medicating Ingredient Brochures.	Fall 2016
PHAC: Update the 2014 *"National and International Infection Prevention and Control Key Activities and Initiatives: An Environmental Scan"* to reflect current status, including a full analysis and identification of existing gaps in promoting effective infection prevention and control practices.	Fall 2016

ACTIVITY	TARGET COMPLETION DATE
CIHR lead with support from PHAC: Support research and dissemination of results regarding research on stewardship measures.	December 2019

ACTION 3: Work with the animal agriculture sector partners to strengthen the regulatory framework on veterinary medicines and medicated feeds, including facilitating access to alternatives and encourage the adoption of practices in order to reduce the use of antimicrobials.

In addition to efforts to improve infection prevention and control measures, as well as promote education and awareness, the Government of Canada has an important role in the regulation of animal health products in Canada, including the importation, licensing, and sale of veterinary drugs, medicated feeds, and vaccines.

In support of this area, both Health Canada and the Canadian Food Inspection Agency will continue to prioritize the modernization of the regulatory frameworks for veterinary medicines and medicated feeds. Consultations are well underway in both areas and one of the key areas of focus is the long-standing need to strengthen control on the importation of veterinary drugs for "personal" use ("own use importation" or OUI) and as Active Pharmaceutical Ingredients (APIs) in support of public health and food safety. Health Canada will implement measures to address OUI of veterinary drugs, and strengthen its control over the importation of veterinary active pharmaceutical ingredients.

In addition, Health Canada, in collaboration with the Canadian Food Inspection Agency, is working with provincial partners and animal health stakeholders to strengthen veterinary oversight of medically-important antimicrobials for food-producing animals. Both Health Canada and the Canadian Food Inspection Agency believe that professional oversight on the use of existing antimicrobial drugs in food animal production is necessary and would be critical to attaining the goal of facilitating the prudent use of antimicrobials and conserving antimicrobial effectiveness. Efforts are focused on addressing several in-water and in-feed veterinary antimicrobial drugs that were approved as over the counter (OTC) products prior to the implementation of more stringent microbiological safety standards in 2004. These efforts will be coordinated closely with the US to ensure Canadian and US practices remain aligned.

Health Canada will continue to address the regulatory aspect of strengthening stewardship through appropriate regulation of human and veterinary antimicrobial drugs. By evaluating the safety, quality and effectiveness of these drugs, including post-market monitoring through collection and analysis of adverse reaction reports, Health Canada aims to preserve the effectiveness of authorized antimicrobials.

The Canadian Institutes of Health Research is putting in place a new initiative on the Environments and Health. Environmental factors intersect and contribute both positively and negatively to our health, including AMR. This initiative focuses on three critical areas of investigation (nexus): agri-food, resource development, and urban form. Each of these areas has prevention as its core and is underpinned by three fundamental research components: etiology, data platform enhancements, and intersectoral prevention research.

The Canadian Food Inspection Agency will also continue to verify through premarket assessment, inspection, and sampling, that medicated feeds that are imported, manufactured or sold in Canada meet the standards set by Health Canada as per the Compendium of Medicating Ingredient Brochures or prescribed by a veterinarian.

Utilizing forums such as the National Value Chain Roundtables, Agriculture and Agri-Food Canada will work with the livestock and poultry sectors to encourage the increased adoption of animal health practices that ultimately reduce the use of antimicrobials in animal production. This includes the expansion of the national livestock traceability system and implementation of enhanced biosecurity measures. In addition, in response to industry requests, the Department's Science and Technology Branch will utilize its expertise to assist the sectors in validating the efficacy of commercially available alternatives.

Specific activities that will be undertaken moving forward include the following:

ACTIVITY	TARGET COMPLETION DATE
HC, CFIA and AAFC: Convene an additional round of multi-lateral discussions with F/P/T partners, stakeholders and other interested parties to further consider and refine federal proposals for strengthening the regulatory framework for veterinary drugs. Objectives of these discussions will be to determine how to establish effective oversight of APIs, as well as to engage stakeholders on measures to promote the prudent use of antimicrobials and to facilitate access to alternatives.	Spring 2015
AAFC: Support industry-led research to validate the efficacy of commercially available alternatives to in-feed antibiotics when appropriate.	Summer 2015
HC and CFIA: Implement the requirement to increase veterinary oversight of medically-important antimicrobial drugs used in livestock feed and in water. The approach and timing will be aligned with a similar initiative in the US.	December 2016
HC: Implement measures to address own use importation of veterinary drugs, and strengthen the control over the importation of veterinary active pharmaceutical ingredients (APIs).	2017
CIHR: Support research at the interface between human and animal health and the environment as part of the Environments and Health Signature initiative and through the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) transnational call.	Spring 2020

INNOVATION

Creating new solutions to counteract loss in antimicrobial effectiveness through research and development.

ACTION 4: Promote innovation through funding collaborative research and development efforts on antimicrobial resistance both domestically and internationally.

As outlined in the Federal Framework, the Government of Canada supports ongoing domestic health research and innovation while collaborating with international partners to contribute to global research efforts on AMR, AMU, novel therapies and alternatives. Federal government departments and agencies are already working together on science activities relating to AMR to better leverage the outcomes and results generated by these activities.

The successful introduction of immunization programs to prevent and control vaccine-preventable diseases reduces dependence on antimicrobials, thereby helping reduce risks associated with AMR. 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. Furthermore, the Public Health Agency of Canada and the Canadian Institutes of Health Research 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, Agriculture and Agri-Food Canada will continue to support and/or undertake research and innovation on improvements in animal production practices, disease prevention and treatment, and development of vaccines. These research results will contribute to reducing the requirements for antimicrobials in the animal production industry.

From an innovation perspective, Canada currently has a small number of innovative companies engaged in either drug development, diagnostics, or other related technologies related to AMR. These firms represent a very small part of the overall Canadian life science sector (less than one percent). The existing Science, Technology and Innovation framework at the federal level is supportive of the commercialization of life science innovations, including those involving AMR. In the past, targeted support has been provided to support health policy objectives. For example, as part of the agreement between Canada and the Bill and Melinda Gates Foundation on HIV, Industry Canada established the $13 million Canadian HIV Technology Demonstration program administered through the Industrial Research Assistance Program to support small Canadian firms engaged in the development of HIV vaccines and related technologies. The feasibility of a similar approach involving AMR could be examined.

It is well recognized that despite the very apparent need for new more effective antibiotics, very few are making it to the marketplace. The Public Health Agency of Canada and the National Research Council are working to gain a better understanding of the barriers to innovation deployment both within Canada, and globally, with a view to modelling how such barriers can be overcome. It will be beneficial to inventory existing R&D outputs and AMR

activities (industrial and academic), to identify those that could be further developed and supported to help address Canada's challenges.

It is imperative that all innovation solutions go hand in hand with stewardship to ensure the effectiveness of treatments can be conserved.

The Government of Canada will also explore with international partners a global approach to support innovation in the area of AMR. For example, the Canadian Institutes of Health Research is a founding member and major funder of the Joint Programming Initiative on Antimicrobial Resistance, an association of 19 countries that aim at coordinating resources and actions of the diverse countries to combat the global threat of AMR. Through the Canadian Institutes of Health Research, Canada is able to provide an international leadership role in coordinating research efforts to achieve long-term reductions in resistance levels and better public health outcomes.

Moving forward, the Government of Canada will:

ACTIVITY	TARGET COMPLETION DATE
PHAC, HC, CFIA, CIHR, AAFC, IC, and NRC: Through the Canadian Action Plan on Vaccine Research, Innovation and Development, determine vaccine research priorities. Key stakeholders in human and animal health sectors are being engaged as part of this process.	2015
CIHR: Continue to build knowledge to create innovative tools and alternative therapies to prevent and limit the spread of AMR through research and development via both open competition and strategic funding through partnerships, and in particular collaborate with international groups to promote and leverage Canadian contributions within international research teams:	Ongoing activity
• Canada-United Kingdom partnership on antibiotic resistance (with the United Kingdom's Medical Research Council);	March 2015
• Joint Programming Initiative on Antimicrobial Resistance (JPIAMR): InnovaResistance: Innovative approaches to address antibiotic resistance (group of 12 countries); and	December 2017
• JPIAMR transnational call (19 participating countries).	December 2019
PHAC, HC, CFIA, AAFC, and NRC: Under the federal Genomics Research and Development Initiative, involving eight departments and agencies, a ~$20M five year project will be launched to gain a greater understanding of the critical activities that contribute to the development of antimicrobial resistance and critical exposure pathways by which antimicrobial bacteria reach humans, which could then be used to help validate economically sustainable technologies, practices, and policies to mitigate the development of antimicrobial resistance.	2021

NEXT STEPS

The Government of Canada remains committed to taking action on AMR and AMU. As such, we will continue to work with federal, provincial, territorial and international health and agriculture partners, as well as other stakeholders, to identify how we can strengthen existing and planned activities. We will also continue to work to identify new activities to help combat the spread of AMR.

As noted previously, this Federal Action Plan is the first in a series to keep Canadians informed of our activities and our ongoing progress in implementing the Federal Framework. The Government of Canada will regularly review and update this Action Plan so that it remains reflective of the work that is underway, and our plans for the future.