

## Improving Access to Novel Antibiotics in Canada.

This proposal is the result of a grassroots endeavour to explore and present solutions to the issues surrounding access to and capacity for novel antibiotics in Canada. Jointly led by McMaster University and the Canadian Antimicrobial Innovation Coalition (CAIC), this project was catalyzed by the urgent need to slow the spread of antimicrobial resistance (AMR).

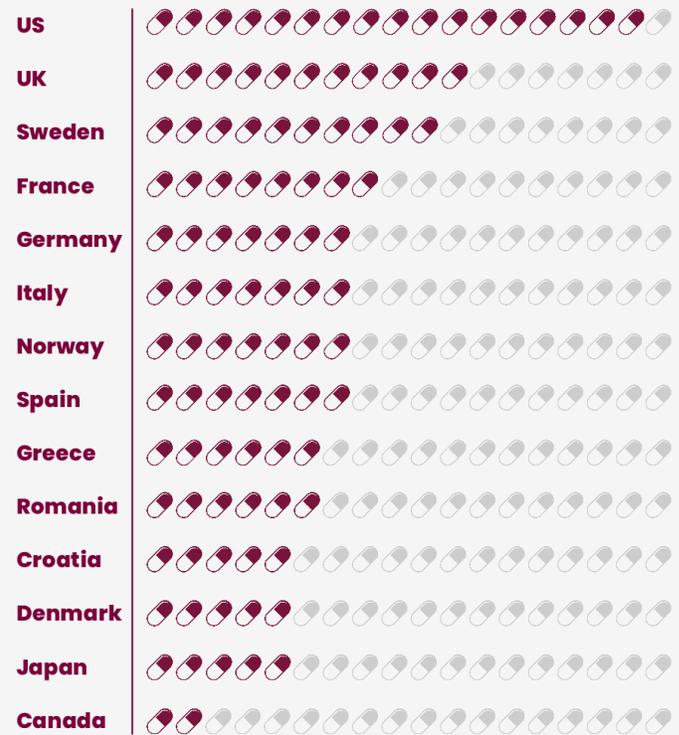
AMR occurs when pathogenic bacteria develop the ability to resist the drugs designed to kill them. These resistant infections come with considerable economic downside, and, more importantly, are costing Canadian patients their lives. AMR was declared by the World Health Organization as one of the top-10 Global Public Health Threats facing humanity. While COVID-19 caught the world by surprise, AMR is a predictable and preventable crisis, but we need to get ahead of it today before it becomes the next pandemic.

Today, a number of novel antibiotics – drugs with efficacy against otherwise resistant bacteria – have been approved for use in other jurisdictions but are unavailable to Canadian patients. For example, of 18 novel antibiotics approved and commercially launched in 14 high-income countries between 2010-2020, only two had been introduced in Canada – the fewest number on the entire list. Meanwhile, other countries, like the U.S., introduced as many as 17 in the same span.

Similarly, many novel antibiotics already approved in Canada are rarely used due to costs and administrative barriers. The result is the overuse of first-line drugs in Canada, which ultimately has implications for resistance rates and health outcomes.

Under the leadership of a steering committee comprised of experts from industry, academia, economics, microbiology, policy, medicine, and beyond, we sought to develop ways in which newer antibiotics could be better accessed by Canadian prescribers, and thereby Canadian patients. Consulting broadly with a range of stakeholders from across Canada and from across sectors, we took a two-pronged approach to addressing the problem:

### Patient access to 18 novel antibiotics in 14 high-income countries



1. We considered ways to improve appropriate, stewarded access to essential, new, and newer antibiotics that are already approved but underutilized in hospitals due to administrative or cost barriers.
2. On a broader scale, we explored ways to improve market access for manufacturers of novel, essential, and new antibiotics currently in the R&D pipeline or newer antibiotics approved in other jurisdictions.

This work resulted in a set of 30 concise recommendations designed to not only improve antibiotic access and capacity, but also to protect these vital medications through stewardship efforts and improved surveillance of resistance in Canada.

These recommendations feed into a proposed integrated solution – a patient-centered model designed to bring more novel antibiotics to Canada through incentivization and

regulatory improvements, and to expand front-line access through measures related to data, costs, distribution, and supply and demand. Our integrated solution proposes to establish:

- ▶ Guaranteed minimum revenue agreements for manufacturers of novel antibiotics
- ▶ Antibiotic-specific and diagnostic-specific funding envelopes for hospitals
- ▶ Data collection and reporting processes, leveraging new and existing information systems
- ▶ Infrastructure to improve antimicrobial stewardship at a pan-Canadian level

The integrated solution is suited to Canada’s healthcare model, where the federal government provides healthcare funding to Canada’s provinces and territories. Canada’s response to the COVID-19 pandemic has demonstrated that the federal government, through the Public Health Agency of Canada and Public Services and Procurement Canada, can play a critical role in securing access to public health products to facilitate product distribution and delivery.

Although our focus is currently on applying the integrated solution to the hospital setting, the model is adaptable and highly relevant to community settings as well.

With respect to economic incentives, our recommendations are in line with the work undertaken at the international level to determine the public funding required to address market challenges. This proposal introduces a funding range for

economic incentives in Canada, through the application of models prepared for other jurisdictions, such as Sweden, the UK, and the US.

We understand that this solution is ambitious – that is why we are proposing that it is initially piloted in a select region using a limited number of antibiotics. This process will expose strengths and weaknesses in our proposed solution, which can then be enhanced or rectified before the solution is subsequently scaled to meet pan-Canadian needs.

In parallel, work will be undertaken to validate and operationalize incentives policies. Currently, required funding is estimated to range from \$1.7-17.7 million per year over 10 years, depending on where the antibiotic is in its lifecycle, including whether or not it has already been approved in Canada. It is our suggestion that this funding would be provided collaboratively between Health Canada and the Public Health Agency of Canada.

Investing in this AMR pilot project and subsequently expanding it to all provinces and territories in Canada brings along a substantial number of benefits, including a more effective and safer use of antibiotics and antimicrobials, a reduced burden on the Canadian healthcare system, and incentive for the global pharmaceutical industry to continue investing in the Canadian market. Most importantly, however, investing in this project will help improve and even save the lives of Canadian patients, who will now have access to modern treatments that are more responsive to their needs.

Read the full proposal at [iidr.mcmaster.ca/MAAC](http://iidr.mcmaster.ca/MAAC).

### An Overview of the Model

