POLICY BRIEF | 2026

OPENING THE CANADIAN MARKET FOR THE EXPEDITED APPROVAL OF ANTIBIOTICS OF LAST RESORT (ALR)

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EXECUTIVE SUMMARY

This policy framework addresses the growing challenge of antimicrobial resistance (AMR) in Canada by proposing reforms to improve access to novel antibiotics of last resort. It recommends modernizing the antimicrobial review process through expedited pathways, international regulatory collaboration, harmonized approval standards, and a new Targeted Antimicrobial Approval Pathway (TAAP) tailored to high-priority antimicrobial therapies. The framework also promotes expanded use of the Special Access Program and improved regulatory guidance for pharmaceutical manufacturers to reduce barriers to market entry.

LAY SUMMARY

Canada needs greater access to new antibiotics as antibiotic-resistant infections continue to increase across the country. Currently, Canada has approved only 2 of the 13 last-resort antibiotics that have already been approved in other countries. Factors such as Canada's small market size, complex healthcare system, and reimbursement processes can discourage manufacturers from seeking approval in Canada. However, the regulatory review process, approval timelines, and navigation of the submission pathway may also create unnecessary barriers that could be reduced to improve access to these important medicines.

We have proposed three policies that address the regulatory framework Canada currently uses to facilitate the quick approval of much needed new antibiotics that can be used to treat infections for which there is no other option. We propose:

- **POLICY 1:** Reform the antimicrobial process for novel antibiotics through expedited reviews, internationally harmonized standards, and a new targeted approval pathway.
- **POLICY 2:** Develop better guidance to ensure that manufacturers are aware of the requirements for Canadian market access.
- **POLICY 3:** Create an incentive structure to drive Canadian drug development and manufacturing.

Depending on the level of intervention taken, these policies independently can have an impact in the number of applications received and ultimately approved.

KEY TERMS

- **Antibiotic[1]:** An antibacterial substance that is used to treat or prevent infections by killing or inhibiting the growth of bacteria in or on the body, that is administered orally, topically, or by injection.
- **Antimicrobial Resistance (AMR)[2]:** occurs when pathogens (e.g., bacteria, viruses, fungi, etc.) evolve to no longer be affected by medications designed to kill them.

https://tinyurl.com/3t8rw3t8

FIG. Sensitivity test to antibiotic drug showing AMR. The lack of bacterial growth (inhibition zone) around the right white pellet compared to no inhibition around the left pellet (i.e., resistance).

- **Antibiotics of Last Resort (ALR):** Broad-spectrum antibiotics that are only given when dealing with multi-drug-resistant infections.

MEASURES OF SUCCESS

POLICY 1:
1. Increased number of new antibiotics approved from the proposed AMR drug review board as compared to standard process.
2. The time of new approvals is significantly lower than regular process.

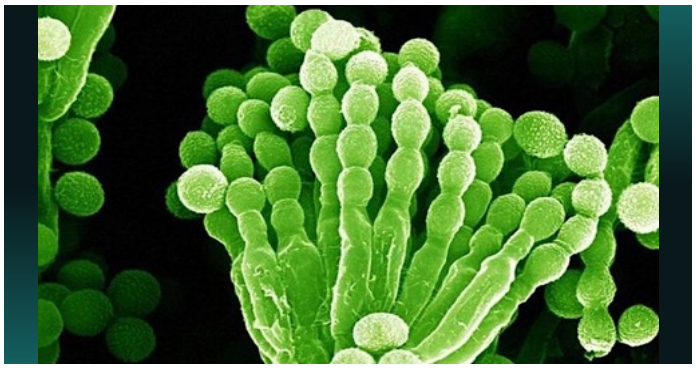
POLICY 2:
1. Positive feedback based on surveys conducted after submission process.

POLICY 3:
1. Have agreements for expanded drug manufacturing.
2. Have agreements for new drug development/ manufacturing.

INTRODUCTION

BACKGROUND

Since their discovery in the early 20th century, **antibiotics** have been a fundamental contributor to human longevity. In the century since the widespread adoption of antibiotics to treat various ailments such as pneumonia, tuberculosis, syphilis, and gonorrhea, the average human lifespan has increased by approximately 23 years (U.S. CDC 1999; Hutchings et al. 2019). One of the first antibiotics to be discovered and widely used was penicillin, when it was found that mold on a contaminated petri dish had killed the growing staphylococcus colonies (Fleming, 1929). Since then, there have been hundreds of antibiotics that effectively kill dangerous human pathogens have been characterized. However, with the widespread adoption and use of antibiotics, there has been a corresponding increase in the number of pathogens that have become resistant to their mode of action.



https://tinyurl.com/yechzmfs

FIG. *Penicillium* mold naturally produces the antibiotic penicillin, which once purified can be used as antibiotic medicine.

As defined in the Report of the Auditor General of Canada to the Parliament of Canada (2023), "**antimicrobial resistance** occurs when pathogens such as bacteria, viruses, and fungi that cause infections in people and animals adapt over time to resist the antimicrobial drugs, such as antibiotics, antivirals, and antifungals, used to treat these infections". The first record of antimicrobial resistance (AMR) in humans dates to the 1930s, with the emergence of sulfonamide resistance (Davies and Davies, 2010). This was quickly followed by the discovery of a bacterial enzyme capable of destroying penicillin in 1940, before the drug had even been introduced as a therapeutic (Davies and Davies, 2010). To combat acquired resistance, the medical community began switching to different antibiotic classes to treat resistant infections (Finland, 1979; Davies and Davies, 2010).

Early recommendations to address antimicrobial resistance (AMR) also included banning non-therapeutic use in agriculture and stricter control over drug distribution and prescription (Swann 1969; Davies and Davies, 2010). Despite these interventions, antibiotic control remains limited in many developing countries, and **AMR rates have continued to rise** (Davies and Davies, 2010; O'Neill, 2016; GBD 2021 Antimicrobial Resistance Collaborators, 2024). Observing this rise in AMR cases across much of the world, the World Health Organization (WHO) began tracking the spread of AMR and developing global. In response to this rise in AMR cases across much of the world, the WHO began tracking the spread of AMR and developing global guidelines for the use of antibiotics in infection management. Many countries also have national working groups and collaborations to monitor and attempt to curb the spread of AMR.

The WHO and partner organizations have been fundamental in raising awareness and tracking the global increase in AMR. AMR is considered a "silent pandemic" and a top 10 public health threat facing the world today (WHO 2019; Office of the Auditor General of Canada, 2023). In 2021, 1.14 million deaths were attributed to AMR, 4.71 million deaths were associated with AMR (GBD 2021 Antimicrobial Resistance Collaborators, 2024). By 2050, this number is expected to rise to 1.91 million deaths attributable to and 8.22 million deaths associated with AMR annually (GBD 2021 Antimicrobial Resistance Collaborators, 2024). The economic impacts of AMR are equally dire, with the World Bank estimating that global healthcare costs due to AMR could reach **$1 trillion (USD)** by 2050 (WHO 2014; WHO 2023).

Despite Canada's advanced economy and comprehensive antimicrobial use (AMU) and AMR surveillance program, AMR continues to threaten the health of all Canadians. In 2018, **26% of infections** in Canada were resistant to first-line antimicrobial drugs, and 5400 deaths were attributed to AMR (Council of Canadian Academies, 2019). The rate of resistant infections is **expected to rise further to 40%** by 2050, with 13,700 associated deaths (Council of Canadian Academies, 2019). In Canada alone, the AMR crisis cost **$1.4 billion in annual healthcare spending** as of 2018, with an additional **$2 billion in lost gross-domestic product (GDP)** (Council of Canadian Academies, 2019). Canadians face additional challenges because Canada only has access to 10 of the 29 antibiotics classified as "reserve" antibiotics or antibiotics of last resort (ALR) by the WHO (Office of the Auditor General of Canada, 2023). The Public Health Agency of Canada (PHAC) estimates that as many as 1 in 3 high-risk, resistant pathogens in Canada could be effectively treated with antimicrobial drugs available elsewhere but not on the Canadian market (Office of the Auditor General of Canada, 2023). This lack of access to novel, effective antimicrobials presents a significant barrier to addressing the AMR crisis in Canada.

INTRODUCTION

Given the urgency and potential catastrophic implications for human health if the level of AMR increases, the Canadian government needs to take **decisive action** and develop an effective strategy to combat AMR that goes beyond current initiatives. In 2023, the Pan-Canadian Action Plan on Antimicrobial Resistance was adopted, with five key pillars: research and innovation, surveillance, stewardship, infection prevention and control, and leadership (Public Health Agency of Canada, 2023). Progress reports from the first two years of this action plan highlight improvements in several areas: expanded surveillance in the human, animal, and environmental health sectors; antimicrobial stewardship initiatives, including a national list of ALR and national prescribing guidelines; and enhanced infection prevention and control programs, particularly for agricultural producers (National Biosecurity Standards and Biosecurity Principles) and Indigenous communities (Public Health Agency of Canada, 2024; Public Health Agency of Canada, 2025). However, there are still significant improvements to be made in the pillars of **research, innovation and leadership**, to improve access to novel antimicrobials.

While Canada has a framework through which the medical community can access approved drugs and a standardized process for approving new drugs by Health Canada's Health Products and Food Branch, there are significant drawbacks to the current system. Health Canada approval timelines are comparable to those of other international regulators, but it still takes an average of 3.3 years for drugs to proceed from conditional to full approval (Lexchin, 2025). In some cases, timelines to full approval can exceed ten years (Lexchin, 2025). While the Priority Review Process can shorten the review time of promising drugs with few alternatives, achieving full approval still has complex requirements (Health Canada, 2020). Health Canada uses data submitted to other regulatory agencies but may also require its own studies to meet its regulatory requirements, and a foreign approval never guarantees approval by Health Canada (Health Canada, 2020). Additionally, the cost for the review of a new active substance exceeds CAD $600,000 (Health Canada, 2025).

This positioning negatively impacts Canadians who are suffering from severe infections but cannot rapidly access drugs that have been approved by other major regulators. Canada is a small market for the purchase of novel antibiotics and coupled with Canada's complex regulatory environment and expensive drug pricing, pharmaceutical companies often choose to delay or skip over the approval process in favour of larger markets such as Europe or the USA (Office of the Auditor General of Canada, 2023).

As part of the Pan-Canadian Action Plan on Antimicrobial Resistance, the Public Health Agency of Canada (PHAC), Health Canada (HC), and other federal agencies have launched the Antimicrobial Economic Incentives Pilot Project for Canada and the Open Science Drug Discovery network to increase development of and access to novel antimicrobials (Government of Canada, 2025; Public Health Agency of Canada, 2025b). These pilot programs are a step in the right direction, but a more comprehensive suite of policies and strategies to rapidly expand access to novel antimicrobials of last resort is essential. It is time for Canada to build on our reputation of strong international collaboration and advocacy and become true leaders in combating the global AMR crisis.

OBJECTIVE

Given the structural challenges in Canada to the attraction and approval of new antibiotics for the Canadian marketplace, this policy proposal addresses the challenge of making Canada a leader in AMR and improving Canadians' access to new antibiotics of last resort by proposing 3 new policy pillars. These policy pillars involve: 1) reform of the antimicrobial review process 2) improved guidance for pharmaceutical manufacturers, and 3) creation of an incentive structure for Canadian drug development and manufacturing. Within these three policy pillars, this proposal outlines seven key objectives for the Canadian government:

POLICY 1:

- **Objective 1:** Development of an AMR panel similar in scope to Project Orbis.
- **Objective 2:** Drive increased use of the Special Access Program (SAP) for Canadian physicians.
- **Objective 3:** Harmonize approval standards with partners to leverage global reviews from major international regulators.
- **Objective 4:** Adopt the Targeted Antimicrobial Approval Pathway (TAAP) to accelerate review of novel antimicrobials.

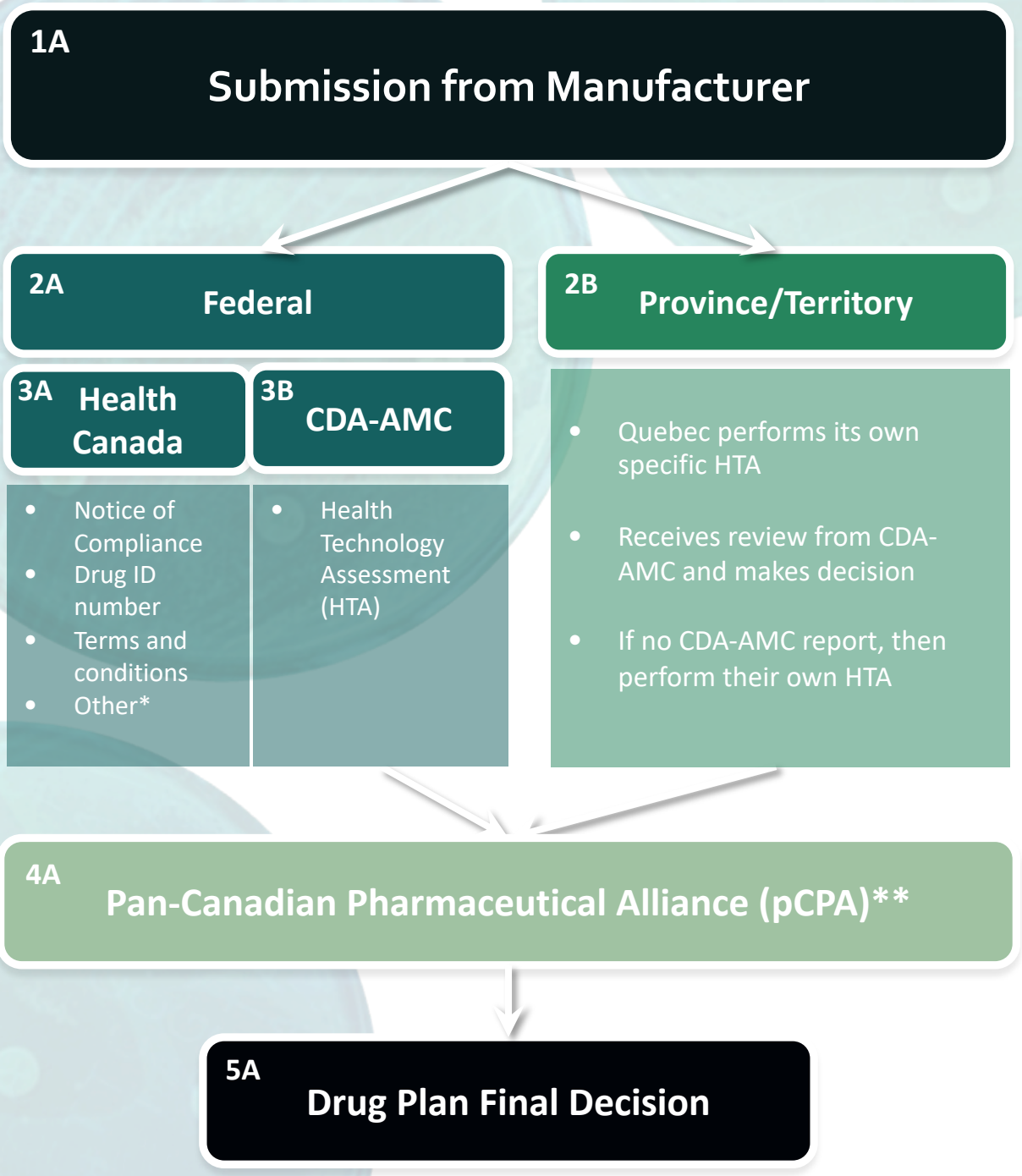
POLICY 2

- **Objective 1:** Develop clear, improved guidance to assist pharmaceutical manufacturers in understanding and navigating Canadian market requirements.

POLICY 3

- **Objective 1:** Development a comprehensive national incubator program to support antimicrobial drug development.
- **Objective 2:** Implement a formal procurement policy to preferentially purchase Canadian-made antibiotics.

INTRODUCTION



* Health Canada can then pass the drug on for special review (i.e., Project Orbis, rolling review, etc.)

** Joint drug negotiations begin and are agreed to in principle.

Adapted from: Drug funding review and approval process | Ontario.ca

1 • REFORM REVIEW PROCESS FOR NOVEL ANTIBIOTICS

Healthcare is primarily a provincial responsibility under the Canadian Constitution. While the federal government can provide oversight, offer recommendations, and grant regulatory approval, the ultimate decisions on drug funding and accessibility are made by provincial health authorities. The federal government, through Health Canada (HC), is responsible for approving drugs for marketing and sale in Canada and ensuring that they meet standards for safety and efficacy. Provincial governments are responsible for determining whether approved drugs will be publicly funded and, if so, under what conditions they may be accessed within the province. Due to this division of authority between the federal and provincial governments, Canada has developed a complex and multi-layered drug approval and reimbursement system.

The federal government is responsible for approving drugs for use in Canada. Before a drug can be marketed, manufacturers must submit applications to both HC and the Canadian Drug Association (CDA). The CDA reviews both the clinical and economic evidence submitted for the drug and provides recommendations regarding whether the drug should be publicly funded and under what conditions. Following HC approval and CDA recommendations, price negotiations with the manufacturer begin. Within HC, the Health Products and Food Branch (HPFB) reviews the submitted materials. Applications include information on preclinical studies, clinical trials, new drug submissions, product labelling, safety data, adverse effects, and marketing claims (Health Canada, 2020). HPFB uses advisory panels and consultants to evaluate the evidence regarding drug safety, efficacy, and risk. These panels also review how the drug will be marketed to clinicians and consumers. If approved, HC issues either a Notice of Compliance (NOC) or a Notice of Compliance with Conditions (NOC/c), along with a Drug Identification Number (DIN). An NOC/c allows a drug to receive conditional approval based on interim clinical evidence, with the requirement that manufacturers later submit additional confirmatory data (Lexchin, 2025). HC may also impose Terms and Conditions requiring manufacturers to provide further information before full approval is granted (Sarazin et al., 2026).

Provincial governments are responsible for determining the accessibility and reimbursement of approved drugs. Drug manufacturers often submit applications to provincial authorities in parallel with federal submissions. Certain drugs, such as some rare-access or hospital-administered therapies, may fall outside the CDA review process and instead undergo direct provincial review.

Provinces have the authority to deny public funding for a drug, restrict its use within hospitals, or limit prescribing authority to specific clinicians or patient populations. To strengthen bargaining power during reimbursement negotiations, provinces participate in the pan-Canadian Pharmaceutical Alliance, which negotiates pricing agreements on behalf of participating provinces and public drug plans. However, each province ultimately retains the authority to decide whether list the drug on its formulary.

Given the responsibilities shared between federal and provincial governments, the Canadian drug approval and reimbursement process can be lengthy and complex. In 2024, HC received more than 1,100 drug submissions. The fee that each drug company must pay for review in the Canadian market is $565,000 (CCA, 2023). For standard new drug submissions, the approximate time from submission to issuance of an NOC is approximately 300 days (ddregpharma). Despite the large number of submissions received, HC has issued only 153 NOC/c approvals since 1998 (Lexchin, 2025), of which only 91 have met the required conditions. Five drugs have taken more than 10 years to complete the confirmatory requirements necessary for full approval. The median time for conditional approvals to transition to full approval is approximately 1,200 days after an NOC/c is issued (Lexchin, 2025). Although HC is currently revising aspects of its submission and approval framework in response to concerns regarding approval timelines, the agency also notes that its approval times are comparable to those of other countries (Pennington et al., 2025).

1 • REFORM REVIEW PROCESS FOR NOVEL ANTIBIOTICS

<u>Sub-section 1:</u> How can Canada streamline the approval of AMR drugs of last resort that have obtained regulatory approval in other countries?

Several special programs currently exist to accelerate access to important therapies. HPFB operates a priority review process for drugs targeting life-threatening diseases or conditions with limited treatment options, such as AIDS, Parkinson's disease, and cancer (Health Canada, 2020). This accelerated review pathway has an approximate decision timeline of 180 days and generally requires evidence demonstrating substantial clinical benefit (ddregpharma). In addition, the pan-Canadian Oncology Drug Review provides a specialized oncology review process that considers factors such as limited treatment alternatives, severe disease burden, and incremental survival benefits.

For urgent cases in which drugs have not yet received HC approval, clinicians may apply through the Special Access Program (SAP). SAP eligibility generally requires that patients face a serious or life-threatening condition for which conventional therapies have failed, are unsuitable, or are unavailable in Canada (Health Canada, 2020). The SAP process is relatively rapid, processing approximately 1,000 requests per month, with approvals sometimes occurring within hours. Responsibility for funding SAP drugs may fall to hospitals, provincial governments, private insurers, or drug manufacturers.

Despite ongoing regulatory modernization efforts and expedited review pathways, several aspects of Canada's system remain less efficient than those of comparable international regulatory agencies. For example, when HC requests additional confirmatory studies to support approval, it does not require manufacturers to provide expected completion timelines, whereas both the U.S. Food and Drug Administration and the European Medicines Agency do (Lexchin, 2025). Information on submission status, confirmatory trials, and regulatory progress is also less transparent within HC than at the FDA and EMA. HC does not consistently disclose whether confirmatory trials are ongoing, when they are expected to conclude, or when results are completed and submitted (Lexchin, 2025). Although manufacturers must provide yearly updates regarding NOC/c obligations, these reports are not publicly available. In contrast, the FDA has the authority to impose financial penalties for delays in confirmatory work (Lexchin, 2025), while the EMA grants conditional marketing authorizations for only one year at a time, requiring annual reassessment (Lexchin, 2025).

<u>Proposal 1.1:</u> Canada develops an AMR regulatory review panel resembling Project Orbis.

Project Orbis is a program created in 2019 that is aimed at giving oncology patients faster access to experimental cancer treatments (Health Canada, 2022). It is made up of nine regulatory bodies comprising the countries of Canada, the United Kingdom, Singapore, Australia, Brazil, Switzerland, Israel and the United States. It uses a collaborative approach so that each country can share their results of drug reviews or collaborate on drug reviews to facilitate speedy approvals in each country or for simultaneous approvals (FDA, 2024). In the first year of its inception, there were 38/60 approvals made (de Claro, 2020).

We believe that another group of international collaborators is needed for the approvals of antibiotics of last resort. Being modelled off the Orbis working group, the new AMR group would function in the same way by reducing the time of approval in the represented countries by having the health organizations work together to review the data presented by the drug applicants. Each country would still have its own policies and decisions on whether to approve the drug or the level of funding; however, it would free up resources to look at many more antibiotics. Research has shown that applications in project Orbis have been approved in approximately 1.5 months compared to a previous approval time of >6 months (de Claro, 2020).

<u>Proposal 1.2:</u> Broaden the Special Access Program (SAP) to allow flexible, needs-based access to novel drugs of last resort.

Currently, clinicians can access drugs not available in Canada through the special access program. As described previously, there needs to be no other available treatment available, and it must be approved by HC prior to access. Given that the need for antibiotics of last resort is still minimal, the new drugs are still expensive while the Canadian market is small, and drug companies may not choose to submit to Health Canada, more resources could be put into the SAP. The cost of treating a sporadic number of antibiotic cases with an unapproved drug may still be cheaper than the approval process or the cost assumed by the health care plans to adequately stock and maintain the drugs.

1 • REFORM REVIEW PROCESS FOR NOVEL ANTIBIOTICS

<u>Proposal 1.3:</u> Create a streamlined system for which Health Canada accepts other international regulators' application packages and scores between them accordingly.

In the review of Project Orbis, it was noted that the European Medicines Agency (EMA) had a system for which was not conducive to the approval systems of the Orbit member states (de Claro, 2020). With the continuing advancement of artificial intelligence (AI), We propose a unique solution that allows Health Canada to work with international collaborators and design a system for which the submissions to other agencies have a simplified ranking/parallel score.

<u>Sub-section 2:</u> How can Canada overhaul the regulatory approval process for novel AMR drugs to reduce barriers to access?

Canada's current drug approval pathway is not well-suited for antibiotics of last resort (ALR). The existing pathway requires many agencies' approval and extensive clinical data to validate a drug's safety and efficiency (Health Canada, 2015). Due to the length of this review process, this pathway should be unique to antibiotics targeting broad populations. However, ALRs require a much faster approach to respond to the immediate needs of high-risk patients. Canadian patients have significantly less access to essential ALRs compared to patients from other high-income countries. For these reasons, Canada should adopt a dedicated antimicrobial regulatory pathway inspired by international models. These models, like in the UK and U.S., are tailored to high-risk, low-volume antibiotics.

The U.S. Food and Drug Administration (FDA) approves novel antimicrobials at a much higher rate than Health Canada, treating patients with complicated infections promptly. The Generating Antibiotic Incentives Now (GAIN) Act was introduced in 2012 to promote antimicrobial resistance research (Shlaes et al, 2013; Tillotson and Tillotson, 2015). It gives companies a 5-year supplemental market exclusivity for qualified infectious disease products (QIPD) as well as an accelerated 6-month review by the FDA. New antimicrobial drugs become an investment opportunity for pharmaceutical companies, since these drugs are reviewed much quicker and are protected from competing companies for an extended period (Tillotson and Tillotson, 2015). This creates an incentive for firms to invest in ALR research and results in increased accessibility to these drugs. However, pharmaceutical companies are less likely to invest into ALRs in smaller populations.

Other regulatory pathways should be analyzed to determine how new antimicrobials can remain affordable for smaller patient populations. The UK has developed a subscription-based model to encourage pharmaceutical companies to develop and supply antimicrobials for smaller or limited-use markets. Since 2022, payments have been delinked from sales volume to incentivize market participation (Leonard et al., 2023). The fixed annual fee is based on the overall medical value of the antimicrobial, rather than the number of doses a hospital uses (NHS England, 2024). This directly limits the motivation to overuse antibiotics to make a profit. Maintaining good stewardship is important to slow the development of AMR.

As the expectations of the current Canadian system misalign with the clinical reality of ALRs, the introduction of a new pathway that supports faster approval of these critical antibiotics in Canada is imperative (Health Canada, 2015; Public Health Agency of Canada. 2024). The **Targeted Antimicrobial Approval Pathway (TAAP)** will be presented as the key to regulating new antimicrobials that Canadian patients require. TAAP is an adaptive regulation model structured around five components that are key to addressing accessibility barriers: limited-population review, conditional approval, rolling data submission, use of international data and prioritization of high-risk pathogens **(Table 1).**

<u>LIMITED-POPULATION REVIEW</u>

Limited-population review allows approval of ALRs that are based on small or limited clinical trials, rather than Phase III studies (Health Canada, 2020). Large trials for ALRs are unrealistic due to their high cost and the difficulty to recruit a sizeable number of patients within an appropriate time (Stewart et al., 2019). Since MDR infections are low-incidence but high-impact, large clinical trials are simply not suitable. As a result, waiting for traditional trail sizes would delay patient access to these life-saving antimicrobials. This approach comes with more uncertainty, particularly with long-term effectiveness and the potential for resistance development. To address this, TAAP includes the use of observational data and real-world evidence to complement limited clinical trial findings.

<u>CONDITIONAL APPROVAL</u>

Conditional approval improves suitable access to ALRs, while maintaining oversight (European Medicines Agency**)**. This balances the urgency of access with higher post-market confirmation of safety and efficacy. This part of the TAAP framework responds to situations where large delays could result in significant patient harm.

1 • REFORM REVIEW PROCESS FOR NOVEL ANTIBIOTICS

Conditions included in the approval require additional clinical trials, surveillance and periodic safety reporting. Conditional approval acknowledges that absolute certainty before approval may not be realistic for MDR infections.

ROLLING DATA SUBMISSION

Rolling data submission reduces the delay in regulatory review, by allowing manufacturers to submit clinical data as it becomes available (Tillotson and Tillotson, 2015). This reduces the time lost between data generation and evaluation by shortening the overall time to authorization. Regulators can assess emerging evidence in increments as opposed to bottlenecking the evaluation process with single submissions. Rolling data submission also encourages more flexibility and communication between manufacturers and regulators. This may increase workload or procedural complexity for both parties. However, the responsiveness of TAAP is necessary in high-risk situations where ALRs are required.

USE OF INTERNATIONAL DATA

Use of international data reduces the duplication of regulatory efforts by using clinical data from comparable regulators (Tacconelli et al., 2018). The objective is to avoid repeated evaluation of clinical evidence, especially when antimicrobials are developed in global clinical trials. Greater reliance on international evidence allows for more efficient processing of novel antimicrobials at a reduced cost (World Health Organization, 2025). Many comparable regulatory agencies have already generated and validated data that may be applicable to the Canadian context. Importantly, this data must be interpreted in the context of regional resistance patterns and populations.

PRIORITIZATION OF HIGH-RISK PATHOGENS

Prioritization of high-risk pathogens aligns approvals by TAAP with urgent public health threats. The Canadian Antimicrobial Resistance Surveillance System (CARSS) is a federal program established in 2015 that integrates AMR resistance and uses data from the Public Health Agency of Canada and its surveillance partners (Public Health Agency of Canada, 2024). By using an established grounded in the Canadian context, regulatory resources can be on the most urgent clinical needs. This risk-based approach allows pathogens to be differentiated according to their public health impact and AMR liability.

Proposal 1.4: Adopt the Targeted Antimicrobial Approval Pathway (TAAP) for review of novel antibiotic drugs.

We propose that the Canadian government take proactive steps to reduce the administrative burden and long timeframes caused by the current regulatory approval system. The urgent nature and high turnover rate of AMR drugs of last resort are sufficient justification for drugs of this nature to be exempted from Canada's current drug approval pathway. Adopting the TAAP framework can be expected to reduce barriers currently impeding the rapid review of novel antibiotic drugs and allow Canadians to benefit from these innovative and life saving drugs.

Table 1. Targeted Antimicrobial Approval Pathway (TAAP) regulatory components. Summary of the five components of the TAAP framework and their roles in addressing accessibility and market barriers in antimicrobial development.

COMPONENT	OBJECTIVE	PROPOSED ACTION
Limited-population review	Allow approval despite small patient population	Accept targeted clinical trials for MDR infections
Conditional approval	Improve access and maintain oversight	Grant approval with post-market surveillance requirement
Rolling data submission	Reduce delays in regulatory reviews	Allow manufacturers to submit clinical data as they obtain it
International data	Reduce duplication of research and development efforts	Permit use of foreign clinical data (from trusted regulators)
Priority pathogens	Align antimicrobial approvals with urgent public health threats	Prioritize pathogens identified by CARSS

2 • GUIDE MANUFACTURERS ON CANADIAN MARKET ACCESS REQUIREMENTS

Here we will give a simplified process that the average novel antimicrobial must go through to be approved for Canadians. At the end, we will discuss the major take-aways from this system. The individual or organization testing the drug is referred to as a **sponsor.** Sponsors can be drug companies, or researchers from hospitals, academic institutions, and private research establishments. Your sponsor must have a Canadian citizen representative. If you have this Canadian sponsor, you have met this requirement. It is possible to enlist a Canadian sponsor where none is immediately available. There are clearly outlined rules for this stage of the process, and they can be accessed here: Health Canada's Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications (Health Canada, 2003).

Read the Government of Canada's information on Good Manufacturing Practices (GMP) as well as Canada's Food and Drugs Act. This information can be found here: Health Canada's Good Manufacturing Practices and Canada's Food and Drug Act and Regulations (Health Canada, 2002; Health Canada, 2008). If you and your organization comply fully with both sets of regulations, you are ready for the next step. If you do not meet the standards of either, however, you will be required to modify every part of your organization to meet this standard. Enforcement of both regulations is left to Health Canada. They can inspect any aspect of operations via the Inspectorate of the Regulatory Operations and Enforcement Branch (ROEB) of Health Canada. Information on the ROEB can be found here : Health Canada's Regulatory Operations and Enforcement Branch (Health Canada, 2017).

In reading Canada's Food and Drug Act you will learn that there are different types of therapeutics. Most antimicrobials will qualify as a drug or pharmaceutical. It is, however, your duty to know what type of therapeutic you are proposing and to follow any type-specific nuances in the application. Information on the terminology used in this process can be found here: Health Canada's Guidance on Management of Drug Submissions and Applicaitons: Definitions, Glossary, Notes (Health Canada, 2025).

If you are at the point of having an antimicrobial you believe is worth the investment needed to bring to the Canadian market, the first step should be to know as much as possible about the drug you are studying. Before clinical trials can start, it is essential that you undergo thorough preclinical trials. These trials will focus on safety, adverse effects, functional characterizations, proof of both the concept (mechanism) and the efficacy, pharmacokinetics, pharmacodynamics (PK/ PD), formulation, establishing dosages, and identifying both the absorption and excretion of the drug (Huang et al., 2020; National Center for Advancing Translational Sciences, 2026; Health Canada, 2021a). Ask yourself if you have completed thorough testing of the product you wish to introduce with the use of cells, tissue cultures, and non-human animals. If you require assistance or want to ensure that you are maximizing your investment, it is worth reaching out to the Canadian Human Health Therapeutics Research Centre. Information on this resource can be found here: National Research Council of Canada's Pre-Clinical Research and Development (National Research Council of Canada, 2024).

If you believe you are prepared for the next step – clinical trials – Health Canada invites sponsors to participate in a Pre-Clinical Trial Application CTA) consultation meeting. Information on this meeting and the next steps can be found here: Pre-Clinical Trial Application (CTA) Consultation Meeting (Health Canada, 2006). Through this portal you will request an application package that will require information on the proposed study, a list of preliminary questions to be addressed by the Directorate during the meeting and sufficient information for Health Canada to assess both the utility of the meeting and identify the appropriate staff necessary for the review If the Directorate agrees to this proposal Health Canada will send an acknowledgement letter that confirms the pre-CTA consultation date and the number of copies of the pre-CTA information package that will need to be provided 30 days before the meeting (Health Canada, 2006).

Clinical trials in Canada must also follow Division 5 of the Food and Drug Regulations, which are found here: Canada's Food and Drug Regulations (C.R.C., c. 870) (Branch, 2025).These trials must also follow good clinical practices, a description of which can be found here: ICH: E6 - Good Clinical Practice (GCP) (ICH, 2025). All clinical trials must protect the health of the people used in the trial, be well designed, be performed by trained professionals, be monitored, report any side effects, and be reviewed by a Research Ethics Board (REB). Information on the REB can be found here: Health Canada's Research Ethics Board: Policies, Guidelines and Resources (Health Canada, 2021b). The regulations of the REB are based on the Tri-Council Policy Statement - Ethical Conduct for Research Involving Humans - TCPS 2 (2022). This can be found here: Canada's Panel on Research Ethics: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2022) (Government of Canada, 2023).

2 • GUIDE MANUFACTURERS ON CANADIAN MARKET ACCESS REQUIREMENTS

Clinical trials must also follow four phases. **Phase 1:** to test an experimental drug on a small group of people for the first time to look at the drug's safety, the safe dosage, and identify side effects. **Phase 2:** to test an experimental drug on a larger group (100+) of people to gather data on the efficacy of the drug, determine its safety in a larger range of people, and to identify the ideal dosage. **Phase 3:** to test an experimental drug on an even larger group (1,000+) of people to ensure its continued efficacy, monitor side effects, compare the drug to other available treatments, and to collect data for its later use in the market. **Phase 4:** to test an approved drug to study its best use, long-term benefits, and risks (Health Canada 2021).

Promising results include a drug's benefits being greater than its risks. If this is shown in clinical trials, the sponsor will apply to Health Canada for market approval. This application includes detailed information about the drug's safety, efficacy and quality such as the results from both pre-clinical and clinical trials, details about manufacturing, packaging, and labelling, and any health claims or side effects. Approval depends on the benefit/risk ratio, but also on the condition that the risks can be lowered. If approved the drug will receive a notice of compliance (NOC).

Information on the NOC can be found here: Health Canada's Notice of Compliance – Drug Products (Health Canada, 2005). The drug will also receive a drug identification number, information for which can be found here: Health Canada's Drug Identification Number (DIN) (Health Canada, 2001).

In summary, the application for a novel antimicrobial to enter the Canadian market is confusing, time consuming, expensive and controlled by multiple regulatory bodies. Combined, these could stifle novel therapeutics from any sponsor other than those who are an expert in Canadian politics and regulations or are financially able to hire expensive consultant firms for this purpose. This creates a biased opportunity for wealthy sponsors, when most patients would likely agree that groundbreaking improvements in pharmaceuticals should be prioritized based on their merit – notably their potential positive impact to all Canadians. While ethics, laws and moral values are integral aspects of our health care system, it is also necessary that changes be made, where possible, that allow for consistently high-quality outcomes while simultaneously attracting new talent, new research, and new ways to save Canadian lives.

3 • INCENTIVIZE CANADIAN DRUG DEVELOPMENT & MANUFACTURING

In the face of shifting geopolitical tensions and supply chain volatility, it is essential to promote drug development within Canada to ensure consistent access to novel antibiotics. While it is crucial for Canadians to gain access to antibiotics of last resort, which are currently approved for use in other countries, the Canadian government must also look forward and address the lack of national antibiotic development capacity. Canada has long recognized the need for economic incentives to attract Canadian pharmaceutical companies into the antibiotic drug development market. A 2015 report by the Public Health Agency of Canada highlighted the need for Canadians to have increased access to antimicrobial drugs of last resort, including by attracting Canadian firms to develop novel drugs for antimicrobial resistance (Office of the Auditor General of Canada, 2023). Given the short lifespan of most AMR drugs of last resort, without Canadian innovative capacity, it will be a constant uphill battle to maintain access to novel AMR drugs. Resolving this gap is a national security concern which will allow Canadians to have reliable access to innovative antibiotics into the future, as global AMR pressures increase.

The current economic incentive structure is not sufficient to promote antibiotic drug development in Canada. Drug development is an inherently laborious and inefficient process, leading pharmaceutical companies globally to cease antimicrobial discovery research in favour of more reliable products such as medications to combat chronic diseases (Patil et al, 2025). Due to antimicrobial resistance concerns, AMR drugs are inherently designed for sparingly short-term use. Limiting the use of said drugs is crucial to preserve their effectiveness; however, it provides a strong economic disincentive for drug development. Furthermore, revenue streams for AMR drugs are even more volatile than for other pharmaceutical products, as they can quickly become outdated if resistant strains emerge (Office of the Auditor General of Canada, 2023).

In Canada specifically, there is a small national market for antibiotics of last resort, coupled with a stringent regulatory environment (Office of the Auditor General of Canada, 2023). These factors can push Canadian talent to drug development in other markets, such as the United States, where drug development risks are mitigated by a shorter regulatory approval process and increased potential for commercialization (CCA, 2023). This directly impacts access; for example, the only country with access to all 13 novel drugs of last resort, the United States, is also responsible for developing nine of these drugs (CCA, 2023). Controlling the supply chain will support access during times of global crisis and beget access to other internationally developed drugs through mutual sharing agreements. It also gives Canada agency to further its global health diplomacy goals by democratizing access to Canadian-developed antimicrobials.

Proposal 3.1: Create a national incubator program to support AMR drug development.

In 2023, the Canadian government established the Open Science Drug Discovery network, allocating $49 million of funding towards innovative Canadian drug and therapeutic discovery, including the development of antimicrobial drugs of last resort (Government of Canada, 2025). This initiative was designed as a financial pull incentive to encourage investment in areas of market failure, despite significant health importance. However, its scope is overly limited, reducing its potential effectiveness at fostering capacity for national AMR drug development. The policy focuses on funding an “open-science model where researchers, industry partners and other stakeholders collaborate by distributing and sharing results”, according to a press release from Innovation, Science and Economic Development Canada (Government of Canada, 2023). However, such open sharing models are primarily conducive to driving innovation in non-profit-oriented sectors, such as university academic research and not-for-profit organizations. To truly drive sustained innovation in Canadian AMR drug development and manufacturing, we propose broadening this funding to provide holistic support across the drug development pipeline. Important stakeholders to receive funding should range from academic researchers to the drug manufacturing sector, promoting basic science research, but also reducing barriers to later stage drug development, such as the financial burden of clinical and pre-clinical testing and ensuring AMR products developed in Canada can also be manufactured in Canada. Broadening existing policy will benefit many sectors of the Canadian economy, in addition to ensuring that Canada retains its sovereignty and agency when facing AMR threats.

3 • INCENTIVIZE CANADIAN DRUG DEVELOPMENT & MANUFACTURING

<u>Proposal 3.2:</u> Create formal policy to preferentially purchase Canadian AMR drugs.

If the Canadian government aims to promote drug manufacturing inside of Canada, assurances must be made to alleviate the financial risks imposed by the limited market for AMR drugs. Please refer to Policy 1 for a description of the avenues through which government policy can mitigate AMR drug development risks. To mitigate the long-term risks to AMR drug access posed by not having reliable access to innovative medicines, the Canadian government is advised to take immediate action to start the long-term process of developing national drug manufacturing capacity.

To accomplish this goal, we recommend that the Canadian government formally commit to prioritizing purchasing AMR drugs of last resort that were developed and manufactured in Canada. This will ensure that when domestic firms assess the risks of entering the limited AMR drug market, they are assured that there will be a predictable demand for their products, and that they will not need to compete with larger international firms for access to the Canadian market.

This policy will complement Proposal 4.1 by encouraging companies who receive drug development and manufacturing funding to remain in Canada and will make the nation more resilient to periods of increased international demand for AMR drugs of last resort. Instead of remaining at the whims of the international drug manufacturers, Canada can become a global leader and leverage its domestic drug development capacity for access to the other AMR drugs of last resort.

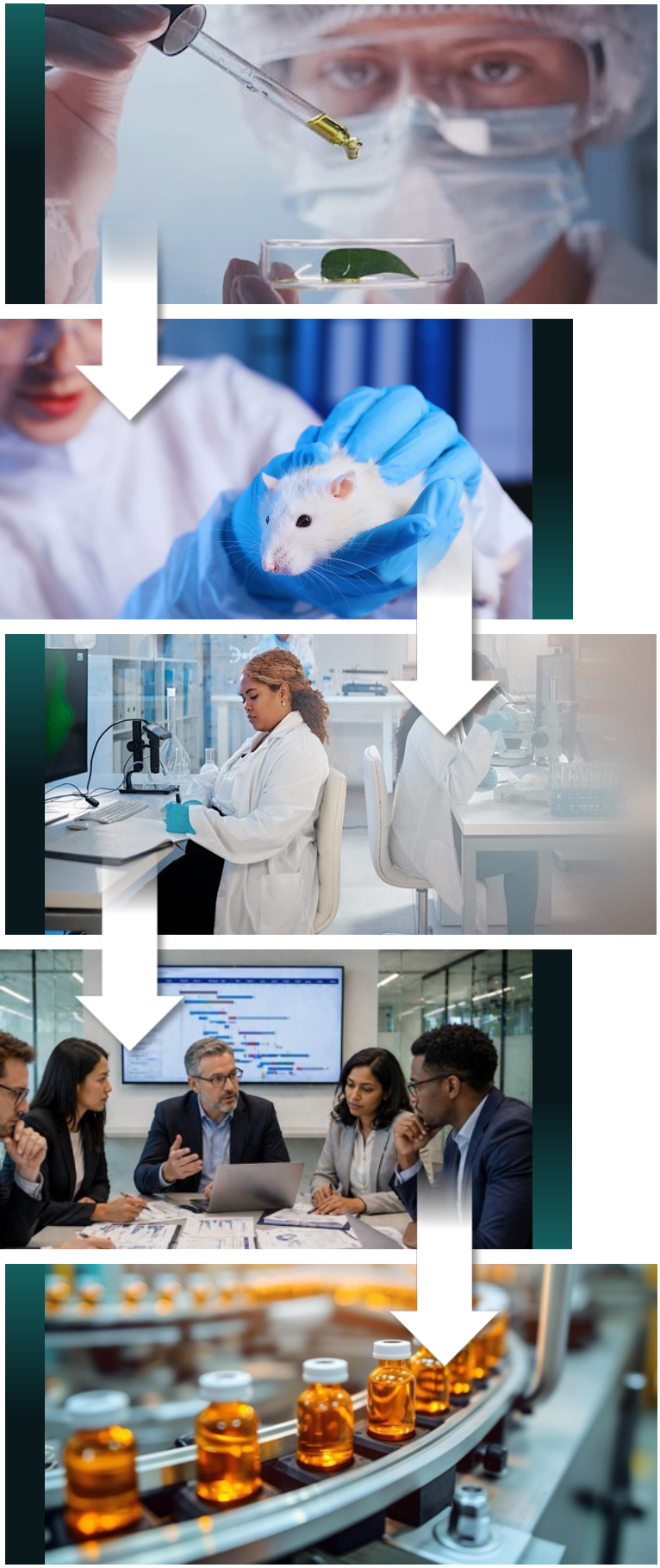


FIG. Drug development starts with discovery of a specific molecule that plays a crucial role in a disease state and can be targeted by a developed drug. Testing consists of preclinical (e.g., in vitro or in vivo) research followed by clinical trials involving humans. Following the phases of clinical trials, a governing body (e.g., FDA) reviews the safety and efficacy of the drug, before it is approved for manufacture, market, and distribution. <u>Information adapted from ThermoFisher Scientific.</u>

PUBLIC COMMUNICATIONS STRATEGY

Effective public communication is critical for demonstrating to Canadians that the federal government, through this policy, is taking action to address the shortcomings identified in the 2023 Report of the Auditor General of Canada to the Parliament of Canada on antimicrobial resistance. Communication is at the heart of who we are as human beings (Rimal and Lapinski, 2009), and effective health communication is essential to the health and wellbeing of the public (Office of Disease Prevention and Health Promotion, 2020). While recent research suggests that most Canadians have some level of awareness regarding the antimicrobial resistance (AMR) crisis (The Strategic Counsel, 2022), many do not see it as an urgent, top ten public health threat or relevant to them personally.

To increase awareness among the public of the severity of AMR, both in Canada and worldwide, a television commercial and related advertising materials have been developed. Additional primary objectives of this communications strategy are to encourage Canadians to consider their preconceptions about AMR, clearly articulate the key points of the Government of Canada's strategy, and encourage Canadians to seek further information on the Government of Canada website. The following series of key messages reflect these objectives and have guided the development of these outreach materials (Box 1).

BOX 1: KEY MESSAGES FOR AMR COMMUNICATIONS & OUTREACH

Antimicrobial resistance (AMR) is a major public health threat in Canada and around the world.

- According to the World Health Organization (WHO), AMR is one of the top 10 public health threats facing our world, with nearly 5 million associated deaths each year (WHO, 2019; WHO, 2023).
- AMR happens when microbes, such as bacteria, viruses, fungi, and parasites, adapt to be able to resist medications that used to be effective in treating them. Antimicrobial drugs include antibiotics, antifungals, antivirals, and more (Office of the Auditor General of Canada, 2023; AMR Aware Canada, n.d.). This means infections that are harder to treat, more dangerous, and more likely to spread.
- Although its impacts are often more severe in underdeveloped nations, AMR affects countries in every region of the world and at all income levels, including Canada (WHO, 2014; WHO, 2023).

Every Canadian is impacted by AMR.

- Resistant microbes can be found in and spread between people, animals, food, and the environment, meaning that antimicrobial use in any of these areas increases the chance that resistance will develop (Office of the Auditor General of Canada, 2023; Public Health Agency of Canada, 2023).
- In 2018, AMR cost Canada $1.4 billion in healthcare costs, plus $2 billion in lost GDP (Council of Canadian Academies, 2019; Office of the Auditor General of Canada, 2023).
- Levels of antimicrobial resistance are continuing to rise, with rates in Canada projected to increase from 26% in 2018 to 40% by 2050 (Council of Canadian Academies, 2019).

PUBLIC COMMUNICATIONS STRATEGY

BOX 1: KEY MESSAGES FOR AMR COMMUNICATIONS & OUTREACH (CONT.)

Canadians lack access to new antibiotics critical to preserving health and safety.

- Currently, 1 in 3 high risk infections in Canada could be treated with drugs that are available in other countries, but not here (Office of the Auditor General of Canada, 2023).
- As of 2021, there were 13 newly developed antibiotics on the WHO reserve list. Canada only has access to two (Office of the Auditor General of Canada, 2023).
- Development of new antibiotics in Canada and worldwide has slowed down significantly (Office of the Auditor General of Canada, 2023).

The Government of Canada is reducing red tape to improve access to new antibiotics and improve the health of Canadians.

- Currently, Canada's small market and complex regulatory system are discouraging pharmaceutical companies from marketing products here. The Government of Canada has developed a new policy with three key pillars to improve access to new antibiotics.
- **Pillar 1:** Reform the drug review process to speed up reviews for new antimicrobials previously approved by other major international regulators and prioritize the approval of new antimicrobials targeting high-risk pathogens. Reforms will include creating a new AMR panel, increasing use of the Special Access Program (SAP) for Canadian physicians, harmonizing standards with international partners, and launching a Targeted Antimicrobial Approval Pathway (TAAP).
- **Pillar 2:** Developing better guidance to improve manufacturer awareness of Canadian market requirements.
- **Pillar 3:** Incentivizing Canadian research and innovation by creating a comprehensive national incubator program to drive drug development and implementing a "buy Canadian" procurement strategy for antimicrobial drugs, ensuring national security and continued access to critical medications for Canadians.

TELEVISION COMMERCIAL FORMAT

The basic television commercial is approximately 30 seconds long, in line with the current industry average (Gula, 2003). The commercial will follow the Design Standard for the Federal Identity Program (Treasury Board of Canada Secretariat, 2021) and comply with all requirements of the Policy on Communications and Federal Identity (Treasury Board of Canada Secretariat, 2025). Text will consist of white lettering on a dark background in regular Helvetica font with a large, easily readable size. The Canada wordmark, Public Health Agency of Canada (PHAC) signature, and PHAC name will be attached to all promotional materials for clear communication and public transparency (Treasury Board of Canada Secretariat, 2021). All messaging will be consistent with and build on prior Health Canada and PHAC publications, including the "Use Antibiotics Wisely: Not All Bugs Need Drugs" campaign (PHAC, 2018), reducing duplication of effort and ensuring other federal agencies can continue to build on this work in the future. Efforts have also been made to ensure messaging is consistent with Public Health Agency of Canada partners, including AMR Aware Canada, which leads the World Antimicrobial Awareness Week campaign within Canada.

PUBLIC COMMUNICATIONS STRATEGY

MEETING CANADIANS WHERE THEY ARE

A standard television commercial forms the basis of this communication strategy to reach a diverse range of Canadians. Recent data from the Canadian Radio-television and Telecommunications Commission (CRTC) indicate that Canadians watch over 2.8 billion hours of television per month (CRTC, 2026). However, although conventional television may still hold a majority share of the audiovisual viewer market, increasing numbers of Canadians are accessing television through alternative streaming platforms (CRTC, 2026). To reach all Canadians, it is critical for the Government of Canada to adopt an integrated, flexible advertising strategy that functions across multiple platforms and formats.

While a shorter commercial is appropriate for conventional television and social media, a longer form (approximately 60 seconds) is common among streaming services. Auditory-only versions of the commercial, both long and short forms, will also be available for radio and podcast listeners. Finally, still frames from the commercial will be formatted as posters for use on billboards, newspapers, magazines, websites, or social media platforms. Advertising across a range of new and traditional media will ensure the Government of Canada can raise awareness about the AMR crisis and drive confidence in government action among a broad segment of the Canadian population.

ACCESSIBILITY

A key aspect of meeting Canadians where they are is ensuring that communication materials are accessible and inclusive of all people. This includes having all materials available in both English and French, in accordance with the obligations of the Canadian government under the Official Languages Act (1985). Where possible, efforts will be made to collaborate with communities to produce materials in local Indigenous languages as well. High-contrast colour schemes will be chosen for visual elements to respect those with visual differences, and commercials will all be available with described audio for the visually impaired. Text will be written in plain language accessible to Canadians of different educational and professional backgrounds. Finally, all communication materials will use gender-neutral, inclusive language to communicate to all Canadians and strive to highlight the diversity in Canada.

EVALUATING SUCCESS

To evaluate the success of the television commercial, key metrics monitored will include how many Canadians are seeing the ad, how often, and how many are going to the PHAC website for more information (advertisement reach, frequency, and conversion rate). PHAC website traffic on AMR-related pages will be closely monitored to generate these metrics. For streaming and social media advertisements, completion rate and click-through rates will also be evaluated.

To assess whether the advertisements have effectively raised awareness among Canadians, a random sample of Canadians will be surveyed on their knowledge of antimicrobial resistance both before and 6 months after the deployment of the advertising campaign. The later survey will also include targeted questions to investigate exposure to PHAC advertisements and their influence on Canadians' understanding of AMR. After six months, survey results and advertising metrics will be analyzed and communication materials will be updated, altered, or retired, as necessary. If communication materials are updated and redeployed, the assessment cycle will be repeated after another six months.

CONCLUSIONS

The policy proposals we present to increase the availability of ALR in Canada target the complex system Canada currently has by making the submission process user friendly, reducing repeated review of clinical data by leveraging our international allies in the drug approval process, harmonizing existing systems, and encouraging more Canadian research and development of novel antibiotics. By adopting these policies, it will increase the number of submitted and approved ALR to the Canadian market and increase the research and development of these antibiotics in the Country. These policies scale from a minimum amount of effort to a large investment to provide various options to the decision makers.

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