# **High-Level Meeting on Antimicrobial Resistance (AMR)**

Hosted by Senator Mohamed-Igbal Ravalia | Ottawa, Canada | 22 September 2025

## **Extended Version and Notes**

#### Introduction

On September 22, 2025, Senator Mohamed-Iqbal Ravalia convened a High-Level Meeting on AMR in collaboration with the Canadian Antimicrobial Innovation Coalition (CAIC), with support from Innovative Medicines Canada, International Federation of Pharmaceutical Manufacturers and Associations, AMR Action Fund, GSK and bioMérieux. The meeting brought together over 100 attendees, representing parliamentarians, global health experts, frontline physicians, economists, veterinarians, industry leaders, and survivors of resistant infections, from G7 countries, in addition to representatives from the WHO, and the European Commission to achieve greater alignment on policy incentives to mitigate the impact of AMR in our societies. While G7 nations have made important commitments, key challenges persist, particularly pertaining to implementing pull incentives, fostering public-private partnerships, and ensuring sustainable funding models.

# The Global Antimicrobial Pipeline and the Case for Coordinated Incentives

# **Sparse and Fragile Pipeline**

The global pipeline for new antimicrobials remains dangerously thin and insufficient to meet growing global health needs. While scientific advances continue, the commercial outlook for antibiotic development is increasingly bleak. Because new antibiotics must be used sparingly to preserve their effectiveness, sales volumes remain chronically low, and potential revenues pale in comparison to other pharmaceutical markets. This structural weakness has eroded private investment, forcing companies and leading researchers to exit the field—further weakening an already fragile innovation ecosystem. Addressing these systemic challenges requires coordinated economic solutions that both stimulate early research and ensure sustainable market returns, as outlined below.

## Need for complementary push and pull incentives

- o Meeting participants agreed on the need for *a suite of economic incentives* that combine early-stage "push" mechanisms with market-enabling "pull" mechanisms.
- **Push incentives** such as grants, tax credits, or milestone payments *de-risk early R&D* and support discovery through preclinical and clinical stages.
  - o Global push funding gap has been estimated at U.S. \$250-400 million per year.
- o **Pull incentives** including subscription models, market entry rewards, or transferable exclusivity vouchers *reward successful development* and ensure sustainable revenues for successfully developed products. A recent estimate puts the collective G7+EU mid-range <u>pull incentive target</u> at U.S. \$363 million per drug per year for 10 years when starting from a Phase II-ready asset. In this scenario, Canada's fair-share contribution is estimated at ~U.S. \$13 million annually.
- o Industry has likewise <u>proposed key pull incentive design principles</u>, including effective pull incentive size, and has developed projections showing that without these, the pipeline is expected to decline further.
- o Immediate priority: *ensuring companies remain solvent during the critical first five years* following regulatory approval.

#### Progress and remaining challenges

- o The G7 has made *notable advances* in piloting and implementing pull incentives, but sustaining momentum requires *long-term coordination* and *cross-national complementarity*.
- o Analyses from the **Global AMR R&D Hub** and **Center for Global Development (CGD)** highlight major roadblocks:
  - Lack of *predictable, long-term financing* mechanisms.
  - Fragmented national approaches and inconsistent program design.
  - Uncertainty over *valuation criteria* and *eligibility rules* for incentive programs.
- o Overcoming these barriers both *domestically within G7 members* and *through collective frameworks* is critical to creating a *durable, globally aligned incentive ecosystem*.

#### • The economic rationale for sustained investment

- o Improving innovation and access to high-quality treatment would cost about US\$ 63 billion per year, offering a global return on investment of 28:1.
- o Broader access to effective antimicrobials could *save millions of lives* and *add nearly* \$1 *trillion to global GDP*.
- o CGD <u>estimates</u> that making new **gram-negative antibiotics** accessible could make the world \$750 billion richer annually by 2050 with \$330 billion of those gains accruing to G7 countries.

#### • Necessity of global coordination

- o AMR cannot be solved by any single country; *collective action across nations and sectors* is indispensable.
- National strategies may differ, but *alignment and coherence* are essential to ensure incentives "pull in the same direction."
- The **Global AMR R&D Hub**, through its Pull *Incentives Working Group*, serves as a key platform for:
  - Sharing national incentive designs and challenges.
  - Fostering technical exchange and mutual learning.
  - Coordinating approaches to "fund smarter and act smarter."

#### • Leadership opportunities for the G7

- The G7 is uniquely positioned to *drive coordinated, sustainable models that support AMR R&D and stewardship frameworks* globally.
- The economic case for leadership is compelling:
  - Over 30 years, **Canada** alone could gain \$31.5 billion in total benefits and save 48,000 lives from coordinated global action and fair-share participation.
  - Even the *least benefiting G7 nation* receives **\$46 in value for every \$1 invested** in new gram-negative antibiotic development.
- o By leveraging their *collective market power*, G7 members can *revitalize innovation* while *facilitating global access* to the antibiotics the world urgently needs.

### **Current Efforts: G7 Country Efforts on AMR and Pull Incentives**

#### • United Kingdom (U.K.)

- $\circ$  Operationalized its *subscription model* for antibiotics compensates new drugs through a fixed annual fee based on *societal value*, delinking revenue from sales volumes.
- o Committed significant funding to AMR research, including support for **CARB-X**, **GARDP**, and the **Fleming Initiative**.
- Meeting its *fair share contribution* toward the global antibacterial revenue target.

#### Italy

- o Likely meeting its *fair share contribution* alongside the UK.
- o Prioritized AMR on its **2024 G7 agenda**.
- o Advancing policies to mitigate AMR's impacts nationally and internationally.

### United States (U.S.)

- o Over halfway toward its *fair share revenue contribution* through current market prices.
- o **The 2023 PASTEUR Act** (subscription model legislation), represents the most impactful proposal anywhere in the world and has previously been submitted to Congress but has not been passed. Stakeholders are working to reintroduce the Bill.

### Germany

- o Promotes *systemic*, *globally coordinated approaches* to AMR.
- o Supports push incentives/public-private partnerships and has enacted pricing reform that is not yet reaching the impact needed.
- Key supporter in establishing the **Global R&D Hub**.

#### Japan

o Implemented its **Antimicrobial Securement Support Program (ASSP)**, which is a revenue guarantee model that primarily supports access.

#### France

- Leading *One Health* implementation on the veterinary front.
- Achieved major *reductions in antibiotic use in livestock*.
- o Inter-Ministerial Roadmap for Prevention and reduction of antibiotic resistance and the fight against antimicrobial resistance (2024-2034)

#### Canada

- Committed to designing and implementing a *pilot project* to initially improve access to new therapies.
- Provided financial support to CARB-X, GARDP and AMR R&D Hub.

#### EU

• The EU, through its One Health approach, is advancing AMR engagement and pull incentive work with the proposed Transferable Exclusivity Vouchers (TEV) - potentially complemented via an access model such as a revenue guarantee by the DG HERA (European Commission). EU also provides continued support for CARB-X and GARDP. DG HERA collaborates with the European Investment Bank on HERA Invest, and has launched a new Medical Countermeasures Strategy.

#### • Overall G7/EU Leadership

- Have accounted for the majority of total global public AMR R&D investment since 2017.
- o Urgent need for *coordinated and complementary pull incentives* across G7 nations to achieve the *critical mass* required to sustain and replenish the global antimicrobial pipeline.

#### Strengthening the R&D Pipeline and Ensuring Access

While there have been significant achievements in expanding the global antimicrobial R&D pipeline, the overall landscape remains insufficient to meet public health needs. Public-private partnerships and coordinated global initiatives have produced tangible results, yet major gaps persist in both innovation and equitable access.

#### • Public-private partnerships driving progress

- While antibiotic R&D efforts remain limited, different examples of promising efforts and recent development successes by larger and smaller companies were highlighted.
- o Initiatives such as **CARB-X** and **GARDP** have delivered measurable impact in advancing early- and in some cases, late-stage antibiotic development.
- o **GARDP** recently successfully completed a Phase III trial for a *first-in-class treatment for antibiotic-resistant gonorrhea*, announcing with Innoviva in June 2025 that FDA had accepted New Drug Application (NDA) and granted the product the Qualified Infectious Disease Product (QIDP) designation.

### Ongoing gaps in innovation

o Some experts at the conference estimated that among future antibiotics, the world needs **approximately ten new, breakthrough innovative antibiotics per decade** to maintain an adequate response. At the current pace—an **estimated 5.1 new such antibiotics** that target WHO priority pathogens and are considered "WHO innovative" are **expected over the next 30 years**—progress is far too slow, described by participants as "not a pipeline, but more like playing roulette."

### Persistent inequities in access

- o Access challenges remain as severe as innovation shortfalls: **fewer than half** of newly approved antibiotics are *widely registered or commercially available*.
- o Roughly **80% of the global population** still lacks access to essential antibiotics.
- As a result, more people die from lack of access to existing antibiotics than from resistance itself.

### • A new global framing: R&D and access as inseparable priorities

- o The **Global Leaders Group on AMR** considers *research, development, and access* as **integrated pillars**, extending the focus to include *diagnostics, infection prevention, and surveillance*.
- This integrated approach is embedded in the process of updating the **WHO Global Action Plan on AMR**, which emphasizes end-to-end system strengthening.

## • WHO's six key recommendations

- Advocate for long-term, predictable financing across the entire value chain —
  from discovery and regulatory approval to manufacturing, supply, and responsible
  use.
- Strengthen global and national regulatory systems to expedite safe, equitable access.
- o **Bolster supply chain resilience and appropriate use frameworks** to ensure innovations reach every health system.
- o **Ensure robust antimicrobial stewardship**, including surveillance, diagnostics integration, and prudent use policies so that new antimicrobials remain effective for as long as possible.
- Guarantee equitable global access, with coordinated procurement, pricing models, and access pathways so that lifesaving products reach low- and middleincome countries.
- Emphasize the need for coordinated, complementary interventions, recognizing that without alignment across financing, stewardship, and access, new treatments risk becoming wasted investments that fail to reach those who need them most.
- o Advocate for *long-term, predictable financing* across the entire value chain—from discovery and regulatory approval to manufacturing, supply, and responsible use.
- Strengthen global and national regulatory systems to expedite safe, equitable access.
- o Bolster *supply chain resilience* and *appropriate use frameworks* to ensure innovations reach every health system.
- $_{\odot}$  Without such complementary interventions,  $new\ treatments\ risk\ becoming\ wasted\ investments,$  failing to reach those who need them most.

#### **AMR: Local and Global Considerations**

Addressing antimicrobial resistance (AMR) requires a response that is both locally grounded and globally coordinated. The issue transcends borders, institutions, and sectors — reminding policymakers that solutions must begin and end with people. Experts emphasized that AMR "does not need a visa or passport," spreading freely across communities and continents alike.

### • The human dimension of AMR

- o Stakeholders stressed that effective AMR communication must *start with personal stories* and lived experiences.
- o The crisis is often discussed in abstract policy terms "this little dungeon," as one panellist described leaving the public unaware that AMR is already affecting everyone's lives.
- o **Patient testimonies** underscored that AMR is *not hypothetical*: it is already eroding the foundations of modern medicine, endangering routine surgeries, chemotherapy, and other essential treatments.

### • Beyond action plans — making AMR real for people

- o Relying solely on an Action Plan for AMR is *necessary but insufficient*; it often fails to make understanding the threat as tangible for citizens and decision-makers.
- o Communicating AMR's impact at the *individual and community level* is essential to generate urgency and public support for policy and funding action.

#### Innovation and access: two sides of the same coin

- Experts agreed that *innovation and access must advance together* one cannot succeed without the other.
- o Investments in developing new antimicrobials will only deliver global impact if *paired* with equitable, sustainable global access models and strong stewardship.
- o **G7 countries**, in particular, have both a *moral and practical responsibility* to lead on R&D incentive implementation and to support the availability of new treatments, recognizing that resistant pathogens will not stay confined to national borders.

### • Local realities: barriers on the front lines

- o **Clinicians in Canada** face difficulties in accessing life-saving drugs through the **Health Canada Special Access Program**, which remains *slow and administratively burdensome*.
- o **Provincial fragmentation** in vaccination programs and data systems hampers early detection of resistance trends and coordinated national responses.
- o **Researchers and developers** contend with *limited and inconsistent funding streams*, resulting in *talent loss* and *company bankruptcies* that weaken the national AMR innovation ecosystem.

#### AMR in Conflict Zones: Urgency and Opportunity for Cooperation

The war in **Ukraine** has starkly revealed how conflict accelerates the spread of antimicrobial resistance (AMR), transforming it from a health crisis into a **national security threat**. In Ukraine, bacteria resistant to last-line antibiotics have been found to be **ten times more common** than in the European Union, underscoring how war devastates infection control, sanitation, and health infrastructure. These realities demand urgent coordination between **defense and public health authorities** to align the application of antimicrobials in both **combat and hospital settings**, ensuring effective stewardship and preparedness across civilian and military systems.

## · Conflict as a force multiplier for AMR

- o Armed conflict acts as a "quintessential One Health dilemma," breaking down infection control systems and creating ideal conditions for resistant pathogens to spread.
- Destruction of health infrastructure, shortages of clean water, and disrupted medical supply chains amplify the misuse and overuse of antimicrobials.
- The result: *immediate and measurable surges* in resistance rates, as demonstrated by Ukraine's alarming data.

### AMR as a security threat, not just a health issue

- Experts called for governments to formally recognize AMR as a *national security challenge* that undermines *military readiness, hospital capacity,* and *economic stability.*
- o Integrating AMR prevention, surveillance, and response capabilities into *defense* planning and procurement is essential to protect both soldiers and civilians.

### Defense and public health alignment

- Coordinated protocols are needed to guide *antimicrobial use in combat medicine, field hospitals, and civilian care settings.*
- o Alignment ensures consistent stewardship practices, avoids overuse of broad-spectrum antibiotics, and strengthens global biosurveillance capacity.
- o Cross-sector training between *military medical units and public health authorities* can improve readiness for biological threats and battlefield infections.

## • A Canadian opportunity: leadership through integration

- o The newly established **Defence Investment Agency (DIA)** provides a unique opportunity to position AMR as a *strategic defense and security priority*.
- o By dedicating a portion of the *expanded defense budget* toward AMR-related R&D—such as *rapid diagnostics, resilient medical supply chains,* and *novel countermeasures*—Canada can enhance both *military resilience* and *national health security.*
- o This aligns with the **DIA's mandate** to take strategic risks and leverage domestic innovation, helping Canada meet its *5% of GDP defense spending target* while reinforcing global leadership in health security.

# • Global cooperation and lessons from past collaboration

- o The intersection of AMR and conflict underscores the need for renewed *international cooperation*, particularly among allies.
- o Past successes—such as the **joint Canada–U.S. trauma registry** initiative during the Afghanistan conflict—demonstrate the potential for *shared surveillance, data, and research frameworks* in complex operational environments.
- o The current moment presents a *strategic opening* to reframe AMR as a domain for defense diplomacy and scientific collaboration, turning crisis into opportunity for *collective security and innovation*.