



Incentives needed to drive innovation in antimicrobial resistance

Panel: The Role of Innovation in Addressing Antimicrobial Resistance

Organized by Industry Canada

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Panelists: **Dr. Roman Szumski**, Vice-President of Life Sciences, National Research Council; *Panelists:* **Patrice Allibert**, CEO, GenePOC; **Brigitte Nolet**, Head of Global Health Policy, F. Hoffmann-La Roche Ltd.; **Dr. Marc Ouellette**, Scientific Director, Canadian Institutes of Health Research (CIHR); **Dr. Sameeh M. Salama**, Vice President, Business Development, NAEJA Pharmaceutical Inc; **Angela Wittlesberger**, Scientific Officer, Innovative Medicines Initiative; **Dr. Gerry Wright**, Director, Michel G. DeGroote Institute for Infectious Disease Research, McMaster University

Takeaways and recommendations

- ✓ Create programs that help bridge the gaps between discovery, clinical testing, development and market
- ✓ Consider a federal framework for AMR similar to U.S. and Europe
- ✓ Incentivize and reward the sustainable use of antibiotics
- ✓ Reward novel discoveries and approaches
- ✓ Create more partnerships between academia and industry
- ✓ Encourage international partnerships between various funders and AMR programs
- ✓ Create partnerships that keep resources and talent within Canada

The policy issue: Antimicrobial resistance (AMR) is a threat to global health, the World Health Organization has said. Antibiotics that we have relied on for years, such as colistin and carbapenem, are proving ineffective against new resistant strains of bacteria. At the same time, there is a dearth of new antibiotics being developed, resulting in the U.S. Centers for Disease Control describing the shortage as a global crisis.

"AMR is a race with the rules changing every day," said Allibert. With a highly mobilized world, resistant strains can travel rapidly around the globe. "We need to react quickly with some easy tests and not wait months."

The key question, said Nolet, is "how can you have a predictable and stable environment with bacteria that are neither predictable nor stable?"

Government programs, private and public companies, and academic institutions in Canada, the U.S. and Europe are organizing around this issue and defining the multi-layered challenges. "The commercialization landscape is very challenging," said Wright, as there is a "limited receptor audience" and a low return on investment.

Wittlesberger added: "It is unattractive for pharmaceutical companies to develop an antibiotic because they need to spend a lot of money and effort to develop something that later should not be used, or only in very specific situations."

Salama said there are few funding or partnering options within Canada that can help academic researchers and small- and medium-sized enterprises (SMEs) maneuver the long and costly road from discovery through to clinical trials, regulatory approval and ultimately clinical use.

"We've lost a lot of talent going into the U.S. and into Europe with the closing down of several companies – AstraZeneca, Boehringer Ingelheim – in Canada," said Salama. "What we are missing is a national strategy."

The options: "Antimicrobial resistance is getting very high on the political agenda," said Ouellette. For example, the Canadian Institute for Health Research (CIHR) has invested \$229 million over the last 15 years on AMR projects.

A recently released *Federal Action Plan on Antimicrobial Resistance and Use in Canada* maps out a coordinated and collaborative approach to combating the threat of antimicrobial resistance. It is a multi-department, said Ouellette, with areas of focus around surveillance for antimicrobial threats, stewardship and innovation.

But it may not be enough. Nolet said "we have to look at the framework around the federal action plan," one that brings together regulators, academia, and provincial governments. "Innovation in antimicrobial resistance is critical but it must be supported by strong government policies that will ensure that it actually reaches the people who need them."

In Europe, the Innovative Medicines Initiative (IMI) has taken steps to address the AMR issue by creating a > 600 million Euro program that helps bridge the gaps between discovery, testing and development, and market. IMI's *New Drugs for Bad Bugs* (ND4BB) program addresses four key challenges: the complexities of clinical testing, the scientific challenges of discovering new molecules, the movement of these molecules toward development, and the design of new economic models to drive innovation, sustainable use, and access.

Canada needs to offer similar opportunities for Canadian research and discovery around antibiotics, building on important learnings in the IMI program and exploring synergies and collaboration with IMI and other initiatives.

"We need to be able to put the technology in a de-risked position where a pharma company is seriously interested," said Salama. Getting there requires partnerships, like the one between small biotech company Fedora and pharmaceutical giant Roche. But Salama noted that without support for small companies and academic researchers, these partnerships could become the exception in Canada.

Those partnerships require significant funding, more than programs like the Industrial Research Assistance Program can provide. Salama said Canada also needs a cohesive environment and culture between industry and academia. This will require incentives to partnering that make sense.

It's also important that homegrown innovations benefit Canada, rather than being sold off to a foreign company that takes the technology out of the country. Nolet said this situation requires different partnership approaches, "from royalty payments, to co-marketing arrangements, and other joint commercialization partnerships that can keep some of that base power in Canada. It doesn't just have to disappear into the global landscape."

Partnerships will be key in ensuring that the novel molecules, approaches and ideas that come out of academia and SMEs advance quickly through the development pipeline.

It's a similar story in the field of diagnostics where, to be effective, there needs to be a global network that monitors resistant strains. "We have to build a strong collection, because then we have to test it, and that's a real challenge," said Allibert. "The clinical trials must be crossed with different resistant strains."

For example, Québec City-based GenePOC Inc. is developing a diagnostic test with a simple procedure anyone can do in an hour. "If we can bring the system closer to the patient," said Allibert, "you can have an actionable result and make a treatment based on the status of the patient."

Relevant documents:

CIHR's Antimicrobial Resistance Initiatives; <http://www.cihr-irsc.gc.ca/e/40485.html>

New Drugs for Bad Bugs Program, Innovative Medicines Initiative;

<http://www.imi.europa.eu/content/nd4bb>

Federal Action Plan on Antimicrobial Resistance and Use in Canada; <http://healthycanadians.gc.ca/publications/drugs-products-medicaments-produits/antibiotic-resistance-antibiotique/action-plan-daction-eng.php>