

Addressing the Multiple Challenges of Antimicrobial Resistance

Public awareness is growing in Canada and around the world about the urgent need for concerted global action to counter the serious health threat posed by antimicrobial resistance (AMR).

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Antimicrobial-resistant infections are becoming more frequent and increasingly difficult to treat. The rapid emergence and spread of AMR infections are exacerbated by the inappropriate use of antimicrobials in human and veterinary

medicine and in the agriculture industry, as highlighted by the [Pan-Canadian Framework for Action for Tackling Antimicrobial Resistance and Antimicrobial Use](#). The dramatic increase in bacterial resistance can imperil our healthcare systems' ability to treat life-threatening infections and also to carry out medical treatments such as surgeries, chemotherapy and organ transplants, where antibiotics have an important role to play. Meanwhile, as existing antibiotics lose their effectiveness, not enough new drugs are being created to replace them, due to various scientific and commercial barriers to antibiotic development.

Unless action is taken on a global scale, it is estimated that by 2050, AMR could result in the deaths of 10 million people around the world every year, according to the United Kingdom's [Review on Antimicrobial Resistance](#). A recent

[World Bank report](#) using economic simulation tools estimates that by 2050, antimicrobial resistance threatens to cause economic damage similar to—and likely worse than—the 2008 global financial crisis.

Canada has recognized the threat of AMR and the urgent need for action with the Public Health Agency of Canada's September 2017 release of a [Pan-Canadian Framework for Action for Tackling Antimicrobial Resistance and Antimicrobial Use](#). This framework was the result of a coordinated effort with input from federal, provincial and territorial governments, academics, non-governmental organizations, industry and subject matter experts representing human health, animal health and agriculture sectors at all levels.

But now greater coordinated action is necessary. Without new ways of diagnosing, preventing and treating infections, we will not overcome the extreme challenges of antimicrobial resistance and protect public health.

The undersigned organizations, representing industry and the scientific community engaged in researching and developing drugs, vaccines, novel approaches to address AMR medical devices, diagnostics and other healthcare products, applaud the Canadian government for its leadership in this area.

We also support the call by a group of [leading Canadian healthcare organizations](#) in September 2017 for Canada to adopt antimicrobial stewardship (AMS) and AMR as a Canadian government signature initiative at the G7



Summit in Charlevoix, Quebec, June 8–9, 2018. AMS can help promote appropriate antibiotic prescribing and usage to optimize treatment and patient outcomes, and prevent the development of multi-drug-resistant organisms. The G7 Summit represents an ideal opportunity for Canada to be an international leader in addressing AMS and AMR.

We are inspired by the [Davos Declaration](#) of January 2016, in which the international pharmaceutical, biotechnology and diagnostics industries identified several interrelated challenges and committed to specific actions

to address them. These challenges include the need for a supply of innovative new antibiotics, the need for all antibiotics to be used cautiously to conserve their effects, and the need in many countries to improve access to existing antibiotics.

In that spirit, we confirm our commitment to work with the federal government and its partners to achieve the goals of the Pan-Canadian framework. In particular, we support the following approaches.



Taking Collective Action

We encourage the government to help strengthen Canada’s end-to-end research capacity for antimicrobial innovation, starting with surveillance, followed by early-stage research and discovery of new antibiotics, novel approaches, vaccines and diagnostics, and through to advanced testing, demonstration projects and post-market studies.

The 2016 Davos Declaration called on governments to create “a sustainable and

predictable market” and also “to commit funding and support the development and implementation of transformational commercial models that (a) enhance conservation of new and existing antibiotics, while (b) improving financial access-related predictability for both industry and health systems.” The undersigned reaffirm industry’s call to action in the Davos Declaration, with specific application to the Canadian government.

Specifically:

- We call on government to work with stakeholders to establish **new business models** that will help improve access to new antibiotics, diagnostics and vaccines globally, while supporting appropriate use and delivering an adequate return to companies.
- We support measures for the **appropriate use** of antibiotics, including implementation of the Pan-Canadian Framework for Action for Tackling Antimicrobial Resistance and Antimicrobial Use and the [World Health Organization’s \(WHO\) Global Action Plan](#) calling for comprehensive stewardship programs and activities that enhance the ability of health systems to use antibiotics appropriately, and also for enhanced integration of fast and accurate point-of-care and laboratory diagnostics

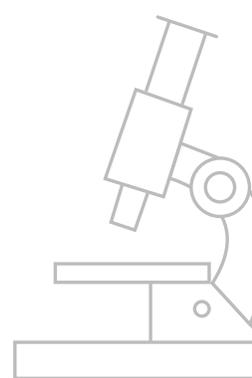




with antibiotics to ensure appropriate use. To enable this, we call for improved reimbursement and use of advanced diagnostics. In addition, we support AdvaMedDx’s [Global Commitment on Diagnostic Tests to Fight Antimicrobial Resistance](#), including a specific commitment to reducing the use of empiric antibiotics by embedding the use of diagnostics into prescribing practices.



- We urge the strengthening of national, regional and local **laboratory capacity**—including increasing laboratory technician workforces and enabling access to rapid diagnostic tests for remote areas, including providing support to low-resource settings.
- To ensure **sustainable investment** in new antibiotics, novel approaches, and diagnostics, we welcome appropriate incentives, coupled with safeguards to sustain the effectiveness of new and existing antibiotics, through the following approaches:
 - Proposals that reduce the link between revenues for new anti-infectives and the amount they are used, while mitigating the financial risk for both developers and health systems. These proposals, which include lump-sum market entry rewards and insurance-like purchase models, may reduce the need for promotional activity by companies.
 - Regulatory measures such as codified accelerated review and fast-track and/or orphan drug designations, and regulatory harmonization to encourage companies to perform clinical trials in, and bring their products to, Canada.
 - Initiatives aimed at incentivizing antibiotics research, development and market access for new drugs and diagnostics at prices reflecting their value and the benefits they bring, with stewardship measures to help prevent overuse. To this end, public health authorities should contribute to assessments of new antibiotics, diagnostics and surveillance informatics to capture their value, taking resistance into account.
 - Aligning incentives for research, development and market access with public health goals will help to drive more timely and accurate diagnosis of infectious diseases.
 - Developing appropriate funding models will enable the appropriate use of technologies that assist in the diagnosis of infections and guide treatment.
 - Health technology assessment (HTA) for evaluating diagnostic tests should be designed according to local and regional decision makers’ needs, and adequate market incentive options that reflect the true value of diagnostics.
 - Ensure adequate resourcing to advance IT infrastructure that enables surveillance and reporting of infections and emerging pathogens within healthcare facilities and the community.
 - Establish comprehensive infection prevention and control programs in healthcare facilities to reduce the incidence of healthcare-associated infections and spread of antimicrobial resistant pathogens.





Commitments by Signatory Organizations

The undersigned organizations are already actively engaged in combating AMR. We stand ready to work in partnership with governments to deliver sustainable solutions to meet this serious challenge. We reaffirm commitments presented in the Davos Declaration and the Global Commitment on Diagnostic Tests, with specific applications to Canada, including:



- **Work to reduce the development of antimicrobial resistance.** Antibiotics should only be used in patients who need them. We support education for clinical professionals on appropriate use of antimicrobials and we welcome the Pan-Canadian Framework for Action for Tackling Antimicrobial Resistance and Antimicrobial Use and the WHO Global Action Plan's focus on improved stewardship. We encourage infection prevention and control through hygiene, vaccination, adherence to best practices for invasive procedures, and preventative treatments to help reduce the number of infections needing antibiotic treatment.



- **Invest in R&D to meet public health needs with new innovative diagnostics, surveillance and treatments.** We are investing in innovative antibiotics, vaccines, novel and adjunctive treatments, and diagnostics for resistant infections. We will continue to support research on new and re-purposed antibiotics. We support open collaboration between industry and public researchers to overcome scientific challenges. We are ready to work with payers and policy makers on new valuation mechanisms and commercial models.



- **Improve access to high-quality antibiotics and novel approaches, and ensure that new ones are available to all.** In keeping with the WHO Global Action Plan, we support mechanisms to ensure access to new and existing antibiotics to patients who need them, wherever they are in the world. We recognize the success of programs to improve global access to drugs in HIV, TB and malaria and call for a similar collaborative approach for antibiotics, while becoming a leader in novel approaches to address AMR for human and agricultural use.



- **Contribute to a holistic and One Health approach to tackling AMR.** We support measures to stop antibiotics and antibiotic-resistant organisms from polluting the environment along with the phased global reduction of unnecessary antibiotic use in livestock, and we applaud moves from major food groups to work towards this goal.



Signed



Arch Biopartners

BD - Canada

BIOTECanada

Canadian Anti-Infective Innovation Network

EKS Business Development

Hoffmann-La Roche Limited (Pharmaceuticals and Diagnostics divisions)

DeNovaMed Inc.

Fedora Pharmaceuticals Inc.

GlaxoSmithKline Inc.

Innovative Medicines Canada

MEDEC

Medicago, Inc.

Merck Canada Inc.

Microbion Corp.

SaNOTize Research and Development Corp.

